

Conclusion

I conclude that Respondent's registration with the DEA would be inconsistent with the public interest.

Recommended Decision

I recommend that Respondent's controlled substances registration be revoked and his application for renewal and modification of his DEA registration be denied.

Dated: June 15, 2010.

Mary Ellen Bittner,
Administrative Law Judge.

[FR Doc. 2011-22093 Filed 8-29-11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Registration

By Notice dated June 7, 2011, and published in the **Federal Register** on June 16, 2011, 76 FR 35241, Wildlife Laboratories, 1401 Duff Drive, Suite 400, Fort Collins, Colorado 80524, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of Etorphine Hydrochloride (9059), a basic class of controlled substance listed in schedule II.

The company plans to import the listed controlled substance for sale to its customers.

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 Wildlife Laboratories to import the basic class of controlled substance is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. DEA has investigated Wildlife Laboratories to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with State and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the above named company is granted registration as an importer of the basic class of controlled substance listed.

Dated: August 16, 2011.

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

[FR Doc. 2011-22088 Filed 8-29-11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated April 15, 2011, and published in the **Federal Register** on April 27, 2011, 76 FR 23627, Cedarburg Pharmaceuticals, Inc., 870 Badger Circle, Grafton, Wisconsin 53024, made application by letter to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of 4-Anilino-N-phenethyl-4-Piperidine (8333), a basic class of controlled substance listed in schedule II.

The company plans to use this controlled substance in the manufacturer of another controlled substance.

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a), and determined that the registration of Cedarburg Pharmaceuticals, Inc., to manufacture the listed basic class of controlled substance is consistent with the public interest at this time. DEA has investigated Cedarburg Pharmaceuticals, Inc., to ensure that the company's registration is consistent with the public interest. The investigation has included inspection and testing of the company's physical security systems, verification of the company's compliance with state and local laws, and a review of the company's background and history. Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the above named company is granted registration as a bulk manufacturer of the basic class of controlled substance listed.

Dated: August 16, 2011.

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

[FR Doc. 2011-22089 Filed 8-29-11; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Harold Edward Smith, M.D.; Revocation Of Registration

On April 17, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Harold Edward Smith, M.D. (Respondent), of Mt. Dora, Florida. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BS4681979, and the denial of any pending applications to renew or modify the registration, on the grounds that Respondent had materially falsified various applications for his DEA registration and had committed acts which render his registration inconsistent with the public interest. Show Cause Order at 1 (citing 21 U.S.C. 824(a)(1) & (4)).

The Show Cause Order alleged that Respondent has "a documented substance abuse history dating back as far as 1982," when he "entered treatment for alcohol and controlled substance abuse." *Id.* The Order alleged that on April 3, 1985, Respondent entered into a consent order with the Georgia Board of Medical Examiners (Georgia Board) based on his "chemical dependency," which placed him on probation for four years and imposed various conditions including that he "abstain from the consumption of alcohol or controlled substances," undergo random drug testing, and "relinquish" his controlled substance privileges. *Id.* The Order then alleged that in June 1990, Respondent tested positive for cocaine and that on October 10, 1990, he "entered into an Interim Consent Order" with the Georgia Board under which his medical license was suspended and he was ordered (1) Not to practice medicine, (2) not to use his DEA registration, and (3) "to participate in a program for impaired physicians." *Id.* at 2.

Next, the Show Cause Order alleged that during 1999 and 2000, Respondent issued prescriptions for hydrocodone to J.R.S. and L.L.S., and had failed to maintain the "records of any examinations, diagnoses, treatment[s] or * * * drugs prescribed to these individuals as required by Section 458.331(1)(q) of the Florida statutes." *Id.* The Order further alleged that based on this conduct, Respondent "entered into a Consent Agreement with the" Florida Board of Medicine, which required him to pay a fine of \$5,000, desist "from prescribing to family members" and to

take “a course on the proper prescribing of [a]busable [d]rugs.” *Id.* (int. quotations omitted).

