

Drug	Schedule
Amphetamine (1100) .....	II
Methamphetamine (1105) .....	II
Methylphenidate (1724) .....	II
Amobarbital (2125) .....	II
Pentobarbital (2270) .....	II
Secobarbital (2315) .....	II
Phencyclidine (7471) .....	II
Phenylacetone (8501) .....	II
Cocaine (9041) .....	II
Codeine (9050) .....	II
Dihydrocodeine (9120) .....	II
Oxycodone (9143) .....	II
Hydromorphone (9150) .....	II
Benzoyllecgonine (9180) .....	II
Ethylmorphine (9190) .....	II
Meperidine (9230) .....	II
Methadone (9250) .....	II
Dextropropoxyphene, bulk (non-dosage forms) (9273) .....	II
Morphine (9300) .....	II
Oripavine (9330) .....	II
Thebaine (9333) .....	II
Levo-alphaacetylmethadol (9648) .....	II
Oxymorphone (9652) .....	II
Fentanyl (9801) .....	II

The company plans to import small quantities of the listed controlled substances for the manufacture of analytical reference standards.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and 952(a) and determined that the registration of Cerilliant Corporation to import the basic classes of controlled substances is consistent with the public interest, and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971, at this time. DEA has investigated Cerilliant Corporation to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic classes of controlled substances listed.

Dated: March 4, 2009.

**Joseph T. Rannazzisi,**

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

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 06-78]

#### Steven M. Abbadessa, D.O.; Grant of Restricted Registration

On August 7, 2006, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Steven M. Abbadessa, D.O. (Respondent), of St. Louis, Missouri. The Show Cause Order proposed the denial of Respondent's pending application for a DEA Certificate of Registration as a practitioner, on the ground that his "registration would be inconsistent with the public interest." *Id.* at 1 (citing 21 U.S.C. 823(f)).

The Show Cause Order specifically alleged that "[o]n or about January 1981, [Respondent] illegally possessed and distributed \* \* \* cocaine in violation of 21 U.S.C. 841(a)(1)," that Respondent was subsequently charged and arrested, and that he had admitted to agents that he had been involved "in the illegal distribution of cocaine, a schedule II controlled substance," but that "no further prosecution was undertaken" because he cooperated with authorities. *Id.*

The Show Cause Order next alleged that on December 4, 2001, Respondent was arrested by local police at a hotel in Clayton, Missouri, where he was found to have in his possession cocaine, as well as two prescription controlled substances—a combination drug containing hydrocodone, a schedule III

controlled substance, and alprazolam, a schedule IV controlled substance. *Id.* The Order further alleged that the hydrocodone and the alprazolam "had been dispensed in the name of an acquaintance" of Respondent. *Id.*

Relatedly, the Show Cause Order alleged that Respondent was subsequently indicted in state court on one felony count of possession of cocaine, and two felony counts of obtaining controlled substances by fraud. *Id.* The Order further alleged that on January 31, 2003, Respondent pled guilty to all three counts, but that he was allowed to withdraw his pleas after he completed a "one-year drug program." <sup>1</sup> *Id.* at 1-2.

Respondent, through his counsel, requested a hearing on the allegations. ALJ Ex. 2. The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who conducted a hearing in St. Louis, Missouri, on May 15 and 16, 2007. At the hearing, both the Government and Respondent put on testimony and introduced documentary evidence into the record. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and argument.

On February 13, 2008, the ALJ issued her recommended decision (ALJ). In her decision, the ALJ concluded that the

<sup>1</sup> The Order also noted that on March 10, 2003, Respondent had surrendered his DEA registration, that in February 2004, the Missouri State Board for the Healing Arts had entered into a settlement agreement with Respondent under which his medical license was placed on probation for seven years, and that in April 2006, Respondent's state controlled substances registration had been restored. *Id.* at 1-2.

Government had established grounds for the denial of Respondent's application. ALJ at 55. The ALJ held, however, that Respondent had accepted responsibility for his misconduct and had "provided ample mitigating evidence and adequate assurances that he is able to responsibly handle [controlled substances] and is willing to abide by restrictions and/or requirements placed upon him." *Id.* at 57. The ALJ thus recommended that Respondent's application be granted subject to three restrictions. *Id.* Thereafter, the Government filed exceptions to the ALJ's decision.

Having considered the entire record in this matter, I adopt the ALJ's recommended decision except for her conclusions regarding the hardship imposed by Respondent's lack of a registration, which is not a relevant consideration under the Controlled Substances Act. I hold that while the Government made out a *prima facie* case to deny the application, Respondent has convincingly demonstrated that he can be entrusted with a new registration subject to conditions. However, I impose additional conditions beyond those recommended by the ALJ. I therefore reject the Government's exceptions and will grant Respondent a new registration subject to the conditions as set forth below. I make the following findings.

