

Dated: May 21, 2007.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. E7-10624 Filed 6-1-07; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 06-4]

Trinity Health Care Corp., D/B/A/ Oviedo Discount Pharmacy; Affirmance of Immediate Suspension

On August 19, 2005, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Trinity Healthcare Corporation, d/b/a/ Oviedo Discount Pharmacy (Respondent) of Oviedo, Florida. The Order immediately suspended Respondent's Certificate of Registration, BT2863668, as a retail pharmacy, based on my preliminary finding that Respondent was filling large quantities of prescriptions for controlled substances that were issued through an internet site, iPharmacy.MD, by physicians who did not have a legitimate doctor-patient relationship with the individuals who ordered the drugs. See Show Cause Order at 5-10. Based on my preliminary finding that Respondent was "responsible for the diversion of large quantities of controlled substances," and that its participation in this scheme "invites the fraudulent procurement of controlled substances on a vast scale," I concluded that Respondent's continued registration pending these proceedings "would constitute an imminent danger to the public health and safety," and therefore immediately suspended its registration. *Id.* at 10.

More specifically, the Show Cause Order alleged that Respondent was filling prescriptions for phentermine, a schedule IV controlled substance, which were issued to the customers of iPharmacy.MD by Richard Carino, a physician located in Port Richey, Florida. *Id.* at 5. The Show Cause Order alleged that Dr. Carino issued prescriptions for phentermine to persons located "throughout the country" based solely on a questionnaire. *Id.* The Show Cause Order further alleged that DEA investigators interviewed various individuals who had been prescribed controlled substances by Dr. Carino; each of these persons stated that they were not patients of Dr. Carino and had not provided him with their medical records. *Id.* at 6.

The Show Cause Order also alleged that on May 6, 2004, DEA investigators conducted an inspection of Respondent during which they obtained its prescription records for the period January 1 through May 6, 2004. *Id.* at 7. The Show Cause Order alleged that between January and May 5, 2004, Respondent had filled 2,196 internet prescriptions for phentermine issued by Dr. Carino to persons located throughout the United States. *Id.* at 7-8.

Finally, the Show Cause Order alleged that on April 15, 2005, a DEA Special Agent (S/A) had accessed the iPharmacy.MD Web site, completed a questionnaire, and ordered 90 tablets of phentermine. *Id.* at 9. The Show Cause Order further alleged that on April 21, 2005, the S/A received a bottle of phentermine which had been filled by Respondent.

Respondent, through its counsel, requested a hearing. The matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner, who conducted a hearing on May 30 through June 2, 2006, in Arlington, Virginia. At the hearing, both parties called witnesses to testify and introduced documentary and/or demonstrative evidence. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and argument.

On October 2, 2006, the ALJ issued her decision. In that decision, the ALJ concluded that Respondent's continued registration would be inconsistent with the public interest and recommended that I revoke Respondent's registration and deny any pending applications for renewal or modification. ALJ Dec. (hereinafter ALJ) at 32. Neither party filed exceptions.

On November 13, 2006, the ALJ forwarded the record to me for final agency action. Having carefully reviewed the record as a whole, I hereby issued this decision and final order. I adopt the ALJ's findings of fact and conclusions of law except as noted herein. Furthermore, while Respondent's registration expired on November 30, 2006, and Respondent did not submit a renewal application, I nonetheless conclude that this case is not moot. See *William R. Lockridge*, 71 FR 77791, 77797 (2006). Accordingly, while I do not adopt the ALJ's recommendation that Respondent's registration be revoked, I will review the propriety of the immediate suspension under section 304(a) of the Controlled Substances Act, 21 U.S.C. 824(a), and make the following findings.

Findings of Fact

Respondent is a corporation, which is owned and operated by Mr. Obi Enemchukwu, a pharmacist, and does business as Oviedo Discount Pharmacy in Oviedo, Florida. ALJ at 2; ALJ Ex. at 3. Respondent held DEA Certificate of Registration, BT2863668, which authorized it to dispense controlled substances in Schedules II through V, from September 1991 until the expiration of its registration on November 30, 2006. ALJ Ex. 3, at 1. Respondent last renewed its registration on October 24, 2003. *Id.* I take official notice of the fact that Respondent did not submit a renewal application prior to the expiration of its registration.¹ Accordingly, I find that Respondent is no longer registered with the Agency. See 5 U.S.C. 558(c).

DEA's 2001 Policy Statement on Internet Prescribing and Dispensing

In April 2001, several years before the events at issue here, DEA published in the **Federal Register** a guidance document entitled "Dispensing and Purchasing Controlled Substances over the Internet." 66 FR 21181 (2001); see also Gov. Ex. 18. DEA issued this document to advise "the public concerning the application of current laws and regulations as they relate to the use of the Internet for dispensing [and] purchasing * * * controlled substances." 66 FR at 21181.

