

Dated: November 8, 2011.

Michele M. Leonhart,

Administrator.

James Hambuechen, Esq., for the Government

Gerald G. Goldberg, Esq., for the Respondent

Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

Timothy D. Wing, Administrative Law Judge. This proceeding is an adjudication governed by the Administrative Procedure Act, 5 U.S.C. 551 *et seq.* to determine whether Respondent's Certificate of Registration with the Drug Enforcement Administration (DEA) should be revoked and any pending applications for renewal or modification of that registration denied. Without this registration, Respondent, Joseph Giacchino, M.D., would be unable to lawfully possess, prescribe, dispense or otherwise handle controlled substances.

On April 22, 2010, the State of Illinois Department of Financial and Professional Regulation, Division of Professional Regulation, ordered that Respondent's Physician and Surgeon License and Controlled Substance License be temporarily suspended pending further state proceedings. On April 30, 2010, the Deputy Assistant Administrator, Office of Diversion Control, DEA, issued an Order to Show Cause why DEA should not revoke Respondent's DEA Certificate of Registration, BG6335485, on the ground that Respondent lacked authority to handle controlled substances in Illinois, the state in which he maintained his DEA registration. Respondent, through counsel, timely requested a hearing on the issues raised in the Order to Show Cause.

The Government subsequently filed a Motion for Stay of Proceedings and Summary Disposition, asserting that on April 22, 2010, the State of Illinois Department of Financial and Professional Regulation, Division of Professional Regulation, ordered that Respondent's Physician and Surgeon License and Controlled Substance License be suspended and that Respondent consequently did not have authority to possess, dispense or otherwise handle controlled substances in Illinois, the jurisdiction in which he maintained his DEA registration. The government contended that such state authority is a necessary condition for DEA registration and therefore asked that I issue an order of temporary stay with regard to further filing deadlines in the instant case. The Government further requested that I grant the

Government's motion for summary disposition and recommend to the Deputy Administrator that Respondent's registration be revoked. Counsel for the Government attached to the motion a copy of the Notice of Temporary Suspension issued to Respondent by the State of Illinois Department of Financial and Professional Regulation, Division of Professional Regulation. The notice included an Order that suspended Respondent's Illinois Physician and Surgeon License and Controlled Substance License, effective April 22, 2010, "pending proceedings before an Administrative Law Judge at the Department of Financial and Professional Regulation and the Medical Disciplinary Board of the State of Illinois."

Respondent replied to the Government's motion on June 23, 2010, asserting that because the suspension of Respondent's Illinois Physician and Surgeon License and Controlled Substances License is merely temporary, the status of Respondent's state license is uncertain. Respondent argues that the Government's motion is therefore premature.

Discussion

Loss of state authority to engage in the practice of medicine and to handle controlled substances is grounds to revoke a practitioner's registration under 21 U.S.C. 824(a)(3). Accordingly, this agency has consistently held that a person may not hold a DEA registration if he is without appropriate authority under the laws of the state in which he does business. See *Scott Sandarg, DMD*, 74 FR 17528 (DEA 2009); *David W. Wang, M.D.*, 72 FR 54297 (DEA 2007); *Sheran Arden Yeates, M.D.*, 71 FR 39130 (DEA 2006); *Dominick A. Ricci, M.D.*, 58 FR 51104 (DEA 1993); *Bobby Watts M.D.*, 53 FR 11919 (DEA 1988). In the instant case, the Government asserts, and Respondent does not deny, that Respondent's Illinois Physician and Surgeon License and Controlled Substance License are temporarily suspended.

Summary disposition is warranted if the period of suspension is temporary, or if there is the potential for reinstatement of state authority because "revocation is also appropriate when a state license has been suspended, but with the possibility of future reinstatement." *Stuart A. Bergman, M.D.*, 70 FR 33193 (DEA 2005); *Roger A. Rodriguez, M.D.* 70 FR 33206 (DEA 2005). Respondent's argument that 21 U.S.C. 824(a)(3) "expressly contemplates a final decision of the state agency" is not supported by agency precedent.

It is well settled that when no questions of fact is involved, or when the material facts are agreed upon, a plenary, adversarial administrative proceeding is not required, under the rationale that Congress does not intend administrative agencies to perform meaningless tasks. See *Layfe Robert Anthony, M.D.*, 67 FR 35582 (DEA 2002); *Michael G. Dolin, M.D.*, 65 FR 5661 (DEA 2000). See also *Philip E. Kirk, M.D.*, 48 FR 32887 (DEA 1983), *aff'd sub nom. Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984); *Puerto Rico Aqueduct and Sewer Auth. v. EPA*, 35 F.3d 600, 605 (1st Cir. 1994).

