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Dated: April 3, 2009.

William S. Haigh,

Field Office Manager.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 07–24]

Patrick W. Stodola, M.D.; Revocation of Registration

On February 7, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Patrick W. Stodola, M.D. (Respondent), of Chicago, Illinois. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, AS2352653, as a practitioner, and proposed the denial of his pending application to renew his registration, on the ground that his ''continued registration is inconsistent with the public interest.'' Show Cause Order at 1.

The Show Cause Order specifically alleged that while Respondent is licensed as a physician only in Illinois, he prescribed controlled substances, via the internet, to persons located in twenty-six other States. *Id.* The Order alleged that Respondent's prescribing constituted the unauthorized practice of medicine because he did not possess the licenses required to practice medicine (and prescribe) in these States, and that the prescriptions he authorized ''were not issued in the usual course of professional practice as required by 21 CFR 1306.04.'' *Id.* at 1–2.

On March 14, 2007, Respondent filed a request for a hearing and the matter was placed on the docket of the Agency's Administrative Law Judges. Following pre-hearing procedures, a hearing was held on October 16, 2007, in Chicago, Illinois. At the hearing, both parties elicited testimony and introduced documentary evidence for the record. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law and argument.

On September 16, 2008, the ALJ issued her recommended decision (ALJ). In evaluating Respondent's experience in dispensing controlled substances and record of compliance with applicable laws, the ALJ concluded that Respondent had violated the medical practice standards adopted by multiple States which specifically require that a physician physically examine a patient before prescribing a drug to him/her. ALJ at 33–34. The ALJ further concluded that Respondent had violated the laws of numerous States by prescribing to their residents without holding the requisites licenses to practice medicine and/or dispense controlled substances. *Id.* at 34. While the ALJ found that Respondent has retained his Illinois medical license and has not been convicted of a crime, she further found that Respondent has ''refus[ed] to acknowledge his wrongdoing.'' *Id.* at 32 & 34. The ALJ thus ''conclude[d] that Respondent is unwilling or unable to accept the responsibilities inherent in a DEA registration,'' and recommended that his registration be revoked and that any pending applications be denied. *Id.* at 35.

Respondent did not file exceptions to the ALJ's decision.[1] Thereafter, the record was forwarded to me for final agency action.

Having considered the entire record in this matter, I adopt the ALJ's conclusions of law with respect to the public interest inquiry. I further adopt the ALJ's recommended sanction. Accordingly, I will revoke Respondent's registration and deny his pending application to renew the registration. I make the following findings.

Findings

Respondent is the holder of DEA Certificate of Registration, AS2352653, which authorizes him to dispensing controlled substances in schedules II through V as a practitioner. According to Respondent's Certificate of Registration, the expiration date of his registration was February 28, 2006. It is undisputed, however, that Respondent filed a timely renewal application. I therefore find that Respondent's registration has remained in effect pending the issuance of this Order. *See* 5 U.S.C. 558(c).

Respondent holds a medical license in Illinois. Tr. 85, 190–91. In his testimony, Respondent acknowledged that he is not licensed to practice medicine in any other State, *id.* at 85 & 191, and that he has never obtained a license to practice in any other State. *Id.* at 85. Moreover, Respondent does not hold a DEA registration for a location in any State other than Illinois. *Id.* at 191.

In early 2006, Respondent read an advertisement which had been placed by Just USA Meds[2] in the employment section of the Chicago Tribune's Web site. *Id.* at 165. Respondent called the phone number contained in the ad, and spoke with Challen Sullivan, Just USA's owner, who told him that his business ''was to be a provider of medical services,'' but not ''a dispenser or a vending machine of any particular medications.'' *Id.* at 87. Thereafter, Respondent entered into an agreement with the entity under which Just USA Meds would arrange for customers, who were seeking controlled substances, to speak with him by telephone. *Id.* at 14. Respondent was paid $20 per consultation and would typically issue a controlled-substance prescription for the patient upon the conclusion of the consultation. *Id.* The prescriptions were then sent to pharmacies which had entered into arrangements with Just USA Meds to dispense the drugs to its customers.

According to Respondent, a customer would contact Just USA Meds, identify himself, and provide a copy of the credit card which he intended to use to pay his bill. *Id.* at 91. Respondent asserted that a customer would then be interviewed by an employee of Just USA Meds, who would ask him the name of his doctor, what other drugs he was taking, and whether he would agree not to seek drugs from another source if Respondent (or the other doctors engaged by Just USA Meds) issued a prescription for him. *Id.* at 92. Just USA would then contact the customer's credit card company to verify whether the card was valid and to request a pre-charge for the anticipated amount of the services and drugs being provided. *Id.* After Just USA obtained the pre-charge, the customer would then be scheduled for a consultation with Respondent or another physician. *Id.* at 104.

Respondent admitted that he did not physically examine any of the persons who were referred to him by Just USA Meds. Tr. 18 (testimony of DI); *id.* at 84 (testimony of Respondent).[3] Rather, Respondent asserted that the customers were required to send in medical records including the documentation of a physical exam which had to be less than one year old. *Id.* at 97–98. He also maintained that persons who claimed ''some sort of structural harm'' were

[1] While the Government filed exceptions, the exceptions do not go to the merits of the proceeding.

[2] In this decision, Just USA Meds will also be referred to as ''Just USA.''

[3] Respondent did not even physically examine those persons he prescribed to who resided in the Chicago area. *See* GX 34 at 24 (resident of Chicago); GX 39 at 63 (resident of Highland Park, Il.); *Id.* at 133 (resident of Arlington Heights, Il.); *Id.* at 171 (resident of Hoffman Estates, Il.).

required to forward imaging documentation such as a CT scan, MRI, or X-Ray, and that if the person did not have a physical that met the above requirement, the person was sent an eleven to twelve-page-long form, which was to be taken to a doctor in his/her community to ''have the history and physical completed.'' *Id.* at 98. Relatedly, Respondent claimed that for those customers who found it inconvenient to go to a doctor's office, Just USA Meds used a company which sent a nurse to the customer's home to obtain a medical history and perform a physical. *Id.* at 100.

Respondent further maintained that he kept copies of each customer's medical records. *Id.* Respondent did not, however, produce any of these records at the hearing.

Respondent also asserted that the phone consultations he conducted were probing and would take between twenty to thirty minutes to complete.[4] *Id.* at 105. Relatedly, he maintained that Just USA Meds ''scolded [him] a couple of times in the beginning'' because the consultations took too much time. *Id.* According to Respondent, the

> consultations were inquiries concerning the history and physical, which was in front of me, the nature and extent of the medications and therapies that they had already received, their response to any medications that they had already received, what medications other than what they were requesting they were already taking, how their condition affected them, and I usually used two or three different tests inquiring from them to find out the nature of their problem.

