



BILLING CODE: 4410-09-P

**DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION**

**ROBERT M. BRODKIN, D.P.M.
DECISION AND ORDER**

On June 6, 2011, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Robert Brodtkin, D.P.M. (hereinafter, Respondent), of Lubbock, Texas. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration as a practitioner because his "registration would be inconsistent with the public interest." GX 10, at 1 (citing 21 U.S.C. § 823(f)).¹

The Show Cause Order alleged that "[b]etween April 7, 2007, and February 19, 2008, [Respondent] ordered nearly 5,000 dosage units of controlled substances . . . and diverted those controlled substances for personal use." *Id.* The Show Cause Order further alleged that Respondent provided "false information" to distributor Henry Schein, Inc., when questioned about his usage of the controlled substances. *Id.*

Next, the Show Cause Order alleged that, on November 20, 2008, Respondent "entered into a Memorandum of Understanding with the [Texas State Board of Podiatric Medical Examiners]" after the State Board issued a "complaint, indicating that [Respondent] had exceeded [his] podiatric practice limitations." *Id.* at 2. The Show Cause Order also alleged that Respondent's previous DEA registration was surrendered "for cause, on April 16, 2008, as a

¹ The Show Cause Order also alleged that Respondent lacks "authority to handle controlled substances in the State of Arizona." GX 10, at 1. This fact is not in dispute, as in his hearing request, Respondent admitted that he "do[es] not have a license to handle controlled substances in the state of Arizona [and has] never made any claim to the contrary." GX 11, at 1. However, it is not apparent why the allegation is material as Respondent's practice is based in Texas, where he does hold both a medical license and a state controlled substance registration and the Show Cause Order does not allege that he committed any misconduct in Arizona, or in any State outside of Texas. *Id.*; see also GX 25. Nor does the Government offer any explanation as to why Respondent's lack of an Arizona license is a basis for the denial of his application.

result of allegations that [Respondent was] using [his] registration for ordering and self-administering controlled substances.” Id. at 1.

The Show Cause Order notified Respondent of his right to request a hearing on the allegations or to file a written statement in lieu of a hearing, the procedures for electing either option, and the consequences of failing to do either. Id. at 2. On June 13, 2011, the Order was served on Respondent by certified mail. Id. at 3.

On June 14, 2011, Respondent submitted a timely hearing request, see GX 11, and the matter was placed on the docket of the Office of Administrative Law Judges. On June 27, 2011, the assigned Administrative Law Judge (“ALJ”) issued an Order for Prehearing Statements. See GX 12. The Government submitted its Prehearing Statement on July 18, 2011, see GX 13, and Respondent submitted his reply on July 28, 2011. See GX 14. The ALJ initially scheduled a prehearing conference for August 2, 2011; upon Respondent’s unopposed request for a continuance, the conference was rescheduled until September 7, 2011. See GX 15.

On September 8, 2011, the ALJ issued a Prehearing Ruling, setting a hearing date of December 13-14, 2011. See GX 16. On November 4, 2011, Respondent requested a continuance of the hearing, citing the competing demands of an “extensive [Medicare] audit procedure.” GX 17. The Government opposed this request. GX 19. Before ruling on the continuance, the ALJ sought to “conduct a conference call with both parties.” GX 20, at 1. In her November 21, 2011 Order Regarding Respondent’s Request for a Continuance, the ALJ noted that previous attempts to “contact Respondent to set up a conference call” had been “unsuccessful,” and she ordered Respondent to submit a “listing [of] the dates and times of his availability” by November 28, 2011. Id. at 1-2.

When Respondent failed to comply with the ALJ's order, the Government moved to terminate the proceeding. See GX 21. Thereupon, on November 29, 2011, the ALJ issued a second Order affording Respondent another opportunity to contact the Court. See GX 22. Therein, the ALJ "warn[ed] Respondent that if he fail[ed] to contact the Court by December 5, 2011, he [would] be deemed to have waived his right to a hearing and [the ALJ] [would] grant the Government's Motion to terminate these proceedings." Id. at 2.

Once again, Respondent failed to comply with the ALJ's order. Accordingly, on December 6, 2011, the ALJ, having found that "Respondent [had] constructively waived his right to a hearing under 21 C.F.R. § 1301.43(c)," granted the Government's Motion to Terminate the proceeding. GX 23, at 2.

