



BILLING CODE: 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Zizhuang Li, M.D.; Decision and Order

On June 10, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Zizhuang Li, M.D. (Applicant), of Leawood, Kansas. GX 5. The Show Cause Order proposed the denial of Applicant's 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)).

As basis for the denial, the Show Cause Order alleged that "[o]n September 27, 2012, the Mississippi State Board of Medical Licensure (Board) found that from April through August 2010, [Applicant] prescribed controlled substances, including oxycodone, carisoprodol, and alprazolam, outside the course of professional practice to four patients." *Id.* Next, the Show Cause Order alleged that the Board found that Applicant "engaged in unprofessional conduct" by failing "to conduct an appropriate risk/benefit analysis for [his] patients," and that he also "failed to document proper written treatment plans." *Id.* (citing Miss. Code Ann. §§ 73-25-29(8)(d) & (13); 73-25-83(a)). The Order then alleged that based on its findings, the Board suspended Applicant's medical license for twelve months.¹ *Id.*

On June 10, 2013, the Government attempted to serve the Show Cause Order by certified mail, return receipt requested, addressed to Applicant at the address he provided on his application for receiving mail from the Agency. GX 6, at 1. However, on July 6, 2013, the

¹ The Show Cause Order also notified Applicant of his right to request a hearing on the allegations or to submit a written statement while waiving his right to a hearing, the procedure for electing either option, and the consequence of failing to elect either option. GX 5, at 2-3 (citing 21 CFR 1301.43).

Government queried the Postal Service's Track and Confirm webpage and determined that the mailing had not been accepted.² Accordingly, on July 9, 2013, the Government mailed the Show Cause Order to Applicant at the same address using first class mail. Id. That same day, DEA also e-mailed an electronic version of the Show Cause Order to two e-mail addresses purportedly used by Applicant, including the address which he had provided on his application for registration.³ Id. Neither e-mail was returned as undeliverable or resulted in an error message. Id.

Based on the above, I find that the Government has complied with its obligation "to provide 'notice, reasonably calculated under all the circumstances, to apprise [Applicant] of the pendency of the action and afford [him] an opportunity to present [his] objections.'" Jones v. Flowers, 547 U.S. 220, 226 (2006) (quoting Mullane v. Central Hanover Bank & Trust Co., 339 U.S. 306, 314 (1950)); see also Emilio Luna, 77 FR 4829, 4830 n.2 (2012) ("[I]t seems relatively clear that when certified mail is returned unclaimed, in most cases, the Government can satisfy its constitutional obligation by simply re-mailing the Show Cause Order by regular first class mail.") (citing Jones, 547 U.S. at 234-35).

On August 20, 2013, the Government submitted its Request for Final Agency Action, along with the Investigative Record. Based on the Government's submission, I further find that more than thirty days have now passed since service of the Show Cause Order was accomplished, and neither Applicant, nor anyone purporting to represent him, has either requested a hearing or submitted a written statement in lieu of a hearing. 21 CFR 1301.43(a) &

² On July 12, 2013, the mailing was returned to DEA and marked as "Return to sender, unclaimed, unable to forward, returned to sender." GX 6, at 1.

³ Regarding the two e-mail addresses, the Diversion Investigator (DI), who investigated the application, "discovered that [Applicant] gave the Board the email address of jacksonstone22@hotmail.com . . . [and] [o]n a residential rental application in San Diego . . . Applicant listed his email address as zizhuangli@yahoo.com." GX 4, at 2. The latter is the same e-mail address Applicant provided on his DEA application.

(c). Accordingly, I find that Applicant has waived his right to a hearing or to submit a written statement. 21 CFR 1301.43(d). I therefore issue this Decision and Final Order based on relevant material contained in the Investigative Record submitted by the Government. I make the following findings of fact.

FINDINGS

Applicant's Registration and Licensure Status

Applicant previously held three DEA Certificates of Registration, pursuant to which he was authorized to dispense controlled substances in schedules II through V. GX 2, at 2; GX 3, at 2. Two of the registrations (at least one of which was for a location in Mississippi) were retired on September 28, 2012, apparently after Applicant voluntarily surrendered them. GX 2. As for the third registration, it was retired on May 1, 2010. Id. However, there is no evidence establishing why this registration was retired.

