

Administration, issued an Order to Show Cause to James Curtis Dilday, M.D. (Respondent) of Little Rock, Arkansas. The Show Cause Order proposed to revoke Respondent's DEA Certificate of Registration, BD1434872, as a practitioner, and to deny any pending applications for renewal or modification of the registration, on the grounds that Respondent's state medical license had been revoked, *see* 21 U.S.C. 824(a)(3), and that Respondent had committed acts that rendered his registration inconsistent with the public interest. *See id.* § 824(a)(4); *see also id.* § 823(f).

The Show Cause Order specifically alleged that on numerous occasions, Respondent had improperly prescribed controlled substances (including Schedule II controlled substances) to ten patients. *See Show Cause Order* at 2–4. The Show Cause Order also alleged that between November 28, 2000, and November 12, 2002, Respondent had submitted fifteen fraudulent claims to insurers for medical services that were not performed. *See id.* at 4–5. The Show Cause Order further alleged that Respondent had pled no contest on behalf of his medical corporation in a state criminal proceeding to fifteen counts of committing fraudulent insurance acts and fifteen counts of theft. *See id.* at 6. Finally, the Show Cause Order alleged that the Arkansas State Medical Board had revoked Respondent's state medical license. *See id.* The Show Cause Order also notified Respondent of its right to a hearing. *See id.* at 7.

Respondent, through his counsel, requested a hearing; the case was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner. Thereafter, on August 11, 2005, the Government moved for summary disposition and to stay the proceeding. The Government's motion for summary disposition was based on the fact that on June 21, 2004, the Arkansas State Medical Board revoked Respondent's state medical license. The Government asserted that as a result of the revocation of Respondent's medical license, Respondent was without authority to handle controlled substances in Arkansas, the State in which Respondent was registered with DEA. Because DEA has consistently interpreted the Controlled Substances Act as barring a federal registration if a practitioner lacks authority under state law to handle controlled substances in the State where he practices, the Government sought a ruling from the ALJ recommending the revocation of Respondent's DEA registration and terminating the proceeding.

On August 12, 2005, the ALJ issued a memorandum to counsel offering Respondent the opportunity to respond to the Government's motion by 4 p.m. eastern time on August 29, 2005. By September 23, 2005, when no response had been filed, the ALJ issued her Opinion and Recommended Decision.

The ALJ explained that Respondent did not deny that he lacked authority under Arkansas law to handle controlled substances in that State. ALJ Dec. at 2. Noting that DEA precedents have "consistently held that a person may not hold a DEA registration if he is without appropriate authority under the laws of the state in which he does business," the ALJ concluded that "[b]ecause Respondent lacks this state authority * * * he is not entitled to retain his DEA registration." *Id.* (citations omitted). Furthermore, as no material fact was in dispute, summary disposition was appropriate. *See id.* The ALJ thus granted the government's motion and recommended that Respondent's registration be revoked and any pending applications be denied. *See id.* at 2–3.

Having considered the record as a whole, I hereby issue this decision and final order. I adopt in its entirety the ALJ's opinion and recommended decision. Because the facts are straightforward and not in dispute, there is no need to elaborate on them. As the ALJ found, Respondent is no longer authorized to distribute controlled substances under State law. Therefore, under our precedents, Respondent is not entitled to maintain his DEA registration. *See Sheran Arden Yeates, M.D.*, 71 FR 39130, 39131 (2006); *Dominick A. Ricci, M.D.*, 58 FR 51104, 51105 (1993); *Bobby Watts, M.D.*, 53 FR 11919, 11920 (1988).

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. §§ 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, BD1434872, issued to James Curtis Dilday, M.D., be, and it hereby is, revoked. I further order that any pending application for renewal or modification of such registration be, and they hereby are, denied. This order is effective October 2, 2006.

Dated: August 22, 2006.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03–8]

Jayam Krishna-Iyer, M.D.; Revocation of Registration

Introduction and Procedural History

On October 17, 2002, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Jayam Krishna-Iyer, M.D. (Respondent), of Clearwater, Florida. The Show Cause Order proposed to revoke Respondent's DEA certification of registration, No. AK2006648, as a practitioner on the grounds that Respondent had committed acts which rendered her continued registration inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4). The Show Cause Order also proposed to deny any applications for renewal or modification of her registration.

The Show Cause Order alleged that between March 24, 1999, and June 24, 1999, the Pinellas County, Florida, Sheriff's Office had conducted four undercover visits to Respondent's medical office. In essence, the Show Cause Order alleged that during three of the visits, Respondent had met with three different undercover operatives who had told her that they were not currently in pain but that they were users of various controlled substances such as Lorcet and Vicodin. *See Show Cause Order* at 2–3. The Show Cause Order further alleged that Respondent had issued prescriptions for controlled substances without performing a physical exam. *See Id.* The Show Cause Order alleged that Respondent had indicated in the patient records for each undercover operative that they had complained of pain when each had "clearly stated that they were not in pain." *Id.* at 3. The Order also alleged that that Respondent had told the undercover operatives that she could offer them a detox program or could "arrange an appropriate treatment plan." *Id.* at 3.

The Show Cause Order further alleged that on the second visit of one of the undercover operatives, the operative had been seen by a nurse practitioner, Ben Mastridge. While Mastridge told him that Respondent would not prescribe narcotics if the operative was not in pain, he nonetheless issued him a prescription, which had been pre-signed by Respondent, for Lorcet, Xanax, and Soma. *See Id.* at 2. The Order further alleged that Mastridge had offered "to initiate Methadone

treatment, but the [operative] preferred simply to attempt to reduce his Lorcet addiction." *Id.*

Based on the above, the Show Cause Order alleged that Respondent had "prescribed controlled substances without a legitimate medical purpose in violation of Federal law." *Id.* at 4. The Show Cause Order further alleged that Respondent "operated a narcotic treatment program without obtaining a separate registration for that purpose." *Id.*

On January 26, 2000, a federal search warrant was executed at Respondent's office. During the search, the authorities seized the medical records for the undercover operatives.

Thereafter, on June 21, 2000, a federal grand jury indicted Respondent on five counts of illegal distribution of various controlled substances in violation of 21 U.S.C. 841(a)(1). Resp. Ex. 110. These counts specifically alleged that Respondent had, on various dates, "knowingly and intentionally dispense[d] and distribute[d], outside the usual course of medical practice, and without a legitimate medical purpose," the drugs Lorcet, Vicodin and Vicodin ES (each being a Schedule III controlled substance), and Xanax (a Schedule IV controlled substance). *Id.* at 1-3. An additional count of the indictment alleged that Respondent had conspired to distribute Schedule III and Schedule IV controlled substances in violation of 21 U.S.C. 841(a)(1). *See* 21 U.S.C. 846. *See also* Resp. Exh. 110, at 1.

The United States Attorney offered Respondent pre-trial diversion. The agreement specifically provided that the period of supervision would last for no more than twelve (12) months, and that if Respondent fulfilled the conditions of the agreement, the charges would be dismissed. As part of the diversion agreement, Respondent also entered a medical supervision agreement. Under this agreement, Respondent was to submit the name of a monitoring physician for the approval of the United States Attorney; the monitoring physician was required to review twenty-five (25) percent of Respondent's patient records on a random basis and all records involving her prescribing of controlled substances to determine the appropriateness of the prescriptions. Respondent satisfactorily completed the supervision period and the indictment was dismissed.

As stated above, on October 17, 2002, this proceeding was initiated.

Respondent requested a hearing.¹ The case was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who conducted a hearing in Tampa, Florida, on July 1 and 2, and August 5 and 6, 2003. At the hearing, both the Government and Respondent called witnesses and introduced documentary evidence. Following the hearing, both the Government and Respondent submitted post-hearing briefs.

On April 15, 2005, the ALJ issued her recommended decision. The ALJ found that the Government had shown by a preponderance of the evidence that Respondent had, in each of the three instances involving the undercover operatives, prescribed controlled substances without a legitimate medical purpose and outside of the usual course of medical practice. *See* ALJ Dec. at 39-41. The ALJ further found that Respondent had "unlawfully prescribed prescriptions for controlled substances." *Id.* at 41. The ALJ also found that the Government had not proved by a preponderance of the evidence that Respondent had conducted a narcotic treatment program without the required registration. *Id.* Finally, the ALJ found that Respondent had refused to acknowledge her misconduct in prescribing the controlled substances, *see id.* at 43, and was "unwilling or unable to accept the responsibilities inherent in a DEA registration." *Id.* at 44. The ALJ thus recommended that Respondent's registration be revoked.

Following the ALJ's decision, Respondent submitted an 87 page brief (Resp. Exceptions). Respondent's brief raised numerous challenges to the ALJ's findings of fact and conclusions of law. Respondent also claimed (1) That DEA's pursuit of this proceeding violates the pre-trial diversion agreement, (2) that DEA should be estopped from contending that Respondent's continued registration is inconsistent with the public interest because of assertions the Government purportedly made in the criminal proceeding, and (3) that the DEA proceeding is a vindictive and retaliatory prosecution in violation of the Due Process Clause of the Constitution.

Having considered the record as a whole, I hereby issue this decision and final order adopting the ALJ's findings of fact and conclusions of law except as expressly noted herein. I have also reviewed Respondent's various claims and find them to be without merit. For reasons set forth below, I concur with the ALJ's conclusion that Respondent's

continued registration would be inconsistent with the public interest. I therefore adopt the ALJ's recommendation that Respondent's registration be revoked and that any pending applications for renewal or modification be denied.

