November 21, 2007: Anticipated posting of Commission report.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street, SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street, SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://www.usitc.gov/secretary/edis.htm.*

FOR FURTHER INFORMATION CONTACT: Timothy McCarty (202–205–3324, *timothy.mccarty@usitc.gov*) or Jonathan Coleman (202–205–3465, *jonathan.coleman@usitc.gov*), Agriculture and Fisheries Division, Office of Industries, for general information, or William Gearhart (202–205–3091, *william.gearhart@usitc.gov*), Office of the General Counsel, for information on legal aspects. The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Background: Section 316 of the North American Free Trade Agreement Implementation Act (NAFTA Implementation Act) (19 U.S.C. 3381) requires that the Commission monitor U.S. imports of fresh or chilled tomatoes (HTS heading 0702.00) and fresh or chilled peppers, other than chili peppers (HTS subheading 0709.60.00), until January 1, 2009, for purposes of expediting an investigation concerning provisional relief under section 202 of the Trade Act of 1974 or section 302 of the NAFTA Implementation Act. Section 316 does not require that the Commission publish reports on this monitoring activity or otherwise make the information available to the public. However, the Commission maintains current data files on tomatoes and peppers in order to conduct an expedited investigation should a request be received. Following enactment of section 316, the Commission instituted investigation No. 332–350, *Monitoring of U.S. Imports of Tomatoes* (59 FR 1763), and investigation No. 332–351, *Monitoring of U.S. Imports of Peppers* (59 FR 1762).

The Commission will continue to make its reports available to the public in electronic form (with the exception of any confidential business information (CBI)), and will maintain electronic copies of its reports on its Web site until one year after the monitoring requirement expires on January 1, 2009. The most recent Commission monitoring reports in this series were published in November 2006 and are available on the Commission's Web site.

Written Submissions: The Commission does not plan to hold a public hearing in connection with preparation of these reports. However, interested persons are invited to submit written statements containing data and other information concerning the matters to be addressed. All submissions should be addressed to the Secretary, and should be received no later than the close of business on September 4, 2007. All written submissions must conform with the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 requires that a signed original (or a copy so designated) and fourteen (14) copies of each document be filed. In the event that confidential treatment of a document is requested, at least four (4) additional copies must be filed, in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). The Commission's rules authorize the filing of submissions with the Secretary by facsimile or electronic means only to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf*). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000).

Any submissions that contain confidential business information must also conform with the requirements of section 201.6 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

The Commission will not publish such confidential business information in the monitoring reports it posts on its Web site in a manner that would reveal the operations of the firm supplying the information. However, the Commission may include such information in any report it sends to the President under section 202 of the Trade Act of 1974 or section 302 of the NAFTA Implementation Act, if it is required to conduct an investigation involving these products under either of these statutory authorities.

By order of the Commission.

Issued: August 27, 2007.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E7–17230 Filed 8–30–07; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 7–21]

United Prescription Services, Inc. Revocation of Registration

On February 13, 2007, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to United Prescription Services, Inc. (Respondent), of Tampa, Florida. The Order immediately suspended Respondent's DEA Certificate of Registration, BU6696073, as a retail pharmacy, based on my preliminary finding that Respondent was diverting large quantities of controlled substances and that its continued registration during the pending of these proceedings ''would constitute an imminent danger to the public health and safety because of the substantial likelihood that [it would] continue to divert controlled substances.'' Show Cause Order at 4 (citing 21 U.S.C. 824(d)). The Order also sought the revocation of Respondent's registration on the ground that its ''continued registration is inconsistent with the public interest.'' *Id.* at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

The Show Cause Order alleged that Respondent distributed large quantities of controlled substances based on prescriptions that it knew or should have known ''were not written for a legitimate medical purpose or were written by a practitioner not acting in the usual course of professional practice.'' *Id.* More specifically, the Show Cause Order alleged that between

October 1, 2005, and January 31, 2006, Respondent distributed 1,808,693 dosage units of controlled substances and that more than 1,275,000 dosage units of these controlled substances were prescribed by a single physician. *Id.* at 3. Relatedly, the Show Cause Order alleged that during this period, Respondent filled 11,830 prescriptions which were written under a single physician's registration. *Id.*

The Show Cause Order further alleged that Respondent ''is owned and operated by Mr. Samuel Ballinger,'' and that Mr. Ballinger also ''controlled and operated University Physician Resources, Inc.,'' (hereinafter, University), which either employed or contracted with physicians and other persons who issued prescriptions for controlled substances that were ordered through several internet sites, and which were then filled by Respondent. *Id.* at 1–2. The Show Cause Order also alleged that Respondent filled prescriptions issued by physicians who were affiliated with other internet sites. *Id.*

The Show Cause Order alleged that Respondent knew or should have known that the prescriptions were invalid. *Id.* at 2. Specifically, the Show Cause Order alleged that ''the prescribing physicians were geographically separated from the majority of their customers,'' thus indicating that it was likely that the physicians had not examined the customers, and that ''[t]he volume of the prescriptions generated by one physician in a given period of time was so excessive as to indicate that the practitioner could not have conducted an appropriate medical exam, obtained a medical history, or made a prior diagnosis.'' *Id.* Relatedly, the Show Cause Order alleged that while Respondent required the physicians ''to submit an affidavit indicating that [they] had supervised and directed a medical exam[,] [it] knew that, in many cases, the prescribing physician had not directed and supervised any examination.'' *Id.*

As for those instances ''in which physicians obtained medical records from other medical professionals prior to issuing'' a controlled-substance prescription, the Show Cause Order alleged that Respondent ''knew the physicians did not consult with the medical professionals who conducted the physical examinations.'' *Id.* The Show Cause Order also alleged that ''Mr. Ballinger directed individuals without a DEA registration to issue prescriptions for controlled substances using the DEA registration of physicians employed by University'' and that Respondent ''then filled those invalid prescriptions for controlled substances.'' *Id.* Relatedly, the Show Cause Order alleged that Respondent filled numerous prescriptions issued by Dr. Wayne Starks after the expiration of Starks' registration and its retirement from the DEA database. *Id.* at 3.

The Show Cause Order also alleged that Respondent violated various other provisions of Federal law and regulations. Specifically, the Show Cause Order alleged that Respondent was purchasing bulk hydrocodone powder and manufacturing controlled substances without a manufacturer's registration as required by 21 U.S.C. 822(b). *Id.* at 4. The Show Cause Order alleged that this activity was not compounding because it was not done ''pursuant to individual prescriptions.'' *Id.* The Show Cause Order also alleged that Respondent violated 21 CFR 1306.05(a) by filling prescriptions which ''either did not contain the full address of the patient or contained an incorrect address for the patient,'' *id.,* and by dispensing a prescription which bore one physician's DEA number but which ''appeared to be signed by'' a different physician. *Id.* at 3.

Finally, the Show Cause Order alleged that Respondent violated various provisions of state law. Specifically, the Show Cause Order alleged that Respondent ''dispensed controlled substances into a number of states in which the dispensing violated the state law'' because the prescription had not been written by a physician licensed under the laws of the patient's state. *Id.* (citing Cal. Health & Safety Code § 11352). Relatedly, the Show Cause Order alleged that Respondent had ''shipped controlled substances into * * * Kentucky in violation of Kentucky law.'' *Id.* at 3–4 (citing Ky. Rev. Stat. Ann. § 315.320).

On February 14, 2007, the Show Cause Order was served on Respondent. Thereafter, on March 5, 2007, Respondent, through its counsel, requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who conducted a hearing on April 9 through 13, 2007, in Arlington, Virginia. At the hearing, both parties elicited the testimony of witnesses and introduced documentary evidence. Following the hearing, both parties submitted briefs containing their proposed findings of fact and conclusions of law.

On May 31, 2007, the ALJ issued her decision. In that decision, the ALJ found ''that the prescriptions that Respondent filled were not issued in the course of a legitimate physician-patient relationship'' and thus were ''not valid prescriptions.'' ALJ at 67. In support of this finding, the ALJ noted that it was ''undisputed that Dr. Reppy'' (who worked for University and wrote a large number of the prescriptions filled by Respondent), ''examined few, if any, of the patients to whom he issued prescriptions.'' *Id.* at 65. While the ALJ acknowledged Dr. Reppy's testimony that he had ''spoke[n] with some of the doctors who had previously treated patients with whom [he] consulted by telephone,'' the ALJ found dispositive that ''there is no evidence that any of these doctors referred their patients to University or Dr. Reppy.'' *Id.* Relatedly, the ALJ noted that there was also ''no evidence whatsoever that any physicians who had examined Respondent's customers had referred them to the physicians who prescribed to them and sent the prescriptions to Respondent to be filled.'' *Id.* at 66. Finally, the ALJ noted that ''in some instances the records show that physicians who had examined these individuals refused to prescribe analgesics to them.'' *Id.* The ALJ thus concluded ''that there was no physician-patient relationship between Dr. Reppy—or any of the other physicians discussed above who issued prescriptions that Respondent filled—and the customers to whom they issued those prescriptions.'' *Id.*

Relatedly, the ALJ found that ''Mr. Ballinger established a scheme whereby University, which he controlled, would employ a physician to issue prescriptions for Respondent to fill, and that representatives of Respondent also actively arranged with operators of websites that solicited customers to obtain prescriptions after telephonic consultations with physicians that the physicians would send those prescriptions to Respondent to be filled.'' *Id.* at 66. The ALJ thus further found that Respondent knew the prescriptions were invalid and violated 21 CFR 1306.04(a) when it filled them. *Id.* at 67.

Moreover, having concluded that the prescriptions Respondent filled were invalid, the ALJ further held that ''Respondent's production of dosage form controlled substances was not compounding within the meaning of the Controlled Substances Act * * * and that * * * Respondent manufactured controlled substances without holding a DEA registration to do so.'' *Id.* The ALJ thus further found that Respondent violated 21 U.S.C. 841(a). *Id.* at 68.

Finally, the ALJ rejected—as unsupported by the record—Respondent's assertion that in January 2007, it changed its practices. *Id.* at 68–69 (quoting Resp. Br. at 12). The ALJ

thus concluded that ''Respondent's continued registration would be inconsistent with the public interest'' and recommended that its registration be revoked and that its pending application for renewal be denied. *Id.* at 69.