On November 16, 2012, Applicant applied for a new registration at the proposed registered address of 20265 Valley Boulevard, Suite E, Walnut, California. GX 1, at 1. Applicant sought authority limited to dispensing controlled substances in schedules IV and V. GX 2, at 1. It is this application which is at issue in this matter.

Applicant also holds a current Physician's and Surgeon's Certificate issued by the Medical Board of California. GX 1, at 1. Applicant's California license is not due to expire until December 31, 2013.⁴ Id.

⁴ Pursuant to 5 U.S.C. § 556(e) and 21 CFR 1316.59, I take official notice that on December 28, 2012, the California Board issued an Accusation/Petition to Revoke Applicant's state license based on the results of the Mississippi Board's action. That matter is still pending.

I have also taken official notice of the fact that Applicant voluntarily surrendered his Louisiana medical license (MD.204358) on October 8, 2012.

Applicant was also licensed by the Mississippi State Board of Medical Licensure. However, as found below, on June 8, 2012, the Board initiated a proceeding against Applicant, alleging twenty-four counts of violations of Mississippi law. GX 3, at 1. Following a hearing on September 27, 2012, at which Applicant was represented by counsel, the Board suspended his state license for a period of twelve months, which was effective immediately. Id. at 23-24. Moreover, “[n]otwithstanding the twelve (12) month period” of suspension, the Board ordered that “Licensee shall not practice medicine in any manner or form, until such time as he appears before this Board, [and] submits proof of compliance with all requirements set forth in [the] order, as well as Miss. Code Ann. [§] 73-25-32.”⁵ Id. at 23. The Board also required that Applicant complete courses in controlled substance prescribing, recordkeeping, and medical ethics, and that he pay “all costs incurred in relation to the . . . matter . . . not to exceed \$10,000.” Id. at 23-24.

The Board’s Findings

Based on the evidence presented at the hearing, the Board made extensive findings regarding Applicant’s prescribing of controlled substances to four patients. GX 3, at 1-23. With respect to Patient #1, a thirty-three year old male, the Board found that Applicant issued him twenty-one (21) prescriptions for controlled substances (totaling 2,415 dosage units) during the period of April 26 through August 18, 2010. Id. at 4. The prescriptions included one prescription for 60 Percocet 10/650mg, six prescriptions for 945 oxycodone 30mg, five prescriptions for 450 Xanax 2mg, 600 Soma (carisoprodol) 350mg, and four prescriptions for

⁵ This statute provides that “[a] person whose license to practice medicine . . . has been revoked or suspended may petition the [Board] to reinstate this license after a period of not less than one (1) year has elapsed from the date of the revocation or suspension.” Miss. Code Ann. § 73-25-32(1). The statute further requires that the petition “be accompanied by two (2) or more verified recommendations from physicians . . . licensed by the Board . . . and by two (2) or more recommendations from citizens each having personal knowledge of the activities of the petitioner since the disciplinary penalty was imposed and such facts as may be required by the Board.” Id. § 73-25-32(2).

360 Neurontin (gabapentin) 300mg.⁶ The Board further found that Applicant repeatedly prescribed multiple drugs to Patient #1 at a visit, including Xanax, Soma, and oxycodone. *Id.* at 5-6.

The Board then identified multiple failures by Applicant to follow its regulations for the “Use of Controlled Substances for Chronic (Non-Terminal) Pain” in prescribing to Patient #1.

These included that:

- 1) Applicant “allowed the patient to dictate his care by continually prescribing controlled substances for pain notwithstanding [his] recommendation that the patient should have surgery”;
- 2) notwithstanding evidence in the patient’s medical record that he “visited multiple pharmacies and physicians in the past,” the record “contained no record of prior treatment and there [was] no information . . . suggesting that [Applicant] conducted an appropriate risk/benefit analysis by reviewing his own records . . . or records” of prior treating physicians;
- 3) there was no documentation that Applicant discussed with Patient #1 “taking medication as prescribed”;

⁶ Carisoprodol did not become a federally controlled substance until January 11, 2012, when its placement into schedule IV of the Controlled Substances Act became effective. See DEA, Schedules of Controlled Substances: Placement of Carisoprodol into Schedule IV, 76 FR 77330 (2011). However, several DEA final orders had previously discussed the abuse of carisoprodol in conjunction with other controlled substances, including opiates such as oxycodone and hydrocodone, and benzodiazepines, such as alprazolam and diazepam. See, e.g., Paul H. Volkman, 73 FR 30630, 30638 (2008) (noting expert’s testimony regarding prescribing of drug cocktails of a narcotic, benzodiazepine, and carisoprodol, and that the cocktail, which “is very popular amongst those individuals who go to doctors’ offices to take drugs to abuse them,” also “increase[s] the likelihood of sedation, respiratory depression and death.”) (other citations omitted).