Under Agency precedent, the failure to comply with an ALJ's orders may constitute a waiver of a hearing request and cause for termination of the proceeding. See Kamir Garces-Mejias, 72 FR 54931, 54932 (2007); Andrew Desonia, 72 FR 54293, 54294 (2007); Brenton D. Glisson, 72 FR 54296 (2007); Alan R. Schankman, 63 FR 45260 (1998); see also Fitzhugh v. DEA, 813 F.2d 1248 (D.C. Cir. 1987) (upholding revocation order entered after a respondent failed to appear for his hearing). Here, Respondent violated two of the ALJ's orders. Moreover, the ALJ's repeated attempts to contact Respondent proved unsuccessful.

I therefore adopt the ALJ's finding that Respondent has waived his right to a hearing and her order terminating the hearing. I further issue this Decision and Order based on relevant evidence contained in the record submitted by the Government.²

² On August 3, 2012, the Government forwarded the investigative record to this office with its request for Final Agency Action.

Having reviewed the record, I further hold that Respondent has committed acts which render his registration “inconsistent with the public interest.” 21 U.S.C. § 823(f). I make the following factual findings.

Findings

Respondent is a Doctor of Podiatric Medicine, whose medical practice is limited to podiatry. GX 1, at 3 and GX 2, at 1-4. Under Texas state regulations, Respondent is authorized to “treat any disease, disorder, physical injury, deformity, or ailment of the human foot.” Tex. Occ. Code § 202.001(4).

On September 29, 2008, Respondent submitted an application for a DEA Certificate of Registration as a practitioner, seeking authority to dispense controlled substances in Schedules II through V. GX 1, at 3. As the application form states, in order to be eligible for a DEA registration, an applicant “MUST be currently authorized to prescribe . . . controlled substances . . . under the laws of the state or jurisdiction in which [he or she is] operating or propose[s] to operate.” Id. at 4 (Section 4 of the application). See also 21 U.S.C. § 823(f). Respondent listed a Texas address but noted that his Texas controlled substance licensure was “pending.” Id. However, on December 2, 2009, Respondent obtained a state controlled substance registration from the Texas Department of Public Safety. GX 25.

In addition to demonstrating that he possesses state authority to dispense controlled substances, an applicant must answer several other liability questions which seek information regarding any prior administrative or criminal proceedings. GX 1, at 4 (Section 5 of the application). When asked if he had “ever surrendered (for cause) or had a federal professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation,” Respondent circled “No” and handwrote in the margin, “invol. surrender under

duress but not ‘for cause.’” Id. at 4 (Section 5, Question 2). In response to the application’s question regarding disciplinary action taken at the state level, Respondent again circled “No” and handwrote in the margin, “non-judicial; non-due process.” Id. at 4 (Section 5, Question 3). Finally, in the explanatory section below the liability questions, Respondent wrote: “there have not ever been any incidents.” Id. at 4 (Section 5).

However, Respondent has been the subject of both federal and state disciplinary action. Respondent previously held DEA Certificate of Registration AB1847043, see GX 24, which he surrendered for cause on April 16, 2008. GX 7. On the “Voluntary Surrender” form, Respondent signed his name under language indicating that he “freely execute[d] this document” in light of his “alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices.” Id.

Shortly after Respondent surrendered his DEA registration, state authorities initiated a disciplinary investigation against Respondent. On April 27, 2008, the Texas State Board of Podiatric Medical Examiners issued him a “Notice of Complaint Allegation.” GX 2, at 7. Citing Respondent’s written communications to the State Board and his letters to drug distributor Henry Schein, Inc., the Complaint alleged that Respondent had “acknowledged self-treatment of diseases, disorders, physical injuries, deformities, or ailments of conditions beyond the foot/ankle limits of [his] Podiatry license.” Id. at 15. The Complaint further contended that Respondent’s “justifications for purchasing drugs/controlled substances [from] Henry Schein, Inc., were misleading, deceptive, and fraudulent given [Respondent’s] own admissions [and] made under false pretenses.” Id.