Thereafter, Respondent filed exceptions. Therein, Respondent ''agrees with the Recommended Ruling's finding that the evidence showed that in many instances, prescriptions by Dr. Reppy were issued based on a telephonic interaction with the patient after review of medical records that included a physical examination which was conducted by a practitioner who did not necessarily have a referral arrangement with Dr. Reppy.'' Resp. Exceptions at 4 n.4.

Respondent argues, however, that the ALJ's proposed decision imposes ''a requirement that a prescribing practitioner either personally conduct a physical examination of a patient or have a referral arrangement with another health care practitioner who personally conducts a physical examination of a patient in order to have a valid doctor-patient relationship.'' *Id.* at 3. Respondent argues that the ALJ's decision thus ''adopts a new national standard for the requirements of a valid doctor-patient relationship that is completely unsupported by current federal law and regulation and which is outside the scope of the Controlled Substances Act.'' *Id.* Respondent thus contends that the ALJ's decision ''seeks to * * * regulate the practice of medicine.''[1] *Id.* at 3 n.2 (citing *Gonzales* v. *Oregon,* 126 S.Ct. 904, 923 (2006)).

On June 26, 2007, the ALJ forwarded the record to me for final agency action. Having reviewed the entire record, I hereby issue this Decision and Final Order. While I do not adopt the ALJ's reasoning with respect to the validity of the prescriptions, the record nonetheless establishes that both Dr. Reppy and the other physicians issued prescriptions in violation of various state laws because the physicians were engaged in unlicensed activity and/or failed to comply with applicable state standards of practice for issuing treatment recommendations including the prescribing of controlled substances. I further conclude that the record establishes that Respondent had reason to know that numerous prescriptions it filled were unlawful because the prescribing physicians either did not establish a valid doctor/patient relationship or were engaged in the unlicensed practice of medicine.

Relatedly, I find Respondent violated Federal law by filling numerous prescriptions issued by a physician whose DEA registration had expired and a physician assistant who lacked authority to prescribe controlled substances under Florida law. I therefore adopt the ALJ's ultimate conclusion that Respondent's continued registration would be inconsistent with the public interest and will revoke its registration and deny its pending application for renewal. I make the following findings.

Findings

Respondent United Prescription Services, Inc., is licensed in the State of Florida as a community pharmacy and as a retail pharmacy wholesaler. Resp. Ex. 1, at 2–5. Respondent also holds or has held[2] numerous out-of-state or non-resident pharmacy licenses. *See id.* at 6–124.

Respondent is also the holder of DEA Certificate of Registration, BU6696073, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy at the registered location of 2304 E. Fletcher Ave., Tampa, Florida. Gov. Ex. 1, at 1. While Respondent's certificate indicates that its registration expired on May 31, 2006, *id.,* Respondent submitted a timely application for renewal of its registration. ALJ Ex. 4, at 1. I therefore find that Respondent holds a current registration (albeit in suspended status) pending the issuance of this Final Order. *See* 5 U.S.C. 558(c).

Respondent was founded by Mr. Robert Carr, a Tampa, Florida personal injury lawyer, ''to fill prescriptions for personal injury patients.'' Gov. Ex. 87, at 2. Mr. Samuel Ballinger, Respondent's current owner, was an administrator at a law firm where Carr practiced. *Id.* According to a statement given by Mr. John Todd Miller, Ballinger and Carr were partners in Respondent. *Id.* However, Respondent introduced into evidence a copy of a sales agreement dated March 25, 2005, under which Carr, who was then the sole shareholder and owner of Respondent sold his interest to Ballinger. Resp. Ex. 5, at 1.

In addition to Mr. Miller's statement, the record contains evidence indicating that Ballinger was involved in the operation of Respondent from before the date of this transaction. For example, Ballinger was listed on several of Respondent's Uniform Business Reports as a corporate officer or director. *See* GX 97, at 6 (Jan. 27, 2001 filing listing Ballinger as Respondent's President/Director); GX 74 (August 18, 2002 filing listing Ballinger as Respondent's President). While on Respondent's January 2003 filing Ballinger was no longer listed as Respondent's President, GX 97, at 9; the record also contains a July 16, 2003 letter from a physician, Mildred E. Watson, to Ballinger, at Respondent's address, in which she expressed her excitement at joining Respondent's ''nationwide physicians network.'' GX 62, at 83.

Moreover, during the cross-examination of Robert Reppy, a physician who worked for Ballinger at University Physician Resources[3] between early 2004 and October 2006, Respondent's counsel stipulated that Ballinger had a relationship/affiliation with Respondent during the period of Reppy's employment at University. Tr. 1172–73. Consistent with Mr. Miller's statement that Carr and Ballinger were partners, *see* GX 87, at 2; Reppy testified that ''Ballinger was a major stockholder'' in Respondent and was Carr's partner. Tr. 1173. Furthermore, Reppy testified that Ballinger directed that the prescriptions he issued be faxed to Respondent. *Id.* at 1179; *see also* GX 87, at 4 (statement of Miller). Thus, even if Ballinger did not have an equity interest in Respondent prior to the sale, it is clear that Ballinger had a relationship with Respondent and its owner during Reppy's employment with University.

According to Mr. Miller, Respondent ''did not do well initially.'' GX 87, at 3. Eventually, Mr. Ballinger obtained ''a computer program for an Internet pharmacy business'' and Ballinger and Carr opened ''their own Internet pharmacy site and began filling internet prescriptions.'' *Id.* Miller also introduced a Florida-based physician, Juan Ibanez, to Ballinger and Carr. *Id.* Thereafter, Ibanez began issuing prescriptions for persons who visited Ballinger's and Carr's Web site. *Id.* Numerous patient files (that were seized from Respondent) indicate that it filled these prescriptions. *See, e.g.*, GX 110 (Excerpt 2 at 4893–94); *id.* (Excerpt 3, at 5277, 5279, 5284), *id.* (Excerpt 6, at 9750, 9758, 9764, 9770), *id.* (Excerpt 9, at 3937, 3938). According to Miller, both the computer servers and call center for the internet business ''were located inside'' Respondent at its Tampa location. GX 87, at 3.

Miller further stated that five or six internet pharmacy Web sites were affiliated with Respondent. *Id.* at 5.

[1] Relatedly, Respondent also contends that it was improper for the ALJ to rely on the testimony of DEA's expert witness, Dr. Carmen Catizone, ''as the basis for a legal standard applicable to the regulation of the practice of medicine.'' *Id.* at 6.

[2] As the ALJ observed, some of these licenses had expired.

[3] University's role is discussed below.

Throughout the patient files, there are numerous documents indicating that Respondent filled prescriptions that were sent to it through internet sites such as *http://www.fedxmeds.com,* PhoneConsultation.Com, and accuratemd.com. *Id.; see also* GX 110 (Excerpt 3, at 5202–03; and Excerpt 4, at 6980, 6994–96); GX 84 at 2 (affidavit of Robert Reppy).

Ballinger was also the owner of University, a clinic which provided both in-office medical treatment and what it termed ''telemedicine.'' *See* GX 22; GX 87, at 4; GX 84, at 1 (affidavit of Robert Reppy). University employed various physicians including Dr. Robert Reppy, a doctor of osteopathy, and a physician's assistant, John Protheroe. GX 84, at 2–4. Ballinger hired Reppy in early 2004, to replace other physicians (Juan Ibanez, M.D., and Richard Long, M.D.) who had left the clinic. *Id.* at 2. With the exception of the period between November 2004 and March 2005 when he was on a leave of absence, Reppy worked for University until October 2006. *Id.* at 2–5. During the course of his employment at University, Ballinger ''directed [its] operations.'' *Id.* at 5.

At University, Reppy, who was licensed only in the State of Florida, *id.* at 1, reviewed the medical records provided by individuals and conducted telephone consultations with them. *Id.* at 3. According to Reppy, ''most of [his] patients * * * were telephone consultation patients who were referred to University by an Internet Web site.''[4] *Id.* Moreover, ''many of [his] patients were from outside the [S]tate of Florida.'' *Id.* Based on his review of a person's medical records and the telephone consultation, Reppy would decide whether to issue a prescription for the person's purported condition. *Id.* Most of the prescriptions Reppy issued were for controlled substances such as schedule III drugs containing hydrocodone and schedule IV benzodiazepines such as alprazolam and diazepam. *See* GX 99, at 15; *see also* GX 66.

At University, Reppy ''consulted with approximately 30 patients per day.'' GX 84, at 3. Reppy also ''reviewed the * * * files for the patients for whom Mr. Protheroe wrote prescriptions,'' which were also based on a review of medical records and a telephone consultation. *Id.* at 2. According to Reppy's affidavit, ''[m]ost of the prescriptions written by Mr. Protheroe were for controlled substances,'' and were then ''sent to [Respondent] to be filled unless otherwise directed by the patient.'' *Id.; see also* Tr. at 1139. Reppy further testified that Ballinger directed that University's prescriptions be faxed to Respondent. *Id.* at 1179.

While Reppy was on his leave of absence, ''Protheroe continued to write prescriptions for controlled substances using [Reppy's] DEA number and electronic signature.'' GX 84 at 4. According to Reppy, Protheroe did not have ''permission to issue prescriptions in my name while I was on leave,'' and was authorized ''to issue prescriptions [only] while he worked under [Reppy's] supervision.'' *Id.*

In his testimony, Reppy stated that Protheroe wrote ''over 14,000 prescriptions'' without his permission during the period of his leave of absence. Tr. at 1182–83, 1193, 1198. To rebut this testimony, Respondent introduced Protheroe's sworn statement in which he ''specifically denied'' having issued prescriptions without Reppy's ''knowledge or permission.'' Resp. Ex. 33.

Respondent also introduced into evidence the affidavit of Richard Furlong, who asserted that he worked at University from February through May 2005. *See* Resp. Ex. 23. In his declaration, Mr. Furlong stated that ''Reppy supervised and authorized prescriptions issued by Mr. Protheroe and was uncompromising that the decision to issue a prescription rested with him.'' *Id.* at 1. Furlong added that while he ''was there on an everyday basis, [he] never heard any discussion about nor saw information indicating that Mr. Protheroe was not practicing under the supervision of Dr. Reppy, or that he took direction from anyone, including Samuel Ballinger, other than Dr. Reppy.'' [5]

The ALJ did not make any findings regarding this factual dispute. *See* ALJ at 67 n.97. As ultimate fact finder, I do. I credit Dr. Reppy's testimony noting that he was subject to Respondent's re-direct examination [6] and stuck to his story. In contrast, Respondent did not call either Protheroe or Furlong to testify and thus they were not subject to cross-examination by the Government. Furthermore, Mr. Furlong was at University for only a short period after Reppy returned to work, and Reppy, in his April 4, 2007 affidavit, stated that he had only ''recently bec[o]me aware'' of these prescriptions. GX 84, at 4. I thus find that at the time Furlong worked at University, Reppy was unaware of Protheroe's activities during his leave of absence. I further find that because Ballinger allowed Protheroe to work out of the office, Tr. 1199–1200, 1210; the records may not even have been in the clinic.

