requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's Handbook on E-Filing, available on the Commission's Web site at *http://edis.usitc.gov*, elaborates upon the Commission's rules with respect to electronic filing.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

**Authority:** These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.12 of the Commission's rules.

Issued: September 19, 2013.

By order of the Commission.

**Lisa R. Barton,**

*Acting Secretary to the Commission.*

[FR Doc. 2013–23277 Filed 9–24–13; 8:45 am]

**BILLING CODE 7020–02–P**

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Gabriel Sanchez, M.D.; Decision and Order

On August 14, 2012, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Gabriel Sanchez, M.D. (hereinafter, Registrant), of Delray Beach, Florida. The Show Cause Order proposed the revocation of Registrant's DEA Certification of Registration AS9790420, and the denial of any pending applications for renewal or modification of the registration, on the ground that his ''continued registration is inconsistent with the public interest.'' GX 9, at 1 (citing 21 U.S.C. 824(a)(4) and 823(f)).

The Show Cause Order alleged that in July of 2010, the Registrant issued prescriptions for oxycodone, a schedule II controlled substance, and carisoprodol, a schedule IV controlled substance under Florida law, to two undercover law enforcement officers (UCs). *Id.* The Show Cause Order alleged that these prescriptions ''were not for a legitimate medical purpose in the usual course of professional practice because'' the Registrant: (1) Did not ''provide a legitimate diagnosis to warrant'' the prescriptions; (2) ''failed to conduct a sufficient physical exam to determine a legitimate medical need'' for the controlled substance prescriptions; (3) ''prescribed controlled substances to the UCs despite evidence that they had illegally obtained, and were attempting to illegally obtain and abuse controlled substances''; and (4) ''prescribed oxycodone in large quantities to the UCs absent any reliable evidence'' that they were opioid tolerant. *Id.* at 1–2.

The Show Cause Order thus alleged that the oxycodone prescriptions issued by the Registrant ''to the UCs were for other than a legitimate medical purpose in the usual course of professional practice in violation of Federal law.'' *Id.* at 2 (citing 21 U.S.C. 829, 841(a) and 21 CFR 1306.04(a), 1301.71). Additionally, the Show Cause Order alleged that ''[t]he prescriptions for oxycodone and carisoprodol that [the Registrant] issued to the UCs'' violated Florida law because the prescriptions ''were for other than a legitimate medical purpose in the usual course of professional practice.'' *Id.* (citing Fla. Stat. Ann. § 456.072(1)(gg) and Fla. Admin. Code r. 64B8–9.013).

The Show Cause Order also notified the Registrant 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 electing either option, and the consequences of failing to do either. *Id.* On August 16, 2012, the Government accomplished service by personally serving the Registrant with the Order to Show Cause at the DEA Miami Field Division. GX 6. Registrant neither submitted a request for a hearing nor a written statement in lieu of a hearing. Req. for Final Agency Action, at 1.

On May 20, 2012, the Government submitted a Request for Final Agency Action along with the investigative record it compiled. Having reviewed the record, I find that more than thirty days have now passed since the date of service of the Show Cause Order and neither Registrant, nor any one purporting to represent him, has filed a request for hearing or submitted a written statement in lieu of a hearing. Accordingly, I find that Registrant has waived his right to a hearing or to submit a written statement in lieu of a hearing and issue this Decision and Final Order based on relevant evidence contained in the record submitted by the Government. 21 CFR 1301.43(d) & (e). I make the following findings.

### Findings

Registrant is a physician who is currently registered with DEA as a practitioner in schedules II–V at the registered address of 16244 South Military Trail, Suite 490, Delray Beach, Florida 33484. GX 8. Registrant's registration expires by its terms on February 28, 2015. *Id.*

In July of 2010, Registrant was working as a physician at Pompano Beach Medical, located at 553 E. Sample Road, Pompano Beach, Florida 33064. GX 7. According to the affidavit of a DEA Diversion Investigator, on July 15, 2010, two DEA Task Force Officers (hereinafter, TFO One and TFO Two) conducted undercover visits to this medical facility and were seen by the Registrant. *Id.* at 2.

