Under Virginia law, a ''prescription * * * may be issued only to persons * * * with whom the practitioner has a bona fide practitioner-patient relationship.'' Va. Code Ann. § 54.1–3303(A). The statute defines the term ''bona fide practitioner-patient-pharmacist relationship'' as ''one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice.'' *Id.* To establish a ''bona fide practitioner-patient relationship,'' the ''practitioner shall'' meet the following criteria:

(i) [E]nsure that a medical or drug history is obtained;

(ii) [P]rovide information to the patient about the benefits and risks of the drug being prescribed;

(iii) [P]erform 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; and

(iv) [I]nitiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. *Id.*

Respondent violated the CSA's prescription requirement because she did not establish a bona fide doctor-patient relationship with the Telemed customers. While Respondent was a resident of Virginia, her practice was located a substantial distance from the majority of the Virginia residents she prescribed to through Telemed. Most significantly, Respondent admitted to Investigators that she prescribed on the basis of telephonic consultations and did not conduct a physical examination of the customers; she also admitted that she did not maintain medical records for them.

In her letter responding to the allegations, Respondent maintained that her ''actions met [Virginia's] definition of a practitioner-patient relationship.'' Resp.'s Ltr. at 1. First, Respondent maintained that patients submitted their medical records, that Telemed scrutinized the documents for legitimacy, and that she reviewed records and called the customer's primary care physician and/or consultant. *Id.* Second, Respondent stated that she provided information to her customers regarding the risks and benefits of each medication and that this information was documented in the Telemed medical record. *Id.* Third, Respondent maintained that she only continued a treatment plan initiated by the primary care provider or specialist, and that she did not ''make a new diagnosis or initiate a new medication.'' *Id.* Finally, Respondent wrote that the Telemed customers were ''required to see their primary care physician or consultant at least every three months to update their condition, diagnosis and/or treatment plan.'' *Id.*

In her letter, Respondent maintained that based on her ''literal reading of the Virginia code,'' her actions met the definition of a practitioner-patient relationship. *Id.* Respondent also argued that under ''case law and other sources,'' a physician patient ''relationship is established when a patient seeks medical care and/or advice from a practitioner, and the practitioner knowingly provides medical care and/or advice to the patient.'' *Id.* at 2.

That may be as a matter of tort liability, but that does not mean that the relationship complies with accepted standards of medical practice necessary to properly diagnose a patient and issue treatment recommendations, including prescribing a controlled substance. Indeed, the Virginia Board found Respondent's position unavailing, concluding that she ''issu[ed] prescriptions to [customers of the website] despite the fact that her contact with the individuals was solely by telephone and despite the fact that she never saw these individuals in person, and did not perform any examination of them either physically or by the use of instrumentation and diagnostic equipment.'' Consent Order at 1–2. The Board further concluded that Respondent ''prescribed controlled substances including opioids * * * to numerous individuals outside of a bona fide practitioner-patient relationship.'' *Id.* at 1.

In numerous other cases involving practitioners who prescribed controlled substances over the internet and telephone to persons they had never physically examined and with whom they did not establish a bona-fide doctor-patient relationship, DEA has denied pending applications and revoked registrations pursuant to its authority under 21 U.S.C. 824(a)(4). *See Ladapo O. Shyngle, M.D.,* 74 FR 6056 (2009) (denying application for DEA registration after Respondent issued prescriptions outside bona fide doctor-patient relationship with customers of a website); *see also Ronald Lynch, M.D.,* 75 FR 78745 (2010); *George Mathew, M.D.,* 75 FR 66138 (2010); *Patrick W. Stodola, M.D.,* 74 FR 20727 (2009); *Dale L. Taylor, M.D.,* 72 FR 30855 (2007); *Andre DeSonia, M.D.,* 72 FR 54293 (2007). Likewise, several Federal courts have held that such prescribing constitutes a criminal violation of the CSA. *United States* v. *Nelson,* 383 F.3d 1227, 1231–32 (10th Cir. 2004); *cf. United States v. Smith,* 573 F.3d 639, 657–58 (8th Cir. 2009); *United States* v. *Fuchs,* 467 F.3d 889 (5th Cir. 2006).

I therefore conclude that because Respondent failed to establish a legitimate physician-patient relationship with various persons found above, she lacked a legitimate medical purpose and acted outside of the usual course of professional practice in prescribing controlled substances to them and thus violated Federal law. *See* 21 CFR 1306.04(a); 21 U.S.C. § 841(a)(1). I further conclude that Respondent's experience in dispensing controlled substances (factor two) and record of compliance with applicable laws related to controlled substances (factor four) establishes that granting Respondent's application for a new registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f). Finally, based on Respondent's letter, I find that Respondent has failed to accept responsibility for her misconduct and has therefore not rebutted the Government's *prima facie* case. *See, e.g., Krishna-Iyer,* 74 FR at 464; *see also Hoxie,* 419 F.3d at 483. Accordingly, Respondent's application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Stacey J. Webb, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This order is effective September 8, 2011.

Dated: August 2, 2011.

Michele M. Leonhart,

Administrator.

[FR Doc. 2011–20046 Filed 8–8–11; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 09–1]

Liddy's Pharmacy, L.L.C. Denial of Application

On September 15, 2008, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA or ''Government''), issued an Order to Show Cause to

Liddy's Pharmacy, L.L.C. (Respondent), of Lakeland, Florida. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BD8523335, as a retail pharmacy, and the denial of any pending applications for renewal or modification of its 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).'' Show Cause Order at 1.

More specifically, the Show Cause Order alleged that Respondent ''knowingly engaged in a scheme to distribute controlled substances based on purported prescriptions that were issued for other than legitimate medical purposes and by physicians acting outside the usual course of professional practice, in violation of Federal and State law.'' *Id.* The Order further alleged that Respondent ''aided physicians in the unauthorized practice of medicine in those states that require physicians to be licensed by the state before prescribing controlled substances to state residents and in those states that require a physical examination by the physician prior to prescribing controlled substances.'' *Id.* at 1–2.

By letter of September 29, 2008, Respondent, through its attorney, requested a hearing on the allegations and the matter was placed on the docket of the Agency's Administrative Law Judges (ALJs). Thereafter, on January 13, 2009, an ALJ conducted a hearing in Orlando, Florida at which only the Government presented evidence. Following the hearing, both parties filed briefs containing their proposed findings of fact, conclusions of law, and argument.

On October 6, 2009, the ALJ issued her recommended decision (also ALJ). Therein, the ALJ began by noting that under Federal law ''[a] prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his practice'' and that a pharmacist has ''a corresponding responsibility'' not to fill an unlawful prescription. ALJ at 19 (quoting 21 CFR 1306.04(a)). The ALJ then found that ''the evidence shows that the Respondent filled over 42,000 prescriptions written by doctors for patients in states where those doctors were not licensed.'' *Id.* at 20. Having found that ''these physicians were * * * engaged in the unauthorized practice of medicine in at least nine states,'' the ALJ concluded that the ''prescriptions issued by such practitioners * * * are therefore invalid under the Controlled Substances Act [(CSA)]'' and that ''Respondent violated the CSA by filling them.'' *Id.* at 22.

The ALJ also found that while Respondent ''is only licensed to practice pharmacy in Florida, Texas, and Illinois,'' it ''nevertheless dispensed medication to patients in Arkansas, Connecticut, New Hampshire, California, and Louisiana'' and thus ''engaged in the unlicensed practice of pharmacy in violation of the laws of these states.'' *Id.* The ALJ further found that Respondent violated Florida law when, despite being ''on notice by the [Florida] Board [of Pharmacy] that prescriptions for controlled substances must be manually signed,'' it ''continued to fill controlled-substance prescriptions containing electronic signatures.'' *Id.* at 23.

Finally, the ALJ found that Respondent ''knowingly filled prescriptions issued in the name of a doctor whose DEA registration was suspended.'' *Id.* Describing such conduct as ''a blatant violation of the pharmacy's corresponding responsibility under the [CSA] and DEA regulations,'' the ALJ found that this conduct ''demonstrate[d] a disturbing lack of appreciation for the responsibilities of a DEA registrant'' and ''threatens the public health and safety by creating a substantial risk of diversion of controlled substances.'' *Id.* at 24. The ALJ thus concluded that ''in total, the Government has proven by a preponderance of the evidence its prima facie case.'' *Id.*

The ALJ then turned to whether Respondent had rebutted the Government's prima facie case. Noting that ''both Mr. Liddy and Mrs. Liddy,'' who are Respondent's owners, ''invoked their Fifth Amendment privilege against self-incrimination'' and refused to testify, the ALJ further found that ''Respondent presented no evidence or testimony whatsoever to rebut any of the Government's evidence.'' *Id.* Accordingly, the ALJ ''conclude[d] that it would be inconsistent with the public interest to allow * * * Respondent to maintain its DEA registration.'' *Id.* at 25. Citing Respondent's ''extensive record of unlawful conduct,'' its ''callous disregard for the serious responsibilities of a DEA registrant,'' as well as its ''failure to present any evidence to show that it has corrected'' its unlawful practices, the ALJ recommended that Respondent's registration be revoked. *Id.* at 25–26.