More specifically, the guidance document advised that "[o]nly practitioners acting in the usual course of their professional practice may prescribe controlled substances. * * * A prescription not issued in the usual course of professional practice * * * is not considered valid. Both the practitioner and the pharmacy have a responsibility to ensure that only legitimate prescriptions are written and filled." *Id.*

The guidance document also discussed the legality under existing law of prescribing controlled substances based on an on-line questionnaire. After noting DEA's regulation that a prescription for a controlled substance is not effective unless it is "issued for

¹ Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding—even in 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 this fact, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of the order.

a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice,” the document further explained that “[u]nder Federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship.” *Id.* at 21182 (quoting 21 CFR 1306.04(a)). The guidance document also explained that the factors typically necessary under existing law to establish the existence of a legitimate doctor-patient relationship include: That the “patient has a medical complaint”; “[a] medical history has been taken [and a] physical examination has been performed”; and that there must be “[s]ome logical connection * * * between the medical complaint, the medical history, the physical examination, and the drug prescribed.” *Id.* at 21182–83. Relatedly, the guidance document advised that “[c]ompleting a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship.” *Id.* at 21183

Finally, the guidance document advised that “[s]ome internet pharmacy sites do not require that you have a prescription from your doctor[,]” but rather, “require the customer to complete a medical questionnaire,” which then “will be reviewed by a doctor, and the drug will be prescribed and sent to you, if appropriate.” *Id.* The guidance document further stated that these types of internet pharmacy sites “operate in a manner that is not consistent with state laws regarding standards of medical practice and may be engaging in illegal sales of controlled substances.” *Id.*

The Investigation of Respondent

At some date not specified in the record, but likely in the fall of 2003, Mr. Terry Butler, the owner and president of iPharmacy.MD (hereinafter iPharmacy) and Drug-storemd, called Mr. Enemchukwu to recruit his pharmacy to fill prescriptions for his business. Tr. 807–08, ALJ at 3. According to Mr. Enemchukwu, Mr. Butler told him that iPharmacy had a Web site “which would screen patients, and if they qualified * * * would refer them to physicians who wrote them prescriptions,” and “that he would like [him] to fill these prescriptions and * * * send them to the patient.” Tr. 808. In late December 2003, Mr. Enemchukwu met with Mr. Butler to discuss the proposed arrangement and asked him whether the physicians who would do the prescribing were qualified. *Id.* at 810–11. Butler told him

that the doctors were qualified and would be “acting ethically.” *Id.* at 811. Mr. Enemchukwu further testified, however, that he did not do any research into the background of iPharmacy. *Id.* at 818.

On January 7, 2004, Mr. Enemchukwu and Mr. Butler entered into a contract through their respective entities (Oviedo Discount Pharmacy and Drug-storemd). ALJ at 4, Gov. Ex. 95, at 1. Under the contract, Drug-storemd engaged Respondent “to provide medicinal products to Drug-storemd’s customers.” Gov. Ex. 95, at 1. Drug-storemd further agreed to provide to Respondent “[a]n electronic * * * prescription for medication, properly, legally, and ethically authorized by a licensed physician in good standing in Florida or any other relevant state.” Gov. Ex. 95, at 3. Drug-storemd also agreed to pay Respondent \$8.00 for each order filled and to reimburse Respondent for the cost of the drugs it dispensed. *Id.* at 4.

The contract also included several provisions which Mr. Enemchukwu proposed as an addendum. *See id.* at 7. These included a requirement that the prescribing physicians supply Respondent “with copies of their credentials including their location, address and other pertinent information,” that Respondent “be able to communicate with the prescribing physician,” and that it “reserve[d] the right to use [the] professional judgment of the pharmacist according to law to deem a prescription not to be filled.” *Id.* 7–8. iPharmacy did not, however, provide Respondent with copies of its physicians’ credentials; Mr. Enemchukwu did not insist that it do so because it provided him with other information such as the numbers of the physicians’ DEA registrations and state medical licenses. Tr. 817, 820

According to the record, Respondent was given a password which allowed it to access a webpage at the iPharmacy Web site and obtain a list of the prescriptions it was to fill. *Id.* at 737–38, 757. According to the testimony, Mr. Enemchukwu would print out both the prescriptions and the shipping labels, which had been prepared in advance by iPharmacy.MD. *Id.* at 738, 757, 768. Mr. Enemchukwu would then enter the customer’s name and information into a computer and perform a drug utilization review. *Id.* at 763.

On January 6, 2004, (even before the contract was apparently signed), Respondent began by filling fifteen prescriptions which were written by Dr. Richard Carino—a physician based in Port Richey, Florida, Gov. Ex. 15—and allocated to it by iPharmacy. *See Gov. Ex. 77, at 1.* Of these prescriptions,

twelve of them were for either phentermine or Adipex-P. *Id.*

The Government’s evidence established that early on in the arrangement (in early March 2004), it should have been obvious that many of Dr. Carino’s “patients” resided in other States and thus were not likely to be patients at all. More specifically, the Government produced copies of controlled substance prescriptions, which showed that the “patients” resided in such far-flung places as Houston, Texas (Rx# 44122); Martinsville, Indiana (Rx# 44131); Dallas, Texas (Rx# 43947); Corbin, Kentucky (Rx# 43948); Woodward, Oklahoma (Rx# 43949); Cliffside Park, New Jersey (Rx# 43950); Cincinnati, Ohio (Rx# 43951); Hanahan and Greenville, South Carolina (Rx#s 44012 & 44016); Carver, Massachusetts (Rx# 44013); Pocono Lake, Pennsylvania (Rx# 44015); and Berwyn, Illinois (Rx# 43953).² *See Gov. Ex. 81.*³

Notwithstanding that many of the prescriptions were for persons who resided at a great distance from Port Richey, Florida (the location of Dr. Carino)—thus rendering it highly improbable that the patients were ever physically examined by Carino—Respondent proceeded to fill an ever increasing number of prescriptions issued by this physician. For example, on March 9, 2004, Respondent filled 82 prescriptions for controlled substances that were issued by Dr. Carino. *See Gov. Ex. 77, at 42–45.* The prescriptions were for phendimetrazine and Didrex (benzphetamine), both schedule III stimulants, *see* 21 CFR 1308.13(b), and phentermine, a highly abused schedule IV controlled substance in both generic and branded drugs such as Adipex-P. *See id.* at 21 CFR 1308.14(e); Tr. 583–844, 596. On May 26, 2004, Respondent filled 182 prescriptions issued by Dr. Carino for controlled substances including Didrex, phendimetrazine, diethylpropion (another schedule IV