### TFO One's Visit

On July 15, 2010, TFO One conducted an undercover visit at Pompano Beach Medical under the name of Larry Olsen. *Id.* During this visit, TFO One filled out a follow-up medical form,[1] and paid $200 in cash. *Id.* On this form, TFO One indicated that without medication, his pain level was between zero and two. GX 4, at 3.

Before being seen by Registrant, TFO One was seen by Leah Gustavson, a medical assistant. *Id.* at 1–2; GX 7, at 2. When questioned by Gustavson about his pain level being between zero and two, TFO One stated that ''the pain hasn't been near as bad as it . . . as it . . . uh . . . You know. It has been good.'' GX 4, at 3. TFO One informed Gustavson that his pain was good even without medication, as long as he ''watch[ed] what [he is] doing.'' *Id.* He also indicated that his pain level had decreased even without the medication, leading Gustavson to indicate that the doctor would probably decrease his dosage. *Id.* at 4–5.

TFO One then informed Gustavson that he ''may miss [his] next visit because [he would be] visiting the Baltimore area,'' and was concerned about having enough medication to last him through the visit. *Id.* at 5. Gustavson informed TFO One that ''[w]e're not allowed to give you extra.'' *Id.* Gustavson then asked if TFO One was experiencing any side effects from his medication. *Id.* at 5–6. TFO One stated that he did not have any side effects, and noted that he does not ''really get sick of medication . . . to be honest with you.'' *Id.* at 6. However, TFO One indicated that he was

[1] TFO One had visited the clinic twice before this visit, once in May, and once in June; at these visits, he was seen by another doctor. GX 7, at 2; GX 3, at 21–22. During the May visit, TFO One received prescriptions for 150 dosage units of oxycodone 30 mg, sixty dosage units of oxycodone 15 mg, and sixty dosage units of carisoprodol. GX 3, at 22. During the June visit, TFO One received prescriptions for 160 dosage units of oxycodone 30 mg, ninety dosage units of oxycodone 15 mg, and sixty dosage units of carisoprodol. *Id.* at 21.

experiencing sleep problems. *Id.* Gustavson then asked TFO One to complete ''a series of range of motion tests, such as touching his toes and standing on the back of his heels.'' GX 7, at 2. During these tests, Gustavson asked whether TFO One felt any tenderness, to which TFO One stated that he did not. GX 4, at 7.

Following these tests, Registrant entered the room, greeted TFO One, and inquired about his symptoms. *Id.* at 8–9. TFO One replied: ''Oh! Lower back.'' *Id.* Registrant then asked TFO One to lay down, face up, on the examination table, and proceeded to perform a series of range of motion tests. *Id.* at 9; GX 7, at 2. When asked if he experienced any pain during these tests, TFO One answered, ''[n]ot much.'' GX 4, at 9–10; GX 7, at 2.

After discussing TFO One's previous visits to the clinic where he was seen by another doctor, Registrant noted that he had ''bulging of the disc'' but that there was no ''compression of the nerves of the spinal cord. . . .'' GX 4, at 10–11. Despite this finding, Registrant informed TFO One that he would be getting the same medication. *Id.* at 11. Registrant also suggested that TFO One could ''go swimming,'' and ''may not need medications'' because his ''MRI [didn't] show any compression of the nerves.'' *Id.* Nonetheless, Registrant then noted that TFO One was also taking Soma (carisoprodol), and said that he would get the same medication. *Id.*

TFO One then asked Registrant if he ''[w]ould . . . increase the medicine if the person is going out of town for any period of time.'' *Id.* at 12. After initially saying no, Registrant asked TFO One how long he would be out of town. *Id.* TFO One replied, ''[p]robably three (3) weeks or so.'' *Id.* Registrant asked TFO One if he would come back in eight weeks; TFO One confirmed that he would. *Id.* Registrant then asked, ''[t]hat's what you want,'' to which TFO One answered: ''[y]eah,'' and noted that he would probably miss his next appointment with Registrant. *Id.* Registrant then prescribed to TFO One 200 dosage units of oxycodone 30 mg, 120 dosage units of oxycodone 15 mg, and sixty dosage units of carisoprodol. GX 3, at 19. Registrant noted that he had increased TFO One's medication, directed him to save some of the oxycodone 30 mg pills, and told him that he needed to come back in six weeks. GX 4, at 12–16.