Findings of Fact

Respondent obtained her doctor of medicine degree in 1975 from Calicut University Medical College, in Kerala, India. Following a one year residency in New Delhi, Respondent attended the University Rene Descartes in Paris, France, from 1977 through 1981. There, she obtained additional training in anesthesia, critical care, and pain medicine. Respondent then moved to Pittsburgh, Pennsylvania, where she served a residency in anesthesia at Allegheny General Hospital from 1981 until 1984. Because Respondent had already trained in anesthesia, she spent most of her time in pain management. Upon completion of her residency, Respondent moved to Clearwater, Florida, and took a position as an anesthesiologist at the Belleair Surgery Center (Belleair).²

Respondent worked at Belleair from 1984 until 1999, and eventually became its medical director. While at Belleair, Respondent treated chronic pain patients and in 1994 or 1995, opened her own clinic. In 1999, Respondent left Belleair to concentrate on her pain management practice. Respondent testified at the hearing that she had approximately 800 to 1000 recurring patients and saw around 3,000 patients per year. Respondent has between fifteen and eighteen employees, and during the spring of 1999, employed Ben Mastridge, a Certified Addiction Registered Nurse. According to Respondent, Mastridge identified patients who were addicted to narcotics and helped patients address their mental health issues.

The Criminal Investigation

In September 1998, Dale Carnell, a prescription fraud detective with the Pinellas County Sheriff's Office, contacted Ira Wald, a Diversion Investigator (DI) assigned to DEA's Tampa office. Detective Carnell told the DI that the Sheriff's Office had received "numerous complaints" about Dr. Iyer. Tr. 101-102. The DI proceeded to contact Walgreen's, a pharmacy chain, and obtained from it a printout of Dr. Iyer's controlled substance prescriptions for the previous twelve (12) months. *Id.* at 141. The DI testified that the printout

¹ Respondent also sought to enjoin the proceeding. The district court, however, denied her motion for an injunction.

² Respondent is board certified in anesthesiology and pain management.

was "the most voluminous" he had seen in his twenty-three years as a DI, *Id.* at 102 & 142, that it "was many hundreds of pages," *Id.* at 140, and that it "weighed five or six pounds." *Id.* at 141.

Based on the printout, the DI and Detective Bernie McKenna of the Pinellas Sheriff's Office decided to conduct undercover visits to Respondent's office. The first visit was conducted by Mr. Chris Massey, an informant for the local authorities who was then on probation following his guilty plea for having obtaining hydrocodone prescriptions by fraud.

The First Undercover Visit

On March 24, 1999, Massey went to Respondent's clinic and was seen by her. During the visit, Massey wore a wire; a transcript of his conversation with Respondent was admitted into evidence. According to the transcript, Respondent asked Massey who had sent him to see her. *See* GX-2, at 1. Massey told Respondent that he had been referred by a customer of his window tinting business. *See id.* Respondent then asked Massey, "[w]here is your pain?" *Id.* Massey answered: "I'm not really in pain. He [the customer] said to come up. He said, you know, you're real understanding, just come up and be honest with you. I, uh, I had a shoulder surgery about 4½ years ago." *Id.*

Respondent asked: "[r]ight shoulder?" Massey answered that "the problem was more or less cured." *Id.* at 1-2. Massey then told Respondent that "I was wanting to take Lorcet and Soma." *Id.* at 2. Massey also told Respondent that "I have been taking it * * * [e]ver since then," an apparent reference to the surgery. *Id.* Massey added that he was "sick of going to look for em." *Id.*

Respondent then told Massey: "Okay, look. We can, look, we can help you anyway." *Id.* In response, Massey then stated, "I mean I'm being honest, I mean I'm not really in—I don't—I mean they make me feel good, make me get work done, I mean I'm not abusing them." *Id.* Following a discussion of how many pills Massey was taking per day, Respondent told Massey "[w]e'll give you your medicine. The question for you is this—you can tell—you can tell me that you want to come out of drugs. We have intensive detox, we can help you." *Id.*

Later in the conversation, Respondent asked Massey "who gives you the medicine now?" *Id.* at 3. Massey replied, "I've been getting them from my girlfriend but me and her just split up." *Id.* Respondent then asked Massey what his job was and again asked about his shoulder. Massey told Respondent, "I

mean like I said, it's not, it doesn't bother me." *Id.*

Respondent then asked Massey, "what do you take, Lorcet 10?" *Id.* at 4. After Massey told her that he took Lorcet 10/650, Respondent stated: "Lorcet 10/650. See, this is a shame then that you have to take the medicine for the habit, you know." *Id.* Respondent once again asked Massey who had referred him. Massey told Respondent that his name was Bill and that he did not know Bill's last name, but that "he's been going to you for a while you know, you're real understanding." *Id.* After stating that "this is a pain center, you know," Respondent added: "We don't want to give out drugs. So that's why we have to have a psychologist and a substance abuse counselor." *Id.* In response, Massey said "Right." Respondent then added: "We have massage therapist, physical therapist and everybody here, you know. But you are honest, you are telling the truth, and we are here to help you." *Id.* Massey replied: "That's what he said, he said if you're honest with her, you know, go in there and tell her you're not in pain. This is your problem. You've been taking them." *Id.*

Respondent then asked Massey how many Lorcets he was taking per day. Massey told her four. Respondent stated "that's 124 a month" and told him not to lose his medicine or run out of it because she would not call in a refill. *Id.* at 5. Massey then paid Respondent \$175. *Id.* Respondent then told Massey, "I'd be happy to see patients like you," and then told him that she could give him a refill on his SOMA prescription. She would not, however, give Massey a refill on the Lorcet. Respondent then gave Massey a prescription for 120 Lorcet 10 with no refill and 60 SOMA with one refill.³ *See* Gov. Exh. 3.

The Government submitted into evidence the medical record which Respondent prepared for Massey's visit. Under the heading "Chief Complaint," the History and Physical record states:

Complains of neck and shoulder pain for the last several years. This began since he had surgery about 3-4 years ago. He complains of ongoing pain and has been taking Lorcet and Soma for a long time. He is having difficulty coming off of this and would like to get rid of the narcotics if he can. It is very difficult because of his daily activities etc. He has ongoing right shoulder pain and discomfort. Sometimes it is

³The ALJ found that "Respondent * * * said that she would give him sixty Soma, but would not list any refills on the prescription until she knew him better and knew that he was not abusing the medication." ALJ Dec. at 10. In light of the actual prescriptions written, I conclude that Respondent's statement that "Sorry there's no refill on it[,] was made in reference to the Lorcet.

manageable and when the pain gets worse he has to take the medication as soon as possible.

Gov. Exh. 4, at 1.

The second page of this document records the findings of a physical exam although Respondent admitted that she never performed one on Massey. *See* Tr. 495. Under the heading "Musculoskeletal," the record states: "Bilateral paracervical muscle spasms at the C6-7 area. Decreased range of motion of the right shoulder." *Id.* The record also includes the diagnosis of "chronic right shoulder pain." *Id.*

The medical records also include a questionnaire on which a patient indicates such information as the nature and source of his pain. The first question on this form is "How long have you had this pain?" Gov. Exh. 4, at 13. Massey left this blank. *See id.* Massey apparently did make a mark on both the front and back drawings of the human body in the area of the right shoulder. *See id.* Item 2 of this form directs the patient to "circle all the words that best describe your pain" and lists twenty-four adjectives that describe pain. *Id.* Massey did not circle any of these words. *See id.*

Respondent testified that she understood the mark that Massey had made in the shoulder region to indicate that he was "suffering from chronic pain injury" and that the marks were "the location area of the pain." Tr. 481. Respondent testified that Massey was not a typical pain patient as most of her patients "have been to many doctors, many operations and had been through many treatments." *Id.* at 482. She further testified that she "thought maybe he's suffering from chronic pain, something manageable that which may not have to be maintained on lots of oral narcotics" because "[i]t's not difficult pain for the patient." *Id.*

Later on direct examination, Respondent was asked what she understood Massey's statement that "I'm not really in pain" meant. *Id.* at 483. Respondent answered that because Massey was "already on medications[,] [m]aybe he doesn't have pain at that time when I see him in the office," but that if he wasn't taking the medication, "[p]ain would be there." *Id.* Respondent further testified that she believed that Massey's statement that he had undergone shoulder surgery four and a half years earlier to mean that he had developed a calcification in his shoulder which leads to chronic pain even though the pain "can be intermittent." *Id.* at 483-84. Later, however, Respondent testified that it was her impression that Massey had a

work-related shoulder sprain although she acknowledged that Massey “did not say that.” *Id.* at 489. Respondent also testified that chronic pain patients may see her on days that they do not have pain. *Id.* at 490