### Findings

Respondent is a Doctor of Osteopathy (D.O.) and a board-certified proctologist. Respondent holds a license as an Osteopathic Physician and Surgeon from the Missouri State Board of Registration for the Healing Arts. RX 16, at 25. Effective February 9, 2004, Respondent's state license was placed on probation for a period of seven years. *Id.* Respondent also held a DEA Certificate of Registration from 1987 until he surrendered it on March 7, 2003. GX 4.

Respondent is, however, currently authorized to practice medicine subject to numerous conditions. These include, *inter alia*: (1) That he "abstain completely from the personal use or possession of controlled substances \* \* \* unless that use of the drug has been prescribed by a person licensed to prescribe such drug and with whom [he] has a bona fide physician/patient relationship," RX 16, at 26; (2) that he participate in the Missouri State Medical Association's Physician Health Program (MPHP), *id.* at 25–26; (3) that he completely abstain from the use of alcohol, *id.* at 27; (4) that he "submit to biological fluid testing" at his own expense and that the presence of any drug not supported by a valid

prescription which had been submitted to the Board is a violation of his discipline, *id.*; (5) that he "cause a letter of evaluation from [a] chemical dependency professional or from the rehabilitation or aftercare program to be submitted to the Board" each quarter, *id.*; and (6) that he agree to "unannounced visits from the Board's representatives to monitor his compliance with" the agreement. *Id.* at 28.

On November 10, 2003, Respondent applied for a new Missouri Controlled Substance Registration, his previous state registration having lapsed on March 31, 2003. GX 10, at 6. On August 24, 2004, the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) denied Respondent's application and issued an administrative complaint.<sup>2</sup> *Id.* On April 6, 2005, Respondent and the State entered into a stipulation and consent order under which Respondent acknowledged that the State had "sufficient evidence" to support the allegations of the denial letter and that cause existed to deny Respondent's application. *Id.* The parties agreed, however, that Respondent would accept the State's denial of his application, but that the State would consider a new application on or after January 1, 2006, and would grant the application provided that he did not commit new violations of controlled-substance laws and regulations and complied with his agreements with the state medical board and the Missouri Physicians Health Program. *Id.* at 8.

On or about January 5, 2006, Respondent submitted a new application for a state controlled substances registration. GX 11, at 3. On April 3, 2006, Respondent and the State entered into a settlement agreement under which Respondent again agreed that cause existed under Missouri law to deny his application. *Id.* at 3–4. The parties agreed, however, that the State would grant him a new registration subject to extensive probationary terms. *Id.* at 4.

The terms included, *inter alia*: (1) That Respondent maintain duplicate copies of "serially numbered" prescriptions and that copies be "maintained separately from each patient's charts," (2) that Respondent "not prescribe or administer controlled substances for himself, his immediate family or his employees except in a life-threatening emergency," (3) that Respondent "not order, purchase, or accept controlled substances," (4) that Respondent "not obtain" any controlled

substance unless it is prescribed to him by a practitioner with whom he "has a legitimate practitioner-patient relationship," and that he inform any treating practitioner "of his prior chemical dependence before he is given a prescription," (5) that Respondent ensure that any prescribing practitioner notify the BNDD of any prescription that was issued to him including the medical purpose of the prescription, (6) that Respondent shall remain a member of MPHP and ensure that quarterly reports were released to the BNDD, (7) that the BNDD "shall have authority to obtain biological \* \* \* and hair samples" at Respondent's expense, and (8) that both state and DEA investigators "shall have access to all required controlled drug records at any time during regular office hours." *Id.* at 4–6. Respondent was thus granted a new state controlled substance registration; the probationary terms remain in effect until April 3, 2011. *Id.* at 1.

### Respondent's Drug-Related Incidents

#### *The 1981 Incident*

In 1981, DEA Agents in Kirksville, Missouri, were notified by an informant that Respondent was a "large cocaine dealer." Tr. 51. Through the informant, a meeting was arranged at which an Agent posed as someone interested in buying cocaine from Respondent. *Id.* at 52–53. Respondent told the Agent that he could supply him with "two to three ounces of cocaine" and gave him a sample to test. *Id.* at 52. Respondent wanted money upfront, but the Agent refused to provide it. *Id.* Respondent and the Agent ended the meeting by agreeing to meet at a later date. *Id.* at 53.

The following day, Respondent and the Agent had a telephone conversation during which the former told the latter that he could get him "all the cocaine he wanted," which he thought was "three or four ounces." GX 3, at 2. Respondent did not, however, consummate a deal with the Agent. *Id.* Respondent did not hear again from the Agent for several weeks, when the latter called and told Respondent that he had some marijuana and cocaine for sale and asked if Respondent would "take it on consignment." *Id.*

Respondent agreed to meet the Agent. *Id.* Upon his arrival at the meeting, Respondent was arrested and charged with cocaine distribution. *Id.* Respondent cooperated with the authorities; as a result of his cooperation, two other persons were arrested. Tr. 99. Because of his cooperation, Respondent's case was sealed and he was not convicted of an offense. *Id.* at 98–99.