**TFO Two's Visit**

A second TFO, who used the name Gregory Martin, also visited Pompano Beach Medical on July 15, 2010. GX 7, at 2; GX 2, at 2. As was the case with TFO One, TFO Two had been seen by another physician at the clinic during two prior visits. GX 7, at 2; GX 2, at 25–28. At the first visit, in May 2010, TFO Two was prescribed 160 dosage units of oxycodone 30 mg, and sixty dosage units of carisoprodol. GX 2, at 28. At the next visit, in June 2010, TFO Two received prescriptions for 190 dosage units of oxycodone 30 mg, and sixty dosage units of carisoprodol. *Id.* at 25.

During the July 2010 visit, TFO Two ''paid $200 cash . . . and filled out a patient follow-up form.'' GX 7, at 2. He then was seen by Leah Gustavson, who noted that his ''pain is pretty well controlled,'' to which TFO Two replied,''[y]eah.'' GX 5, at 2. Gustavson confirmed that TFO Two's pain was in his mid-back, and asked whether he was experiencing any side effects. *Id.* at 2–3. TFO Two reported that he did not have any side effects. *Id.* at 3. Gustavson then proceeded to conduct a series of range of motion tests, which included asking TFO Two to ''stand up and touch [his] toes.'' *Id.* at 4–5. TFO Two and Gustavson discussed the TFO's current prescriptions, with the TFO mentioning that at his previous visit, the other doctor had stated that he would give the TFO a prescription for oxycodone 15 mg for breakthrough pain. *Id.* at 7. After making a note of TFO Two's request, *id.,* Gustavson told him that she was going to break up his prescription for 190 dosage units of oxycodone 30 mg into two prescriptions, because ''[s]ome [pharmacies] don't like to dispense more than one hundred eighty (180).'' *Id.* at 8. While discussing his carisoprodol prescription, TFO Two informed Gustavson that he was taking ''maybe one a day,'' leading Gustavson to suggest reducing the prescription to thirty dosage units, or giving him forty so he will ''have a couple of extra.'' *Id.* at 8–9.

Registrant then entered the room to see TFO Two. *Id.* at 13. After discussing TFO Two's back pain, Registrant had him perform additional range of motion tests, during which he did not indicate significant pain. *Id.* at 14. Instead, TFO Two stated that he had some stiffness in his legs, and a ''little twitch'' when moving his head to the left. *Id.* at 14–15. Registrant noted that he did not ''see too much of the problem,'' and when examining the TFO's purported injury, observed that there was ''no compromise of . . . the nerves at all.'' *Id.* at 15. TFO Two then described his pain as ''an annoyance.'' *Id.*

Registrant questioned TFO Two's need for the amount of oxycodone he was being prescribed, noting that 190 dosage units ''is a big dose,'' and reiterating that he did not ''have any compression of the nerves, or the spinal column, or the nerve root,'' and that it was ''difficult to understand that [he] ha[d] so much pain in there.'' *Id.* at 16–17. TFO Two again mentioned his having discussed receiving a prescription for oxycodone 15 mg with the previous physician; Registrant told the TFO that he would ''get [the TFO] some . . . to take in between then.'' *Id.* at 17.

However, Registrant then observed that TFO Two was taking ''a lot of oxycodone'' for ''that little problem.'' *Id.* Registrant again reiterated that there was ''no compromise in the nerves'' and asked the TFO if he exercised. *Id.* Registrant told the TFO that swimming ''could improve the flexibility of the abs and strengthening of the muscles,'' and encouraged him to ''[t]ry to do it often.'' *Id.* at 17–18. Registrant then informed the TFO that he was writing the prescription for oxycodone 15 mg at his request. *Id.* at 18. Registrant also discussed with the TFO splitting the prescription for oxycodone 30 mg into two prescriptions to avoid issues with pharmacies refusing to fill the prescription. *Id.* at 18–19. TFO Two received two prescriptions for oxycodone 30 mg: one for 180 dosage units, and the other for ten dosage units; a prescription for 100 dosage units of oxycodone 15 mg; and a prescription for forty dosage units of carisoprodol. GX 2, at 22.