As noted above, in the instant case it is clear that there are no material disputed facts. The Government asserted and Respondent did not deny that Respondent is without state authority to handle controlled substances in Illinois at the present time. In these circumstances, I conclude that further delay in ruling on the Government's motion for summary disposition is not warranted. I therefore find that the motion of summary disposition is properly entertained and granted.

Recommended Decision

I grant the Government's Motion for Summary Disposition and recommend that Respondent's DEA registration be revoked and any pending applications denied.

Dated: July 9, 2010.

Timothy D. Wing,

Administrative Law Judge.

[FR Doc. 2011-29692 Filed 11-16-11; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Scott D. Fedosky, M.D.; Denial of Application

On March 30, 2010, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Scott D. Fedosky, M.D. (Respondent), of Fayetteville, Arkansas. 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." Show Cause Order, at 1 (citing 21 U.S.C. 823(f)).

More specifically, the Show Cause Order alleged that "from December 1999 through September 2003," Respondent had "issued fraudulent prescriptions for

controlled substances, specifically hydrocodone under other names to obtain [the drug] for [his] personal use,” and that he had “voluntarily surrendered” his previous registration “for cause.” *Id.* at 1. The Show Cause Order further alleged that on February 16, 2006, Respondent applied for a new registration but that he “[s]ubsequently * * * admitted to obtaining and diverting the controlled substance, Nubain for [his] own use and voluntarily withdrew [his] application for registration.” *Id.* Finally, the Show Cause Order alleged that Respondent “illegally possessed controlled substances in violation of the Arkansas Medical Practice Act” and that his “repeated drug abuse and diversion of controlled substances is inconsistent with the public interest.” *Id.* at 2.

On May 3, 2010, Respondent submitted a letter to the Hearing Clerk, Office of Administrative Law Judges, in which he acknowledged receipt of the Show Cause Order. Letter from Respondent to Hearing Clerk (May 3, 2010). Respondent further waived his right to a hearing and submitted the letter “as a written statement of position.” *Id.* Thereafter, the Government filed with my Office a Request for Final Agency Action along with the Investigative Record.

Having considered the entire record, including Respondent’s statement of position and supporting letter, I conclude that the Government has made out a *prima facie* case to deny his application. I further conclude that while Respondent has accepted responsibility for his misconduct, his evidence is not sufficient to establish that he can be entrusted with a new registration. Accordingly, his application will be denied. I make the following findings of fact.

Findings

On June 12, 2009, Respondent, who holds a medical license issued by the Arkansas State Medical Board, applied for a DEA Certificate of Registration as a practitioner in schedules II through V. Respondent previously held DEA Registration BF5374234. However, between December 1999 and September 2003, Respondent wrote fraudulent prescriptions for hydrocodone, a schedule III controlled substance, “in the name of family members and an individual identified as ‘S.J.’” to obtain drugs which he diverted “for his own use.” Order at 1, *In re Scott David Fedosky, M.D.* (Ark. Med. Bd. Feb. 17, 2004). On October 8, 2003, Respondent voluntarily surrendered his registration.

On February 6, 2004, Respondent appeared before the Arkansas Board. *Id.*

On February 17, 2004, the Board found that Respondent had “violated the laws of the United States or the State of Arkansas regulating the possession, distribution and prescribing of scheduled medication, more specifically, the writing of fraudulent prescriptions for scheduled medication and diverting the same for his own use and benefit.” *Id.* The Board also found that Respondent had violated state law in that he “ha[d] exhibited habitual or excessive use of narcotics or other dangerous or habit forming drugs.” *Id.* The Board then revoked Respondent’s medical license but stayed the revocation provided that he, *inter alia*, enter into, and comply with, a “rehabilitation and monitoring” contract “with the Arkansas Medical Foundation for five (5) years.” *Id.* at 2.