Neurontin (gabapentin) is not a federally controlled substance.

- 4) there was no indication that Applicant sought “outside consultation to determine the origin of the patient’s pain,” or recommended treatment modalities (beyond prescribing controlled substances) other than “warm baths and heating pads”;
- 5) there was “only one urine drug screen” in Patient #1’s chart, which was done at his initial visit and there were “[n]o subsequent drugs screens [in] the record to document compliance with treatment”;
- 6) Patient #1 “continued to come early for each visit and [Applicant] continued to write prescriptions on each early visit”;
- 7) Patient #1’s file “contained . . . ‘red flags’ suggesting possible drug abuse by Patient #1”; and
- 8) Applicant “issued Patient #1 prescriptions at times when [he] should not have finished taking the same medication from a previous prescription had the . . . directions been properly followed or the correct dosage . . . taken.”

GX 3, at 7-9.

As for Patient #2, the Board found that from April 6 through August 9, 2010, Applicant “issued to [him] twenty four (24) prescriptions totaling approximately 2,178 dosage units of controlled substances,” including six (6) prescriptions for 352 Lortab 10/500mg (hydrocodone/acetaminophen), six prescriptions for 704 Soma (carisoprodol) 350mg, six prescriptions for 704 oxycodone 30mg, and six prescriptions for 418 Xanax 2mg. GX 3, at 9. Here again, the Board’s findings show that Applicant repeatedly dispensed prescriptions for all four of these drugs to Patient #2 on a single day.

The Board then identified multiple failures on Applicant’s part in complying with its regulations. These included:

- 1) Patient #2's "chart shows very little physical exam conclusions and hardly any pathology . . . which would indicate the therapeutic nature for prescribing the particular controlled substances in the quantities and strengths so noted";
- 2) Applicant noted in the chart that he recommended that Patient #2 see an orthopedic specialist, yet there was "no documentation or further mention of whether a referral was made or if Patient #2 saw an orthopedist";
- 3) Applicant issued Patient #2 new prescriptions on June 11, 2010, "only 18 days after [his] visit on May 24," while noting in the chart that the visit had occurred on June 21, 2010, and there was no explanation in the chart for issuing the prescriptions early, nor "any significant change in the verbal pain scale" to support the "increased consumption of the prior issued medications";
- 4) Applicant "continued to prescribe controlled substances for pain without any analysis regarding the effectiveness of the medications" and there was "no documentation of other treatment modalities (other than recommending warm baths and heating pads)";
- 5) Applicant "allowed Patient #2 to dictate his care by simply continuing previous prescriptions for controlled substances, failing to follow up on his own recommendations regarding referral to an orthopedist, and, at a minimum, failing to recognize non-compliance by the patient"; and
- 6) Patient #2's chart "contained indicators or 'red flags' suggesting possible drug abuse," including: a) documentation suggesting that Patient #2 had previously been terminated for noncompliance with a treatment plan by a prior pain management physician; b) a printout from a pharmacy showing that Patient #2 was obtaining

controlled substances from multiple doctors; and c) Applicant “continued to write new prescriptions for controlled substances at a time when the previous prescriptions for the same medications would not have been completed had the patient followed” the dosing instructions.

Id. at 11-13.

With respect to Patient #3, the Board found that from April 7 through August 2, 2010, Applicant issued twenty-three controlled prescriptions to her “totaling approximately 2,515 dosage units.” Id. These included five prescriptions for 880 Norco (hydrocodone/apap) 10/325mg, five prescriptions for 600 Soma 350mg, one prescription for 10 oxycodone 15mg, two prescriptions for 35 oxycodone 30mg, five prescriptions for 540 Xanax 2mg, and five prescriptions for 450 Fiorinal with codeine. Id. Here again, Applicant issued the patient up to four controlled substance prescriptions at a single visit. Id. at 14.