The Show Cause Order further alleged that on February 16, 2007, the Florida Board indefinitely suspended Respondent’s medical license “based in part” on his “admission of” having “relapse[d] on crack cocaine” and “failure to submit to a urine screen while under contract with the Board’s impaired physicians’ program.” *Id.* The Order then alleged that on June 26, 2007, the Florida Board reinstated Respondent’s medical license “subject to several probationary terms.” *Id.*

Finally, the Show Cause Order alleged that “[o]n April 22, 2002, February 28, 2005, and again on January 31, 2008,” Respondent had “submitted applications for renewal” of his DEA registration. *Id.* The Order alleged that each of these applications was materially false because Respondent failed to disclose the various sanctions imposed on his state licenses by the Georgia and Florida Boards, as well as the previous “surrenders” of his DEA registration. *Id.*

On May 8, 2009, the Show Cause Order, which also notified Respondent of his right to request a hearing on the allegations (or to submit a written statement in lieu of a hearing) and the consequences if he failed to do so, *Id.* at 2, was served on Respondent by certified mail to him at the address given on his most recent application as his registered location. Since that date, neither Respondent, nor any person purporting to represent him, has filed a request for a hearing or submitted a written statement in lieu of a hearing. As thirty days have now passed since Respondent was served with the Order to Show Cause, I find that Respondent has waived his right to a hearing. See 21 CFR 1301.43(d). I therefore enter this Final Order without a hearing based on relevant evidence contained in the Investigative Record. See *Id.* at 1301.43(e). I make the following findings.

Findings

Respondent currently holds DEA Certificate of Registration BS4681979, which authorizes him to dispense controlled substances in schedules II through V as a practitioner, at the registered address of 2875 S. Orange Ave., Suite 500–600, Orlando, Florida. While Respondent’s registration was to expire on February 29, 2008, on February 7, 2008, he submitted an application to renew his registration. In accordance with the Administrative Procedure Act, Respondent’s registration remains in effect pending

the issuance of this Final Order. See 5 U.S.C. 558(c).

The State Proceedings Against Respondent

In April 1983, Respondent, who was then licensed in Arkansas and Tennessee, was discharged from an impaired physicians program. Thereafter, Respondent applied for a Georgia medical license. On April 17, 1985, Respondent entered into a Consent Order with the Georgia Board, which noted that he had “completed a treatment program for chemical dependency.” Consent Order at 1, *In re Harold Edward Smith, Jr., M.D.*, No. 91328–85 (Ga. Bd. Med. Exam’rs, April 17, 1985). Pursuant to the Consent Order, the Georgia Board issued Respondent a medical license and placed him on probation for four years subject to several conditions. *Id.* at 2–4. The conditions included that he “completely abstain from the consumption of alcohol or controlled substances, except as prescribed by a duly licensed practitioner for a legitimate purpose,” that he “undergo random alcohol/drug screening at his own expense,” that he “not possess a DEA permit or any triplicate prescription forms or Federal order forms,” and that he relinquish his right (until further order by the Board) “to prescribe, administer, dispense, order or possess (except as prescribed, administered or dispensed to [him] by another person authorized by law to do so) controlled substances.” *Id.* Respondent was also required to “submit quarterly reports regarding his physical and mental condition to the Board * * * including a report on any medication being prescribed to” him. *Id.* at 3. In April 1989, Respondent was “discharged from probation.” Interim Consent Order for Suspension of License During Treatment at 1, *In re Harold Edward Smith, Jr., M.D.*, No. 90–499 (Ga. Bd. Med. Exam’rs, Oct. 10, 1990).

In June 1990, physicians at Respondent’s place of employment requested that he provide a specimen for drug testing. *Id.* at 2. The specimen tested positive for cocaine. *Id.* Subsequently, the Georgia Board ordered Respondent to “undergo a 72-hour inpatient mental/physical examination evaluation” and thereafter, Respondent entered “treatment for relapse of chemical dependence.” *Id.*

On October 10, 1990, Respondent entered into an Interim Consent Order with the Georgia Board pursuant to which he agreed that his license would be “suspended until further order of the board”; that during the suspension, he

would “not engage in the practice of medicine or be authorized to utilize his DEA registration for controlled substances”; and that he would not resume practicing medicine or use his DEA registration “without the prior written approval of the Board.” *Id.* at 3 & 8. Respondent also agreed to “remain in treatment,” to “abide by all conditions of his treatment/aftercare program,” and to submit “quarterly reports on his mental/physical condition and progress in rehabilitation.” *Id.* at 3. Moreover, as a condition of the Board’s lifting of the suspension (after he completed treatment and executed an aftercare contract), Respondent was required to submit: (1) A certification by his monitoring physicians that he had “successfully completed treatment” and “is able to resume the practice of medicine with reasonable skill and safety,” (2) a plan to return to practice under a “physician who would actively supervise [his] practice,” and (3) “a summary of continuing education activity in the last year.” *Id.* at 4–5.