On October 27, 2009, Respondent filed Exceptions to the ALJ's decision, and on November 9, 2009, the record was forwarded to me for final agency action. On April 14, 2010, Respondent's owner executed a voluntary surrender of its registration. Notice of Surrender and Motion To Terminate Proceedings, at 1. Thereafter, the Government moved to terminate the proceeding on the ground that it is now moot. *Id.* at 2.

Having reviewed the voluntary surrender form (DEA–104), I conclude that this case is not moot because that form contains no language manifesting that Respondent has withdrawn its pending application. Moreover, even if Respondent had withdrawn its application, under the Agency's regulation, once an applicant is served with an order to show cause, an application may only be ''withdrawn with permission of the Administrator * * * where good cause is shown by the applicant or where the * * * withdrawal is in the public interest.'' 21 CFR 1301.16(a). In light of the extensive resources that have been expended in both the litigation and review of this case, the egregious misconduct established by this record, and that neither the voluntary surrender form nor Agency regulations bar Respondent from immediately re-applying for a new registration or impose any time-bar on its reapplying, I conclude that allowing Respondent to withdraw its application would be contrary to the public interest.[1] Accordingly, I conclude that the case is not moot. The Government's motion to terminate the proceeding is therefore denied.

Having considered the entire record in this matter, including Respondent's exceptions, I adopt the ALJ's recommended decision in its entirety except as noted herein. Accordingly, Respondent's pending application will be denied. I make the following findings.

Findings

At the time of the hearing, Respondent held DEA Certificate of Registration BD8523335, which authorized it to dispense controlled substances in schedules II through V as a retail pharmacy at its Lakeland, Florida location. GX 1; ALJ Ex. 5, at 1. While Respondent's registration was initially to expire on March 31, 2009, on February 2, 2009, it timely filed a renewal application. GX 1; ALJ Ex. 5, at 1. Accordingly, Respondent's registration remained valid until April 14, 2010, when Respondent's owner surrendered it. *See* 5 U.S.C. 557(c). However, as explained above, the Voluntary Surrender form contains no language manifesting Respondent's intent to withdraw its application. I

[1] I further note that there is no evidence that Respondent and its owners intend to permanently cease the practice of pharmacy.

therefore find that Respondent's application remains pending before the Agency.

Respondent, which is licensed as a pharmacy in the states of Florida, Texas, and Illinois, Tr. 42, is owned by Mr. Robert Bruce Liddy, Sr., and Mrs. Melinda Carol Liddy. GX 5. Respondent is also known by the name ''Discount Mail Meds.'' Tr. 19; *see also* GX 9.

At the hearing, the Government called both Mr. and Mrs. Liddy to testify. *Id.* at 12, 15. However, both Mr. and Mrs. Liddy asserted their Fifth Amendment right against self-incrimination and thus did not answer questions on various subjects including on whether Respondent was also known as ''Discount Mail Meds,'' on ''all matters regarding [Respondent's] operations,'' and on Respondent's ''association'' with Internet Web sites, doctors, or Web site operators regarding the filling of prescriptions for those Web sites. *Id.* at 12–13, 15–16.

At some point not established by the record, multiple law enforcement agencies including DEA commenced an investigation into Respondent's practices, specifically focusing on its filling of prescriptions for hydrocodone (a Schedule III controlled substance), alprazolam (a Schedule IV controlled substance), and Soma or carisoprodol (a drug controlled under Florida law), which were issued by doctors who did not appear to have valid physician-patient relationships with the recipients of the prescriptions because the latter were located throughout the country. *Id.* at 20–21.

According to the DEA's lead investigator, Respondent was associated with four to five internet prescribing Web sites, including ExpressReliefServices.com and NationwidePills.com. *Id.* at 22; *see also* GXs 7 & 8. Generally, the Web sites offered a person the ability to purchase prescription medication, including controlled substances, based on a person's completion of an online questionnaire and without the prescribing physician's having performed a physical exam of him/her. Tr. at 22; *see also* GX 7, at 3 (terms and conditions for Nationwidepills.com) (''You understand that an on-line medical consultation will not include a physical examination. You hereby waive a physical exam at this time and agree to obtain a timely medical follow-up examination with a physician before you take treatments prescribed by Nationwidepills.com.''). Moreover, while some of the Web sites required medical records and/or identification, others did not. Tr. 22. Physicians who held DEA registrations ''lent their DEA numbers for the filling of * * * prescriptions.'' *Id.* However, the actual creation of the prescriptions ''appear[ed] to have been done by a physician's assistant frequently without the knowledge of the physician.'' *Id.*

Between June and August 2006, DEA Investigators from the Cleveland District Office made four undercover purchases of 10 mg. strength hydrocodone drugs by accessing several unidentified Web sites, completing questionnaires, providing medical records, and speaking with a physician's assistant. *Id.* at 23. The shipments of hydrocodone medication arrived via either UPS or FedEx and had been filled by Respondent. *Id.* at 23–24. Moreover, at some unspecified date in either 2005 or 2006, a DEA Diversion Investigator went to Respondent and interviewed its owners. Tr. 82.

Approximately one year later, on July 30, 2007, a search warrant was executed at Respondent and five other locations. *Id.* at 34; GX 5, at 1. During the search, another DI interviewed Robert Bruce Liddy, Sr.; the DI subsequently provided an affidavit about that interview.

According to the affidavit, Mr. Liddy was first approached by the owner of Express Relief Services (ERS) in December 2004. GX 5, at 1. The owner of ERS was ''seeking a pharmacy to fill prescriptions generated from his 'network of physicians' in the telemedicine field.'' *Id.* At a dinner meeting, ERS's owner explained that Respondent would ''receive prescriptions via facsimile directly from the doctor's [sic] office'' and be paid a '''dispensing fee of $28–$30 for each'' prescription it filled. *Id.* Respondent received ''approximately 500–750 new prescriptions per week'' from ERS's Web site and also filled requests for refills. *Id.* According to the affidavit, ''Mr. Liddy stated that at one point his pharmacy would fill more than 180 prescriptions a [sic] day for Express Relief Services'' for such drugs as hydrocodone, alprazolam and carisoprodol, with the vast majority of the prescriptions being for hydrocodone products. *Id.*

Mr. Liddy told the DI that Respondent received the prescriptions directly from the prescribing physicians, among them one Dr. Jorge Alsina. *Id.* at 2. Mr. Liddy further told the DI that the owner of ERS, whom Mr. Liddy believed to be ''addicted to hydrocodone,'' would ''pick up hydrocodone prescriptions for himself and 'his friends,' '' and that these prescriptions were also written by the doctors who worked for ERS. *Id.*

During the interview, Mr. Liddy stated that, while he worked for ERS, he also contracted with other Internet Web sites to fill prescriptions for them. *Id.* Also at the interview, Mrs. Liddy ''revealed that [Respondent] was also working with Opti Health, First Priority, Nationwide Pills, Pharmanet, U.S. Meds, and CDR.'' *Id.*

Mr. Liddy asserted that he had a pharmacy license ''in each state where he had out-of-state customers.'' *Id.* He also claimed that he was not breaking the law ''because he believed there were safeguards in place against the wrong people getting the drugs.'' *Id.* He further stated his belief that '''people will get the drugs''' anyway and that he '''was not the prescription police.''' *Id.*

During the execution of the search warrant, Respondent's dispensing records were seized by downloading them from the hard drives of its computer system. Tr. 53, 55, 97. The Government introduced into evidence both summaries of data seized at the execution of the search warrant prepared by the National Drug Intelligence Center (NDIC) and DEA's forensic digital laboratory in Lorton, Virginia, as well as data from DEA's Automated Reports and Consummated Order System (ARCOS) which showed the monthly amounts of hydrocodone (in dosage units) which Respondent purchased between January 1, 2004 and September 16, 2008. *Id.* at 91 & 95; GX 3. The latter showed that Respondent's purchases of hydrocodone increased from a total of 47,900 dosage units in calendar year 2004, to 3,688,500 dosage units in 2005, and to 4,557,840 in 2006. GX 3.

