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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 14-6]

Abbas E. Sina, M.D.; Decision and Order

On May 15, 2015, the then-Administrator of the Drug Enforcement Administration issued the attached order. Therein, based on her review of the record, the then-Administrator concluded that, in the event Respondent presented evidence that he has continued to comply with his Professionals Resource Network (PRN) contract and has passed all drug tests since the closing of the record, he is entitled to be registered subject to the extensive conditions set forth in her order. The then-Administrator thus ordered Respondent to provide such evidence.

In response to the order, Respondent provided his drug test results, all of which have been negative. Respondent did not, however, provide evidence of his compliance with the other terms of his PRN contract. Accordingly, on July 27, 2015, I issued an order directing Respondent to "provide a sworn letter from the PRN attesting to his continued compliance with his PRN contract." Order of the Administrator, at 1 (July 27, 2015).

Respondent has now complied and submitted a notarized letter from Penelope P. Ziegler, M.D., the PRN's Medical Director, attesting that he has remained fully compliant with his PRN contract. I therefore conclude that Respondent has met the requirements for obtaining a new registration as set forth in the May 15, 2015 order (which is attached and incorporated as the

Decision in this matter), and that he is entitled to be registered subject to the conditions set forth therein.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Abbas E. Sina, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, granted, subject to the conditions set forth in the then-Administrator's Order of May 15, 2015. This Order is effective immediately.

Date: August 26, 2015.

Chuck Rosenberg
Acting Administrator

Anthony Yim, Esq., for the Government.

William W. Tison, III, Esq., for the Respondent.

ORDER OF THE ADMINISTRATOR
May 15, 2015

On November 12, 2013, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Abbas E. Sina, M.D. (hereinafter, Respondent), of St. Pete Beach, Florida. ALJ Ex. 1, at 1. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration as a practitioner, on the ground that his "registration would be inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f)." *Id*.

As jurisdictional facts, the Show Cause Order alleged that Respondent had previously held a DEA Certificate of Registration which he surrendered "for cause on July 13, 2011," *id*. at 2, and that on July 13, 2012, he had applied for a new practitioner's registration seeking authority to dispense controlled substances in schedules II through V. *Id*. at 1. The Order then alleged that during an interview with a DEA Investigator regarding his application, Respondent admitted to a history of abusing controlled substances including heroin. *Id*.

More specifically, the Show Cause Order alleged that Respondent admitted that "[o]n or about February 26, 2003," he had "purchased heroin from street dealers" and "overdosed," after which he was arrested and charged with possessing heroin, possessing drug paraphernalia, and

driving under the influence. *Id*. The Order then alleged that Respondent was allowed to resolve the charges by entering a pre-trial diversion program, but that in 2004, he had again begun to abuse controlled substances. *Id*. at 1-2.

Next, the Show Cause Order alleged that between June 19, 2004 and March 23, 2005, Respondent had written eleven prescriptions for OxyContin 80mg, which authorized the dispensing of 720 dosage units, "without establishing a valid doctor-patient relationship," and that "a medical expert who reviewed [his] actions concluded that [the] prescriptions . . . were for other than a legitimate medical purpose and outside the usual course of professional practice." *Id*. at 2 (citing 21 U.S.C. § 841(a)(1); 21 CFR 1306.04(a)). The Order further alleged that the Florida Board of Medicine had instituted a proceeding against him based on his misconduct but that he had been "allowed to settle the case without admitting to the underlying allegations." *Id*.

The Show Cause Order further alleged that during his September 2012 interview, Respondent admitted that he had again begun "abusing heroin in late 2009/early2010," and that his use of heroin had tripled over the course of several months. *Id.* The Order then alleged that during the interview, Respondent admitted that "on or about February 4, 2011," he had been arrested at Tampa International Airport and charged with possession of heroin with intent to distribute; possession of methadone, a schedule II drug; possession of Xanax, a schedule IV drug; possession of drug paraphernalia; and trafficking in illegal drugs. *Id*. The Order also alleged that Respondent was allowed to resolve the charges by entering a pre-trial diversion program. *Id*.

Respondent timely requested a hearing on the allegations. ALJ Exs. 2 & 3. The matter was placed on the docket of the Office of Administrative Law Judges, and assigned to Administrative Law Judge (ALJ) McNeil who, following pre-hearing procedures, conducted an

evidentiary hearing in Clearwater, Florida on March 4-5, 2014. Following the hearing, both parties filed briefs containing their proposed findings of fact, conclusions of law, and recommended order.

On May 7, 2014, the ALJ issued his Recommended Decision. Therein, the ALJ found that the Government had established a *prima facie* case to deny Respondent's application. With respect to Factor Two – Respondent's experience in dispensing controlled substances – the ALJ noted that Respondent had "significant positive training and credentials relating to prescribing controlled substances," which included his training as a medical resident, his twenty-three years as an emergency room physician, his completion of a course in the proper prescribing of controlled substances, and his studying to become board certified in addiction medicine. R.D. at 36-37.

However, the ALJ further explained that "while he was buying heroin and other drugs on the street, [Respondent] has become very well acquainted with those in the community who have chosen to traffic in heroin" and that "[a] person with that kind of experience, particularly one authorized to write prescriptions for narcotics and other controlled substances, holds a highly valuable key recognized by those in our society who are likely to try to exploit that authority to advance their own illicit goals." *Id*. at 37. Continuing, the ALJ reasoned that restoring Respondent's "ability to prescribe controlled substances carries with it some risk, given the unique skill set [he] developed while seeking heroin and other drugs on the street." *Id*. at 38. The ALJ then reasoned that while Respondent "may well be able to resist efforts from those in the trafficking trade to recruit him during periods of sustained stable recovery, were he to relapse those illicit efforts may well prove successful, creating a significant risk of prescription drug

diversion." *Id*. The ALJ thus concluded that "Factor Two neither supports nor contradicts granting [his] application." *Id*.

As for Factor Four – compliance with applicable laws related to controlled substances – the ALJ noted that Respondent had conceded that the Government had established a *prima facie* case to deny his application. *Id*. The ALJ then noted that Respondent had unlawfully possessed heroin and drug paraphernalia in 2003; that he had unlawfully prescribed 720 dosage units of OxyContin to his girlfriend, which he then diverted for his own use; that he had misled state authorities "by withholding from them the fact that he was diverting the [drugs] for his own use"; and that in 2011, he unlawfully possessed heroin, methadone, and Xanax, as well as drug paraphernalia. *Id*. at 39. The ALJ thus concluded that the evidence with respect to Factor Four provided "a legally sufficient basis" to deny his application. *Id*.

As for Factor Five – such other conduct which may threaten public health and safety – the ALJ noted that Respondent's self-abuse of controlled substances itself supports denying his application. *Id*. at 40. The ALJ further noted that independent of the evidence of his abuse of controlled substances, the evidence showed that during his periods of abuse, he "has a demonstrated tendency towards lying in the course of responding to governmental processes." *Id*. The ALJ also suggested that Respondent had given false testimony in this proceeding when he testified that the report of a physician, who had reviewed the investigative file prepared by a Florida DOH investigator for the DOH, was "100 percent accurate" because it "made no mention of the whole truth," that being that Respondent was diverting the drugs for his own use. *Id*.

However, the ALJ then noted that Respondent does not currently present[] a threat to the public due to a predisposition to prevaricate" and that he "can be relied upon to be forthright and candid during his recovery." *Id*. at 41. The ALJ further noted that he "was impressed with

[Respondent's] demeanor, his expressions of regret and apology, and with his determination to succeed in his recovery." *Id.* The ALJ nonetheless concluded that Respondent's "chronic history of substance abuse" and "pattern of misleading governmental officials" created "an unacceptably strong likelihood that [he] would revert to his past behavior and would attempt to either self-medicate or self-destruct" and thus provided a "legally sufficient and independent basis" to deny his application. *Id.*

Addressing the evidence of remediation, the ALJ found that the record as a whole supported the conclusion that Respondent has accepted responsibility for his misconduct. *Id.* at 42. However, based on the testimony of two of Respondent's witnesses, the ALJ concluded that Respondent's "risk of relapse remains high, and will continue to be high . . . throughout the five years following the commencement of his recovery" and "that insufficient time in stable recovery has passed to support a finding that corrective action has been taken." *Id.* While acknowledging that "steps that may lead to effective corrective action have begun, … those steps are not complete, and in the absence of complete corrective action the Respondent has not, by a preponderance, presented evidence that would permit the restoration of his" registration. *Id.* at 42-43. The ALJ thus recommended that Respondent's application be denied.

Thereafter, the parties filed a Joint Statement Regarding the Proposed Stipulations. However, only the Government filed Exceptions to the Recommended Decision.