The federal and state disciplinary investigations stemmed from Respondent's alleged practice of self-prescribing medication outside the scope of his podiatry practice. Between April 2007 and February 2008, Respondent obtained controlled substances from Henry Schein, Inc., and Moore Medical LLC. GX 6. These controlled substances included 225 ampules of Demerol 50 mg/ml (meperidine, a schedule II narcotic); 1200 tablets of diazepam (a schedule IV benzodiazepine); 1500 tablets of hydrocodone/acetaminophen 10/500 mg and 1700 tablets of hydrocodone/acetaminophen 10/325 mg (both schedule III narcotics); 100 vials of midazolam 1gm (a schedule IV benzodiazepine); 200 tablets of propoxyphene (a schedule IV narcotic); and four bottles of testosterone cypionate 10 ml/bottle (a schedule III anabolic steroid). Id.

On May 7, 2007, Respondent sent a letter to Henry Schein, Inc., responding to the company's questioning of his controlled substance orders. GX 3. In the letter, Respondent claimed that he did "12 to 15 surgical cases per week," including "major-type foot surgeries," necessitating that he have a steady supply of pain control medications:

In general, in my clinic I do three major-type foot surgeries per week, usually one each on Monday, Wednesday and Friday. On some weeks we will add one or two additional case[s] on either Tuesday or Thursday. So, the baseline total of cases comes out to 12 to 15 surgical cases per week.

Id. at 1-2. Respondent then explained how he was administering drugs such as Demerol, Valium, and midazolam to his surgical patients, as well as dispensing additional drugs including hydrocodone tablets to the purported patients for post-operative pain control. Id. at 2-3.

Following the letter, Schein continued to distribute controlled substances to Respondent. GX 6, at 1-2.

However, in an April 4, 2008 letter to the Executive Director/Investigator of the Texas State Board of Podiatric Medical Examiners, Respondent wrote that he had "voluntarily quit doing foot surgery in June of 2002" due to his severe back pain. GX 8, at 1. Respondent further

admitted that he “voluntarily quit seeing patients directly as of June, 2003” and that his practice “consisted of my supervising highly trained podiatry assistants in providing mycotic nail care for elderly patients.” Id.

Respondent’s letter to the State Board’s Investigator was thus fundamentally inconsistent with his earlier statements to Schein that he was “do[ing] three major-type foot surgeries per week,” plus additional cases for a total of “12 to 15 surgical cases per week.” GX 3, at 1. Moreover, in his letter to the Board, Respondent intimated that he had been using the controlled substances he ordered from Henry Schein and Moore Medical to treat his own back pain.³ For example, Respondent explained that he had stopped seeing patients due to a “hellish pain” in his lower back. GX 8, at 1. Respondent then offered a description of his use of controlled substances:

I was able to quit taking Lortab pills, a Class III substance for pain control in January, 2008 for the simple reason that I no longer needed them. The last time I ordered any [C]lass II products was also in January, 2008; I simply did not need this powerful a substance to control what had been nearly unendurable pain. I still had a generalized achiness about my entire back[,] and I am now using a low dose Class IV product.

Id. at 2.

On April 16, 2008, Respondent voluntarily surrendered his DEA registration. GX 7. Two days later, Respondent wrote a letter to a DEA Diversion Investigator, in which he denied being “a drug addict” or “hav[ing] any addiction issues.” GX 5, at 1. Respondent also explained that “any pain medications [he] previously utilized were indeed used under medical supervision, in an entirely proper and correct fashion to control what would otherwise be severe pain of the most intense nature.” Id. at 2. Moreover, in his Request for Hearing, Respondent replied to the allegations of the Show Cause Order, asserting that:

³ Respondent later confirmed these allegations in his Request for Hearing and Pre-Hearing Statement. See GX 11, at 3; GX 14, at 3.

[t]he fact is that the State Board did use the terminology ‘cease and desist’ but only in regard to my having been practicing general medicine, i.e., self-treating my severe, life-threatening back pain prior to the sixth and last definitive back surgery having been performed on October 2nd, 2007. That is to say, my State Board recognized that my self-prescription of pain medication was in fact, medical practice”

GX 11, at 3 (emphasis in original).⁴

On November 20, 2008, Respondent entered into a Memorandum of Understanding with the Texas State Board. See GX 2. Respondent signed the Memorandum in lieu of disciplinary action, acknowledging that “[p]odiatrists can write prescriptions to treat any disease, disorder, physical injury deformity or ailment of the human foot, but only for a valid medical purpose supported by proper medical record documentation and limited to the Foot/Ankle scope of practice.” GX 2, at 3 (emphasis added).