Respondent further testified that Massey’s statement that “the problem was more or less cured” meant to her that the problem was “more or less cured for the surgeon, but the pain persists.” *Id.* at 484. Moreover, Respondent testified that Massey’s comment that he had been taking Lorcet and Soma since the surgery meant that he was taking medications “[t]o control the pain, so that they [the patient] can have a decent, normal life.” *Id.* at 485. As for Massey’s comment that he was being honest, that the drugs made him feel good and get work done, and that he was not abusing them, Respondent testified that “[e]ven today when people take narcotics they feel ashamed of themselves” and that “maybe he’s ashamed of telling me he has to take pain medication to have a very active pace of living.” *Id.* at 485–86. She then stated: “he’s not abusing, that he’s not taking too many, that he’s taking the [drugs] to control the daily activities of living.” *Id.* at 486. Respondent added: “Drug addicts don’t take three, four [pills] a day to get work done. * * * Drug addicts take to get high and they don’t do their job. They sit at home and watch TV.” *Id.*

Respondent testified that “[o]ur job is to believe the patient.” *Id.* at 491. Respondent was then asked what she meant when she told Massey, “[t]his is a shame then that you have to take the medicine for the habit.” *Id.* Respondent answered: “See, whenever there is a pain, they take a pain pill to feel better. So, there are other habits we can create with them like the physical therapy, home exercises, so they don’t have to depend on that habit of taking a pill for every little thing.” *Id.*

Respondent further testified that Massey appeared honest to her. *Id.* 494. When asked whether it was significant that Massey “was honest with you and didn’t exaggerate his symptoms or seek additional—more medication than he was taking,” Respondent answered: “Yes, he’s not a drug-seeking person.” *Id.*

Respondent then admitted that she had not conducted a physical exam and that it was not “proper” to record the results of an exam that was never done. *Id.* at 496. When asked why she filled in the form, she answered that it was “the end of the day when I was preparing—looking at the charts because the blanks, probably I filled in what I could have seen.” *Id.* at 497.

Respondent insisted, however, that the comments she entered on the record as Massey’s “Chief Complaint” were based on what Massey told her. *Id.*

The ALJ found disingenuous Respondent’s testimony that she thought Massey had told her that he was not in pain because he was then taking medication. *See* ALJ Dec. at 40. I agree and note that the ALJ observed Respondent’s testimony and was in the best position to evaluate her credibility on these issues of historical fact. *See Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951). Indeed, Respondent’s story is implausible and inconsistent. Respondent testified that Massey was not “a typical pain patient,” and indeed, showed up without a referral. Given this, it is strange that Respondent proceeded to prescribe controlled substances without performing a physical exam and did so notwithstanding that Massey told Respondent numerous times that he was not in pain and that he was taking the drugs because they made him feel good. Indeed, in light of Respondent’s testimony that she found Massey to be honest, and that it was her job “to believe the patient,” it is puzzling that she did not accept Massey’s statements that he was not in pain and was taking the drugs because they made him feel good.

Massey’s statement that his girlfriend had been the source of his drugs begs the question of why, if he truly was in pain, he had obtained his drugs that way rather than through legitimate means. Furthermore, Respondent’s statements that (1) “[w]e’ll give you your medicine * * * you can tell me that you want to come out of drugs,” (2) that “this is a shame * * * that you have to take the medicine for the habit,” and (3) “we don’t want to give out drugs * * * that’s why we have * * * a psychologist and a substance abuse counselor,” demonstrate that Respondent understood that Massey was not seeking the prescription to treat pain, but rather to abuse them.

Finally, the ALJ found that “the descriptions of the alleged pain that Respondent wrote in [Massey’s record was] not—by any stretch of the imagination—based on what [he] told her.” ALJ Dec. 43. That is putting it charitably. The record was false. As Dr. Rafael Miguel (one of the Government’s experts) explained, the record was likely created because Respondent knew exactly what she had done—prescribed a controlled substance without a legitimate medical purpose—and thus did so “to justify the opioid prescriptions.” Gov. Exh. 18, at 2.

The Second Undercover Visit

On April 22, 1999, Massey returned to Respondent’s office for a follow-up visit. Massey did not see Respondent during this visit. Instead, he saw Ben Mastridge, a Certified Addiction Registered Nurse. After Mastridge asked Massey how he was “pain wise,” Massey initially stated that “it’s into my joint there,” that he had been put on Lorcet “years ago for a shoulder surgery,” but then added “I’m not in no pain.” Gov. Exh. 6, at 2. Massey used similar language several times to convey his condition to Mastridge. *See id.* at 2–3. Notwithstanding the double negative in Massey’s statements, Mastridge clearly understood that Massey did not have pain. *See id.* at 3. (Mastridge stating “if you’re not having pain then you don’t need” narcotics.)

Mastridge and Massey discussed what drugs the latter was taking; Mastridge suggested that “I can give you like an Ativan⁴ or something.” *Id.* Massey told Mastridge that “I don’t want no mind medication.” *Id.* Massey also told Mastridge that he could “function without” the Lorcet, but that he took it “to work and to get, you know to get chores done on work days.” *Id.* Massey then suggested that if Mastridge put him “on Xanax we could probably level me out a little bit.” *Id.* Massey also told Mastridge that he took the Soma because he was “so used to taking them” and that he was not having muscle spasms. *Id.* at 4.

Mastridge then told Massey that “using narcotics when there is no pain isn’t acceptable.” *Id.* Mastridge added that “just to prescribe * * * narcotics because you’re physically dependent on it * * * that’s, that’s that’s unacceptable.” *Id.* Mastridge then suggested that “we can come up with a plan [to] decrease by one pill every, one pill a day every two weeks * * * and see how you do.” *Id.* at 5. Mastridge also suggested that he could put Massey on “just methadone and decrease the Lorcet or we can * * * just decrease the Lorcet.” *Id.* at 6. Massey told Mastridge that he was “definitely not going to go without the Lorcet.” *Id.*

Later in the conversation, Massey again told Mastridge that his shoulder was “cured,” and added that he was “over the cocaine and all the stuff I went through in my early days,” but that “these pills make me feel good.” *Id.* at 8. Mastridge told Massey that he was going to give him a prescription for Xanax because it “will help to take the edge off of bringing the coke down.” *Id.* at 9. Mastridge further stated that “we

⁴ Ativan, or Lorazepam, is a Schedule IV controlled substance. 21 CFR 1308.14(c).

are going to put down that you are starting the detox program and it will run over a period of fifty to ninety days" and that Massey had agreed to start the program "over the next 60 days." *Id.* at 10.

Massey then told Mastridge that "I don't have no physical problem" and "it's just I like these pills." *Id.* Mastridge replied that "as far as the physical dependence on it goes * * * we can come up [with] other treatment options once we try some things here." *Id.* Mastridge then told Massey that he would be getting 105 Lorcet tablets, which he should take three times a day, 90 Soma, which he should take three times a day, and Xanax .5, which he should take twice a day. *Id.* at 10–11.

Massey then asked whether "oxycontin or dilaudid would be easier on my body?" *Id.* at 11. Mastridge answered that "it is not legal to prescribe narcotics long term if there is no pain," and that "it's easier to take you down off the Lorcet than it would be off the oxycontin because of the types of doses." *Id.* When Massey suggested that oxycontin 10 tablets were available, Mastridge replied that "the bottom line is you need to be off the narcotics." *Id.* at 11–12.

Mastridge then gave Massey the prescriptions for Lorcet, Soma, and Xanax discussed above and a questionnaire, which he instructed him to complete in the waiting room. *Id.* at 12–13. Observing that the prescriptions were pre-signed, Massey asked Mastridge, "So what do you do? You just fill these out and the doctor already signs them?" *Id.* at 13. Mastridge answered: "Yes." *Id.* Massey then stated, "I thought that the Doctor had to fill the prescriptions out and sign it." *Id.* Mastridge replied: "Oh no, no * * * as long as she is in the building I am being supervised and as long as I'm being supervised, I can do anything that she can do because she signs her name to the treatment agreement, there's a place for her to sign it, too." *Id.*

The Government entered into evidence the patient chart for Massey's April 22nd visit. The chart states that the patient "report[s] no current pain." Gov. Ex. 4, at 3. The chart also states that Massey reported "good sleep, appetite" and that he had agreed to start outpatient "detox over [the] next 60 days." *Id.* In addition, the questionnaire which Massey completed on this visit asked whether, "[d]uring the past month," he had "been bothered by any illness, bodily disorder, pains, or fears about your health?" *Id.* at 6. Massey checked the box for "none of the time." *Id.*

Mr. Mastridge did not testify in this proceeding. Respondent did, however, testify regarding this visit. In her testimony, Respondent acknowledged that at the time of the visit, Mr. Mastridge was not authorized under Florida law to dispense a controlled substance. Tr. 641. Respondent attempted to justify her conduct testifying that she "was in the office," that Mastridge "never saw the patient alone," and that "I was right there." *Id.* at 641–42. Respondent admitted, however, that she was "[n]ot in the same room" when Mastridge issued the prescriptions for Lorcet, Soma, and a new drug Xanax. *Id.* at 642.