As for the Joint Statement Regarding the Proposed Stipulations, therein, the parties averred that "it was their impression and understanding that" they had agreed only to the Government's Proposed Stipulations numbers one (1) through eight (8) (apparently as set forth in the Supplemental Prehearing Statement) and Respondent's Proposed Stipulations one (1)

through four (4). The parties further stated that they did not agree to Respondent's Proposed Stipulations five (5) through twenty-four (24).

Thereafter, the record was forwarded to this Office for final agency action. Having considered the entire record, I agree with the ALJ's conclusion that the Government has satisfied its *prima facie* burden of showing that Respondent's registration would be inconsistent with the public interest. R.D. 49. However, in the event Respondent has continued to remain in compliance with his PRN contract and has passed all of his drug tests since January 28, 2014 and produces such evidence within thirty (30) days of the date of this Order, I conclude that he will have produced sufficient evidence to rebut the Government's *prima facie* case. *Id*. at 50. I make the following findings.[1]

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[1] Because the parties jointly agree that the Government never agreed to Respondent's proposed stipulations numbers five (5) through twenty-four (24), I do not consider those stipulations as proving their factual assertions. However, having read the relevant portion of the transcript, I do not find the Government's argument well taken, and but for the fact that Respondent agreed that the Government had not agreed to the stipulations, I would have rejected the Government's contention.

According to the transcript, the following colloquy occurred:

> ALJ: Okay. All those stipulations are now considered as facts that I will use in the analysis and recommendations that I prepare in this case.
>
> ALJ: [Government Counsel], the Government was able to stipulate to the four facts shown in my order of January 28, 2014, but it was not able to stipulate to the remainder of those stipulations proposed by the Respondent. Those appear in the Respondent's initial prehearing statement. Do you have that statement?
>
> [Government Counsel]: I do your honor.
>
> ALJ: Are there any proposed stipulations there for which the Government cannot agree?
>
> Government Counsel: No, your honor.

Tr. 45-46. The Government contends that the ALJ "erred" in "interpret[ing] this colloquy as the Government's agreement to stipulate to the nineteen stipulations to which it had previously declined to agree in writing." Gov. Exceptions, at 5. This argument, however, begs the question of why the ALJ would ask the Government if it was stipulating to the same four stipulations which it had already agreed to during the conference held by the ALJ on January 28, 2014. *See* Tr. 13. (ALJ: "Are there any of those that you agree can be considered as fact?" Government Counsel: "Stipulations 1 through 4, your honor." ALJ: "1 through 4 are admitted as evidence without further evidence being required to establish those as fact then.").

I find that the ALJ's question was clear enough to put the Government on notice that he was asking about those stipulations offered by Respondent which the Government had not previously agreed to. To extent the Government

FINDINGS OF FACT

Respondent's Licensure and Registration Status

Respondent is a medical doctor licensed by the Florida Board of Medicine. RX A. Respondent, who has been licensed for nearly thirty years, is board certified in internal medicine. *Id*. Following his residency, Respondent practiced as an emergency room physician for more than twenty years. *Id*.

Respondent previously held a DEA Certificate of Registration, pursuant to which he was authorized to dispense controlled substances in schedules II through V as a practitioner. *See* GX 2, at 3. However, on July 13, 2011, Respondent surrendered this registration for cause. *See* GX 3. On July 12, 2012, Respondent applied for a new practitioner's registration, seeking authority to dispense controlled substances in schedules II through V. *See* GX 1; GX 2, at 1-2. It is this application which is at issue in the proceeding.

Respondent's History of Substance Abuse

While Respondent has practiced medicine for nearly thirty years (including his residency), in his testimony he admitted to a long history of abusing alcohol and controlled substances. Indeed, he admitted to using alcohol; prescription controlled substances without a prescription; as well as street drugs including marijuana, heroin, cocaine, Ecstasy, and LSD. Tr. 194. Indeed, when asked what drugs he had used beside alcohol, prescription drugs, and heroin, he replied that "[i]t would be easier to say that I think there's three drugs that I haven't used in my lifetime." *Id*. at 193.

Respondent admitted to using alcohol and marijuana beginning at the age of fourteen. *Id*. at 194. Moreover, while Respondent testified that he "stopped after some bad things happen[ed]

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was unclear as to which stipulations the ALJ was asking it about, it was incumbent on the Government to clarify which stipulations it had agreed to.

to friends" and that he "lost the desire to do that around college time and medical school," he began drinking a "few years into" his practice as an emergency room physician. *Id*. at 195.

Moreover, Respondent admitted that beginning in 1998, he began abusing Vicoprofen (a controlled substance which contains hydrocodone) samples that he received. *Id*. at 192. Moreover, Respondent testified that because he had back problems, he had previously obtained some oxycodone "from a friend who finished his prescription," and that on September 11, 2001, he "woke up and the whole world seemed like it was coming to an end" so he injected himself with the oxycodone. *Id.* at 198. According to Respondent, "it was a very stressful situation that I responded very poorly to by turning to something that I would never have [and had] never done before and didn't see the significance of that action." *Id*. However, the oxycodone "didn't work because I didn't get it in right and I didn't feel anything." *Id*.

As for his abuse of heroin, Respondent testified that in 2003, he encountered J.R., his ex-wife's former boyfriend, at a bar. *Id*. at 197. According to Respondent, his ex-wife had previously told him to stay away from J.R. because he did heroin. *Id.* However, because he "got curious and wanted to try it," Respondent apparently approached J.R., who told him that "he knew where he could get it [heroin] in Tampa, and if I was to buy [J.R.'s], he would . . . make the purchase." *Id*.

Respondent drove J.R. to Tampa, and after J.R. procured the heroin, both he and J.R. injected themselves with heroin while in Respondent's car. *Id*. Subsequently, the police were called to a location in Tampa where they found Respondent and J.R. in the former's vehicle, which was parked with three wheels over the curb and one wheel on the road. GX 4, at 7. Respondent was in the driver's seat, with his eyes open, but was unresponsive when a police officer knocked on the window and shined his flashlight onto Respondent's face. *Id*.

Initially, Respondent was motionless, but he then began to shake every ten seconds. *Id*. After a short period, J.R. came to and a police officer removed him from Respondent's car and placed him in his patrol car. *Id*. The officer then returned to Respondent's car and observed a Tampa Fire Department unit giving aid to Respondent (which included the administration of Narcan) and removing him from his car. *Id*. at 7-8. From outside Respondent's car, the officer saw a metal spoon, which contained a brown substance, on the floor behind the driver's seat. *Id*. at 7. The officer seized the spoon and field tested the brown substance, which tested positive for heroin. *Id*. The Office also found an Altoids can on the dashboard in front of the driver's seat; the can held two Q-tip swabs in a small zip-lock bag, a cotton ball, and an alcohol wipe. *Id*.

Another police officer conducted a DUI investigation of Respondent which resulted in his arrest. *Id*. Thereafter, Respondent's vehicle was impounded and an inventory search was conducted; the search found numerous syringes and a vial of sterile water in the vehicle's console. ***Id.***

Thereafter, Respondent was criminally charged with possession of heroin. ALJ Ex. 16 (Gov. Stipulation #5). However, Respondent was offered a pretrial drug intervention program, which he successfully completed and the charges were *nolle prossed*. *Id*.; Tr. 231.

According to Respondent, as part of the program he was required to undergo an evaluation; however, he told the evaluator that the drugs were not his but J.R.'s, and that he had remained in a nightclub while J.R. had gone out to the car and used the drugs. Tr. 200. As part of the program, he also was required to pass drug tests over the course of a six-month period. *Id*.; *see also id*. at 231. Regarding his false statement to the evaluator, Respondent testified that "unfortunately – this was an opportunity for me to change . . . to fix the problem, and I don't blame anybody but me because I'm the one who weaseled out of it." *Id*.; *see also id*. at 230

("Now I look at that as an opportunity to change my life, and I blame no one but myself for not giving the real information to the counselor. . . .").

Respondent further testified that at the time, he did not think he was an addict, although he "really was," because he had not become physically dependent on heroin and did not go through withdrawal. *Id*. However, he then explained that he was both "emotionally" and psychologically dependent" on the drug. *Id*. According to Respondent, while he "knew there was a problem, [he] thought [he] could handle that problem, and that was the biggest problem of it all." *Id*. at 231.

As Respondent further testified, "that's a big problem among physicians because we're supposed to be the ones that fix people. And so if we can't fix ourselves, we have to admit to ourselves that we are not capable of fixing other people either. And that's a pride issue." *Id*.

The evidence further shows that in March 2005, a pharmacist contacted the DOH and reported that over a period of several months, she had received prescriptions written by Respondent to B.B. for steadily increasing dosages of OxyContin 80mg, including a recent prescription for 120 dosage units for which B.B. paid $1,172.99 in cash. GX 11, at 3. The pharmacist also reported that Respondent was an emergency room physician and yet he had been writing the prescriptions on blanks that listed his home address and cell phone number. *Id*. The pharmacist also reported that she had run a physician profile on Respondent and found that all of the other prescriptions that the pharmacy had filled had been written on the prescriptions of the hospital where he worked. *Id*.