At some point, Respondent moved to Florida and obtained a medical license from the Florida Department of Health (DOH). On October 18, 2002, the DOH filed an Administrative Complaint against him. See Administrative Complaint, *Department of Health v. Smith*, No. 2000–12434 (Fla. DOH). The Complaint alleged that “[f]rom on or about July 24, 1999 to on or about August 14, 2000,” Respondent wrote hydrocodone prescriptions for J.R.S., and that “[f]rom on or about January 14, 2000 to on or about June 30, 2000,” Respondent wrote hydrocodone prescription for L.L.S., both of whom were alleged to be related to him. *Id.* at 2. The Complaint further alleged that Respondent “did not keep records of [his] examinations, diagnoses, treatment or * * * drugs prescribed” for either person. *Id.*

On June 18, 2003, Respondent entered into a Consent Agreement with the DOH. Consent Agreement at 6–7. Therein, Respondent neither admitted nor denied the allegations. *Id.* at 2. However, he agreed to pay a fine of \$2,000, to reimburse the DOH for its costs in the amount of \$4,776.58, and to complete a course entitled “Protecting Your Medical Practice, Clinical, Legal and Ethical Issues in Prescribing Abusable Drugs.” *Id.* at 2–4.

On August 18, 2003, the Florida Board of Medicine rejected the Consent

¹ The Order further noted that “[t]he terminal condition of Respondent’s mother understandably contributed to poor judgment for the time he provided prescriptions for her.” Consent Agreement at 4.

Agreement and offered a counter agreement, which the parties accepted. Final Order at 1. The Agreement increased the fine to \$5,000, imposed a restriction on his license requiring him to “remain in compliance with any and all terms of” his contract with the Professional Resource Network (PRN), and prohibited him “from writing prescriptions for controlled substances for any family member.” *Id.* at 1–2.

On May 31, 2006, the DOH filed another Administrative Complaint against Respondent. Administrative Complaint, *Department of Health v. Harold Smith, M.D.*, No. 2005–67946. The Complaint alleged that on approximately August 9, 2005, Respondent had ceased complying with his PRN contract and that, on August 16, 2005, a PRN monitor had contact with him and “recommended,” based on his “body language and general demeanor[,] * * * that [he] undergo a psychiatric evaluation.” *Id.* at 4–5. PRN then allegedly “requested that Respondent submit to a psychiatric evaluation and drug screen”; however, Respondent failed to “present for his drug screen.” *Id.* at 5. The Complaint further alleged that three weeks later, “Respondent contacted PRN and admitted to a relapse on crack cocaine and agreed to be evaluated.” *Id.*

The Complaint alleged that on or about October 7, 2005, Respondent was evaluated and “diagnosed with cocaine dependence” and “opioid dependence, in apparent relapse.” *Id.* The Complaint further alleged that the evaluator found that “Respondent was not safe to practice medicine” and recommended that he enter a “structured detoxification and stabilization unit and undergo intensive psychotherapy.” *Id.* at 5–6. The Complaint alleged that while Respondent completed this portion of his treatment, he subsequently refused to enter into a halfway house, did not have a phone, and had no money to pay for urine screens. *Id.* at 6. The State thus alleged that Respondent was “unable to practice medicine with reasonable skill and safety to patients due to his substance abuse problems and his unwillingness to undergo additional treatment” and monitoring by PRN. *Id.* at 7.

In February 2007, the Florida Board of Medicine issued a Final Order adopting a settlement agreement which Respondent had entered into with the State. Final Order at 2, *DOH v. Harold Smith, M.D.*, No. 2005–67946 (Fla. Bd. Med., Feb. 15, 2007). Apparently (as the agreement is not part of the record), Respondent had agreed to the suspension of his medical license. See Order on Reinstatement, *DOH v. Harold*

Smith, M.D., No. 2005–67946 (Fla. Bd. Med., June 26, 2007).