<sup>2</sup> The incident which prompted the denial (and this proceeding) is discussed below.

### *The 1992 Incident*

In 1992, Respondent was treated for headaches by a neurologist, who prescribed Vicodin to him. Tr. 255–56. When Respondent continued to seek refills of the Vicodin over a sustained period of time, the neurologist raised with him the subject of whether he was addicted. *Id.* at 256. Respondent agreed to contact the MPHP and underwent an in-patient evaluation which lasted seven to eight days. *Id.* Upon being discharged, Respondent participated in the MPHP program for approximately six years, during which he attend weekly Caduceus meetings and submitted to drug testing. *Id.* at 259. Respondent left the program in 1998, thinking that he “was okay.” *Id.* at 260. While Respondent was fine for a little while, he eventually started drinking again and then abusing drugs again. *Id.*

### *The 2001 Incident*

On December 4, 2001, an employee of a Ritz-Carlton hotel located in Clayton, Missouri contacted local police and reported that he had observed cocaine in the room in which Respondent was staying. *Id.* at 14–15. Upon their arrival, the police went to Respondent’s room, knocked on the door, and were let in by a cab driver named Rodney. *Id.* at 16. Respondent walked out of the bedroom area, observed the officers who were in uniform, and ran back into the bedroom. *Id.* at 16–17. The officers pursued Respondent and subdued him. *Id.* at 17. On a table, the officers found a bag containing 14.38 grams of cocaine, a black plastic container which held seven-tenths of a gram of cocaine, and assorted paraphernalia used to prepare and snort the drug such as plates, straws, a calling card and a credit card. *Id.* at 18.

The officers also seized two prescription drug vials; one contained thirty-seven tablets of hydrocodone, the other contained forty-one tablets of alprazolam. *Id.* at 18–19. The labels on the vials listed Rodney as the patient and Respondent as the prescriber (and included his DEA number); the quantities dispensed were forty tablets of hydrocodone and forty-two tablets of alprazolam. *Id.* Respondent was subsequently arrested and taken to the police station for booking. *Id.* at 22.

Rodney told the police that he had first met Respondent two days earlier when he drove him from a restaurant to his home; on that occasion, Respondent had asked Rodney for his business card because he was having car problems. *Id.* at 20–21. Upon meeting Respondent on December 4th, Respondent told Rodney that he was going to call in some

prescriptions in Rodney’s name and asked Rodney if he could pick them up at the pharmacy. *Id.* at 21. Respondent gave him money, and Rodney picked up the prescriptions that were found in the hotel room. *Id.*

At the police station, Respondent admitted that he had written the two prescriptions. *Id.* at 23. He was also observed as being in “an agitated state, pacing back and forth in his cell” and hitting his head against the wall. *Id.* According to the arresting officer, who had extensive experience in narcotics investigations, Respondent showed signs of impairment. *Id.* at 24.

Respondent was subsequently charged with three felony offenses under state law: One count of possession of a controlled substance, and two counts of fraudulently attempting to obtain a controlled substance. GX 5. On January 31, 2003, Respondent pled guilty to the charges and was allowed to enter into the St. Louis County Drug Court Program. GXs 5 & 7. Under the program, Respondent was required to, *inter alia*, undergo treatment, submit to urine and breath tests, not possess or use either controlled substances (unless prescribed by his doctor) or alcoholic beverages, and attend weekly court sessions for a minimum period of one year. GX 7. Respondent successfully completed the program and was allowed to withdraw his guilty pleas. GX 8.

### **Respondent’s Evidence Regarding His Rehabilitation**

Following his December 2001 arrest, and before even entering the Drug Court Program, Respondent sought treatment from the MPHP program. Tr. 140–42. On December 17, 2001, Respondent entered the Talbott Recovery Campus to be treated for chemical dependency. RX 6, at 1. Respondent was treated at Talbott for approximately four months and was discharged on April 6, 2002. *Id.* According to the discharge summary, Respondent had “progressed well though his treatment process and \* \* \* was able to develop healthier and more positive ways of coping with life without engaging in self destructive behaviors.” *Id.* at 5.

On February 7, 2003, Respondent’s attending physician at Talbott wrote a letter to Respondent’s counsel. RX 5. The attending physician noted that Respondent “has complied with all the recommendations of our treatment team in aftercare. He has been active in recovery groups and attends our Return Visits. His urine drug screens have remained negative.” *Id.*

The physician further wrote that Respondent “is doing well in recovery.

He impresses us as willing to comply with all recommendations and continued participation in recovery activities.” *Id.* Finally, the physician stated his belief that Respondent “is competent to practice medicine. He appears committed to his patients and his profession. We would support any administrative decision to allow him to continue to practice medicine.” *Id.*

As further evidence of his rehabilitation, Respondent introduced an affidavit (dated March 15, 2007) of Ms. Tina Steinman, Executive Director of the Missouri State Board of Registration for the Healing Arts. RX 4, at 1–2. According to Ms. Steinman, “[a]s of the date of [the] affidavit,” Respondent “is in compliance with the *Settlement Agreement* that he signed with the [state board] that was effective February 9, 2004.” *Id.* at 1.