² The prescriptions also indicated the date and time of approval. While these records are not complete, and represent only a small portion of the prescriptions written by Dr. Carino, they do suggest that he approved prescriptions in a rapid-fire manner. *See, e.g., id.* at 4–9 (indicating that Dr. Carino approved six prescriptions in a period of less than ninety seconds); *see also Gov. Ex. 76* (prescriptions issued by Drs. Duncan and Mercado-Francis).

³ *See also Gov. Ex. 61* (providing copies of prescriptions issued by Carino and filled by Respondent for persons living in Tulsa, Oklahoma (Rx# 45291); Seattle, Washington (Rx# 45296); Manchester, Kentucky (Rx# 45297); New Orleans, Louisiana (Rx# 45299); Jacksonville, Florida (Rx# 45302); Morrow, Ohio (Rx# 45306); Prestonburg, Kentucky (Rx# 45311); Statesville, North Carolina (Rx# 45314); Westerville, Ohio (Rx# 45315); Concord, Virginia (Rx# 45317); Houston, Texas (Rx# 45318); and Cape May, NJ (Rx# 45325)).

stimulant, *see* 21 CFR 1308.14(e)), and, of course, branded and generic phentermine. *See* Gov. Ex. 77, at 174–79. And on July 30, 2004, Respondent filled 337 prescriptions issued by Dr. Carino for controlled substances including Didrex, phendimetrazine, diethylpropion, and phentermine. *Id.* at 421–30.⁴

For some reason not established by the record, in late August/early September 2004, Respondent apparently stopped receiving prescriptions that were issued by Dr. Carino. *See* Gov. Ex. 77, at 554; Tr. 856. Respondent, however, began filling controlled substance prescription issued by two other physicians retained by iPharmacy, Dr. Michael Duncan, who was based in Nashville, Tennessee, and Dr. Jose Mercado-Francis, who was based in Isla Verde, Puerto Rico. *See* Gov. Ex. 77, at 554, 641–42; Gov. Ex. 73.

On September 10, 2004, Respondent filled 134 controlled substance prescriptions issued by Dr. Duncan for phentermine, phendimetrazine, benzphetamine, and diethylpropion. *See* Gov. Ex. 77, at 554–557. Less than a week later, on September 16, 2004, Respondent filled 272 controlled substance prescriptions issued by Dr. Duncan for these same drugs. *See id.* at 574–81. And on September 29, 2004, Respondent filled 107 controlled substance prescriptions for these same drugs that were issued by Dr. Mercado-Francis. *Id.* at 642–48. Respondent continued to fill large quantities of controlled substances prescriptions issued by both physicians until early May 2005. *See generally id.* at 582–1172.

With respect to these physicians, the Government introduced copies of the controlled substance prescriptions issued by them during the period April 20–26, 2005. *See* Gov. Ex. 76, at 1–404. Here, again, the prescriptions were for persons in such far flung locations as Sherman Oaks, California (Rx# 84929); Westfield, Massachusetts (Rx# 84932); Beaumont, Texas (Rx# 84933); Isanti, Minnesota (Rx# 84938); Watertown, South Dakota (Rx# 84939); Lockport, Louisiana (Rx# 84940) and Oklahoma City, Oklahoma (Rx# 84943). *See id.* at 2, 6, 7, 10, 11, 12, 15. The ALJ also found that between January 2004 and May 3, 2005, “Respondent filled at least 43,203 prescriptions, the vast majority of them

[being] for controlled substances.” ALJ at 22; *see also* Gov. Ex. 77. This finding is supported by substantial evidence.

On July 19, 2005, DEA investigators executed a search warrant at Dr. Duncan’s residence and interviewed him. Tr. 39–41. During the interview, Dr. Duncan stated that in September 2004, he had entered into a contract with iPharmacy.MD, under which he reviewed questionnaires submitted by iPharmacy’s customers and either approved or did not approve a prescription for the drug (typically phentermine, but also including other stimulants which are controlled substances) requested by its customers. Tr. 45–47. More specifically, Duncan told investigators that he would approve the prescriptions if the person indicated that they had a Body Mass Index greater than thirty and indicated that they were in good health. *Id.* at 47. Duncan would then e-mail the prescription to either Respondent or another pharmacy that filled prescriptions for iPharmacy. *Id.*

Duncan told investigators that he reviewed approximately 1100 questionnaires each week (for which he was paid \$ 3.00 each). *Id.* at 47–48. Duncan further admitted that he never saw any of the “patients” or talked with a patient, and that he did not review any document other than the on-line questionnaire which was submitted by iPharmacy’s customers.⁵ *Id.* While Dr. Duncan held a DEA registration, it did not authorize him to dispense schedule IV controlled substances such as phentermine. *See* Gov. Ex. 16.

