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Robert E. Maher, Jr.,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Jose Gonzalo Zavaleta, M.D.; Denial of Application

On February 23, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause (Order) to Jose Gonzalo Zavaleta, M.D. (Applicant), of Pineville, Louisiana. The Order proposed the denial of Applicant'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." Order at 1 (citing 21 U.S.C. 823(f)).

The Order alleged that Applicant voluntarily surrendered his DEA Certificate of Registration, BZ5998250, on March 26, 2008, after being charged with six counts of prescribing controlled substances beyond authority and accepted medical treatment, in violation of La. Rev. Stat. Ann. § 40:971 (C)(1)(2008) (effective Aug. 15, 2006). *Id.* The Order further alleged that Applicant prescribed controlled substances to undercover agents with "cursory or no medical examinations, and without a legitimate medical purpose in violation of 21 U.S.C. 841(a)(1)." *Id.* More specifically, the Order alleged that Applicant prescribed a total of 75 dosage units of hydrocodone (including Lortab and/or Lorcet), which are schedule III narcotics; 20 dosage units of Xanax, a schedule IV controlled substance; and six ounces of Phenergan with codeine, a schedule V narcotic cough syrup. *Id.* Finally, the Order that alleged "[Applicant] facilitated the undercover officers' procurement of drugs by fraudulent means" when he advised them to "provide false medical

information" to justify "illegitimate prescriptions." *Id.* at 2.

On March 2, 2009, the Order, which also notified Applicant of his right to either request a hearing on the allegations or to submit a written statement in lieu of a hearing, the procedures for doing so, and the consequence if he failed to do so, was served on Applicant by certified mail addressed to him at the address listed on his application. *Id.* at 2 (citing 21 CFR 1316.47; 21 CFR 1301.43). Since service of the Order, more than thirty days have now passed and neither Applicant, nor anyone purporting to represent him, has either requested a hearing or submitted a written statement in lieu of a hearing. *See* 21 CFR 1301.43(b)-(d). Accordingly, I find that Applicant has waived his rights to a hearing or to submit a written statement. *Id.* 1301.43(d). I therefore issue this Decision and Final Order without a hearing based on relevant material contained in the investigative record submitted by the Government. I make the following findings.

Findings

Applicant was previously the holder of DEA Certificate of Registration, BZ5998250, which authorized him to dispense controlled substances in schedules II through V as a practitioner at the registered location of 5629 Jackson Street Ext, Alexandria, Louisiana. Affidavit of Diversion Investigator (hereinafter, DI Aff.), at 1; Applicant Registration Information, at 1. However, on March 26, 2008, concurrent with Applicant's arrest on state drug charges (the circumstances of which are set forth below), he voluntarily surrendered his registration. DI Aff., at 1. Applicant's registration was then retired by DEA on March 27, 2008. Applicant Registration Information, at 1. On July 28, 2008, Applicant applied for a new DEA registration as a practitioner in schedules IV and V. *Id.*

Applicant first came to the attention of law enforcement on January 17, 2008, when Louisiana State Police received a call from a pharmacist that he had authorized prescriptions for "excessive amounts of name brand narcotics with no generic substitutions allowed." DI Aff., at 2. Upon receipt of this information, an undercover state trooper (UC1) visited Applicant's clinic with audio/video recording equipment on January 23, 2008. *Id.* When Applicant asked UC1 "why he was there," UC1 responded by requesting "[h]ydrocodone pain pills." *Id.* UC1 "initially denied that he was in pain but, after negotiating with [Applicant],

he agreed to falsely state that he was suffering from a sexually transmitted disease," and Applicant recorded this false information in UC1's medical file. *Id.* Then, Applicant, without any physical examination to verify the claim of illness or symptoms, wrote prescriptions for 15 Lortab¹ pills and an antibiotic. *Id.* The undercover agent paid \$100 for the visit. *Id.*

Five days later, on January 28, 2008, UC1 returned to Applicant's clinic seeking additional "pain pills." *Id.* However, Applicant denied his request for more pain pills "because 'big brother' was watching him." *Id.*

Thereafter, on January 30, February 8, and February 28, 2008, a second state trooper (UC2) visited Applicant's clinic in an undercover capacity, while equipped with an audio/video recording device. *Id.* At UC2's first visit, Applicant issued her a prescription for hydrocodone,² notwithstanding UC2's "initially den[ying] she was in pain" and "later stat[ing] she was in pain in order to obtain a prescription for hydrocodone." *Id.* At her second visit on February 8, Applicant provided prescriptions for hydrocodone and Phenergan with codeine,³ the latter being a cough syrup, "even though she had no cough or congestion and exhibited no such symptoms." *Id.* On UC2's third visit, she requested and obtained from Applicant, prescriptions for hydrocodone and Xanax.⁴ *Id.* To justify issuing the prescriptions, Applicant "coached" UC2 about what to say and recorded the coached statements in her medical file. *Id.* At the undercover visits, Applicant never "require[d] any medical records nor did he conduct any physical examinations." *Id.*

On March 20, 2008, after a state court judge issued a warrant for Applicant's arrest, Louisiana State Police alerted DEA to the investigation and pending arrest. *Id.* Thereafter, on March 26, 2008, Applicant was arrested and charged with "six counts of prescribing beyond authority and accepted medical treatment, a violation of Louisiana Revised Statute 40:971C(1)." *Id.* at 3. Based on Applicant's arrest, a DEA Diversion Investigator asked for the voluntary surrender of his DEA

¹ Lortab, which is a combination drug containing hydrocodone and acetaminophen, is a schedule III controlled substance. 21 CFR 1308.13(e)(iv).