The Board then identified multiple failures on Applicant’s part in complying with its regulations. These included:

- 1) that the most recent MRI was five years old, and while it showed that Patient #3 had “degenerative disc and hypertrophy issues along with prolapse of L5-S1,” there was “no mention of consultation or referral to a specialist to attempt other modalities of treatment”;
- 2) Applicant “determined that the best course of treatment was to continue the prescriptions previously issued to [her] by prior physicians, along with warm baths and use of heating pads”; however, “[t]here [was] no . . . justification as to why the patient needed this particular combination of medications in these particular quantities and strengths”;

- 3) Patient #3's medical record "contained no psychiatric analysis to determine the necessity for the use of Xanax. If the Xanax was prescribed for the purpose of muscle relaxation, then there [was] no indication to include Soma in the medication regime";
- 4) Patient #3's file "contained indicators or 'red flags' suggesting possible drug abuse by" her, including that she was driving from Kenner, Louisiana to Picayune, Mississippi; that she claimed to have gone to the emergency room (ER) for pain related reasons, but Applicant did not attempt to verify her claim; and that after Patient #3 claimed to have gone to the ER, Applicant added oxycodone 15mg to her medications, and then increased the dosage to 30mg on a subsequent visit, even though Patient #3 reported a "significant pain reduction and improvement" during that period; and
- 5) Applicant issued Patient #3 new prescriptions "at times when [she] should not have finished taking the same medication from a previous prescription had the prescription directions been properly followed."

Id. at 15-17.

As for Patient #4, the Board found that from May 19 through August 10, 2010, Applicant issued her twelve (12) controlled substance prescriptions for a total of approximately 1,290 dosage units. Id. at 17. These included four (4) prescriptions for 570 Lorcet (hydrocodone/acetaminophen) 10/650mg, four prescriptions for 480 Soma 350mg, and four prescriptions for 240 Xanax 2mg. Id. Here again, Applicant issued prescriptions for all drugs at each of her four visits. Id. at 17-18.

The Board then identified multiple failures on Applicant's part in complying with its regulations. These included:

- 1) that while Patient #4 reported a very high pain level throughout treatment, "there was no real analgesic response to the medication or improvement in general; and the continued prescribing of opiates and other controlled medications for pain was not supported";
- 2) Patient #4's MRI "show[ed] some mild degenerative changes," but was otherwise "unremarkable" and did not support "the amount of pain the patient was reporting"; however, "there [was] no outside consultation to determine the etiology of the patient's severe pain";
- 3) there was "no psychiatric evaluation" to support the prescribing of Xanax, and if "Xanax was being prescribed for muscle relaxation, then there [was] no justification for the additional prescribing of Soma";
- 4) Applicant subjected Patient #4 to a single urine drug screen, which occurred at her initial visit; however, given her history, "it was not appropriate to test [her] once at the beginning of treatment and not . . . during the treatment";
- 5) Applicant "continued the prescriptions previously issued to [her] by previous physicians and there [was] no indication or justification as to why [she] need[ed] this particular combination of medications in these particular quantities and strengths"; Applicant also recommended no treatment modalities "[o]ther than controlled substances, warm baths and heating pads";
- 6) Patient #4's file contained various red flags suggesting drug abuse, including that she had been discharged by a Louisiana pain clinic for testing positive on multiple

- occasions for drugs she had not been prescribed. The red flags included: a) an incident, four months earlier, when she tested positive for oxycodone, which had not been prescribed to her and she admitted that she used her husband's Percocet; and b) two incidents, which had occurred only two and three months before Applicant began prescribing to her, in which she attempted to use another person's urine during a urine drug screen. While Applicant obtained these records the day before he first prescribed controlled substances to Patient #4, he did not document having discussed these incidents with her; and
- 7) Applicant issued new prescriptions to Patient #4 "at times when [she] should not have finished taking the same medication from a previous prescription had the prescription directions been properly followed or the correct dosage taken."

Id. at 18-20.