The ALJ found that between January 2004 and April 2005, Respondent had purchased a total of 2,002,700 dosage units of phentermine which was comprised of 58,700 (15 mg.) tablets, 374,200 (30 mg.) tablets, and 1,569,800 (37.5 mg.) tablets. Gov. Ex. 57 & 98; ALJ at 21. On a monthly basis, Respondent thus purchased an average of

⁵ Among the phentermine prescriptions which Duncan issued were two obtained by a DEA Special Agent (acting in an undercover capacity) on January 7, 2005, and April 14, 2005. *See* Tr. at 128; Gov. Exs. 37, 47, 101, 102. Respondent filled the second of these prescriptions. Gov. Exs. 62 & 102. With respect to this prescription, Mr. Enemchukwu testified that he did not knowingly fill a fraudulent prescription. Tr. 782.

The iPharmacy questionnaire expressly stated that “To order *weight loss products* (i.e. Phentermine) your BMI (Body Mass Index) must be over 30. Your body mass index is automatically calculated to the right based on the values you enter above.” Gov. Ex. 40, at 2. Obviously, iPharmacy’s customers could enter any values they wanted because there was no verification of the information as would occur in a physical exam. Indeed, the Special Agent testified that to obtain the prescription she entered her height as 5’1” and her weight as 160 lbs. Tr. 93–94. While the Special Agent entered her correct height, her actual weight was 130 lbs. *Id.*; *see also* Gov. Ex. 45.

approximately 125,168 tablets of the drug.

To demonstrate the excessiveness of these purchases, the Government obtained data regarding the dispensing of phentermine by forty Walgreens’ stores in the metropolitan Orlando area during the period September 1, 2004, through July 30, 2005. *See* Gov. Ex. 65. This data showed that the forty stores combined filled 6,317 phentermine prescriptions and dispensed a total of 188,541 dosage units. *Id.* On a monthly basis, the stores dispensed an average of 14.3 prescriptions per month and 428 tablets. In contrast, between January 2004 and May 2005, Respondent dispensed approximately 43,200 prescriptions for various controlled substances which predominately included phentermine for an average of 2700 prescriptions per month. *See* Gov. Ex. 77.

The Government also elicited testimony from several expert witnesses. The first of these was Dr. Carmen Catizone, a registered pharmacist and the Executive Director of the National Association of Boards of Pharmacy. Gov. Ex. 89. Dr. Catizone testified that “[a] valid prescription is one where the pharmacy or pharmacist has ascertained that there is a bona fide patient/doctor relationship, and the prescription is within the scope of practice * * * and * * * is legitimate for the patient, and the patient’s condition, and does not contraindicate * * * with any other medications that the patient is taking.” Tr. 479. Dr. Catizone further testified as to the State of Florida’s regulations pertaining to the prescribing of weight loss drugs which include reviewing the patient’s body mass index, conducting a physical examination,⁶ and the physician’s obligation to personally present the prescription to the⁷ patient. *Id.* at 480. Dr. Catizone also stated that while it is not illegal for a physician to prescribe for a patient in another State,

⁶ While the Florida rule pertaining to the prescribing of anti-obesity drugs allows a physician to delegate the performance of the physical exam to a trained licensed physician’s assistant or a licensed advanced registered nurse practitioner, the rule requires that “the delegating physician must personally review the resulting medical records prior to the issuance of an initial prescription.” Fla. Admin. Code R. 64B8–9.012(3). Respondent produced no evidence to show that Dr. Carino practiced in this manner. Beyond that, as found above, the raw number of prescriptions being issued by Dr. Carino was staggering and should have at least triggered some inquiry of Dr. Carino as to how he could issue so many prescriptions on a daily basis.

⁷ Dr. Catizone further testified as to the dangers posed by illegitimate Internet pharmacies including the ease in which persons are able to obtain controlled substances without having to undergo a physical examination and the potential for fraud. Tr. 485–91.

⁴ The above are only representative samples to show the growth and the extent of Respondent’s dispensing pursuant to its contract with iPharmacy. Respondent filled increasing and frequently extraordinary quantities of controlled substance prescriptions issued by Dr. Carino on numerous other days until August 27, 2004. *See* Gov. Ex. 77, at 1–554.

“that patient would have had to have an in-person examination by that physician”; in other words, a “face-to-face” physical exam.⁸ *Id.* at 538–39.

Based upon his review of Respondent’s prescription records, and more specifically, the records pertaining to Dr. Carino’s prescribing, *see* Gov. Ex. 77, Dr. Catizone further testified that “as a pharmacist [it] would be very unusual to see that many prescriptions sequentially for this type of practice.” Tr. 504. With respect to the prescriptions issued by Dr. Duncan (who was in Tennessee) and filled by Respondent, Dr. Catizone opined that “[t]he pattern there again does not follow traditional practice.” *Id.* at 505. Noting that “in this case, you have a physician located in a completely different State, and the patient is located in a completely different State than the pharmacy,” Dr. Catizone concluded that “[t]here appears to be no relationship between the prescriber and the patient, and the pharmacy.” *Id.* Dr. Catizone concluded by testifying that Respondent’s dispensing of controlled substances to Internet customers was not in compliance with accepted standards of pharmacy practice. *Id.* at 508.

On cross-examination, Dr. Catizone was asked a series of questions regarding how a pharmacist would know whether a prescription was suspicious and had not been issued for a legitimate medical purpose. *Id.* at 516–17. More specifically, Respondent’s counsel asked Dr. Catizone how a pharmacist is “to know that the prescription was generated from an on-line questionnaire or cyberspace evaluation?” *Id.* at 517. Dr. Catizone answered that if a pharmacist “received one prescription from a physician, [he] probably wouldn’t have a suspicion. But if [he] receive[s] multiple prescriptions from a physician, and that physician is writing for controlled substances, that would invoke a suspicious relationship.” *Id.* When pressed by Respondent’s counsel as to what number of prescriptions “would invoke a suspicion,”⁹ Dr. Catizone explained that “any more than 10 prescriptions per day for a physician would invoke a suspicion.” *Id.* at 517–18. I credit all of Dr. Catizone’s testimony.