² Hydrocodone is typically combined with acetaminophen. In this formulation, it is a schedule III controlled substance. 21 CFR 1308.13(e)(iv).

³ Phenergan with codeine cough syrup consists of a combination of promethazine and codeine; it is a schedule V controlled substance. 21 CFR 1308.15(c).

⁴ Xanax (alprazolam) is a schedule IV controlled substance; 21 CFR 1308.14(c)(1).

registration; Applicant agreed and signed a DEA-104, Voluntary Surrender of Controlled Substance Privileges. *Id.*

Four months later, on July 28, 2008, Applicant submitted a DEA application for a new registration as a practitioner in schedules IV and V. Zavaleta Application Information at 1. On his application, Applicant stated that “the medical board says there is no merit for any disciplinary action,” he “can continue working,” and his “license is clear.” *Id.* Applicant further stated that the State Police had yet to charge him and that the charges may be dropped. *Id.*

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 this matter, while I have considered all of the factors, I conclude that it is not necessary to make findings with respect to factors one (the recommendation of the state licensing board), three (applicant’s conviction record) and five (such other conduct which may threaten public health and safety). I find that the Government’s evidence with respect to Applicant’s experience in dispensing controlled substances (factor two) and his compliance with applicable Federal and

State laws related to the distribution and dispensing of controlled substances (factor four) makes out a *prima facie* case that Applicant has committed acts which render his registration “inconsistent with the public interest.” 21 U.S.C. 823(f), 824(a)(4). I will therefore order that his pending application for registration be denied.

Factors Two and Four—Applicant’s Experience in Dispensing Controlled Substances and Compliance with Applicable Laws Related to Controlled Substances

Under a longstanding DEA regulation, 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). This 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 related to controlled substances.” *Id.*; see also *La. Rev. Stat. Ann.* § 40:961(33) (2008) (effective Aug. 15, 2004);⁵ *La. Rev. Stat. Ann.* § 40:1238.2(A) (2008) (effective Aug. 15, 2006).⁶

As the Supreme Court recently explained, “the [CSA’s] 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

⁵ Louisiana law defines the term “prescription” to mean “a written request for a drug * * * issued by a licensed physician * * * for a legitimate medical purpose, for the purpose of correcting a physical, mental, or bodily ailment, and acting in good faith in the usual course of his professional practice.” *La. Rev. Stat. Ann.* § 40:961(33).

⁶ This statute provides that:

A prescription, in order to be effective in legalizing the possession of legend drugs, shall be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs. An order purporting to be a prescription issued to a drug abuser or habitual user of legend drugs, not in the course of professional treatment, is not a prescription within the meaning and intent of this Section. Any person who knows or should know that he or she is filling such a prescription or order to a drug abuser or habitual user of legend drugs, as well as the person issuing the prescription, may be charged with a violation of this Section.

La. Rev. Stat. Ann. § 40:1238.2(A).

La. Rev. Stat. Ann. § 40:1238.2(A) (2008) (effective Aug. 15, 2006).

Under the CSA, it is fundamental that a practitioner must establish and maintain a bonafide doctor-patient relationship in order to act “in the usual course of * * * professional practice” and to issue a prescription for a “legitimate medical purpose.” *Laurence T. McKinney*, 73 FR 43260, 43265 n.22 (2008); see also *Moore*, 423 U.S. at 142–43 (noting that evidence established that physician “exceeded the bounds of ‘professional practice,’” when “he gave inadequate physical examinations or none at all,” “ignored the results of the tests he did make,” and “took no precautions against * * * misuse and diversion”). The CSA generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. See *Kamir Garcés-Mejías*, 72 FR 54931, 54935 (2007); *United Prescription Services, Inc.*, 72 FR 50397, 50407 (2007); but see 21 U.S.C. 829(e)(2)(B) (providing Federal standard for prescribing over the Internet).

Under the regulation of the Louisiana Board of Medical Examiners, in the treatment of “intractable pain * * * a physician shall comply” with the Louisiana Pain Rules, including the requirements that a physician perform an “[e]valuation of the [p]atient” and make a “[m]edical [d]iagnosis.” *La. Admin. Code tit. 46:XLV.6921(A)* (2008). “Evaluation of the patient shall initially include relevant medical, pain, alcohol and substance abuse histories, an assessment of the impact of pain on the patient’s physical and psychological functions, a review of previous diagnostics studies, previously utilized therapies, an assessment of coexisting illnesses, diseases, or conditions, and an appropriate physical examination.” *Id.* (emphasis added); see also *Armstrong v. La. State Bd. of Med. Examiners*, 868 So. 2d 830, 840 (La.App. 4 Cir. Feb. 18, 2004) (upholding two year suspension of physician’s license; noting that when prescribing controlled substances for relief of non-malignant pain is “unaccompanied by appropriate testing, diagnosis, oversight and monitoring * * * the physician falls below generally accepted standards of care”); *Pastorek v. La. State Bd. of Med. Examiners*, 4 So. 3d 833 (La.App. 4 Cir. Dec. 17, 2008). The Board’s rules further require a “medical diagnosis * * * be established and fully documented in the patient’s medical record.” *La. Admin. Code tit. 46:XLV.6921(A)(2)* (2008).

