hereby is, granted, subject to the conditions set forth above. This Order is effective immediately.

Dated: February 26, 2009.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 06–28]

Joseph Gaudio, M.D.; Suspension of Registration

On September 16, 2005, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Joseph Gaudio, M.D. (Respondent) of Alpine, New Jersey. The Show Cause Order sought the revocation of Respondent's DEA Certificate of Registration, which authorizes him to handle controlled substances as a practitioner, and the denial of any pending applications to renew or modify his registration, on the ground that he had committed acts which rendered his continued registration ''inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

The Show Cause Order alleged that Respondent had issued prescriptions for controlled substances which lacked a legitimate medical purpose, and that in doing so, he had acted outside of the usual course of professional practice. *Id.* at 1 & 6. The Show Cause Order specifically alleged that Respondent had ''prescrib[ed] controlled substances to Internet customers despite never establishing a genuine doctor-patient relationship with the Internet customer.'' *Id.* at 5. Relatedly, the Show Cause Order alleged that Respondent ''did not see customers, had no prior doctor-patient relationships with the Internet customers, did not conduct physical exams, * * * did [not] create or maintain patient records,'' and that ''[t]he only information usually reviewed prior to issuing drug orders was the customer's online questionnaire.'' *Id.* at 6.

The Show Cause Order also alleged that ''[a] review of prescriptions filled by [Carrington Healthcare System/ Infiniti Services Group] revealed that [Respondent] ha[d] issued drug orders for controlled substances to Internet customers throughout the United States, including Georgia, Texas, Pennsylvania, Alabama, Louisiana, and Kentucky.'' *Id.* The Show Cause Order further alleged that ''[a] review of prescriptions filled by [Carrington/Infiniti] for the period October 13, 2004 to January 21, 2005, revealed that [Respondent] ha[d] issued 16 drug orders to Internet customers in at least nine different states.'' *Id.*

On October 21, 2005, Respondent, through his counsel, requested a hearing on the allegations. The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who conducted a hearing on May 2–5, 2006, in New York, NY. At the hearing, both parties put on testimony and introduced documentary evidence. Thereafter, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and arguments.

On November 2, 2007, the ALJ issued her recommended decision. In her decision, the ALJ concluded that ''[t]he Government has clearly demonstrated that the Respondent's Internet practice and his resulting issuance of controlled substance prescriptions * * * violated the Controlled Substances Act.'' ALJ at 43. Applying the totality of the circumstances test, the ALJ concluded, however, that the revocation of Respondent's registration was not warranted. *Id.* at 43–44.

The ALJ specifically noted that ''Respondent's conduct encompassed a one year period,'' that Respondent had ''voluntarily cease[d]'' his conduct, but that he had not done so until three months after he was served with the Show Cause Order. *Id.* at 43. While the ALJ deemed Respondent's cessation of his conduct as ''commendable because of its voluntary nature,'' she further explained that he ''demonstrated a lack of sound judgment'' in ''continuing to'' prescribe after being served with the Show Cause Order. *Id.* at 44. The ALJ also found of concern ''Respondent's failure to be totally truthful during his testimony.'' *Id.*

The ALJ reasoned, however, that Respondent was ''a very educated, dedicated and talented physician practicing in a sometimes difficult specialty, pain management,'' and that the revocation of his registration would render him ''being unable to handle controlled substances'' in his specialty. *Id.* Because the record demonstrated that Respondent had practiced medicine for eleven years, and that ''the only instances of [his] improper handling of controlled substances were related to his'' Internet prescribing, the ALJ recommended that Respondent's registration be continued subject to the condition that he ''not engage in any activity involving prescribing controlled substances and the Internet.'' *Id.*

Having considered the entire record in this matter, I hereby issued this Decision and Final Order. I adopt the ALJ's conclusions that Respondent violated both the Controlled Substances Act (CSA) and various state standards of medical practice in issuing prescriptions to persons who ordered drugs through an Internet site. For reasons explained below, I reject the ALJ's recommended sanction as inconsistent with agency precedent and will order the suspension of Respondent's registration for a period of one year. I make the following findings.

Findings

Respondent is a medical doctor who is board certified in both anesthesiology and pain management and is licensed to practice medicine in the States of New York and New Jersey. Tr. 488. Respondent is also the holder of a DEA Certificate of Registration, which authorizes him to dispense controlled substances in schedules II through V as a practitioner. GX 1, at 2. While the expiration date of Respondent's registration was September 30, 2006, Respondent submitted a renewal application on August 4, 2006. *See* Reply to Respondent's Status Report, at 1. I therefore find that Respondent's prior registration has remained in effect pending the issuance of this Final Order and that Respondent also has an application pending before the Agency. *See* 5 U.S.C. 558(c).

Respondent attended medical school at The Autonomous University of Guadalajara, and the New York Medical College. RX 1, at 2. Subsequently, Respondent did his residency in anesthesiology at St. Luke's/Roosevelt Hospital, an institution which is affiliated with the Columbia University College of Physicians and Surgeons, where he received an award given to the Outstanding Graduate Resident in Anesthesiology. *Id.* Respondent also did a fellowship in Pain Management at the Memorial Sloan Kettering Cancer Center, where he was elected Chief Fellow. *Id.* at 1.

Upon completion of his fellowship, Respondent joined New Jersey Anesthesia Associates (NJAA), a group of physicians which provides anesthesia services at St. Barnabas Medical Center. Tr. 345–47. Respondent is a partner in NJAA. *Id.* at 347. In addition to providing anesthesia, Respondent also treats both acute and chronic pain patients. *Id.* at 555–56. Respondent is also an attending physician and clinical professor at St. Barnabas, where he trains residents in anesthesia. *Id.* at 360.

Respondent came to the attention of the Agency during its investigation of a

large criminal conspiracy which was run by Johar Saran, and which used the Internet to unlawfully distribute controlled substances. *Id.* at 156–159; *see also* GX 16 (Indictment, *United States* v. *Saran, et al.,* No. 305–CR–0240P (N.D. Tex. 2005). As part of the investigation, DEA Investigators conducted trash runs at the premises of Carrington Health Care System, an entity owned by Saran which was located at 301 E. Stephens, Suite 100, Arlington, Texas. Tr. 159, 185. During the trash runs, investigators found various documents including ''Drug Prescription'' sheets and copies of some prescription labels which are placed on pill vials. *See* GXs 17–29.