Pursuant to the contract, Respondent was required “to refrain from the use of any scheduled medication not prescribed by a physician” and from taking any prescribed medication prior to reporting it to the Arkansas Medical Foundation; he was also required “to attend meetings” of one of several self-help organizations such as AA or NA and to provide proof of his attendance to the Foundation. Order at 2, *In re Scott David Fedosky, M.D.* (Ark. Med. Bd. Feb. 9, 2005). However, on October 20, 2004, Respondent “tested positive for a metabolite of Propoxyphene, thus violating the terms of his contract with the” Foundation. *Id.* at 3. Moreover, Respondent also failed to attend Caduceus meetings as required by his contract. *Id.*

The Board thus found that Respondent had violated its previous order and the Arkansas Medical Practice Act, and required him to enter into a new five-year contract with the Arkansas Medical Foundation. *Id.* The Board also required Respondent to undergo a psychiatric evaluation, that he provide reports from his psychiatrist every two months, and that he “obtain a sponsor to counsel him and assist him in rehabilitation”; the Board also re-imposed the other conditions of the 2004 order. *Id.*; see also Amendment to Order at 1 (Ark. Med. Bd. Mar. 31, 2005).

On June 8, 2006, the Board conducted another hearing, at which it found that Respondent had “obtained and diverted for his own use Nalbuphine,” and had thus violated his contract with the Arkansas Medical Foundation. Order at 2, *In re Scott David Fedosky, M.D.*, (Ark. Med. Bd. June 21, 2006). The Board again found that Respondent had violated the Medical Practice Act, its February 9, 2005 order, as well his contract “by taking controlled

substances or mind altering drugs.” *Id.* The Board then revoked Respondent’s medical license. *Id.* at 3.

On December 7, 2007, Respondent appeared before the Board to discuss his status. The Board agreed to allow him to reapply upon his presenting proof that he had passed the Special Purpose Examination, which is used to assess a previously licensed (or currently licensed) physician’s level of medical knowledge. On February 7, 2008, Respondent appeared before the Board and presented evidence that he had passed the examination. The Board then voted to reinstate Respondent’s medical license with the stipulations that he continue to comply with his contract with the Arkansas Medical Foundation and that he attend Caduceus meetings; the Board, however, barred him from re-applying for a DEA registration.

On October 3, 2008, Respondent again appeared before the Board and sought permission to re-apply for a DEA registration. The Board, however, unanimously rejected his request. On June 5, 2009, Respondent again appeared before the Board and sought permission to re-apply for a DEA registration. The Board voted unanimously to approve his request. DEA, however, denied his request and served him with the Show Cause Order, which initiated this proceeding.

In his letter which he submitted in lieu of his hearing, Respondent wrote that he had “carefully reviewed the information in the Order To Show Cause,” that “DEA rightfully accepted the surrender of [his] license [in] 2004,” and that “the history as set forth [in the Order] is factual.” Resp. Ltr. at 1. Continuing, Respondent wrote: “The fact that the prescriptions were obtained fraudulently understandably creates the issue of self treatment and misuse of the privilege of a DEA license and could be construed as my being a threat to the public welfare.” *Id.* Acknowledging that his medical license had been revoked for this reason, Respondent explained that “[s]ince that time I have come to a very real understanding that having a license to practice medicine is a privilege and not a right connected to my level of education. My DEA license was also a privilege that I did not, at that time, appreciate or protect as I should have.” *Id.*

Respondent also wrote that he had “voluntarily entered into a monitoring program with the Arkansas Medical Foundation in September 2006 and have documented sobriety since that time,” and that the Arkansas Board, has “deemed it appropriate for me to reapply for the DEA registration, giving their support in June 2009.” *Id.*

Respondent stated that in his sixteen years of medical practice, he had never harmed a patient nor ever been the subject of a complaint by a patient. He further explained that:

I have other accountability factors in my life that are a part of my current situation that is markedly different than my previous situation. These include, but are not limited to, attending 12 step and caduceus meetings regularly, continued monitoring by the Arkansas Medical Foundation and the Arkansas State Medical Board and the strong support of my spouse, my family and my friends.

Id. Respondent thus maintained that he does “not pose a threat to the public” and “respectfully request[ed] reinstatement of [his] DEA license.” *Id.*

In support of his application, Respondent submitted two other documents: 1) A May 3, 2010 letter from J.B.B., an attorney who stated that he is a friend of Respondent; and 2) a June 15, 2009 letter from the Executive Secretary of the Arkansas State Medical Board. In his letter, J.B.B. acknowledged “that there has been good reason for [Respondent] not to have a license,” but that there are three reasons why he believed his application should be granted. These were: (1) That no patient had ever filed a complaint against Respondent; (2) that no physician or pharmacist had ever filed a complaint against him “for over prescribing or misprescribing to a patient,” and (3) that he had only “prescribed to himself and had done no harm to the public.” J.B.B. further stated his “opinion that [Respondent] has adequately addressed his personal problem fully.”