The Third Undercover Visit

On May 12, 1999, Detective Jeff Esterline of the Pinellas Sheriff's Office went to Respondent's office to conduct an undercover visit. Using the name Jeff Scott, Esterline told Respondent that he had recently moved from Iowa and that he worked as an electrician's helper. Respondent asked Esterline what had happened to his back. *See* Gov. Ex. 9, at 1. Esterline told Respondent that he had been referred by Chris Massey, that Massey had seen her before, and had "said you were a good doctor to come to." *Id.* at 2. Respondent then told Esterline to "[t]ell me about your pain." *Id.* Esterline stated: "I don't have any pain really, I didn't know if they would let me in to talk to you if I didn't tell them something, so I don't have any pain, really." *Id.* Esterline added that he was taking four to five Vicodin a day. *Id.* Respondent asked Esterline how he got his drugs. Esterline stated that he had been "getting them from a friend." *Id.*

Respondent then told Esterline that her clinic offered a detox program. *Id.* She then asked, "you don't have pain but you are taking vicodin? Why were you taking vicodin?" *Id.* After Respondent repeated her question, Esterline told her that he had "started taking them quite a while ago" and that he thought he "function[ed] a lot better with them." *Id.* at 3. When Respondent asked if he got the drug from friends, Esterline answered in the affirmative. *Id.*

Respondent then asked Esterline if he "want[ed] to go to substance abuse program or do you want to be maintained on the vicodin?" *Id.* Esterline answered that he would like to remain on drugs as he felt like he functioned "real well" while taking them. *Id.*

Respondent then warned Esterline that narcotics "are habit forming" and can cause liver damage. *Id.* Esterline responded that he didn't think he had

any problems and that he had started taking them when his mother had died a year and a half earlier. *Id.* He added that "I feel, just feel like I function real well with them" and "I don't abuse them." *Id.*

Respondent then told Esterline: "you don't have to start if you don't want to be on vicodin" and "there is no reason you should be on it." *Id.* at 4. Esterline responded that "I feel like I, I function better," and that "I don't think I'm not taking so many of them that I feel like I have a real problem, but I just function better, just keeps me even." *Id.*

Respondent then stated that "[i]f you didn't get vicodin, you know, you know it is okay, too, right?" *Id.* She added that "we don't want to start you on some narcotics that you don't have to be on it." *Id.* Esterline responded that Massey "said that you know if I just was honest with you that you know, that that you'd helped him." *Id.* Respondent then stated that she thought she remembered Massey but didn't know. *Id.* Respondent also told Esterline that her assistant Ben Mastridge "can help you to get off narcotics. He can do a methadone, whatever." *Id.*

Esterline replied that he "was just hoping to get" Vicodin and again told Respondent that he took three or four a day. *Id.* Respondent advised Esterline that drugs could be toxic, that he could build up a tolerance to them and that "the more you take the more you need," and then asked him if he was "willing to take all these risks?" *Id.* Esterline stated that he was and that the drug helped him to "function better." *Id.* Respondent then referred to various potential causes of pain. Esterline once more stated that "I don't really have any problem, I don't really have any pain," and again added that "I feel like I function better" when taking the drugs. *Id.*

Respondent then asked Esterline if he "would like to start on the vicodin?" *Id.* at 5. Esterline told Respondent "Yeah, that's what I was here for." *Id.* Respondent told Esterline to "[s]tart with the four a day," and that her employee Ben Mastridge "can counsel you with medication and narcotics and everything." *Id.*

Later on, Respondent stated "[s]o you don't want to come out to the narcotic clinic, you know this is for the people to come here so they don't do drugs, you know, and too, maybe I'm sympathetic to the people that allow themselves to slip into drugs." *Id.* Respondent then told Esterline that "narcotics are good and bad," and that "[y]ou don't want to get hooked on drugs." *Id.* Esterline again told Respondent that he did not think that he was addicted, that he went to

work every day, and that the drugs made him “feel better.” *Id.*

Respondent then asked Esterline if he had been on vicodin “for a while?” *Id.* at 6. When Esterline answered “yes,” Respondent asked him if he could “confirm it” by bringing in “left over [prescription] bottles” he had gotten through other doctors. *Id.* Esterline told her that he had “been having trouble getting them for so long” and offered to look at home for the bottles. *See Id.* at 6. Respondent then again told Esterline that “[y]ou don’t want to make a new habit” and get “hooked on drugs.” *Id.* Esterline reassured Respondent that he was not addicted. *See Id.*

Respondent then stated that she would give him a prescription for 60 Vicodin ES with two refills and that the drugs “should easily last you for 1 month.” *Id.* Respondent then suggested that Esterline make an appointment to see Mastridge. *Id.* She also told Esterline that her clinic had a massage therapist and a physical therapist and that “you need to feel good—you’re taking it just to feel good.” *Id.* at 7. Esterline paid \$180 for the visit. Gov. Ex. 10.

The government entered into evidence various patient records pertaining to Detective Esterline’s visit. Describing Esterline’s chief complaint, the “History and Physical” record states: “He has a terrible pain in his neck. This started 1½ years ago. Ever since his mother’s death, he has had ongoing pain. He does a lot of construction work, wiring, etc., which makes the condition worse.” Gov. Ex. 11, at 1. The entry for Esterline’s Musculoskeletal system likewise states: “chronic pain.” *Id.*

The records also include a questionnaire used by patients to report their symptoms and other information relevant in diagnosing and treating their condition. The first question on the form is “How long have you had this pain?” *Id.* at 2. Esterline wrote “none.” The form also lists twenty-four adjectives to describe pain and instructs the patient to “circle all the words that best describe your pain.” *Id.* Esterline did not circle any word. *See Id.*

The form also contains front and back representations of the human body, on which patients are instructed to shade the area where they have pain. *See Id.* The forms have several small markings in the area of the neck. *Id.* Detective Esterline testified that he did not make the markings. Tr. 58. Respondent maintained that he did. *Id.* at 519.

Respondent testified that she “probably” “missed” Detective Esterline’s answer of “none” to the question “How long have you had pain?” Tr. 523. She further testified that

Esterline was not typical of the pain patients she sees because “[h]e has a soft tissue injury, neck pain. He didn’t have any x-ray or MRI.” *Id.* She added that a typical patient would be “a construction worker, car accident patient who had an MRI x-ray workup” and that Esterline hadn’t “had anything done.” *Id.* at 524.

Respondent’s counsel then asked her about Esterline’s statements that he didn’t have any pain, that he had indicated he did because he did not think the office staff would let him in otherwise, that he was taking four to five Vicodin a day, and that he did so because he functioned better when he took them. Respondent testified that “some patients are very reluctant to admit that they need Vicodin to control their pain,” and that he was “taking medications to be able to do his job.” *Id.* at 526–27. Respondent also testified that she believed that Respondent had obtained his Vicodin through a lawful prescription. *Id.* at 528. Respondent further testified that she asked Esterline what type of work he did “to find out whether he’s having pain because of the type of job he does,” and that electricians (the job Esterline said he had) commonly have neck pain. *Id.* at 529.

When asked on direct what Esterline meant when he said “I don’t really have any pain,” Respondent answered: “He’s contradicting himself[,]” and that “he is in pain, but when he takes medications he doesn’t have any pain.” *Id.* at 530. When asked whether Esterline had “in any way exaggerated his symptoms?,” Respondent answered “No”; when asked whether he appeared to be honest, Respondent answered “yes.” *Id.* at 531. Respondent also testified that Esterline did not seek more medication than he was currently taking and that he seemed like a patient who was seeking treatment for chronic pain. *Id.* at 532.

Respondent admitted on cross-examination that she did not conduct a physical examination on Esterline. *Id.* at 645. She also testified that her handwritten notes for the physical exam were based on what she “would have done with a patient” with neck pain. *Id.* at 533–34. She further admitted that it was inappropriate to make these notations. *Id.* at 534. She testified, however, that she believed her prescribing of controlled substances to Esterline was within the standard of care. *Id.* at 537.

Here, again, the ALJ, who personally observed Respondent testify, found disingenuous Respondent’s testimony that she thought Esterline was not in pain because he was taking medication. *See ALJ* at 40. I agree and further note

that it is strange that a patient who is “honest,” does not “exaggerate his symptoms,” told Respondent multiple times that he did not have pain, and that he took the drugs because they helped him function better, would then be disbelieved as to why he was taking the drugs. Furthermore, while Respondent testified that she believed Esterline had obtained the drugs through a lawful prescription, Esterline told her at least twice that he had gotten them through friends and that he had also been “having trouble getting them for so long.” Finally, Respondent made several incriminating statements such as when she asked Esterline if he “want[ed] to go to substance abuse program or do you want to be maintained on the vicodin?,” and stated “maybe I’m sympathetic to the people that allow themselves to slip into drugs.”

The Fourth Undercover Visit

On June 24, 1999, Detective Randall Keys of the Tampa Police Department,⁵ using the name Ronald Briers, made an undercover visit to Respondent’s office. Respondent asked him if he had abdominal pain. Gov. Ex. 12, at 1. Keys told Respondent that he did not have pain, but that he “had to put something down on” the form. *Id.* Keys then added that “[a] friend of mine suggested that I come to talk to you about it.” *Id.* Respondent asked: “About what? Detox?” *Id.* Keys told Respondent, “I need some * * * vicodin.” *Id.*

Respondent asked Keys why he needed vicodin. *Id.* Keys answered, “Well it, basically it makes me feel better. It just kind of takes the edge off.” *Id.* After discussing Keys’ job, Respondent stated: “We do not give drugs out to people. And now, if you want to go to substance abuse program, we have Ben [Mastridge] here for you.” *Id.* Denying that he was addicted, Keys stated again that the drug “just kind of helps me. Just—it just takes the edge off.” *Id.*

After stating that she did not want “to promote the intake of drugs,” Respondent asked Keys who had sent him. Keys told her Chris Massey. *Id.* at 2. Respondent reiterated that “We don’t want to give drugs out to people, you know, and ruin our reputation.” *Id.* Respondent then suggested that Keys try her acupuncture program. *Id.*

Respondent declined, stating that he did not “have any pain or anything like that” and that he took the Vicodin because “they just take the edge off.” *Id.*

Respondent and Keys discussed how many he took a day. *Id.* Keys said three.