Dr. Jorge Alsina was listed as a prescribing physician in records seized from Respondent. *Id.* at 42–43; GXs 13, 14 & 19. Dr. Alsina was licensed to practice medicine only in the State of Florida. Tr. 43. Initially, he received $1,000 per week for writing prescriptions for Respondent; subsequently, according to the DI, he received $2,000 per week. *Id.* at 58–59.

The DI further testified as to manner in which ERS operated. According to the DI, an ERS clerk would request medical records and a copy of a driver's license from a customer; the records were then faxed to either Dr. Alsina or to Mr. Folder, who was a physician's assistant. However, in an interview, Dr. Alsina stated that he did not have a registered supervisory relationship with Folder as required by Florida law. *Id.* at 60–63.

Dr. Alsina also ''did not necessarily review'' the medical records which he would fax to the physician's assistant; Alsina would also e-mail the prescription to Folder as well. *Id.* at 64–65; 67. However, according to Dr. Alsina, sometimes his part in the e-mail

chain was skipped and the prescription was sent directly from the physician's assistant to Respondent. *Id.* Alsina indicated that ERS had a template with his signature so that with the ''hit[ing] of a button,'' his signature could be generated by either himself or Folder. *Id.* at 69, 70.

The Government introduced into evidence eight prescriptions for controlled substances that were sent as e-mail attachments from ''Matthew and Gayle Folder'' to ''Bruce Liddy.'' GX 4, at 2, 4, 8, 10, 12, 14, 18, and 20. All of the prescriptions were dated March 19, 2005 and bore Dr. Alsina's electronic signature. *See id.* The DI testified that these prescriptions were ''representative of the vast majority of the prescriptions that were seized from [Respondent's] computers.'' *Id.* at 85.

The Government also entered into evidence an e-mail dated September 10, 2004, from Danna E. Droz, Executive Director, Board of Pharmacy, State of Florida, to Mr. Liddy at the e-mail address: *bruce@discountmailmeds.com*. GX 11. The e-mail specifically explained that ''[e]lectronic prescriptions such as would come from a PDA or a computer to a pharmacy's fax machine or to a pharmacy's computer may be used only for prescriptions for non-controlled substances.'' GX 11. Continuing, Ms. Droz explained that ''[a] prescription for a controlled substance must be manually signed at this time.'' *Id.;* Tr. 87. While the e-mail further noted that DEA is in the process of developing regulations to permit the electronic transfer of a prescription,'' GX 11, the requirement that a controlled substance prescription be manually signed remained in effect as of the date of the hearing under the regulations of both DEA and the State of Florida. Tr. 88.

The DI testified that the ''vast majority'' of the seized prescriptions did not comply with the manual signature requirement. *Id.* Moreover, the eight prescriptions contained in Government Exhibit 4 were issued subsequent to the date on which Mr. Liddy received notice that controlled substance prescriptions must be manually signed.

Based on the records seized from Respondent, the NDIC prepared a chart compiling the number of prescriptions dispensed by Respondent by each prescriber for hydrocodone, alprazolam and other drugs. GX 14. According to the chart, Respondent filled 19,447 prescriptions which were written by Dr. Alsina; 12,796 of the prescriptions were for hydrocodone products and 5,860 were for alprazolam. GX 14, at 1; GX 15. Only 791 prescriptions were for other drugs, some of which may have also been controlled substances.[2] GX 14, at 1.

Moreover, between October 2004 and the end of December 2005, Respondent dispensed prescriptions written by Dr. Alsina to patients in such states as West Virginia (4,308 prescriptions), Tennessee (4,307 prescriptions), Ohio (2,455 prescriptions), Kentucky (2,346 prescriptions),[3] Virginia (2,345 prescriptions), Alabama (633 prescriptions), Florida (425 prescriptions), California (311 prescriptions), Indiana (275 prescriptions), and North Carolina (177 prescriptions). GX 19, at 1; GX 20, at 1–68.[4] Even if all of the remaining 791 prescriptions which were not specifically identified as being for controlled substances were for non-controlled drugs and are subtracted from the various state figures, the evidence still shows that Dr. Alsina prescribed large quantities of controlled substances to individuals in West Virginia, Tennessee, Ohio, Kentucky, and Virginia, if not the other States as well.

As an example of Dr. Alsina's prescribing of controlled substances across state lines, on July 6, 2005, he issued 351 prescriptions[5] to residents of various States and in the following quantities: West Virginia (98), Tennessee (98), Virginia (65), Ohio (58), Alabama (6), North Carolina (5), Arizona (4), Michigan (4), Indiana (3), Georgia (2), Arizona (1), Connecticut (1), Maryland (1), New Hampshire (1), and Utah (1). GX 20, at 48. Obviously, Dr. Alsina did not fly or drive all over the country on a single day to conduct physical exams on these patients. Nor does it seem likely that any of these patients travelled from all over the country to see him (this was, after all, an internet-based operation). In any event, seeing 351 patients in a single day would be a remarkable achievement for any physician. I therefore find that Respondent either had to have known, or willfully closed its eyes to the fact, that Dr. Alsina could not possibly have issued all of these prescriptions pursuant to a legitimate doctor-patient relationship.

DEA suspended Dr. Alsina's Certificate of Registration on September 26, 2005. Tr. 44–45; GX 10. Dr. Alsina notified Respondent of this fact by an e-mail of October 5, 2005, which Respondent acknowledged with another e-mail of the same date. Tr. 47–48; GX 12. However, Respondent's records reflect that through December 2005, Respondent continued to fill prescriptions issued using Dr. Alsina's registration. GX 20, at 66–68. More specifically, it appears that Respondent filled 67 prescriptions from the time of the suspension through the end of December 2005. GX 20; GX 13; *see also* ALJ at 9 n.10.[6] However, the Government's evidence does not identify what drugs these prescriptions were for.

Respondent's pharmacy records also listed Dr. Dora Fernandez as a prescribing physician. Tr. 43; GXs 13–14, 19 & 20. Dr. Fernandez is only licensed to practice medicine in the State of Florida. Tr. 43.

The NDIC data indicate that Dr. Fernandez wrote a total of 13,603 prescriptions which were filled by Respondent. Of these, 3,242 were for hydrocodone, 60 were for alprazolam, and 301 were for other medications. GX 14, at 1; GX 15. Between February 2006 and the end of April 2007, Respondent dispensed prescriptions written by Dr. Fernandez to individuals in numerous States, in the following quantities: Florida (1,448 prescriptions), Texas (1,387 prescriptions), Alabama (856 prescriptions), Virginia (837 prescriptions), New York (702 prescriptions), Washington (690 prescriptions), Michigan (652 prescriptions), Pennsylvania (497 prescriptions), Ohio (476 prescriptions)

[2] The Government's evidence lists the prescriptions as being in one of three categories: hydrocodone, alprazolam, or ''other'' medications. GX 14. The evidence does not, however, further identify the drugs listed under ''other'' medications and whether this category includes any controlled substances. *See* GXs 14–20.

[3] As the ALJ noted in her recommended decision, there is a slight discrepancy between the raw data in Government Exhibit 13 and the NDIC-prepared data in Government Exhibit 19, the source cited here. *See* ALJ at 9 n.8. The count in Government Exhibit 13 for Kentucky is 2,345 and not 2,346. Other discrepancies are as follows: Alabama, 632, not 633; Florida, 424, not 425; and California, 310, not 311. *See id.* I concur in the ALJ's determination that, while ''the Government's calculated exhibits may be slightly inaccurate,'' they nevertheless ''are sufficiently close to the actual numbers'' for the purposes of this decision. *See id.*

[4] The ALJ treated all of the prescriptions as if they were for controlled substances including those listed as ''other'' drugs and which were not specifically identified as being for controlled substances. *See* ALJ at 9 (FOF 19 and 20) (discussion of ''Unlicensed Practice of Medicine''). However, even after subtracting out all of the ''other'' prescriptions, it is still clear that the physicians wrote numerous controlled substance prescriptions for residents of States where they were not licensed. The ALJ's error is therefore inconsequential. *See* ALJ at 20–21.

[5] He also issued eight prescriptions to individuals in Florida, for a total of 359 prescriptions on that date. GX 20, at 48.