Based on these findings, the Board found Applicant guilty of four counts of "administering, dispensing, or prescribing . . . narcotic drugs, or other drugs having addiction-forming or addiction-sustaining liability otherwise than in the course of legitimate professional practice." Id. at 21 (citing Miss. Code Ann. § 73-25-29(3)). It also found Applicant guilty of four counts of "prescribing controlled substances or other drugs having addiction-forming or addiction-sustaining liability for chronic pain in a non-therapeutic manner." Id. at 22 (citing id. § 73-25-29(13)). The Board further found Applicant guilty of four counts of "prescribing controlled substances for the treatment of chronic pain to a patient who has consumed or disposed of controlled substances and other drugs having addiction forming or addiction

sustaining liability other than in strict compliance with [his] directions.” Id. (citing Miss. Code Ann. § 73-25-29(13)).”⁷

The Board also found that during his testimony, Applicant “expressed very little understanding of the disease of addiction and possible drug abuse,” and that this, when, combined “with [the] clear evidence” that he “failed to comply with the Board’s rules . . . increased the risk of harm to the public.” Id. The Board further found that Applicant “either failed to identify or chose to ignore clear evidence of drug seeking behavior by the very patients he has an obligation to treat, heal and protect.” Id. Finally, the Board found that Applicant “willingly participated in a medical clinic . . . [which] had [the] primary purpose [of] hand[ing]-out controlled substances.” Id. at 22-23.

DISCUSSION

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner’s registration may be denied “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 this 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) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

⁷ In addition, the Board found Applicant guilty of four counts of “failing to conduct an appropriate risk/benefit analysis by review of previous medical history which was provided by another treating physician, which indicates there is a need for long-term controlled substances therapy,” as well as “fail[ing] to clearly enter into the record the analysis and a consultation/referral report which determines the underlying pathology or cause of the chronic pain.” GX 3, at 21 (citing Miss. Code Ann. § 73-25-29(13)). Finally, the Board found Applicant guilty of four counts of “failing to document a written treatment plan which contains stated objectives as a measure of successful treatment and planned diagnostic evaluations, e.g., psychiatric evaluation or other treatments.” Id. at 21-22 (citing Miss. Code Ann. § 73-25-29(13)).

Id. “These 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 registration [should be] denied.” Id.; see also Kevin Dennis, M.D., 78 FR 52787, 52794 (2013); MacKay v. DEA, 664 F.3d 808, 816 (10th Cir. 2010).

The Government has the burden of proving, by substantial evidence, that the requirements for the denial of an application, pursuant to 21 U.S.C. § 823(f), are met. 21 CFR 1301.44(e). This is so even in a non-contested case. Gabriel Sanchez, M.D., 78 FR 59060, 59063 (2013). Having considered all of the factors,⁸ I conclude that the Government’s evidence with respect to factors two and four establishes, prima facie, that the issuance of a new registration to Applicant “would be inconsistent with the public interest.” 21 U.S.C. § 823(f).

Factor One: The Recommendation of the Appropriate State Licensing Board

Noting the various findings of the Mississippi Board, the Government argues that “[i]n light of the Board’s Order, factor one weighs heavily in favor of a finding that granting Applicant’s . . . registration would be inconsistent with the public interest.” Request for Final Agency Action, at 4. While the Government is undoubtedly correct that the Board’s findings strongly support the denial of Applicant’s application – indeed, for reasons explained later, they are conclusive – its contention that factor one supports the denial of the application is misplaced.

Here, Applicant does not seek a new registration in Mississippi, where, because he has not been reinstated to practice medicine, he does not even meet the CSA’s threshold requirement that he be “authorized to dispense . . . controlled substances under the laws of the State in which he practices.” 21 U.S.C. § 823(f). Rather, he seeks registration in California, where, while he is

⁸ Having considered all of the factors, I conclude that it is not necessary to make findings with respect to factors three (the applicant’s conviction record) and five (such other conduct which may threaten public health and safety). See Jose G. Zavaleta, M.D., 76 FR 49506, 49507 (2011).

the subject of an Accusation filed by the Medical Board of California (MBC) (which is based on the Mississippi Board's Order), he nonetheless holds a current Physician's and Surgeon's Certificate. Because Applicant seeks registration in California, the MBC, and not the Mississippi Board is the "appropriate [s]tate licensing board" for the purpose of factor one.

Here, the MBC has not made a formal recommendation to the Agency as to what action should be taken in this matter. Moreover, Applicant currently holds an active California medical license.