The ''Drug Prescription'' sheets listed a patient's name, address, birth date, age, sex, phone number, medication history, and allergies. *See* GXs 17–24. In the block titled ''Physician,'' the sheets listed Respondent's name, address, phone numbers, and DEA number. *Id.* In the block titled ''Rx,'' the sheets gave the date, drug name (which in each instance was a schedule III controlled substance containing hydrocodone), quantity, number of refills, instructions for taking the drug, instructions to the pharmacist as to whether substitution was permitted or the drug was to be dispensed as written, and bore the electronic signature of Respondent. *See id.* In a block entitled ''Pharmacy Services Use Only,'' each of the sheets listed a number, as well as the date and time of a consultation, and included the notation ''LBRTY.'' *Id.*[1] Finally, each of the sheets included shipping information. *Id.*

The prescription labels listed ''Triphasic Pharmacy,'' with an address of ''301 E. Stephens St. Ste 100'' in Arlington as the dispensing pharmacy. GXs 25–31. The labels also listed the patient's name, the drug, a date, the quantity dispensed, a prescription number, instructions for taking the drug, number of refills, and a physician's name. *Id.* Respondent was listed as the prescribing physician on eight of the prescription labels, each of which indicated that the customer had received a schedule III controlled substance containing hydrocodone. *See id.*

Several months later, Respondent was served with the Show Cause Order. Tr. 51–52. When asked by a DI whether he had prescribed over the Internet, Respondent admitted that ''he had a contract with a company called Liberty Med,'' that ''he reviewed on-line patient applications of Liberty Med,'' and that he ''was paid $20 per on-line patient consultation.'' *Id.* at 52. Respondent also told the DI that he reviewed MRIs and X-rays. When asked if he maintained patient records, Respondent told the DI that Liberty Med ''kept them.'' *Id.* at 53.

In his testimony, Respondent explained that in October 2004, one of his partners in NJAA introduced him to Liberty Medical and Mr. Craig Boswell, whose mother ran the company. Tr. 371–72. Respondent's partner told him that ''he understood [that Liberty] was a legitimate company that practices Internet-based medicine and that I might be interested in talking to Craig Boswell concerning possibly doing work for them.'' *Id.* at 371.

Respondent met with Boswell, who told him that the company ''was not one of these companies opening and shutting in a week or month, [that it] was a legitimate company, [and that] they wanted to set up consultation services doing this internet website.'' *Id.* at 373. Boswell further advised Respondent that Liberty ''deal[t] with patients who have medical records, who have been seen by other physicians, who have radiological evidence of pain.'' *Id.* Boswell also told Respondent that Liberty would carefully screen the patients, that ''they would make sure that the patient wasn't sourcing meds from another facility,'' and that ''they would also obtain'' the address and phone number of the patient's primary physician ''so that we could call them if there is any question as to whether'' the person was ''a legitimate patient.'' *Id.* at 374.

Boswell subsequently asked Respondent if he would perform on-line consultations for Liberty. *Id.* The consultations were to involve ''interview[ing] the patients'' and ''mak[ing] a recommendation'' to prescribe drugs based ''on all the information.'' *Id.*

In his testimony, Respondent maintained that he asked Boswell whether this was permissible. *Id.* at 375. Respondent stated that Boswell ''assured [him] that everything was legitimate,'' that Boswell told him that ''he was in the Armed Forces,'' and that ''he had two men in his squad [who] were in the DEA and [that] he constantly bounced questions off of them * * * always to make sure that he was within the limits of the law.'' *Id.* Boswell also told Respondent that ''there were certain states that did not allow internet prescribing'' and that persons from these states would be excluded. *Id.* at 376.

Respondent did not, however, seek legal advice regarding the lawfulness of Boswell's proposal. *Id.* at 375. Moreover, even though he understood that he would be prescribing to patients throughout the country, he did not undertake any inquiry on his own into the laws of any State pertaining to the propriety of the proposed activity. *Id.* at 512. Instead, he concluded that Liberty was engaged in legitimate activity because Boswell had been referred to him by his partner and Boswell was ''concerned about making sure that everything was done correctly,'' *id.* at 375, and had told him that ''he had reviewed all the laws pertaining to this.'' *Id.* at 512.[2]

In November 2004, Respondent entered into a written contract with Liberty; Respondent performed online consultations and prescribings for it from approximately December 2004 through December 2005. *Id.* at 507. Respondent was paid $20 per consultation and received the same fee regardless of whether he prescribed a drug.[3] *Id.* at 382–83, 508, 601. Respondent did consultations for Liberty five days a week, and did so every week between December 2004 and December 2005, except for three weeks during which he took vacation. *Id.* at 516. Respondent performed twenty to fifty consultations a week; he also testified that while he was ''not exactly sure,'' he issued twenty to thirty prescriptions a week. *Id.* The record is, however, unclear as to how many of the prescriptions were for controlled substances. *Id.* at 568.[4] According to

[1] At the top of all but one of the sheets was the notation: ''From: Dr. Joseph Gaudio, M.D.,'' and a date and time which was typically only a short period after the date and time listed for the consultation. *See* GXs 17, 18, 20, 21, 22, 23.

[2] Respondent also maintained that ''to find out more'' he had talked with another physician who performed online consultations for Liberty. *Id.* at 509. Respondent did not, however, testify as to the specifics of this conversation. *Id.* Respondent did not meet any of the medical professionals who worked for Liberty and did not know where the business was located. *Id.*

[3] Respondent maintained that his compensation from Liberty was only ''a very small part of [his] income'' and that ''it was more of my interest in telemedicine that drove me to do it.'' Tr. 383. Respondent testified that he was involved in a start-up company, Technology Integrated for Medical Application (TIMA), which conducted academic research with major institutions, and that TIMA was developing systems to engage in medical monitoring of people from remote locations. *Id.* at 505. Respondent explained that ''[w]e can speculate that some day we'll be able to diagnose patients from a distance where you can have a doctor in a remote location who doesn't have the expertise in a certain area that can receive expertise from * * * physicians in another area based on giving real time information back to those physicians.'' *Id.* at 506.

[4] Respondent testified that he prescribed both narcotics and non-narcotics and that the estimated number of prescriptions referred to ''all in total.'' Tr. 568. Notably, the Government introduced no evidence showing the number of controlled-substance prescriptions he issued during the course of his contract with Liberty; nor did it introduce evidence showing the number of controlled

Respondent, he prescribed hydrocodone, Vicodin (a schedule III controlled substance which contains hydrocodone), and oxycodone, a schedule II controlled substance. *Id.* at 547. *See Physicians' Desk Reference* 526 (59th ed. 2005); see also 21 CFR 1308.12(b)(1) & 1308.13(e).