⁵Detective Keys was then assigned to a DEA task force. Tr. 70.

Respondent then asked Keys where he got the drug. *Id.* At first, Keys said that he got it from a person, but when asked how much he paid for it, Keys said it was actually from “like a family member who has a prescription.” *Id.* at 3. Respondent then told Keys that “[t]his is a real test for me” and “we don’t want to give narcotics to like creating drug use.” *Id.*

Thereupon, Respondent apparently summoned Ben Mastridge to the examining room. After again discussing Chris Massey, Respondent briefed Mastridge on Keys’ situation telling him that Keys took “about 2 to 3 vicodin a day” and that “now he’s wondering whether we will be able to promote or support his pain with the 3 Vicodin a day.” *Id.* After telling Mastridge that they had not discussed “[t]he issue of people coming here asking for a drug,” Respondent then told Keys that “Ben is our AR and he does my detoxification for narcotics. He is the director for narcotics program.” *Id.*

Shortly thereafter, Mastridge asked Keys how many Vicodin he was taking and how long had he been taking the drug? *Id.* Keys answered that he usually took about three and had been doing it for six months. *Id.* Mastridge then asked Keys whether the Vicodin had been prescribed to him. *Id.* at 4. Keys answered “no.” *Id.* Respondent then told Keys that “we want to help people with pain,” to which Keys responded “Right.” *Id.* Respondent then stated that “we don’t want to promote a drug habit.” *Id.* Keys responded: “No, I understand.” *Id.* Mastridge then told Keys “[j]ust throwing pills at the situation, that’s where people end up taking—if they are taking 3 Vicodin a day now, in 6 or 8 or 12 months they’re taking 15 of them a day.” *Id.*

After discussing the need to provide “some sort of concurrent treatment to go along with [the vicodin] to address the source of the pain,” *Id.*, Mastridge asked “is it muscle spasms that are actually going on here?” *Id.* at 5. Respondent interjected, “Pain, pain, you’re right.” *Id.* Mastridge continued stating: “What, what’s the source of the pain? I guess that’s what the ultimate question is. And since you weren’t diagnosed by anybody in primary care or anything.” *Id.* Respondent replied: “I guess he feels no pain, he just feels better.” *Id.* Mastridge then asked Keys, “You just feel better?” Keys answered, “They just kind of mellow you out I guess * * * it makes me feel okay.” *Id.*

After discussing various treatments available at her clinic, Respondent told Keys that she was going to give him a prescription for 60 vicodin, *see Id.*, and Mastridge told Keys that they would

discuss his condition and “the best course of treatment” during his next visit. *Id.* Respondent then explained the costs for the clinic’s various services and added “[i]t’s a way of letting you know * * * we will not be supporting just a drug habit.” *Id.* at 6. Respondent then told Keys that Ben “will write the prescription for you too, He writes my prescriptions. When you see him, you don’t have to see me.” *Id.*

The government entered into evidence various patient records pertaining to Detective Keys’ visit. The History and Physical record describes the patient complaint as: “Ronald Bryers presents to my office with low-back pain and anterior abdominal pain, which is ongoing. He works as an automobile detailer, getting under cars, etc., and the constant physical labor makes the pain worse. * * * He has had this pain for the past several years.” Govt. Exh. 14, at 1.

The document also reports the results of a physical exam. Under the musculoskeletal heading, the record states that “[m]inimal paralumbar muscle spasm is noted, with minimal facet tenderness.” *Id.* The report also contains a diagnosis of “chronic low-back pain.” *Id.* Respondent admitted, however, that she did not perform a physical exam on Keys, Tr. 647, and Keys testified that he did not believe that he had discussed his medical history with Respondent. *Id.* at 84.

Respondent testified that Detective Keys was seeing her for abdominal and lower back pain but that “[h]is history was kind of not clear to me.” *Id.* at 541. Moreover, Keys was a “very unusual” patient. *Id.* Respondent explained: “Patients come to me after being diagnosed, after being treated. * * * I wonder, what is he doing in my office without being diagnosed and we don’t want to be a clinic where we give out medications for reasons not needed.” *Id.* at 546.

Respondent testified that because she “didn’t feel right,” *Id.* at 541, she sought out Mr. Mastridge to assist her in evaluating Keys because of Mastridge’s knowledge of substance abuse and psychological problems. Respondent testified that she thought that Mastridge could help her diagnose whether Keys was “taking medicine to control the pain or for any behavioral problems.” *Id.* at 542.

Respondent testified that Keys’ statement that he took Vicodin because it took “the edge off” meant that the drug took the “[e]dge off the pain,” and that the term “edge off” is commonly used in the pain context. *Id.* at 544. As for Keys’ statements that he didn’t have pain, Respondent testified that she

thought this was because he was “on pain medication,” that “people do not have to have the pain all the time,” and that pain levels can fluctuate. *Id.* at 545. She further stated that even though Keys may not have had pain at the time of his visit, “they wouldn’t come to my pain clinic if [they] don’t have the pain.” *Id.*

Respondent also testified that when she discussed with Mastridge doing narcotics detoxification, she meant “medication reduction.” *Id.* at 549. She further testified that when she told Keys that “we want to help people with pain” and that “we don’t want to promote a drug habit,” she understood Keys’ answers as meaning that he was in pain and was agreeing to her proposed treatment. *Id.*

Respondent admitted that because she had not performed a physical exam, she should not have filled out the form as she did but maintained that the patient record’s “history part is true.” *Id.* at 647. Respondent testified that the physical exam part of the record was “missing” “because I went and got Ben [Mastridge] because this patients [sic] were not my true pain patients,” *Id.* at 647–48, and that she had made it up “because of the confused cases brought to me.” *Id.* at 648–49.

Respondent added: “I don’t see patients like this at all in the office. These are like the strange weirdos coming to my office.” *Id.* at 648. Respondent further testified that she was “astonished to see patients like [Keys] in the pain clinic” and that “[t]hese are not my typical pain patients.” *Id.*

Respondent was then asked whether it was within the standard of care in the State of Florida to prescribe controlled substances without performing a physical exam. In response, Respondent testified: “that’s what we learn when we go to medical school. Take a history and physical examination. Chronic pain, these patients who are very difficult to evaluate. Physical examination is part of our job.” *Id.* at 650. Upon further questioning Respondent added that performing a physical exam “is the standard of practice. That’s our Rule No. 1.” *Id.* at 651.

Respondent then denied, however, that she had intentionally and knowingly dispensed controlled substances. *See Id.* at 652. She testified:

Intentionally I did not dispense medication, I did not distribute outside of the usual course of medical practice. In the context of the clinical pain management, I knew the medication not to transfer, not to sell the drug to the street or anything. My intention here is believe the patient, give them the benefit of chronic pain, and

evaluate them, and do what is appropriate for them.

Id. at 652–53.

As with the other undercover visits, the ALJ did not find credible Respondent's assertion that she prescribed Vicodin to Keys because she believed his use of the drug was the reason he was not in pain. *See* ALJ Dec. at 40. Again I agree. The transcript of the visit provides substantial evidence that Respondent knew that Keys was seeking drugs for illegitimate use. Not only did Keys state that he did not have pain and that the drug took the "edge off," when Mastridge asked what the source of Key's pain was, Respondent stated: "I guess he feels no pain, he just feels better." Shortly thereafter, Respondent explained the costs for the clinic's various services and added that "we will not be supporting just a drug habit." Finally, I am perplexed as to why if a patient is a "strange weirdo" and causes astonishment because he is not a "typical pain patient," a physician would then proceed to write a prescription for a controlled substance without performing a physical exam as required by "Rule No. 1."⁶

The Expert Testimony

Both the Government and Respondent introduced expert opinion evidence on the subject of Respondent's prescribing practices. Dr. Daniel Frazier, M.D., of Tampa, Florida, a Board Certified Family Practice Physician with more than thirty years of experience, and an Assistant Clinical Professor of Family Practice at the University of South Florida (USF) College of Medicine, reviewed the tapes and transcriptions of the undercover visits. In a statement dated February 1, 2001, Dr. Frazier declared that "[i]t is inappropriate to prescribe pain medication in uncontrolled environments," and that "[t]he physician must determine the level of pain that he/she is treating by means of examination and discussion with the patient." Gov. Exh. 16. Dr. Frazier further stated that "the physician must closely monitor the patient to see that there is a medical need" for a controlled substance. *Id.*

Dr. Frazier concluded that Respondent "was not in control of the patients; the patients were in control of her." *Id.* Moreover, "[t]he patients actively sought pain pills for non-appropriate reasons and the patients were given the pain medication without

examination or significant review of their symptoms. Such care on the part of the physician constitutes inappropriate medical treatment[,"] and "a failure to appropriately practice medicine within the acceptable standard of care." *Id.* I credit Dr. Frazier's statement.