After determining that Respondent had not treated B.B. at the hospital where he worked, a DOH Investigator obtained the original prescriptions. The prescriptions showed that between June 19, 2004 and March 23, 2005, Respondent had issued B.B. eleven prescriptions for

OxyContin 80mg, which authorized the dispensing of 720 dosage units. GX 11, at 11-19. Consistent with pharmacist's report, the quantity of the dispensings increased from approximately 60 to 120 dosage units per month. *Id*. at 12.

Thereafter, the DOH Investigator, accompanied by a Detective with the Pinellas County Sheriff's Office, went to Respondent's residence where they interviewed both Respondent and B.B. *Id*. at 3. B.B. told the Investigators that she was Respondent's fiancé and lived with him. *Id*. at 4. She also told the Investigators that she had injured her neck in a car accident seven years earlier and had reinjured it during the previous year while on a ski trip. *Id*. She further told the Investigators that she did not seek treatment at the time of the injury because Respondent "took over her" treatment, but that he "did not do any diagnostic studies of her neck" nor "refer her to a specialist." *Id.* Instead, "he just prescribed OxyContin for pain." *Id.*

During his interview, Respondent stated that he was an ER physician at a local hospital and that he "did not have an outside practice." *Id*. He admitted to writing the prescriptions and corroborated B.B.'s statement that she had reinjured her neck when they were on ski trip. *Id*. Respondent also eventually admitted that he did not have any medical records for his treatment of B.B., that he had not done a diagnostic workup, and that he had not referred her to a specialist. *Id*. He then stated that he intended to refer B.B. to a specialist, but had yet to do so. *Id*.

Subsequently, the DOH retained a medical expert who reviewed its investigative file. GX 8. The expert concluded that Respondent's "care fell well <u>below the standard of care</u> as defined by Floirda[sic] state, local and national norms," that OxyContin is "a strong and highly addictive medication" which "requires careful diagnosis and regular reassessment of the patient," and that "[i]t is unacceptable to prescribe the medicine without adequate examination and documentation." *Id*. at 2. The expert further noted that Respondent did not maintain any medical

records on B.B., that there was "no evidence that [Respondent] assessed the patient's medical problems" and there were "no known x-rays, lab tests or evaluations." *Id.* The expert thus concluded that Respondent's "diagnosis was therefore inappropriate and inadequate." *Id.*

The expert further concluded that while "[a] specialist's care was not absolutely essential for such a patient" and that an "internist could care for such a patient under different circumstances," Respondent committed an "egregious error" by prescribing OxyContin to "an intimate partner . . . over a prolonged period." *Id*. He also noted that "[n]o obvious plan for long term treatment was identified." *Id.* He thus opined that Respondent's prescribing "was strikingly inappropriate." *Id.*

Thereafter, the DOH issued an administrative complaint to Respondent. The complaint charged Respondent with: 1) failing to practice medicine with that level of care, skill, and treatment of "a reasonably prudent similar physician . . . under similar conditions and circumstances"; 2) prescribing "a legend drug, including any controlled substance, other than in the course of the physician's professional practice"; and 3) failing to keep medical records justifying the course of treatment. GX 5, at 15-16, 18.

Respondent was allowed to enter into a settlement agreement with the DOH, pursuant to which he was not required to admit the facts of the Administrative Complaint, but did admit that if those facts were proved, they would establish violations of Florida law as alleged in the Complaint. GX 5, at 4. The DOH then reprimanded Respondent; fined him $15,000; required that he reimburse the DOH's costs in an amount up to $2,000; required that he perform 100 hours of community service; and required that he take a course on "Prescribing Abusable Drugs." *Id*. at 4-7.

Regarding these events, Respondent admitted that the facts alleged in the DOH's complaint "are the facts," that his prescribings to B.B. were outside the usual course of professional practice, and that he "did not" have a proper medical justification to prescribe to B.B. Tr. 201-03. He also testified that he "[a]bsolutely" agreed with the conclusions contained in the DOH Expert's report. *Id*. at 203. When then asked: "Is there any part of this report you do not agree with," Respondent answered: "No. It's 100 percent accurate." *Id.*

When asked whether the episode had scared him straight or whether he had continued to abuse narcotics, Respondent testified:

> I was scared into stopping the use of any – doing anything wrong for almost a year after that. But unfortunately I never – because I lied – I may as well – I lied about using the medicines that I prescribed to her myself. Well, I didn't lie. I just never said anything. Nobody asked. Nobody from the Department of Health asked, and I didn't volunteer that information. And unfortunately, as far as I'm concerned, it's a lie, and that lie got me no treatment and no help. And to this day – first of all, if I would have said something the first time with the heroin thing to PRN, my whole life would be different.

Id. at 204.

Respondent further explained that he and his girlfriend, who had a "bad neck to begin with," were on a one-week long ski-trip in Colorado, and that on the first day, she had "wiped out on a snowboard" and "couldn't move," so he called in a prescription for hydrocodone. *Id*. at 205. Respondent was not sure if he had taken any of the hydrocodone, but believed that he had not because the prescription was for a small quantity which his girlfriend needed to get through the trip. *Id*. at 205-06. However, upon returning to Florida, Respondent began prescribing oxycodone, and Respondent admitted that by the second prescription, he was "definitely" using her oxycodone. *Id*. at 205. Respondent further admitted that he had changed her prescription to oxycodone because "if she had them I might be able to get to them." *Id*. at 207.

Respondent maintained that after the visit from the DOH and the Detective, he stopped using the drugs but developed "physical withdrawal symptoms." *Id*. at 208. He then started drinking to deal with the stresses in his life. *Id*. at 209.

Sometime around 2009 or 2010, Respondent was involved in a lawsuit and began injecting heroin again. *Id*. at 210. Because his use of heroin caused withdrawal symptoms, he also used methadone, which he obtained from his heroin supplier, to counteract those symptoms. *Id*. at 211. However, because his use of heroin was intermittent, it disturbed his sleep. *Id*. at 212-13. Respondent testified that he would occasionally use Xanax, which he took from his girlfriend's prescription. *Id*. at 213.

Eventually, Respondent's use of heroin escalated into daily use and the dose needed to avoid becoming sick "would pretty much double every two or three days." *Id*. at 213-14. Respondent tried to stop twice by going "cold turkey," including once prior to a scheduled ski trip, when he had arranged to have two weeks off from work. *Id*. at 214. Respondent testified that he had planned on telling his friends that he couldn't go on the trip. *Id*. at 215. However, after three days of withdrawal his symptoms became unbearable, so he decided to go and "bought a whole bunch [of] heroin and got as much methadone as [he] could." *Id*.

On February 4, 2011, Respondent attempted to leave on the trip. Tr. 84. However, upon going through security at the airport, Respondent was observed "sweating profusely and shaking" and was found to be "in possession of a controlled substance without a prescription." *Id*. Respondent was arrested, and during the search of his person, the police found 34 bags of heroin. *Id*. at 85. Respondent admitted to the police that the bags contained heroin; a subsequent analysis by a Florida Department of Law Enforcement lab confirmed this. *Id*. at 85-86. At the time of his arrest, the police also retrieved his checked bags from the airline, and upon searching

them, discovered twelve syringes. *Id*. at 85. Respondent stipulated that at the time of his arrest, he "was also in possession of" thirty-seven tablets of methadone 10mg and three tablets of Xanax 2mg, and that he did not have a prescription for either drug. ALJ Ex. 16, at 2 (Gov. Stipulations #9); *see also* RX C, at 1.

While Respondent was again criminally charged, the charges were eventually *nolle prossed* as well. Tr. 79. However, in contrast to the two previous episodes, Respondent sought the assistance of the Professional Resource Network (hereinafter, PRN), an entity under contract with the DOH to provide assistance to "licensed professionals . . . who are experiencing difficulties due to some form of impairing illness." *Id.* at 298. Respondent was referred to a treatment program (Health Care Connection) which is run by Dr. David Myers, a Certified Addiction Professional who is both a Diplomate of the America Board of Addiction Medicine and a Fellow of the American Society of Addiction Medicine. *Id*. at 104; RX E. Dr. Myers testified that he has twenty-five years of experience "working with chemically dependent people," and that "for the last twenty years," his focus has been "on recovering professionals." Tr. 97.

Dr. Myers testified that his program has been recognized as a PRN compliant program. *Id*. at 101. His program evaluates new patients, detoxes and stabilizes them, and "begin[s] to introduce them into recovery techniques and whatever therapy they may need." *Id*. at 102. According to Dr. Myers, a new patient receives an extensive interview and is subject to either a drug screen or a hair screen after which a treatment recommendation is made. *Id*. at 105-06.