Respondent also called several witnesses to testify regarding his rehabilitation, including Robert Bondurant, the coordinator of the MPHP. Tr. 111. In his testimony, Mr. Bondurant explained that if a physician failed a drug test or had “some other adverse activity,” he would not support the physician before the licensing authority. *Id.* at 118. Mr. Bondurant further explained that MPHP used several monitoring mechanisms including random testing for both street drugs and prescription drugs; contacting the physician’s family members, employers and colleagues; and monitoring the physician’s attendance and participation in support groups and Caduceus meetings. *Id.* at 122 & 138.

With respect to Respondent, Mr. Bondurant explained that he joined the MPHP shortly after being treated at Talbott and had signed a new agreement in 2004 after the State Board placed him on probation. *Id.* at 143. Mr. Bondurant further testified that Respondent had done everything that Talbott had recommended for his aftercare, and that he had joined MPHP two years before he was ordered to do so by the State Board. *Id.* at 144–45. Moreover, at the time of the hearing, Respondent, who was then five years into the process of his rehabilitation, was continuing to go to AA and Caduceus meetings. *Id.* at 146.

Mr. Bondurant also testified that Respondent had been subjected to numerous drug tests as part of both the Drug Court Program and MPHP, and that every test was negative. *Id.* at 152–53. Mr. Bondurant testified that MPHP will randomly call Respondent for a drug test and that he had never refused to undergo a test. *Id.* at 153–54. Respondent is also required to call the State Board every morning to determine whether he has been selected for testing.

*Id.* at 154. The State Board has never reported to Mr. Bondurant that Respondent has tested positive for a controlled substance.<sup>3</sup> *Id.* Nor has Mr. Bondurant received any other adverse information from the Board regarding Respondent. *Id.* at 156.

Mr. Bondurant further testified that he had no information that would indicate that Respondent was currently using or abusing controlled substances that had not been prescribed to him. *Id.* at 161. He also opined that Respondent is “in a very solid recovery,” but that his addiction is “going to be a lifetime issue for him.” *Id.* at 162. Finally, Mr. Bondurant testified that he believed that Respondent could safely handle and prescribe controlled substances, and that he had “no reason to believe that he” poses a threat to public safety. *Id.* at 166.

Respondent also elicited the testimony of R.S., a dentist who, at the time of hearing, had known him for six years from his participation in the St. Louis Caduceus group. *Id.* at 201–02, 210. R.S. testified that Respondent’s “level of commitment to his recovery is outstanding,” that Respondent had operated on him, and that he would not have let Respondent do so if he did not “have his head in the right place.” *Id.* at 212. R.S. also stated that he had referred his wife and several friends to Respondent and that he could not think of any reason as to why he would not safely prescribe controlled substances. *Id.* at 212 & 214.

Respondent further called Ralph Orlovick, Ph.D., a clinical psychologist, who specializes in the treatment of chemical dependency and who has run the MPHP’s aftercare program (Caduceus Group) since 1995. *Id.* at 270; RX 15. Dr. Orlovick explained that Respondent “accept[s] responsibility for his own behavior,” Tr. 295–96, and “has an extremely deep acceptance of the fact that he is an addict in recovery and has established a lifestyle that maintains and protects that \* \* \* recovery.” *Id.* at 287. He also testified that Respondent was “a different person \* \* \* than he was” when he first entered the program, *id.* at 289–90; that he had “no fears or concerns about” Respondent’s regaining a registration, *id.* at 294; and that “the length of [his] recovery and the ways he has been managing his life [were] excellent indices reflecting his readiness to get a [registration] in a responsible way.” *Id.* at 295. Dr. Orlovick further testified that he did not know of any reason why the Agency should not grant

Respondent’s application, and that he had the tools necessary to continue his recovery. *Id.*

Respondent testified that while he was allowed to withdraw his guilty pleas to the three charges which arose out of his December 2001 arrest, the acts “absolutely happened and I take full responsibility.”<sup>4</sup> *Id.* at 352. Respondent further testified that he was never sanctioned for non-compliance during his participation in the drug-court program, and that he did all of the things he was required to do as part of the program. *Id.* at 354–56.

Respondent also testified regarding the settlement agreement he had entered into with the Missouri Board. In this testimony, Respondent acknowledged that he was chemically dependent. *Id.* at 358–60. He also testified regarding the various terms of the agreement, including that he must call every morning to determine whether he has been selected to provide either a urine or hair sample. *Id.* at 360.