⁸Dr. Catizone acknowledged that a second physician could rely on the medical records created by another physician who conducted a physical exam or a physical exam conducted by another physician and observed by video conferencing. Tr. 539–40. Respondent did not, however, produce any evidence to show that the three iPharmacy physicians issued prescriptions based on physical exams they observed via video conferencing or their review of a medical record of an exam performed by another physician.

The Government also called to testify Dr. George J. Van Komen, the former President of The Federation of State Medical Boards of the United States and former Chairman of the State of Utah’s Physicians Licensing Board. Gov. Ex. 88, at 3. Based upon his review of Respondent’s prescription records, (compiled in Government Ex. 77), Dr. Van Komen concluded that Dr. Carino was engaged in “a rogue practice, because there is no way that a physician in a normal setting could see anywhere from fifty to a hundred patients, and appropriately and properly manage their weight.” Tr. 602–03. After noting that Carino was writing prescriptions for patients located all over the country, Dr. Van Komen further testified that:

The prescribing behavior and practices for Dr. Carino and Dr. Duncan were identical. Both of them wrote large numbers of prescriptions, far larger than one would expect anyone to be able to take care of [in the] normal appropriate safe practice of medicine. And his [Dr. Duncan’s] behavior also shows that his prescriptions were going to patients all over the United States as well. *Id.* at 604.

Finally, Dr. Van Komen testified that the manner in which Drs. Carino and Duncan were prescribing controlled substances over the Internet “was totally against any conceivable standard” of medical practice. *Id.* at 605. On cross-examination, however, Dr. Van Komen acknowledged that it was possible that a physician who had four physician assistants working for him could write over one hundred valid prescriptions a day. *Id.* at 612–13.

Mr. Enemchukwu testified that he stopped filling controlled substance prescriptions from iPharmacy in May 2005, after receiving various materials regarding Internet prescribing which were sent by the DEA Miami office in April 2005 including the 2001 guidance document. *Id.* at 732; Gov. Ex. 18. Mr. Enemchukwu stated, however, that he had no knowledge that iPharmacy was engaged in improper activity. Tr. 733. Mr. Enemchukwu further testified that “the reason why [he] decided to stop filling those controlled substance prescriptions was not because [he] knew that the doctor was not doing what he was supposed to do,” i.e., enter into a valid patient-doctor relationship with iPharmacy’s customers. *Id.* at 736. Rather, the reason was that if “the DEA might in any way frown on this, I [didn’t] want to be a part of it.” *Id.*

Mr. Enemchukwu further claimed that he did not obtain knowledge that the iPharmacy prescriptions were not issued in the course of a legitimate patient-doctor relationship until “[i]n these proceedings.” *Id.* Mr.

Enemchukwu also claimed that he never went to the iPharmacy webpages that were used by its customers and thus “did not know” that its customers could select their drugs, the dosage, and count, before submitting their requests to the physicians. *Id.* at 739–40.

Mr. Enemchukwu further testified that he was not familiar with regulations issued by the State of Florida governing the prescribing of obesity drugs. *Id.* at 782; *see also* Gov. Ex. 86. Under these regulations, an initial evaluation must “be conducted prior to the prescribing, * * * dispensing, or administering of any drug * * * and such evaluation shall include an appropriate physical and complete history; appropriate tests related to medical treatment for weight loss; * * * all in accordance with general medical standards of care.” Fla. Admin. Code Ann. R.64B8–9.012(3) (reproduced at Gov. Ex. 86, at 2). Moreover, while an initial evaluation can be “delegated to either a physician’s assistant or to an advanced registered nurse practitioner, * * * the delegating physician must personally review the resulting medical records prior to the issuance of an initial prescription.” *Id.* Furthermore, under the Florida rule, “[a]t the time of delivering the initial prescription or providing the initial supply of such drugs to a patient, the prescribing physician must personally meet with the patient and personally obtain an appropriate written informed consent from the patient.” *Id.* R.64B8–9.012(5).

Mr. Enemchukwu further maintained that “[p]harmacists are not mini-doctors,” and what a pharmacist does “is completely separate from what the doctor does.” Tr. 796. When asked on cross-examination how he would know that iPharmacy was “not a fly-by-night operation that [was] only interested in getting money?,” Mr. Enemchukwu answered: “I was filling prescriptions that I believed were valid prescriptions, and prescribed by qualified physicians.” *Id.* at 819–20. When asked, however, whether as a pharmacist he had a corresponding obligation “to ensure that the prescriptions are filled properly?,” Mr. Enemchukwu answered: “[t]hat the prescriptions are filled properly and prescribed properly, yes.” *Id.* at 820. Later, when asked whether a pharmacist is “just as responsible if they filled an unlawful prescription” as the physician who issued it?, Mr. Enemchukwu answered: “No.” *Id.* at 824. Mr. Enemchukwu further maintained that “[i]t would not be fair to hold [a pharmacist] responsible for what somebody else did if they did not know that the prescription was not authorized.” *Id.* at 824–25.