Liberty gave Respondent a user name and password, which he used to access PSDOCTOR, a Web-based software program which listed his appointments; according to Respondent, he ''would call the patient and obtain a detailed history.'' *Id.* at 377. Respondent testified that through PSDOCTOR, he could retrieve patient records including a patient's history (including the patient's complaint, what drugs the patient was taking, what surgeries the patient had undergone, and the patient's name and address), charts, and exams including radiological reports. *Id.* at 377–78. Respondent also testified that ''sometimes [the patients] would * * * also submit physical exams.'' [5] *Id.* at 378.

Respondent maintained that he would ''call the patients because [he] want[ed] to actually talk to the patients before [he] made any decisions on the patient,'' that ''[t]he history was very important,'' *id.* at 378–79, and that the calls would last an average of twenty minutes. *Id.* at 615. He also testified that he performed a telephonic consultation with every patient he prescribed to. *Id.* at 614–15.

Relatedly, Respondent maintained that based on his experience as a pain doctor, he could ''get a sense of whether the patient was telling me the truth because certain pains in certain areas elicit certain responses.'' *Id.* at 379. He also testified that most patients did not ''have the savvy'' to dupe him and that ''sometimes [he] would lead patients down the wrong path to see if they were telling the truth * * * because there are a lot of drug seekers out there.'' *Id.* at 381–82. He also stated that if a patient told him something that did not match what was in their medical record, ''we would either call their primary doctor'' or ''deny them.'' *Id.* at 382. Respondent also testified that he ''denied a lot of patients and some of the records will show that.'' *Id.*

The ALJ found that some of Respondent's testimony was contradicted in several material respects by other evidence. *See* ALJ at 12 (¶ 36). While Respondent testified that he never prescribed without conducting a telephone consultation with the patient, and that the consultations lasted twenty minutes on average, Ms. A.B., who received hydrocodone pursuant to a prescription issued by Respondent on December 8, 2004, *see* GX 17, stated to a DI that within a couple of hours after she faxed medical records to Liberty,[6] she received a telephone call from a doctor which lasted approximately ''one minute.'' GX 35, at 1–2. The doctor, whose name she did not recall, asked her what her pain was. *Id.* at 2. Ms. A.B. told the doctor that she had previously been treated by a doctor in North Carolina for headaches caused by nerve damage incurred in an automobile accident; the doctor then agreed to prescribe for her, ninety tablets of hydrocodone/apap.[7] *Id.* Ms. A.B. further stated that the doctor did not discuss with her how her progress would be monitored, what to do if she experienced side effects, and how to contact him in an emergency. *Id.*

Another DI interviewed K.B., who had also obtained a combination drug containing hydrocodone through the Liberty Web site. *See* GX 21; Tr. 116–151. K.B. told the DI that she had become aware of Liberty through a pop-up ad and that she went to the Web site and filled out a questionnaire. Tr. 117. On August 4, 2004, K.B. sent Liberty an MRI report showing that she had a herniated disk. *Id.* at 118; RX 15, at G0190–91. ''A couple of days later,'' Tr. 118, K.B. was contacted by a woman who stated that she was a representative of Liberty. *Id.* According to K.B., the woman performed a consultation and told K.B. that a prescription had been approved by Respondent.[8] *Id.* at 118 & 131.

On or about December 15, 2004, K.B. received ninety tablets of Lortab (hydrocodone/apap (10/500)), a schedule III controlled substance, pursuant to a prescription issued by Respondent. *Id.* at 119–20, GX 21; *see also PDR* at 3240. K.B. received approximately twenty-five prescriptions through Liberty, the majority of which were authorized by Respondent. Tr. 132, 141, 148, 150. K.B. never had a conversation with Respondent, *id.* at 140, and had no contact with Liberty with respect to any of the subsequent orders she placed other than when she contacted the Web site to determine the status of an order. *Id.* at 121. K.B. further told the DI that she became addicted to hydrocodone. *Id.* at 122. K.B. also obtained drugs from another Web site during a portion of the period in which she obtained drugs through Liberty; her primary care physician did not know that she was acquiring drugs through the internet. *Id.* at 120–22.[9]

DEA Investigators also attempted to contact the persons identified in Respondent's Exhibits 19–45, as patients who were denied prescriptions. Tr. 470. The DIs could not contact most of the individuals and were able to speak with only eight of them. *See id.* at 634–44. Of these eight persons, the record establishes that Respondent prescribed to only one of them, Ms. S.A. *See* GX 26.[10] More specifically, on

prescription he issued during a defined period of time.

[5] Respondent testified that ''on the average,'' the physical exam had to be no more than ''approximately six months'' old, but that ''sometimes we required records more recent than six months and sometimes patient[s] could have records up to eight months [old] or more.'' Tr. 571. Respondent maintained, however, that in each instance, he would have a conversation with a patient before prescribing and that this provided ''an independent basis'' to determine whether the patient's symptoms were continuing.'' *Id.* at 572.

Moreover, the ''Consent for Treatment'' forms that are in several patient files indicate that a patient could receive the ''first prescription with an agreement that I will fax my medical records and a photo ID * * * within 27 days and before my next prescription is due for refill.'' RX 11, at G0156 (signed on ''12/8/04''); RX 10, at G0151 (signed on ''12/5/05''). This suggests that in some instances, Respondent may have issued prescriptions without even reviewing a patient's records.

[6] Those records included a progress note dated September 16, 2004, which indicated that A.B.'s physician had prescribed ninety Lorcet (10/650 mg.), with no refills. RX 6, at G0050. Lorcet is a schedule III controlled substance which combines hydrocodone with acetaminophen. *See PDR,* at 1287.

[7] Apap is an abbreviation for acetaminophen.

[8] Having found that K.B. faxed a copy of the MRI report on August 4, 2004, four months before Respondent began his contract with Liberty, I find that Respondent did not issue the initial prescription which K.B. received from Liberty. I do find, however, that Respondent issued a prescription to K.B. on December 15, 2004. *See* GX 21.

[9] Investigators also attempted to interview several other persons whose names were listed on the prescription sheets found during the trash runs. Some of the individuals could not be located, Tr. 162 & 165, others were uncooperative. *Id.* at 163. Investigators were unable to contact the persons named on the prescription labels because the labels did not contain addresses. *Id.* at 169.