Respondent also testified regarding his obtaining a new state controlled substances registration and indicated that while he had not yet had to institute the terms and conditions imposed by the Missouri BNDD because he is still unable to legally prescribe a controlled substance, he was “absolutely” willing to do so, and that it would be “no” problem for him to do so. *Id.* at 369–70. Respondent testified that his probation with the BNDD would last for “five years.” *Id.* at 372. He also testified that he considered holding a DEA registration to be “an absolute privilege,” *id.* at 373; that he had attended a three-day continuing medical education course on the prescribing of controlled substances, *id.* at 375; and that he “would do anything required” to regain his registration, including agreeing to warrantless searches, submitting to drug testing, and maintaining a prescription log. *Id.* at 385.

Finally, Respondent testified that he had not harmed any patient during the period in which he was abusing drugs and there is no evidence to the contrary. *Id.* at 388. Nor is there any evidence that Respondent has ever used his prescribing authority to deal drugs to others.

The Government put on no rebuttal case.<sup>5</sup>

<sup>4</sup> On cross-examination, Respondent was asked if he “attribute[d] this whole [1981] incident to like youthful indiscretion or how do you characterize this?” Tr. 391. Respondent answered: “Yes.” *Id.*

<sup>5</sup> In applying for a new registration, Respondent submitted extensive documentation regarding the 2001 incident, the criminal charges and their disposition, the voluntary surrender of his DEA

## 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 Act requires the consideration of 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.*

“[T]hese factors are considered in the disjunctive.” *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 an application for a registration should be denied. *Id.* Moreover, I am “not required

registration, and the actions taken by both the Missouri Board and BNDD. See RX 16. He also included various letters of support. These included the letter from his attending physician at Talbott; a letter from the MPHP supporting his application to the state BNDD which indicated that he was “in complete compliance” with the program, and that both the program’s Medical Director and Coordinator (Mr. Bondurant) supported his request for a state registration; and finally, a letter from Dr. Orlovick which discussed Respondent’s participation in the Caduceus Group and concluded that “[h]e is now fully ready, and deserving, of receiving his BNDD and DEA number.” RX 16, at 8, 47, & 49.

At the hearing, a Diversion Group Supervisor (GS) who oversaw the pre-registration investigation acknowledged that these materials had been submitted as part of the application. Tr. 84. The GS testified, however, that while he reviewed the application, he had not reviewed all of the attachments and had not talked about Respondent’s application with any person other than the DI who was assigned the investigation. *Id.* at 105.

The GS also testified that the DI who performed the investigation obtained no evidence that any of the information provided by Respondent was inaccurate or that Respondent was again abusing controlled substances. *Id.* at 86. Finally, the DI testified that in light of all of the information contained in Respondent’s application, he could not explain why it would now be inconsistent with the public interest to grant his application. *Id.* at 101. When asked “what more” Respondent had to do to establish that his registration would be consistent with the public interest?, the GS answered: “My personal opinion, I believe he’s had two or three chances to abide by the regulations \* \* \* to handle controlled substances and I believe he failed at that.” *Id.* at 108–09.

<sup>3</sup> The record establishes that the testing screens for prescriptions opiates including hydrocodone and oxycodone.

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).

In this case, it is not disputed that Respondent violated Federal law both in 1981, when he was charged with cocaine distribution, and most significantly, in December 2001, when he possessed cocaine and obtained for his own use, two prescription controlled substances, hydrocodone and alprazolam, by writing fraudulent prescriptions which were issued in the name of a cab driver. The Government has therefore made out a *prima facie* case to deny his application.

This Agency has repeatedly held, however, that a proceeding under section 303 “is a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused \* \* \* their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be entrusted with the responsibility carried by such a registration.” *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988)). Therefore, where, as here, “the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must ‘present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.’” *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (quoting *Jackson*, 72 FR at 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988))), *aff’d*, *Medicine Shoppe-Jonesborough v. DEA*, slip. op. at 9–10 (6th Cir. Nov. 13, 2008). “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; accord *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).

The Government raises two arguments in support of its contention that Respondent’s application should be denied. In its proposed findings, the Government contends that “[a]lthough

Respondent presented substantial expert and peer testimony in support of his rehabilitation, he does not appear to have taken full responsibility for his past forays into addiction and drug abuse.” Gov. Proposed Findings at 6. In its Exceptions, however, the Government argues that “[t]he evidence that the applicant presented at the hearing as to his rehabilitation was sparse and less than convincing.” Gov. Exceptions at 2.

As for the contention that Respondent has not taken “full responsibility for” what it describes as his “past forays,” apparently the Government relies on Respondent’s testimony regarding the 1981 episode, as well as the reasons he gave for the problems he had in 1991 and 2001. The Government’s contention is wholly unpersuasive.

As for the 1981 arrest for cocaine distribution, twenty-seven years have elapsed since this event and there is no evidence that Respondent ever subsequently engaged in the unlawful distribution of either illicit (street) or prescription controlled substances to others. Furthermore, Respondent did not deny that he had committed the acts.