On June 26, 2007, the Board reinstated Respondent’s license and placed him “on probation for a period to run concurrent with his [PRN] contract.” *Id.* at 1. The Board imposed the following conditions: That he comply with his PRN contract; that he appear before the Board’s “Probationer’s Committee” each quarter; that he submit a practice plan to the Committee; that he practice only “under the indirect supervision” of a “monitoring physician” approved by the Committee, who is required to submit quarterly reports to the Committee on Respondent’s compliance and to “[r]eview 25 percent of [his] patient records selected on a random basis at least once each month” and who is also required to report any violations of applicable laws and regulations to the Board. *Id.* at 1–5. Finally, the Board prohibited Respondent “from writing prescriptions for controlled substances until such time as he is authorized to do so by the * * * Probationer’s Committee.” *Id.* at 5.

Respondent’s DEA Applications

On April 22, 2002, Respondent submitted an application to renew his DEA registration. In section 3 of the application, Respondent was required to answer four questions regarding whether he had ever been convicted of a controlled substance offense, and whether sanctions had ever been imposed against his DEA registration, any state medical license, or any state controlled substance registration.

More specifically, question 3(d) asked: “Has the applicant ever surrendered or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation? Is any such action pending?” Respondent circled “no.”

On February 28, 2005, Respondent submitted another application to renew his registration. Respondent was required to answer the same four questions as on the previous application. Once again, in answering question 3(d), Respondent circled “no.”

On January 31, 2008, Respondent submitted another application to renew his DEA registration. While there were some minor changes to the application, Respondent was required to answer the same four questions as on the previous applications. This time, however, Respondent answered “yes” to the question: “Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked,

suspended, denied, restricted, or placed on probation, or is any such action pending?” In the application’s block for explaining the “nature of incident” and the “result of incident,” Respondent wrote “see attached.” Respondent attached a copy of the Florida Board of Medicine’s June 2007 Order on Reinstatement and a letter to him from a DOH Compliance Officer relating the minutes of a September 7, 2007 meeting of the Board’s Probation Committee. The letter related that the Committee had lifted the restriction on his prescribing authority. Respondent did not, however, disclose the two Georgia proceedings or the 2003 Florida proceeding.

Discussion

Section 304(a)(1) of the Controlled Substances Act (CSA) provides that a registration “may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has materially falsified any application pursuant to or required by this subchapter.” 21 U.S.C. 824(a)(1). Section 304(a)(4) also provides that a registration to “dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.” 21 U.S.C. 824(a)(4). With respect to a practitioner, the CSA requires that the following factors be considered in making the public interest determination:

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

(2) The [registrant’s] experience in dispensing * * * controlled substances.

(3) The [registrant’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.

21 U.S.C. 823(f).

“[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 give each factor the weight I deem appropriate in determining whether to revoke an existing registration or to deny an application to renew a registration. *Id.* Moreover, I am “not required to make findings as to all of the factors.” *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005); see also

Volkman v. DEA, 567 F.3d 215, 222 (6th Cir. 2009).

Having considered the evidence, I conclude that the record establishes that Respondent materially falsified his 2002, 2005, and 2008 applications for DEA registrations. While there is evidence suggesting that Respondent is still abusing controlled substances, in light of my conclusion with respect to the material falsification allegations, I deem it unnecessary to rule on the Government's alternative ground for seeking the revocation of Respondent's registration.²

The Material Falsification Allegations

As found above, on both April 22, 2002 and February 28, 2005, Respondent submitted an application to renew his DEA registration on which he answered "no" to the question: "Has the applicant ever surrendered or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation?" In both instances, Respondent's answer was false because he failed to disclose (1) The Georgia Board's 1985 consent order which placed him on probation for four years, and (2) the Georgia Board's 1990 Consent Order which suspended his license. Moreover, Respondent's statement on his 2005 application was false for the further reason that in 2003, the Florida Board had imposed restrictions on his license which included that he remain in compliance with the PRN contract and was prohibited from writing controlled substance prescriptions "for any family member."

As for his January 31, 2008 application, it is true that Respondent gave a "yes" answer to the question regarding his state license and included a copy of the Florida Board's June 2007 reinstatement order. However, the statement was still false because Respondent failed to disclose the Georgia Board's 1985 and 1990 consent orders, as well as the 2003 Florida consent agreement.