In his testimony, Reppy maintained that his practice did not involve making new diagnoses, but rather, ''monitoring stable patients whose diagnoses are already well known.'' *Id.* at 1109. Dr. Reppy further asserted that many of his patients contacted him because their original doctors were ''not willing to do pain management for them because that's not their main purview.'' *Id.* at 1116. Dr. Reppy also stated that ''many'' of his patients ''have tried to get pain management from their local hospital or pain management centers,'' but ''they are expected to come in'' either every two weeks or every month, and that their ''prescriptions are not refilled unless they show up in person,'' and that these office visits ''will often cost them $150 or more.'' *Id.*

Reppy further asserted that he had ''rejected hundreds'' of ''patients'' because they ''cannot prove that they have the condition they claim'' or had submitted ''fraudulent records.'' *Id.* at 1117–18. Reppy also maintained that he never ''diagnose[d] over the phone'' because ''[t]hat would be inappropriate medicine,'' *id.* at 1123, that the initial diagnosis was performed by the ''local doctor that actually saw them and performed the physical examination,'' *id.*, and that the ''patients are required to submit documentation from their own local physicians, including radiology reports'' before he would conduct a consultation. *Id.* at 1124. Reppy also testified that there are certain conditions that are too complex to be ''appropriately * * * treated in a telemedicine format'' such as heart conditions and pancreatitis. *Id.* at 1125–26.

Reppy further testified that during his consultations he would ask his patients to subjectively rate their pain on a scale of one-to-ten, with the latter being ''the worst pain they can imagine.'' *Id.* at 1129–30. Reppy acknowledged, however, that this was ''not as useful as the evaluation of the pain you're getting from the'' notes of the doctor who examined the patients, ''but it's still useful because you're getting an idea of the patient's own perception of'' his pain level, and that it was useful to evaluate the evolution of a patient's ''pain over time.'' *Id.*

[4] According to Dr. Reppy's sworn statement, when he started working at University, his ''patients'' were referred to him by fedexmeds.com and this continued until he went on his leave of absence. GX 84, at 2–3. When, in March 2005, Reppy returned to University, fedexmeds was no longer referring ''patients'' to it. *Id.* at 3. Other websites were, however, and Reppy admitted that he continued to issue prescriptions based on medical records and a telephonic consultation. *Id.*

[5] In his testimony, Reppy denied knowing Furlong. Tr. 1207–08.

[6] Reppy was called by Respondent.

Reppy also stated that ''[i]t's always preferable to see * * * the patient face to face,'' and that he ''strongly urge[s] the patient to make a visit to the office here in Florida.'' *Id.* at 1130. Reppy further testified that he took a medical history on every patient, that he was convinced that each patient had a medical complaint, that there was a logical connection between the prescription he wrote and the complaint, and that there was a valid doctor-patient relationship with every person he issued a prescription for. *Id.* at 1164–65; see also *id.* at 1152.

On cross-examination, Reppy admitted that since the year 2000, he has not held a medical license in any State other than Florida. *Id.* at 1166. Reppy also admitted that the medical records of his telemedicine patients were ''usually'' sent to him by his patients rather than by the physician who had examined them. *Id.* at 1170–71. Reppy also admitted that sometimes the records for the patients that were referred to him by fedexmeds.com were provided by the Web site. *Id.* at 1171.

Reppy admitted that ''less than five percent'' of his ''telemedicine patients'' went to Florida to obtain a physical exam from him. *Id.* at 1174. Reppy also acknowledged that he ''generally did not'' consult ''on a regular basis'' with the physicians who had performed the physical examinations of his telemedicine patients, and that he did so ''less than once a day'' and only when he ''had specific questions.'' *Id.* at 1175. Finally, Reppy stated that when his patient's refills ran out, he required a new physical exam before issuing a new prescription only if the physical exam was ''too dated.'' *Id.* at 1176. The Government did not, however, ask Reppy at what point a physical exam becomes too dated.

The record establishes that during the period between October 1, 2005, and January 31, 2006, Respondent filled 11,830 prescriptions issued by Dr. Reppy, which totaled 1,275,400 dosage units of both controlled and non-controlled drugs. GX 99, at 13–16. Approximately 1.058 million of these dosage units (83%) were for drugs containing hydrocodone. *Id.* at 15–16. During this period, Reppy also authorized prescriptions totaling 41,651 dosage units of alprazolam, a schedule IV controlled substance, and approximately 84,000 dosage units of other controlled substances. *Id.*

Moreover, during this period, Reppy's prescribing accounted for approximately seventy-one percent of the prescriptions filled by Respondent and seventy percent of the dosage units dispensed by it. *Id.* at 8–11. Moreover, only 1094 (approximately 9.2%) of Reppy's prescriptions were for Florida residents. *Id.* at 13–14.

Respondent's dispensing log for December 2005 establishes that Reppy issued numerous controlled-substance prescriptions to persons resident in States where he was not licensed to practice. *See* GX 101, Excerpt 18. My review of the log found that during this month alone, Reppy issued new controlled-substance prescriptions to residents of Tennessee (89 Rxs), California (65 Rxs), Illinois (32 Rxs), North Carolina (18 Rxs), and Louisiana (14 Rxs).

In addition, during December 2005, Reppy issued numerous controlled-substance prescriptions to persons resident in States which clearly require that the prescribing physician perform a physical exam of a patient except in limited situations not applicable here. These States include California, Tennessee, Louisiana, and Indiana (9 new Rxs).

I take official notice [7] of the following State statutes: Cal. Bus. & Prof. Code §§ 2052 [8] (unlicensed practice) & 2242.1(a) (internet prescribing); Cal. Health & Safety Code § 11352(a) (prohibiting furnishing a controlled substance ''unless upon the written prescription of a physician * * * licensed to practice in this state''); 225 Ill. Comp. Stat. Ann. § 60/3 (licensure requirement), § 60/3.5 (prohibiting unlicensed practice); § 60/49 (listing acts constituting holding oneself out to the public as a physician); § 60/49.5 (requiring persons engaged in telemedicine to hold Illinois license); N.C. Gen. Stat. § 90–18 (''prescribing medication by use of the Internet or a toll-free telephone number, shall be regarded as practicing medicine'' in the State).

I also take official notice of the following state administrative rules: 844 Ind. Admin. Code § 5–3–3 (''issuing a prescription, based solely on an on-line questionnaire or consultation is prohibited'') & *id.* § 5–4–1 (prohibiting the issuance of a controlled-substance prescription ''to a person who the physician has never personally physically examined and diagnosed'' except for ''in institutional settings, on-call situations, cross-coverage situations, and situations involving advanced practice nurses with prescriptive authority practicing in accordance with standard care arrangements''); Tenn. Comp. R. & Regs. 0880–2.14(7) (prerequisites to issuing prescriptions); [9] & *id.* 0880–2.16 (requiring telemedicine license).[10]

I also take official notice of the Louisiana State Board of Medical Examiner's Statement of Position on ''Internet/Telephonic Prescribing,'' which was issued on May 24, 2000. According to the Louisiana Board, ''it is unlawful for a physician to prescribe medication, treatment or a plan of care generally if the physician has not examined the patient and established a diagnostic basis for such therapy.'' *Id.* at 2. After discussing the acts which establish a doctor-patient relationship, the Board further stated that ''an online or telephonic evaluation by questionnaire for an individual that a physician has never seen is inadequate.'' *Id.* at 2–3. The Board also explained that ''[a]n individual who issues a prescription or orders medication for an individual who is a resident of or located in Louisiana, who does not possess a Louisiana medical license or other authorization to practice medicine in this state, is necessarily engaged in the unauthorized practice of

[7] In accordance with the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. § 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order, which shall commence with the mailing of the order.

[8] In *Hageseth* v. *Superior Court*, 59 Cal. Rptr.3d 385 (Ct. App. 2007), the California Court of Appeal upheld the State's jurisdiction to criminally prosecute an out-of-state physician who prescribed a drug to a California resident over the internet, for the unauthorized practice of medicine.

[9] The text of this rule is discussed shortly below.

[10] I also take official notice of the Medical Board of California's Decision and Order in Jon Steven Opsahl, M.D., at 3 (Med. Bd. Cal. 2003) (revoking medical license and finding 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'' and that ''[a] physician cannot determine whether there is a medical indication for prescription of a dangerous drug without performing a physical examination''); *see also id.* at 17.

In addition, the Medical Board of California has issued numerous Citation Orders to out-of-state physicians for internet prescribing to State residents. *See*, e.g., Citation Order Harry Hoff (June 17, 2003); Citation Order Carlos Gustavo Levy (Nov. 30, 2001). It has also issued press releases announcing its position on the issuance of prescriptions by physicians who do not hold a California license. *See* Medical Board of California, Record Fines Issued by Medical Board to Physicians in Internet Prescribing Cases (News Release Feb. 10, 2003) (available at *http://www.mbc.ca.gov/NR_2003_02–10_Internetdrugs.htm*). I also take official notice of these materials.

medicine in contravention of the Medical Practice Act.'' *Id.* at 3.[11]

In addition to the prescriptions issued by Reppy, Respondent also filled numerous prescriptions issued by physicians who were affiliated with phoneconsultation.com. These physicians included Dr. Dora Fernandez, who was located in, and licensed by, the Commonwealth of Puerto Rico, *see* GX 58 at 3, 7, 16; and George Wallace Merkle, who was located in, and licensed by the State of Indiana. *See* GX at 64, at 5, 9–10. Neither of the files which Respondent kept on these two physicians contains any additional medical licenses. *See generally* GX 58 & 64. Moreover, Respondent produced no evidence to show that either of these physicians had additional medical licenses beyond those contained in their files. I therefore find that Dr. Fernandez was licensed only in Puerto Rico and Dr. Merkle was licensed only in Indiana.