On February 12th (eight days after his arrest), Respondent entered Dr. Myers' program and underwent an initial assessment. According to Dr. Myers, Respondent "was very transparent," "did not make any attempts to muddy the water," and told him "exactly what

happened." *Id*. at 117. A drug test confirmed Respondent's story regarding the drugs he had been abusing. *Id*. at 110. His treatment included detoxification, followed by 60 days of partial hospitalization which included group therapy, and then entry into a halfway house. *Id*. at 119-21. Respondent passed all of his drug tests, and according to Dr. Myers "did very well." *Id*. at 122-23.

On May 18, 2011, Respondent entered into a contract with the PRN for a period of five years. RX B, at 6. Pursuant to the contract, Respondent agreed, *inter alia*, to participate in random drug testing "within twelve hours of notification"; to abstain completely from the use of any medications, alcohol or other mood altering substances unless prescribed by his physician and to send copies of all such prescriptions to the PRN; to attend recovery group meetings three times per week; and to agree to attend a weekly PRN monitored professional group with his monitoring professional. *Id*. at 2-3. He also agreed to notify PRN of any changes in his physical or mental health, as well as any change of address or employer; to provide releases for urine screen results, treatment center records and therapist reports; to notify the PRN in the event of his use of "mood altering substances without a prescription"; to not hold a state dispensing practitioner's license; and to withdraw from practice at PRN's request "if any problem develops that potentially interferes with [his] professional practice." *Id*. at 3-4.

Dr. Myers further testified that Respondent works for him at Health Care Connection and that he performs histories and physicals, "helps with the detox regimens," and helps with sick call. Tr. 124-25. Moreover, Dr. Myers has used Respondent "to cover the detox unit at" the Agency for Community Treatment Services, a non-profit, public detoxification unit in Tampa. *Id*. at 125. According to Dr. Myers, Respondent "does a good job" and has "learned how to share his recovery with other people who are struggling in a way that is appropriate and within a

set of medical boundaries." *Id*. at 128. He further testified that if he had "any doubt that he was risky, I couldn't use him" because "[m]y practice is too high profile in my county." *Id*. at 133. Dr. Myers then stated that he "considers [Respondent] safe or [he] wouldn't have him." *Id*.

Dr. Myers also testified that he expects Respondent to continue to do well and that he is fully committed to his recovery. *Id*. at 132. While Dr. Myers acknowledged that Respondent will never be cured, he expressed his belief that Respondent "is making it" and will "continue to make it." *Id*. Dr. Myers also testified that Respondent had started a new group for recovering doctors in Pinellas County. *Id*. at 149 & 161.

On cross-examination, Dr. Myers acknowledged that he could not guarantee that Respondent would not relapse. *Id*. at 142. However, when asked if there is a correlation between the length of a person's abuse and the likelihood of relapse, Dr. Myers testified that while "[t]here are a number of factors which can help predict relapses," he did not believe that a correlation has been established between the length of use and the likelihood of relapse. *Id*. Notably, the Government put forward no evidence to refute Dr. Myers's testimony on this point.

For reasons not entirely clear – given that at the time of the hearing, Respondent had been complying with his PRN contract for nearly three years – the Government then asked Dr. Myers:

> Q. So you're telling me that a person has the same amount of percentage of relapsing . . . [who] is drug tested weekly, [goes to] weekly community meetings, you think that that provided the same type relapse percentage as a person who is without any supervision . . . at all?
>
> A. We know that it takes five years to reach maximum benefit in recovery, where the relapse rates then become pretty consistent over time, whether it's five years or 10 years or 15 years.

Id. at 143. Dr. Myers then explained that this was based on "five years of monitoring." *Id*. at 144.[2]

Another physician, who is both a fellow staff member at Health Care Connection and a recovering physician who participated in the same recovery group as Respondent, *id*. at 159-62, testified that Respondent has been "very open and honest about his addiction as well as his recovery" and that "he definitely has an interest in helping others who are afflicted with the same disease." *Id*. at 163. Still another physician, who has worked with and supervised Respondent at Health Care Connection testified that he had not observed Respondent engage in any conduct demonstrating that he is not "a safe and responsible" physician and that Respondent is "passionate about" his recovery. *Id*. at 182-83.

Respondent also called as a witness, Dr. Penelope Ziegler, the Medical Director and CEO of PRN, Inc. *Id*. at 298. Dr. Ziegler is board certified in Psychiatry and Addiction Psychiatry, as well as certified in Addiction Medicine by the American Board of Addiction Medicine. *Id*. at 299. Since the completion of her residency in 1982, Dr. Ziegler has "focused [her] professional activities on the treatment of addiction" as well as "other psychiatric disorders." *Id*. Prior to her present positions, she was the medical director of similar programs in Pennsylvania and Virginia. *Id*.

After explaining the PRN's program, Dr. Ziegler testified that Respondent "has been entirely compliant with his contract and [that] we have received all of his reports as scheduled . . . indicating continued progress." *Id*. at 306. She further testified that "all of [Respondent's]

[2] The Government then asked Dr. Myers if he had "compared data for treated monitoring versus untreated monitoring?" Tr. 144. While Dr. Myer replied that "[t]hat has been done, but only in the first two to three years of the recovery process," *id*., the record does not establish what "untreated monitoring" involves.

Subsequently, Dr. Myers testified that the PRN had initially used "a two-year contract" but found that "too many docs and . . . healthcare professionals [were] relapsing following the two years." *Id*. at 147. Dr. Myers then explained that the PRN contract was lengthened "to five years, which is what studies suggest . . . is a solid recovery time" and that "the percentage of relapse is very low" for those persons who complete five years. *Id*.

urine screens have been negative," and thus she believes that he has not been using controlled substances illegally. *Id*. Corroborating Dr. Ziegler's testimony, Respondent submitted a Test History Report listing each drug test he had undergone between June 6, 2011 and January 28, 2014; the report indicates that each test was negative. RX D.

Dr. Ziegler further testified that Respondent's contract is scheduled to end on May 18, 2016. Tr. 307. She then explained that PRN offers most doctors the "opportunity to extend their monitoring beyond the five years if they choose," and that if a doctor agrees to do so, they are given a contract for "extended monitoring." *Id.* While this contract does not require continued attendance at group meetings, it still requires urine screening. *Id*. Dr. Ziegler also noted that in some cases, PRN offers a physician a "licensure long contract." *Id*. at 308. Dr. Ziegler explained that a "licensure long contract . . . is sometimes required by the Board of Medicine" where the Board believes that a physician is an "ongoing risk of relapse without monitoring." *Id*. However, a physician can voluntarily request a licensure-long contract, which remains in effect until the physician retires, voluntarily relinquishes his license, or some "untoward circumstances" arise. *Id*. at 309.

Dr. Ziegler testified that one of the terms of Respondent's PRN contract is that he is required to obtain "permission from PRN to return to practice." *Id*. at 310. She further testified that Respondent has complied with each of the conditions of the contract, as well as all federal and state laws related to controlled substances while he has been in the PRN's program. *Id*. at 311-12.

On cross-examination, Dr. Ziegler acknowledged that Respondent could "walk away from" his PRN contract at any time if he chose to do so. *Id*. at 312. However, she also explained that if he did so, he would be "immediately reported" to the DOH. *Id*. at 313. She also

maintained that if she had reason to believe that he poses "an immediate danger to the public health," she would also contact the Chief of the DOH's Prosecutorial Services Unit. *Id*. at 314. However, Dr. Ziegler acknowledged that in such a scenario, only the DOH has authority to issue an emergency suspension of Respondent's medical license. *Id*. at 321; 323.

When asked (on re-direct examination) if granting prescribing authority to Respondent would pose "any safety issue," Dr. Ziegler testified:

> No. And people at his stage of recovery and at his point in monitoring with us, lots of those practitioners hold DEA certificates and use them in the course of their practice of medicine. You know, having prescribing privileges, there's a certain amount of risk associated with it. But at his stage of the game it certainly is not something we would be concerned about because he is doing very well.

Id. at 317-18.

Dr. Ziegler then explained that if Respondent was to obtain employment in an emergency room, the PRN would "want to have some kind of an understanding with his employer . . . so that we had permission to talk to them if we were concerned or they had permission to talk to us if they were concerned," and that Respondent would have to agree to this before the PRN would allow him to accept the position. *Id*. at 318. And she further testified that were Respondent to accept a position in an emergency room without notifying the PRN, this would constitute a material breach of the PRN contract and he would be immediately pulled from practice and required to undergo a new evaluation. *Id*.