**Evaluation of TFO Visits By the Government's Expert**

Dr. Reuben Hoch, M.D., reviewed the medical files for both TFOs, along with the recordings and transcripts of their visits with Registrant, and provided ''an expert opinion regarding the prescribing practices of [Registrant].'' GX 10, at 1. Dr. Hoch is an interventional pain medicine specialist and anesthesiologist practicing at Boca Raton Pain Medicine in Boca Raton, Florida. GX 10, at 1–2. Dr. Hoch received his medical degree from the Sackler School of Medicine at Tel Aviv University in 1988 and is Board Certified in Anesthesiology and Pain Medicine by the American Board of Anesthesiology. *Id.* at 1; GX 1, at 1. Dr. Hoch has ''served as an expert witness on approximately ten different occasions.'' GX 10, at 1.

Based on his review of the medical files, transcripts and recordings, Dr. Hoch noted, *inter alia,* that Registrant ''performed a brief and cursory physical exam'' of both TFOs, and that ''in each case, the officer received prescriptions for more oxycodone than he had during each officer's previous two visits at the clinic.'' *Id.* at 2. Dr. Hoch's observations

led him to ''conclude that, in [his] opinion, the Registrant failed to establish a sufficient doctor patient relationship with either TFO [One] or TFO [Two] and that the prescribing of controlled substances was outside the usual course of professional practice and for other than a legitimate medical purpose.'' *Id.*

In support of this conclusion, Dr. Hoch found that the Registrant did not conduct ''an adequate evaluation of either patient,'' observing that ''a complete medical history was not taken.'' *Id.* Nor, according Dr. Hoch, did it appear from the records ''that the registrant made a serious inquiry into the cause of each patient's pain,'' which is required ''[i]n a valid doctor/patient relationship.'' *Id.* Dr. Hoch further explained that in order to complete a sufficient medical history, a physician should ''review the records of other physicians who have treated the patient.'' *Id.* Dr. Hoch noted that while both TFOs signed releases allowing access to their medical records, there were ''no prior medical records included or referenced in the medical file.'' *Id.*

Dr. Hoch further observed that the Registrant did not ''conduct an adequate physical examination of [either] officer,'' and stated that ''during Registrant's (or his medical assistant's) examinations, neither officer demonstrated pain sufficient to justify the repeated prescribing of controlled substances.'' *Id.* Dr. Hoch also found that Registrant did not adequately address ''the effect of pain on the officers' physical and psychological function,'' which Dr. Hoch characterized as an ''important standard of pain management.'' *Id.*

Dr. Hoch's also found that Registrant ''failed to create and/or document a sufficient treatment plan.'' *Id.* Dr. Hoch noted that Registrant did not recommend any ''further diagnostic evaluations or other therapies except to suggest that each officer attempt swimming,'' even though each officer's MRI ''failed to demonstrate serious enough pathology for the officers to receive the large amounts of controlled substances that were prescribed.'' *Id.* at 2–3. Dr. Hoch then observed that the pathologies shown on the MRI ''can usually be addressed by other means, such as physical therapy, exercise, work strengthening programs, abdominal core training, anti-inflammatories, and at times, injections such as nerve blocks with corticosteroids.'' *Id.* at 3.

Based on Registrant's statements during his examinations of each TFO, Dr. Hoch also noted that even Registrant had doubts as to whether ''there was a legitimate medical need to prescribe the large amounts of opioid medications that were prescribed.'' *Id.* However, Dr. Hoch observed that ''there was no attempt by Registrant to evaluate the appropriateness of continued treatment except to express doubt about the continued prescribing of opioid medications.'' *Id.* Moreover, notwithstanding the doubts Registrant expressed about utility of this course of treatment, he actually increased the amount of controlled substances prescribed to both TFOs. *Id.* Dr. Hoch thus opined that these actions demonstrate that ''there was an insufficient review of the course of treatment. . . .'' *Id.*

Dr. Hoch further concluded ''that Registrant failed to sufficiently monitor the officers' compliance in medication usage.'' *Id.* This conclusion was based on the fact that Registrant increased both oxycodone prescriptions for TFO One, ''despite Registrant's expressed doubts about the need for so much medication.'' *Id.* Dr. Hoch then observed that Registrant increased these prescriptions based solely on TFO One's request and accompanying representation that he might miss his next appointment. *Id.* Dr. Hoch stated that TFO One's behavior ''should have indicated a possible red flag for drug abuse.'' *Id.*