[10] For example, while a DI spoke to L.L.'s daughter (RX 20), she did not know whether her mother ever spoke with Respondent. Tr. 635. R.T. (RX 24) stated that he never received drugs from Liberty, Tr. 637, and there is no evidence to the contrary. While M.A. stated that he did not speak with Respondent, *id.* at 637–38, documentary evidence indicated that Respondent did not issue a prescription because he felt that M.A. ''IS WANTING MEDS FOR SOMEONE ELSE.'' RX 26. Again, there is no evidence establishing that Respondent issued a prescription to M.A.

A.F. (RX 27) acknowledged taking Vicodin and sending medical records somewhere. Tr. 638. He did not, however, remember where, *id.;* and in any event, there is no evidence that Respondent prescribed to him. M.K. (RX 31) acknowledged receiving hydrocodone from Liberty ten times, that he received his first order without a consultation, and that his ''subsequent orders usually did involve a two to three minute conversation with someone claiming to be a physician or a physician's assistant.'' Tr. 640. Again, there is no evidence establishing that Respondent (as opposed to other doctors who worked for Liberty) prescribed to him. RX 31.

Continued

December 7, 2004, Respondent prescribed to S.A. ninety tablets of hydrocodone/apap (7.5/750 mg.).

Ms. S.A. stated that she ordered hydrocodone from Liberty ''at least ten times and that she did not speak to any physician on the first two occasions.'' [11] Tr. 643. S.A. further stated that on subsequent orders, she had ''very short conversations lasting approximately one minute or less,'' but could not recall the name of any person she had talked to. *Id.* at 643–44.

Respondent testified that S.A.'s medical record supported the prescription he issued and that the drug and dosage he prescribed was appropriate for her condition. Tr. 451. Yet the evidence suggests that the most recent medical report available to Respondent was an ''Operative Report'' for a procedure which had been performed nearly eight months earlier. *See* RX 7, at G0112. Moreover, Respondent offered no explanation as to why S.A.'s condition was of such a nature as to justify prescribing based on an eight-month-old report.

A DI also interviewed R.Z., to whom Respondent prescribed 90 tablets of Vicodin ES (7.5/750 mg.), on January 5, 2005. GX 18. R.Z. told the DI that she had become aware of Liberty in approximately November 2004; someone at Liberty put R.Z. in contact with a man ''who claimed to be a doctor.'' Tr. 72. R.Z. could not, however, remember the name of the doctor, but did recall having a phone conversation of ''approximately ten minutes'' duration with him in which she was asked questions about her condition, what type of pain she had, what type of pain medication she needed, how she tolerated pain medications, and her blood pressure. *Id.* at 73. The doctor then told R.Z. that he would prescribe to her ninety tablets of Vicodin. *Id.* at 74. R.Z. also told the DI that she had faxed to Liberty an x-ray report which showed that she had a bulging disk.[12] *Id.* R.Z. further told the DI that she had received from Liberty monthly prescriptions for ninety tablets of Vicodin over ''a thirteen to fourteen-month period.'' [13] *Id.* at 77–78.

Respondent testified that the prescription he issued was consistent with the findings contained in the x-ray report. *Id.* at 459; RX 10, at G0154. The x-ray report contains the notations: ''Record Received on 1/31/05,'' and ''Verified on 1/31/05 By MW.'' *Id.* In addition, the record includes a handwritten note dated ''1/31/05,'' which states in relevant part: ''Attention Leisha, Here are the results of the xray I had on my back. * * * I would like my refill sent when it becomes time to do so.'' *Id.* at G0153. Respondent further testified that ''I don't see a physical exam here but it would be something that we would require.'' Tr. 459. He also maintained that in order for R.Z. to get an x-ray, ''she had to have some history,'' because ''you can't refer yourself for an x-ray.'' *Id.*

Even so, that a patient needs a referral to obtain an x-ray, does not establish that Respondent reviewed R.Z.'s history and a physical exam report before he prescribed to her. Indeed, the absence of a physical exam report in R.Z.'s file is consistent with her statement that she sent in only the x-ray report. *See* Tr. 89. I therefore find that contrary to Respondent's testimony, he did not review a physical exam report before prescribing to R.Z.[14]

As for Respondent's statement that the Vicodin prescription he issued to R.Z. was consistent with the findings of the x-ray report, the evidence shows that he issued the prescription on January 5, 2005, nearly four weeks before Liberty received the x-ray report. Respondent therefore could not have issued the prescription on the basis of the report.

With respect to K.B. (whose interview with a DI is described above), Respondent also maintained that a report for an MRI which had been done ten months earlier, *see* RX 15, at G0190; established that the hydrocodone prescription he issued was appropriate. Tr. 467. Respondent then testified that Respondent ''had been on Toradol and Ultram and had not received results.'' *Id.* Continuing, Respondent stated that ''[s]he also had gotten Lortab it seems. If you look at G0195, in the middle where it says 2/19/04, it says renewed her Lortab and Flexeril.'' *Id.* at 467–68.

Notably, both pages G0194 and G0195, which appear to contain progress notes of various visits K.B. made to an orthopedic clinic between January 15, 2003, and November 29, 2004, have the notations: ''Record Received on 1/31/05,'' and ''Verified on 1/31/05 By MW.'' RX 15, at G0194–95. Moreover, each page has a header indicating that it was faxed on January 31, 2005. *See id.* As found above, Respondent issued the prescription to K.B. on December 15, 2004, approximately six weeks before these documents were faxed to Liberty. GX 21. Here again, Respondent could not have relied on the documents when he issued the prescription to K.B., notwithstanding his testimony that ''we would require'' a physical exam. Tr. 459.[15]

M.B. (RX 33) acknowledged that he received hydrocodone from Liberty four times and ''recalled talking to someone at the Liberty Meds Web site but [did not] remember who.'' Tr. 641. K.K. (RX 36) acknowledged ordering hydrocodone ''four or five'' times, but identified a different doctor as the prescriber. Tr. 641–42. Similarly, T.A. (RX 37) stated that he had ordered hydrocodone from Liberty ''two or three'' times, and that he had conversations with either a doctor or physician's assistant lasting ''two to three minutes,'' but could only identify a different doctor as the person he spoke to. *Id.* at 642. As above, there is no evidence establishing that Respondent prescribed to either M.B. or T.A.

[11] Here again, the evidence shows that S.A. faxed her records to Liberty on August 25, 2004, four months before Respondent began his contract with Liberty. RX 7, at G0113–14.

[12] R.Z. stated that she had sent in only the x-ray report and filled out an online questionnaire. Tr. 89. R.Z. was never directed to obtain further tests (such as a new x-ray), and stated that she did not believe that Liberty ever contacted her primary doctor. *Id.* at 79, 89–90.