Id. at 104. Respondent also maintained that he asked the customer to rate their pain ''on a scale of 1 to 10,'' whether he/she had previously ''taken hydrocodone,'' and if so, how it affected the customer's pain level and whether the drug had caused various adverse events. *Id.* at 105. Respondent maintained that ''those were all discussed by me each and every time,'' and that ''[t]here were no exceptions.'' *Id.*

Relatedly, Respondent asserted that the consultations ''were meaningful interviews that took as long or longer than is customarily had in a physician's office with the patient physically in front of them,'' and ''that the interviews were comprehensive and medically appropriate.'' *Id.* at 106. According to Respondent, ''probably about 90 percent of the patients who were inquiring were requesting some sort of pain relief.'' *Id.* Respondent also asserted that he would ''sometimes'' negotiate with the customers to ''alter their request'' for drugs and or ''to use some other medicine.''[5] *Id.*

According to various prescription records which were entered into evidence, Respondent issued in excess of three hundred controlled-substance prescriptions for Just USA, the overwhelming majority (approximately eighty-five to ninety percent) of which were for combination drugs containing hydrocodone, a schedule III controlled substance, and acetaminophen. *See* GXs 34, 35, & 39; 21 CFR 1308.13(e). Invariably, the prescriptions were for those formulations which contained the stronger concentrations (7.5 or 10 mg.) of hydrocodone. *See* GXs 34, 35, & 39.

As I have noted in numerous other decisions, these drugs are highly popular with drug abusers. *See Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36503 (2007) (noting 2004 survey of National Institute of Drug Abuse found that ''9.3 percent of twelfth graders reported using Vicodin, a brand name Schedule III controlled substance without a prescription in the previous year''); *William R. Lockridge,* 71 FR 77791, 77796 (2006) (noting that in 2002, the abuse of hydrocodone products resulted in more than 27,000 emergency room visits).[6] Respondent also issued smaller numbers of prescriptions for Didrex (benzphetamine, a schedule III controlled substance), as well as various schedule IV drugs including alprazolam, diazepam, Ambien (zolpidem) and phentermine. *See* GXs 34, 35, & 39; *see also* 21 CFR 1308.13(b)(2); *Id.* 1308.14(c) & (e).

As the prescriptions records indicate, the customers were located throughout the United States, and the overwhelming majority of them resided in States other than Illinois. *See* GXs 34, 35, & 39. More specifically, the records in evidence show, *inter alia,* that Respondent issued hydrocodone prescriptions in the following amounts: forty-eight to residents of Texas, forty to residents of California, nineteen to residents of North Carolina, thirteen to residents of both Ohio and of Virginia, ten to residents of Indiana, nine to residents of Colorado, eight to residents of both Massachusetts and Mississippi, seven to residents of Georgia, six to residents of Missouri, and four to residents of Oklahoma.[7] *See generally* GXs 34, 35, & 39.

As early as March 2006, Respondent spoke with a DEA Diversion Investigator to inquire as to why the Agency had not approved his renewal application. Tr. 87. During the conversation, the DI asked him ''what [he] was doing to make a living as a doctor.'' *Id.* Respondent told the DI that he worked at several clinics and ''had some telemedicine internet practice going.'' *Id.* The DI then told Respondent ''that there might be a problem with that.'' *Id.* Respondent nonetheless continued his prescribing for Just USA Meds until January 2007. *Id.* at 178.[8]

Throughout the hearing, Respondent maintained that his ''prescribing was appropriate.'' *Id.* at 99. Furthermore, on cross-examination, Respondent acknowledged that he found evidence that Just USA Meds had used his name and registration to back-date several prescriptions which had been dispensed before he commenced working for the

[4] The prescription records suggest that this testimony stretches the limits of credulity. According to GX 35, on February 9, 2006, Respondent would have performed approximately thirty consultations, and the following day, he would have performed approximately thirty-three consultations. Respondent would thus have spent between ten and seventeen hours a day consulting. While this is not out of the realm of possibility, it seems most unlikely. However, because most (if not all) of Respondent's prescribings were illegal regardless of how long the consultations lasted for, it is unnecessary to determine whether this testimony is credible.

[5] The prescriptions records, however, cast doubt on the credibility of this testimony. As found above, Respondent invariably issued prescriptions for combination drugs which contained either 7.5 or 10 mg. of hydrocodone (rather than those drugs which contain only 5 mg.), and rarely issued prescriptions for such non-controlled drugs which are used to treat pain such as Tramadol and Fioricet.

The various prescription records entered into evidence show that Respondent also wrote a miniscule number of prescriptions for non-controlled drugs including Soma (carisoprodol), Tramadol, and Fioricet (a combination of butalbital, acetaminophen and caffeine).

[6] In his testimony, Respondent asserted that drugs containing hydrocodone are not addictive or ''dangerous.'' Tr. 158–59. As found above, combination hydrocodone drugs are among the most highly abused controlled substances. I therefore reject Respondent's testimony as self-serving.

[7] The Government also introduced into evidence the sworn declaration of George Van Komen, M.D. GX 41. Respondent, however, objected to the admission of the exhibit on the ground that the declaration was testimonial in nature and that he was unable to cross-examine Dr. Van Komen. Tr. 58–59. The ALJ overruled Respondent's objection and admitted the declaration. *Id.* at 59.

I do not rely on the exhibit, however, because it is unclear whether the declaration was properly admitted. While the Government provided notice of its intent to use the Declaration in its Supplemental Prehearing Statement, the Statement does not disclose the substance of the Declaration. Moreover, the record does not establish whether a copy of the Declaration was provided to Respondent in advance of the hearing. While hearsay is admissible in these proceedings, a testimonial declaration must be timely provided to the other party in order to afford it with the opportunity to determine whether to request a subpoena of the witness.

[8] The record suggests that Respondent had additional discussions with DEA Investigators in both May and September 2006 regarding his practices. The record does not, however, establish with reasonable specificity the content of these discussions.

entity. *Id.* at 170. Respondent testified that he did not authorize this use of his registration which he discovered ''within the first couple of weeks'' after he started working for Just USA. *Id.* at 169.

Respondent failed to report the incident to the Agency, asserting that Just USA had told him that ''only one or two'' prescriptions had been back dated. *Id.* at 170. Respondent admitted, however, that he ''had no way of confirming'' the validity of Just USA's representation that the backdating had occurred in ''only one or two instances.'' *Id.*

Respondent also maintained that on multiple occasions, he engaged in due diligence to determine whether his conduct was legal. Respondent contends that shortly after he entered into his arrangement with Just USA, he was sent a document entitled ''Ordering and Registration Instructions,'' which indicated the procedures which the ''patients'' were required to complete to purchase drugs which included providing a copy of an identification card, medical records, and physician reports, etc. RX 7A. Moreover, the document listed seven States that Just USA's pharmacies did not ship to including Arizona, Kentucky, Missouri, Nevada, Pennsylvania, South Carolina, and Tennessee. *Id.* In his testimony, Respondent maintained that Just USA had sent this document to him after he asked how he would know that he was permitted to prescribe to residents of States other than Illinois. Tr. 95. Respondent further claimed that Just USA told him that it had ''already done an examination of the law, and we do not service'' the above States, because they ''required a face-to-face meeting between the prescribing doctor and the patient,'' or the State prohibited an out-of-state doctor from prescribing to its residents, or the State did not permit telemedicine. *Id.* at 95–96; *see also id.* at 184. According to Respondent, ''it was good enough for me that they had ruled out certain states that it was not appropriate to go to.'' [9] *Id.* at 96.

On cross-examination, however, the Government identified multiple instances in which Respondent had issued prescriptions to patients who lived in these States. *See* Tr. 186–90. More specifically, the Government identified controlled prescriptions Respondent issued to residents of Arizona (GX 39 at 6), Kentucky (*id.* at 21), Missouri (*id.* at 23), Nevada (*id.* at 75), Pennsylvania (*id.* at 67), and South Carolina (*id.* at 182). When confronted with this evidence, Respondent did not ''know how that happened'' and claimed that he ''wasn't aware that it happened.'' *Id.* at 194.