Notwithstanding that he was filling numerous prescriptions for phentermine which were issued by Dr. Carino, Mr. Enemchukwu admitted that he never spoke with Carino and never inquired in to whether he ran a diet practice. *Id.* at 829–30. Mr. Enemchukwu further maintained that it was his understanding that Carino could prescribe to patients in different parts of the country but admitted that he did not inquire as to whether Carino actually could. *Id.* at 830–31. Mr. Enemchukwu justified this stating that he did not know “what the medical boards of other States are allowing. I don’t know what doctors are authorized to do * * * as far as prescribing outside Florida.” *Id.* at 831.

Later, the Government asked Mr. Enemchukwu whether a physician could issue a legitimate prescription based solely on a questionnaire and without performing a physical examination. *Id.* at 843–44. Mr. Enemchukwu answered: “I would not approve that, and if I know that as a pharmacist, I would not fill the prescription.” *Id.* at 844. When asked whether he was “aware that Dr. Carino was doing examinations on a patient prior to your pharmacy dispensing or issuing a prescription?,” Mr. Enemchukwu stated: “[i]t was my impression that he was doing these examinations himself or doing what a physician practicing good medicine would do.” *Id.* at 844. Mr. Enemchukwu then tried to justify his filling the Carino prescriptions on the grounds that the “patients” could have been physically examined by physician assistants or other physicians, or Carino could have “had offices in multiple States.” *Id.* at 844–45. Mr. Enemchukwu admitted, however, that he never inquired with Carino as to whether the latter had persons in other parts of the country who were doing physical examinations for him. *Id.* at 849.

Relatedly, Mr. Enemchukwu testified that the frequency of the prescriptions he was filling did not raise his suspicion even though none of the local physicians whose prescriptions he filled for walk-in customers prescribed at the rate of Dr. Carino. *Id.* at 850. When pressed by the Government as to how Carino’s rate of prescribing compared to that of local physicians, Mr. Enemchukwu asserted that “everything we are looking at now is from hindsight.” *Id.* Mr. Enemchukwu further testified that “[t]here were questions that I did not ask because I thought everything was okay.” *Id.* at 852.

Likewise, Mr. Enemchukwu testified that he had had only one conversation with Dr. Duncan, which was about a

particular prescription, and that he never asked Duncan about his practice because it was “obvious” that he operated a diet practice. *Id.* at 858. When asked whether he had assumed that Duncan had authority “to practice in different parts of the country,” Mr. Enemchukwu answered: “I did not know what his prescribing rights was [sic].” *Id.* at 858–59. Mr. Enemchukwu then added that “[i]n Florida, we are allowed to fill prescriptions prescribed by out-of-state doctors.” *Id.* at 859. Here, too, Mr. Enemchukwu insisted that he “had no reason to believe that” the prescriptions issued by Drs. Duncan and Carino were unlawful. *Id.* at 864.

The ALJ specifically declined to credit Mr. Enemchukwu’s testimony that he believed that the prescriptions he filled for iPharmacy were issued by its physicians pursuant to a legitimate doctor-patient relationship and that he had no reason to believe to the contrary. See ALJ at 29. As the ALJ reasoned, “it defies [the] imagination to believe that [Mr. Enemchukwu] did not think that something might be wrong when a physician in one state issued prescriptions—thousand of them—to purported patients in other states.” *Id.* at 30. As the ALJ further explained, “between January 2004 and May 2005, Respondent filled more than 43,000 prescriptions, or more than 2,700 prescriptions per month, the vast majority of which were for controlled substances and issued by only [three]⁹ physicians to individuals all over the United States.” *Id.* The ALJ thus further found that “Mr. Enemchukwu knew but refused to acknowledge that the prescriptions he filled were not issued pursuant to a legitimate physician-patient relationship.” *Id.*

I adopt both of the ALJ’s findings. With respect to the finding that Mr. Enemchukwu’s testimony (that he had no reason to believe that the iPharmacy prescriptions were invalid) was disingenuous, the ALJ personally observed Mr. Enemchukwu’s testimony and was in the best position to evaluate his credibility on this issue of historical fact. See *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951).

Indeed, Mr. Enemchukwu’s testimony is implausible. As found above, early on in Trinity’s relationship with iPharmacy it was apparent that the prescriptions were illegal. Even under Respondent’s theory that it would be possible for a physician using four physician assistants to write over one hundred valid prescriptions a day, as early as

May 26, 2004, Respondent filled, on a single day, 182 prescriptions for controlled substances issued by Carino. And by July 30, 2004, Respondent filled, on a single day, 337 prescriptions issued by this same doctor. Moreover, the prescriptions were for “patients” located throughout the United States. Notwithstanding this information, Mr. Enemchukwu made no inquiry as to the legitimacy of Carino’s prescriptions. Nor did Mr. Enemchukwu inquire as to the legitimacy of Dr. Duncan’s prescriptions.

Substantial evidence thus supports the conclusion that Mr. Enemchukwu knew early on in his company’s relationship with iPharmacy that the prescriptions were not the result of a legitimate doctor-patient relationship. I therefore also adopt the ALJ’s further finding that Mr. Enemchukwu knew that the iPharmacy prescriptions were invalid. Relatedly, I reject as disingenuous Mr. Enemchukwu’s testimony that he did not recognize that the prescriptions were illegal until this proceeding.

Discussion

Mootness

At the outset, this case presents the question as to whether this proceeding is now moot. As found above, Respondent’s registration expired on November 30, 2006 (shortly after the record was forwarded to me), and Respondent has not submitted a renewal application. Therefore, Respondent no longer has a registration and there is no application to either grant or deny. See *Lockridge*, 71 FR at 77796; *Ronald J. Riegel*, 63 FR 67132, 67133 (1998).