Discussion

Under the Controlled Substances Act, the “Attorney General may deny an application for [] registration . . . if the Attorney General 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,” 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 In his Pre-Hearing Statement, Respondent likewise wrote:

During the period starting approximately in 2004, I developed an extremely severe level of low back pain. I consulted with numerous specialist physicians . . . in unsuccessful attempts to determine the precise cause of the pain. Many of the consulted doctors, looking strictly at MRI scans which were presumably done on inferior quality MR scanning devices, claimed that no pathology existed. Why would any doctor prescribe pain medications for a condition that they incorrectly believed did not actually exist? As the condition continued to worsen, I utilized pain medication, in a regimen of medical treatment supervised by myself, in order to alleviate at least a small portion of the pain present.

GX 14, at 3.

- (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.

The public interest factors are considered in the disjunctive. Robert A. Leslie, 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and may give each factor the weight I deem appropriate in determining whether to deny an application for a registration. Id. Moreover, I am “not required to make findings as to all of the factors.” Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); see also MacKay v. DEA, 664 F.3d 808, 816 (10th Cir. 2011); Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

The Government has “the burden of proving that the requirements for [] registration . . . are not satisfied.” 21 CFR 1301.44(d). As no DEA regulation provides that the consequence of waiving a hearing is a default, the Government must therefore support its proposed action with substantial evidence.

Having considered all of the factors, I conclude that the Government’s evidence pertinent to Factors Two (Respondent’s experience in dispensing controlled substances) and Four (Respondent’s compliance with applicable laws related to controlled substances), establishes that Respondent has committed acts which render his registration “inconsistent with the public interest.” 21 U.S.C. § 823(f).⁵ Because there is no evidence that Respondent acknowledges his misconduct, I conclude that his application should be denied.

⁵ Factor one does not support a finding either for, or against, the continuation of Respondent's registration. The Podiatry Board has not made a recommendation to DEA, and in any event, while Respondent currently possesses authority under Texas law to dispense controlled substances, thus satisfying a prerequisite for obtaining a registration, the Agency has repeatedly held that a practitioner’s possession of state authority is not dispositive of question of whether his registration would be consistent with the public interest. See 21 U.S.C. § 823(f); see also Patrick W. Stodola, 74 FR 20727, 20730 n.16 (2009) (citing Mortimer B. Levin, 55 FR 8209, 8210 (1990)).

Factors Two and Four - Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

The CSA makes it “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.” 21 U.S.C. § 844(a). Moreover, 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.” *Id.* § 843(c)(3).

Under the CSA, a practitioner is bound by the scope of his professional practice. As the Supreme Court has explained, “the scheme of the [CSA], viewed against the background of the legislative history, reveals an intent to limit a registered physician’s dispensing authority to the course of his ‘professional practice.’” *United States v. Moore*, 423 U.S. 122, 140 (1975). (emphasis added). See also 21 U.S.C. § 802(21) (Defining “[t]he term ‘practitioner’ [to] mean[] a physician . . . licensed, registered, or otherwise permitted, by the . . . jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substances in the course of professional practice.”); *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994) (“[A] licensed physician who prescribes controlled substances outside the bounds of his professional medical practice is subject to prosecution.”); 21 CFR 1306.04(a) (“A prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. . . . An order

As for factor three, there is no evidence in the record that Respondent has been convicted of an offense related to the manufacture, distribution, or dispensing of controlled substances. *See id.* § 823(f)(3). However, DEA has long held that this factor is not dispositive. *See, e.g., Edmund Chein*, 72 FR 6580, 6593 n.22 (2007).

purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of” the CSA.).

As found above, Respondent is a podiatrist, and under Texas law, his practice is limited to “treat[ing] any disease, disorder, physical injury, deformity, or ailment of the human foot.” Tex. Occ. Code § 202.001(4). See also GX 2, at 2 (Memorandum of Understanding between Respondent and Texas State Board of Podiatric Medical Examiners) (Respondent “takes notice that the practice of Podiatry in Texas is limited to treatment of the Foot/Ankle.”). Moreover, as the Memorandum of Understanding makes clear, “Podiatrists can write prescriptions to treat any disease, disorder, physical injury, deformity or ailment of the human foot, but only for a valid medical purpose supported by proper medical record documentation and limited to the Foot/Ankle scope of practice.” Id. at 3.