Respondent admitted, however, that the customer's names and addresses were in the medical records, which he claimed he had access to. *Id.* at 196. He also admitted that ''in most instances,'' he did not look at where the customer lived, *id.,* but instead relied on the employees of Just USA to screen out the customers. *Id.* at 200–01.

Respondent also entered into evidence an Agency document which stated that it was clarifying DEA's ''policies regarding the dispensing and prescribing of controlled substances as they pertain to the internet.'' RX 7C. This document specifically noted the prescription requirement of Federal law, *see* 21 CFR 1306.04(a), and made explicit reference to the Agency's 2001 Guidance Document, *Dispensing and Purchasing Controlled Substances over the Internet,* 66 FR 21181. The document further stated: ''As noted in the guidance document, it is unlikely that such a relationship could be established through the use of an online questionnaire completed by a consumer prior to the purchase of controlled substances.'' RX 7C, at 1.

The Agency's 2001 Guidance expressly stated that ''[u]nder Federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship.'' 66 FR at 21182. Continuing, the Guidance observed that ''[f]or purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate doctor/patient relationship has been established: A patient has a medical complaint; A medical history has been taken; A physical examination has been performed; and Some logical connection exists between the medical complaint; the medical history, the physical examination, and the drug prescribed.'' *Id.* at 21182–83. The Guidance further stated that ''[c]ompleting a questionnaire that is then reviewed by a doctor hired by the internet pharmacy could not be considered the basis for a doctor/patient relationship.'' *Id.* at 21183.

Of further relevance, the Guidance explained that ''[o]nly practitioners acting in the usual course of their professional practice may prescribe controlled substances. These practitioners *must be registered with DEA and licensed to prescribe controlled substances by the State(s) in which they operate*.'' *Id.* at 21181 (emphasis added).[10]

As further support for his contention that he performed due diligence in attempting to ascertain whether his prescribing practices were legal, Respondent introduced into evidence a document which appears to be a legal opinion (dated June 21, 2006) prepared by a Tampa, Florida-based lawyer.[11] *See* RX 7D. In stating the issue, the opinion noted that ''[a]s your Pharmacy and Prescribing Doctors are located within the States of Florida, this Memorandum's analysis focuses on Florida law as well as Federal law concerning appropriate prescribing standards.'' *Id.* at 6. Continuing, the opinion observed that ''[t]he state laws and professional standards concerning telemedicine and prescribing practices vary from state to state, and because I am licensed to practice in the State of Florida, this Memorandum's analysis is limited to Florida law as well as Federal law concerning appropriate prescribing standards.'' *Id.* The opinion further noted that it ''specifically'' did not address such issues as ''physician and pharmacy licensure.'' *Id.*

As for its legal conclusions, the opinion stated that ''[p]rescribing standards vary dramatically from state to state and in some instances vary within a particular state for the prescription of specified pharmaceutical items (e.g., some states have heightened standards for prescribing controlled substances and diet drugs).'' *Id.* at 1.[12]

[9] Respondent subsequently stated that after he stopped working for Just USA he learned that there were two or three other States (in addition to the seven States listed in RX 7A) where his prescribing was illegal. Tr. 161.

[10] Respondent also cites a ''Flow Chart,'' RX 7B, which was prepared by Just USA Meds Pharmacy and which sets forth the purported process by which customers obtained drugs as evidence of his having engaged in due diligence. The document does not set forth any legal advice and is merely cumulative of Respondent's testimony as to the procedures used by Just USA to process customer orders.

Respondent also submitted a document which contains several e-mail messages from July 27 and 28, 2006, which discuss an e-prescribing initiative introduced in Illinois, one of which originated from Mudri Associates, a DEA Consultancy. RX 7E. Respondent asserts that this evidence establishes that he contacted the consultant ''following [its] inspection of all of the procedures followed by [J]ust USA * * * [and] the pharmacies with which [J]ust USA had arrangements.'' Resp. Br. (Pt. II) at 14. The e-mail does not, however, discuss any issue other than various proposals that were part of an Illinois patient safety initiative.

[11] The text of the letter appears to have been cut and inserted into various internet-based text messages which occurred between Respondent and Challen Sullivan, the owner of Just USA Meds. *See* RX 7–D; Tr. 119 & 125–26. Nor does the text of the memorandum appear in the exhibit in the order that is customarily used by lawyers in preparing legal opinions for their clients. *See id.*

[12] The opinion provides a lengthy discussion of Florida's standards, and appears to conclude that under Florida law and regulations, a physician need

Continued

Moreover, in addition to its discussion of Florida law, the opinion notes that ''[o]ther states have adopted statutes specifically relating to prescribing standards and the business of Internet pharmacy—*often requiring a face to face physical examination and making non-compliance a crime subject to heavy penalties. These statutes are usually more comprehensive in requiring compliance by all of the website operators, physicians and pharmacies involved.* Most sophisticated and established Internet pharmacy operators avoid conducting business in these more restrictive states.'' *Id.* at 4 (emphasis added).[13]

The opinion also discussed Federal prescribing standards. In discussing this Agency's 2001 Guidance, the opinion states that ''[a]lthough the DEA acknowledges that state law ultimately controls the issue of whether a prescription is written in the usual course of professional practice, the DEA feels that the weight of legal and professional authority requires the [four] elements [set forth in the Guidance] to be present in order to establish a bona fide doctor/patient relationship.'' *Id.* The letter then quoted verbatim the four elements set forth in the Guidance.

Furthermore, the opinion also noted that ''DEA has in some instances over the past year informally challenged some pharmacies and medical professionals participating in a Medical Records Based Prescribing pharmacy business. The DEA has asserted in such instances that in its opinion Medical Records Based Prescribing does not meet applicable local legal standards which require that an adequate physician-patient relationship exists for the prescription.'' RX 7D at 5.

The opinion, however, rejected the Agency's view as to the legality of Medical Records Based Prescribing, citing among other things, its author's ''understanding that the three largest drug wholesalers * * * have concluded that the DEA does not have a legal basis for making these assertions,'' the 2003 failure of Congress to enact the Ryan Haight Internet Pharmacy Consumer Protection Act (which prohibits a practitioner's prescribing to a person he/she has not physically examined),[14] and the December 2005 testimony of Agency officials to Congress to the effect that the Controlled Substances Act does not provide a statutory definition of ''what constitutes a valid 'doctor/patient' relationship.'' *Id.* at 5. The opinion thus concluded that ''the Websites' Medical Records Based Prescribing Procedures appear to comply with the DEA's published rules and Federal law.'' *Id.*[15]

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to ''dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). Moreover, section 303(f) of the CSA provides that ''[t]he Attorney General may deny an application for [a practitioner's] registration if he determines that the issuance of such registration would be inconsistent with the public interest.'' 21 U.S.C. 823(f). In making the public interest determination, the Act requires the consideration of the following factors:

(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, 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 to revoke an existing registration or to deny an application to renew a registration. *Id.* Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

Having considered all of the factors, I acknowledge that the record contains no evidence that the State of Illinois has taken action against Respondent's medical license (factor one) or that Respondent has been convicted of an offense related to controlled substances (factor two).[16] The record contains, however, an abundance of evidence that Respondent's experience in dispensing controlled substances (factor two) and record of compliance with applicable Federal and State laws (factor four) is characterized by his repeated violation of the CSA's prescription requirement, as well as numerous state laws and regulations prohibiting the unlicensed practice of medicine and setting the standards for prescribing a drug.