[6] The ALJ did not count the prescriptions listed under February 1, 2006 and July 26, 2006, noting that the ''date filled'' for those prescriptions is one year earlier in 2005, when Dr. Alsina's license was still valid. Like the ALJ, I conclude that the dates of February 1 and July 26, 2006 are typographical errors. *See* ALJ at 10 n.12.

and Georgia (467 prescriptions). *See* GXs 19, at 1, & GX 20, at 68–195. Even if all of the remaining 301 prescriptions which were not specifically identified as being for controlled substances were for non-controlled drugs, Dr. Fernandez prescribed controlled substances to residents of each of these ten States. Moreover, she also prescribed controlled substances to residents of at least nine States where she did not possess licensure and could not practice medicine.

As an example of her prescribing across state lines, on November 13, 2006, Dr. Fernandez issued 91 prescriptions.[7] GX 20, at 152–53. The States and number of prescriptions are as follows: New York (11), Michigan (8), Arizona (7), Georgia (7), Alabama (6), Texas (6), Virginia (5), Washington (5), Connecticut (4), Ohio (3), Wisconsin (3), Arkansas (2), Colorado (2), Indiana (2), Kansas (2), Pennsylvania (2), Alaska (1), California (1), Iowa (1), Idaho (1), Minnesota (1), Montana (1), New Mexico (1), Oklahoma (1), Oregon (1), Rhode Island (1), and South Carolina (1).

Given the respective locations of Dr. Fernandez and those she prescribed to, it is implausible that Dr. Fernandez conducted physical examinations of these persons and established bona fide doctor-patient relationships with them. Here again, Respondent clearly had reason to know that Dr. Fernandez could not have established a bona fide doctor-patient relationship with these persons. Tr. 43–44.

Respondent's records also listed Dr. Jose Mercado Francis as a prescribing physician. Tr. 43; GXs 13–15, 19 & 20. Dr. Francis is only licensed to practice medicine in the State of Michigan.

The NDIC data indicates that Dr. Francis wrote 7,319 prescriptions which were filled by Respondent, including 5,135 for hydrocodone products, 1,135 for alprazolam, and 1,049 for other medications. GX 14, at 1. Between February 2006 and the end of April 2007, Respondent dispensed prescriptions written by Dr. Francis to individuals in a number of States, the top ten being as follows: Alabama (1,294 prescriptions), California (568 prescriptions), Louisiana (518 prescriptions), Texas (486 prescriptions), Washington (456 prescriptions), Ohio (404 prescriptions), Florida (386 prescriptions), Georgia (337 prescriptions), Virginia (272 prescriptions), and Maine (268 prescriptions). GXs 19, at 1; GX 20, at 195–270. Again, even assuming that all of the non-specified prescriptions were for non-controlled drugs and subtracting them out, Dr. Francis still clearly issued numerous controlled substance prescriptions to residents of Alabama.

As an example of his prescribing across state lines, on March 3, 2006, Dr. Francis issued thirty prescriptions to residents of the following States: Georgia (7), South Carolina (4), Florida (3), Maryland (3), Ohio (3), California (2), Indiana (2), Louisiana (2), Colorado (1), Maine (1), North Carolina (1), and Texas (1). GX 20, at 196. Clearly, Dr. Francis could not have established bona fide doctor-patient relationships with these patients or performed physical examinations on them. Here again, Respondent, when it filled these prescriptions, had reason to know this.

Respondent's records list Dr. Edward Cheslow as a prescribing physician. Tr. 44; GXs 13–14, 19–20. Dr. Cheslow is only licensed to practice in the State of New York. Tr. 44.

NDIC data show that Dr. Cheslow wrote 6,577 prescriptions which were filled by Respondent; of these, 6,362 were for hydrocodone products, 36 were for alprazolam, and 179 were for other medications. GX 14, at 1. From February 2006 through May 1, 2007, Dr. Cheslow wrote prescriptions for medications which were filled by Respondent for residents of numerous States, the top ten being California (2,831 prescriptions), Texas (349 prescriptions), Florida (299 prescriptions), Georgia (232 prescriptions), New York (206 prescriptions), New Jersey (185 prescriptions), Ohio (177 prescriptions), Washington (168 prescriptions), Virginia (162 prescriptions), and Alabama (140 prescriptions). GX 19, at 1–2; GX 20, at 270–343. Subtracting out the 179 prescriptions for ''other'' medication, the evidence still shows that Dr. Cheslow wrote controlled substance prescriptions for individuals in California, Texas, Florida, Georgia, and New Jersey.

As an example of Dr. Cheslow's daily prescribing, on October 23, 2006, he issued thirty prescriptions to residents of States where he was not licensed to practice as follows: California (16), Texas (3), Florida (2), Mississippi (2), Alabama (1), Maine (1), Minnesota (1), New Jersey (1), Ohio (1), Utah (1), and Virginia (1). GX 20, at 305. Again, Respondent dispensed these prescriptions having reason to know that Dr. Cheslow was prescribing to persons who resided in States where he was not licensed to practice medicine and that he was prescribing to persons he did not physically examine and with whom he did not establish a bona fide doctor-patient relationship.

Respondent's records list Dr. Gerard Romain as a prescribing physician. Tr. 44; GXs 13–14, 19–20. Dr. Romain is only licensed to practice medicine in the State of Florida. Tr. 44.

The NDIC data indicate that Respondent filled 6,121 prescriptions issued by Dr. Romain, of which 5,103 were for hydrocodone products, 681 were for alprazolam, and 337 were for other medications. GX 14, at 2. Between May 2004 and June 18, 2007, Respondent dispensed prescriptions issued by Dr. Romain to individuals in numerous States, the top ten being as follows: Virginia (672 prescriptions), California (433 prescriptions), West Virginia (367 prescriptions), Ohio (354 prescriptions), Florida (339 prescriptions), Tennessee (321 prescriptions), Alabama (309 prescriptions), Texas (294 prescriptions), Georgia (231 prescriptions), and Indiana (205). GXs 19, at 2, & 20, at 428–517. Again, even if the 337 prescriptions for other medications were for non-controlled drugs, at a minimum, Dr. Romain prescribed controlled substances to residents of Virginia, California, West Virginia, and Ohio, and likely other States as well.

As an example of Dr. Romain's daily prescribing, on September 23, 2005, he issued twenty-two prescriptions to individuals in the following States: West Virginia (6), Virginia (5), Ohio (3), California (2), Washington (2), Alabama (1), Connecticut (1), Kansas (1), and Texas (1). GX 20, at 435. Again, in filling these prescriptions, Respondent had reason to know that Dr. Romain did not physically examine the patients and could not have established bona fide doctor-patient relationships with them.

Respondent's pharmacy records also list Dr. Felix Llamido as a prescribing physician. Tr. 44; GXs 13–14; GXs 19–20, at 343–428. Dr. Llamido is only licensed to practice in the State of Florida. Tr. 44.

According to the NDIC data, Respondent filled 6,481 prescriptions written by Dr. Llamido, of which 6,290 were for hydrocodone products, 32 were for alprazolam, and 159 for other medications. GX 14, at 1. Between February 2006 and the end of April 2007, Respondent dispensed prescriptions written by Dr. Llamido to patients in numerous States, the top ten being California (766 prescriptions), New Jersey (582 prescriptions), Georgia (550 prescriptions), Massachusetts (518 prescriptions), Maryland (470 prescriptions), Texas (363 prescriptions), Illinois (350

[7] She additionally issued seven prescriptions to individuals in the State of Florida. GX 20, at 152.

prescriptions), Florida (302 prescriptions), New Hampshire (215 prescriptions), and Washington (175 prescriptions). GX 14, at 2; GX 20 at 343–428. Thus, at a minimum, Dr. Llamido issued controlled substance prescriptions to individuals in California, New Jersey, Georgia, Massachusetts, Maryland, Texas, Illinois, New Hampshire and Washington.

As an example of his daily prescribing, on March 27, 2006, Dr. Llamido issued thirty-nine prescriptions to residents of the following states: California (6), Maryland (5), New Hampshire (3), Ohio (3), Pennsylvania (3), New Jersey (2), Texas (2), Virginia (2), Washington (2), West Virginia (2), Connecticut (1), Georgia (1), Hawaii (1), Indiana (1), Minnesota (1), Mississippi (1), Oklahoma (1), Utah (1), and Wisconsin (1). GX 20, at 350. Again, Respondent had reason to know that Dr. Llamido could not have performed physical examinations on these patients and did not have bona fide doctor-patient relationships with them.