The Medical Board’s letter noted that Respondent had appeared before it during the June 4–5 meeting. The letter further stated that the Board had voted to allow him “to reapply for [his] DEA permit.”

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner’s registration may be denied upon a determination “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 in the case of a practitioner, Congress directed that the following factors be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant’s experience in dispensing * * * controlled substances.

(3) The applicant’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

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. *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) (citing *Morall v. DEA*, 412 F.3d 165, 173–74 (DC Cir. 2005)).

In the case of a practitioner, the Government has the burden of proving with substantial evidence that granting an application would be inconsistent with the public interest. However, where the Government makes out a *prima facie* case to deny an application, the burden shifts to the applicant to show why granting the application would be consistent with the public interest.

In this matter, I conclude that the Government has established a *prima facie* case to deny Respondent’s application. While I find that Respondent’s written statement establishes that he has accepted responsibility for his misconduct, I conclude that he has not produced sufficient evidence on the issue of his rehabilitation.

Factors One and Three—the Recommendation of the State Licensing Board and Respondent’s Record of Convictions Related to the Manufacture, Distribution or Dispensing of Controlled Substances

The record establishes that on June 5, 2009, Respondent appeared before the Arkansas State Medical Board and that the Board voted to allow him to apply for a new DEA registration. However, neither the Executive Secretary’s letter, nor the minutes of the Board’s June 5, 2009 meeting, state that the Board was recommending that DEA grant his application.

Accordingly, while Respondent now satisfies the CSA’s requirement for obtaining a registration that he be “authorized to dispense * * * controlled substances under the laws of the State in which he practices,” 21 U.S.C. 823(f), under Agency precedent, this factor is not dispositive of the public interest inquiry. *Patrick Stodola*, 74 FR 20727, 20730 n.16 (2009); *Mortimer Levin*, 57 FR 8680, 8681 (1992).

I also note that there is no evidence in the record that Respondent has been convicted of an offense under either Federal or State law related to manufacture, distribution, or dispensing of a controlled substance. This factor thus supports a finding that granting Respondent’s application would not be inconsistent with the public interest. However, because there are multiple reasons why a person may never be convicted of a criminal offense falling under factor three, let alone prosecuted for such an offense, DEA has long held that this factor is not dispositive. *Edmund Chein*, 72 FR 6580, 6593 n.22 (2007).

Factors Two, Four, and Five—Respondent’s Experience in Dispensing Controlled Substances, Record of Compliance With Applicable Laws Related to Controlled Substances, and Such Other Conduct Which May Threaten Public Health and Safety

As established by the Arkansas Board’s findings, between December 1999 and September 2003, Respondent wrote fraudulent prescriptions for hydrocodone, a schedule III narcotic,¹ in the names of family members and another individual, to obtain drugs which he then personally abused. Under Federal law, it is “unlawful for any person knowingly or intentionally * * * to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge[.]” 21 U.S.C. 843(a)(3).² The Board also found that Respondent violated state law by “exhibit[ing] habitual or excessive use of narcotics or other dangerous or habit forming drugs.” Order at 1, *In re Scott David Fedosky, M.D.* (Ark. Med. Bd. Feb. 17, 2004) (citing Ark. Code Ann. § 17–95–409(a)(2)(h)).

While the Board placed Respondent on probation and required that he enter into a rehabilitation and monitoring contract with the Arkansas Medical Foundation, which prohibited him from taking any scheduled medication that was not prescribed to him by a physician, approximately eight months later, he tested positive for a metabolite of propoxyphene, a schedule IV narcotic;³ in addition, the Board found that Respondent had failed to attend Caduceus meetings. The Board found that Respondent had violated its previous order (and his contract with the Foundation), required that he enter into a new five-year contract with the Foundation and imposed additional

¹ See 21 CFR 1308.13(e).

² This was also a violation of Arkansas law.

³ See 21 CFR 1308.14(b).

terms, including that he undergo a psychiatric evaluation and submit reports from his psychiatrist to the Board every two months. However, on June 8, 2006, the Board found that Respondent had “obtained and diverted to his own use Nalbuphine,” and thus violated both Arkansas law and his rehabilitation and monitoring contract.