The record contains substantial evidence that Respondent dispensed to himself controlled substances and acted outside of the usual course of his professional practice. In various statements to both state and agency officials, Respondent provided evidence that he was administering controlled substances to himself to treat a back injury. While in some of these statements, Respondent merely alluded to back injuries which caused him to suspend his podiatry practice while continuing to order pain medications, in several statements Respondent expressly admitted that he was self-administering controlled substances. See GX 11, at 3 (Resp. Req. for Hearing; Statement; “my State Board recognized that my self-prescription of pain medication was in fact, medical practice”); GX 14, at 3 (Resp. Pre-Hearing Statement; “During the period starting approximately 2004, I developed an extremely severe level of low back pain. . . . As the condition continued to worsen, I utilized pain medication in a regimen of medical treatment supervised by myself.”).

By engaging in the self-administration of controlled substances to treat his back injury, Respondent exceeded the bounds of his professional practice as a Podiatrist. Indeed, he acknowledged as much in the Memorandum of Understanding. GX 2, at 3 & 5. And because he did not obtain the controlled substances he self-administered “pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice,” Respondent unlawfully possessed those controlled substances. 21 U.S.C. § 844(a).

The evidence also supports a finding that Respondent obtained controlled substances from Henry Schein, Inc., by misrepresentation, fraud, or deception. *Id.* § 843(a)(3). When questioned by the company as to his ordering of controlled substances, Respondent represented that he was performing three major foot surgeries a week, as well as additional procedures for a total of “12 to 15 surgical cases per week.” Respondent then explained how he was administering drugs such as Demerol, Valium, and midazolam to his purported surgical patients, as well as dispensing additional drugs including hydrocodone tablets to the purported patients for post-operative pain control. However, as Respondent admitted in his letter to the State Board’s Executive Director, because of his back pain, he had “voluntarily quit doing foot surgery in June of 2002” and had “voluntarily quit seeing patients directly as of June, 2003.” Thus, I conclude that Respondent’s statements to Henry Schein, Inc., were intentional misrepresentations of the nature of his medical practice which he made to induce Schein to continue to distribute controlled substances to him, which it did.

Accordingly, I find that the Government has established that granting Respondent’s application “would be inconsistent with the public interest.” 21 U.S.C. § 823(f). I will therefore order that Respondent’s application for a new registration be denied.⁶

⁶ While I have reviewed Respondent’s Pre-Hearing Statement and treated it as if it was a statement submitted in lieu of a hearing, see 21 CFR 1301.43(c), the only mitigating evidence contained therein is the statement that the State

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f), as well as 28 CFR 0.100(b), I order that the application of Robert M. Brodtkin, D.P.M., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective [**INSERT DATE THIRTY DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

Dated: December 3, 2012

Michele M. Leonhart
Administrator

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Board's "inquiry was closed with a 'Memorandum of Understanding' that the practice of podiatric medicine and surgery in Texas does not include the medical treatment of back problems. I agreed with this and agreed to abstain from any further general medical practice of any sort, particularly the medical treatment of severe back pain." GX 14, at 4. Nothing in Respondent's statement manifests that he acknowledges the illegality of his acts of self-dispensing and obtaining controlled substances by misrepresentation. See, e.g., Jeri Hassman, 75 FR 8194, 8236 (2010) ("To rebut the Government's prima facie case, [the Respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts."). See also Ronald Lynch, 75 FR 78745, 78753-54 (2010) (registrant's attempts to minimize misconduct held to undermine acceptance of responsibility); George Mathew, 75 FR 66138, 66140, 66145, 66148 (2010) (registrant's failure to address misconduct warranted revocation of his registration); Steven M. Abbadessa, 74 FR 10077, 10078 (2009) (registrant's acceptance of responsibility and demonstration of corrective measures supported granting application); Jayam Krishna-Iyer, 74 FR 459, 463 (2009) (registrant granted new registration following suspension where she finally acknowledged her wrongdoing).