Finally, Respondent's pharmacy records listed Dr. Caroline Moore as a prescribing physician. Tr. 44; GXs 13–14, 19–20, at 517–35. Dr. Moore is licensed only in the State of Florida. Tr. 44.

The NDIC data shows that Respondent filled 2,687 prescriptions written by Dr. Moore, including 1,884 for hydrocodone products, 659 for alprazolam, and 144 for other medications. GX 14, at 1–2. From January 2, 2005 through the end of December 2006,[8] Dr. Moore issued prescriptions to individuals in numerous States, the top ten including West Virginia (790), Ohio (463), Virginia (422), Alabama (106), California (94), Florida (89), Tennessee (70), Texas (57), Georgia (53), and Indiana (44). GXs 19, at 2, & 20, at 517–35. Again, even subtracting out the 144 prescriptions for other medications, Dr. Moore clearly issued controlled substance prescriptions to individuals in West Virginia, Ohio, and Virginia.

As an example of Dr. Moore's out-of-state prescribing practices, on November 21, 2005, she issued seventy-two prescriptions to residents in States other than Florida, as follows: West Virginia (22), Ohio (14), California (10), Virginia (3), Georgia (2), Indiana (2), Massachusetts (2), Missouri (2), North Carolina (2), New Jersey (2), New York (2), Pennsylvania (2), Texas (2), Arkansas (1), Arizona (1), Illinois (1), Oklahoma (1), and Washington (1). GX 20, at 524. Given the geographically diverse locations of Dr. Moore's ''patients,'' in filling these prescriptions, Respondent clearly had reason to know that Dr. Moore did not physically examine them and did not establish bona fide doctor-patient relationships with them.

The Government also entered into evidence a letter from Robert Bruce Liddy, Sr., to Peter A. Grasso, Chief Compliance Investigator, New Hampshire Board of Pharmacy, dated November 18, 2005. GX 9. In the letter, Mr. Liddy wrote that Respondent did not ''solicit prescription sales [from] the State of New Hampshire or any other state outside of Florida.'' *Id.* He also indicated that Respondent had ''three customers who winter in Florida and reside in New Hampshire during the summer months.'' *Id.* According to Mr. Liddy, Respondent's records showed that Respondent had ''mailed 3 packages to New Hampshire in the past two years'' of its operation. *Id.* Mr. Liddy added that ''[i]f in the future I increase or determine it beneficial for my business to advertise or solicit for prescription sales in your state I will certainly abide by the guidelines set forth by the New Hampshire Board of Pharmacy for Non-Resident Pharmacy licensure.'' *Id.*

The Government submitted into evidence data showing that between May 25, 2004 and May 14, 2007, Respondent dispensed a total of 472 prescriptions to New Hampshire residents; the evidence also shows that Respondent dispensed twenty-four prescriptions prior to the date of the above-referenced letter. GX 18, at 1, 11. Moreover, prior to Mr. Liddy's letter, Respondent had dispensed seven prescriptions for controlled substances (as well as refills for several of the prescriptions) for drugs which included alprazolam, temazepam, hydrocodone, and oxycodone. *See* GX 13 (spreadsheet lines ## 10930 (alprazolam), 25397 (oxycodone/acetaminophen), 45243–45, 46893–95, 53407–09, and 68484–86 (all for hydrocodone/acetaminophen and including two refills) and 55611 (temazepam)). Moreover, subsequent to Liddy's letter, Respondent continued to dispense controlled substance prescriptions (typically for hydrocodone) to New Hampshire residents. *See, e.g. id.* (spreadsheet lines ## lines 109622–23, 110538–39, 112493, 112502, 115778).

Respondent rested without calling any witnesses or introducing any other evidence. Moreover, as noted above, when called to testify by the Government, Respondent's owners invoked their privilege under the Fifth Amendment and refused to answer any questions regarding their ownership of Respondent, the pharmacy's operations and its association with various Web sites. Tr. 12–13 (testimony of Robert Bruce Liddy, Sr.); *id.* at 15–16 (testimony of Melinda Carol Liddy).

Discussion

Section 303(f) of the Controlled Substances Act (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 determining the public interest, section 303(f) directs that the following factors be considered:

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

(2) The applicant's experience in dispensing * * * controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id.

''[T]hese factors are * * * considered in the disjunctive.'' *Robert A. Leslie,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked or an application should be denied.'' *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 (DC Cir. 2005).

Having considered all of the factors, I conclude that the evidence pertaining to factors two and four is dispositive and establishes that Respondent has committed acts which render the issuance of a registration to it ''inconsistent with the public interest.'' [9]

[8] There appear to be some typographical errors in GX 20, page 535. The page lists a prescription on December 30, 2006 and then jumps to three prescriptions supposedly written in November 2008 and one prescription in December 2008. GX 20, at 535. Obviously, that would be impossible, as the four prescriptions in 2008 would postdate the execution of the search warrant of July 30, 2007.

[9] This Agency has repeatedly held that the possession of a valid state license is not dispositive of the public interest inquiry. *See Patrick W. Stodola,* 74 FR 20727, 20730 n.16 (2009); *Robert A. Leslie,* 68 FR at 15230. DEA has long held that ''the Controlled Substances Act requires that the Administrator * * * make an independent determination as to whether the granting of controlled substances privileges would be in the

21 U.S.C. 823(f). I also find that Respondent has not rebutted the Government's *prima facie* showing. Accordingly, Respondent's pending application to renew its registration will be denied.

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Its Compliance With Applicable Federal, State and Local Laws Relating to Controlled Substances

Under a longstanding DEA regulation, a prescription for a controlled substance is unlawful unless it has been ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). Moreover, while ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner * * * a corresponding responsibility rests with the pharmacist who fills the prescription.'' *Id.* Accordingly, the ''person knowingly filling such a purported prescription, as well as the person issuing it, [is] subject to the penalties provided for violations of the provisions of laws relating to controlled substances.'' [10] *Id.*

The Agency has interpreted this regulation as ''prohibiting a pharmacist from filling a prescription for controlled substances when he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose.' '' *Trinity Healthcare Corp.,* 72 FR 30849, 30854 (2007) (quoting *Medic-Aid Pharmacy,* 55 FR 30043, 30044 (1990)); *see also United Prescription Services, Inc.,* 72 FR 50397, 50407 (2007); *Frank's Corner Pharmacy,* 60 FR 17574, 17576 (1995); *Ralph J. Bertolino,* 55 FR 4729, 4730 (1990); *see also United States* v. *Seelig,* 622 F.2d 207, 213 (6th Cir. 1980). The Agency has further held that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR at 4730 (citations omitted); *see also United Prescription Services,* 72 FR at 50407.

As I explained in *United Prescription Services,* ''when a pharmacy receives a prescription which indicates that the prescriber and patient are located nowhere near each other, it should be obvious that further inquiry is warranted to determine whether the prescription was issued pursuant to a valid doctor-patient relationship.'' 72 FR at 50409. ''Determining whether a physician has acted in accordance with this standard necessarily requires that the pharmacist have knowledge of the applicable State's law.'' 72 FR at 50405 n.19 (citing *United States* v. *Smith,* 2006 WL 3702656 (D. Minn. 2006)).

Moreover, ''[a] physician who engages in the unauthorized practice of medicine is not a 'practitioner acting in the usual course of * * * professional practice.' '' *United,* 72 FR at 50407 (quoting 21 CFR 1306.04(a)). Under the CSA, the ''term 'practitioner' means 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); *see also* 21 U.S.C. 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'').

Consistent with the statutory text, 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.'' *United States* v. *Moore,* 423 U.S. 122, 140–41 (1975). Accordingly, a controlled substance prescription issued by a physician who lacks the license necessary to practice medicine within a State is therefore unlawful under 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''); *see also United Prescription Services,* 72 FR at 50407.