That being said, "the Agency has long held that possession of state authority is not dispositive of the public interest inquiry." George Mathew, 75 FR 66138, 66145 (2010), pet. for rev. denied, Mathew v. DEA, No. 10-73480, slip. op. at 5 (9th Cir. Mar. 16, 2012). Instead, "the Controlled Substances Act requires that the Administrator . . . make an independent determination [from that made by state officials] as to whether the granting of controlled substance privileges would be in the public interest." Mortimer Levin, 57 FR 8680, 8681 (1992). Thus, the fact that Applicant currently has an active California license neither weighs in favor of, or against a finding that issuing a new registration "would be inconsistent with the public interest." 21 U.S.C. § 823(f).

Factors Two and Four: The Applicant's Experience in Dispensing Controlled Substances and Compliance with Applicable State or Federal Laws

To effectuate the dual goals of conquering drug abuse and controlling both the legitimate and illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." Gonzales v. Raich, 545 U.S. 1, 13 (2005). With respect to the dispensing of controlled substances, the closed system is maintained by a longstanding Agency regulation, which provides that "[a] prescription for a controlled substance

[is not] effective [unless it is] issued for a legitimate medical purpose by an individual practitioner acting in the usual course of [his] professional practice.” 21 CFR 1306.04(a). The regulation further provides that “an order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. § 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” Id.

As the Supreme Court recently explained, “the prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.” Gonzales v. Oregon, 546 U.S. 243, 274 (2006) (citing United States v. Moore, 423 U.S. 122, 135, 143 (1975)); see also United States v. Alerre, 430 F.3d 681, 691 (4th Cir. 2005), cert. denied, 547 U.S. 1113 (2006) (prescription requirement stands as a proscription against doctors acting not “as a healer[,] but as a seller of wares”).

As found above, following a hearing before the Mississippi Board, at which Applicant was represented by counsel, the Board made extensive factual findings regarding his treatment of four patients. Most significantly, the Board found Applicant guilty of four counts of “administering, dispensing, or prescribing . . . narcotic drugs, or other drugs having addiction-forming or addiction-sustaining liability otherwise than in the course of legitimate professional practice.” GX 3, at 21 (citing Miss. Code Ann. § 73-25-29(3)) (emphasis added). It also found Applicant guilty of four counts of “prescribing controlled substances or other drugs having addiction-forming or addiction-sustaining liability for chronic pain in a non-therapeutic manner.” Id. at 22 (citing id. § 73-25-29(13)) (emphasis added). The Board further found Applicant guilty of four counts of “prescribing controlled substances for the treatment of chronic pain to a patient

who has consumed or disposed of controlled substances and other drugs having addiction forming or addiction sustaining liability other than in strict compliance with [his] directions.” Id. (citing Miss. Code Ann. § 73-25-29(13)).

Because Applicant had a full and fair opportunity to litigate the issues raised in the Mississippi Board proceeding – and in fact, was represented by counsel and did apparently litigate the issues – the Board’s findings are entitled to preclusive effect in this proceeding. See Robert L. Dougherty, M.D., 76 FR 16823, 16830 (2011) (citing cases); see also Univ. of Tenn. v. Elliot, 478 U.S. 788, 797-98 (1986) (“When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata[.]”) (internal quotations and citations omitted); David A. Ruben, M.D., 78 FR 38363, 38365-67 (2013) (collateral estoppel precludes a party from re-litigating issues of fact or law that were previously decided against him in a state board proceeding); cf. Jose G. Zavaleta, M.D., 78 FR 27431, 27431-34 (2013) (“[a]llowing an applicant to relitigate issues which he/she had a full and fair opportunity to litigate in a prior proceeding but chose not to” will likely result in unnecessary waste of agency resources).

Moreover, the Board’s findings that Applicant prescribed controlled substances “otherwise than in the course of legitimate professional practice” and “in a non-therapeutic manner,” in violation of State law, also establish that he acted outside of “the usual course of professional practice” and without a “legitimate medical purpose” in prescribing to the four patients identified in the Board’s Order, and thus also violated the CSA.⁹ 21 CFR 1306.04(a);

⁹ In addition, the Board found Applicant guilty of four counts of “failing to conduct an appropriate risk/benefit analysis by review of previous medical history which was provided by another treating physician, which indicates there is a need for long-term controlled substances therapy” and by “fail[ing] to clearly enter into the record the analysis and a consultation/referral report which determines the underlying pathology or cause of the chronic pain.”