Following questioning by the parties, the ALJ asked Dr. Ziegler "what significance [she] attach[ed] to the premise of a stable recovery [being] measured in terms of five years?" *Id*. at 325. Dr. Ziegler answered:

> Right now that is sort of a standard accepted practice in all of the professional monitoring programs that are members of a group called the Federation of State Physician Health Programs.

> It used to be three years and it was extended to five years because there was [sic] some research studies that showed that three years may not be long enough and that relapses did frequently occur at the three-year point, although we don't really fully understand why because the research isn't there to demonstrate it. But that's pretty much a standard operating procedure for most of these monitoring programs around the country.
>
> It definitely seems to correlate with outcome data that says the chances of relapse after five years of stable monitored recovery is greatly lessened compared to people who are not monitored. And that's kind of the best answer I can give you. There's nothing really all that magic [sic] about five years. It's just that that's kind of a standard these days.

Id. at 325-26.

The ALJ then asked Dr. Ziegler what "it means to represent that someone is safe to practice?" *Id*. at 326. Dr. Ziegler answered:

> Well, when we make that kind of representation, we're basing that on reports that we receive from the treating professional involved with this person's individual situation at the outset and then as we go along, also with the results of our frequent random drug testing and our contact with the person, mostly over the phone, as they go through our program.
>
> . . . what I usually say if I'm writing a letter to the Board of Medicine or to a potential employer or to an insurance company or to the DEA is in my professional opinion[,] this person is safe to practice with reasonable skill and safety.
>
> I believe that when somebody is in our monitoring program and has done well for a period of time that they are as safe to practice with reasonable skill and safety as someone who has never been identified as having a problem.

Id. at 326-27.

Finally, the ALJ noted that Respondent's PRN contract includes a provision which states that PRN "agrees to assume an advocacy role with [the] Professional Licensing Board, hospital board, and *other appropriate agencies*, provided the above listed terms are agreed to and met." RX B, at 6 (emphasis added). The ALJ then asked Dr. Ziegler whether DEA was considered to be "such an agency." Tr. 329. Dr. Ziegler answered:

> Well, I'm not wild about that term "advocacy," but I'll buy it temporarily and say yes. I mean, advocacy means that we are willing to do something like today . . . . You're having a hearing and I'm willing to come and testify that this person has done the right thing and is safe to practice and whatever. If that's what you mean by advocacy, yeah, that's what we do, part of what we do.
>
> And the other part of what we do is we withdraw advocacy if it's no longer wanted or warranted . . . because otherwise our credibility is no good. . . . Our credibility depends upon our willingness to withdraw our advocacy if the person no longer warrants that advocacy.

Id. at 329-30.

On further questioning by Respondent's counsel, Dr. Ziegler testified that it was "correct" that 85 to 90 percent of PRN's patients "comply with their contract[s] and "make it." *Id*. at 331. However, on re-cross examination, Dr. Ziegler acknowledged that she could not guarantee that Respondent would never relapse. *Id*. at 331-32.

In addition to his previous testimony regarding the various incidents, Respondent admitted that he had probably used drugs when he was working. *Id*. at 216. When asked how long he would continue to be actively monitored, Respondent answered: "the rest of my life, if it can happen." *Id*. at 219; *see also id*. at 256 (expressing willingness to sign lifelong PRN contract). He further testified that during the fourth year of monitoring, he would be subject to eighteen urine tests as well as a hair test every three months, and that in the fifth year of his PRN contract, he would be subject to twenty-four urine tests. *Id*. at 220. However, Respondent did not know how many urine tests would be conducted each year if he contracted for additional monitoring. *Id*. Respondent then acknowledged that both the DOH and this Agency could require that he stay in the PRN program. *Id*. at 221.

Respondent also acknowledged that as an emergency room physician, at times he did experience "great stress." *Id*. at 224. Respondent explained, however, that "most of the time, I was able to handle that, and that's without having any knowledge [of] how to do it." *Id*.

Respondent further agreed that his recovery will be "a lifelong struggle" and that he could not guarantee that he will never relapse. *Id*. at 225-26. He further testified that he accepted all responsibility for "all of these violations that [he] had both as related to controlled substances and the way that [he] practice[d] medicine outside . . . of [the] standards of care." *Id*. at 249.

DISCUSSION

Section 303(f) of the Controlled Substances Act (CSA) provides that "[t]he Attorney General may deny an application for [a practitioner's] registration . . . if [he] 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, the CSA directs that the following factors be considered:

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

Id.

"[T]hese factors are . . . considered in the disjunctive." *Robert A. Leslie*, 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to deny an application for a registration. *Id.* Moreover, I am "not required to make findings as to all of the factors." *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

The Government has "the burden of proving [by substantial evidence] that the requirements for . . . registration . . . are not satisfied." 21 CFR 1301.44(d); *see also* 5 U.S.C. § 556(d). However, where the Government has met its *prima facie* burden of showing that issuing a new registration to the applicant would be inconsistent with the public interest, a respondent must come forward with "sufficient mitigating evidence" to show why he can be entrusted with a new registration. *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988))). Moreover, because "'past performance is the best predictor of future performance,' *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." *Medicine Shoppe*, 73 FR at 387; *see also Jackson*, 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Cuong Tron Tran*, 63 FR 64280, 64283 (1998); *Prince George Daniels*, 60 FR 62884, 62887 (1995). *See also Hoxie v. DEA*, 419 F.3d at 483 ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[]" in the public interest determination). Even so, at all times, the burden of proof on the ultimate issue of whether an applicant's registration is inconsistent with the public interest remains with the Government. 5 U.S.C. § 556(d); 21 CFR 1301.44(d).

Having considered all of the factors,[3] I hold that the Government has met its *prima facie* burden of showing that Respondent has committed acts which render his registration

[3] As for factor one, the recommendation of the state licensing authority, the DOH has not made a recommendation to the Agency as to whether Respondent should be granted a new DEA registration. Moreover, although Respondent is currently licensed by the State and thus satisfies an essential condition for obtaining a registration, *see* 21 U.S.C. §§ 802(21) & 823(f), this "'is not dispositive of the public interest inquiry.'" *George Mathew*, 75 FR 66138, 66145 (2010), *pet. for rev. denied Mathew v. DEA*, No. 10-73480, slip op. at 5 (9th Cir., Mar. 16, 2012); *see also Patrick W. Stodola*, 74 FR 20727, 20730 n.16 (2009); *Robert A. Leslie*, 68 FR 15227, 15230 (2003). As the Agency has further held, "the Controlled Substances Act requires that the Administrator . . . make an independent

"inconsistent with the public interest." 21 U.S.C. § 823(f). However, I further find that Respondent has accepted responsibility for his misconduct. Moreover, I hold that in the event Respondent produces evidence that he has continued to comply with his PRN contract and has passed all drugs tests administered to him since January 28, 2014, he will have produced sufficient evidence of his successful rehabilitation and will have rebutted the Government's *prima facie* case.

Factor Two - Respondent's Experience in Dispensing Controlled Substances

Pursuant to a longstanding agency regulation, "[a] prescription for a controlled substance [is not] effective [unless it is] issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). The 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*

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determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest." *Mortimer Levin*, 57 FR 8680, 8681 (1992). Thus, this factor is not dispositive either for, or against, the granting of Respondent's application. *Paul Weir Battershell*, 76 FR 44359, 44366 (2009) (citing *Edmund Chein*, 74 FR 6580, 6590 (2007), *pet. for rev. denied Chein v. DEA*, 533 F.3d 828 (D.C. Cir. 2008)).

Regarding factor three, there is no evidence that Respondent has been convicted of an offense related to the manufacture, distribution or dispensing of controlled substances. However, as there are a number of reasons why a person may never be convicted of an offense falling under this factor, let alone be prosecuted for one, "the absence of such a conviction is of considerably less consequence in the public interest inquiry" and thus, it is not dispositive. *David A. Ruben*, 78 FR 38363, 38379 n. 35 (2013) (citing *Dewey C. MacKay*, 75 FR 49956, 49973 (2010), *pet. for rev. denied MacKay v. DEA*, 664 F.3d 808 (10th Cir. 2011)).

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) (the prescription requirement 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 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 doctor-patient relationship. *Volkman*, 73 FR at 30642.

As found above, it is undisputed that Respondent issued multiple prescriptions for a total of 720 dosage units of OxyContin 80mg in a manner which violated both the CSA's prescription requirement and Florida law. As the evidence shows, while Respondent wrote the prescriptions for his girlfriend, and maintained that he had done so because she had re-injured her neck while snowboarding on a ski trip, he admitted that shortly after returning from the trip, he had changed her prescription from hydrocodone to OxyContin so that he could obtain the drugs to abuse them and that he took some portion of the OxyContin he prescribed. Tr. 205 & 207.