[13] R.Z. also stated that she had conversations every three to four months regarding her condition with a woman from Liberty who claimed to be a physician. Tr. 76, 87. R.Z. testified that she had a single conversation with a male caller. *Id.* at 96.

[14] The ALJ noted that it ''is unclear * * * whether or not the Respondent had access to, or actually reviewed medical records prior to prescribing controlled substances to any of Liberty's customers discussed at the hearing.'' ALJ at 19 n.10. While this is correct with respect to some patients, with respect to R.Z., it is clear that Respondent prescribed without having any medical records that supported the prescription.

In the context of discussing his prescribing through Liberty, Respondent also testified that ''I will always'' have some ''data'' and ''I won't just place them on a prescription.'' Tr. 442. Perhaps Respondent was testifying about his prescribing practices at the time of the hearing. Or perhaps he considered the answers Liberty's customers gave to the questionnaires to be ''data.'' In any event, the evidence establishes that he prescribed to R.Z. without either reviewing a physical exam report or the x-ray report.

[15] As found above, Respondent never spoke with K.B. Tr. 140. During the period she was obtaining controlled substances from Liberty, K.B. was under the care of another physician; K.B., however, never told the latter physician that she was receiving drugs from Liberty. *Id.* at 122, 142–43.

Respondent maintained that Liberty was ''unable to provide all the records'' because of problems it was having with its ''IT person.'' Tr. 410. However, the files for some of the patients appear extensive, *see* RXs 3 (22 pages), 5 (18 pages), 6 (64 pages), 7 (17 pages), & 14 (23 pages), thus prompting the question of why Liberty was able to provide so much documentation for these patients but not for some of the others. Moreover, the patient files indicate that the patients almost always faxed or mailed their records to Liberty. Thus, even if the records were scanned into Liberty's computer system, Respondent offered no evidence to establish what happened to the original records. Finally, there is no evidence that Respondent requested a subpoena for the records. While the ALJ apparently found that Respondent credibly testified that he did not receive all of the information he requested, ALJ Dec. at 13 n.3., I conclude that the patient files Respondent introduced into evidence fairly reflect the patient files as obtained by Liberty.

The ALJ further reasoned that Respondent's testimony supported ''the requirement that [he] maintain his own patient records.'' Id. It is further noted that under the New Jersey Board of Medical Examiners' regulation which governs the prescribing of controlled substances, ''[t]he practitioner shall keep accurate and complete

Other Patients

On January 5, 2005, Respondent issued a prescription to K.A., a Texas resident, for ninety tablets of hydrocodone/apap (10/500mg). GX 27. The record contains extensive progress notes showing that K.A. was being treated by a San Antonio, Texas pain management specialist during 2004 and 2005 for neck pain.[16] See RX 3. Respondent testified that K.A. ''has various different problems * * * that would cause one to have a ton of severe pain.'' Tr. 426. Respondent testified that based on his review of the record, the medication and dosage he prescribed was appropriate. *Id.* at 432. Respondent offered no testimony, however, as to whether he contacted the pain management specialist who was treating K.A. *See generally id.* at 426–32.

On December 20, 2004, Respondent prescribed to P.G., a Minnesota resident, ninety tablets of hydrocodone/apap (10/500 mg.) with one refill. GX 19. Although the most recent progress note in P.G.'s record, which was dated April 13, 2004, indicated that he had ''[c]hronic low back with right lower extremity radicular pain,'' and that his local physician had issued him a prescription for twenty tablets of Percocet p.r.n., P.G.'s physician further observed that ''[l]ong-term use of narcotics for back pain is not in his best interest and therefore he is given only 20 tablets at this time.'' RX 4, at G0024. While Respondent testified that his prescription was appropriate, Tr. 435, when asked on cross-examination whether the eight-month-old progress note was of sufficient recency to make a diagnosis, he testified: ''It really depended also on the patients and the physical findings but this does seem like it was two months later than we usually accept. * * *'' *Id.* at 525.

On January 5, 2005, Respondent prescribed to D.C., a resident of Georgia, ninety tablets of hydrocodone/apap (10/325 mg.). GX 24. The most recent progress note in her file prior to this prescribing was dated June 24, 2004, and indicated that the physician's impression was: ''Probable right C7 radiculopathy.'' RX 5, at G0035. When asked by his counsel whether this would ''indicate that pain should be in a particular area?,'' Respondent answered: ''Yes, she should have the pain in the right upper extremity. *If I had spoken* with this person about giving her a treatment, I would have first tried to elicit where her pain was coming from.'' Tr. 437 (emphasis added). Respondent then discussed the findings of a physical exam which occurred on April 21, 2005, and which he obviously could not have relied on when he issued the prescription three months earlier. *See id.* at 437–38.

Next, Respondent maintained that he would try to confirm with the patient whether their reported pain matched with ''what it should be.'' *Id.* at 439. He also maintained that his prescribing was consistent with the drug (Vicodin 7.5) that the physician, who physically examined her three months later, had prescribed. *Id.* at 440; RX 5, at G0032.

On cross-examination, Respondent acknowledged that while the medical records showed that D.C. had been by an orthopedist and neurologist, neither had referred her to him. Tr. 527. When asked what his treatment plan was for D.C., Respondent could not recall. *Id.* He also did not refer her to a pain clinic near where she lived. *Id.* at 528.

On December 15, 2004, Respondent prescribed to S.K., a resident of Texas, ninety tablets of hydrocodone/apap (10/325mg.), with one refill. GX 22. Again, Respondent testified that the prescription he wrote ''would be consistent with what she's experiencing on physical exam here.'' Tr. 454. While Respondent testified that S.K.'s records ''were accessed through PSDoctor,'' *id.* at 455; the only medical exam report in S.K.'s file is dated ''6/1/05,'' and was faxed on June 10, 2005. *See* RX 8, at G0129–31. Respondent therefore could not have relied on the report in issuing the prescription.

On January 6, 2005, Respondent prescribed to S.B., a South Carolina resident, ninety tablets of Lortab (10/500mg.). GX 27. SB's patient file contains only three documents: a copy of her driver's license, a ''consent for treatment'' form dated ''12/8/04,'' and the results of a blood test taken on October 28, 2003. *See* RX 11. Respondent maintained that S.B.'s file was ''incomplete,'' and that ''she would'' have been asked to provide other data. Tr. 460. The ALJ did not, however, make any findings regarding the credibility of Respondent's testimony pertaining to S.B. In light of the other instances in which Respondent prescribed even though a patient's file was missing information, I find that it is more likely than not that he prescribed to S.B. without obtaining any additional medical documentation.