The government also submitted the statement of Rafael Miguel, M.D. At the time of his review, Dr. Miguel was a Professor and Interim Chairman of the Department of Anesthesiology, as well as the Director of the Pain Management Program at the USF College of Medicine. Dr. Miguel clearly states that he reviewed the medical records, transcripts of the undercover visits, and Respondent's pre-hearing statements. Gov. Exh. 18, at 1.⁷ Dr. Miguel stated that "[t]here is no currently accepted therapeutic use of opioids but for the relief of pain. Administering opioids to patients with no pain is inappropriate and clearly constitutes practice below the standard of care." Gov. Exh. 18, at 2.

Dr. Miguel observed that "[i]f the concern was that patients were drug abusers and the intent was to wean them from opioids, this should have been done in an addiction treatment facility with trained personnel. * * * Addiction is a complex problem and physical dependence is a small part of the pathophysiology of the disease." *Id.* Dr. Miguel further explained that "[p]rescribing opioids to known addicts is inappropriate and clearly constitutes practice below the standard of care." *Id.*

Finally, Dr. Miguel discussed Respondent's failure to perform physical exams and record keeping practices. According to Dr. Miguel, "the documentation does not concur with the reported complaints. While the reported complaints did not include pain, high levels of pain interfering with daily life were documented. This was apparently done to justify the opioid prescriptions." *Id.* Dr. Miguel also stated that "[i]t does not appear that the patients were physically examined, yet there is documentation of heart and lung sounds, abdominal palpitation, even paracervical muscle spasms and decreased range of motion in joints impossible to assess without a physical exam." *Id.* Dr. Miguel concluded that "[t]his may constitute medical fraud and is clearly practice below the standard of

care." *Id.* I likewise credit Dr. Miguel's statement.

Respondent introduced a statement of Walter E. Afield, M.D., a psychiatrist. Dr. Afield stated that he had reviewed Dr. Frazier's statement and was "not in agreement." Resp. Ex. 55. He asserted that "based on statements made to the doctor, there are sufficient reasons for prescribing the medications in question." *Id.* In Dr. Afield's opinion, Respondent "felt these patients were dependent on these medications to function and were functioning and that they needed to be placed in a medically supervised program to detoxify the patients and find alternative treatments for them." *Id.* Dr. Afield further stated that his "[r]eview of the entire record of the patient indicates those medicines were given within the parameters of her specialty." *Id.*

I agree with the ALJ's declination to credit Dr. Afield's statement for several reasons. First, while Dr. Afield has had a distinguished career in psychiatry, it is not clear what expertise he has in the area of pain management or the general diagnosis and treatment of physical injuries. If his opinion was offered as an expert in treating addiction, I note that Respondent maintained repeatedly that she prescribed the drugs to all three patients because she believed the patients were in pain and not because she was treating an addiction.

Second, his opinion is vague and it is not clear whether he viewed Respondent's prescribing to be appropriate because the patients were in pain or because they were addicted. Indeed, to the extent Dr. Afield's statement that "the patients were dependent on these medications to function" and that the patients "needed to be placed in a medically supervised program to detoxify them," was intended to suggest that Respondent's prescribing was appropriate because the patients were addicted, it is clearly wrong because the CSA prohibits the prescribing of controlled substances for this purpose. *See* 26 CFR 1306.04(c) ("A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for 'detoxification treatment' or 'maintenance treatment.'"). DEA's regulations make clear that a physician who is not registered to conduct a narcotics treatment program may administer, but not prescribe, "not more than one day's medication" of narcotics for up to three days to a person suffering "acute withdrawal systems when necessary while arrangements are being made for referral for treatment." 26 CFR 1306.07(b). A physician cannot,

⁶ I acknowledge that in December 1999, the investigators attempted an additional undercover visit. Respondent's receptionist refused to admit the officer because he did not have a referral. *See* Resp. Ex. 46.

⁷ I note and reject Respondent's contention that the ALJ did not know what Dr. Miguel based his opinion on. *See* Resp. Br. 39–40. The factual basis for Dr. Miguel's opinion is clear from his statement. *See* Gov. Exh. 18, at 1. Moreover, Respondent could have sought to subpoena Dr. Miguel to testify if there was any dispute as to the factual basis of his opinion. 21 CFR 1316.52(d). She did not.

however, issued a prescription for this purpose.

Third, to the extent he believed that Respondent prescribing was appropriate because the undercover operatives were in pain, Dr. Afield stated that he "review[ed] the entire record of the patient." *Id.* It is undisputed, however, that Respondent falsified the medical records of the three undercover operatives and there is nothing in the statement that suggests that Dr. Afield relied on non-falsified records. An expert opinion based on falsified records is obviously not probative of the issues.

Fourth, Dr. Afield's statement does not address why it would be appropriate to prescribe a controlled substance without performing a physical exam. This is especially noteworthy in light of Respondent's acknowledgement that performing a physical exam is "Rule 1."

Respondent also called as a witness Robert A Guskiewicz, M.D. Dr. Guskiewicz is the Director of the Pain Fellowship Program and a Clinical Assistant Professor in the Department of Anesthesiology, University of Florida College of Medicine. Resp. Exh. 57. Dr. Guskiewicz also served as the court monitor under the pre-trial diversion agreement.

Dr. Guskiewicz testified that in his opinion Respondent had legitimately prescribed controlled substances to all three undercover visitors. Tr. 813. He further testified that his opinion was based on the indications of pain on the patient questionnaires that were completed by the undercover visitors. *Id.* at 814. Dr. Guskiewicz added that Massey had indicated that "he did have pain in the past," and that the medications he had used had "helped to improve his function in doing his job." *Id.* He also testified that the same was true for the patients portrayed by Detectives Esterline and Keys. Dr. Guskiewicz stated that while "[t]here was some vagueness," he could determine that the medications had helped these patients improve their functionality. *Id.* at 815. Dr. Guskiewicz also testified that he teaches his students to "give the patient the benefit of the doubt," *Id.* at 824, but to provide them with a "limited supply of medications" such as either a two-week or one-month supply, and to "do our due diligence." *Id.* at 825.

On cross-examination, Dr. Guskiewicz was asked "[w]hat is required of a physician who wanted to establish a course of treatment?" *Id.* at 818. Dr. Guskiewicz answered: "[p]hysical examination, assessment and diagnosis." *Id.* Later in the cross-examination, Dr. Guskiewicz was asked

a series of questions related to whether he knew that Respondent had made up the part of the record that supposedly were the findings of a physical exam. One of the questions was whether it was "outside of the practice in the state of Florida" to falsify a patient record. *See Id.* at 827. Dr. Guskiewicz testified that "[n]ot performing the examination would not be outside the practice, but saying you performed the examination when you did not would be." *Id.* Dr. Guskiewicz acknowledged, however, that the assumption that a person comes to a pain management clinic because they are in pain does not relieve a physician from the responsibilities of performing a physical exam and inquiring into the patient's medical history. *Id.* at 829.

The ALJ declined to credit Dr. Guskiewicz's opinion that Respondent had properly prescribed controlled substances. I likewise decline to credit Dr. Guskiewicz's opinion on this point. As an initial matter, I note that Dr. Guskiewicz's opinion was based, in part, on the fact that Massey had indicated that he had "pain in the past." But Massey also stated that he had had shoulder surgery four and a half years ago and that the "problem was more or less cured." Thus, Massey's statements do not provide an adequate basis for concluding that a patient is still in pain, or would be in pain but for the taking of a controlled substance.

Indeed, I note that Respondent did not do "due diligence" by performing a physical exam even when she admitted that the undercover patients were "not typical" or were "strange weirdos." Furthermore, Dr. Guskiewicz eventually, although apparently with some reluctance, conceded that it is essential to perform a physical exam before prescribing a controlled substance. Thus, Dr. Guskiewicz appears to have rendered his opinion on direct examination regarding Respondent's prescribing to the undercover patients without considering material facts.

Other Evidence

I note that Respondent did comply with the terms of the pre-trial diversion agreement and that the United States Attorney dismissed the indictment. I also note that Respondent retained the services of a private investigation firm to review her patient records and determine which patients were likely substance abusers and should be discharged from her practice. I also note that the private investigation firm developed procedures to address, and trained Respondent's employees in, such matters as spotting drug abusers,

doctor shopping, failed drug tests, claims of lost, stolen or destroyed medications, prescription fraud and forgery, and patients with a drug-related criminal history. The private investigation firm conducted criminal history checks on more than 500 people and interviewed nearly 280 patients and their associates. I further acknowledge that one of Respondent's private investigators testified that prescription drug abusers would target foreign doctors, that they would provide forged medical records such as MRI reports, and that most of the patients he interviewed admitted to lying to Respondent to obtain narcotics. I note, however, that none of the undercover operatives used false records to induce Respondent to prescribe to them and that none of them claimed to be in pain.

Respondent testified that she had discharged or not accepted "may be in the hundreds" of patients. *Id.* at 426. She also testified that she stopped pre-signing prescriptions and that she was no longer accepting patients without a referral. *Id.* at 470.

Finally, Respondent called several patients to testify on her behalf. In general, the patients testified that Respondent's treatments had greatly helped them to control their pain and had helped them improve their functionality. Respondent also submitted numerous letters from patients that were to similar effect.

Discussion

Respondent's Challenges to the Proceeding

Before analyzing this case under the public interest factors, *see* 21 U.S.C. 823(f), I note that Respondent has raised several challenges to DEA's authority to bring this proceeding. Therefore, I will address these claims to determine whether any of them have merit.