Louisiana law further prohibits a physician from “[a]ssist[ing] a patient or any other person in obtaining a controlled dangerous substance through

misrepresentation, fraud, forgery, deception, or subterfuge.” La. Rev. Stat. Ann. § 40:971.2 (2008) (effective Aug. 15, 2005). It is also unlawful for a physician to “prescribe * * * legally controlled substances beyond his respective prescribing authority or for a purpose other than accepted medical treatment of disease, condition, or illness. *Id.*, at § 40:971(C)(1) (2008) (effective Sept. 9, 1988).

As found above, on four occasions, Applicant prescribed drugs containing hydrocodone (including Lortab and/or Lorcet), which are schedule III narcotics; Xanax, a schedule IV controlled substance; and Phenergan with codeine, a schedule V narcotic cough syrup, to Louisiana State Troopers acting in undercover capacities. *See* DI Aff., at 2. Notably, Applicant issued these prescriptions without conducting a physical examination at any of the visits and the undercover agents received these prescriptions even though they did not demonstrate the conditions or symptoms that would justify the prescriptions. *Id.*

Moreover, both undercover agents initially denied they were in pain, but Applicant assisted the agents in obtaining controlled substances by encouraging them to make false statements. *See id.* For example, while he denied being in pain, UC1 asked Applicant for “[h]ydrocodone pain pills,” and then “negotiate[d]” with Applicant to “falsely state” he had a sexually transmitted disease. *Id.* Likewise, Applicant also “coached” the second undercover agent on what to say to “justify issuing the prescriptions and wrote her coached statements in a medical file.” *Id.* Therefore, I conclude that Applicant failed to establish a physician-patient relationship, lacked a legitimate medical purpose, and acted outside of the usual course of professional practice in prescribing controlled substances to the undercover agents and thus violated Federal law. *See* 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1); *see also Louisiana v. Moody*, 393 So. 2d 1212, 1215 (La. 1981) (holding that physician furnished prescriptions for “other than a legitimate medical purpose” based on evidence showing that prescriptions were issued in response to specific requests of patients and physician did not conduct physical examinations or take medical histories).

I therefore hold that granting Applicant’s application for a new registration “would be inconsistent with the public interest.” 21 U.S.C. 823(f). Accordingly, I will order that

Applicant’s pending application be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Jose Gonzalo Zavaleta, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This order is effective September 9, 2011.

Dated: July 27, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–20284 Filed 8–9–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Office of Disability Employment Program

“Add Us In” Initiative

AGENCY: Office of Disability Employment Policy, Department of Labor.

ACTION: Correction to the Funding Opportunity Number and Closing Date.

SUMMARY: The Office of Disability Employment Policy, Department of Labor is correcting the New Notice of Availability of Funds and Solicitation for Grant Applications (SGA) for Cooperative Agreements published in the **Federal Register** on August 4, 2011 at 76 FR 150. Specifically, we are correcting the Funding Opportunity Number to SGA 11–05 and the Closing Date for receipt of applications to September 2, 2011. The full Solicitation for Grant Applications is posted on <http://www.grants.gov> under U.S. Department of Labor/ODEP. If you need to speak to a person concerning these grants, you may telephone Cassandra Mitchell at 202–693–4570 (not a toll-free number).

Signed in Washington, DC, this 4th day of August 2011.

Cassandra R. Mitchell,

Grant Officer.

[FR Doc. 2011–20211 Filed 8–9–11; 8:45 am]

BILLING CODE 4510–FT–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 11–073]

NASA Advisory Council; Science Committee; Earth Science Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Earth Science Subcommittee of the NASA Advisory Council (NAC). This Subcommittee reports to the Science Committee of the NAC. The Meeting will be held for the purpose of soliciting from the scientific community and other persons scientific and technical information relevant to program planning.

DATES: Wednesday, August 31, 1 p.m. to 3 p.m. E.D.T.

ADDRESSES: This meeting will take place telephonically. Any interested person may call the USA toll free conference call number 888–603–9610, pass code ESS, to participate in this meeting by telephone.

FOR FURTHER INFORMATION CONTACT: Ms. Marian Norris, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–4452, fax (202) 358–4118, or mnorris@nasa.gov.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. The agenda for the meeting includes the following topics:

—Government Performance and Results Act Review

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants.

August 5, 2011.

Susan M. Burch,

Acting Director, Advisory Committee Management Division, National Aeronautics and Space Administration.

[FR Doc. 2011–20275 Filed 8–9–11; 8:45 am]

BILLING CODE 7510–13–P