According to the December 2005 Daily Audit Log, in just the last twelve days of the month, Dr. Fernandez issued new controlled-substance prescriptions to residents of various States where she was not licensed including Tennessee (35 Rxs), California (29 Rxs), Louisiana (26 Rxs), Illinois (9 Rxs), and North Carolina (8 Rxs). Dr. Fernandez violated the laws of these States by engaging in the unlicensed practice of medicine. Moreover, in light of the respective locations of Dr. Fernandez and her ''patients,'' it is most unlikely that she complied with the laws of Tennessee, California, Louisiana, and Indiana (8 new Rxs) regarding the prerequisites for prescribing a drug.

During December 2005, Respondent also filled new controlled-substance prescriptions issued by Dr. Merkle to residents of States where he was not licensed including California (17 Rxs), North Carolina (9 Rxs), and Louisiana (2 Rxs). Likewise, given the respective locations of Dr. Merkle (in Indiana) and his ''patients,'' it is highly improbable that he complied with either the regulations of his own State or the laws of California and Louisiana which require the performance of a physical examination before prescribing a drug.

Finally, Respondent also filled numerous controlled substances prescriptions issued by Dr. Elizabeth Jamieson, another Tampa-based physician, who is licensed only in Florida and Pennsylvania. *See* GX 63, at 3. During December 2005, Dr. Jamieson issued new controlled-substance prescriptions to residents of Tennessee (31 Rxs), California (23 Rxs), Illinois (6 Rxs), Louisiana (5 Rxs), and North Carolina (5 Rxs).[12]

The patient files also establish that Respondent filled numerous prescriptions issued by Dr. Wayne Starks of Detroit, Michigan, who was affiliated with ermeds.com. GX 101 (Excerpt 8, at 9998). While Dr. Starks held a DEA Registration, it expired on February 28, 2003, and Starks did not submit a new application until August 23, 2004, which he withdrew on March 21, 2005.[13] *See* GX 103; *see also* GX 93, at 12 (Stark's file maintained by Respondent). Starks was therefore without authority to prescribe controlled substances after February 28, 2003. GX 103.

The patient file for J.I., a resident of Alabama, indicates that Starks issued him prescriptions for 120 Lortab (10 mg.), a schedule III controlled substance containing hydrocodone and acetaminophen on January 9, 2004 (with two refills), April 16, 2004 (with two refills), June 24, 2004 (with no refills) and September 22, 2004 (with two refills). GX 101 (Excerpt 8, at 9997–99, 10008). Respondent filled each of these prescriptions including the refills. *See id.*

The patient file of K.Q., a resident of Texas, includes numerous prescriptions which Starks issued for Xanax (alprazolam) and Norco (hydrocodone/acetaminophen) after the expiration of his DEA registration and which Respondent filled. *See* GX 101 (Excerpt 9). More specifically, Starks issued K.Q. prescriptions for these drugs with refills on July 29, 2003; October 14, 2003; December 31, 2003; March 16, 2004; May 25, 2004; August 12, 2004; and October 27, 2004.[14] *See id.* at 3877, 3885, 3895, 3905, 3907, 3912, 3914, 3917, 3921, 3923, 3928, 3930. Respondent filled each of the new prescriptions and refilled these prescriptions numerous times.

The patient files also indicate that Respondent filled prescriptions issued by Dr. Richard Kienzle of Copperhill, Tennessee, a Tennessee-licensed physician. *See* GX 101 (Excerpts 6, 7, & 14); GX 60, at 2. More specifically, Kienzle issued T.H., a California resident, prescriptions for 90 Norco (10/325) with two refills on January 25, 2003; April 22, 2003; July 10, 2003; October 1, 2003; and 120 Norco on December 19, 2003. GX 101 (Excerpt 6 at 9744, 9738, 9732, 9726, & 9720). Respondent filled all of the prescriptions including the refills. *See generally id.* at 9720–44.

Respondent also filled several Vicodin prescriptions Kienzle issued to K.H., a Pennsylvania resident. Specifically, on December 7, 2003, and March 1, 2004, Kienzle prescribed 120 Vicodin ES (hydrocodone/apap 7.5/750) with two refills.[15] *Id.* (Excerpt 7, at 9585 & 9579), Respondent filled both the initial prescriptions and the refills. *See id.* On November 18, 2003, Kienzle issued to R.J., another Pennsylvania resident, prescriptions for 120 Norco (10/325) with two refills, and on February 2, 2004, a prescription for 120 Lortab (10/500) with two refills. *Id.* (Excerpt 14 at 4731, 4736). Respondent filled both the initial prescriptions and the refills. *Id.* The patient file also includes copies of documents entitled ''Fedxmeds Management Index,'' which were faxed to Respondent by Kienzle. *Id.* at 4674–75.

On July 20, 2005, pursuant to an Agreed Order with the Tennessee Board of Medical Examiners, Kienzle agreed to surrender his medical license. *See* GX 60, at 29. Kienzle also admitted that he had prescribed through several internet sites including FedexMeds.com, numerous dosage units of various controlled substances including compounds containing hydrocodone and codeine, as well as alprazolam, diazepam, and lorazepam and other scheduled drugs, to persons located in forty-six different States. *Id.* at 20. The Order also related that Kienzle had ''admitted in correspondence to treating

[11] The Board recognized that ''prescribing for a patient whom the physician has not personally examined may be suitable under certain, limited circumstances.'' Internet/Telephonic Prescribing, at 3 n. 7. According to the Board, these ''may include admission orders for a newly hospitalized patient, prescribing for a patient of another physician for whom the prescriber is taking the call or continuing medication on a short-term basis for a new patient prior to the patient's first appointment.'' *Id.* The Board also explained that it was not ''attempt[ing] * * * to limit true consultations between out-of-state physicians and Louisiana licensed physicians.'' *Id.* at 4. None of these exceptions applies to the conduct of the prescribing physicians in this case.

[12] A review of Respondent's January 2006 daily audit log shows that Reppy issued new controlled-substance prescriptions to residents of Tennessee (121 Rxs), California (72 Rxs), Illinois (30 Rxs), North Carolina (16 Rxs), Louisiana (15 Rxs), and Indiana (10 Rxs). Dr. Fernandez issued new controlled-substance prescriptions to residents of California (23 Rxs), Tennessee (22 Rxs), Louisiana (6 Rxs), North Carolina (5 Rxs), Illinois (5 Rxs), and Indiana (3 Rxs). Dr. Merkle issued new controlled-substance prescriptions to residents of California (43 Rxs), Louisiana (10 Rxs), Tennessee (9 Rxs), and North Carolina (6 Rxs).

[13] Starks has also submitted two additional applications, which are currently under review. GX 103.

[14] The Norco prescriptions were for 120 Norco 10/325 (hydrocodone/acetaminophen); the Xanax (alprazolam) prescriptions were either for 45 (2 mg.) tablets or 30 (1 mg.) tablets.

[15] The record also includes copies of a document entitled ''Fedxmeds Management Index'' for K.H., which indicate that they were faxed to Respondent from Dr. Kienzle on December 7, 2003, and February 3, 2004. GX 101 (Excerpt 7, at 9530–31).

via the internet or other electronic means, approximately one thousand eighty four (1,084) patients by and through his affiliation with'' two websites which included FedexMeds.Com. *Id.* at 20–21. Kienzle also admitted that ''as a matter of routine course, [he] utilized 'telephone consultations' conducted in reliance on data derived from the * * * FedexMeds.com internet database[ ], to speak with patients whose credibility and authenticity he could not verify, and whose symptoms he could not evaluate through tactile examination, visual observation, or through other means of clinical evaluation required by the standard of care.'' *Id.* at 23.

Kienzle further admitted that his internet prescribing violated various provisions of the Tennessee Medical Examiners Practice Act, including prohibitions on unprofessional conduct and dispensing controlled substances in violation of State or Federal law. *Id.* at 24–28. Most significantly, Kienzle admitted that his internet prescribing violated the Board's Rule 0880–2–.14(7), which sets forth the ''prerequisites to issuing prescriptions or dispensing medications in person, electronically, and over the internet.'' *Id.* at 27. This provision states that it is ''a prima facie violation'' of the State's Medical Practice Act:

> for a physician to prescribe or dispense any drug to any individual, whether in person or by electronic means or over the internet or over telephone lines, unless the physician, or his/her licensed supervisee pursuant to appropriate protocols or medical orders, has first done and appropriately documented, for the person to whom a prescription is to be issued or drugs dispensed * * * an appropriate history and physical examination[.] [16]

GX 60, at 27 (quoting Tenn. Comp. R. & Regs. 0880–2–.14(7)).

The Government also introduced evidence showing that Respondent was engaged in the compounding of large quantities of controlled substances. More specifically, Respondent was purchasing hydrocodone bitartrate powder and compounding it with either acetaminophen or dextromethorpan hydrobromide in various combinations. *See* GX 37 (invoices for hydrocodone bitartrate powder); *see also* GX 36 (compounding log). Moreover, Respondent was also compounding a formulation of phentermine and lorazepam (both schedule IV controlled substances, *see* 21 CFR 1308.14). GX 36, at 16. The run size of the compoundings was 7500 capsules. *See generally* GX 36.

In another proceeding, Mr. Decker, Respondent's pharmacist-in-charge, testified that approximately one-third of the drugs it dispensed were compounded. *See* Resp. 25, at 177. Mr. Decker also testified that Respondent never had on hand ''more than 15 days'' supply of compounded drugs. *Id.* at 178. Mr. Decker further stated in an affidavit that the drugs were ''compounded only to the extent that they are prescribed by the physician, and to fulfill remaining refills as indicated on the original prescription.'' GX 70, at 1. Respondent is registered as a retail pharmacy and not as a manufacturer. *See* GX 1.