Respondent's first contention is that this proceeding "violates the plain terms, meaning and understanding of the" pre-trial diversion agreement she entered into with the United States Attorney. Resp. Br. 72. In particular, Respondent asserts that "the Government agreed that it would dismiss the charges against [Respondent] (assuming [her] compliance with the [agreement] and that she would continue to practice pain management including the prescribing of Schedule II-V controlled substances." *Id.* at 71. Respondent thus contends that this proceeding violates "the understanding that Dr. Iyer would continue to practice pain management and to prescribe" controlled substances.

I disagree. Nothing in the plain language of the agreement manifests the government's assent that Respondent would be able to continue prescribing controlled substances without being held to account by DEA, or purports to waive DEA's authority to seek the revocation of her registration. *See* Resp. Exh. 52. Nor is there any merit to Respondent's contention that this proceeding violates the understanding of the parties. Respondent got exactly what she bargained for—a dismissal of the federal indictment. Immunity from a DEA revocation proceeding was not part of the deal. Beyond that, the United States does not waive its sovereign authority by implication. *Cf. United States v. Cherokee Nation of Oklahoma*, 480 U.S. 700, 707 (1987) (“[A] waiver of sovereign authority will not be implied but instead must be ‘surrendered in unmistakable terms.’”) (quoting *Bowen v. Public Agencies Opposed To Social Security Entrapment*, 477 U.S. 41, 52 (1986) (int. quotations and other citation omitted)).

Furthermore, a United States Attorney does not have authority to bind the Drug Enforcement Administration from instituting proceedings seeking the revocation of a registration under the Controlled Substances Act. As the Eleventh Circuit has observed in a case involving the INS, which was then a sister agency of DEA in the Department of Justice, “Congress did not expressly grant the United States Attorney authority to bind the INS, or any other governmental agency.” *San Pedro v. United States*, 79 F.3d 1065, 1069 (11th Cir. 1996).

Rather, Congress vested the authority to revoke a registration in the Attorney General, *see* 21 U.S.C. 823(f) & 824(a), and this authority has been delegated exclusively to the Administrator and Deputy Administrator of DEA. 28 CFR 0.100(b) & 0.104. Therefore, a United States Attorney cannot enter into either a pre-trial diversion agreement or a plea bargain that binds DEA from instituting revocation proceedings without DEA's express written authorization. *See United States v. Fitzhugh*, 801 F.2d 1432, 1434–35 (DC Cir. 1986) (rejecting contention that plea agreement implicitly prohibited DEA proceeding noting that AUSA lacked authority to bind DEA); *Noell v. Bensinger*, 586 F.2d 554, 559 (1978) (“Neither the prosecutor nor the district court * * * had the authority to speak for the” DEA.); *Cf. San Pedro*, 79 F.3d at 1069–70; *United States v. Igbonwa*, 120 F.3d 437, 444 (3d Cir. 1997) (“[T]he United States Attorney's Office lacks the authority to make a promise pertaining to deportation in the prosecution of a

criminal matter that will bind INS without its express authorization.”).

Respondent's estoppel arguments based on the diversion agreement are equally unpersuasive. Respondent asserts that DEA is estopped from seeking the revocation of her registration because she “relied on the government's representations in the * * * Diversion Agreement that it was in the interest of the United States and in the interest of justice that she continue to practice pain management and to prescribe narcotics.” Resp. Br. 72. Respondent further contends that “[i]f she had known that the Government would seek to revoke her DEA Certificate, she would not have given up her right to a speedy trial and would not have entered the Pretrial Diversion Program.” *Id.*

As an initial matter, I note that the diversion agreement's “interest of the United States” language is part of the standard diversion agreement form, which is used for a wide variety of federal crimes, and is thus boiler plate. The language is clearly not a reference to the “public interest” standard that Congress had directed me to apply in administering the CSA.

More importantly, it well settled that the United States “may not be estopped on the same terms as any other litigant.” *Heckler v. Community Health Services of Crawford Cty., Inc.*, 467 U.S. 51, 60 (1984). But “even assuming that the Government is ever subject to estoppel, a ‘private party surely cannot prevail without at least demonstrating that the traditional elements of an estoppel are present.’” *Lyng v. Payne*, 476 U.S. 926, 935 (1986) (quoting *Heckler*, 467 U.S. at 61). Most significantly, the Supreme Court has explained that “[a]n essential element of any estoppel is detrimental reliance on the adverse party's misrepresentations.” *Id.* (citing *Heckler*, 467 U.S. at 59).

Here, Respondent has produced no evidence of affirmative misconduct by the government that induced her to enter into the diversion agreement. Indeed, it would be strange to make such an argument in light of the fact that Respondent was represented in the criminal proceeding by a former United States Attorney for the Middle District of Florida (*See* Resp. Exh. 64), who was presumably well aware of the limits on a United States Attorney's power to bind an agency such as DEA and the Eleventh Circuit's case law holding that a United States Attorney has no such authority. *See San Pedro*, 79 F.3d at 1069–70. Thus, even if the United States Attorney had made a representation that DEA would not seek to revoke her registration, it would have been

unreasonable for Respondent to rely on it.

Moreover, Respondent has not established detrimental reliance because Respondent cannot show that she is worse off for having accepted pre-trial diversion. Even if Respondent had gone to trial and been acquitted, DEA could still have sought to revoke her registration. *See United States v. One Assortment of 89 Firearms*, 465 U.S. 354, 359–62 (1984). As the Court explained therein: “an acquittal on criminal charges does not prove that the defendant is innocent; it merely proves the existence of a reasonable doubt as to his guilt.” *Id.* at 361.

A jury verdict in a criminal action does “not negate the possibility that a preponderance of the evidence could show that” one had engaged in illegal activity. *Id.* at 362. Thus, “it is clear that the difference in the relative burdens of proof in * * * criminal and civil actions precludes the application of the doctrine of collateral estoppel.” *Id. See also Helvering v. Mitchell*, 303 U.S. 391, 397 (1938) (“That acquittal on a criminal charge is not a bar to a civil action by the Government, remedial in its nature, arising out of the same facts on which the criminal proceeding was based has long been settled.”). Thus, Respondent's estoppel contentions are meritless.

Finally, Respondent argues that this proceeding violates the Due Process Clause because it is vindictive and was initiated to retaliate against her for exercising various rights including her right to complain about governmental conduct. *See* Resp. Br. 81. There is, however, “a presumption of regularity” that supports prosecutorial decision-making, and where probable cause exists the decision to bring a charge “generally rests entirely” in the prosecutor's “discretion.” *United States v. Armstrong*, 517 U.S. 456, 464 (1996) (int. quotations and citations omitted); *see also Hartman v. Moore*, 126 S.Ct. 1695, 1699 (2006) (plaintiff in retaliatory prosecution action must plead and prove a lack of probable cause).

Here, there clearly was probable cause to believe that Respondent had committed several violations of the Controlled Substances Act and that her continued registration would be inconsistent with the public interest. The grand jury's indictment of Respondent provides an independent determination of probable cause although such a determination is not required to initiate a show cause proceeding. Moreover, the evidence in this case clearly establishes probable cause.

Finally, as far as any claim that the proceeding was brought to retaliate against Respondent for complaining about the conduct of a DEA employee, the decision to initiate a Show Cause Proceeding is made by senior officials at DEA headquarters and not by field personnel. Respondent has not come forward with any objective evidence that established that this proceeding was brought to retaliate against her.⁸ I thus find this contention unpersuasive as well.

The Public Interest Factors

The Controlled Substances Act provides that a practitioner's registration "may be suspended or revoked * * * upon a finding that the registrant * * * has committed such acts as would render [her] registration * * * inconsistent with the public interest." 21 U.S.C. 824(a)(4). In making this determination, the Act requires that I consider the following factors:

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

Id. § 823(f).

"These factors are considered in the disjunctive." *John H. Kennedy, M.D.*, 71 FR 35705, 35708 (2006); *Robert A. Leslie, M.D.*, 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 a registration should be revoked." *Leslie*, 68 FR at 15230. In this matter, I have considered the entire record including the evidence of Respondent's efforts to improve her practice's procedures. Nonetheless, I remain deeply troubled by Respondent's disingenuous insistence that she had a

legitimate medical purpose for prescribing the controlled substances to each of the undercover operatives. I therefore conclude that revocation of Respondent's registration is necessary to protect the public interest.

Factor One—The Recommendation of the State Medical Board

It is undisputed that the Florida state authorities did not suspend or revoke Respondent's state medical license. This factor thus supports a finding that Respondent's continued registration would be in the public interest. It is well established, however, that a "state license is a necessary, but not a sufficient condition for [DEA] registration," and thus the fact that Respondent retains her state license is not dispositive. *Kennedy*, 71 FR at 35708.

Factor Two—Respondent's Experience in Handling Controlled Substances

For the reasons stated above in the findings section, I agree with the ALJ that in each of the undercover visits, Respondent violated federal law and DEA regulations by prescribing controlled substances without a legitimate medical purpose. *See* 21 CFR 1306.04(a). As the ALJ found, Respondent's contention that she prescribed controlled substances to each of the three operatives because she believed that their taking the drugs was the reason they were not in pain is disingenuous. Indeed, as explained above, Respondent's testimony was frequently inconsistent or implausible. Moreover, in each case she failed to conduct a physical exam and falsified medical records.