Moreover, I reject Respondent's contention that his conduct should be excused because he engaged in due diligence in attempting to ascertain the legal requirement for his prescribing. Even if I was to recognize such a defense in the context of a prescribing practitioner, the record establishes that Respondent's efforts were half-baked at best, and that when he did receive information that his activities were likely illegal, he ignored it. Finally, while Respondent eventually ceased his internet-related prescribing activities, his testimony manifests that he has not accepted responsibility for his misconduct, but rather blames others.

not have personally performed a physical examination in order to prescribe a drug (other than a diet drug). *Id.* at 2–3. However, as found above, Respondent prescribed to residents of numerous other States.

[13] The opinion also observed that the American Medical Association's ''standards suggest that the physician must personally conduct the physical examination,'' RX 7D at 3, and while suggesting that the AMA's positions were inconsistent, quoted another AMA guideline which states in relevant part: ''Licensure: Physicians who prescribe medications via the Internet across state lines, without physically being located in the state(s) where the patient (clinical) encounter(s) occurs, must possess appropriate licensure in all jurisdictions where patients reside.'' *Id.* at 4.

[14] On October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law No. 110–425, 122 Stat. 4820 (2008). Section 2 of the Act prohibits the dispensing of a prescription controlled substance ''by means of the Internet without a valid prescription,'' and defines, in relevant part, the ''[t]he term 'valid prescription' [to] mean [ ] a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least 1 in-person medical evaluation of the patient.'' 122 Stat. 4820. Section 2 further defines ''[t]he term 'in-person medical evaluation' [to] mean [ ] a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.'' *Id.* These provisions do not, however, apply to Respondent's conduct.

[15] Respondent also cites a December 1, 2006 rulemaking which amended DEA regulations to require that a practitioner obtain a separate registration for each State in which he practices, and a December 22, 2006, memo written by the same Tampa-based attorney regarding the applicability of the new rule to internet prescribers. *See* RX 7G. In light of the fact that almost (if not) all of the actual prescriptions which are in evidence in this matter were issued by Respondent prior to his having reviewed either of these documents, I find it unnecessary to make any findings based on them.

[16] This Agency has long held that a State's failure to take action against a practitioner's authority to dispense controlled substances is not dispositive in determining whether the granting of an application for registration would be consistent with the public interest. *See Mortimer B. Levin,* 55 FR 8209, 8210 (1990). I further note that the absence of a criminal conviction is not dispositive of the public interest inquiry. *See, e.g., Edmund Chein,* 72 FR 6580, 6593 n.22 (2007).

I therefore conclude that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f). Accordingly, Respondent's registration will be revoked and his application to renew his registration will be denied.

Factor Two and Four—Respondent's Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Controlled Substance Laws

The primary issue in this case is whether the prescriptions Respondent issued pursuant to his agreement with Just USA Meds were lawful prescriptions under the CSA. 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 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)).

Under the CSA, it is fundamental that a practitioner must establish a bona fide doctor-patient relationship in order to act ''in the usual course of * * * professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Moore,* 423 U.S. at 141–43. At the time of the events at issue here, the CSA generally looked to state law to determine whether a doctor and patient have established a bona fide doctor-patient relationship. *See Kamir Garces-Mejias,* 72 FR 54931, 54935 (2007); *United Prescription Services, Inc.,* 72 FR 50397, 50407 (2007); *Dispensing and Purchasing Controlled Substances Over the Internet,* 66 FR at 21182–83; *but see* n.14, *supra* (discussing the Ryan Haight Act).

Moreover, shortly after the CSA's enactment, the Supreme Court explained that ''[i]n the case of a physician [the Act] contemplates that *he is authorized by the State to practice medicine* and to dispense drugs in connection with his professional practice.'' *Moore,* 423 U.S. at 140–41 (emphasis added). Accordingly, ''[a] physician who engages in the unauthorized practice of medicine'' under state laws ''is not a 'practitioner acting in the usual course of * * * professional practice' '' under the CSA. *United Prescription Services,* 72 FR at 50407 (quoting 21 CFR 1306.04(a)). This rule is supported by the plain meaning of the Act, which defines the ''[t]he term 'practitioner' [to] mean [ ] a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to * * * dispense * * * a controlled substance,'' 21 U.S.C. 802(21), and ''[t]he term 'dispense' [to] mean [ ] to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner.'' *Id.* § 802(10). *See also id.* § 823(f) (''The Attorney General shall register practitioners * * * to dispense * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.'').

A controlled-substance prescription issued by a physician who lacks the license or other authority required to practice medicine within a State is therefore unlawful under the CSA. *See* 21 CFR 1306.04(a) (''An order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning an intent of'' the CSA); *cf.* 21 CFR 1306.03(a)(1) (''A prescription for a controlled substance may be issued only by an individual practitioner who is * * * [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession[.]'').

The record establishes that in issuing the prescriptions for Just USA's customers, Respondent repeatedly violated the CSA's prescription requirement. 21 CFR 1306.04(a). This is so for two reasons: (1) Respondent prescribed without establishing a valid doctor-patient relationship in violation of the medical practice standards of numerous States because he failed to physically examine the patients, and (2) Respondent's prescribing typically constituted the unauthorized practice of medicine in the States where the patients were located because he was licensed to practice medicine (and authorized to prescribe) only in Illinois. Furthermore, Respondent issued unlawful prescriptions even where various States had either enacted laws and regulations, rendered decisions in adjudications, or issued policy statements making clear that his prescribing practices were illegal.

For example, as found above, Respondent issued forty hydrocodone prescriptions to residents of California. In 2000, California enacted Cal. Bus. & Prof. Code § 2242.1,[17] which specifically prohibits the prescribing or dispensing of a dangerous drug ''on the Internet for delivery to any person in this state, without an appropriate prior examination and medical indication therefore, except as authorized by Section 2242.'' Moreover, the statute, which provides for a fine or civil penalty of twenty-five thousand dollars for a violation, further directs that ''[i]f the person or entity that is the subject of an action brought pursuant to this section is not a resident of this state, a violation of this section shall, if applicable, be reported to the person's or entity's appropriate professional licensing authority.'' *Id.* at (e).

Relatedly, in 2003, the Medical Board of California revoked a physician's medical license for engaging in the same type of prescribing practices as Respondent did here. *See In re John Steven Opsahl, M.D.,* Decision and Order, at 3 (Med. Bd. Cal. 2003) (available by query at *http://publicdocs.medbd.ca.gov/pdl/mbc.aspx*). In *Opsahl,* the Medical Board expressly found that ''[b]efore prescribing a dangerous drug, a physical examination must be performed.'' *Id.* Continuing, the Board found that ''[a] physician cannot do a good faith prior examination based on a history, a review of medical records, responses to a questionnaire and a telephone consultation with the patient, without a physical examination of the patient.'' *Id.* Finally, the Board found that:

> Medical indication means having a condition that warrants specific treatment. It is determined after the physician takes a history, performs a physical examination and makes an assessment about the patient's condition. * * * A physician cannot determine whether there is a medical indication for prescription of a dangerous drug without performing a physical examination.

Id.[18]

[17] This statute was effective January 1, 2001.