The record further establishes that Respondent violated Kentucky law by failing to report its dispensing of controlled substances to Kentucky residents through the State's electronic monitoring system (KASPER). *See* GX 85 (affidavit of Jennifer Shearer, Agent Manager, Kentucky Bureau of Investigation (KBI) (citing KRS §§ 218A.202 & 315.0351)). More specifically, Agent Shearer recounted that on June 1, 2006, a KBI agent received information from the United Parcel Service that it was ''shipping 'a lot' of packages'' that came from Respondent. GX 85, at 1. Upon receiving this information, Agent Shearer contacted the Inspector General's office of the Kentucky Cabinet of Health Services and determined that Respondent had not filed its KASPER reports since April 2005. *Id.*

On June 9, 2006, KBI agents obtained a search warrant ''for any and all packages being shipped by [Respondent] by [UPS] from June 5, 2006–June 9, 2006.'' *Id.* The agents subsequently seized fifty-four bottles of prescription drugs which included the controlled substances alprazolam, diazepam, clonazepam and hydrocodone. *Id.* On the same date, Agent Shearer was contacted by an employee of Respondent who wanted to know why its shipments had been seized. *Id.* Agent Shearer told the employee that the packages had been seized because Respondent ''had not been reporting to KASPER.'' *Id.* Agent Shearer also advised Respondent's employee that the prescriptions it was dispensing were illegal because ''none of the Kentucky residents * * * had ever seen'' the prescribing physician and ''there was no physician/patient relationship.'' *Id.* Agent Shearer then told the employee that Respondent must stop shipping to Kentucky residents until it complied with the State's law.[17]

Thereafter, KBI agents received information that Respondent had begun shipping prescription drugs under the name of ''Makes and Models Magazine,'' another business owned by Ballinger. *Id.* at 2; *see also* GX 84, at 5; GX 87 at 5. Accordingly, on June 16, 2006, KBI agents obtained another search warrant ''for any and all packages being shipped by [Respondent] and Makes and Models Magazine by [UPS] from June 9, 2006–June 16, 2006.'' GX 85, at 2. Upon executing the warrant, KBI agents seized twelve bottles of drugs which contained alprazolam, diazepam, and hydrocodone. *Id.* Makes and Models Magazine is not licensed as an out-of-state pharmacy under Kentucky law. *Id.*

In another proceeding, Mr. Decker (Respondent's Pharmacist-in-Charge) testified that Respondent had shipped under the ''Makes and Models'' name based on the suggestion of its UPS account representative. Resp. Ex. 25, at 171. In this testimony, Decker claimed that Respondent's personnel thought that the packages had been stolen and were unaware that they had been seized by the KBI. *Id.* at 174. Decker admitted, however, that Respondent did not report the purported thefts to either DEA or the KBI. *Id.* at 174–75; *see also* 21 CFR 1301.76(b) (requiring reporting of a theft of controlled substances).

Based on Respondent's failure to report the purported thefts and Agent Shearer's statement that on June 9, 2006 (the date the first warrant was executed), she was contacted by an employee of Respondent who wanted to know why the packages had been seized, I reject Respondent's claim that the reason it shipped controlled substances under the ''Makes and Models'' label was to prevent them from being stolen. *See* Resp. Proposed Findings at 21. Instead, I find that Respondent knew that the packages had

[16] The rule also requires that the physician has ''[m]ade a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good medical care,'' ''[f]ormulated a therapeutic plan and discussed it, along with the basis for it,'' and ''[i]nsured availability of the physician or coverage for the patient for appropriate follow-up care.'' GX 60, at 28.

[17] In similar vein, the record also contains a copy of various documents of the Wyoming Board of Pharmacy. *See* GX 41, at 1. These include a March 31, 2005 letter to Respondent notifying it that the Board had become aware that it had dispensed a prescription issued by Dr. Reppy to a Wyoming resident and expressing that the Board had ''strong reasons to believe that no doctor/patient relationship has been established between [the resident] and the prescribing physician * * * other than via the internet,'' and that ''[a] prescription * * * dispensed based solely on a web-based questionnaire without establishing a valid doctor/patient relationship is considered to be a violation of the Wyoming Pharmacy Act.'' *Id.* The letter further requested that Respondent ''cease dispensing to Wyoming residents immediately.'' *Id.* The record also includes a copy of an April 8, 2005 letter from the Wyoming Board to the Florida Department of Health filing a complaint against Respondent for its dispensing to this resident. *Id.* at 12.

been seized by the KBI and that it used the ''Makes and Models'' label to circumvent Kentucky law.

The record also includes files that Respondent maintained on the various prescribing physicians. The files typically include copies of each physician's state license and DEA registration. *See generally* GXs 55–65. Most of the files also include a copy of an affidavit and/or letter in which the physician was required to state that ''any prescription sent to [Respondent] will be for a legitimate medical purpose within the usual course of professional practice and based on [a] legitimate patient-physician relationship.'' *See, e.g.*, GX 56, at 74 (Reppy).

These affidavits and/or letters also required the physicians to state that their practice had policies and procedures in place to satisfy the following criteria:

> Our records include a positive identification of the patient.
>
> The patient's medical complaint has been verified.
>
> The patient's chart includes copies of prior medical records.
>
> An extensive physician interview and consultation has been accomplished.
>
> That if an in-person examination was not possible that we have supervised and directed an examination by a consulting medical professional, for which a copy is in the patient file.
>
> That in review of all of the above criteria contained in our medical file we have determined the appropriateness of medications and have issued a prescription based upon our patient/physician relationship.

Id.

The Expert Testimony

The Government called as an expert witness, Carmen Catizone, Executive Director, National Association of Boards of Pharmacy. GX 81. Mr. Catizone is a registered pharmacist in Illinois and holds a Bachelor of Science degree in pharmacy and a Master of Science degree in pharmacy administration and has worked as a pharmacist and as a pharmacist-in-charge. *Id.* at 2–5. Mr. Catizone also holds an honorary Doctor of Pharmacy license from the Oklahoma State Board of Pharmacy. *Id.* Mr. Catizone has been qualified as an expert in administrative proceedings in all States except Alaska and has previously been qualified as an expert in the United States District Court for the District of Minnesota and in other DEA proceedings. Tr. 313. The Government offered Mr. Catizone ''as an expert witness in pharmacy practice, pharmacy regulation, pharmacy legislation and internet pharmacy practices.'' *Id.*

Mr. Catizone testified that under ''all state pharmacy practice acts,'' a ''pharmacist is responsible to ensure that the prescription is valid, has been written within the scope of practice for that prescriber, [that] the prescriber is appropriately licensed[,] and that [the] prescription is valid for [the] patient's disease, symptoms or conditions.'' *Id.* at 323. Mr. Catizone also testified that for a prescription to be valid under federal and state laws, it must be based on ''a bona fide relationship between the prescriber and the patient.'' *Id.* at 322.

Mr. Catizone also reviewed Respondent's daily audit logs for the periods March 30–31, 2005, and November 9 through December 9, 2006 (GXs 18 & 39). Based on his review, Mr. Catizone opined that the prescriptions showed ''disturbing patterns.'' Tr. 333. Most significantly, Mr. Catizone observed that ''the overwhelming majority of prescriptions [were] written by one physician, and that physician is located in [a] different state[] than all of the patients.'' *Id.* Moreover, ''the overwhelming prescription drug written for is hydrocodone, which you do not see that volume or that selectivity in any other retail pharmacy that I'm aware of.'' [18] *Id.*

Mr. Catizone testified that he had not seen a dispensing mix like Respondent's ''except for internet pharmacies that we've studied in the past that have been involved in illegal activities involving controlled substances.'' *Id.* at 334. Mr. Catizone further testified that he had ''not seen these types of prescribing patterns for physicians unless they were pain medication specialists * * * except in instances where we've looked at internet pharmacies that were operating illegally and prescribing controlled substances illegally.'' *Id.* at 335.

Finally, Mr. Catizone testified that based on the dispensing records, Respondent had not met its corresponding responsibility to ensure that the prescriptions it filled had been issued in the usual course of professional practice. *Id.* at 343–44. Moreover, based on his review of the dispensing records and the fact that Reppy was licensed only in Florida, Mr. Catizone further testified that Respondent had not fulfilled its responsibility to ensure that that there was sufficient evidence of a legitimate doctor-patient relationship before filling Dr. Reppy's prescriptions. *Id.* at 344.

On cross-examination, Mr. Catizone explained that he formed his opinion solely on the basis of the dispensing records and had not done any further investigation to determine whether Reppy's prescriptions were issued pursuant to a legitimate doctor-patient relationship or whether Reppy treated chronic pain patients. *Id.* at 352–53. Mr. Catizone also testified he had not done any similar investigation with respect to the other doctors whose prescriptions were filled by Respondent. *Id.* at 353–54. Mr. Catizone further stated that his opinion was based strictly on ''the numbers and the prescribing patterns and the location of the patients.'' *Id.* at 355.

Mr. Catizone agreed that under federal and state laws it is not ''a necessary prerequisite to the issuance of a prescription that the prescriber be the person who conducted the physical examination.'' *Id.* at 355–56; *see also id.* at 359–61. He further asserted, however, that ''[t]he federal requirement is that there's a bona fide relationship. And if that relationship can be established as a referral from another prescriber or physician that's made that examination,'' then the prescriber does not have to have performed the physical examination. *Id.* at 356. Clarifying his testimony, Mr. Catizone asserted that there had to be a relationship between the examining physician and the prescriber, ''as well as between the patient and the initial physician who has performed the medical examination. If care is shifted to the other physician, then that physician also has to have a relationship with that patient to ongoingly prescribe medications.'' *Id.* at 357.

Relatedly, Mr. Catizone acknowledged that under Florida law, a physician may issue a prescription even though he did not physically examine the patient. *Id.* at 359. Mr. Catizone then testified that if one physician ordered a diagnostic test and the results of those tests were sent to another practitioner for review and that practitioner took a medical history and talked to the patient, the practitioner could then issue a prescription. *Id.* at 361.

On further cross-examination, Mr. Catizone was shown Government Exhibit 86 which memorialized several interviews conducted by a Diversion Investigator of Dr. Reppy's patients. In some instances, these persons told the DI that they had been required to obtain a physical exam from another physician or that they had at some point been physically examined by Reppy. GX 86 at 2, 10, & 12. Others, however, told the investigator that they had not been seen by Reppy and had not been required to obtain a physical exam. *Id.* at 4, 6–9. While Mr. Catizone acknowledged that it was ''important to have the entire picture,'' he also noted that in some instances the ''patients'' could not even recall the prescribing physician's name.

Tr. 366; *see also* GX 86 at 3, 7 & 8. Mr. Catizone then added that this exhibit ''substantiate[d] my contention * * * that the practices were not legal and not meeting the standards of care.'' Tr. 367.