Cf. Kenneth Harold Bull, 78 FR 62666, 62674-75 n. 9 (2013) (rejecting ALJ’s conclusion that state board’s finding established violations of 21 CFR 1306.04(a), noting that state board’s “injudicious prescribing” standard was “not equivalent to the standard imposed under 21 CFR 1306.04(a)”). As the Board further found, Applicant “willingly participated in a medical clinic . . . [which] had [the] primary purpose [of] hand[ing]-out controlled substances.” GX 3, at 22-23. Thus, I conclude that the State Board’s findings support a finding that Applicant knowingly and intentionally diverted controlled substances. See 21 U.S.C. § 841(a)(1). I therefore hold that the Government has met its prima facie burden of showing why issuing a new registration to Applicant “would be inconsistent with the public interest.” Id. § 823(f).¹⁰

It is acknowledged that Applicant does not seek authority to dispense controlled substances in schedules II and III, but rather only those in schedule IV and V. GX 2, at 1. Be that as it may, the findings of the State Board conclusively establish that his misconduct is

GX 3, at 21 (citing Miss. Code Ann. § 73-25-29(13)). Finally, the Board found Applicant guilty of four counts of “failing to document a written treatment plan which contains stated objectives as a measure of successful treatment and planned diagnostic evaluations, e.g., psychiatric evaluation or other treatments.” Id. at 21-22 (citing Miss. Code Ann. § 73-25-29(13)). Not that it is needed given the Board’s findings which are discussed above, these findings provide additional support for the conclusion that Applicant acted outside the usual course of professional practice and lacked a legitimate medical purpose in prescribing controlled substances to the four patients. 21 CFR 1306.04(a).

¹⁰ The Board also found that Applicant ignored multiple red flags that the four patients were abusing controlled substances. These included that the patients sought early refills and did not comply with his dosing instructions, two patients had been terminated by prior physicians for non-compliance (one of whom was obtaining controlled substances from multiple doctors), another patient was driving a long distance to see him, and another patient had not only tested positive for a controlled substance which had not been prescribed to her, but twice attempted to use another person’s urine when subjected to a urine drug screen.

These findings provide further support for the conclusion that issuing a new registration to Applicant “would be inconsistent with the public interest.” 21 U.S.C. § 823(f). As the Administrator has held, “[a] practitioner who ignores the warning signs that [his] patients are either personally abusing or diverting controlled substances commits ‘acts inconsistent with the public interest,’ 21 U.S.C. § 824(a)(4), even if [he] is merely gullible or naive.” Jayam Krishna-Iyer, M.D., 74 FR 459, 460 n.3 (2009); see also Bienvenido Tan, M.D., 76 FR 17673, 17689 (2011) (quoting Paul J. Caragine, Jr., 63 FR 51592, 51601 (1998)) (“Just because misconduct is unintentional, innocent or devoid of improper motivation, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify” the revocation of an existing registration or the denial of an application for a registration.).

egregious and that he cannot be entrusted with authority to dispense controlled substances in any schedule, a conclusion which stands unrefuted given that Applicant waived his right to a hearing or to submit a written statement. Accordingly, because there is no evidence that Applicant acknowledges his misconduct and has undertaken any remedial measures,¹¹ I conclude that denial of his application is necessary to protect the public interest. See, e.g., Medicine Shoppe-Jonesborough, 73 FR 364, 387 (2008) (“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”); see also Jose G. Zavaleta, M.D., 76 FR 49506, 49507 (2011) (denying application for DEA registration in schedules IV and V where doctor violated federal law by, inter alia, issuing prescriptions outside the usual course of professional practice). Accordingly, I will order that his application be denied.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f), as well as 28 CFR 0.100(b) and 0.104, I order that the application of Zizhuang Li, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This order is effective immediately.

Dated: November 21, 2013

Thomas M. Harrigan
Deputy Administrator

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¹¹ As found above, the Mississippi Board required Applicant, as a condition of reinstatement, to take courses in controlled substance prescribing, recordkeeping, and medical ethics. There is, however, no evidence that he has taken any of these courses.