Dr. Hoch found ''the evidence of possible drug abuse . . . even more obvious'' with respect to TFO Two. *Id.* Dr. Hoch's conclusion was based on the fact that ''TFO [Two] simply asked for more medication, not because of any new symptoms or pathology, but because another doctor had allegedly promised him more medication for 'breakthrough [pain]' at his last appointment.'' *Id.* Despite this warning sign, and ''without consulting the medical record,'' Registrant issued a prescription for 100 dosage units of oxycodone 15 mg to TFO Two. *Id.* Dr. Hoch concluded ''that Registrant failed to give the required special attention to the officers who . . . both demonstrated that they were at risk for misusing their medications.'' *Id.* at 3–4. Dr. Hoch further concluded that Registrant's actions in providing TFO Two with additional oxycodone for ''breakthrough pain'' lacked a legitimate medical justification and was based solely on the TFO's request for that medication. *Id.* at 4.

Finally, Dr. Hoch concluded that ''there was no legitimate medical justification for prescribing carisoprodol . . . to either TFO [One] or TFO [Two].'' *Id.* Dr. Hoch noted that neither TFO's medical record contained ''any medical evidence justifying the need for prescribing carisoprodol.'' *Id.* Dr. Hoch's expert opinion regarding Registrant's treatment of and prescribing to the TFOs stands unrefuted and ''is sufficiently reliable to be accepted and relied upon in this [Order].'' *See Cynthia M. Cadet, M.D.,* 76 FR 19450, 19458 (2011).

**DI McRae's Interview of Registrant**

Following the July 2010 visits by the TFOs with Registrant, and Dr. Hoch's evaluation of their medical records and recordings and transcripts of the visits, a DEA Diversion Investigator (DI) and a third TFO interviewed Registrant regarding ''his employment at Pompano Beach Medical.'' GX 7, at 3. During this interview, Registrant informed the DI and the third TFO that he was currently employed at an entity named: ''A Pain Clinic of Delray, Inc.'' *Id.* Regarding his employment at Pompano Beach Medical, Registrant stated that ''he was taught that if he prescribed fewer than 200 pills of oxycodone in a single prescription and conducted a physical examination, there would not be a 'problem' with the prescription.'' *Id.* Registrant admitted that due to ''the large volume of patients he was required to see at the clinic, a physical exam lasted only 5–10 minutes.'' *Id.*

**Discussion**

Under the CSA, ''[a] registration pursuant to section 823 of this title to manufacture, distribute, or 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.'' [2] 21 U.S.C. 824(a)(4). In determining ''the public interest'' with respect to 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 [registrant's] experience in dispensing, or conducting research with respect to 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).

[2] Pursuant to 28 CFR 0.100(b), this authority has been delegated by the Attorney General to the Administrator of the Drug Enforcement Administration.

''[T]hese factors are . . . considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). It is well settled that I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem appropriate in determining whether a registration should be revoked.'' *Id.; see also MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222 (quoting *Hoxie,* 419 F.3d at 482)).[3]

The Government has the burden of proving, by a preponderance of the evidence, that the requirements for revocation or suspension pursuant to 21 U.S.C. 824(a) are met. 21 CFR 1301.44(e). This is so even in a non-contested case.

In this matter, while I have considered all of the factors,[4] I conclude that the Government's evidence with respect to Registrant's experience in dispensing controlled substances (factor two), and his compliance with applicable laws related to controlled substances (factor four), establishes that Registrant's continued registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f). Because Registrant waived his right to present evidence in rebuttal of the Government's *prima facie* case, I will order that his registration be revoked.

[3] ''In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer,* 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *See MacKay,* 664 F.3d at 821.

[4] As for factor one, the Government presented no evidence regarding the status of Registrant's state license. However, even assuming that Registrant currently holds a valid state license authorizing him to prescribe controlled substances, this factor is not dispositive of the public interest determination ''because DEA has [a] separate oversight responsibility with respect to controlled substances.'' *MacKay,* 664 F.3d at 818.