[18] Dr. Opsahl's prescribing practices involved ''verifying patient identity,'' ''obtaining and reviewing medical records,'' ''having direct contact with the patient, though personal contact was not required,'' and ''having an opportunity for follow-up.'' Decision at 4. Opsahl prescribed both non-controlled and controlled drugs including combination drugs containing hydrocodone, benzodiazepines, schedule three drugs containing codeine, as well as Ambien, phentermine, and phendimetrazine. *Id.* at 6.

Moreover, prior to Respondent's engaging in internet-based prescribing, the Medical Board of California had issued numerous Citation Orders to out-of-state physicians for internet prescribing to California residents. These Orders invariably cited not only the physicians' failure to perform ''a good faith prior examination,'' but also their lack of ''a valid California Physician and Surgeon's License to practice medicine in California.'' Citation Order, Martin P. Feldman (Aug. 15, 2003); *see also* Citation Order, Harry Hoff (Jun. 17, 2003); Citation Order, Carlos Gustavo Levy (Jan. 28, 2003); Citation Order, Carlos Gustavo Levy (Nov. 30, 2001). Moreover, the Board had issued several press releases setting forth its position that internet prescribing is unlawful. *See* GX 11 at 9 (Feb. 2004 Action Report) (''The Board has taken action against California physicians and licensees from other states for prescribing over the Internet without a good faith prior exam, and continues to investigate cases as it becomes aware of the practice.''); *Record Fines Issued by Medical Board to Physicians in Internet Prescribing Cases* (News Release Feb. 10, 2003) (available at *http://www.mbc.ca.gov/board/media/releases_2003_02-10_internet_drugs.html*). Respondent thus clearly violated both California law and the CSA in issuing these prescriptions.

Respondent issued forty-eight prescriptions for hydrocodone drugs to residents of Texas. Respondent did not, however, hold a Texas medical license. *See* Tex. Occ. Code § 155.001; *see also id.* § 151.056(a) (''A person who is physically located in another jurisdiction but who, through the use of any medium, including an electronic medium, performs an act that is part of a patient care service initiated in this state, * * * and that would affect the diagnosis or treatment of the patient, is considered to be engaged in the practice of medicine in this state and is subject to appropriate regulation by the board.''); 22 Tex. Admin. Code § 174.4(c) (''Physicians who treat and prescribe through the Internet are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside.'').

Respondent also lacked the state registration required to prescribe a controlled substance. *See* Tex. Health & Safety Code § 481.061(a) (requiring state registration to dispense); *id.* § 481.063(d) (requiring as a condition for registration that ''a practitioner [be] licensed under the laws of this state''). Respondent thus also violated Texas law, and the CSA, in prescribing controlled substances to that State's residents. *See Moore*, 423 U.S. at 140–41 (''In the case of a physician [the CSA] contemplates that *he is authorized by the State to practice medicine* and to dispense drugs in connection with his professional practice.'') (emphasis added); *United Prescription Services*, 72 FR at 50407 (''A controlled-substance prescription issued by a physician who lacks the license [or other authority required] to practice medicine within a State is * * * unlawful under the CSA.''); 21 U.S.C. 802(10) (defining '' 'dispense' [to] mean[ ] to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner'').

Respondent issued nineteen prescriptions for drugs containing hydrocodone to North Carolina residents. Respondent did so notwithstanding that under North Carolina law, ''prescribing medication by use of the Internet or a toll-free telephone number, shall be regarded as practicing medicine'' in the State and subjects the practitioner to North Carolina law ''and appropriate regulation by the North Carolina Medical Board.'' N.C. Gen. Stat. Ann. § 90–18(b). North Carolina law further provides that ''[n]o person shall practice medicine * * * nor in any case prescribe for the cure of diseases unless the person shall have been first licensed and registered to do so.'' *Id.* § 90–18(a). Moreover, if ''the person so practicing without a license is an out-of-state practitioner who has not been licensed and registered to practice medicine and surgery in this State, the person shall be guilty of a Class I felony.'' *Id.*[19]

In addition, in February 2001, the North Carolina Medical Board issued a Position Statement entitled: *Contact With Patients Before Prescribing*. GX 25 at 11. Therein, the Board stated ''that prescribing drugs to an individual the prescriber has not personally examined is inappropriate except as noted * * * below.'' *Id.* The Board further explained that ''[b]efore prescribing a drug, a physician should make an informed medical judgment based on the circumstances of the situation and on his or her training and experience. Ordinarily, this will require that the physician personally perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, a part of which might be a prescription.'' *Id.* While the North Carolina Board recognized that it may be appropriate to prescribe to a patient without having performed a physical exam ''under certain circumstances,'' none of these apply to Respondent.[20] I thus conclude that Respondent violated both North Carolina law and the CSA in prescribing to the State's residents.

Respondent issued thirteen prescriptions for hydrocodone to Ohio residents. Ohio law defines '' 'the practice of telemedicine' [to] mean[ ] the practice of medicine in this state through the use of any communication, including oral, written, or electronic communication, by a physician outside th[e] state,'' and authorizes ''[t]he holder of a telemedicine certificate [to] engage in the practice of telemedicine in this state.'' Ohio Rev. Code Ann. § 4731.296(A) & (C). *See also id.* § 4731.41 (''No person shall practice medicine and surgery, or any of its branches, without the appropriate certificate from the state medical board to engage in the practice.''). Moreover, under the regulations of the State Medical Board of Ohio, ''a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substances to a person who the physician has never personally examined and diagnosed'' except for in limited situations not applicable here.[21] Ohio Admin. Code § 4731–11–09(A). I thus conclude that Respondent violated both Ohio law and the CSA in issuing prescriptions to Ohio residents.

Respondent issued thirteen prescriptions for hydrocodone to Virginia residents. Under Virginia law, it is ''unlawful for any person to practice medicine * * * in the Commonwealth without a valid unrevoked licensed issued by the Board of Medicine,'' Va. Code Ann. § 54.1–2902; and ''[a]ny person shall be

[19] While North Carolina exempts from these requirements an out-of-state practitioner who ''on an irregular basis, consults with a resident registered physician,'' Respondent does not maintain that he was consulting with a North Carolina physician. N.C. Gen. Stat. Ann. § 90–18(c)(11).

[20] These circumstances ''may include admission orders for a newly hospitalized patient, prescribing for a patient of another physician for whom the prescriber is taking call, or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.'' GX 25 at 11. The Board also noted that ''[e]stablished patients may not require a new history and physical examination for each new prescription, depending on good medical practice.'' *Id.*

[21] The exceptions are for ''institutional settings, on call situations, cross coverage situations, situations involving new patients,'' (but limited to where ''the physician has scheduled or is in the process of scheduling an appointment to examine the patient and the drugs are intended to be used pending that appointment''), ''protocol situations,'' ''nurses practicing in accordance with standard care arrangements, and hospice settings.'' Ohio Admin. Code § 4731–11–09.

regarded as practicing the healing arts who actually engages in such practice as defined in this chapter.'' *Id.* § 54.1–2903; *see also id.* § 54.1–2900 (the ''[p]ractice of medicine'' * * * means the prevention, diagnosis and treatment of human physical or mental ailments, conditions, diseases, pain or infirmities by any means or method''); *id.* § 54.1–2929 (''No person shall practice * * * medicine * * * without obtaining a license from the Board of Medicine'').[22] Furthermore, ''[a] prescription for a controlled substance may be issued only by a practitioner of medicine * * * who is authorized to prescribe controlled substances.'' Va. Code § 54.1–3303(A). Moreover, ''[t]he prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons * * * with whom the practitioner has a bona fide practitioner-patient relationship.'' *Id.*

The Virginia statute also provides that ''a bona fide practitioner-patient relationship means that the practitioner shall * * * perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; *except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself*, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription.'' *Id.* (emphasis added). I thus conclude that Respondent violated Virginia law and the CSA in prescribing to Virginia's residents.

Respondent issued ten prescriptions for hydrocodone to Indiana residents. Under Indiana law, ''[i]t is unlawful for any person to practice medicine * * * in this state without holding a license or permit to do so.'' Ind. Code § 25–22.5–8–1. Moreover, the practice of medicine includes the ''prescription * * * of any form of treatment, without limitation.'' *Id.* § 25–22.5–1–1.1(a)(1)((B); *see also id.*§ (a)(4).

The Medical Licensing Board of Indiana has also adopted a regulation (similar to Ohio's), which provides that except for in limited situations, ''a physician shall not prescribe, dispense, or otherwise provide, or cause to be provided, any controlled substance to a person who the physician has never personally physically examined and diagnosed.'' 844 Ind. Admin. Code 5–4–1(a).[23] This rule has been effect since October 2003. I thus conclude that Respondent violated Indiana law and the CSA in prescribing to Indiana residents.

Respondent issued nine prescriptions for hydrocodone to Colorado residents. In November 2000, the Colorado State Board of Medical Examiners issued a policy statement entitled ''Guidelines Regarding Prescribing for Unknown Patients.'' In this statement, the Colorado Board declared that:

> It is unprofessional conduct for a physician to provide treatment and consultation recommendations, including issuing a prescription via electronic or other means, unless the physician has obtained a history and physical evaluation of the patient adequate to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided. Issuing a prescription on the basis of a questionnaire, Internet-based consultation, or a telephonic consultation, all without a valid pre-existing patient/practitioner relationship does not constitute an acceptable standard of care.
>
> Before prescribing a drug, a physician should make an informed medical judgment based on the circumstances of the situation and on his/her training and experience. Ordinarily, this will require that the physician perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan, a part of which might be a prescription.[24]

GX 12 at 14. I thus conclude that Respondent acted outside of the course of professional practice in issuing the prescriptions to Colorado residents and violated the CSA.

Respondent issued eight prescriptions for hydrocodone to Mississippi residents. In May 2000, the Mississippi State Board of Medical Licensure issued a policy statement on Internet Prescribing. *See* GX 21 at 6. The Mississippi Board advised that the ''[e]ssential components of proper prescribing and legitimate medical practice requires [sic] that the physician obtains a thorough medical history and conducts an appropriate physical examination before prescribing any medication for the first time.'' *Id.*

Moreover, since 1997, Mississippi law has provided that ''no person shall engage in the practice of medicine across state lines (telemedicine) in this state, hold himself out as qualified to do the same, or use any title, word or abbreviation to indicate to or induce others to believe that he is duly licensed to practice medicine across state lines in this state unless he has first obtained a license to do so from the State Board of Medical Licensure and has met all education and licensure requirements as determined by the State Board * * *.'' Miss. Code Ann. § 73–25–34(2). The statute specifically defines the terms ''telemedicine, or the practice of medicine across state lines,'' as including ''[t]he rendering of treatment to a patient within this state by a physician located outside this state as a result of transmission of individual patient data by electronic or other means from within this state to such physician or his agent.'' *Id.* § 73–25–34(1)(b).[25] I thus conclude that Respondent violated Mississippi law and the CSA when he prescribed to the State's residents.

Respondent also issued eight prescriptions for hydrocodone to residents of Massachusetts, whose law follows nearly verbatim the CSA's prescription requirement. *Compare* Mass. Gen. Laws ch. 94C, § 19(a), *with* 21 CFR 1306.04(a). In December 2003, the Massachusetts Board of Registration in Medicine issued the following interpretation of the State's prescription law:

> [t]o satisfy the requirement that a prescription be issued by a practitioner in the usual course of his professional practice, there must be a physician-patient relationship that is for the purpose of maintaining the patient's well-being and the physician must conform to certain minimum norms and standards for the care of patients, such as taking an adequate medical history and conducting an appropriate physical and/or mental status examination and recording the results. Issuance of a prescription, by any means, including the Internet or other electronic process, that does not meet these requirements is therefore unlawful.

Commonwealth of Massachusetts, Board of Registration in Medicine, *Policy 03–06 INTERNET PRESCRIBING* (Adopted Dec. 17, 2003).[26] As the

[22] Respondent does not claim that his prescribing came within one of the limited exceptions for out-of-state practitioners recognized by Virginia law. *See* Va. Code Ann. § 54.1–2901(A)(7) (authorizing ''[t]he rendering of medical advice * * * through telecommunications from a physician licensed to practice medicine in * * * an adjoining state to emergency medical personnel acting in an emergency situation'').

[23] The exceptions are for ''institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority.'' 844 Ind. Admin. Code 5–4–1(a). Respondent does not claim that his prescribing falls within any of these exceptions.

[24] The Colorado Board has also recognized limited exceptions similar to those adopted by Ohio and Indiana.

[25] Mississippi exempts an out-of-state physician from the licensure requirement when the physician provides an evaluation, treatment recommendation, or medical opinion at the request of ''a physician duly licensed to practice medicine in th[e] state,'' and the requesting physician ''has already established a doctor/patient relationship with the patient to be evaluated and/or treated.'' Miss. Code Ann. § 73–25–34(3). Respondent, however, produced no evidence that any physician had ever requested that he evaluate a Just USA patient.

[26] The ALJ also concluded that Respondent was required to be licensed to practice medicine in Massachusetts and violated its law by prescribing

Continued

Board's interpretation makes plain, Respondent acted outside of the usual course of professional practice when he prescribed controlled substances to residents of Massachusetts, and therefore violated both Massachusetts law and the CSA.

Respondent issued seven prescriptions for hydrocodone for residents of Georgia. Under the rules of the Georgia Composite State Board of Medical Examiners, it is ''unprofessional conduct'' to ''[p]rovid[e] treatment and/or consultation recommendations via electronic or other means unless the licensee has performed a history and physical examination of the patient adequate to establish differential diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended.'' Ga. Comp. R. & Regs. 360–3-.02(6).[27] Moreover, Respondent violated Georgia law because he engaged in the unlicensed practice of medicine. *See* Ga. Code Ann. § 43–34–31.1.[28] I thus conclude that Respondent violated the CSA in prescribing to Georgia residents.

Respondent issued six prescriptions for hydrocodone to Missouri residents. Under Missouri law—which was last amended in 1998—it is ''unlawful for any person not now a registered physician within the meaning of the law to practice medicine [or] * * * to engage in the practice of medicine across state lines * * * except as herein provided.'' Mo. Ann. Stat. § 334.010(1). The statute defines ''the practice of medicine across state lines'' to mean in relevant part, ''[t]he rendering of treatment to a patient within this state by a physician located outside this state as a result of transmission of individual patient data by electronic or other means from within this state to such physician or physician's agent.'' *Id.* § 334.010(2)(2). While the statute exempts from the licensure requirement an out-of-state physician who consults with a Missouri-licensed physician when the latter ''retains ultimate authority and responsibility for the * * * diagnoses and treatment * * * of the patient located within th[e] state,'' *id.* § 334.010(3), Respondent makes no claim that his prescribing falls within this exemption.[29] Respondent thus violated both Missouri law and the CSA when he prescribed to the State's residents.

Finally, Respondent issued four prescriptions for hydrocodone to Oklahoma residents. In January 2001, the Oklahoma State Board of Medical Licensure and Supervision issued its *Policy on Internet Prescribing*. GX 27, at 19. Therein, the Oklahoma Board explained that ''[u]nprofessional conduct includes 'prescribing * * * a drug * * * without sufficient examination and the establishment of a valid physician/patient relationship'* * * . The members of the Oklahoma Medical Board have interpreted that a 'sufficient examination' and 'establishment of a valid physician/patient relationship' can NOT take place without an *initial face to face encounter* with the patient.'' *Id.* (emphasis in original and quoting Okla. Stat. tit. 59, § 509–13). I thus conclude that Respondent acted outside of the usual course of professional practice when he prescribed to Oklahoma residents and thus violated the CSA.

As the forgoing demonstrates, Respondent, in issuing the prescriptions for Just USA, repeatedly violated both state laws prohibiting the unlicensed practice of medicine and those establishing standards of medical practice. As the California Court of Appeal has noted, ''the proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can reasonably be claimed, and certainly not by persons * * * who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine.'' *Hageseth* v. *Superior Court*, 59 Cal. Rptr. 3d 385, 403 (Ct. App. 2007). The same is true of the standards for establishing a valid doctor-patient relationship.

I thus hold that Respondent acted outside of ''the usual course of * * * professional practice,'' and lacked ''a legitimate medical purpose,'' 21 CFR 1306.04(a), in issuing numerous prescriptions for the customers of Just USA. I further conclude that Respondent has committed acts which render his continued registration ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

Sanction

Under Agency precedent, where, as here, ''the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must 'present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.' '' *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988))). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA*, 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that 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.'' *Medicine Shoppe*, 73 FR at 387; *see also Jackson*, 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Prince George Daniels*, 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA*, 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor'' in the public interest determination).

Respondent contends that his conduct should be excused because he ''exercised due diligence to ensure that his medical behavior was within the law.'' Resp. Br. (Pt. II) at 11. In Respondent's words, ''[d]ue diligence, of course, does not mean that all mistakes were avoided. What it means, is that every effort is being made to search out whether or not any mistakes were being made.'' *Id.* Respondent further contends that ''his due diligence was not a one time, flash-in-the pan'' effort, and that he ''pursu[ed] and

to residents of that State. ALJ at 34. In light of the Massachusetts' Board clear interpretation as set forth in its policy on Internet Prescribing, I conclude that it is unnecessary to address whether Respondent also violated the State's provisions requiring a license and controlled substance registration which appear to allow an out-of-state practitioner to issue a prescription to a state resident in some instances. *Id.* Mass. Gen. Laws ch. 94C, 18(c).

[27] It is noted that the rule does ''not prohibit a licensee who is on call or covering for another licensee from treating and/or consulting a patient of such other licensee.'' Ga. Comp. R. & Regs. 360–3–.02(6). Respondent did not maintain that he was covering for, or consulting with, other physicians who were treating the Georgia residents he prescribed to.

[28] This statute provides:

(a) A person who is physically located in another state * * * and who, through the use of any means, including electronic * * * or other means of telecommunication, through which medical information or data is transmitted, performs an act that is part of a patient care service located in this state * * * that would affect the diagnosis or treatment of the patient is engaged in the practice of medicine in this state. Any person who performs such acts through such means shall be required to have a license to practice medicine in this state and shall be subject to regulation by the board.

Ga. Code Ann. § 43–34–31.1(a). While the statute includes exceptions when, *inter alia*, the physician ''[p]rovides consultation services at the request of a physician licensed in this state,'' or ''[p]rovides consultation services in the case of an emergency,'' *id.* § 43–34–31.1(b)(1) & (2), neither exception applies to Respondent.

[29] The Missouri statute contains two other exemptions which are not remotely applicable to Respondent's conduct. *See* Mo. Ann. Stat. § 334.010(3) (providing medical opinion or testimony in judicial or administrative proceeding) & (4) (performing ''utilization review'').

persist[ed] in his efforts to assure compliance with the law.'' *Id.*

Even were I to recognize a due diligence defense in the context of a practitioner's obligation to know the law, Respondent's contention is wholly unpersuasive. First, while Respondent testified that he relied on Just USA's representation that it did not ship to seven States because it had examined their laws and determined that these States either required a face-to-face meeting between the patient and doctor, or prohibited an out-of-state doctor from prescribing to State residents, Tr. 95, Respondent nonetheless issued multiple prescriptions to persons who resided in those States.

Respondent attempted to justify his issuance of these prescriptions, explaining that he relied on the employees of Just USA to screen out such customers. Respondent's explanation ignores that he is the physician and is thus ultimately responsible for his prescribing. In short, his explanation is nothing more than excuse-making.

More broadly, Respondent is a licensed physician, and is thus properly charged with the obligation to determine what the law required with respect to his prescribing activities. *See, e.g., Hageseth,* 59 Cal. Rptr. 3d at 403 (licensed health care provider cannot ''reasonably claim ignorance'' of state provisions regulating medical practice). Moreover, those who voluntarily engage in commerce by dispensing controlled substances to persons located in other States are properly charged with knowledge of the legal requirements applicable to the practice of medicine in those States. *United,* 72 FR at 50407.

In this regard, Respondent offered no evidence that he contacted any of the Medical Boards of the various States where the recipients of his prescriptions resided, to determine what their laws required with respect to both obtaining a license and establishing a legitimate doctor-patient relationship. Indeed, for all of his professed interest in the internet, Respondent does not maintain that he ever visited the Web site of any state board to research what the legal requirements were to prescribe.

In his brief, Respondent also claims that the legal opinion prepared by a Florida-based lawyer (RX 7D) ''expresses * * * the idea that Respondent * * * behave[d] within the law.'' Resp. Br. (Pt. II) at 14. According to Respondent, this document was offered ''purely and exclusively to show that [he] had exercised due diligence, regardless of what the letter said in its content.'' *Id.* Moreover, it shows that ''in the middle of the year 2006, [he] was continuing to persist in the due diligence investigation of his * * * practice.'' *Id.*

It is clear why Respondent does not rely on the content of the opinion. The opinion expressly stated that it was limited to Florida law, that it was not addressing issues such as physician licensure, warned that ''[p]rescribing standards vary dramatically from state to state,'' noted that other States had adopted prescribing standards which ''often require[] a face to face physical examination and mak[e] non-compliance a crime subject to heavy penalties.'' RX 7D at 4 & 6. Respondent nonetheless prescribed to persons in States whose prescribing standards did require face-to-face examinations, and did so even after he received the opinion—in June 2006 according to his brief and testimony. *See generally* GX 39. It is thus clear that even when Respondent was provided information as to the potential illegality of his activities, he ignored it.[30]

In his brief, Respondent also maintains that as part of his efforts he reviewed various DEA pronouncements, and that in them, ''there is not one word regarding face-to-face physical examinations being required by federal rules or instructions.'' Resp. Br. (Pt. II) at 12–13. Respondent further contends that ''[a]ny requirements for face-to-face physical examinations are to be found exclusively in State laws.'' *Id.* at 13.