On January 5, 2005, Respondent prescribed to K.S., a resident of Texas, ninety tablets of hydrocodone/apap (10/500) with one refill. GX 29. K.S.'s records include extensive progress notes which show that she had last been seen by a physician on September 28, 2004, and had last been prescribed a controlled substance (codeine/apap) on December 20, 2004. RX 14, at G0182.

Respondent testified that ''[i]t seemed like she had really good follow-up here according to these progress notes,'' Tr. 462–63, and that the prescription he wrote ''would be appropriate for'' the condition documented in the record. *Id.* at 465. Respondent offered no explanation as to why he was prescribing to a patient who had received a controlled substance prescription from another physician only two weeks earlier. Moreover, given his acknowledgment that K.S.'s records showed that she was receiving good follow-up care, he offered no testimony that he had contacted K.S.'s physician to coordinate her care and ensure that she was not engaged in doctor shopping.[17]

On January 3, 2005, Respondent prescribed ninety tablets of hydrocodone/apap (10/325 mg.) to E.M., a New Hampshire resident.[18] Beside two copies of E.M.'s driver's license, her patient file contains two forms: (1) A Family and Medical Leave Act certification that E.M. had a serious illness, and (2) an Office of Workers Compensation Programs' form documenting a medical examination (performed on October 1, 2004) and diagnosis and supporting the need for certain restrictions on E.M.'s work-related duties. *See* RX 16 at G0200–01. The latter form indicates that E.M. had low back pain and tendonitis in her hand and shoulder. *Id.* at G0201. The form, however, contains no

records.'' N.J. Adm. Code 13:35–7.6(g) (emphasis added). There is, however, no requirement under federal law that an ''individual practitioner * * * keep records of controlled substances in Schedules II, III, IV, and V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.'' 21 CFR 1304.03. I do not decide whether it was permissible under the New Jersey regulation for Respondent to maintain medical records through the Liberty Web site.

[16] Based on the progress notes as well as K.A.'s Texas driver's license, I find that K.A. was a resident of Texas. *See* RX 3, at G0001.

[17] K.S.'s file includes a letter which forwarded some records to Liberty. On the letter, there is a handwritten notation that the records had been reviewed, but that the clinic, which treated K.S., was ''closed for lunch.'' RX 14, at G0170.

[18] While the ALJ found that E.M. was a Texas resident, ALJ at 27 (FOF 90), RX 16 includes copies of E.M.'s driver's license which appears to indicate that she was a New Hampshire resident. Moreover, the fax header indicted that the documents were faxed to Liberty from a phone number with a 603 area code, which is an area code for New Hampshire.

The ALJ also noted that the prescription label (GX 29) was dated ''1/3/04.'' ALJ at 27 n.18. Based on the undisputed evidence that Respondent did not commence working for Liberty until December 2004, the ALJ found that the actual date of the prescription was January 3, 2005. Id.; *see also* Tr. 535. I adopt this finding.

documentation of her vital signs. *See id.* Moreover, when asked by his counsel whether the prescription he issued to E.M. was appropriate, Respondent answered that ''we do prescribe medicine for'' tendonitis and carpal tunnel, but that ''it seems like this chart is incomplete,'' Tr. 469, and that ''[i]t might have been missing EMGs or other things.'' *Id.* at 536. He again testified that it was his practice to look for other data before prescribing such as ''radiographic or EMGs.'' *Id.* at 537. While Respondent acknowledged that E.M.'s record did not have any such data, he then maintained that ''this might be an incomplete record.'' *Id.*

Yet several of the documents contained in E.M.'s patient file indicate that they were faxed to Liberty on December 31, 2004. *Id.* at G0202–03.[19] Again, Respondent offered no credible explanation as to why E.M's file as turned over to him had these documents (which Liberty obtained shortly before he issued the prescription to her) but not the others which ''might have been missing.'' *Id.* at 536. I therefore find that there were no such additional documents in E.M.'s patient file when he prescribed to her.

On December 15, 2004, Respondent issued to L.F., a resident of New Jersey, a prescription for ninety tablets of hydrocodone/apap (7.5/750mg.) with one refill. GX 23. Respondent testified that L.F.'s records showed that his physician ''did a physical exam,'' and that ''[t]here is also one on 10/8/04 by the same physician which was consistent with what was found on 10/8/03, * * * you can see the same vertebral bodies marked off, so it's very consistent with what the patient is having.'' Tr. 456. Respondent maintained that L.F. had a condition which ''merit[ed] intervention for pain,'' *id.,* and that the dosage he prescribed was consistent with his condition. *Id.* at 457.

On cross-examination, the Government asked Respondent to compare the handwriting of the two reports of ''Examination Findings,'' which were dated ''10/8/03'' and ''10/8/04'' respectively. *Id.* at 530; *see also* RX 9, at G0142 & G0145. Respondent acknowledged that ''[a]ll the handwriting [on the two reports] is in exactly the same position.'' Tr. 530. Respondent testified, however, that when he prescribed to L.F., he ''did not'' recognize that one of the documents had probably been falsified. *Id.* Moreover, none of the documents in L.F's file contained his vital signs. *See* RX 9. And as with the other Liberty patients, Respondent did not physically examine L.F., even though he lived in northern New Jersey, and near where he practiced.[20] *See id.* at G0147, GX 23.

On December 7, 2004, Respondent prescribed to L.W., another New Jersey resident, ninety tablets of hydrocodone/apap (10/325 mg.) with one refill. GX 20. L.W.'s patient file consisted of three pages: a progress note dated June 17, 2004, a sheet indicating that L.W. was faxing her driver's license, and a blurred copy of a driver's license. *See* RX 12. The progress note lists several diagnostic codes and under the handwritten notation of ''CODES,'' states: ''polycystic ovaries,'' ''adhesions,'' and ''pelvic pain.'' RX 12, at G0158. Next to the column for history, the document includes a notation of ''Percocet # 120.'' *Id.*

With respect to L.W., Respondent maintained that ''[t]hese patients have pelvic pain generally to the lower abdomen.'' Tr. 461. Respondent then testified that ''[t]here is no radiological exam that you would do to tell you anything differently[,] [b]ut obviously they know she has polycystic ovaries according to this physician's history and physical.'' *Id.* Respondent testified that the prescription was appropriate for a patient with this condition, and that he believed someone had verified L.W.'s identity with her physician because ''her license was blurred.'' *Id.* Respondent did not, however, testify that he called Respondent's physician.