For example, Respondent testified that she thought Chris Massey was honest. Yet she prescribed controlled substances to him notwithstanding that he told her repeatedly that he was not in pain. Furthermore, Respondent made several statements to Massey that indicate that she knew he was seeking the drugs to abuse them. Massey also told her that his girlfriend had been the source of his drugs.

The same can be said about Respondent's conduct and testimony regarding Detective Esterline's visit. Respondent testified that Esterline was "honest" and did not "exaggerate his symptoms." Notwithstanding that Esterline told her several times that he did not have pain, that he took the drugs because they helped him function, and told her twice that he got the drugs from friends, Respondent nonetheless gave him a prescription for a controlled substance. Here, again Respondent made several incriminating statements,

such as when she asked Esterline whether he wanted "to go to [a] substance abuse program" or "be maintained on the Vicodin?," and when she stated "maybe I'm sympathetic to the people that allow themselves to slip into drugs." In short, Respondent knew that Esterline was seeking the drugs to abuse them and not to treat pain.

Detective Keys told Respondent that he did not have pain and at one point during the visit, Respondent stated to Mr. Mastridge that "I guess he feels no pain, he just feels better." Keys also told Respondent that he was getting the drugs from non-legitimate sources. Respondent also made several other incriminating statements such as when she told Keys that "we will not be supporting just a drug habit."

Respondent further violated federal law and DEA regulations by giving Ben Mastridge pre-signed prescriptions and allowing him to issue them to a patient she had not attended to. While I agree with the ALJ that this conduct of Respondent violated 21 CFR 1306.05(a), *see* ALJ Dec. at 42, this is not simply a matter of prescription forms being improperly completed.

The record makes clear that Mastridge was not authorized under Florida law to prescribe controlled substances. *See* Tr. 641–42. He was therefore without authority to prescribe under the CSA and, of course, was not registered to do so. *See* 21 U.S.C. 823(f); 21 CFR 1306.03. Nonetheless, Mastridge issued prescriptions under Respondent's signature for two controlled substances, Lorcet and Xanax. Significantly, he exercised independent medical judgment by decreasing the dosage of Massey's Lorcet prescription and by giving him a prescription for a new drug, Xanax, which he stated was for the purpose of taking "the edge off of bringing the coke down."

Indeed, there is substantial evidence in the record that Respondent delegated her prescribing authority to Mastridge. This includes Respondent's statement to Det. Keys that Ben "will write prescriptions for you too, He writes my prescriptions. When you see him, you don't have to see me." *See* Gov. Exh. 12, at 6. Moreover, when Massey stated to Mastridge that "I thought that the Doctor had to fill the prescription out and sign it," Mastridge replied "no," and added that "as long as she is in the building I am being supervised and * * * I can do anything that she can do because she signs her name to the treatment agreement." *See* Gov. Exh. 6, at 13.

While DEA's regulations authorize "a secretary or agent" to prepare a prescription form for the practitioner's

⁸ Respondent's further contention that the proceeding was brought to penalize her for having successfully completed the pre-trial diversion agreement is also unpersuasive. Given that Respondent had been indicted for multiple violations of the CSA, and that one of the grounds for revoking a registration is that a registrant has been convicted of a felony under the CSA or any other federal law relating to controlled substances, *see* 21 U.S.C. 824(a)(2), it makes sense to delay the administrative proceeding until the criminal case has been resolved. A Show Cause Proceeding based on a felony conviction typically takes far less than the four days of hearings that it took to litigate this case and requires substantially less in terms of agency resources.

signature, 21 CFR 1306.05(a), the CSA does not authorize a practitioner to delegate her authority to prescribe a controlled substance to another employee. Respondent clearly delegated her authority to prescribe controlled substances to Mastridge, who lacked authority to prescribe a controlled substance. This constitutes a serious violation of the Act. *See United States v. Singh*, 390 F.3d 168, 184–87 (2d Cir. 2004) (affirming criminal conviction of physician for aiding and abetting illegal distribution of controlled substances where physician gave pre-signed blank prescription pads to nurses, who although not authorized to prescribe, wrote patients prescriptions for controlled substances).⁹

Factor Three—Respondent's Conviction Record

It is undisputed that Respondent has never been convicted of violating any federal or State law relating to the manufacture, distribution, or dispensing of controlled substances. While this factor is not dispositive, it does support a finding that Respondent's continued registration would not be inconsistent with the public interest.

Factor Four—Respondent's Compliance With Applicable Federal, State, or Local Controlled Substances Laws

As explained above under factor two, Respondent violated 21 U.S.C. 829(b), and 21 CFR 1306.04, when she prescribed controlled substances without a legitimate medical purpose to the undercover operatives. While I agree with the ALJ that Respondent's pre-signing of prescriptions violated 21 CFR 1306.05(a), I further find that Respondent violated Federal law by giving the prescription forms to Mr. Mastridge and delegating to him the authority to prescribe controlled substances when he was not registered to do so under Federal law and could

⁹ Respondent asserts that her conduct in pre-signing prescriptions "was not willful or knowing, but was done in good faith and only after advising the nurse first of the parameters of the prescription." Resp. Br. 62. Respondent did not, however, testify that she met with Mastridge and discussed what controlled substances Mastridge was to prescribe for Massey on the April 22nd visit. Respondent's testimony contains only vague generalities on the subject of Mastridge's prescribing. *See* Tr. 469–72.

As for Respondent's contention that she believed in good faith that it was legal to do so, there are numerous DEA final orders sanctioning registrants for engaging in this practice. *See, e.g., Walter S. Gresham, M.D.*, 57 FR 44213, 44214 (1992); *Maimoona Hakim Husain, M.D.*, 54 FR 16173, 16174 (1989); *William T. McPhail, M.D.*, 53 FR 47275, 47276 (1988); *Richard T. Robinson, M.D.*, 53 FR 15153, 15154 (1988); *James Beale, M.D.*, 53 FR 15149, 15150 (1988). I therefore reject Respondent's contention.

not lawfully prescribe them under State law. *See* 21 CFR 1306.03(a). This factor thus supports a finding that Respondent's continued registration would be inconsistent with the public interest.

Factor Five—Other Conduct Which May Threaten Public Health and Safety

As I recently held, DEA precedents establish that "an applicant's acceptance of responsibility for [her] prior misconduct is a highly relevant consideration under this factor." *Kennedy*, 71 FR 35709; *see also Barry H. Brooks*, 66 FR 18305, 18309 (2001); *Prince George Daniels, D.D.S.*, 60 FR 62884, 62887 (1995); *Carmel Ben-Eliezer, M.D.*, 58 FR 65400, 65401 (1993). Here, the ALJ found that Respondent had refused to accept responsibility for her misconduct in prescribing controlled substances to the three undercover visitors when there was no legitimate medical purpose for doing so. *See* ALJ Dec. at 43.

I recognize that Respondent admitted that she should not have given pre-signed prescription forms to Mr. Mastridge, that she should have performed a physical exam on the patients, and that she should not have created false records. Respondent, however, persisted in maintaining that she had validly prescribed controlled substances to the undercover operatives. For example, when cross-examined about whether she had knowingly and intentionally distributed a controlled substance to Detective Keys, Respondent insisted that she had not. When asked whether she had committed this offense she testified: "No, it says here, did knowingly. No, it's not true. Patients come to us in chronic pain. I assume they have pain." Tr. 652. Respondent further testified that:

Intentionally I did not dispense medication, I did not distribute outside of the usual course of medical practice. In the context of the clinical pain management, I knew the medication [was] not to transfer, not to sell the drug to the street or anything. My intention here is believe the patient, give them the benefit of chronic pain, and evaluate them, and do what is appropriate for them.

Id.

I am deeply troubled by Respondent's testimony and her evident misapprehension of a registrant's obligations under the CSA. Contrary to Respondent's understanding, a practitioner violates the Act by prescribing a controlled substance without a legitimate medical purpose. It is no less a violation that the "patient"

will personally use the drug rather than sell it on the street.

I recognize the substantial measures undertaken by Respondent to reform her practice. But in the case of a practitioner, the most important control against diversion is the individual registrant herself. When the individual registrant's conduct is the source of the problem, and that registrant refuses to acknowledge her responsibilities under the law, all of the aforementioned reforms will still not adequately protect public health and safety.

Therefore, I conclude that factor five supports a finding that Respondent's continued registration would threaten public health and safety and indeed, that this factor is dispositive in determining that her continued registration is inconsistent with the public interest.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b) and 0.104, I hereby order that DEA Certificate of Registration, No. AK2006648, issued to Respondent Jayam Krishna-Iyer, M.D., be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This order is effective October 2, 2006.

Dated: August 22, 2006.

Michele M. Leonhart,
Deputy Administrator.

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BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Nashville Wholesale Company, Inc.; Denial of Application

On July 12, 2005, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Nashville Wholesale Company, Inc., (Respondent) of Nashville and Memphis, Tennessee. The Show Cause Order proposed to deny Respondent's pending application for registration as a non-retail distributor of List I chemicals on the ground that Respondent's registration would be inconsistent with the public interest. *See* 21 U.S.C. 823(h); Show Cause Order at 1.

The Show Cause Order specifically alleged that Respondent, through its owner Nael Abodabba, submitted an application to distribute pseudoephedrine, a List I chemical