Contrary to the allegations of the Show Cause Order, Nalbuphine is not a federally controlled substance. See 21 CFR Pt. 1308. The record nonetheless establishes that Respondent issued fraudulent prescriptions for hydrocodone, which he then diverted, and that he has abused both hydrocodone and propoxyphene. See 21 U.S.C. 843(a)(3); see also *id.* 844(a) (“It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice, or except as otherwise authorized by this subchapter * * *”). In addition to these violations, which are properly considered under Factors Two and Four, DEA has also long held that a practitioner’s self-abuse of a controlled substance can be considered under Factor Five even if there is no evidence that the practitioner abused his prescription-writing authority or otherwise engaged in an unlawful distribution to others. See *Tony T. Bui, M.D.*, 75 FR 49979, 49989–90 (2010) (collecting cases); see also *David E. Trawick*, 53 FR 5326, 5327 (1988). Accordingly, I conclude that the Government has established a *prima facie* case to deny Respondent’s application.

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.’”⁴ *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))), *aff’d*, *Medicine Shoppe-Jonesborough v. DEA*, 300 Fed. Appx. 409 (6th Cir.

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).

In his statement of position, Respondent acknowledged that the allegations set forth in the Show Cause Order were “factual” and that the Agency had “rightfully accepted the surrender of” his DEA registration. Respondent further explained that “[t]he fact that the prescriptions were obtained fraudulently understandably creates the issue of self treatment and misuse of the privilege of a DEA license and [that his conduct] could be construed as * * * being a threat to the public welfare.” Respondent also wrote that he now recognizes that holding a DEA registration is “a privilege” which he did not previously “appreciate or protect as I should have.” I conclude that Respondent’s statement is sufficient, even though it is unsworn, to establish that he accepts responsibility for his misconduct.

However, as explained above, to successfully rebut the Government’s *prima facie* case, Respondent must also present sufficient evidence to establish that he will not repeat his prior misconduct. While Respondent explained that he has “other accountability factors in [his] life,” which he did not have at the time he was self-abusing controlled substances, such as his attendance at 12-step and Caduceus meetings, as well as monitoring by the Arkansas Medical Foundation and Arkansas State Medical Board; that he has “documented sobriety” since September 2006; and that he has “the strong support of” his family and friends; he did not produce any evidence to corroborate any of these statements. More specifically, he did not produce the testimony or reports of those professionals who have evaluated and treated him, as well as of those persons who have sponsored him at various recovery meetings. In addition, there is no evidence establishing the extent to which he has been subject to random drug testing and the results of

such tests. See *Steven M. Abbadessa*, 74 FR 10077, 10079–80 (2009) (discussing evidence sufficient to support practitioner’s claim of rehabilitation).⁵

I therefore conclude that Respondent has not rebutted the Government’s *prima facie* case. Accordingly, I will deny Respondent’s application.

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 order that the application of Scott D. Fedosky, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This order is effective December 19, 2011.

Dated: November 8, 2011.

Michele M. Leonhart,
Administrator.

[FR Doc. 2011–29722 Filed 11–16–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of the Secretary

Labor Advisory Committee for Trade Negotiations and Trade Policy

ACTION: Meeting notice.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, as amended), notice is hereby given of a meeting of the Labor Advisory Committee for Trade Negotiation and Trade Policy.

Date, Time, Place: November 30, 2011; 2–4:30 p.m.; U.S. Department of Labor, Secretary’s Conference Room, 200 Constitution Ave. NW., Washington, DC.

Purpose: The meeting will include a review and discussion of current issues which influence U.S. trade policy. Potential U.S. negotiating objectives and bargaining positions in current and anticipated trade negotiations will be discussed. Pursuant to 19 U.S.C. 2155(f) it has been determined that the meeting will be concerned with matters the disclosure of which would seriously compromise the Government’s negotiating objectives or bargaining positions. Accordingly, the meeting will be closed to the public.

FOR FURTHER INFORMATION CONTACT: Gregory Schoepfle, Director, Office of Trade and Labor Affairs; *Phone:* (202) 693–4887.

⁵ While I have also considered J.B.B.’s letter, it offers no factual support for Respondent’s claim that he is rehabilitated. Instead, it offers only his personal opinion that Respondent’s has “adequately addressed his personal problem fully.”

⁴ This Agency has repeatedly held 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.” *Jackson*, 72 FR at 23853 (quoting *Miller*, 53 FR at 21932).