Regarding factor three, there is no evidence that Registrant has been convicted of an offense related to the manufacture, distribution or dispensing of controlled substances. However, as there are a number of reasons why a person may never be convicted of an offense falling under this factor, let alone be prosecuted for one, ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is thus not dispositive. *Dewey C. MacKay,* 75 FR 49956, 49973 (2010), *pet. for rev. denied, MacKay,* 664 F.3d at 810.

*Factors Two and Four—The Registrant's Experience in Dispensing Controlled Substances and Compliance With Applicable Federal and State 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* Fla. Stat. § 893.05(1) (''A practitioner, in good faith and in the course of his or her professional practice only, may prescribe . . . a controlled substance[.]''); *id.* § 893.13(1)(a) (rendering it ''unlawful for any persons to sell, manufacture, or deliver . . . a controlled substance'' except as authorized by the Florida Comprehensive Drug Abuse Prevention and Control Act, Fla. Stat. §§ 893.01 *et seq.*); *id.* § 458.331(q) (providing that prescribing ''any controlled substance, other than in the course of the physician's professional practice,'' is grounds for ''disciplinary action'').[5]

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)).

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 Garces-Mejias,* 72 FR 54931, 54935 (2007); *United Prescription Servs., Inc.,* 72 FR 50397, 50407 (2007); *but see* 21 U.S.C. 829(e)(2)(B) (providing federal standard for prescribing over the internet).

[5] Florida law defines the term ''prescription'' to mean, in relevant part, ''an order for drugs . . . written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs . . ., issued in good faith and in the course of professional practice.'' Fla. Stat. § 893.02(22).

At the time of the TFOs' visits, the Florida Board of Medicine had, by regulation, adopted Standards for the Use of Controlled Substances for the Treatment of Pain.[6] In promulgating these standards, the Board explained that it ''will consider prescribing . . . controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain *or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain* and in compliance with applicable state or federal law.'' Fla. Admin. Code r.64B8–9.013(1)(e) (2009) (emphasis added). The Board further explained that the standards were ''not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.'' *Id.* at § 1(g).

Of particular relevance here is the Board's then-existing ''Evaluation of the Patient'' standard. This standard provided that:

> A complete medical history and physical examination must be conducted and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.

*Id.* § (3)(a).

[6] In October 2010, the Board issued a new regulation which, *inter alia,* amended various provisions of the guidelines by substituting the word ''shall'' for ''should.'' For example, before the amendment, the standard governing the treatment plan stated that ''[t]he written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved psycho social function.'' Fla. Admin. Code r.64B8–9.013(3)(b). So too, the informed consent standard provided that ''[t]he physician should discuss the risks and benefits of the use of controlled substances with the patient.'' *Id.* § (3)(c). Following the amendment, both of these provisions use the word ''shall'' rather than ''should.''

Here, the Government's Expert provided substantial evidence that Registrant acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed controlled substances to the TFOs. As the Expert explained, and notwithstanding the Florida Board's ''Evaluation of the Patient'' standard, Registrant did not conduct an adequate evaluation of the TFOs in that he failed to take a complete medical history, did not make ''a serious inquiry into the cause of each [TFO's] pain,'' and did not ''conduct an adequate physical examination of'' of either TFO. GX 10, at 2. The Expert further observed that during the examination of the TFOs, ''neither officer demonstrated pain sufficient to justify the repeated prescribing of controlled substances'' and that Registrant did not adequately address ''the effect of pain on the officers' physical and psychological function.'' *Id.*

The Expert thus concluded that ''Registrant failed to establish a sufficient doctor patient relationship with either TFO . . . and that [his] prescribing of controlled substances [to them] was outside the usual course of professional practice and for other than a legitimate medical purpose.'' [7] *Id.* at 2. Accordingly, I find that Respondent violated the CSA's prescription regulation and that he knowingly or intentionally diverted controlled substances when he prescribed oxycodone to the TFOs. *See* 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1); *see also* Fla. Stat. §§ 893.05(1), 893.13(1)(a).

I therefore hold that the Government's evidence with respect to factors two and four establishes that Registrant ''has committed such acts as would render his registration . . . inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).[8] Because Registrant waived his right to a hearing (or to submit a written statement in lieu of a hearing), there is no evidence in the record to refute the conclusion that his continued registration is ''inconsistent with the public interest.'' *Id.* Accordingly, I will order that Registrant's registration be revoked and that any pending applications be denied.

## Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration AS9790420, issued to Gabriel Sanchez, M.D., be, and hereby is, revoked. I further order that any pending application of Gabriel Sanchez, M.D., to renew or modify the above registration be, and it hereby is, denied. This Order is effective October 25, 2013.

Dated: September 17, 2013.

**Michele M. Leonhart,**

*Administrator.*

[FR Doc. 2013–23285 Filed 9–24–13; 8:45 am]

**BILLING CODE 4410–09–P**

[7] The Expert also noted that Registrant ''failed to create and/or document a sufficient treatment plan''; failed to order ''further diagnostic evaluations,'' even though each TFO's MRI ''failed to demonstrate serious enough pathology for the officer to receive the large amounts of controlled substances that were prescribed''; and that the pathologies observed on their MRIs ''can usually be addressed by other means, such as physical therapy, exercise, work strengthening programs, abdominal core training, anti-inflammatories, and at times, . . . nerve blocks with corticosteroids.'' GX 10, at 2–3.

As further support for his conclusion, the Expert noted that Registrant had increased the amount of controlled substances he prescribed to the two TFOs, notwithstanding that he expressed doubt as to whether either TFO needed the medications they were getting. *Id.* at 3. As the found above, Registrant told TFO One that he ''may not need medications'' because his ''MRI [didn't] show any compression of the nerves.'' GX 4, at 11. And as for TFO Two, Registrant noted that 190 dosage units of oxycodone 30 mg ''is a big dose,'' and that it was ''difficult to understand'' why TFO Two had ''so much pain in there'' given that the TFO did not ''have any compression of the nerves, or the spinal column, or the nerve root.'' GX 5, at 16–17.

Finally, the Expert noted that with respect to TFO One, Registrant increased the prescriptions based solely on the TFO's request that he do so because he might miss his next appointment, and that with respect to TFO Two, Registrant gave him an additional prescription for 100 dosage units of oxycodone 15mg based solely on the TFO's representation that the doctor he had previously seen at the clinic had promised him additional medication for breakthrough pain and did so ''without consulting the medical record.'' GX 10, at 3.

[8] While the Government alleged in the Show Cause Order that Registrant's prescribing of carisoprodol also lacked a legitimate medical purpose, it is noted that carisoprodol was not federally controlled at the time of the events at issue here. *See Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV,* 76 FR 77330 (Dec. 12, 2011) (final rule). However, the Expert opined that Registrant did not have a legitimate medical justification for prescribing carisoprodol, which was then controlled under Florida law, to either TFO. *See* GX 10, at 4; Fla. Stat. § 893.03(4)(jjj) (2010). While the Expert's opinion would support a finding that Registrant violated Florida law in prescribing carisoprodol to the TFOs, *see* Fla. Stat. §§ 893.05(1), 893.13(1)(a), and such a violation is relevant in assessing a registrant's likelihood of future compliance with the CSA (under either factor four or five), *see John V. Scalera,* 78 FR 12092, 12100 (2013) (citing cases), the Government did not rely on this conduct in its Request for Final Agency Action. Accordingly, nor do I.

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### Importer of Controlled Substances; Notice of Application; Fisher Clinical Services, Inc.

Pursuant to Title 21 Code of Federal Regulations (CFR) 1301.34 (a), this is notice that on June 21, 2013, Fisher Clinical Services, Inc., 7554 Schantz Road, Allentown, Pennsylvania 18106, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

| Drug | Schedule |
|---|---|
| Methyphendiate (1724) | II |
| Levorphanol (9220 | II |
| Noroxymorphone (9668) | II |
| Tapentadol (9780) | II |

The company plans to import the listed substances for clinical trials, analytical research and testing.

The import of the above listed basic classes of controlled substances will be granted only for analytical testing and clinical trials. This authorization does not extend to the import of a finished FDA approved or non-approved dosage form for commercial distribution in the United States.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic class of controlled substance may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43, and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODW), 8701 Morrissette Drive, Springfield, Virginia 22152; and must be filed no later than October 25, 2013.

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, 40 FR 43745–46, all applicants for registration to import a basic classes of any controlled substances in schedule I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements