do not ask their customers whether they are purchasing from other distributors; and (4) Mr. Mitchell acknowledged that he continued to sell to stores even when he knew they were obtaining "large quantities" from other distributors. Regarding these four deficiencies, Mr. Mitchell addressed only one of them—the storage of products on its trucks—and did so only with respect to when the trucks were at his facility.[45]

The evidence also showed that Respondent failed on six occasions to report suspicious monthly sales to a store as required by Federal law even though Mr. Mitchell acknowledged that the transactions were suspicious. Here again, Respondent did not offer any evidence that it has instituted a program to identify and report suspicious orders.

Relatedly, when asked whether he had "ever pause[d] to think" that the ephedrine products his firm distributes could be resold to traffickers, Mr. Mitchell explained: "I've guess I've taken the attitude that I have no control on what the retail public does with the product." Tr. 404. As noted above, consistent with this attitude, Mr. Mitchell admitted that his firm had continued to sell to stores even when he knew the stores were buying large quantities from other distributors. And as if further evidence of Mr. Mitchell's and his firm's indifference to their obligations to comply with the law is needed, the record further showed that Respondent violated the CSA by selling a product whose likely use is as drug paraphernalia, and did so even after the DI told Mr. Mitchell that the product was used for this purpose.

Mr. Mitchell's and his firm's clear disregard of their responsibility to protect against diversion and comply with the law "is fundamentally inconsistent with the obligations of a DEA registrant." *Holloway,* 72 FR at 42124; *see also D & S Sales,* 71 FR 71 FR at 37610 (noting that a registrant is "required to exercise a high degree of care in monitoring its customers' purchases") (int. quotations and citations omitted). Because it is clear that Mr. Mitchell does not understand the nature of his firm's obligations, I conclude that Respondent's continued registration "would be inconsistent with the public interest." 21 U.S.C. 823(h). Accordingly, Respondent's registration will be revoked and any pending application will be denied.

[45] It is acknowledged that Respondent undertook to ensure that its customers obtained the necessary certifications required by the CMEA. Tr. 399. Yet this is only one of many factors that are properly considered in assessing whether Respondent's registration is consistent with the public interest.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(h) and 824(a), as well as by 28 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration, 004413RAY, issued to R & M Sales Company, Inc., be, and it hereby is, revoked. I further order that any pending application of R & M Sales Company, Inc., for renewal or modification of its registration, be, and it hereby is, denied. This order is effective January 18, 2011.

Dated: December 3, 2010.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 2010–31640 Filed 12–15–10; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 08–43]

Ronald Lynch, M.D.; Revocation of Registration

On April 4, 2008, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Ronald Lynch, M.D. (Respondent), of Sanford, Florida. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BL6686541, and the denial of any pending applications to renew or modify his registration, on the ground that Respondent's "continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(f), 824(a)(4)." ALJ Ex. 1, at 1.

The Show Cause Order alleged that Respondent "authorized controlled substance prescriptions for Internet customers throughout the United States from approximately June 2002, through September 2004, on the basis of online questionnaires and/or telephone consultations." *Id.* The Order alleged that Respondent "issued these prescriptions without a legitimate medical purpose and outside the usual course of professional practice, in violation of 21 CFR 1306.04(a) and 21 U.S.C. 841(a)(1)." *Id.* The Order further alleged that, while Respondent authorized controlled substance "drug orders" for "online customers throughout the United States," he is only licensed to practice medicine in the State of Florida and that he "violated state laws that prohibit the unauthorized practice of medicine, including unlicensed, out-of-state physicians issuing controlled substance prescriptions to state residents." *Id.* at 2 (citations omitted). Finally, the Order alleged that Respondent "violated Florida law and regulation prohibiting licensed physicians from issuing controlled substance prescriptions in excessive or inappropriate quantities, and from issuing prescriptions via the Internet without a documented patient evaluation and discussion between the physician and patient regarding treatment options." *Id.* (citing Fla. Stat. § 458.331(q) and Fla. Admin. Code Ann. r. 64B8–9.014).

On May 7, 2008, Respondent's counsel requested a hearing on allegations, ALJ Ex. 2, and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJs). On March 24–25, 2009, a hearing was held in Arlington, Virginia.

At the hearing, the Government called several witnesses (including the Respondent) to testify and introduced documentary evidence. Respondent also testified on his own behalf. Following the hearing, both parties filed briefs containing their proposed findings of fact, conclusions of law, and argument.

On September 18, 2009, the ALJ issued her recommended decision (also ALJ). Therein, the ALJ, after considering the five public interest factors, *see* 21 U.S.C. 823(f), concluded that "Respondent has misused his DEA registration [in] the past and has not shown any indication that he will not do so in the future." ALJ at 46. The ALJ thus recommended that Respondent's "registration be revoked and that any pending applications be denied." *Id.*

As to the first factor—the recommendation of the appropriate state licensing board—the ALJ found that Respondent's continued licensure by the State of Florida "throughout the relevant time period" weighed "in favor of a finding that his continued registration would not be inconsistent with the public interest." *Id.* at 34. However, the ALJ also noted that "state licensure is a necessary but not sufficient condition for [holding a] DEA registration" so that "this factor is not dispositive." *Id.*

Examining factors two and four together—Respondent's experience in handling controlled substances and his compliance with applicable Federal, State or local laws—the ALJ determined that "both the Controlled Substances Act and the Florida telemedicine standards require that the prescribing physician or a provider under his supervision personally conduct a physical examination." *Id.* at 38–39. The ALJ found that because Respondent failed to perform such examinations, "he did not establish a proper doctor-patient

relationship" and, as a result, "was not a practitioner 'acting in the usual course of his professional practice' " and thus "violated 21 U.S.C. 841(a)(2)."[1] *Id.* at 39. The ALJ also concluded that Respondent's "failure to review medical records prior to prescribing controlled substances was a violation of Florida standards for telemedicine" and that he therefore "failed to satisfy the requirements for a doctor-patient relationship; did not act in the usual course of his professional practice; and thereby violated the Controlled Substances Act." *Id.* at 40.

The ALJ further found that Respondent had permitted "Ken Drugs to use a rubber stamp bearing his signature to issue prescriptions for controlled substances" and that this constituted a violation of 21 CFR 1306.05(a), which generally requires that prescriptions "be manually signed by the practitioner." *Id.* at 40–41; 21 CFR 1306.05(a). Next, the ALJ found that "Respondent authorized refills for controlled substance prescriptions without a legitimate purpose" such that "the decision whether or not to dispense these refills was made by Ken Drugs personnel, and not by Respondent," thereby violating Florida Administrative Code r. 64B8–9.014. ALJ at 41. The ALJ therefore concluded that "factors two and four weigh in favor of a finding that Respondent's continued registration would be inconsistent with the public interest." *Id.* at 43.

With respect to the third factor—Respondent's conviction record under Federal or state laws relating to controlled substances—the ALJ found that "Respondent has never been convicted" of an offense related to the manufacture, distribution or dispensing of controlled substances. *Id.* However, the ALJ also noted that this factor was not dispositive. *Id.*

As for factor five—other conduct which may threaten public health and safety—the ALJ found that "Respondent maintained throughout the hearing . . . that any shortcomings involving Ken Drugs' Internet patients were due largely to the system set up by the Kennedee Group, and not to any irresponsibility on his part." *Id.* Noting that "[a]s a DEA registrant, Respondent bears full responsibility for understanding his obligations under the Controlled Substances Act and related Federal regulations," the ALJ found that Respondent's "claims merely demonstrate [his] unwillingness to accept his responsibilities as a DEA registrant" and that his "refusal or inability to acknowledge outright that he acted improperly in basing prescriptions on these telephone conversations suggests an unwillingness to recognize that he abrogated his responsibilities as a DEA registrant." *Id.* at 43 & 44.

The ALJ thus found that Respondent had failed "to accept responsibility for his actions" and that his continued registration "poses a threat to the public health and safety." *Id.* at 45. She thus concluded that factor five also supported "a finding that Respondent's continued registration would be inconsistent with the public interest." *Id.*

Neither party filed exceptions to the ALJ's recommended decision. Thereafter, the ALJ forwarded the record to me for final agency action.

Having considered the entire record in this matter, I adopt the ALJ's findings of fact including those related to the credibility of the witnesses. I also adopt her conclusions of law except for her conclusion that under the Florida telemedicine rule, Respondent, as the prescribing physician, was required to conduct the physical examination or to direct another health care provider in the performance of the examination. *See* ALJ at 38. However, I agree with the ALJ's conclusion that Respondent violated the Florida telemedicine rule in those instances when he prescribed without having obtained a documented patient evaluation, *id.,* and that Respondent has failed to accept responsibility for his misconduct. I further conclude that Respondent violated various state laws and the Controlled Substances Act by prescribing controlled substances to residents of States where he was not authorized to practice medicine, as well as by prescribing controlled substances without having performed a physical exam on the residents of various States, whose laws require a prescribing physician to have personally performed a physical exam of his patient. I therefore adopt the ALJ's recommendation to revoke Respondent's registration and to deny any pending applications. I make the following factual findings.

Findings

Respondent is a physician who is board-certified in family practice and holds a medical license issued by the State of Florida.[2] Tr. 191 & 279. In 1999, Respondent also obtained a license to practice medicine in the State of New York; however, he believes that this authority has now expired. *Id.* at 191–92. He is not, and never has been, licensed in any other State. *Id.* at 193.

Respondent currently holds DEA Certificate of Registration BL6686541, which was last renewed on March 8, 2006 and was due to expire on March 31, 2009. GX 1. However, on February 9, 2009, Respondent submitted an application to renew his registration. Accordingly, because Respondent's application was timely submitted in accordance with the Agency's rule, his registration has remained in effect pending the issuance of this Decision and Final Order. *See* 5 U.S.C. 558(c); 21 CFR 1301.36(i).

In 2002, Respondent began working for the Kennedy Medical Clinic, Inc.,[3] as a family physician.[4] *Id.* at 194. On April 8, 2002, Kenneth Shobola, a Florida-registered pharmacist, incorporated Kennedy Medical Clinic, Inc., under the laws of the State of Florida; Shobola is the president and registered agent of the corporation, which operated two medical clinics in Tampa, Florida. GX 2, at 8.

On the same date, Shobola also incorporated Ken Drugs, Inc. *Id.* at 7. Shobola also served as president of this entity and was its sole shareholder. *Id.* This entity owned four pharmacies, three of which were located in Tampa, the other in Kissimmee, Florida. *Id.* at 7–8.

Shobola also incorporated and was the president of the Kennedee Group, Inc.[5] *Id.* at 8. Two websites, medsviaweb.com and medsviaweb.net, were registered to the Kennedee Group at the address of 1612 W. Waters Ave., Tampa, Florida; this was also the address of one of the Ken Drugs pharmacies. *Id.* at 7.

In September 2002, the DEA Tampa Diversion Group received information that prescriptions for hydrocodone, a schedule III controlled substance, were being sent to another pharmacy through the medsviaweb.com website and that refills of these prescriptions were being filled by the Ken Drugs pharmacy

[1] This appears to be a typographical error given that there is no evidence that Respondent was unlawfully distributing or dispensing "a counterfeit substance." 21 U.S.C. 841(a)(2). The correct provision is section 841(a)(1).

[2] Respondent testified that he is a member of the American Academy of Environmental Physicians. Tr. 282.

[3] Throughout this proceeding, the clinic was referred to simply as the "Kennedy Clinic."

[4] At some point while he was working for the Kennedy Clinic, Respondent also started his own practice, Integrative Natural Solutions. *Id.* at 68, 73, 194. Integrative Natural Solutions occupied one floor of an office building at the same address as the Kennedy Clinic in Kissimmee, Florida when, on September 21, 2004, a search warrant was executed at both offices, as well as at other locations. *Id.* at 16, 68.

[5] This entity was previously named Kenadee Group, Inc., and was also known as the Kenaday Group. GX 2, at 8.

located on W. Waters Ave. in Tampa. *Id.* at 9–10. Moreover, "the vast majority of clients seeking hydrocodone were from states other than Florida." *Id.* at 10.

Based on this information, DEA opened an investigation. During the investigation, DEA, along with personnel from the Florida Department of Law Enforcement, the Florida Department of Health, the Kentucky State Police, and the Tampa Police Department made seventeen undercover purchases through either the medsviaweb.com website or through Ken Drugs of such drugs as hydrocodone and Xanax (a schedule IV controlled substance). *Id.* at 11.

The Investigators obtained the drugs by filling out an online questionnaire, giving names, addresses, credit card information, dates of birth and purported medical conditions. Tr. 15; GX 2, at 10; *see also* GXs 6 & 10. After providing this information, a clerk from Ken Drugs' Tampa, Florida headquarters would call the Investigator and shortly thereafter, connect him/her with one of five different physicians employed by the Kennedee Group. Tr. 15; GX 2, at 11. A brief telephone consultation would occur with a physician who then issued a prescription for a controlled substance. Tr. 15; *see also* GX 2, at 11 ("After the receipt of consultation payment * * *. the undercover purchaser would talk by telephone to an employee of Kennedee Group * * * who advised that the purchaser would have to telefax a medical record accompanied by a photocopy of his or her driver's license. Regardless of these requirements, the employee of Kennedee Group * * * customarily resumed telephonic contact with the aspirant purchaser immediately after payment of the $120 or $125 fee to advise that a doctor was available for an expeditious medical consultation soon after which, according to the employee, the controlled substances prescribed would be delivered to the purchaser by UPS or FedEx.").

According to a DEA Diversion Investigator (DI), 97 percent of the prescriptions were for hydrocodone, with the other 3 percent being for the schedule IV controlled substances alprazolam (generic for Xanax), and occasionally, diazepam (generic for Valium). *See* 21 CFR 1308.14(c); Tr. 15; *see also* GX 2, at 23 ("Between June 17 and September 9, 2004, a review of the Ken Drugs pharmacy records revealed that 4,842 prescriptions were written for Schedule[] II, III, and IV controlled substances.[6] The vast majority of the prescriptions were for hydrocodone and only a small number were for other controlled substances such as diazepam (Valium) and alprazolam (Xanax)"). The prescriptions were filled at one of Shobola's Ken Drug pharmacies in either Tampa or Kissimmee and then shipped to the customer. Tr. 16.

In February 2004, the DI, using the undercover name "Michael Patrick," made an undercover purchase from Ken Drugs. *Id.* at 39 & 44. Upon accessing *http://www.medsviaweb.com,* the DI registered as a patient and provided "biographical data, credit card data, address data, information about allergies, [and] medical conditions." *Id.* at 49–50; *see* GX 6 (screens printed out from medsviaweb.com). Next, because he lacked an undercover credit card, the DI called Ken Drugs in Tampa to ask whether he could purchase the controlled substance he was seeking with a postal money order; an employee of Ken Drugs approved this arrangement. Tr. 50.

On February 6, the DI purchased the money order for $125 and sent it to Ken Drugs; several days later, the DI received a telephone call from Ken Drugs during which he was told that a medical consultation would follow if he would send a copy of his driver's license and medical records. *Id.; see* GX 8, at 1. While the DI could not remember whether he sent in a copy of his undercover driver's license, he did not send in any medical records. Tr. 50.

The Government then played into the record Government Exhibit 7, an audio recording of the DI's telephone consultation with a Kennedee Group physician. A speaker, who identified herself as Jennifer, arranged for the consultation once she had confirmed that the DI's money order had been received. Tr. 31–32. Jennifer then asked the DI whether he had faxed his driver's license and medical records; the DI answered, "Yes." *Id.* at 34. Jennifer then put the DI through to an individual who identified himself as Respondent. *Id.*

The DI stated that he suffered "back pain from an automobile crash" and requested "Vicodin extra strength." *Id.* He further explained that several years earlier another physician had "recommended" Vicodin and that it had "helped." *Id.* at 35. He also stated that he had not used Vicodin in several months. *Id.*

Respondent recommended Lortab because it was something with less "Tylenol."[7] *Id.* He then inquired as to the extent of the DI's back pain. *Id.* at 35–36. The DI stated that the back pain "interfere[d] with [his] sleeping, can last for hours some days and for minutes in [sic] other days," and amounted to "a little bit of interference." *Id.* at 36. The DI further offered that prior x-rays indicated that there was no structural damage. *Id.* Respondent then asked the DI how many pills he thought he would need per day; the DI responded two to three per day. *Id.* at 37. Respondent then stated: "Let's say two, two would be fine," and indicated that the DI would be sent "something that's actually a little safer for you and better than what you were asking for." *Id.* at 37–38.

On February 12, 2004, the DI picked up the Lortab in person at Ken Drugs #3, which was located at 4730 North Havana Avenue in Tampa. *Id.* at 44. He received sixty tablets of hydrocodone/apap (10/500), a drug which combines 10 mgs. of hydrocodone with 500 mgs. of acetaminophen in each tablet. *Id.* at 46; GX 8, at 2, 4. Laboratory testing confirmed that the tablets contained hydrocodone. Tr. 47. The label identified the prescribing physician as Respondent. GX 8 at 2, 4.

The DI further testified that no physical examination was performed, that he did not know whether Respondent had a copy of the online questionnaire in front of him when he prescribed the Lortab, and that Respondent did not take a medical "history" or give him a "treatment plan." Tr. 41, 77–78.

At DEA's request, on July 20, 2004, a Medical Quality Assurance Investigator with the Florida Department of Health (DOH) made an undercover purchase of hydrocodone through the website modernlifestylemeds.com; this prescription was also authorized by Respondent. Tr. 148; GX 9. According to the DOH Investigator, he registered as a customer, giving his undercover name of "Donald Huntley," date of birth, home address, telephone number, and a medical complaint; he then requested Percodan. Tr. 149, 152–53; GX 9, at 1. On July 29, the DOH Investigator filled out a medical history form and received an e-mail confirming his name, date of birth, phone number, and his medical complaint. Tr. 150–152; GX 9, at 1. The

[6] According to an affidavit prepared by an IRS Special Agent who participated in the investigation, "[a] review of the prescriptions filled by the KEN DRUGS pharmacy on Waters Avenue in Tampa, Florida, from June of 2002 through of 2003, reveals that 50,237 Schedule II, III, and IV prescriptions were filled. Further, that 48,793 prescriptions were written by Hameed, Lynch, Oluwole, Osuji, and Shyngle, and the vast majority were for hydrocodone." GX 2, at 23.

[7] Respondent testified that the voice on this recording sounded like his own. Tr. 223. As indicated *infra,* the prescription label on the vial identified the prescribing physician as Dr. Ronald Lynch. I therefore find that the individual identifying himself as Dr. Lynch in the telephone conversation recorded in Government Exhibit 7 is Respondent.

following day he received a telephone call from "Jasmine at Modern Lifestyles," who asked "what type of medication [he] was trying to obtain." Tr. 152; GX 9, at 1. After the DOH Investigator told her that he wanted Percodan, Jasmine replied that he could not get this drug (which is a schedule II controlled substance), but that he would be able to get Lortab at a cost of $177 for a thirty-day supply; she also instructed him to send in a copy of his driver's license and his medical records. Tr. 152; GX 9, at 1.

On August 1, the DOH Investigator faxed a copy of his undercover driver's license but not his medical records, and on August 2, Jasmine called again to confirm that he wanted Lortab. Tr. 153; GX 9, at 1. Jasmine told the Investigator that he could not personally pick up the medication and that he would need to pay by credit card; he then gave her his undercover credit card information. GX 9, at 1. Jasmine did not ask about the medical records which the Investigator had failed to provide; she then put the Investigator through to an individual who identified himself as Respondent. GX 9, at 1; Tr. 154, 157.

Respondent [8] asked the Investigator his age and the cause of his pain. Tr. 154; GX 9, at 1. The Investigator responded that he was sixty years old and that he had injured his back some four to five years earlier while helping his son move furniture. Tr. 155; GX 9, at 1. Respondent further asked about other medications that the Investigator was taking and about whether he had any liver damage; the latter responded that he was taking Vicodin and Lortab and did not have liver damage. Tr. 155; GX 9, at 1. Respondent then asked the Investigator to provide the name of the physician he was currently seeing; the Investigator named a Dr. Cichon. Tr. 155; GX 9, at 1. After some three to five minutes, the conversation ended with Respondent stating that he would prescribe Lortab with three refills. Tr. 156; GX 9, at 1.

In his testimony, the Investigator stressed that he never sent the required medical records, never met Respondent in person, and never underwent a physical examination by Respondent or anyone associated with the website he had accessed to obtain the medication. Tr. 157–158; *see also* GX 9, at 1–2.

On August 4, the Investigator received a vial which contained hydrocodone/apap 10/500. Tr. 156; GX 9, at 2. The prescription was dispensed by Ken Drugs, Inc.'s pharmacy #3, which was located at 4730 North Habana Avenue in Tampa, Florida. Tr. 158; GX 9, at 2. The label on the vial indicated that it contained ninety pills and that Respondent was the prescribing physician. Tr. 159–60; GX 9, at 2; GX 10, at 2, 3.

On September 21, 2004, DEA executed a search warrant at seven locations associated with Ken Shobola and his Ken Drugs enterprise, two in Kissimmee and five in Tampa, including Respondent's Integrative Natural Solutions business, which was located at the same address as one of the Kennedy Clinic's offices. Tr. 16, 68, 73. As part of the search, the Investigators "imaged [and] downloaded" the files on thirty-three computers; they also seized another computer and sent it to the DEA forensics laboratory for analysis. *Id.* at 17.

Among the items seized were records of ten controlled substance prescriptions which Respondent issued to residents of California, Ohio and Tennessee. *Id.* at 67; GX 18. Only one prescription bore Respondent's actual signature; this prescription was clearly faxed to the Kennedee Group. Tr. 226, GX 18, at 6. The other prescriptions bore a stamped signature and were electronically transmitted by Respondent. Tr. 226; GX 18, at 5–6.

Three of the prescriptions were dispensed to residents of California; all of these prescriptions were for 90 tablets of hydrocodone/apap, containing either 7.5 or 10 mgs. of hydrocodone per tablet. GX 18, at 1–6. Six prescriptions were dispensed to residents of Tennessee; four of these were for 90 tablets of hydrocodone/apap containing 10 mgs. of hydrocodone, one was for 90 tablets of alprazolam, and one was for 60 tablets of diazepam. *Id.* at 7–10, 13–18. The remaining prescription, which was dispensed to a customer in Ohio, was for 90 hydrocodone/apap (10/500). *Id.* at 11–12.

At least three physicians who worked for Shobola's scheme were interviewed by DEA Investigators. The lead DI testified that on October 20, 2004, he interviewed a Dr. Ladapo Shyngle at his Tampa residence. Tr. 23; GX 2, at 9. During the interview, Dr. Shyngle stated that he did not have face-to-face meetings with the Ken Drugs customers he prescribed hydrocodone to; he also admitted that he did not review the customers' medical records in every case before prescribing controlled substances to them. Tr. 24; GX 5, at 15–16, 20; GX 17, at 2.

Dr. Shyngle further admitted that as the number of Ken Drugs' customers increased, he saw their medical records before prescribing only approximately thirty percent of the time. GX 5, at 20–21; GX 17, at 1–2. According to Shyngle, Ken Drugs "hired an institution" that performed physical examinations for them. GX 5, at 25. Shyngle admitted, however, that the physicians were "not always" "actually able to look at the information" documenting those physical exams before they prescribed. *Id.*

The DI also testified that on November 17, 2004, he interviewed a Dr. Chuma Osuji, Director of Medicine for Ken Drugs.[9] Tr. 19–20, 82; GX 2, at 8; GX 4, at 5. The Government entered into evidence a transcript of the taped 2-hour interview of Dr. Osuji; the DI also testified as to the substance of the interview. Tr. 20–22; GX 4.

In the interview, Dr. Osuji admitted that he did not see the patients to whom he prescribed controlled substances;[10] that most of the prescriptions he wrote were for hydrocodone; that, while he sometimes saw the medical records prior to, or at the time of prescribing, he "frequently" did not; and that all of the prescriptions authorized by the physicians retained by the Kennedee Group were filled at pharmacies owned by Ken Shobola. Tr. 20–21; GX 4, at 9–10, 30.

Dr. Osuji also stated that he issued prescriptions by completing a form authorizing the prescription and faxing it to one of the Ken Drugs pharmacies for filling; the authorization was not "manually" signed. Tr. 88–89; GX 4, at 29–30. Dr. Osuji stated that Ken Drugs contracted with another company which was supposed to provide physical examinations of patients so Dr. Osuji assumed that the customers had undergone physical examinations prior to his prescribing to them. GX 4, at 25, 38. Also according to Dr. Osuji, one or two months earlier, he had learned that patients were not getting physical examinations (apparently after someone complained that he had paid for a physical and not received one). Tr. 21; GX 4, at 38–40, 47.

[8] At this point in the hearing, counsel for Respondent objected to the witness referring to this individual as Dr. Lynch, the Respondent. Tr. 155. The ALJ overruled this objection. *Id.* In his testimony, Respondent did not dispute that he had prescribed to either the DEA or DOH Investigators. Moreover, the prescription label for the medication that was dispensed to the Investigator indicated that the prescribing physician was Dr. Ronald Lynch. GX 10, at 2–3. I therefore find that Respondent was the individual who identified himself as Dr. Lynch.

[9] According to Dr. Osuji, although he was to be the medical director from the initial plans with Ken Shobola, there turned out to be "many medical directors" so that Dr. Osuji ultimately was not in charge of "oversee[ing]" the operation. GX 4, at 7. Apparently, there were a total of six medical directors. *Id.* at 42.

[10] According to Dr. Osuji, the customers were supposedly seen by "doctors, nurses, and [physicians assistants]" before he spoke with them. GX 4, at 8.

Another DI testified that she participated in an interview of Respondent on the day the search warrant was executed. Tr. 168–69. She testified that Respondent conducted two different kinds of medical practice, the first an "individual practice, which involved holistic medicine" and was named Integrative Natural Solutions; the other was an "internet pharmacy business, which was connected to the Ken Drugs business." *Id.* at 169.

Respondent was hired by Shobola to write prescriptions for the Kennedee Group and was paid $30 per telephone consultation. *Id.* at 173. However, Respondent admitted that he was not paid if he did not authorize a prescription. *Id.* at 198. Respondent stated that he conducted approximately fifty consultations per week, "usually no more than about 10 a [sic] day." *Id.* Respondent primarily prescribed hydrocodone. *Id.* at 171. The prescriptions were always filled by Ken Drugs. *Id.*

Respondent contacted the customers by accessing the website "through the Kenned[ee] Group Corporation" and then did telephone consultations with them. *Id.* at 170, 172–73. Respondent stated that he "talk[ed] with the patient [sic] regarding their medical concern, their medical need, if they had any problems, liver damage, if they had been taking medication, [and] what drugs or medication in particular they were seeking." *Id.*

Respondent maintained that the customers' medical records were filed at the corporate offices of the Kennedee Group and that he would "periodically" look at the records to determine patients' medical needs. *Id.* Respondent admitted, however, that his examination of the records did not "necessarily" occur "before he dispensed the medication." *Id.* Respondent allowed the corporate office to "use a rubber stamp with his signature, a custom stamp," to complete prescription authorizations. *Id.* at 172. He also told the Investigators that he was electronically transmitting the prescriptions to the pharmacy. *Id.* at 181.

During the interview, Respondent stated that he "believed that what he was doing was in line, because he thought that the Kenned[ee] Group were [sic] known. They [sic] had a big business and he felt he was doing what he thought was appropriate." *Id.* at 177. Respondent also stated that he believed that Shobola "had looked into the legalities of the business[;] and he felt that with the size of the business, surely, what they were doing could not be wrong. He trusted the insight of Ken Shobola." *Id.* at 185.

The Government also called Respondent to testify. The ALJ found, however, that Respondent's "testimony was frequently at odds with that of the [other] Government witnesses" and that he "displayed a lack of candor and appeared to shade his testimony to support his position on the issues." ALJ at 32. She accordingly found "the [other] Government witnesses more credible." Id.

According to Respondent, the Ken Drugs corporate center was designed for telemedicine and not for the physical receiving and treating of patients. Id. at 202. He described the business as "a nation-wide endeavor" in which patients were serviced by regional staff which conducted home visits to ascertain such matters as whether the customers were minors. Id. at 203–04.

In his testimony, Respondent admitted that the Ken Drugs scheme "[o]bviously[] did not lend itself to do[ing] any physical examination." *Id.* at 212–13. He further maintained that "[v]ery often, the majority of the time * * * [a]t least 75 to 85 percent of the time" he conducted his telephone consultations with the customers' medical records in front of him. *Id.* at 206. The ALJ did not find this testimony credible in light of his admission during the September 21, 2004 interview that he did not necessarily review the records before he prescribed. ALJ at 39. Moreover, both the DEA and DOH Investigators testified that they did not send in their medical records prior to Respondent's prescribing hydrocodone to them. For the same reason, the ALJ did not credit Respondent's testimony that he would have to turn away Internet patients who did not provide medical records.[11]

As to the potential for fraud in prescribing to persons he never met, Respondent admitted that "the real doctor/patient relationship is based upon honesty," and that if the patients "were liars" "they could break through." *Id.* at 206–07. Respondent then testified that the Shobola scheme used "the team approach" and that other employees were responsible for confirming the customers' identities and screening the required medical records and physical examination before he did his telephone consultations with them. *Id.* at 206–07, 220. According to Respondent, prior to his contacting the customers, the other employees obtained the required medical records, imaging studies, and sometimes, documentation of an actual in-person consultation with what he called a "mid-level provider." *Id.* at 199–200. This was so Respondent would not have "to waste [his] time with being a police agent or * * * a lawyer." *Id.* at 208.

He also maintained that customers "wouldn't get me on the phone until they had gone through some of these hurdles." *Id.* at 208. Here again, Respondent's testimony is contradicted by the purchases made by the DEA and DOH Investigators, both of whom obtained hydrocodone without sending in their medical records.

Later in his testimony, Respondent claimed that he could make a "judgment" that persons were either drug abusers or drug seekers based on their "voice," "diction," and "answers to some of the questions that I might have posed to them." *Id.* at 230. However, he then admitted that this "is, by no means, any criteria to determine who is being evasive and who is being under-handed or who is legitimately seeking a substance. It is very, very less than perfect." *Id.* at 231.

Respondent further maintained that "[t]here was not one letter, not one comment from any medical quality boards or anyone, regarding safety, regarding guidance in any way" as to "the practice of telemedicine." *Id.* at 209. However, as explained below, at the time Respondent issued the prescriptions, substantial guidance was available as to the legality of this practice. Respondent further claimed that he was "very glad that since that faithful [sic] day in September 2004" (apparently the date on which the search warrant was executed) he had "not returned to internet medicine because [he] do[es] think it does have some holes in it." *Id.*

Respondent also asserted that he visited the Ken Drugs corporate headquarters to meet the clerks and the personnel handling the telephone consultation transfers because he "need[ed] to talk to them and find out that everything [was] happening legitimately and appropriately." *Id.* at 202. The record, however, contains no evidence that Respondent sought to independently determine whether the practices he was engaging in were legal. Moreover, the ALJ found Respondent's "asserted reliance on Ken Drugs' administrative personnel disingenuous at best." ALJ at 44.

Respondent further maintained that he kept medical records "of every conversation or most of the conversations" in one of his notebooks. Tr. 210. However, when asked whether he wrote the prescriptions contained in Government Exhibit 18, Respondent stated that he did not bring his records with him to the hearing. *Id.* at 225–26.

Respondent further asserted that he discussed the patients' diagnoses with the patients and that he "absolutely" discussed alternative treatments such as physical therapy, magnetic therapy, acupuncture and eating "certain anti-inflammatory foods." *Id.* at 210, 214–15. He also maintained that he discussed the risks and benefits of treatment with controlled substances, *i.e.,* the risk of "habituation and the risk of acetaminophen damage," the latter concern compelling him to inquire always about blood tests, liver damage and kidney function. *Id.* at 216–17.

While the evidence pertaining to the undercover purchases indicates that Respondent did discuss the risks to liver function caused by taking too much acetaminophen, there is no evidence that he discussed the risk of addiction caused by taking narcotics with either Investigator. Nor did Respondent even discuss, let alone recommend, to the DEA and DOH Investigators that they try alternative treatments.

For Florida residents, Respondent claimed that he provided outside referrals and that it was "fairly infrequent" that customers did not have "background" MRIs, blood work, or x-rays. *Id.* at 213–14. However, he claimed that he could not do this for his out-of-state patients. *Id.* at 213.

According to Respondent, the audio recording of his telephone consultation with the DEA DI was "[n]ot necessarily" representative of his typical consultation, as it was the "minority of the time" that he participated in a consultation without the medical records in front of him; he also claimed that he would later review the medical record if it was not available at the time of the consultation. *Id.* at 224–25. He also maintained that he was "[s]ometimes" available to customers to review the "course and efficacy of the treatment." *Id.* at 218.

As for the prescriptions identified in Government Exhibit 18, Respondent maintained that he had actually signed only one of them. Tr. 226 (discussing GX 18, at 6). As for the others, Respondent stated that they looked like they had been stamped. *Id.* at 228. However, he admitted that the stamp was a facsimile of his signature and that he "may have" provided the Kennedy clinic with a stamp containing his signature. *Id.* He then stated that while "it was [his] practice to sign" the prescriptions "when he could," he had granted "the pharmacist" at Ken Drugs "some permission to use the stamp, if [he] was not able to do that" himself. *Id.* at 229. With respect to those prescriptions which were stamped, Respondent could not even address whether he did "indeed, * * * have a consultation with these * * * individuals." *Id.* at 228.

Respondent also testified on his own behalf. Respondent primarily testified about his professional background and that in 2006, he had attended a course offered by the American Academy of Pain Management which included classes about DEA, controlled substances, and the use or misuse of opioids.[12] *Id.* at 281–84. Respondent also further asserted that he has identified drug seeking patients in his "current practice" and that he handles them by discharging them. *Id.* He further testified that from 2005 on, he sees 100 percent of his patients in "a face to face setting," and that he will diagnose a person he does not know over the telephone only in an emergency. *Id.* at 290.

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). In the case of a practitioner, Congress directed that the following factors be considered in making the public interest determination:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing * * * 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).

"[T]hese factors are considered in the disjunctive." *Robert A. Leslie,* 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors and give each factor the weight I deem appropriate in determining whether to revoke or renew an existing registration. *Id.* Moreover, I am "not required to make findings as to all of the factors." *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005); *see also Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009).

[12] His testimony as to what subjects were covered was vague.

In this matter, I acknowledge that the State of Florida has taken no action against Respondent's medical license (factor one) and that Respondent has not been convicted of an offense related to controlled substances (factor three). However, under settled Agency precedent, "neither of these factors is dispositive." *Joseph Gaudio,* 74 FR 10083, 10090 n.25 (2009) (citing *Edmund Chein,* 72 FR 6580, 6590 n.22 (2007) and *Mortimer B. Levin,* 55 FR 8209, 8210 (1990)).

Rather, the gravamen of the Government's case is that Respondent violated the CSA and numerous state laws by: (1) Prescribing controlled substances to persons whom he never met and physically examined, and (2) by engaging in the unauthorized practice of medicine because he lacked the state licenses required to prescribe to the residents of various States. Gov. Br. at 5–9 (discussing factors two and four). The Government further argues that Respondent's conduct in prescribing over the Internet creates an extraordinary threat to public health and safety. *Id.* at 9–10. While Respondent offered some testimony as to changes he has made in his medical practice, as explained below, I agree with the ALJ's finding that his testimony was evasive and that he repeatedly failed to accept responsibility for his misconduct.

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

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." *Gonzalez* v. *Oregon,* 546 U.S. 243, 274

(2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135 (1975)).

Under the CSA, it is "fundamental" that a practitioner must establish a bonafide doctor-patient relationship to act "in the usual course of * * * professional practice" and to issue a prescription for a "legitimate medical purpose." *Gaudio,* 74 FR at 10090 (citing *Moore,* 423 U.S. at 141–43). Moreover, at the time of the events at issue here, whether a doctor and patient have established a bona fide doctor-patient relationship under the CSA was generally a question of state law. *Id.; see also 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 (DEA Guidance Document), 66 FR 21181, 21182–83 (2001).

Moreover, "[a] physician who engages in the unauthorized practice of medicine" under state law "is not 'a practitioner acting in the usual course of * * * professional practice' " under the CSA. *Gaudio,* 74 FR at 10090 (quoting *United Prescription Services,* 72 FR at 50407). As the Supreme Court explained shortly after the CSA's enactment, "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." *Moore,* 423 U.S. at 140–41. This rule derives from the plain text of the statute which defines the 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 the term "dispense" to mean "to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of a practitioner." 21 U.S.C. 802(10). Thus, a controlled-substance prescription issued by a physician who lacks the license or other authority necessary to practice medicine within a State is unlawful under the CSA. *See* 21 CFR 1306.04(a); *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 Respondent repeatedly violated the CSA when he prescribed controlled substances for the customers of the Kennedee Group. He did so for two reasons: (1) He failed to establish a bona fide doctor-patient relationship as required by the laws of the States where the patients resided, and (2) because he was licensed only in Florida (and possibly New York at the time), he engaged in the unauthorized practice of medicine in those States (other than Florida and possibly New York) where the customers lived. Nor can Respondent credibly claim that "[t]here was not one letter, not one comment from any medical quality boards or anyone, regarding safety, regarding guidance in any way" as to the practice of telemedicine." *Id.* at 209.

As found above, Respondent issued three prescriptions for schedule III controlled substances containing hydrocodone to residents of California. However, in 2000, California enacted a provision which 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." Cal. Bus. & Prof. Code § 2242.1. Moreover, in 2003 (and prior to the three prescriptions identified in GX 18), the Medical Board of California (MBC) revoked a physician's medical license when he engaged in practices similar to those of Respondent. *See In re 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 MBC explained that "[b]efore prescribing a dangerous drug, a physical examination must be performed." *Id.* The MBC held 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.* The MBC also held that a "medical indication" is determined only after the taking of a history, the conducting of a physical examination, and an assessment of "the patient's condition." *Id.* The MBC further explained that "[a] physician cannot determine whether there is a medical indication for prescription of a dangerous drug without performing a physical examination." *Id.*

In approximately the same time-frame, MBC also issued numerous Citation Orders to out-of-state physicians for prescribing over the Internet to California residents. These Orders cited both the physicians' failure to conduct "a good faith prior examination" and 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 (June 17, 2003); Citation Order, Carlos Gustav Levy (Jan. 28, 2003); Citation Order, Carlos Gustav Levy (Nov. 30, 2001).

As the evidence shows, Respondent has never held a California Physician and Surgeon's license. Moreover, given Respondent's admission that the scheme "[o]bviously, did not lend itself to do any physical examinations," Tr. 212–13, I conclude that Respondent did not conduct a physical examination of any of the three California residents he prescribed to (and who were identified in GX 18). Accordingly, I conclude that in prescribing to these three persons, Respondent violated California law by engaging in the unauthorized practice of medicine and by prescribing "without an appropriate prior examination and medical indication therefore." Cal. Bus. & Prof. Code § 2242.1. I further hold that these prescriptions lacked a "legitimate medical purpose" and were issued "outside of the usual course of [his] professional practice" and therefore violated the CSA as well. 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1).

Respondent issued a prescription for hydrocodone to an Ohio resident. As does every State, Ohio prohibits the practice of medicine without a state license. Ohio Rev. Code Ann. § 4731.41 (1998). Moreover, Ohio has enacted a statute which defines "telemedicine" as "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 requires that a physician obtain a "telemedicine certificate" to lawfully prescribe within the State, *id.* § 4731.296 (effective 4–10–01), and a "special activity certificate." *Id.* § 4731.294 (effective 4–10–01). Moreover, in 2002, Ohio adopted a regulation which, except for in circumstances not at issue here, prohibits the dispensing of controlled substances "to a person who the physician has never personally examined and diagnosed." Ohio Admin. Code § 4731–11–09(A).

Respondent did not possess either an Ohio medical license or Ohio "telemedicine certificate" and thus, he was not authorized to prescribe to an Ohio resident. Moreover, because Respondent did not perform a physical examination of the Ohio resident as required by the State's rule, he did not establish a legitimate doctor-patient relationship with this person. In prescribing hydrocodone to this person, not only did Respondent violate Ohio law and regulation, he also acted outside of the usual course of professional practice and lacked a legitimate medical purpose and

therefore violated the CSA as well. 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1).

Respondent issued six prescriptions for controlled substances (which included hydrocodone, as well as alprazolam and diazepam), to residents of Tennessee. Tennessee law prohibits the practice of medicine within the State without a license issued by the State. Tenn. Code Ann. § 63–6–201(a) (2002); *see also id.* § 63–6–204 (2002) (defining "a person [who is] regarded as practicing medicine" as one "who treats, or professes to diagnose, treat, operate[] on or prescribes for any physical ailment or any physical injury to or deformity of another"). Like Ohio, Tennessee also provides for "restricted licenses and special licenses based upon licensure to another state for the limited purpose of authorizing the practice of telemedicine." *Id.* § 63–6–209(b) (1996).

Prior to the prescribings at issue here, Tennessee had also promulgated a regulation which provided clear notice that, prior to issuing a prescription for a controlled substance "by electronic means or over the Internet or over telephone lines," a physician must "[p]erform[] an appropriate history and medical examination," "[m]a[k]e a diagnosis based upon the examinations and all diagnostic and laboratory tests consistent with good medical care," "[f]ormulate[] a therapeutic plan," and "[i]nsure[] availability of the physician or coverage for the patient for appropriate follow-up care." Tenn. Comp. R. & Regs. 0880–2–14.(7)(a) (2002). Here again, Respondent did not possess a Tennessee license and violated state law when he issued the six prescriptions to Tennessee residents. He also violated Tennessee's regulation because he did not perform a medical examination of the persons he prescribed to. Because Respondent did not establish a legitimate doctor-patient relationship and lacked the necessary State license, in issuing these prescriptions, he acted outside of the usual course of professional practice and lacked a legitimate medical purpose and therefore violated the CSA as well.[13]

Respondent also violated both Florida's telemedicine regulation (which was promulgated in September 2003) and the CSA when he prescribed hydrocodone to the DEA and DOH Investigators. The Florida rule defines "the term 'telemedicine' " to include the "prescribing [of] legend drugs" made to patients via the internet, telephone, or facsimile. Fla. Admin. Code Ann. r. 64B8–9.014(5). The rule provides that prescribing medications solely on the basis of an electronic questionnaire "constitutes the failure to practice medicine with that level of care, skill, and treatment which is recognized by reasonably prudent physicians as being acceptable under similar conditions and circumstances, *as well as prescribing legend drugs other than in the course of a physician's professional practice.*" Fla. Admin. Code Ann. r. 64B8–9.014 (emphasis added). The rule further provides that physician shall not issue a prescription, through electronic or other means, unless following are done:

> (a) A documented patient evaluation, including history and physical examination to establish the diagnosis for which any legend drug is prescribed.
>
> (b) Discussion between the physician * * * and the patient regarding treatment options and the risks and benefits of treatment.
>
> (c) Maintenance of contemporaneous medical records meeting the requirements of [Fla. Admin. Code] Rule 64B8–9.003.

Id. r. 64B8–9.014(2).

In her recommended decision, the ALJ noted that "the Florida regulation governing telemedicine standards does not specify who must conduct the physical examination." ALJ at 38. Rather than research whether the Florida Medical Board had resolved this apparent ambiguity, the ALJ found "it reasonable to infer that the examination must be conducted by the prescribing physician or a health care provider under his direction (such as a nurse or physician assistant)." *Id.*

The ALJ did not, however, cite any authority such as an administrative or judicial opinion of the Florida Board of Medicine, the Florida Attorney General, or the Florida courts definitively construing the regulation as imposing this requirement. Moreover, as the Supreme Court has made clear, while DEA has authority under the public interest standard to determine whether a physician has complied with state law, it does not have the power to "authoritatively interpret" ambiguous provisions of State law. *Gonzales* v. *Oregon,* 546 U.S. 243, 264 (2006) (noting "the obvious constitutional problems" were the Attorney General to "do[] so"). Thus, while it may be reasonable to construe the regulation as the ALJ did, absent either an administrative or judicial decision interpreting the regulation in this manner, I am compelled to reject the ALJ's conclusion that Florida's telemedicine rule "require[s] that the prescribing physician or a provider under his supervision personally conduct a physical examination." ALJ at 38–39.

In any event, whatever the rule requires as far as who can perform the physical exam, it does not matter because the rule clearly requires that a physician cannot prescribe a drug unless there is "[a] documented patient evaluation" and neither the DEA nor DOH investigator provided any medical records to Ken Drugs.[14] Thus, it is clear that Respondent violated the Florida rule when he prescribed hydrocodone to the DEA and DOH investigators. Moreover, it is clear that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose and thus violated the CSA.[15] 21 CFR 1306.04(a); 21 U.S.C. 841(a)(1).

[13] In addition to these statute and rules, which had been promulgated prior to his conduct, in April 2001, DEA published a guidance document entitled *Dispensing and Purchasing Controlled Substances over the Internet,* 66 FR 21181. 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).

[14] The ALJ also found that "the record establishes that Respondent failed to review medical records for most, if not all, of his patients." ALJ at 38. While there is evidence that Respondent failed to review the medical records of the DEA and DOH Investigators, and there is evidence that other doctors admitted that in many instances they did not review medical records before prescribing, it is not necessary to decide whether the ALJ's finding is supported by substantial evidence. Given that: (1) the Investigators obtained prescriptions without providing medical records, and (2) even putting aside the ALJ's finding that Respondent's testimony that he had the medical records in front him "[a]t least 75 to 85 percent of the time," Tr. 206, was not credible, ALJ at 39; it is still clear that Respondent frequently prescribed without reviewing a person's medical record. Beyond this, given the clear requirements of California, Ohio, and Tennessee that the prescribing physician must perform the physical examination, whether he reviewed medical records of these persons is immaterial.

[15] In his brief, Respondent argues that "there is no requirement that the prescribing physician personally conduct a physical examination of a patient for a valid doctor-patient relationship to exist." Resp. Br. at 10 (citing *Forlaw, M.D.* v. *Fitzer,* 246 So.2d 432, 435 (Fla. 1984)). However, as explained above, in California, Ohio and Tennessee there is such a requirement. Moreover, with respect

In his testimony, Respondent appeared to deny having personally issued all but one of the prescriptions contained in Government Exhibit 18. Tr. 228–29. However, as found above, in an interview, Respondent admitted that he was electronically transmitting prescriptions to Ken Drugs, and in his testimony, Respondent admitted that he had provided a stamp with his signature to at least one of the Ken Drugs pharmacies. Thus, it is clear from his testimony that Respondent's intent in doing so was to authorize Ken Drugs to dispense prescriptions under his registration number. *Id.* at 229 ("It was my practice to sign them when I could and when everything was variable and proper and there would be some permission to use the stamp, if I was not able to do that myself."). I thus reject Respondent's contention that he did not authorize the nine stamped prescriptions.[16]

Moreover, Respondent did not claim that these were oral prescriptions. Thus, Respondent also violated DEA regulations because he did not manually sign the prescriptions. *See* 21 CFR 1306.05(a) ("Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner.")[17]

As the foregoing demonstrates, Respondent's experience in dispensing controlled substances and his record of compliance with laws related to controlled substances is characterized by his repeated prescribing in violation of state laws prohibiting the unauthorized practice of medicine as well as those requiring that a physician personally perform a physical examination of a patient he prescribes to. These prescriptions also violated Federal law because in issuing them, Respondent lacked "a legitimate medical purpose" and acted outside of "the usual course of [his] professional practice." 21 CFR 1306.04(a). I thus hold that the Government has satisfied its *prima facie* burden of showing that Respondent has committed acts which "render his 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, [he] 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).

It is acknowledged that Respondent ceased his internet prescribing activities shortly after the execution of the search warrant. It is also acknowledged that Respondent took a course of the American Academy of Pain Management, which included subjects pertaining to the prescribing of controlled substances.

The ALJ found, however, that Respondent has not accepted responsibility for his misconduct. ALJ at 43–45. As support for this finding, the ALJ cited: (1) Respondent's statement to the investigators that he believed the Ken Drugs' scheme was lawful because the Kennedee Group was well known, had a large business, and that Shobola had researched its legality, (2) his testimony that he relied on Ken Drugs' employees to screen for drug abusers, which she characterized as "disingenuous at best," and (3) his "evasive and unresponsive" testimony in "describing his interactions with Ken Drugs patients." ALJ at 43–44.

The ALJ's finding is well supported by the record. With respect to Respondent's contention that he believed that what he was doing was lawful, I have previously held that "a licensed physician * * * is * * * properly charged with the obligation to determine what the law require[s] with respect to his prescribing activities." *Patrick W. Stodola, M.D.,* 74 FR 20727, 20735 (2009). In short, Respondent's various contentions as to why he believed Shobola's internet prescribing scheme was lawful are absurd on their faces.

Indeed, further evidence of Respondent's failure to accept responsibility is his testimony that "[t]here was not one letter, not one comment from any medical quality boards or anyone, regarding safety, regarding guidance in any way" as to "the practice of telemedicine." Tr. 209.[18] As noted above, this is utter nonsense, as prior to his prescribing, each of the three States whose residents he prescribed to (California, Ohio, and Tennessee) had enacted statutes and/or promulgated regulations which clearly prohibited his prescribing without obtaining a state license and without physically examining his patients.

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 state law standards for establishing a valid doctor-patient relationship.

Respondent's testimony regarding how Ken Drugs screened for drug abusers likewise manifests a degree of irresponsibility that is incompatible

to the undercover purchases, the argument provides no comfort to Respondent because he prescribed without obtaining a "documented patient evaluation, including [a] physical examination" and the Florida rule expressly provides that such prescribing is not "in the course of a physician's professional practice." Fla. Admin. Code Ann. R. 64B8–9.014.(1) & (2).

Respondent also testified that Ken Drugs had "other locations that were designed for seeing patients" and that the patients "would be directed to an office where they could get a physical examination, where they could go through getting their vital signs and so forth." Tr. 203. Respondent did not, however, produce any evidence showing that any of the patients identified in Government Exhibit 18 were physically examined at these "other locations." Nor did he offer any evidence showing that the so-called regional staffers were qualified to perform physical exams and diagnose patients. Finally, Respondent does not cite to any law or regulation of the States of California, Ohio or Tennessee authorizing this practice.

[16] Even if he did not authorize the prescriptions, the evidence supports a finding that Respondent authorized the pharmacist to issue prescriptions under the authority of his registration. Under DEA case law, a registrant who authorizes others to use his registration is responsible for any misuse of his registration by these individuals. *See Paul H. Volkman,* 73 FR 30630, 30644 n.42 (2008); *Rose Mary Jacinta Lewis,* 72 FR 4035, 4040 (2007); *Robert G. Hallermeier,* 62 FR 26818, 26820 (1997); *Summer Grove Pharmacy,* 54 FR 28522, 28523 (1989).

[17] An oral prescription must be "reduced to writing by the pharmacist" and "contain[ ] all information required by 21 CFR 1306.05, except for the signature of the practitioner." 21 CFR 1306.21(a).

[18] Notably, at an earlier point in his testimony, Respondent stated: "We were all constantly reviewing legalities and making certain that we were responding to the best practice possible." Tr. 202. *See also* Tr. 222 ("there were very, very few guidelines").

with what DEA expects of a registrant. While Respondent testified that other employees were responsible for screening the patients, he acknowledged that if the patients "were liars * * * they could break through" and that "a lot of fraud can happen." He then justified his prescribing notwithstanding the obvious diversion risk, claiming that he is not a lawyer or police agent and that as "a physician * * * I take people at their word" and "as a family physician, I have patients that come to me face-to-face and can be dishonest with me." *Id.* at 206–09.

Later, Respondent claimed that he could identify drug abusers and drug seekers by their voice or diction, but then acknowledged that this was "by no means, any criteria to determine who is being evasive" and that it was "very, very less than perfect." *Id.* at 230–31. Putting aside the obvious risk of diversion by prescribing to people one never meets, if Respondent, as a trained physician, could not identify drug abusers and drug seeking patients, it should have been apparent that Ken Drugs' employees could not either. Yet he proceeded to prescribe controlled substances to numerous persons even though he had no idea as to whether they were legitimate patients or drug seekers and abusers.[19]

The ALJ was also unimpressed by Respondent's testimony regarding his interactions with Ken Drugs' patients. For example, Respondent testified that Ken Drugs' customers would not be able to get him "on the phone until they had gone through some of these hurdles" such as sending in their medical records. *Id.* at 206. He also claimed that there were times when the customers got through to him without having provided their medical records, and that he "would have to say, 'No, we can't help you.'" *Id.* at 214. Yet he prescribed to both the DEA and DOH Investigators who had not sent in any records. He also testified that he discussed "the risk of habituation" with the persons he prescribed to. *Id.* at 217. Once again, he did not do so when he prescribed to either the DEA or DOH Investigators.

As the ALJ found, much of Respondent's testimony was self-serving and disingenuous. Moreover, Respondent repeatedly attempted to minimize his misconduct, which is egregious. In short, Respondent has failed to acknowledge any wrongdoing on his part. Accordingly, I agree with the ALJ's finding that Respondent has failed to accept responsibility for his misconduct and that this "warrants the finding * * * that his continued registration poses a threat to the public health and safety." ALJ at 46.[20] Having concluded that Respondent has failed to rebut the Government's *prima facie* case, his registration will be revoked and any pending application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a)(4), as well as by 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, BL6686541, issued to Ronald Lynch, M.D., be, and it hereby is, revoked. I further order that any application for renewal or modification of such registration be, and it hereby is, denied. This Order is effective January 18, 2011.

Dated: December 3, 2010.

Michele M. Leonhart,

Deputy Administrator.

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BILLING CODE 4410–09–P

[19] The National Center on Addiction and Substance Abuse (CASA) has reported that "[t]he number of people who admit abusing controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003." National Center on Addiction and Substance Abuse, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.* 3 (2005) (cited in *Stodola,* 74 FR at 10089 n.24). Moreover, "[a]pproximately six percent of the U.S. population (15.1 million people) admitted abusing controlled prescription drugs in 2003, 23 percent more than the combined number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (328,000)." *Id.* Relatedly, "[b]etween 1992 and 2003, there has been a * * * 140.5 percent increase in the self-reported abuse of prescription opioids"; in the same period, the "abuse of controlled prescription drugs has been growing at a rate twice that of marijuana abuse, five times greater than cocaine abuse and 60 times greater than heroin abuse." *Id.*

CASA has further reported that teenagers "represent an especially vulnerable group," because "[t]eens may view prescription drugs as relatively safe either when abused alone or in combination with alcohol or other drugs." *Id.* According to CASA, "[i]n 2003, 2.3 million teens ages 12 to 17 (9.3 percent) reported abusing a controlled prescription drug in the past year; 83 percent of them reported abusing opioids." *Id.* Moreover, "[b]etween 1992 and 2002, the number of [first time] teenage prescription opioid abusers increased by 542 percent." *Id.*

Finally, CASA noted that "[i]nternet sites not adhering to state licensing requirements, medical board standards or Federal law have enabled consumers to obtain controlled prescription drugs without a valid prescription or physician supervision and without regard to age." *Id.* at 63. CASA also noted that "illegal [i]nternet pharmacies have introduced a new avenue through which unscrupulous buyers and users can purchase controlled substances for unlawful purposes." *Id.* Moreover, "[t]he age of the customers appears not to be an issue for Internet pharmacies," and that there are "no mechanisms in place to block children from purchasing controlled drugs over the Internet." *Id.* at 66.

[20] *See also Stodola,* 74 FR at 20730–31 (practitioner's continued registration deemed inconsistent with the public interest where, *inter alia,* "he has not accepted responsibility for his misconduct but blames others"); *Leslie,* 68 FR at 15231 (revoking registration where, *inter alia,* "Respondent refuse[d] to take responsibility for his past misconduct" and "remain[ed] steadfast in his insistence upon denying any previous wrongdoing"); *Prince George Daniels,* 60 FR 62881, 62887 (1995) (registrant's "lack of candor * * * as to the full extent of his involvement in the cocaine incident creates concern about his future conduct"); *John Stanford Noell,* 59 FR 47359, 47361 (1994) (denying Respondent's application for registration where, as to factor five, "Respondent has exhibited no remorse for his illegal activities").

DEPARTMENT OF LABOR

Office of the Secretary

Bureau of International Labor Affairs; Notice of Publication of 2010 Update to the Department of Labor's List of Goods From Countries Produced by Child Labor or Forced Labor

AGENCY: Bureau of International Labor Affairs, Department of Labor.

ACTION: Announcement of Public Availability of updated list of goods.

SUMMARY: This notice announces the publication of an updated list of goods—along with countries of origin—that the Bureau of International Labor Affairs ("ILAB") has reason to believe are produced by child labor or forced labor in violation of international standards ("List"). ILAB is required to develop and make available to the public the List pursuant to the Trafficking Victims Protection Reauthorization Act of 2005 ("TVPRA").

FOR FURTHER INFORMATION CONTACT: Director, Office of Child Labor, Forced Labor, and Human Trafficking, Bureau of International Labor Affairs, U.S. Department of Labor at (202) 693–4843 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: ILAB's Office of Child Labor, Forced Labor, and Human Trafficking (OCFT) carries out the mandates of section 105(b)(1) of the TVPRA, Public Law 109–164. For complete information on OCFT's TVPRA activities, please visit the Web site listed below. Previous **Federal Register** notices issued on this subject include: *Notice of Proposed Procedural Guidelines for the Development and Maintenance of the List of Goods From Countries Pursuant to the Trafficking Victims Protection Reauthorization Act of 2005* (72 FR 55808, Oct. 1, 2007); *Notice of Procedural Guidelines for the Development and Maintenance of the List of Goods from Countries Produced by Child Labor or Forced Labor; Request for Information* (72 FR 73374, Dec. 27, 2007); *Notice of Public Hearing to Collect Information to Assist in the Development of the List of Goods From Countries Produced by Child Labor or*