An expert retained by the DOH found that Respondent did not maintain medical records, that there was no evidence that he had assessed his girlfriend's medical problems and that his diagnosis was "inappropriate and inadequate." GX 8, at 2. The DOH's expert also found that Respondent had not created a treatment plan. The DOH's expert thus concluded that

Respondent's prescribing "fell well below the standard of care as defined by" both state and national norms and that he committed "egregious error" by prescribing to "an intimate partner . . . over a prolonged period." *Id.* Moreover, Respondent fully admitted that he did not have a proper medical justification to prescribe to his girlfriend and that the prescriptions were issued outside of the usual course of professional practice.

I therefore find that Respondent violated both the CSA's prescription regulation, *see* 21 CFR 1306.04(a), and Florida law, which prohibits the prescribing of "any controlled substance, other than in the course of the physician's professional practice." Fla. Stat. § 458.331(1)(q); *see also* 21 U.S.C. § 841(a)(1) ("[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally . . . to dispense . . . a controlled substance").

Against this evidence, Respondent testified as to the training he received in his residency regarding the dispensing of controlled substances, his more than twenty years of experience in dispensing controlled substances as an emergency room physician, and there is no evidence that he has otherwise knowingly diverted controlled substances. He also testified that pursuant to the DOH's order, he had taken a course on the proper prescribing of controlled substances.

Be that as it may, the finding that he violated both the CSA and federal law in issuing the OxyContin prescriptions is evidence of his experience in dispensing controlled substances even if it is also evidence of his noncompliance with applicable laws related to controlled substances. And by itself, this finding is sufficient to support the conclusion that the Government has established a *prima facie* case to deny Respondent's application. I thus reject the ALJ's conclusion that factor two "neither supports nor contradicts" Respondent's application.

The ALJ's analysis of Factor Two nonetheless warrants further discussion. More specifically, the ALJ opined that:

> [T]here also is evidence of acts by [Respondent] that do not constitute noncompliance with law but still suggests experience that may threaten the public interest. There is, for example, no law against being familiar with that part of society that deals in illicit drug trafficking. Over the years while he was buying heroin and other drugs on the street, [Respondent] has become very well acquainted with those in the community who have chosen to traffic in heroin. A person with that kind of experience, particularly one authorized to write prescriptions for narcotics and other controlled substances, holds a highly valuable key recognized by those in our society who are likely to try to exploit that authority to advance their own illicit goals.
>
> Restoring to [Respondent] the ability to prescribe controlled substances carries with it some risk, given the unique skill set [Respondent] developed while seeking heroin and other addictive drugs on the street. While he may well be able to resist efforts from those in the trafficking trade to recruit him during periods of sustained stable recovery, were he to relapse those illicit efforts may well prove successful, creating a significant risk of prescription drug diversion.

R.D. at 37-38.

The ALJ's reasoning finds no warrant in the text of Factor Two. Contrary to the ALJ's understanding, factor two does not call for an inquiry into a practitioner's life experience generally or even his experience related in any manner to controlled substances, but rather, only his "experience in dispensing, or conducting research with respect to controlled substances." *See* 21 U.S.C. § 823(f)(2). While writing controlled substance prescriptions which were then traded for street drugs would clearly be actionable misconduct under this factor, there is not even an iota of evidence in this record that Respondent ever traded controlled substance prescriptions for drugs he obtained on the street. In the absence of any such evidence, the ALJ's reasoning is nothing more than unsupported speculation. Accordingly, I reject it.

Factor Four – The Applicant's Compliance With Applicable Laws Related To Controlled Substances

In addition to the prescribing violations discussed above, Respondent committed additional violations of both the CSA and Florida laws when he unlawfully possessed controlled substances and drug paraphernalia. With respect to the 2003 incident, Respondent clearly

possessed heroin and drug paraphernalia (*i.e.*, a syringe) when he injected himself with the heroin. Respondent's conduct violated both the CSA, *see* 21 U.S.C. § 844(a) (simple possession), as well as Florida law. *See* Fla. Stat. § 893.13(6)(a) (unlawful possession); *id*. § 893.147(1)(b) (prohibiting use of drug paraphernalia "[t]o inject . . . a controlled substance in violation of this chapter"); *id*. § 893.145(11) (defining drug paraphernalia as including "[h]ypodermic syringes, needles, and other objects used, intended for use, or designed for use in parenterally injecting controlled substances into the human body").

So too, because Respondent did not obtain the OxyContin he admitted to abusing "pursuant to a valid prescription from a practitioner," or obtain it in a manner otherwise authorized by the CSA, he also unlawfully possessed those drugs. 21 U.S.C. § 844(a); *see also* Fla. Stat. § 893.13(6)(a). Likewise, at the time of the 2011 Tampa Airport incident, Respondent was in found to be in possession of heroin, methadone, and Xanax (alprazolam), as well as multiple syringes.

Heroin is a schedule I drug, as it has no accepted medical use; Respondent thus had no authority to possess the drug under his registration. *See* 21 CFR 1308.11(c); GX 2, at 3; 21 U.S.C. § 822(b). Nor did Respondent dispute that he did not have prescriptions for the methadone and Xanax. Thus, here again, Respondent violated the CSA and Florida law by unlawfully possessing controlled substances. 21 U.S.C. § 844(a); *see also* Fla. Stat. § 893.13(6)(a). Moreover, his possession of the syringes also violated Florida law. Fla. Stat. § 893.147 (prohibiting the possession, with intent to use, of drug paraphernalia); *id*. § 893.145(11).

Here again, Respondent does not dispute that he engaged in the above acts. Respondent's extensive record of non-compliance with the CSA and Florida laws related to controlled

substances thus provides further support for the conclusion that the Government has established a *prima facie* case to deny his application.

Factor Five – Such Other Conduct Which May Threaten Public Health and Safety

DEA precedent has long recognized that a practitioner's self-abuse of controlled substances constitutes misconduct which is actionable under this factor. *Tony T. Bui*, 75 FR 49979, 49989 (2010) (citing, *inter alia*, *David E. Trawick*, 53 FR 5326, 5327 (1988); *William H. Carranza*, 51 FR 2771 (1986)). Here, it is undisputed that Respondent has a long and disturbing history of abusing controlled substances. Moreover, Respondent admitted that he had probably been under the influence of controlled substances while at work. This factor thus provides further support for the Government's *prima facie* case.

The ALJ further found that beyond this evidence, Respondent, when "not in stable and sustained recovery . . . has a demonstrated tendency towards lying in the course of responding to governmental processes." R.D. 40. As support for his conclusion, the ALJ explained that "[h]is decision to deny his possession of heroin when interviewed by a court evaluator following his 2003 overdose is one example; his failure to disclose to the Florida Department of Health that he was diverting OxyContin for his own use in 2006 is another example." *Id.*

The ALJ then suggested that Respondent gave false testimony in this proceeding. More specifically, the ALJ reasoned that:

> Further, his testimony in these proceedings, to the effect that the expert evaluation presented to the Florida [DOH] in 2005 by [its] expert was "100 percent accurate" cannot be reconciled with the fact that [the expert's] report made no mention of the whole truth here – that [he] had been diverting [his girlfriend's] OxyContin for his own use, for two years. Dr. Greenstein's report was not "100 percent accurate," and it was inaccurate with respect to a material condition that apparently has never been disclosed to the Florida medical authorities.

Id.

However, the ALJ then explained that "that the evidence does not compel, or even permit, a finding that [Respondent] currently presents a threat to the public due to a predisposition to prevaricate." *Id*. at 41. The ALJ further explained that he did "not detect a *present threat* here," as he believed that Respondent "can be relied upon to be forthright and candid during his recovery." *Id*. (emphasis added). Nonetheless, because Factor Five directs that the Agency consider "conduct which *may threaten* the public health and safety," the ALJ then reasoned that "[a] chronic history of substance abuse, *coupled with a pattern of misleading governmental officials* when the abuse created significant problems for [him], is evidence of conduct that may threaten public health and safety." *Id*. (emphasis added).

As stated above, I agree with the ALJ that the evidence shows that Respondent has a chronic history of substance abuse. However, I reject his conclusion that the evidence establishes that Respondent has "a demonstrated tendency towards lying" to government officials and a "pattern of misleading" them. To be sure, the evidence shows that in 2003, Respondent falsely stated to the evaluator for the pretrial drug intervention program that the heroin found in his vehicle was not his.

The evidence does not, however, support either the ALJ's conclusion that he lied to the Florida Department of Health because he failed to disclose to it that he was using the OxyContin he prescribed to B.B. or the ALJ's suggestion that he gave false testimony in this proceeding. As for the former, there is no evidence that Respondent was ever asked by the DOH's investigator whether he was using the OxyContin and Respondent testified that "[n]obody from the [DOH] asked, and I didn't volunteer that information." Tr. 204. Thus, Respondent did not lie to the DOH. To the extent the ALJ's conclusion rests on the theory that Respondent misled the DOH by failing disclose to it that he was using the OxyContin, the Government made no such

argument and the ALJ cited no authority for the proposition that Respondent had a duty under Florida law to disclose this information to the DOH.

So too, I find unwarranted the ALJ's suggestion that Respondent gave false testimony when he testified that the DOH expert's report was "100 percent accurate." R.D. at 40. While the ALJ reasoned that the expert's "report was not '100 percent accurate'" because it "made no mention of the whole truth," that being that Respondent was using his girlfriend's OxyContin, there is no evidence that the expert ever interviewed Respondent. Indeed, the expert's report stated that he had only reviewed the investigative file prepared by the DOH.

Moreover, the ALJ's suggestion cannot be sustained upon reviewing the entirety of Respondent's testimony regarding the DOH expert's report. *Cf. Meyers v. United States*, 171 F.2d 800, 806-07 (D.C. Cir. 1948) (a "statement may not be isolated and thereby given a meaning wholly different from the clear significance of the testimony considered as a whole"). As found above, Respondent answered "absolutely" when asked by the Government whether he agreed with the expert's conclusions. Tr. 203. Notably, those conclusions included that there was no evidence that he had assessed B.B.'s medical problems and that his "diagnosis was therefore inappropriate and inadequate"; that his "care fell well below the standard of care as defined by Florida statute, local and national norms"; that the "prescription of OxyContin was strikingly inappropriate"; that he committed an "egregious error" by providing "high-volume, long duration" prescriptions "of a highly abused narcotic to a patient with whom he had an intimate relationship." GX 8, at 2-3. Respondent thus admitted to having committed egregious misconduct. Viewed in this context, his answer to the Government's subsequent question, which

asked if there was "any part of" the report that he did "not agree" with, and to which he answered, "No. It's 100 percent accurate," cannot reasonably be construed as false.[4]

Accordingly, I reject the ALJ's analysis that Respondent has demonstrated a pattern of misleading governmental officials when his substance abuse "created significant problems for" him. R.D. at 41. However, his substance abuse alone supports a finding that he has engaged in conduct which may threaten public health and safety.

Summary

As found above, the Government's evidence with respect to factors two, four and five, establishes that Respondent wrote unlawful prescriptions, unlawfully possessed controlled substances, unlawfully possessed drug paraphernalia, and has a long history of substance abuse. Accordingly, the Government has established a *prima facie* case to deny Respondent's application on the ground that his registration "would be inconsistent with the public interest." 21 U.S.C. § 823(f). Indeed, in his post-hearing brief, Respondent concedes as much.

SANCTION

As explained above, where the Government has met its *prima facie* burden of showing that issuing a new registration to the applicant would be inconsistent with the public interest, a respondent must come forward with """sufficient mitigating evidence""" to show why he can be entrusted with a new registration. *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988))). "Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the

[4] Indeed, while the ALJ reasoned that the report was not 100 percent accurate because it made no mention of Respondent's diverting the drugs to his own use, there is not a single statement in the report which appears to be untrue.

registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." *Medicine Shoppe*, 73 FR at 387; *see also Jackson*, 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Prince George Daniels*, 60 FR 62884, 62887 (1995). *See also Hoxie v. DEA*, 419 F.3d at 483 ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[]" in the public interest determination).

Here, the ALJ found that Respondent has accepted responsibility for his misconduct. R.D. at 42. However, the ALJ concluded that Respondent has not produced sufficient evidence of his rehabilitation to rebut the Government's *prima facie* case. *Id.* As the ALJ explained:

> The record before me establishes that when sober and compliant with his recovery program, [Respondent] can be relied upon to avoid engaging in behavior that threatens the public interest. Thus, the risk of relapse becomes critical in determining what steps are warranted when determining the public interest. Here, testimony from Drs. Ziegler and Myers establishes that the risk of relapse is high, and will continue to be high for [Respondent], throughout the five years following the commencement of his recovery. The evidence fully supports a finding that [Respondent's] recovery since February 2011 has been stable and successful. The evidence also supports a finding, however, that insufficient time in stable recovery has passed to support a finding that corrective action has been taken. . . . Surely steps that may lead to effective corrective action have begun, but those steps are not complete, and in the absence of evidence of complete corrective actions the Respondent has not, by a preponderance, presented evidence that would permit the restoration of his . . . [r]egistration.

Id. at 42-43.

I do not dispute the ALJ's premise that "the risk of relapse [is] critical in determining what steps are warranted" to protect the public interest. I reject, however, the ALJ's conclusion that until Respondent successfully completes a full five years in the PRN's program, he presents an unacceptable risk of relapse. Not only does the ALJ's conclusion rest on a misreading of the testimony of both Drs. Myers and Dr. Ziegler, it cannot be reconciled with numerous agency precedents which have granted new registrations to self-abusing practitioners who have undergone treatment and demonstrated rehabilitation well before completing five years of

treatment in a PRN program.[5] While there may be a variety of factors present in any self-abuse case which support a finding that a practitioner continues to poses an unacceptable risk of relapse (even after completing multiple years of sustained recovery), a categorical rule that a practitioner cannot be registered before completing five years in a PRN program is inherently arbitrary.

Contrary to the ALJ's reasoning, neither the testimony of Dr. Myers nor Dr. Ziegler "established [that] a material risk of relapse exists during the first five years of stable recovery" for either professionals generally or Respondent specifically. Indeed, in concluding that Respondent continues to present an unacceptable risk of relapse and will do so until he completes a full five years in the PRN program, the ALJ ignored extensive evidence offered by Respondent to the contrary.

As found above, Dr. Myers testified that the PRN initially used "a two-year contract" but found that "too many docs and . . . healthcare professionals [were] relapsing following the two years." Tr. 147. He then explained that PRN lengthened the contract term to five years because "studies suggest" that five years "is a solid recovery time" which provides "maximum benefit" and that "the percentage of relapse is very low" for those persons who complete the five-year contract. *Id*.

Notably, Dr. Myers did not testify as to the specific relapse rate of those doctors who had completed a two-year contract. Most significantly, his testimony suggests only that the relapse rate was unacceptably high for those doctors who had completed their two-year contracts and were no longer subject to monitoring and other contract requirements. This, of course, says

[5] *See Perry T. Dobyns*, 77 FR 45656 (2012) (granting restricted registration based on less than three years of demonstrated sobriety following physician's relapse); *Stephen Reitman*, 76 FR 60889 (2011) (granting restricted registration where evidence at hearing established only one year of sobriety); *Michael Moore*, 76 FR 45867 (2011) (suspending but not revoking registration where physician, who abused marijuana, had demonstrated sobriety for less than four years); *Karen Kruger*, 69 FR 7016 (2004) (granting registration after three and a half years of demonstrated sobriety); *Jimmy H. Conway, Jr.*, 64 FR 32271 (1999) (granting registration after three years of demonstrated sobriety).

nothing about the relapse rate of those doctors who continued to be subject to monitoring after completing a two-year contract.

As for Dr. Myers' further testimony that various studies suggests that five years "is a solid recovery time" which provides "maximum benefit" and that the "percentage of relapse is very low" for those persons who complete a five-year contract, while this explains why PRNs have lengthened their contracts to five years, it too says nothing about the actual risk of relapse for those physicians who remain subject to, and in compliance with, a PRN contract through years three, four, and five of their contracts.

To be sure, Dr. Ziegler testified that PRN contracts "used to be three years" but were "extended to five years because . . . some research studies . . . showed that three years may not be long enough and that relapses did frequently occur at the three-year point." Tr. 325-26. However, even assuming that these studies involved physicians who were still subject to PRN monitoring at the time of their relapses, no further testimony was elicited from Dr. Ziegler as to what the actual rate of relapse was at three years and various times thereafter. [6]

In short, neither the testimony of Dr. Myers nor of Dr. Ziegler establishes what the relapse rate is for physicians who remain subject to monitoring during the fourth and fifth years of a PRN contract as a general matter, let alone for physicians who present particular risk factors for relapse. And in any event, Respondent is now well past three years of successful compliance with his PRN contract and through the closing of the record, he has passed every drug test since seeking treatment in February 2011.

[6] The conclusion that because PRN programs have extended their monitoring contracts to five years, a physician under such a contract invariably presents an unacceptable risk of relapse until he completes a full five years of compliance, was refuted by Dr. Ziegler's testimony. *See* Tr. 317-18. The Agency's case law also suggests that this conclusion is inconsistent with the understanding of state medical boards, which have frequently issued new licenses to practitioners before the practitioners have demonstrated five years of sobriety.

Moreover, both Dr. Myers and Ziegler offered extensive evidence of Respondent's commitment to his recovery and compliance with his PRN contract. Yet this evidence is barely acknowledged in the recommended decision. Notably, Dr. Myers, who, in addition to being a Diplomate of the American Board of Addiction Medicine and a Fellow of the American Society of Addiction Medicine, has twenty-five years of experience working with chemically dependent persons, with twenty of those years focused on recovering professionals, testified that he employs Respondent in his practice, that he considers him safe, and that if he had "any doubt that [Respondent] was risky, he couldn't use him." Tr. at 133. Dr. Myers also testified that while Respondent will never be cured, he believes that Respondent is fully committed to his recovery, that he "is making it" and that he will "continue to make it." *Id.* at 132.

Dr. Ziegler, who is board certified in Psychiatry and Addiction Psychiatry, as well as Addiction Medicine, and has focused her professional activities on the treatment of addiction, testified that Respondent has passed all of his urine screens and "has been entirely compliant with his contract." Tr. 312. In his decision, the ALJ asserted that, because the PRN contract obligates the PRN "to assume an advocacy role" with licensing agencies provided Respondent complied with the terms of his contract, her testimony "should be treated as advocacy, rather than as independent and unbiased medical testimony." R.D. at 32. However, Dr. Ziegler further explained that PRN will "withdraw our advocacy if the person no longer warrants that advocacy." Tr. 330. Accordingly, I do not find that the existence of the PRN contractual provision warrants giving less than full weight to her testimony.[7]

[7] Notably, other than the contractual provision, there is no evidence on Dr. Ziegler's part of the existence of any other of the typical sources of partiality.

Of further note, neither the Government nor the ALJ identify a specific instance in which Dr. Ziegler's testimony lacked objectivity.

While Dr. Ziegler testified that she could not guarantee that Respondent would never relapse, she also testified that granting Respondent prescribing authority would not pose a safety issue. As she explained:

> people at his stage of recovery and at his point in monitoring with us, lots of those practitioners hold a DEA certificate and use them in the course of their practice of medicine. . . . [H]aving prescribing privileges, there's a certain amount of risk associated with it. But at this stage of the game it certainly is not something we would be concerned about because he is doing very well.

Tr. 317-18.

Dr. Ziegler also testified that when PRN represents to a licensing body that a practitioner is safe to practice, its representation is based on the reports it has received from the physician's treating professional who is aware of the physician's individual situation, the results of the random drugs screens it has conducted, and its contact with the physician as he/she goes through the program. *Id*. at 326-27. And she further testified "that when somebody is in our monitoring program and has done well for a period of time [he/she is] as safe to practice with reasonable skill and safety as someone who has never been identified as having a problem." *Id*. at 327.

The Government also argues that Respondent's application should be denied because he failed to produce evidence supporting his application "from independent medical professionals." Gov. Br. 20. It is not entirely clear what, in the Government's view, qualifies a medical professional as "independent." However, in self-abuse cases, this Agency has never required a practitioner to present evidence from a medical professional who either does not have a doctor-patient relationship with the physician or is not otherwise involved in the physician's recovery.[8]

As for Dr. Myers, the Government argues that his testimony should be given "the same scrutiny as Dr. Ziegler['s]" because he has a long association with PRN and "should be viewed as an agent of PRN." Gov. Br. at 21-22. Here again, I find the Government's argument unpersuasive and do not find that any portion of his testimony lacks credibility.

[8]It is far from clear whether, under Florida law, Dr. Ziegler, as PRN program director, has a doctor-patient relationship with the PRN's clients.

Rather, the Agency has frequently granted new registrations to practitioners based on the reliable testimony of treating professionals. To the extent the Government believes that neither Dr. Myers nor Dr. Ziegler were objective witnesses in their assessments of Respondent's risk of relapse, it bears noting that there is independent medical evidence of Respondent's successful rehabilitation - this being the numerous random drug tests he has passed. And nothing prevented the Government from retaining an expert who could have reviewed Respondent's treatment records and rendered an opinion on whether he presents an unacceptable risk of relapse.

The Government also argues that because of "his long-term drug abuse," Respondent should not be granted a registration until he has completed a minimum of "five years of monitored treatment." Gov. Br. at 19. Notably, the Government produced no evidence establishing that physicians with a long history of abuse have a greater risk of relapse than other physicians. Indeed, when asked by the Government whether there is a correlation between a physician's length of abuse and the likelihood of relapse, Dr. Myers testified that while "there are a number of factors which can help predict relapses," he did not believe that a correlation has been established between the length of abuse and the likelihood of relapse.

The Government offered no evidence to refute this testimony. Moreover, while Dr. Myers testified that there are a number of factors that predict relapses, the Government did not elicit any testimony from Dr. Myers or offer any other evidence establishing what those factors are and whether they are present in Respondent's case.

It bears noting that while Respondent had the burden of producing sufficient evidence to establish that he has undertaken sufficient corrective measures such that he is not likely to re-offend, the Government, at all times, retains the burden of proving that granting his application is inconsistent with the public interest. 5 U.S.C. § 556(d); 21 CFR 1301.44(d). Accordingly, I

reject the Government's contention that Respondent presents an unacceptable risk of relapse until he successfully completes a full five years in the PRN program.

I therefore conclude that provided Respondent has continued to comply with his PRN contract and has passed all drug tests since the closing of the record, he is entitled to be registered. Accordingly, Respondent is directed to provide evidence of all drug test results conducted since January 28, 2014 and his continued compliance with his PRN contract.[9] In the event Respondent has failed any of the drug tests, or has not remained in compliance with his PRN contract, his application shall be denied. In the event he has passed all of these tests and remained in compliance, he shall be granted a registration, subject to the following conditions which are supported by the record.

First, the Government notes that Respondent can walk away from his PRN contract at any time. While there is evidence that in the event Respondent were to do so, the PRN would report him to the DOH, the record does not establish what action the DOH would take in response. Accordingly, I conclude that Respondent's registration shall be conditioned on his remaining in compliance with his PRN contract. In the event Respondent fails to comply with his PRN contract, his registration shall be subject to an Immediate Suspension Order.

Second, while Respondent's PRN contract expires in May 2016, Dr. Ziegler noted that PRN offers its clients a licensure-long contract. Moreover, in his testimony Respondent acknowledged that his recovery will be "a lifelong struggle" and expressed a willingness to enter into a licensure-long contract; he also acknowledged that DEA could require that he stay in the PRN program. Accordingly, I conclude that Respondent's registration shall be conditioned on his entering into a licensure-long contract upon the completion of his initial five-year contract.

[9] Respondent shall provide this evidence to the Office of the Administrator no later than thirty (30) days from the date of this Order. Respondent shall also provide a copy of his filing to Government counsel. In the event Respondent fails to comply, his application will be denied.

Moreover, if, following the completion of his initial five-year contract, Respondent fails to enter into a licensure-long contract, his registration shall be subject to an Immediate Suspension Order.

Third, Respondent may not accept any position as a physician without first obtaining approval of the PRN program. Respondent's acceptance of a position without first obtaining the PRN's approval shall subject his registration to suspension or revocation.

Fourth, Respondent shall enter into an agreement with the PRN pursuant to which he authorizes and directs the PRN to report the results of any drug test he fails to the nearest DEA Field Division Office; a copy of this agreement must be provided to the DEA Field Division Office prior to the issuance of the registration. In the event Respondent is ordered to undergo a drug test and fails to comply in accordance with the PRN's rules, this shall be deemed a failed test. In the event Respondent fails any drug test, his registration shall be subject to an Immediate Suspension Order.

Respondent is prohibited from possessing any controlled substances except for those he obtains pursuant to a lawful prescription or which are lawfully dispensed to him by a duly authorized health care provider. Respondent shall not order any controlled substances, nor accept any controlled substances (including manufacturer's samples) from any person (other than those which are lawfully dispensed to him), including a manufacturer's or distributor's sales representative. Moreover, Respondent shall not be authorized to administer controlled substances to any person until such time as PRN approves such activity; upon such approval, Respondent shall be authorized to possess such controlled substances. In the event Respondent violates the provisions of this paragraph, his registration shall be subject to an Immediate Suspension Order.

If PRN approves Respondent to engage in the administration of controlled substances, Respondent shall provide a copy of a letter from PRN to this effect to the nearest DEA Field Division Office prior to engaging in such activity.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f) and 28 CFR 0.100(b), I order that the application of Abbas E. Sina, M.D., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, held in abeyance pending his submission of all drug test results since January 28, 2014. I further order that in the event Respondent has passed all drug tests since January 28, 2014 and remained in compliance with his PRN contract, his application shall be granted subject to the conditions set forth above. I further order that in the event Respondent has not passed all drug tests since January 28, 2014 or other remained in compliance with his PRN contract, or fails to submit this evidence within the time set forth above, his application shall be denied. This Order is effective immediately.

Date: **May 15, 2015**

s/Michele M. Leonhart
Administrator

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