As found above, Respondent dispensed millions of dosage units of hydrocodone (a schedule III controlled substance, *see* 21 CFR 1308.13(e)) and alprazolam (a schedule IV controlled substance, *see* 21 CFR 1308.14(c)), based on prescriptions issued by physicians who were prescribing to persons who resided in States where the physicians were not licensed to practice medicine (although they were required to be) and were thus engaged in the unauthorized practice of medicine. The prescriptions violated both the CSA and the laws of the respective States including, *inter alia,* Alabama, California, Georgia, Indiana, North Carolina, Ohio, Texas, and Virginia. *See* Ala. Code §§ 34–24–50 (defining practice of medicine to include prescribing), 34–24–51 (requiring a license for the practice of medicine), 34–24–502 (requiring special license for practice of medicine across state lines); Cal. Bus. & Prof. Code §§ 2052 (criminalizing the practice of medicine without state license); Ga. Code Ann. §§ 43–34–26(a) (requiring license), 43–34–31 (requiring state license for medical treatment of individual in state by physician in another state); Ind. Code Ann. §§ 25–22.5–8–1 (prohibiting the practice of medicine without a state license) & 25–22.5–1–1.1(a) (defining practice of medicine); N.C. Gen. Stat. Ann. § 90–18 (prohibiting practice of medicine across state lines unless licensed in state); Ohio Rev. Code Ann. §§ 4731.296 (prohibiting out-of-state practice of telemedicine without a special permit), 4731.41 (prohibiting practice of medicine without state license); Tex. Occup. Code Ann. §§ 155.001 (requiring license to practice medicine), 151.056(a) (making out-of-state treatment of individual in state the practice of medicine in state); Va. Code Ann. §§ 54.1–2902 (prohibiting practice of medicine without state licensure), 54.1–2903 (making prescribing the practice of medicine), 54.1–2929 (requiring license for the practice of medicine).[11]

As found above, five of the doctors whose prescriptions Respondent filled were licensed to practice medicine only in Florida and yet wrote controlled substance prescriptions to residents of States where they were unlicensed and thus engaged in the unauthorized practice of medicine. More specifically, the evidence clearly establishes that Dr. Alsina wrote controlled substance prescriptions for residents of Virginia, Ohio, California, Alabama, and Georgia; that Dr. Fernandez wrote controlled substance prescriptions for residents of Texas, Ohio, and Georgia; that Dr. Romain wrote controlled substance prescriptions to residents of Virginia, California, and Ohio; that Dr. Llamido wrote controlled substance prescriptions for residents of California, Georgia, Texas; and that Dr. Moore wrote controlled substance

public interest.'' *Mortimer Levin,* 57 FR 8680, 8681 (1992). Nor is the lack of any criminal convictions related to controlled substances dispositive. *Edmund Chein,* 72 FR 6580, 6593 n.22 (2007). Thus, the fact that Respondent may still hold its Florida pharmacy license and that neither it, nor its owners, have been convicted of a criminal offense is not dispositive.

[10] As the Supreme Court has 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)).

[11] All cited statutes were enacted and in effect at the time of the conduct in question.

prescriptions for residents of Ohio and Virginia, as well as other States.

The record also establishes that while Dr. Francis was licensed to practice medicine only in Michigan, he wrote controlled substance prescriptions to residents of Alabama and other States. Finally, while Dr. Cheslow was licensed to practice medicine only in New York, he wrote controlled substance prescriptions in California, Texas, and Georgia as well as other States.

As found above, Respondent filled prescriptions written by each of the above doctors on a regular basis for a lengthy period of time, and in each case, Respondent received prescriptions (which it filled) which were written by a physician on a single day for persons located in numerous States in which the physicians were not licensed. As explained above, ''[a] physician who engages in the unauthorized practice of medicine is not a 'practitioner acting in the usual course of * * * professional practice.' '' *United,* 72 FR at 50407 (quoting 21 CFR 1306.04(a)). The prescriptions were therefore unlawful under the CSA and Respondent had ample reason to know that these physicians were engaged in the unauthorized practice of medicine and that the prescriptions they issued were unlawful under both Federal and state laws.

In its Exceptions, Respondent invokes an Agency rulemaking which clarified the registration requirements for practitioners to argue that prior to January 2, 2007 (when the regulation became effective), ''a physician could prescribe in any state provided the physician held a [DEA] registration in a single state.'' Exceptions at 4 (discussing DEA, Final Rule, *Clarification of Registration Requirements for Individual Practitioners,* 71 FR 69478 (Dec. 1, 2006)). Respondent further maintains that ''there was no evidence produced that [it] was aware that the physician may have been acting outside the scope of their certificate or aided in any way the unlicensed practice of medicine by filling prescriptions for patients in other states.'' *Id.*

Beyond the fact that Respondent simply misstates the Agency's published interpretation of the authority conveyed by a DEA registration (and which had been published before much of the conduct at issue here had occurred), its argument conflates two separate issues: (1) The requirements for holding a DEA registration for a particular location, and (2) the licensure requirements for prescribing under state law. As the Agency explained in its Notice of Proposed Rulemaking, ''[t]o be valid in a particular jurisdiction, a controlled substance prescription must be written by a practitioner *who possesses valid state authority in that jurisdiction* and, equally important, the practitioner must possess a DEA registration predicated upon valid state authority in that jurisdiction.'' DEA, Notice of Proposed Rulemaking, *Clarification of Registration Requirements for Individual Practitioners,* 69 FR 70576 (Dec. 7, 2004) (emphasis added).

Contrary to Respondent's contention that there is no evidence that it aided the unlicensed practice of medicine, the evidence exists in the thousands of prescriptions it filled which indicated that the patients resided in one State and the prescribing physician practiced in another. *See, e.g.,* GX 4. Moreover, as the California Court of Appeals 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). As a state-licensed pharmacy and participant in the health care industry, Respondent (and its owners) cannot reasonably claim ignorance of the fact that prescribing a drug constitutes the practice of medicine and that a physician must be licensed to do so.

The controlled substance prescriptions Respondent filled were unlawful for a further reason. 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.' '' *Patrick W. Stodola,* 74 FR 20727, 20731 (2009) (citing *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 has established a bona fide doctor-patient relationship with an individual.[12] *Stodola,* 74 FR at 20731; *see also Kamir Garces-Mejias,* 72 FR 54931, 54935 (2007); *United Prescription Services,* 72 FR at 50407. As explained below, prior to the dispensings at issue here, numerous States had either enacted legislation or promulgated administrative rules which generally prohibited (except for in narrow circumstances not relevant here) a physician from prescribing a controlled substance to a person without first performing a physical examination.

Since January 2001, California has prohibited 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.'' Cal. Bus. & Prof. Code § 2242.1. In 2003, the Medical Board of California made clear that ''[b]efore prescribing a dangerous drug, a physical examination must be performed'' by the prescribing physician. *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*). Furthermore, the Medical Board of California determined 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 conversation with the patient, without a physical examination of the patient.'' *Id.*

Moreover, well before Respondent commenced to dispense the prescriptions at issue here, the Medical Board of California had issued numerous Citation Orders to out-of-state physicians for prescribing over the Internet 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 (August 15, 2003); *see also* Citation Order, Harry Hoff (June 17, 2003); Citation Order, Carlos Gustavo Levy (Jan. 28, 2003); Citation Order, Carlos Gustavo Levy (November 30, 2001).

Doctors Cheslow, Romain, and Llamido all wrote a substantial number of controlled substance prescriptions based on internet consultations with

[12] On October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law 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 (codified at 21 U.S.C. 829(e)(1) & (2)). 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.* (codified at 21 U.S.C. 829(e)(2)(B)). These provisions do not, however, apply to Respondent's conduct.

California residents which Respondent then dispensed. Given the respective locations of the physicians (New York for Dr. Cheslow and Florida for Drs. Romain and Llamido) and the California residents, it was obvious that doctors Cheslow, Romain and Llamido were not performing physical examinations and did not establish bona fide doctor-patient relationships with the Californians. Respondent and its owners had ample reason to know that these prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice and therefore violated both state and Federal law. *See, e.g.*, Cal. Bus. & Prof. Code § 2242.1; 21 CFR 1306.04(a). By dispensing the prescriptions, Respondent violated its corresponding responsibility under Federal law. 21 CFR 1306.04(a).

Similar to California, regulations adopted by the States of Ohio and Indiana require that a physician perform a physical examination of his/her patient prior to prescribing a controlled substance, except in limited circumstances not applicable here. Ind. Admin. Code § 5–4–1(a); Ohio Admin Code § 4731–11–09(A). Doctors Llamido and Moore issued a substantial number of prescriptions for controlled substances to individuals in Indiana; Doctors Alsina, Fernandez, Romain, and Moore issued a substantial number of controlled substance prescriptions to individuals in Ohio. These doctors violated Indiana and Ohio law respectively, as it is inconceivable that they went to Indiana or Ohio to perform physical examinations on the patients when they were not licensed to practice in those States (or that the patients travelled to see them) and were also issuing numerous prescriptions to the residents of multiple States on the same day. And as explained above, given the respective locations of the patients and the physicians, Respondent had reason to know that the prescriptions were issued outside of the usual course of professional practice and lacked a legitimate medical purpose. 21 CFR 1306.04(a). By dispensing the prescriptions, Respondent further violated the CSA.