Finally, Respondent's counsel asked Mr. Catizone whether his conclusion that Respondent had dispensed invalid prescriptions would be altered by the fact that Respondent had verified that the prescriber was licensed and had a DEA registration, that ''there had been direct communication between the patient and the physician,'' and that it had obtained ''an affidavit from the physician attesting to the existence of a physician/patient relationship.'' *Id.* at 371–72. Mr. Catizone testified that these facts would not lead him to change his testimony ''unless [it] was documented for every single patient.'' *Id.* at 372.

Respondent excepted to the testimony of Mr. Catizone, asserting that he ''is not competent to offer any expert opinion, much less an opinion on the requirements of a valid doctor-patient relationship.'' Resp. Exceptions at 4. Respondent asserts that Mr. Catizone is ''little more than a fraud'' because he ''refers to himself as 'Dr. Catizone''' when ''he has never earned a doctorate degree nor even been conveyed with an honorary one from an academic institution,'' but rather, holds an ''honorary title'' granted by the Oklahoma Board of Pharmacy. *Id.* at 4–5.

The short answer to Respondent's contention is that whether Mr. Catizone can properly call himself Dr. Catizone is irrelevant because what matters are his qualifications to testify as an expert. And contrary to Respondent's contention, a witness can be qualified as an expert by virtue of his skill, training, knowledge, education or experience. *Cf.* F.R.E. 702. Accordingly, Mr. Catizone's lack of a degree at the doctoral level does not disqualify him from testifying as an expert. Nor does the fact that he ''has not worked in a clinical pharmacy setting since 1995.'' Resp. Exceptions at 5. Mr. Catizone's expertise in pharmacy practice is amply established by his prior work as a practicing pharmacist, his professional experience as the Executive Director of the National Association of Boards of Pharmacy, and his extensive writings. I therefore find that Mr. Catizone was competent to testify as to the scope of a pharmacist's obligations under Federal law and the pharmacy practice acts of the various States.

Respondent also excepted to Mr. Catizone's testimony on the ground that there is no evidence that he has ''received any medical training or has ever been involved in patient care in any form which would provide him a basis to opine on the requirements of a doctor-patient relationship.'' *Id.* Relatedly, Respondent argues that the Government has not shown ''that Mr. Catizone has received any legal training which would qualify him to interpret uncited, yet apparently relied upon, court cases regarding same.'' *Id.*

I need not resolve this issue because I decline to adopt the ALJ's reasoning as to why the prescriptions written by Dr. Reppy and the other physicians were not based on valid doctor-patient relationships. The States have the primary responsibility for regulating the practice of medicine. I therefore conclude that the appropriate course in determining whether Dr. Reppy and the other physicians prescribed pursuant to valid doctor-patient relationships is to examine the specific legal authorities of the various States.[19]

The Government also introduced the declaration of George Van Komen, M.D., the former President of the Federation of State Medical Boards (FSMB), as well as Dr. Van Komen's testimony in *In re Trinity Health Care Corp.,* 72 FR 30849 (2007). *See* GXs 78 & 83. In his written declaration, Dr. Komen explained the standard for establishing a legitimate doctor-patient relationship under the FSMB's guidelines:

> The standard in terms of forming a legitimate doctor-patient relationship is that there needs to be a documented face-to-face history and physical * * * evaluation of the patient, and then if this patient chooses to receive further consultative work or be established with a physician who practices on the Internet, that the Internet physician first of all and most importantly needs to be identified, and he needs to have a license in the state in which the patient resides.
>
> * * * * *
>
> And we also feel that [the] primary care doctor who did the history and physical needs to stay in touch with the patient, even though the patient might be seeking further consultation from another physician through the Internet.

GX 78, at 14–15.[20]

In *Trinity Healthcare,* Dr. Van Komen testified, however, that ''under certain circumstances,'' a physician can write a lawful prescription without ever meeting the patient. GX 83 (Tr. 608). Besides the situation where a physician is covering for another physician, Dr. Van Komen explained that under the FSMB guidelines, ''there are physicians who have internet practices, and they are provided information from the physician who the patient had previously seen. And they provide them with information through a request of the patient's medical records, and the patient themselves usually do not provide those medical records.'' *Id.* Continuing, Dr. Van Komen explained: ''[s]o there [are] no alternate medical records by the patients themselves and then the physician who has an internet practice uses that history and physical from what I call the primary care physician with whom the patient has had face-to-face contact.'' *Id.* at 609.

Dr. Van Komen's testimony raises a strong suspicion that Reppy's prescriptions were not issued pursuant to a valid doctor-patient relationship. But neither Dr. Van Komen's declaration nor his *Trinity Health Care* testimony addressed whether the laws of Florida (where Dr. Reppy was located) or any other State where the prescribers or the patients were located, prohibit a physician from prescribing because he received the medical records from the patients themselves. [21]

Respondent also put on an expert witness, Dr. Thomas E. Johns. Dr. Johns holds a Doctor of Pharmacy degree and serves as the Assistant Director, Clinical Pharmacy Services, Department of Pharmacy, Shands at the University of Florida, a teaching hospital which is affiliated with the University of Florida. RX 28, Tr. 1256. Dr. Johns also teaches at the University of Florida College of Pharmacy as an adjunct faculty member. Tr. 1256. Dr. Johns has responsibilities related to the institution's compliance

[19] This is not to say that Mr. Catizone is not competent to testify in this area. A pharmacist has a ''corresponding responsibility'' to ascertain whether a prescription 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). Determining whether a physician has acted in accordance with this standard necessarily requires that the pharmacist have knowledge of the applicable State's law. *See United States* v. *Smith,* 2006 WL 3702656 (D. Minn 2006).

[20] In his written declaration, Dr. Van Komen further explained that ''[t]here is no way to detect abuse or monitor the appropriate treatment or care of a patient by reviewing an online questionnaire, because a doctor has no way of knowing that the person that filled out that questionnaire filled it out honestly. If I had to describe a drug addict by using one word, the word I would use is 'dishonest.''' GX 78, at 17. Dr. Van Komen did not, however, address the legitimacy of prescribing using the methods employed by Dr. Reppy.

[21] Dr. Van Komen's testimony also does not establish at what point a physical exam becomes too dated to be relied upon. Finally, while Dr. Van Komen also testified in Trinity Healthcare that ''[t]here is absolutely no way that you can continue to prescribe controlled substances without a review of how the patient is doing[,] [a]nd that cannot be evaluated without a face-to-face confrontation,'' GX 83 (Tr. 579), his testimony did not specify at what point this encounter must occur. I therefore do not make any findings as to whether Reppy issued unlawful prescriptions because he relied on physical examinations which were too dated or continued to prescribe without requiring an in-person follow-up examination.

with applicable pharmacy laws and regulations.[22] *Id.* 1260–61.

On direct examination, Dr. Johns asserted that both the Agency's 2001 guidance document on dispensing controlled substances over the internet [23] and the Pharmacist's Manual were unclear regarding the scope of a pharmacist's corresponding responsibility under 21 CFR 1306.04(a). Tr. 1273. Dr. Johns testified that if a prescription creates a suspicion that it has been issued ''for an illegitimate purpose or that the [doctor-patient] relationship is not valid,'' then the pharmacist should call the doctor. *Id.* at 1275. Dr. Johns further asserted that if the physician affirms that there ''is a valid doctor/patient relationship,'' then ''no further action is really needed or warranted on the part of the pharmacist.'' *Id.* Dr. Johns also testified that the DEA Pharmacist Manual states that the ''frequency and volume [of prescriptions] in and of itself is not indicative of fraud or abuse.'' *Id.* at 1277; *see also id.* at 1278.[24]

Dr. Johns further testified that in his experience, it is not ''the usual and customary practice in the distributive pharmacy setting to verify the existence of a doctor/patient relationship before filling a prescription.'' *Id.* at 1280 (quoting question of Respondent's counsel). Dr. Johns also testified that it is not ''the usual and customary practice'' in the distributive pharmacy setting to verify the prescriber's medical license and DEA registration. *Id.* Finally, Dr. Johns testified that it is not the responsibility of a pharmacist to ''second guess'' a prescribing practitioner's diagnosis. *Id.*

On cross-examination, Dr. Johns admitted that in preparing for his testimony, he was only ''actually shown the first or second page of a prescription log'' and nothing ''other than that.'' *Id.* at 1286; *see also id.* at 1289. Dr. Johns further admitted that he had never been in a pharmacy which asked physicians to send in the medical records of its customers as Respondent did. *Id.* at 1286–87; *see also* GXs 29 & 30 (patient files). Dr. Johns further stated that he could not think of a reason why a retail pharmacy would require a physician to send in a customer's medical records. Tr. 1286–87.

Dr. Johns further testified that he had never visited Respondent, id. at 1289, and that his knowledge regarding Respondent's actual operations was based on the Show Cause Order and a document ''which described [its] business model.'' *Id.* at 1290. Dr. Johns also acknowledged that volume in combination with other factors could raise a suspicion that a particular physician's prescriptions were not legitimate. *Id.* at 1292. Dr. Johns then admitted that ''it could'' create a suspicion if a physician was located in Puerto Rico and issuing eighty new prescriptions a day to persons who were not located in Puerto Rico. *Id.* at 1293. He also acknowledged that ''if the pharmacist knew that patients were being solicited over the internet [it] would certainly raise a red flag to that pharmacist that there could be an invalid doctor/patient relationship.'' *Id.*

Relatedly, Dr. Johns testified that if a prescription indicated that it was faxed from a website, it would make him ''curious'' as to what the website was engaged in, *id.* at 1311, and that it would create a suspicion that the drugs would be diverted. *Id.* at 1317. Dr. Johns also admitted that it is not the usual course of practice for a pharmacy to solicit physicians to send their prescriptions to it and that it is inappropriate for a pharmacy to do so. *Id.* at 1296–98.

Dr. Johns maintained, however, that it was ''probably'' not inappropriate to fill a prescription for controlled substances issued by a practitioner whose DEA registration had expired even if the pharmacy had a copy of the expired registration on file. *Id.* at 1300. Subsequently, Dr. Johns admitted that while a pharmacist is not required to ''proactively * * * determine whether the physician has [a] valid DEA number,'' if ''something raises a suspicion of irregularity, then perhaps a more thorough investigation'' is required. *Id.* at 1301.