Respondent's Other Evidence

Respondent also testified that he had proposed that Liberty use a narcotic contract under which a patient was required to agree not to give or sell his drugs to others, as well as not to seek drugs from other physicians. Tr. 384; *see also* RX 11, at G0156. According to the contract, a patient would be dismissed for failing to comply. Tr. 384. Yet Respondent was not ''sure how'' Liberty determined whether a patient was obtaining drugs from other sources such as another Web site. *Id.* at 385.

Respondent gave conflicting testimony as to whether he had prescribed oxycodone to Liberty's patients. First, he testified that he did so at a frequency that was ''pretty much equal'' to that of his hydrocodone prescribing. *Id.* at 585. Later, however, when Respondent was asked by the ALJ as to whether he ever recalled prescribing schedule II controlled substances to a Liberty patient, he appeared to backtrack from this testimony answering: ''Yes, there was a patient in our system you mean.'' *Id.* at 605.[21]

Respondent further testified that he believed that his prescribing practices complied with New Jersey's regulations and were consistent with a 2001 DEA Guidance Document. With respect to the New Jersey regulation, which provides that ''a practitioner shall not dispense drugs or issue prescriptions to an individual, * * * without first having conducted an examination, which shall be appropriately documented in the patient record,'' except for in six defined circumstances, N.J. Admin Code § 13:35–7.1A, Respondent testified that exceptions three (''[f]or continuation medications on a short term basis for a new patient prior to the patient's first appointment'') and four (''[f]or an established patient who, based on sound medical practice, the physician believes does not require a new examination before issuing a new prescription''), ''could apply.'' Tr. 589; *see also* N.J. Admin. Code § 13:35–7.1A(b)(3) & (4). Respondent did not, however, identify any patient he prescribed to over the

[19] Again, while Respondent testified that the records that he requested from Liberty were incomplete, he offered no explanation as to why Liberty was able to provide some records for a patient but not the missing ones. Moreover, the evidence indicates that many of the patients faxed their records to Liberty. Even if these records were scanned into a database, Respondent offered no evidence as to what became of the original documents.

[20] Respondent practiced pain management at a clinic in Livingston, New Jersey. RX 1; ALJ at 5. L.F. lived in Wallington, and L.W. lived in Warren, New Jersey. RXs 20 & 23. In accordance with 5 U.S.C. § 556(e), I take official notice of the fact that all three of these cities are located in northern New Jersey. *See* 5 Rand McNally, *Business Traveler's Road Atlas 62,* 68–69 (1994). Notwithstanding the proximity of his clinic to L.F.'s and L.W.'s residences, Respondent did not require them to appear for a physical examination.

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). In accordance with the Administrative Procedure Act and DEA's regulation, 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). Accordingly, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of the order.

[21] The ALJ also found that Respondent authorized refills of schedule II controlled substances and that he ''was unaware of the forms needed to actually prescribe a schedule II controlled substance.'' ALJ 14 (citing Tr. 604–05). Respondent testified, however, that he was not ''aware of'' ''a requirement for a Schedule II substance to be prescribed on a specifically identified form.'' Tr. 605.

Except for in an emergency situation, the dispensing of a schedule II controlled substance requires ''a written prescription signed by the practitioner,'' and the ''original written, signed prescription [must be] presented to the pharmacist for review prior to the actual dispensing of the controlled substance.'' 21 CFR 1306.11(a). However, no special form is required to prescribe a schedule II drug and Respondent's testimony was correct. Federal law does, however, prohibit the refilling of a schedule II controlled substance. 21 U.S.C. 829(a).

Internet who later came in for an appointment. Nor did he testify that any of the persons whose names were found on the prescription sheets and labels was an established patient.

Respondent also maintained that his Internet prescribing was consistent with the statements in this Agency's Guidance Document, *Dispensing and Purchasing Controlled Substances Over the Internet,* 66 FR 21181 (2001). More specifically, Respondent maintained that his practices were consistent with the Guidance Document because ''[w]e always had the patient's chief complaint, history was taken, a physical examination was done by another physician, and we collected all the evidence together and then I made my decision based on all the evidence including the radiographical evidence.'' Tr. 417. Respondent further maintained that ''it was not'' his practice to prescribe based solely on Internet correspondence. *Id.*

Finally, Respondent's counsel read to him the following question and answer from the Guidance Document:

I am a Physician. Does the need for a Physical Exam Mean that I Cannot Engage in Telemedicine and Prescribe Controlled Substances?

No, DEA does not intend to limit the ability of doctors to engage in telemedicine. If the patient cannot travel to your office, but you supervise an exam given by a nurse or other professional, you can then prescribe the needed medications based on the results, to the extent that State law allows. In this case, your decision on the appropriateness of the medication is based on facts (symptoms, blood pressure, etc.) that have been verified by a qualified third party and observed by you electronically.

GX 6, at 5; Tr. 418.[22]

Respondent was then asked by his counsel whether his Internet practice was consistent with this statement. Tr. 418–19. Respondent answered: ''Yes. In fact, we've exceeded those, also communicating with the physicians, not just electronically but via telephone.'' *Id.* at 419. Respondent then explained that ''the radiographical reports were read by a physician radiologist, the physical exams were done by another physician, so sometimes we have a couple of physicians involved in the process. *Id.*[23]

Respondent did not, however, identify a single instance in which he supervised and observed a physical exam as it was being performed by another qualified medical professional. Moreover, Respondent did not have any recollection as to having spoken to any of the physicians who were identified in the patient records that were introduced into evidence in this proceeding. *Id.* at 573. Finally, he was unaware as to whether any of the patient notes he made were ever sent by Liberty to the primary care physicians of those he prescribed to. *Id.* at 614. He also never gave written referrals for Liberty patients to see local doctors. *Id.* at 512.

Respondent testified that he had stopped performing telemedicine consultations for Liberty in late December of 2005. *Id.* at 487. He also represented that it was not his ''present intention'' to resume internet based prescribing. *Id.*

As noted above, Respondent introduced into evidence a number of printouts from Liberty's software with the heading ''Patient Information for Appointment.'' *See* RXs 19–45. These printouts establish that in several instances, patients were denied drugs because they were receiving them from other sources. *See* RXs 19, 21, 27, 32, 33, 39. Moreover, in other instances Respondent did not approve a prescription, *see* RX 23, 34, 43; and in at least one case, Respondent denied a prescription because he felt the person ''was wanting meds for someone else.'' RX 26. Moreover, the printouts suggest that in other instances, either Liberty or Respondent denied requests because the person was seeking the drugs too soon, RX 22, 35, 36; the patient's records had not been verified, RX 28; or the patient needed to be evaluated and send in records before Respondent approved a refill. RX 42 & 44. Only one of these printouts, however, corresponds with a patient (S.A.) who was identified above as having received a prescription which was issued by Respondent.[24] *Compare* RX 44 with GX 26.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that a registration to ''dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). With respect to a practitioner, the Act requires the consideration of the following factors in making the public interest determination:

(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, 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 matter, it is undisputed that neither the State of New York nor the

[22] At the hearing, Respondent's counsel slightly altered the text of the answer published in the Guidance Document. The alteration did not, however, materially change the meaning of the answer.