This proceeding began, however, with the immediate suspension of Respondent’s registration. As *Lockridge* noted, the issuance of an order of immediate suspension may impose collateral consequences which preclude a finding of mootness. As several courts have noted in cases involving licensed professionals, “even a temporary suspension followed by a reinstatement does not moot a challenge to the initial suspension because the action ‘is harmful to a [professional’s] reputation, and the mere possibility of adverse collateral consequences is sufficient to preclude a finding of mootness.’” *Lockridge*, 71 FR at 77797 (quoting *In re Surrick*, 338 F.3d 224, 230 (3d Cir. 2003) (quoting *Dailey v. Vought Aircraft Co.*, 141 F.3d 224, 228 (5th Cir. 1998))). See also *Kirkland v. National Mortgage Network, Inc.*, 884 F.2d 1367, 1370 (11th Cir. 1989) (attorney’s appeal of the revocation of his *pro hac vice* status was not moot following dismissal of the

⁹ As found above, in fact, Respondent filled prescriptions written by three iPharmacy physicians (Carino, Duncan, and Mercado-Francis).

underlying case because “the brand of disqualification on grounds of dishonesty and bad faith could well hang over his name and career for years to come”).

It is indisputable that an immediate suspension harms a registrant’s reputation. Moreover, were Respondent to apply for a new DEA registration in the future, it would be required to disclose the suspension. See DEA Form–224, at Section 5. And Respondent may also be required to report this suspension to state authorities. Given that Respondent remains in business,¹⁰ and under DEA’s regulations, can apply for a new registration at any time, it is not pure speculation to conclude that Respondent may be impacted by the collateral consequences that attached with the issuance of the immediate suspension order. Moreover, under federal law, title to any controlled substances seized when the immediate suspension was served is dependent upon the outcome of this proceeding. 21 U.S.C. 824(f).

Besides these collateral consequences, I note that neither party has moved to dismiss the proceeding as moot. Moreover, given the resources that both the Government and Respondent have invested in this proceeding, it makes little sense to dismiss this case without issuing a ruling on the merits even if that ruling is limited to assessing whether the suspension of Respondent’s registration was warranted under section 304(a), 21 U.S.C. 824(a). I therefore conclude that this case is not moot.

The Statutory Factors

Section 304(a) of the Controlled Substance Act 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).

¹⁰ The case thus stands in contrast to one where a registrant has either gone out of business or ceased professional practice.

In determining the public interest, the Act directs that the Attorney General consider the following factors:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant’s experience in dispensing * * * controlled substances.
- (3) The applicant’s conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Id. section 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 the suspension of Respondent’s registration was justified under factors two and four.

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

As explained above, 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). 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.* “[T]he 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 consistently interpreted this provision 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.” *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). This is also apparently the standard applicable under Florida law. See Fla. Stat. § 465.016(s) (dispensing drug when “pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship” is grounds for discipline).

Respondent concedes that the iPharmacy prescriptions were not legitimate. See Resp. Br. at 13. Respondent contends, however, that the Government did not meet its burden of proof because various government witnesses “testified that it was possible for these prescriptions to have been legally and properly issued (although they were not) through the use of physician assistants or referring physicians.” *Id.* According to Respondent, the Government failed to show “that Respondent knew or had reason to believe that the prescriptions were improper.” *Id.*

The Government did, however, prove that it was more likely than not that Respondent knew that these prescriptions were illegitimate.¹¹ While it is true that one of the Government’s witnesses acknowledged that it would be possible for a physician using four physician assistants to write over one hundred valid prescriptions a day, the dispensing records showed that Respondent was filling prescriptions far in excess of this figure. As found above, on May 26, 2004, Respondent filled 182 controlled substance prescriptions issued by Dr. Carino, and on July 30, 2004, Respondent filled 337 controlled substance prescriptions issued by Carino. Moreover, on September 16, 2004, shortly after Dr. Duncan began issuing prescriptions, Respondent filled 272 of them on a single day. These are only representative examples; the dispensing log is replete with evidence showing that through May 2005, Respondent dispensed a similar volume of prescriptions issued by iPharmacy’s

¹¹ See *Metropolitan Stevedore Co. v. Rambo*, 521 U.S. 121, 137 n.9 (1997) (other citation omitted) (preponderance standard requires only that the ultimate factfinder “believe that the existence of a fact is more probable than its nonexistence before * * * find[ing] in favor of the party who has the burden to persuade the [factfinder] of the fact’s existence”).

physicians on almost every other day it was open for business.

As recognized in other cases, the sheer volume of prescriptions thus establishes that it more likely than not that Respondent's owner knew that the prescriptions were illegitimate and intentionally ignored this. *See, e.g., Bertolino*, 55 FR 4729, 4730. Beyond that, the prescriptions were being sent to persons in every part of the country. Moreover, there is also some evidence that the iPharmacy physicians performed their reviews in rapid-fire fashion. Yet none of this prompted Respondent's owner to question the legality of the prescriptions. Contrary to Mr. Enemchukwu's assertion that "everything we are looking at now is from hindsight," Tr. 850, shortly into the relationship with iPharmacy, Mr. Enemchukwu was receiving abundant evidence—on a nearly daily basis—to know that iPharmacy (and its doctors) were engaged in illegal activity.¹²

I thus conclude that Respondent is responsible for the dispensing of more than 43,000 illegal prescriptions and the diversion of more than two million dosage units of various controlled substances. Not only is this a violation of federal law, *see* 21 U.S.C. 841(a), and appears to be a violation of Florida law,¹³ *see* Fla. Stat. 465.016(s), it is manifest that diversion on this scale creates an extraordinary threat to the public health and safety. Respondent's experience in dispensing controlled substances and its record of compliance with applicable laws thus provide abundant reason to conclude that Respondent committed acts which rendered its registration "inconsistent