The Government then asked whether it would be suspicious ''if a physician was practicing medicine in a jurisdiction where [he wasn't] licensed?'' Dr. Johns answered: ''If [he] knew that [he wasn't] licensed in that jurisdiction.'' *Id.* at 1302. Dr. Johns then admitted that a pharmacy must know not only a State's law regarding pharmacy practice, but also the law of the State where the dispensing is occurring regarding the requirements for a lawful prescription. *Id.* Relatedly, Dr. Johns testified that a pharmacy has ''a professional obligation to know the law.'' *Id.* at 1303. Finally, Dr. Johns testified that if he ''knew that [a] physician was away from his practice and prescriptions were being issued under his name, [he] would be suspicious.'' *Id.* at 1320.

Discussion

Section 304(a) of the Controlled Substance 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). Section 304(d) further provides that ''[t]he Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety.'' 21 U.S.C. 824(d).

In determining the public interest, the CSA 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.* § 823(f).

''[T]hese factors are * * * considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[ ] appropriate in determining whether a registration should be revoked.'' *Id.* Moreover, case law establishes that I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall v. DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

In this case, I conclude that factors two and four are dispositive and establish that Respondent's continued registration would ''be inconsistent with the public interest.'' 21 U.S.C. 823(f). I also find unpersuasive Respondent's contention that it is attempting to comply with the law. Accordingly,

[22] As is the case with Mr. Catizone, Dr. Johns does not actively engage in the actual dispensing of prescription drugs. Tr. 1271.

[23] *See* DEA, Dispensing and Purchasing Controlled Substances over the Internet, 66 FR 21181 (2001). The guidance document is included in the record as GX 6.

[24] Dr. Johns also addressed the allegation that Respondent should not have filled prescriptions that lacked the patient's address. Tr. at 1279. Dr. Johns testified that while there are certain items of information that appear on a prescription which a pharmacist ''cannot change'' even in consultation with the physician, ''the pharmacist is authorized to fill in the patient's address if it's not on the prescription.'' *Id.* DEA's regulations are, however, to the contrary. *See* 21 CFR 1306.05(a).

Respondent's registration will be revoked and its pending application for renewal of 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

Under DEA's 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 law relating to controlled substances.'' *Id.*

DEA has interpreted the 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 Health Care Corp.,* 72 FR 30849, 30854 (2007) (quoting *Medic-Aid Pharmacy,* 55 FR 30043, 30044 (1990)); *see also 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). This 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).

As the ALJ recognized, one of the primary issues in this case is whether the prescriptions Respondent filled were issued by physicians pursuant to valid doctor-patient relationships. Reasoning that ''[t]here is no evidence * * * that any physicians who had examined Respondent's customers had referred them to the physicians who prescribed to them and sent the prescriptions to Respondent to be filled,'' the ALJ concluded that ''there was no physician-patient relationship between Dr. Reppy—or any of the other physicians * * * who issued prescriptions that Respondent filled'' and its customers. ALJ at 66. The ALJ thus held that the prescriptions were not issued pursuant to valid doctor-patient relationships. *Id.*

The ALJ did not, however, cite any legal authority for this holding. Instead, the ALJ apparently based her holding on Mr. Catizone's testimony that ''if the prescriber has not performed the physical examination, then there must be some relationship between the person who did conduct the examination and the physician who issues the prescription.'' *Id.* at 65.

Mr. Catizone's testimony was not supported by reference to the laws, regulations, or decisions (either judicial or administrative) of any particular State. While Mr. Catizone's testimony appears to be consistent with the guidance of the American Medical Association, *see* GX 3, at 5; the AMA's statement does not have the force and effect of law absent its adoption by competent state authorities. Moreover, this Agency has not promulgated such a rule through either notice-and-comment rulemaking or adjudication.

That there is no Federal standard requiring a referral or consultative arrangement between the examining and prescribing physicians does not mean that the prescriptions issued by Dr. Reppy and the other physicians were lawful under Federal law. As the 2001 Guidance Document explained, the CSA looks to state law in determining whether a physician has established a valid doctor-patient relationship. *See* 66 FR at 21182–83. Moreover, the CSA also requires that a physician be acting ''in the usual course of * * * professional practice'' in order to issue a lawful prescription. 21 CFR 1306.04(a). Finally, as noted above, the public interest inquiry mandates that a registrant's compliance with applicable state laws be considered. 21 U.S.C. 823(f)(4).

As found above, in December 2005, Respondent filled numerous prescriptions issued by prescribers who were engaged in the practice of medicine without the required state licenses in violation of various state laws. For example, even though Dr. Reppy was licensed only in Florida, he issued new controlled-substance prescriptions to residents of California, Tennessee, Illinois, North Carolina, and Louisiana. Both Dr. Fernandez (who was licensed only in Puerto Rico) and Dr. Jamieson (who was licensed only in Florida and Pennsylvania) also issued new controlled-substance prescriptions to residents of these same States. Finally, Dr. Merkle, who was licensed only in Indiana, issued new controlled substance prescriptions to residents of California, North Carolina, and Louisiana.

A physician who engages in the unauthorized practice of medicine is not a ''practitioner acting in the usual course of * * * professional practice.'' 21 CFR 1306.04(a). Under the CSA, the ''[t]he 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.''). As the Supreme Court has explained: ''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.'' *United States* v. *Moore,* 423 U.S. 122, 140–41 (1975) (emphasis added). 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[.]'').

Respondent had ample reason to know that these prescriptions were unlawful under both Federal and state law. 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). Moreover, as Respondent's expert admitted, 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. *See* Tr. at 1302.

While this allegation was included in the Show Cause Order and litigated, *see* ALJ Ex. 1, at 3; in its brief, Respondent largely sweeps it under the rug.[25] *See*

[25] In its proposed findings, Respondent asserts that ''there is a conflict in California law'' regarding

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Resp. Prop. Findings at 22. I find, however, that Drs. Reppy, Jamieson, Fernandez, and Merkle, repeatedly issued unlawful prescriptions when they prescribed controlled-substances to residents of States where they were not licensed to practice medicine. Respondent knew the physicians were generally licensed in only one State and yet dispensed the prescriptions. I thus find that Respondent had ample reason to know that these prescriptions were unlawful, that it deliberately ignored these state licensure requirements, and thus, that it repeatedly violated the CSA. *See* 21 CFR 1306.04(a).

Ignoring these patent violations of both Federal and state laws, Respondent contends that Dr. Reppy and the other physicians were engaged in the legitimate practice of ''telemedicine'' because ''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. Proposed Findings and Conclusions of Law at 26 (¶ 143). In support of its contention, Respondent argues that the practitioners whose prescriptions it filled ''required, at a minimum, the patient to provide recent medical records, including a physical examination, to substantiate the objective portion of the diagnosis, prior to the telephonic consultation with the doctor.'' *Id.*

I also reject this contention. Even if Dr. Reppy's (and Dr. Jamieson's) conduct established a valid doctor-patient relationship under Florida law (a dubious proposition at that, *see* GX 56, at 53–54), both physicians violated the laws of other States which clearly require that the prescriber personally perform the physical exam except in limited situations not applicable here. Dr. Reppy violated the laws of California, Tennessee, Indiana, and Louisiana. Dr. Jamieson (and Dr. Fernandez) violated the laws of California, Tennessee, and Louisiana. Moreover, Dr. Merkle violated the laws of California, Tennessee, and his own State, Indiana.[26]

In its exceptions, Respondent argues that it is the victim of ''unclear'' guidance because the Agency's regulations and Practitioner's Manual do not state ''that the *prescribing physician* [must] personally conduct a physical examination.'' Resp. Exceptions at 9–10. This argument misses the mark because as the 2001 Guidance Document recognized, whether certain acts by a physician establish a bonafide doctor-patient relationship is a question of state law, *see* 66 FR at 21182–83, and as explained above, some States allow a physician to prescribe without performing a physical exam in various, but limited, circumstances.

The rules (and/or interpretations) adopted by the States of California, Tennessee, Indiana, and Louisiana (among others) requiring that a prescribing physician perform the physical exam were issued well in advance of the conduct at issue here.[27] These rules and interpretations were also clear enough to put Respondent on notice that the prescriptions being issued to residents of those States were unlawful.

Respondent argues that before it filled prescriptions, it ''required the physicians to execute an affidavit attesting that the physician issued their prescriptions for a legitimate medical purpose within the usual course of their practice and based on a valid physician-patient relationship.'' Resp. Proposed Findings at 4 (¶ 15, citing Resp. Ex. 3 & GX 55, at 17–19). Relatedly, Dr. Johns testified that it is not ''the usual and customary practice in the distributive pharmacy setting to verify the existence of a doctor/patient relationship before filling a prescription.'' Tr. 1280 (quoting Resp.'s Counsel).

As for Dr. Johns' testimony, Respondent was not engaged in ''the usual and customary practice of'' pharmacy. Rather, it was filling prescriptions that were issued by physicians who were frequently located nowhere near their ''patients.'' Indeed, that is undoubtedly why Respondent required the physicians to sign letters attesting to the purported validity of their doctor-patient relationships.

The letters/affidavits were not a bona fide method of determining the legitimacy of the prescriptions. Rather, they were a sham, and as such, do not immunize Respondent from its obligations to know the laws of each State into which it sent controlled substances and to independently determine whether the physicians were in compliance with the States' licensure requirements and specific standards for issuing treatment recommendations and prescribing controlled substances.

I therefore also find that Respondent repeatedly violated 21 CFR 1306.04(a) by filling numerous prescriptions that it had reason to know were issued by physicians who had not established valid doctor-patient relationships under the laws of various States. Both this finding and my previous finding regarding Respondent's filling of prescriptions issued by unlicensed physicians provide independent and adequate grounds to conclude that Respondent has committed acts ''inconsistent with the public interest,'' and which warrant the revocation of its registration. 21 U.S.C. 824(a)(4).

While this conduct provides reason alone to revoke Respondent's registration, the record also contains substantial evidence of additional violations. As found above, Respondent filled numerous prescriptions issued by Dr. Starks well after his DEA registration expired on February 28, 2003. Moreover, Respondent did so even though it had on file a copy of Respondent's registration. For example, Starks issued new prescriptions (with refills) for Lortab, which Respondent filled, to J.I. of Alabama on January 9, 2004, April 16, 2004, June 24, 2004, and September 22, 2004. Starks also issued new prescriptions (with refills) for Norco and Xanax, which Respondent filled to K.Q. of Texas, on seven separate occasions between July 29, 2003, and October 27, 2004.