It is likewise clear that Respondent's failure to disclose the various state proceedings on each of the three applications was a materially false statement under the CSA. A false statement is material if it "has a natural tendency to influence, or was capable of influencing, the decision of the

decisionmaking body to which it was addressed." *Kungys v. United States*, 485 U.S. 759, 770 (1988) (int. quotation and other citations omitted). While the evidence must be "clear, unequivocal, and convincing," the "ultimate finding of materiality turns on a substantive interpretation of the law." *Id.* at 772 (int. quotations and citations omitted). See also *Craig H. Bammer*, 73 FR 34327, 34328 (2008).

Respondent's false statements were material because, under the public interest standard, the Agency is required to consider, *inter alia*, the applicant's experience in dispensing controlled substances, his compliance with applicable state and federal laws related to controlled substances, and whether his conduct threatens public health and safety. See 21 U.S.C. 823(f). Disclosure of each of the state orders would have provided significant information to the Agency showing that Respondent has a significant problem with drug abuse; DEA has long held that a practitioner's self-abuse of a controlled substance is a relevant consideration under factor five of the public interest standard and is grounds for the revocation of an existing registration or the denial of an application for registration even where there is no evidence that a practitioner has abused his prescription-writing authority.³ See *Kenneth Wayne Green, Jr., M.D.*, 59 FR 51453, 51454 (1994) (registrant's "continued drug usage and relapses lead[] to the conclusion that he cannot be entrusted with the responsibilities of a DEA registrant and that his continued possession of a registration would be contrary to the public interest"); *David E. Trawick*, 53 FR 5326, 5327 (1988) ("offenses or wrongful acts committed by a registrant outside of his professional practice, but which relate to controlled substances may constitute sufficient grounds for the revocation of a" registration).

Disclosure of the 2003 Florida proceeding (on the 2005 and 2008 applications) would have also provided information that Respondent had been accused of writing unlawful prescriptions for hydrocodone, a schedule III controlled substance. 21 CFR 1308.13(e). This information is material to the Agency's investigation and assessment of Respondent's experience in dispensing controlled substances and his compliance with applicable laws related to the dispensing of controlled

substances.⁴ See 21 U.S.C. 823(f)(2) & (4).

I thus conclude that Respondent materially falsified his 2002, 2005 and 2008 applications to renew his DEA registration.⁵ Only one of these material falsifications is necessary to support the revocation of Respondent's registration; that there are three such instances manifests a shocking level of dishonesty on his part. 21 U.S.C. 824(a)(1). Accordingly, Respondent's registration will be revoked and his pending application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration, BS4681979, issued to Harold Edward Smith, M.D., be, and it hereby is, revoked. I further order that the pending application of Harold Edward Smith, M.D., to renew his registration, be, and it hereby is, denied. This Order is effective September 29, 2011.

Dated: August 17, 2011.

Michele M. Leonhart,
Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Dale J. Bingham, P.A.; Revocation of Registration

On February 4, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Dale J. Bingham, P.A. (Registrant), of Ash Fork, Arizona. The Show Cause Order proposed the revocation of Registrant's DEA Certificate of Registration MB1048746, which authorizes him to dispense controlled substances in schedules II through V, as a mid-level practitioner, on the ground that Registrant had entered into a consent agreement with the Arizona Regulatory Board of Physician Assistants, pursuant to which he no longer has "authority to handle

⁴ That the State did not require Respondent to admit to the allegations in the consent agreement does not make his failure to disclose the proceeding any less material.

⁵ While the Agency did not grant Respondent's 2008 application, "[i]t makes no difference that a specific falsification did not exert influence so long as it had the capacity to do so." *United States v. Alemany Rivera*, 781 F.2d 229, 234 (1st Cir. 1985). Moreover, Respondent's false statements on his 2002 and 2005 applications obviously did influence the Agency's decision to grant them.

² As found above, while the DOH 2006 complaint makes the allegations that Respondent had admitted to a relapse on crack cocaine and had been diagnosed as being dependent on cocaine and opioids, neither the Board's Final Order nor the Order on Reinstatement contain factual findings establishing the validity of these allegations.

³ It is also relevant in assessing Respondent's compliance with applicable laws related to controlled substances. See 21 U.S.C. 823(f)(4).