That much is true—at least for the prescriptions at issue here which were written before the enactment of the Ryan Haight Act—but it provides no comfort to Respondent. As I have previously explained, ''in enacting the CSA, Congress did not adopt a federal standard for determining whether a valid doctor-patient relationship exists,'' and that ''on this issue, the CSA recognizes the traditional role of the States in regulating the practice of medicine.'' *Paul H. Volkman,* 73 FR 30630, 30643 (2008) (citing *Gonzales,* 546 U.S. at 270). Taking the steps necessary to establish a valid doctor-patient relationship under state laws and medical practice standards is thus fundamental to a practitioner's establishing that he acted in ''the usual course of professional practice'' and issued a prescription for ''a legitimate medical purpose'' as required by Federal law. Most significantly, nothing in the 2001 Guidance Document or any other Agency pronouncement can reasonably be construed as stating that Respondent's prescribing practices were legal under Federal law.[31]

As the forgoing demonstrates, when Respondent did obtain legal advice that his practices were likely unlawful, he ignored it and continued to prescribe in violation of the laws of numerous States and the CSA. Moreover, when Respondent was confronted at the hearing with the evidence that he had prescribed to residents of States where—according to his testimony—it was illegal to do so, he denied that he was responsible and instead blamed others.

The record thus amply demonstrates the absurdity of Respondent's contentions that he made ''heroic'' and ''serious efforts to assure himself that he was behaving correctly * * * relative to the law,'' that any ''mistakes and errors * * * would have been readily corrected had they been brought to his attention,'' and that ''[i]t would be rare to find someone who is attempting so studiously to abide by the law.'' Resp. Br. (Pt. II) at 15. In short, Respondent's contentions are disingenuous.

Moreover, the record establishes that Respondent was aware of the fact that Just USA had used his registration to issue several backdated prescriptions. These too were violations of the CSA, because a prescription ''may be issued only by an individual practitioner who is: (1) [a]uthorized to prescribe * * * by the jurisdiction in which he is licensed to practice * * * and (2) [e]ither registered or exempted from registration,'' *see* 21 CFR 1306.03(a) &

[30] While the opinion letter concluded that ''the Websites' Medical Records Based Prescribing Procedures appear to comply with the DEA's published rules and Federal law,'' the opinion was based on its analysis of Florida's telemedicine rule and did not purport to analyze whether these practices were legal in any other State. Nor did it address whether under Florida law, a physician who is not licensed in the State, can prescribe a controlled substance to a Florida resident. Rather, in its conclusion the opinion states only that ''Florida's laws and professional standards * * * indicate * * * that a prescribing physician *located in Florida* can prescribe using Medical Records Based Prescribing procedures.'' RX 7D at 1 (emphasis added).

[31] Respondent also contends that ''there was zero testimony regarding any complaints or inquiries directed toward [him] by any State.'' Resp. Br. (Pt. II) at 13. The contention is beside the point as there is no evidence in the record that any of the States whose laws Respondent violated were aware of his misconduct. Moreover, even if a State was aware of Respondent's misconduct and declined to take action, DEA would not be precluded from acting because Congress vested authority to enforce the CSA in the Attorney General and not state officials. *See Edmund Chein,* 72 FR 6580, 6590 (2007).

Respondent also contends that the DI ''never suggested what it is that [he] might have been doing wrong.'' Resp. Br. (Pt. II) at 15. The testimony establishes, however, that when Respondent told the DI that he ''had some telemedicine internet practice going,'' the DI responded ''that there might be a problem with that.'' Tr. 87. Even if it is the case that the DI did not specifically identify why Respondent's telemedicine prescribing was unlawful, it is not as if the DI told him it was lawful.

1306.04, and obviously lacked a legitimate medical purpose. *See also* 21 U.S.C. 822(a)(2) (''Every person who dispenses * * * shall obtain from the Attorney General a registration. * * *''); *id.* § 841(a)(1) (''Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally * * * to * * * distribute, or dispense * * * a controlled substance''); *id.* § 843(a)(2) (''It shall be unlawful for any person knowingly or intentionally * * * to use in the course of the * * * distribution[] or dispensing of a controlled substance * * * a registration number which is * * * issued to another person'').

Respondent did not report the violations, Tr. 170, and in his brief he trivialized the violations as just ''mistakes'' of the sort that ''[c]lerks, and other people who work for doctors, make.'' Resp. Br. (Pt. II) at 22. Notwithstanding the illegal nature of these acts (which had happened shortly after Respondent began his arrangement with Just USA), and that Respondent had no way of confirming the validity of Just USA's representation that its employees had used his name and registration to backdate prescriptions only once or twice, Respondent continued to work for them.

As the record demonstrates, Respondent issued hundreds of illegal prescriptions for highly abused and dangerous controlled substances.[32] While Respondent ceased his illegal activity—after engaging in it for approximately one year—he maintained throughout the hearing that his ''prescribing was appropriate,'' Tr. 99, and that it was illegal in only about two or three other States in addition to the seven States identified by Just USA and where he prescribed to anyway. *Id.* at 161. Moreover, when confronted with the evidence showing that that he had prescribed to persons in those seven States, Respondent's did not accept responsibility for having done so, but rather blamed others.

I thus conclude that Respondent has not accepted responsibility for his misconduct and that he has failed to rebut the Government's *prima facie* showing that his continued registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f). Accordingly, Respondent's registration will be revoked and his pending application will be denied.

[32] As found above, Respondent maintained at the hearing that hydrocodone is not addictive or dangerous. Yet in 2002, the abuse of hydrocodone drugs resulted in more than 27,000 emergency room visits. Moreover, the drug is also highly abused by teenagers, among others. Respondent's testimony buttresses my conclusion that Respondent cannot be trusted to acted responsibly.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, AS2352653,[33] issued to Patrick W. Stodola, M.D., be, and it hereby is, revoked. I further order that any pending application to renew or modify the registration be, and it hereby is, denied. This Order is effective June 4, 2009.

Dated: April 24, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–10245 Filed 5–4–09; 8:45 am]

BILLING CODE 4410–09–P

[33] While the Show Cause Order did not expressly reference Respondent's registration number XS2352653, which authorizes him to dispense narcotic drugs for the purposes of maintenance or detoxification treatment, the holding of a practitioner's registration under 21 U.S.C. 823(f) is a prerequisite for obtaining the separate registration required to conduct narcotic treatment under 21 U.S.C. 823(g). *See id.* § 823(g)(2)(D)(i). Accordingly, the revocation of Respondent practitioner's registration requires the revocation of his registration under 21 U.S.C. 823(g).

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–65,680]

SMTC Enclosure Systems Division Franklin, MA; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on March 26, 2009 in response to a petition filed by a company official on behalf of workers of SMTC, Enclosure Systems Division, Franklin, Massachusetts.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 31st day of March 2009.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E9–10210 Filed 5–4–09; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–65,162]

Dana Holding Corporation, Humboldt, TN; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on February 6, 2009 in response to a worker petition filed by the American Federation of Labor and Congress of Industrial Organizations (AFL–CIO) on behalf of workers of Dana Holding Corporation, Humboldt, Tennessee.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 31st day of March 2009.

Elliott S. Kushner,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E9–10212 Filed 5–4–09; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–65,231]

Rawlings Sporting Goods, Washington, MO; Notice of Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, as amended, an investigation was initiated on February 12, 2009 in response to a petition filed by a company official on behalf of workers of Rawlings Sporting Goods, Washington, Missouri.

The petitioner has requested that the petition be withdrawn. Consequently, the investigation has been terminated.

Signed at Washington, DC, this 26th day of March 2009.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. E9–10215 Filed 5–4–09; 8:45 am]

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