The Government apparently also finds fault with Respondent’s testimony regarding what led to his becoming addicted in 1991. See Prop. Findings at 4 (“He attributed his 1991–1992 drug use to chronic headaches.”). The Government, however, offered no evidence to refute Respondent’s testimony that he was prescribed controlled substances as treatment for a legitimate medical condition, and that he became addicted over the course of that treatment. Nor is Respondent the first person to become addicted to a drug prescribed in the course of legitimate medical treatment. Related to this incident, the Government also ignores that Respondent voluntarily entered treatment and underwent treatment and aftercare for approximately six years. Moreover, in discussing this period of his life, Respondent did not deny that he was chemically dependent.

Finally, the Government contends that Respondent “attributed his 2001 conviction to personal stress”<sup>6</sup> and that he “failed recovery after several years of rehabilitation.” *Id.* The Government, however, offered no evidence showing that Respondent’s testimony was false, and in any event, it is not clear why his explanation—“a number of things,

personal things, stress,” Tr. 393—regarding the cause of his relapse, establishes that he has failed to accept responsibility.

In any event, the great weight of the evidence refutes the contention. Notably, Respondent fully acknowledged his misconduct in writing the prescriptions to the cab driver. Moreover, with respect to his addiction, Respondent produced ample evidence demonstrating that he acknowledges that he is chemically dependent. This includes both Respondent’s testimony and written admission regarding his addiction. See GX 9, at 3 (settlement agreement with state board; “Respondent has admitted he is chemically dependent”); Tr. 261 (“I went [to treatment] because something had to change \* \* \* I couldn’t keep doing what I was doing”); *id.* at 358–59 (acknowledging his admission in the state board settlement agreement); see also GX 1, at 4 (answer to DEA application’s liability questions; “I am committed to a lifelong recovery program and will follow all continuing recommendations of MPHP and the [state] Board.”).

Moreover, both Dr. Orlovick, the psychologist who runs MPHP’s aftercare program, and Mr. Bondurant, the MPHP Program Coordinator, testified that Respondent acknowledges his addiction. See *id.* at 287 (testimony of Dr. Orlovick; Respondent “has an extremely deep acceptance of the fact that he is an addict in recovery and has established a lifestyle that maintains and protects that \* \* \* recovery”); *id.* at 295 (testimony of Dr. Orlovick; Respondent “accept[s] responsibility for his own behavior”). *Id.* at 164 (testimony of Mr. Bondurant; “over the intervening years [Respondent] has learned that he does have limitations and that the addiction issue is a life-long process and he is not stronger than the addiction”). It is thus clear that Respondent has accepted responsibility for both his misconduct and addiction.

As for the contention that Respondent has not sufficiently established his rehabilitation, in its proposed findings, the Government acknowledged that “Respondent presented substantial expert and peer testimony in support of his rehabilitation,” *Id.* at 6. In its Exceptions, however, the Government does an about-face and now argues that “[t]he evidence that the applicant presented at the hearing as to his rehabilitation was sparse and less than convincing.” Gov. Exc. at 2. Even ignoring the inconsistency between its initial and subsequent positions, I conclude that Respondent put forward compelling evidence of his

<sup>6</sup> The Government’s own exhibit establishes that Respondent was not convicted of any offense related to the 2001 incident, which was nolle prossed. See GX 8.

rehabilitation.<sup>7</sup> Specifically, in addition to his own testimony, Respondent introduced the affidavit of the Missouri Board's Executive Director that he was "in compliance with the *Settlement Agreement*," RX 4, at 1; a letter from the physician who treated him at Talbott, RX 5; and again, the testimony (and letters) of Mr. Bondurant, Dr. Orlovick, and R.S., a dentist who was also a member of Respondent's aftercare group.

More specifically, Respondent's treating physician at Talbott wrote that his drug screens were negative, that he was "doing well in recovery," that he was "willing to comply with all recommendations and continued participation in recovery activities," and that he "is competent to practice medicine." RX 5. Mr. Bondurant testified as to Respondent's compliance with the conditions of the MPHP; that he had never failed or refused to undergo a drug test (whether the test was ordered by the Drug Court, MPHP, or the Board); that he had not received any adverse information regarding Respondent, who is "in a very solid recovery"; and that he had "no reason to believe that [Respondent] would" pose a threat to public safety. Tr. 153–54, 156, 161–62, 166.

To similar effect, Dr. Orlovick testified that Respondent "has established a lifestyle that maintains and protects [his] recovery," and that he had "no fears or concerns about" Respondent's regaining a registration. *Id.* at 287 & 294. Dr. Orlovick also testified that "the length of [Respondent's] recovery and the ways he has been managing his life [are] excellent indices reflecting his readiness to" responsibly hold a registration. *Id.* at 295. Dr. Orlovick further stated that he did know of any reason why Respondent's application should not be granted and that he had the tools necessary to maintain his recovery. *Id.*

Finally, R.S., who has known Respondent for six years from their participation in Caduceus meetings, testified that Respondent's "commitment to his recovery is outstanding." *Id.* at 212. He also stated that he could not think of any reason why Respondent would not responsibly prescribe controlled substances. *Id.* at 214.

In response to this evidence, much of which was available at the time Respondent applied for a new registration, the Government offered

nothing. I hold, however, that Respondent's evidence as to his rehabilitation is convincing and reject the Government's contention to the contrary. Indeed, as the Supervisory DI testified, he could not explain why it would be inconsistent with the public interest for Respondent to hold a registration. I therefore conclude that Respondent has established that granting his application would be consistent with the public interest. 21 U.S.C. 823(f).

#### Sanction

As Respondent himself recognizes, the record nonetheless supports imposing conditions on his registration. Resp. Proposed Findings at 21–22. Under the Settlement Agreement with the State Board, Respondent is required to maintain duplicate serially numbered prescriptions separately from patient charts for each controlled substance prescription he writes. GX 11, at 4. Respondent has agreed to provide or make available these records to this Agency and has also agreed to consent to inspections of these records without the Government having to obtain an administrative warrant. Resp. Prop. Findings at 22. These requirements are therefore imposed as conditions of Respondent's registration.

Relatedly, the record also supports the ALJ's recommendation that Respondent must maintain and submit on a quarterly basis, a log listing in chronological order, all controlled substance prescriptions he issues. The log shall include the prescription number, patient name and address, name, amount and strength of the drug prescribed, and number of refills authorized. The log shall also include any prescriptions and refills authorized by Respondent by telephone.

According to the terms of his agreement with the State BNDD, Respondent is not authorized to "order, purchase or accept" any controlled substances. GX 11, at 5. The BNDD Order further provides that Respondent "shall not dispense any controlled substances other than by administering or prescribing." *Id.*

It is unclear whether Respondent seeks authority to administer controlled substances at his clinic (as opposed to in a hospital setting), whether the BNDD agreement authorizes him to do so, and if he is permitted to do so, how he can legally obtain them.<sup>8</sup> Moreover, the

extent to which Respondent performs procedures in his clinic which require the administration of a controlled substance is also not fully established on this record.

In the event Respondent seeks authority to administer controlled substances at the clinic, he must first provide evidence from the Missouri BNDD clearly stating that he is authorized to do so. Respondent must also explain how any controlled substances will be lawfully obtained (notwithstanding his agreement with the BNDD prohibiting his ordering and purchasing them), how they will be stored, and how they will be accounted for. Respondent shall not administer controlled substances at his clinic until he complies with this condition and receives written approval from this Agency. Respondent can, however, administer a controlled substance in a hospital setting.

Respondent shall not prescribe any controlled substance to himself or any family member. Respondent shall not obtain a controlled substance for his own use unless it has been prescribed by another practitioner in accordance with the prescription requirement of federal law. See 21 CFR 1306.04 ("A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.").

Respondent shall also ensure that the MPHP quarterly status reports are submitted to the Agency. All reports and logs are to be submitted to the Special Agent in Charge (or his designee), St. Louis Field Division, no later than fifteen days following the end of the quarter. Respondent shall also promptly notify the Special Agent in Charge (or his designee) of any action taken by either the State Board or BNDD against his license or state registration. Failure to comply with any of the conditions specified above shall be grounds for the suspension or revocation of Respondent's registration.

#### Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b) & 0.104, I hereby order that the application of Steven M. Abbadessa, D.O., for a DEA Certificate of Registration as a practitioner be, and it

authorized under agreements with the state authorities to stock controlled substances and no controlled substances are currently being stocked at the clinic. The record does not establish how Respondent's partner/associate obtains and maintains the controlled substances which are used at his clinic.

<sup>7</sup> Notwithstanding the suggestion in the Government's proposed findings, there is no evidence that Respondent has relapsed following the treatment he received in 2002.

<sup>8</sup> The record establishes that another doctor, who was alternatively characterized as Respondent's associate or partner, administers controlled substances at his clinic. Tr. 244. According to Respondent, while his associate/partner holds a DEA and state registration, the latter is not

hereby is, granted, subject to the conditions set forth above. This Order is effective immediately.

Dated: February 26, 2009.

**Michele M. Leonhart,**

*Deputy Administrator.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 06-28]

#### Joseph Gaudio, M.D.; Suspension of Registration

On September 16, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Joseph Gaudio, M.D. (Respondent) of Alpine, New Jersey. The Show Cause Order sought the revocation of Respondent's DEA Certificate of Registration, which authorizes him to handle controlled substances as a practitioner, and the denial of any pending applications to renew or modify his registration, on the ground that he had committed acts which rendered his continued registration "inconsistent with the public interest." Show Cause Order at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

The Show Cause Order alleged that Respondent had issued prescriptions for controlled substances which lacked a legitimate medical purpose, and that in doing so, he had acted outside of the usual course of professional practice. *Id.* at 1 & 6. The Show Cause Order specifically alleged that Respondent had "prescribed] controlled substances to Internet customers despite never establishing a genuine doctor-patient relationship with the Internet customer." *Id.* at 5. Relatedly, the Show Cause Order alleged that Respondent "did not see customers, had no prior doctor-patient relationships with the Internet customers, did not conduct physical exams, \* \* \* did [not] create or maintain patient records," and that "[t]he only information usually reviewed prior to issuing drug orders was the customer's online questionnaire." *Id.* at 6.

The Show Cause Order also alleged that "[a] review of prescriptions filled by [Carrington Healthcare System/ Infiniti Services Group] revealed that [Respondent] ha[d] issued drug orders for controlled substances to Internet customers throughout the United States, including Georgia, Texas, Pennsylvania, Alabama, Louisiana, and Kentucky." *Id.*

The Show Cause Order further alleged that "[a] review of prescriptions filled by [Carrington/Infiniti] for the period October 13, 2004 to January 21, 2005, revealed that [Respondent] ha[d] issued 16 drug orders to Internet customers in at least nine different states." *Id.*

On October 21, 2005, Respondent, through his counsel, requested a hearing on the allegations. The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who conducted a hearing on May 2-5, 2006, in New York, NY. At the hearing, both parties put on testimony and introduced documentary evidence. Thereafter, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and arguments.

On November 2, 2007, the ALJ issued her recommended decision. In her decision, the ALJ concluded that "[t]he Government has clearly demonstrated that the Respondent's Internet practice and his resulting issuance of controlled substance prescriptions \* \* \* violated the Controlled Substances Act." ALJ at 43. Applying the totality of the circumstances test, the ALJ concluded, however, that the revocation of Respondent's registration was not warranted. *Id.* at 43-44.

The ALJ specifically noted that "Respondent's conduct encompassed a one year period," that Respondent had "voluntarily cease[d]" his conduct, but that he had not done so until three months after he was served with the Show Cause Order. *Id.* at 43. While the ALJ deemed Respondent's cessation of his conduct as "commendable because of its voluntary nature," she further explained that he "demonstrated a lack of sound judgment" in "continuing to" prescribe after being served with the Show Cause Order. *Id.* at 44. The ALJ also found of concern "Respondent's failure to be totally truthful during his testimony." *Id.*

The ALJ reasoned, however, that Respondent was "a very educated, dedicated and talented physician practicing in a sometimes difficult specialty, pain management," and that the revocation of his registration would render him "being unable to handle controlled substances" in his specialty. *Id.* Because the record demonstrated that Respondent had practiced medicine for eleven years, and that "the only instances of [his] improper handling of controlled substances were related to his" Internet prescribing, the ALJ recommended that Respondent's registration be continued subject to the condition that he "not engage in any activity involving prescribing controlled substances and the Internet." *Id.*

Having considered the entire record in this matter, I hereby issued this Decision and Final Order. I adopt the ALJ's conclusions that Respondent violated both the Controlled Substances Act (CSA) and various state standards of medical practice in issuing prescriptions to persons who ordered drugs through an Internet site. For reasons explained below, I reject the ALJ's recommended sanction as inconsistent with agency precedent and will order the suspension of Respondent's registration for a period of one year. I make the following findings.

#### Findings

Respondent is a medical doctor who is board certified in both anesthesiology and pain management and is licensed to practice medicine in the States of New York and New Jersey. Tr. 488. Respondent is also the holder of a DEA Certificate of Registration, which authorizes him to dispense controlled substances in schedules II through V as a practitioner. GX 1, at 2. While the expiration date of Respondent's registration was September 30, 2006, Respondent submitted a renewal application on August 4, 2006. See Reply to Respondent's Status Report, at 1. I therefore find that Respondent's prior registration has remained in effect pending the issuance of this Final Order and that Respondent also has an application pending before the Agency. See 5 U.S.C. 558(c).

Respondent attended medical school at The Autonomous University of Guadalajara, and the New York Medical College. RX 1, at 2. Subsequently, Respondent did his residency in anesthesiology at St. Luke's/Roosevelt Hospital, an institution which is affiliated with the Columbia University College of Physicians and Surgeons, where he received an award given to the Outstanding Graduate Resident in Anesthesiology. *Id.* Respondent also did a fellowship in Pain Management at the Memorial Sloan Kettering Cancer Center, where he was elected Chief Fellow. *Id.* at 1.

Upon completion of his fellowship, Respondent joined New Jersey Anesthesia Associates (NJAA), a group of physicians which provides anesthesia services at St. Barnabas Medical Center. Tr. 345-47. Respondent is a partner in NJAA. *Id.* at 347. In addition to providing anesthesia, Respondent also treats both acute and chronic pain patients. *Id.* at 555-56. Respondent is also an attending physician and clinical professor at St. Barnabas, where he trains residents in anesthesia. *Id.* at 360.

Respondent came to the attention of the Agency during its investigation of a