¹² Respondent's owner makes no claim that it was reasonable for him to rely on the representations made by Mr. Butler both orally and in the contract regarding the legality of internet prescribing and dispensing. This is rightly so for three reasons: (1) Mr. Enemchukwu is a licensed professional and is responsible for knowing the rules applicable to the practice of his profession. (2) In April 2001, nearly three years before he entered into the contract with Mr. Butler, DEA published guidance which explained the application of existing federal laws and regulations to the proposed arrangement, and (3) other bodies such as the AMA and Federation of State Medical Boards had published information regarding the invalidity of internet prescribing under both ethical and legal standards. *See* Gov. Exs. 3 & 4.

¹³ The Government also argues that Respondent violated various state laws by dispensing to persons in States where it was not licensed to do so. *See* Gov. Br. at 48. In its brief, the Government did not, however, cite to specific laws establishing the licensure requirements of various States. Moreover, the Government's proof was largely confined to an e-mail in which Respondent sought reimbursement for the fees it paid to obtain the permits. The Government's evidence did not cite to specific instances in which Respondent dispensed in violation of a particular State's law. *See* Tr. 361–62. Therefore, I conclude that this allegation had not been proved with substantial evidence.

with the public interest" and thus warranted the suspension of its registration under section 304(a). 21 U.S.C. 824(a)(4).¹⁴

Order

Pursuant to the authority vested in me by 21 U.S.C. 824, as well as 28 CFR 0.100(b) & 0.104, the order of immediate suspension of DEA Certificate of Registration, BT2863668, issued to Trinity Health Care Corporation, d/b/a/Oviedo Discount Pharmacy, is hereby affirmed.

Dated: May 21, 2007,
Michele M. Leonhart,
 Deputy Administrator.
 [FR Doc. E7–10627 Filed 6–1–07; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Dale L. Taylor, M.D.; Revocation of Registration

On February 2, 2007, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to Dale L. Taylor (Respondent) of Winter Haven, Florida. The Order immediately suspended Respondent's Certificate of Registration, BT8732631, as a practitioner, based on my preliminary finding that Respondent was diverting large quantities of controlled substances through an internet-prescribing scheme. Show Cause Order at 2. I therefore concluded that Respondent's "continued registration during the pendency of these proceedings would constitute an imminent danger to the public health and safety because of the substantial likelihood that [he would] continue to divert controlled substances to drug abusers." *Id.* at 3.

The Show Cause Order also alleged that Respondent's "continued registration is inconsistent with the public interest." *Id.* at 1. More specifically, the Show Cause Order alleged that beginning in May 2004, Respondent had been issuing prescriptions for controlled substances

¹⁴ Based on Mr. Enemchukwu's insistence that he did not know and had no reason to believe that the iPharmacy prescriptions were unlawful, the ALJ further concluded that he had failed to acknowledge his wrongdoing and thus was not "willing to accept the responsibilities inherent in a DEA registration." ALJ at 31. While I agree with the ALJ's view of the evidence, there is neither an existing registration to revoke nor a pending application to deny. As this case is now limited to a review of the validity of the suspension, there is no need to consider this finding and weigh it against the slight mitigating evidence in the case.

over the Internet "without the benefit of a legitimate doctor-patient relationship and outside the course of professional practice." *Id.* The Show Cause Order alleged that Respondent had admitted to DEA investigators that he had done such prescribing for three different internet entities including Pacific MD, Norco Worldwide, and *BestRxCare.com*. *Id.* at 1–2.

The Show Cause Order further alleged that Respondent had admitted that he would log onto a Web site and view a list of customers, review their medical records, and then contact each person by telephone. *Id.* at 2. The Show Cause Order alleged that Respondent had admitted that his "role was simply to make sure that the type of medication, strength and quantity were consistent with the online customers' alleged medical need," and he had "never called patients after authorizing their drug orders to provide aftercare." *Id.* Relatedly, the Show Cause Order alleged that Respondent told investigators that he took "the on-line patient's word when determining their need for hydrocodone." *Id.*

The Show Cause Order alleged that *BestRxCare.com*'s orders were filled by CRJ Pharmacy and that the pharmacy's records for the period from July 3, 2006, to January 22, 2007, showed that it had dispensed "approximately 6,000 [i]nternet drug orders that [Respondent] authorized." *Id.* The Show Cause Order alleged that "approximately 85% of these [i]nternet drug orders were for hydrocodone combination products." *Id.*

Finally, the Show Cause Order alleged that Respondent had admitted to investigators that he had "authorized controlled substance [prescriptions] for online customers throughout the United States" even though he acknowledged that he was "only licensed to practice medicine in" Florida. *Id.* The Show Cause Order thus alleged that Respondent had violated various state laws that prohibit "unlicensed, out-of-state physicians issuing controlled substance prescriptions to state residents." *Id.*

On February 6, 2007, DEA Investigators served the Show Cause Order and Immediate Suspension, which notified Respondent of his right to a hearing, by leaving it at his residence with his wife. *Cf.* F.R.C.P. 4(e). Since that time, neither Respondent, nor anyone purporting to represent him, has responded. Because (1) more than thirty days have passed since service of the Show Cause Order, and (2) no request for a hearing has been received, I conclude that Respondent has waived his right to a hearing. *See* 21