Under DEA regulations, a prescription for a controlled substance can be issued only by a practitioner who is properly registered.[28] 21 CFR 1306.03(a). The prescriptions Starks issued after the expiration of his registration were therefore illegal.

Regarding this allegation, Dr. Johns testified that it was ''probably'' not inappropriate to fill a controlled-substance prescription issued by a practitioner whose DEA registration had expired even though the pharmacy had a copy of the expired registration on file. Tr. 1300. This testimony is nonsense. While filling a prescription issued by a practitioner whose registration has recently expired might be excusable, Respondent's repeated filling of

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the legality of an unlicensed physician's issuance of a prescription to a resident of the State. Resp. Prop. Finding at 22. (¶ 120). Respondent does not, however, cite to any statutory language to support its claim of conflict, but rather, relies on a document it created which the Government entered into evidence. *See id.* (citing GX 7, at 1). I therefore reject this contention.

[26] As found above, Respondent also filled numerous controlled-substance prescriptions issued by Dr. Kienzle, a Tennessee-licensed physician who ultimately surrendered his medical license for prescribing over the internet.

[27] California adopted its internet prescribing statute in 2000, *see* Cal. Bus. & Prof. Code § 2242.1 (West 2007). Tennessee published its proposed rule on internet and telephonic prescribing on September 26, 2000; while the rule was subsequently renumbered it became effective shortly thereafter. *See* 26 Tenn. Admin. Reg. 62–63 (Oct. 2000). Likewise, on May 24, 2000, Louisiana issued its position statement on internet and telephonic prescribing. Finally, Indiana adopted its regulation on prescribing to persons not seen by the physician in October 2003. *See* 844 Ind. Admin. Code 5–4–1.1.

[28] Respondent does not contend that Starks was exempt from registration.

numerous prescriptions long after the expiration of Starks' registration clearly was not appropriate and was unlawful. If, in fact, it is the custom of the pharmacy industry to dispense controlled substances in the face of information that the prescriber's registration has expired, then the entire industry is violating the CSA. *Cf. The T.J. Hooper,* 60 F.2d 737, 740 (2d Cir. 1932) (''[T]here are precautions so imperative that even their universal disregard will not excuse their omission.'').

Respondent also violated the CSA by filling prescriptions that were issued by Mr. Protheroe, a physician assistant, who used Dr. Reppy's DEA registration while Reppy was on leave of absence and not supervising him. As Reppy testified, Protheroe was authorized to issue prescriptions only ''while he worked under [Reppy's] supervision,'' and did not have ''permission to issue prescriptions in [Reppy's] name while [Reppy] was on leave.'' GX 84, at 4. These prescriptions violated the State of Florida's regulations (of which I also take official notice) stating that ''[a] supervising physician may delegate to a prescribing physician assistant only such authorized medicinal drugs as are used in the supervising physician's practice, [and are] not listed'' in the State's formulary. Fla. Admin. Code Ann. R. 64B8–30.008(2).

As Reppy testified, during his leave of absence he was not in any sense supervising Protheroe. Indeed, it appears that all of the controlled-substance prescriptions written by Protheroe were illegal because the State's regulations prohibit a physician assistant from prescribing controlled substances even under a physician's supervision. *Id.* R 64B8–30.008(1).[29]

I further conclude that Respondent had reason to know that Protheroe was writing illegal prescriptions and filled them anyway. *See* GXs 16–18 (daily audit logs). The record amply establishes that Ballinger directed the operations of University during the relevant time period. Moreover, while the sale agreement for Respondent indicated that Carr was then its sole owner, both Reppy and Miller testified that Ballinger and Carr were partners in Respondent and other business ventures involving the distribution of controlled substances over the internet prior to the March 2005 sale of Respondent to Ballinger. GX 87, at 2–4; Tr. 1172–73. Moreover, Respondent's counsel stipulated that Ballinger had a relationship with Respondent during Reppy's employment at University. Tr. 1172. Finally, the evidence also establishes that Ballinger directed that University fax its prescriptions to Respondent. *Id.* at 1179. I therefore hold that Ballinger knew that Protheroe was issuing illegal prescriptions and that this knowledge is properly imputed to Respondent. Respondent thus violated 21 CFR 1306.04 by filling these prescriptions. This finding thus provides additional support for the conclusion that Respondent's registration is ''inconsistent with the public interest.'' [30] 21 U.S.C. 823(f).

Finally, Respondent argues that it made ''numerous attempts to meet with DEA to ensure compliance with DEA's interpretations of applicable laws and regulations'' and that it ''change[d] its business model to assuage DEA's concerns.'' Resp. Prop. Findings at 29–30. Respondent further asserts that ''in January 2007, * * * [it] began requiring physicians who issued prescriptions through [it] to have personally physically examined the patient involved.'' *Id.* at 12 (citing Tr. 877).

The purported support is not, however, testimony, but rather, part of a question asked by Respondent's counsel of a DEA witness, to which the latter answered: ''I don't recall that.'' Tr. 877. Likewise, the further statement by Respondent's lawyer during a colloquy with the ALJ that its reforms ''began in earnest in the beginning of January,'' *id.,* is not evidence. Moreover, given the abundant evidence establishing that Respondent filled numerous illegal prescriptions, and the failure of Mr. Ballinger to testify, Respondent's assertion of its new-found willingness to reform cannot be taken seriously. I therefore reject it.[31]

* * * * *

As the Supreme Court recently explained, ''the prescription requirement * * * ensures [that] 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,* 126 S.Ct. 904, 925 (2006) (citing *Moore,* 423 U.S. at 135). Even if it is not the usual and customary practice in the traditional brick-and-mortar pharmacy setting to verify the existence of the doctor/patient relationship before filling a prescription, *see* Tr. 1280 (testimony of Dr. Johns), the prescribing and dispensing of controlled substances over the internet poses an extraordinary threat to public health and safety. *Southwood Pharmaceuticals, Inc.,* 72 FR 36487, 36504 (2007) (discussing reports of the National Center on Addiction and Substance Abuse and the National Institute of Drug Abuse); *see also William R. Lockridge,* 71 FR 77791 (2006). Indeed, as even Respondent's expert admitted, if a prescription was faxed from a Web site, it would create a suspicion that the drugs would be diverted and require the pharmacist to perform additional investigation before filling the prescription. Tr. 1317. Furthermore, 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. This is so regardless of whether the pharmacy is a traditional retail pharmacy or a mail order/internet pharmacy.

In sum, because Respondent's dismal record of compliance with federal and state laws and its experience in dispensing controlled substances amply demonstrate that its continued registration is inconsistent with the public interest, there is no need to address the other statutory factors. Moreover, for the same reasons which led me to find that Respondent's registration posed an ''imminent danger to the public health or safety,'' 21 U.S.C. 824(d), I conclude that the public interest requires that its registration be revoked effective immediately. *See* 21 CFR 1316.67.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, BU6696073, be, and it hereby is, revoked. I further order that any pending applications for renewal or modification of such registration be, and they hereby are, denied. This Order is effective immediately.

[29] The prescriptions were also illegal for the same reasons that Reppy's prescriptions were illegal.

[30] I also find that Respondent violated Kentucky law by failing to report its dispensing of controlled substances.

[31] Given the abundant evidence of Respondent's failure to comply with applicable laws, I conclude that there is no need to address whether its compounding activities also violated the CSA. Moreover, in light of the evidence, I find it unnecessary to draw an adverse inference based on Mr. Ballinger's failure to testify with respect to the conduct alleged in the Show Cause Order and thus do not address Respondent's exception on this point. I do, however, rely on Mr. Ballinger's failure to testify to draw an adverse inference regarding its assertion that it has reformed its practices.

Dated: August 23, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–17223 Filed 8–30–07; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

[OMB Number 1110–0002]

Agency Information Collection Activities: Proposed Collection, Comments Requested

ACTION: 30-day Notice of Information Collection Under Review: Revision of a currently approved collection. Supplementary Homicide Report.

The Department of Justice, Federal Bureau of Investigation, Criminal Justice Information Services Division (CJIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with established review procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register**, Volume 72, Number 122, pages 35071–35072, on June 26, 2007, allowing for a 60-day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment October 1, 2007. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Mr. Gregory E. Scarbro, Unit Chief, Federal Bureau of Investigation, CJIS Division, Module E–3, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306; facsimile (304) 625–3566.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques of other forms of information technology, e.g., permitting electronic submission of responses. Overview of this information collection:

(1) Type of information collection: Revision of a currently approved collection.

(2) The title of the form/collection: Supplementary Homicide Report.

(3) The agency form number, if any, and the applicable component of the department sponsoring the collection: Form 1–704; CJIS Division, Federal Bureau of Investigation, Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract: Primary: City, county, state, federal and tribal law enforcement agencies.

This report will gather data obtained from law enforcement agencies in which a criminal homicide, justifiable homicide, and/or a manslaughter by negligence has occurred.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: There are approximately 17,523 law enforcement agency respondents; calculated estimates indicate 9 minutes per report.

(6) An estimate of the total public burden (in hours) associated with this collection: There are approximately 31, 541 hours, annual burden, associated with this information collection.

If additional information is required contact: Ms. Lynn Bryant, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, United States Department of Justice, Patrick Henry Building, Suite 1600, 601 D. Street, NW., Washington, DC 20530.

Dated: August 27, 2007.

Lynn Bryant,

Department Clearance Officer, PRA, United States Department of Justice.

[FR Doc. E7–17275 Filed 8–30–07; 8:45 am]

BILLING CODE 4410–02–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to request reinstatement and clearance of this collection. In accordance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting OMB clearance of this collection for no longer than 3 years.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information on respondents, including through the use of automated collection techniques or other forms of information technology; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be received by October 1, 2007 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Written comments regarding the information collection and requests for copies of the proposed information collection request should be addressed to Suzanne Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Blvd., Rm. 295, Arlington, VA 22230, or by e-mail to *splimpto@nsf.gov.*

FOR FURTHER INFORMATION CONTACT: Suzanne Plimpton at (703) 292–7556 or send e-mail to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Title of Collection: Recurring Study of National Science Foundation-sponsored Graduate Education Impacts or Legacy (GEIL). (Formerly called the Evaluation of the Initial Impacts of the Integrative