Under Virginia law, a doctor must establish a bona fide practitioner-patient relationship prior to prescribing a controlled substance. Va. Code Ann. § 54.1–3303(A).[13] Moreover, Virginia law expressly requires that a practitioner ''perform or have performed an appropriate examination of the patient, either physically or by use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically'' and that ''except for [in] medical emergencies, the examination 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.*

Doctors Alsina, Fernandez, Romain, and Moore, all of whom were licensed to practice only in Florida, issued controlled substance prescriptions to residents of Virginia. Here again, these physicians issued prescriptions to Virginia residents under circumstances which render it inconceivable that they met the requirements of Virginia for establishing a bona fide doctor-patient relationship prior to prescribing the controlled substances. These physicians thus violated Virginia law. Here again, given the respective locations of the physicians and the patients, Respondent (and its owners) had reason to know that these physicians did not establish bona fide doctor-patient relationships with the individuals to whom they prescribed controlled substances and that the prescriptions were issued outside of the usual course of professional practice and lacked a legitimate medical purpose as required by Federal law. 21 CFR 1306.04(a). By filling these prescriptions, Respondent again failed to comply with its ''corresponding responsibility'' under Federal law to dispense only lawful prescriptions. *Id.*

Respondent simply ignores these various state medical practice standards. Instead, in its Exceptions, Respondent argues that Florida's telemedicine rule ''does not require that the physician issuing the prescription have a face to face consultation with the patient or that the physician issuing the prescription conduct a physical examination, rather that their [sic] be a 'documented patient evaluation.'' Exceptions at 3 (quoting Fla. Admin. Code Ann. r. 64B8–9.003). However, even if it is the case that the State of Florida interprets its regulation as authorizing a physician to prescribe without having personally performed a physical examination of a patient, Florida has no authority to promulgate the standards of medical practice applicable in other States for prescribing a controlled substance to those States' residents. Thus, even if the prescriptions issued by the Florida-based physicians would have been lawful if they had been issued to residents of Florida, they were still illegal under the laws of California, Ohio, Indiana and Virginia.

Finally, Respondent cites to a recommended order of a state ALJ in a proceeding before the Florida Board of Pharmacy to argue ''that it would be 'problematic' to require a pharmacist to 'independently determine the validity of the patient/physician relationship' because the standards used to determine the validity of such a relationship 'differ from state to state.'" Exceptions at 3–4 (quoting *Florida Dept. of Health* v. *RX Network of South Florida*, 2003 WL 124675, at *32 (Fla. Div. Admin. Hrgs. 2003) (Conclusion of Law # 192). Continuing, the state ALJ reasoned that if Florida law ''were construed to require [the pharmacist] to exercise her own judgment on this issue, it is unclear whether [she] would apply Florida law to determine the validity of the professional relationship of a physician licensed outside of Florida or would apply the law of the state where the physician is licensed.'' *Rx Network* at *32.

To the extent the Florida Board adopted the state ALJ's reasoning,[14] its holding as to the scope of a pharmacist's duty under Florida law is not binding on this Agency's interpretation of Federal law and regulations. Moreover, the state ALJ's reasoning is wholly unpersuasive as ''an entity which voluntarily engages in commerce by shipping controlled substances to persons located in other States is properly charged with knowledge of the laws regarding the practice of medicine in those States.'' *United Prescription Services,* 72 FR at 50407. Just as licensed health care providers cannot ''reasonably claim ignorance'' of state laws prohibiting the unlicensed practice of medicine, so too they cannot reasonably claim ignorance of various States' laws and rules which establish the standards of medical practice for prescribing a drug.

Finally, Respondent violated the laws of numerous States by engaging in the unauthorized practice of pharmacy.[15]

[13] This statute was enacted and in effect at the time of the conduct in question.

[14] In its Final Order, the Board expressly noted that it was responding to the ALJ's conclusions of law in which this reasoning is found. *See* Final Order at 9–10, *Department of Health* v. *RX Networks of South Florida, LLC.* (Fla. Bd. of Pharm. 2003). While the Board did not specifically address the ALJ's reasoning that it is ''problematic'' to require a pharmacist to ''determine the validity of the patient-physician relationship'' because standards ''differ from state to state,'' it did note that ''pharmacists must be aware of the regulations governing those health care practitioners who prescribe drugs so that a pharmacist can make a reasoned decision as to whether the professional standards for legitimate dispensing have been met.'' *Id.* at 10.

[15] In its Exceptions, Respondent contends that its failure to obtain pharmacy licenses for those States (other than Florida) which it dispensed into is

Continued

For example, New Hampshire law requires a pharmacy to obtain a license and provides for the licensing of out-of-state pharmacies licensed elsewhere upon the passing of an examination. N.H. Rev. Stat. §§ 318:1 (defining ''pharmacy''), 318:21 (licensure of out-of-state pharmacies), 318:37 (requiring license to operate a pharmacy), and 318:42 (prohibiting the sale of prescription drugs by any other than a licensed pharmacist in a registered pharmacy).[16] Nevertheless, even after consulting with the state's Chief Compliance Officer, Respondent, through Mr. Liddy, continued to dispense prescriptions to individuals in New Hampshire. Moreover, Liddy's statement that his records showed that in the prior two years, his pharmacy had only shipped three packages to New Hampshire residents, was a bald-faced lie. I therefore find that Respondent violated New Hampshire law. Indeed, Liddy's continued violation of the law, even after being placed on notice, and his willingness to lie about his misconduct, makes clear that Respondent cannot be entrusted with a registration.

Most other States also prohibit an out-of-state pharmacy from dispensing medication to state residents without being licensed to do so. *See, e.g.,* Ark. Code Ann. §§ 17–92–301 (prohibiting practice of pharmacy without a license) & 17–92–302 (prohibiting filling of prescription by other than Arkansas-licensed pharmacist); Conn. Gen. Stat. Ann. § 20–627 (requiring registration of nonresident pharmacies); Cal. Bus. & Prof. Code § 4120 (requiring special permit for nonresident pharmacies); La. Rev. Stat. Ann. § 37:1221 (requiring special permit for out-of-state pharmacies to provide pharmacy services to residents of the state).[17] Respondent dispensed prescriptions to residents of all of these States without holding the pharmacy licenses required to do so. *See* GX 17. I therefore find that Respondent violated these laws as well. Respondent's flagrant disregard for the rules governing its profession manifests that it and its owners cannot be trusted to properly comply with Federal law and DEA regulations.

Finally, the evidence shows that Respondent violated DEA regulations by filling controlled substance prescriptions which were unlawful because they were not manually signed by the prescribing practitioner. Under 21 CFR 1306.05(a), ''prescriptions shall be written with ink or indelible pencil and shall be manually signed by the practitioner.'' Moreover, while ''the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations[,] [a] corresponding liability rests upon the pharmacist * * * who fills a prescription not prepared in the form prescribed by DEA regulations.'' *Id.* As the DI testified, the ''vast majority'' of the controlled substance prescriptions Respondent filled did not comply with this requirement. Tr. 88. Rendering these violations especially egregious is that Mr. Liddy had been previously told by the Executive Director of the Florida Board of Pharmacy that ''a control substance prescription must be manually signed.'' GX 11. Once again, Mr. Liddy's flagrant disregard for the law makes it clear that Respondent cannot be entrusted with a DEA registration.[18]

As the forgoing demonstrates, Respondent's experience in dispensing controlled substances and its record of compliance with applicable controlled substance laws is marked by its (and its owner's) repeated and egregious violations in dispensing prescriptions that were unlawful under both the CSA and numerous state laws. I therefore hold that the Government has shown that Respondent has committed numerous acts which render issuing it a new registration ''inconsistent with the public interest.'' [19] 21 U.S.C. 823(f).

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 it 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

outside of the scope of the proceeding. However, '''[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law.''' *Citizens State Bank of Marshfield* v. *FDIC,* 751 F.2d 209, 213 (8th Cir. 1984) (quoting *Aloha Airlines* v. *Civil Aeronautics Bd.,* 598 F.2d 250, 262 (DC Cir. 1979)). *See also Boston Carrier, Inc.* v. *ICC,* 746 F.2d 1555, 1560 (DC Cir. 1984) (quoted in *Edmund Chein,* 72 FR 6580, 6592 n.21 (2007) (''an agency is not required 'to give every [Respondent] a complete bill of particulars as to every allegation that [he] will confront'')). Thus, the failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive, and an issue can be litigated if the Government otherwise timely notifies a respondent of its intent to litigate the issue.

The Agency has thus recognized that ''the parameters of the hearing are determined by the prehearing statements.'' *Darrell Risner, D.M.D.,* 61 FR 728, 730 (1996). Accordingly, in *Risner,* the Agency held that where the Government has failed to disclose ''in its prehearing statements or indicate at any time prior to the hearing'' that an issue will be litigated, the issue cannot be the basis for a sanction. 61 FR at 730. *See also Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 FR 75959, 75961 (2000) (noting that the function of pre-hearing statements is to provide Due Process through ''adequate * * * disclosure of the issues and evidence to be submitted in * * * proceedings''); *cf. John Stafford Noell,* 59 FR 47359, 47361 (1994) (holding that notice was adequate where allegations were not included in Order to Show Cause but ''were set forth in the Government's Prehearing Statement'').

While the Order to Show Cause did not allege that Respondent had failed to obtain the necessary pharmacy licenses to dispense to States other than Florida, in its supplemental prehearing statement, the Government notified Respondent that it intended to litigate the issue by eliciting the testimony of its owner as to its ''licensure status * * * in those jurisdictions where [it] shipped controlled substance prescriptions and whether [it] was licensed as an out-of-state pharmacy in any jurisdiction that required such licensure.'' Gov. Supp. Prehearing Stmt. at 1. The Government also notified Respondent that it intended to litigate the issue of Respondent's communications with the New Hampshire Board of Pharmacy ''regarding the licensure requirement to ship controlled substances into that state.'' *Id.*

[16] These statutes were enacted and in effect at the time of the conduct in question.

[17] These statutes were enacted and in effect at the time of the conduct in question.

[18] The evidence does not, however, establish that Respondent dispensed controlled substance prescriptions issued under the authority of the registration held by Dr. Alsina after he notified Mr. Liddy (on October 5, 2005) that his registration had been suspended. *See* GX 12. While GX 20 lists various dates after October 5, 2005 on which Respondent dispensed prescriptions presumably authorized by Dr. Alsina, the exhibit does not identify what drugs these prescriptions were for. Thus, the evidence does not establish that these prescriptions were for controlled substances. However, given the scope of the violations that have been proved, this allegation is inconsequential.

[19] In numerous decisions, DEA has noted the serious risk of diversion created by internet prescribing and dispensing of controlled substances and the threat this poses to public health and safety. *See Trinity Health Care Corp.,* 72 FR 30849, 30855 (2007) (internet pharmacy dispensed more than 43,000 illegal prescriptions and two million dosage units of controlled substances; ''it is manifest that diversion on this scale creates an extraordinary threat to the public health and safety''); *William R. Lockridge,* 71 FR 77791, 77799 (2006) (noting that internet prescriber ''was a drug dealer'' and that conduct created ''imminent danger to public health and safety''); *Mario Avello,* 70 FR 11695, 11697 (2005); *cf. Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007) (discussing increase in the rates of prescription drug abuse and the Internet's ''role in facilitating the growth of prescription drug abuse''); *see also* National Center on Addiction and Substance Abuse, ''*You've Got Drugs!'' IV: Prescription Drug Pushers on the Internet* (2007), at 8 (''[T]he wide availability of dangerous and addictive drugs on the Internet reveals a wide-open channel of distribution. This easy availability has enormous implications for public health, particularly the health of our children, since research has documented the tight connection between availability of drugs to young people and substance abuse and addiction.'').

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 its actions and demonstrate that it 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); *Cuong Trong Tran,* 63 FR 64280, 62483 (1998); *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).

As the ALJ observed, both of Respondent's owners invoked their Fifth Amendment privilege when called to testify by the Government and refused to answer any questions. ALJ at 24. I therefore find that Respondent (and its owners) have failed to accept responsibility for their misconduct. This alone provides reason to hold that Respondent has not rebutted the Government's *prima facie* showing that issuing it a new registration ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f).

In its Exceptions, Respondent nonetheless contends that ''even though the [Liddy's] invoked their Fifth Amendment Privilege, the record * * * demonstrate[s] that the complained of conduct was no longer present'' and that it had ceased the offending conduct prior to the execution of the search warrant in July 2007. Exceptions at 1–2. Respondent thus asserts that it has changed its practices and that its then–existing registration should not be revoked. *Id.* at 2. However, the evidence shows that at some time in either 2005 or 2006, a DEA Investigator had visited Respondent and interviewed Respondent's owners. Tr. 82.

While the record does not establish the precise subject matter that was discussed, it is not everyday that the DEA comes knocking at one's door, and it is reasonable to infer that the Investigator's visit had something to do with the illegality of Respondent's activities in dispensing the internet prescriptions. Accordingly, even were I to ignore the failure of Respondent's owners to acknowledge their illegal behavior (which I decline to do), the weight to be given Respondent's cessation of its unlawful practices is substantially diminished by the fact that this followed, rather than preceded, its owners becoming aware that they were under investigation. Moreover, as the ALJ noted, Respondent put on no evidence as to what steps it has undertaken to reform its practices. ALJ at 24.

I therefore concur with the ALJ's conclusion that Respondent's ''extensive record of unlawful conduct * * *, its callous disregard for the serious responsibility of a DEA registrant, and its failure to present any evidence to show how it has corrected these practices outweigh'' the fact that the State Pharmacy Board has taken no action against its license (factor one) and the absence of any criminal convictions (factor three). *Id.* at 25. I further adopt the ALJ's conclusion that ''it would be inconsistent with the public interest to allow * * * Respondent to maintain its registration.'' *Id.* at 24. Accordingly, Respondent's pending renewal application will be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I deny the Government's motion to terminate the proceeding as moot. I further order that the application of Liddy's Pharmacy, L.L.C., for a DEA Certificate of Registration be, and it hereby is, denied. This Order is effective September 8, 2011.

Dated: August 2, 2011.

Michele M. Leonhart,

Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10–70]

Sheryl Lavender, D.O. Decision and Order

On October 28, 2010, Administrative Law Judge (ALJ) Timothy D. Wing, issued the attached recommended decision. The Respondent did not file exceptions to the decision.

Having reviewed the record in its entirety [1] including the ALJ's recommended decision, I have decided to adopt the ALJ's rulings, findings of fact, conclusions of law, and recommended Order.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 21 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration, BL1667596, issued to Sheryl Lavender, D.O., be, and it hereby is, revoked. I further order that any pending application of Sheryl Lavender, D.O., to renew or modify her registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: July 27, 2011.

Michele M. Leonhart,

Administrator.

Brian Bayly, Esq.,

for the Government.

Shawn B. McKamey, Esq.,

for the Respondent.

Recommended Ruling, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

Timothy D. Wing, Administrative Law Judge. On July 26, 2010, the Deputy Administrator, DEA, issued an Order to Show Cause and Immediate Suspension (OSC/IS) of DEA COR BL1667596, dated July 26, 2010, and served on Respondent on August 2, 2010. The OCS/IS alleged that Respondent's continued registration constitutes an imminent danger to the public health and safety. The OSC/IS also provided notice to Respondent of an opportunity to show cause as to why the DEA should not revoke Respondent's DEA COR BL1667596 pursuant to 21 U.S.C. 824(a)(4), on the grounds that Respondent lacks authority to handle controlled substances in Florida, the state in which she maintains her DEA registration, and on the grounds that Respondent's continued registration would be inconsistent with the public interest under 21 U.S.C. 823(f). On August 31, 2010, Respondent, acting *pro se,* in a letter dated August 23, 2010, timely requested a hearing with the DEA Office of Administrative Law Judges (OALJ).

I issued an Order for Prehearing Statements on September 8, 2010. On the same date, OALJ sent Respondent a letter informing her of her right to representation under 21 CFR 1316.50.

On September 10, 2010, the Government filed a Motion for Summary Judgment. On September 13, 2010, I issued an order directing Respondent to reply to the Government's motion by September 20, 2010. On September 17, 2010, Respondent, through counsel, filed Respondent's Unopposed Motion for Extension of Time to Allow Respondent to Answer Motion for Summary Judgment, seeking an extension of time so that Respondent might obtain

[1] I note that the Government also cited 21 U.S.C. 824(a)(3) in both the Order to Show Cause and its Motion for Summary Judgment as authority for revoking Respondent's registration. *See* Order to Show Cause, at 2; Mot. for Summ. Judg., at 2–3.