[23] Respondent also testified that the first time he saw the 2001 Guidance Document was at the hearing. Tr. 522.

[24] The National Center on Addiction and Substance Abuse (CASA) has reported that ''[t]he number of people who admit abusing controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003.'' National Center on Addiction and Substance Abuse, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.* 3 (2005) (GX 3). Moreover, ''[a]pproximately six percent of the U.S. population (15.1 million people) admitted abusing controlled prescription drugs in 2003, 23 percent more than the combined number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (328,000).'' *Id.* Relatedly, ''[b]etween 1992 and 2003, there has been a * * * 140.5 percent increase in the self-reported abuse of prescription opioids''; in the same period, the ''abuse of controlled prescription drugs has been growing at a rate twice that of marijuana abuse, five times greater than cocaine abuse and 60 times greater than heroin abuse.'' *Id.* at 4.

CASA has further reported that teenagers ''represent an especially vulnerable group,'' because ''[t]eens may view prescription drugs as relatively safe either when abused alone or in combination with alcohol or other drugs.'' *Id.* According to CASA, ''[i]n 2003, 2.3 million teens ages 12 to 17 (9.3 percent) reported abusing a controlled prescription drug in the past year; 83 percent of them reported abusing opioids.'' *Id.* Moreover, ''[b]etween 1992 and 2002, the number of [first time] teenage prescription opioid abusers increased by 542 percent.'' *Id.* at 35.

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

State of New Jersey has taken action against Respondent's medical license (factor one). It is also undisputed that Respondent has not been convicted of an offense related to controlled substances under federal or state law (factor three).[25] This proceeding focused, however, on Respondent's experience in dispensing controlled substances and his record of compliance with applicable laws. As discussed below, the evidence pertaining to these factors is disturbing and establishes—at a minimum—that Respondent committed numerous violations of both Federal and state laws.

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

Under a longstanding DEA regulation, a prescription for a controlled substance is not ''effective'' unless it is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). This regulation further provides that ''an order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning and intent of [21 U.S.C. 829] and * * * the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' *Id.* As the Supreme Court recently explained, ''the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135 (1975)).

Under the CSA, it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act ''in the usual course of * * * professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Moore,* 423 U.S. at 141–43. The CSA, however, generally looks to state law to determine whether a doctor and patient have established a bonafide doctor-patient relationship. *See Kamir Garces-Mejias,* 72 FR 54931, 54935 (2007); *United Prescription Services, Inc.,* 72 FR 50397, 50407 (2007); *Dispensing and Purchasing Controlled Substances Over the Internet,* 66 FR at 21182–83.[26]

Moreover, ''[a] physician who engages in the unauthorized practice of medicine'' under state laws ''is not a 'practitioner acting in the usual course of * * * professional practice''' under the CSA. *United Prescription Services,* 72 FR at 50407 (quoting 21 CFR 1306.04(a)). As explained therein, this rule is supported by the plain meaning of the Act, which defines the ''[t]he term 'practitioner' [to] mean[] a physician * * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * * to * * * dispense * * * a controlled substance,'' 21 U.S.C. 802(21), and ''[t]he term 'dispense' [to] mean[] to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner.'' *Id.* section 802(10). *See also id.* section 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 I noted in *United Prescription Services*, shortly after the CSA's enactment, the Supreme Court explained that ''[i]n the case of a physician [the Act] contemplates that *he is authorized by the State to practice medicine* and to dispense drugs in connection with his professional practice.'' *Moore*, 423 U.S. at 140–41 (emphasis added) (quoted at 72 FR 50407). A controlled-substance prescription issued by a physician who lacks the license or other authority required to practice medicine within a State is therefore unlawful under the CSA. *See* 21 CFR 1306.04(a) (''An order purporting to be a prescription issued not in the usual course of professional treatment * * * is not a prescription within the meaning an intent of'' the CSA); *cf.* 21 CFR 1306.03(a)(1) (''A prescription for a controlled substance may be issued only by an individual practitioner who is * * * [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession[.]'').[27]

Under the regulation of the New Jersey Board of Medical Examiners, ''a practitioner shall not dispense drugs or issue prescriptions to an individual * * * without first having conducted an examination, which shall be appropriately documented in the patient record.'' N.J. Admin Code § 13:35–7.1A(a). This rule further requires that ''[a]s part of the patient examination, the practitioner shall'':

1. Perform an appropriate history and physical examination;
2. Make a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good medical care;
3. Formulate a therapeutic plan and discuss such plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient; and
4. Ensure the availability of the physician or coverage for appropriate follow-up care.

Id.

It is undisputed that Respondent did not perform a physical examination on any of the Liberty patients he prescribed to, including those who were New Jersey residents. Instead, Respondent asserted that two exceptions provided in the New Jersey rule ''could apply'' to his internet prescribing. Tr. 589. The first of these authorizes the prescribing of ''continuation medications on a short term basis for a new patient prior to the patient's first appointment''; the second authorizes prescribing ''[f]or an established patient who, based on sound medical practice, the physician believes does not require a new examination before issuing a new prescription.'' N.J. Admin Code 13:35–7.1A(b)(3) & (4).

As the record establishes, none of Respondent's Liberty patients were ever expected to see him for a ''first appointment,'' and none did. Moreover, Respondent offered no evidence that any of his Liberty patients were his ''established patients.'' [28]

[25] Under settled precedent, neither of these factors is dispositive. *See Edmund Chein,* 72 FR 6580, 6590 n.22 (2007); *Mortimer B. Levin,* 55 FR 8209, 8210 (1990).

[26] On October 15, 2008, the President signed into law, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. 110–425, 122 Stat. 4820 (2008). Section 2 of the Act prohibits the dispensing of a prescription controlled substance ''by means of the Internet without a valid prescription,'' and defines, in relevant part, the ''[t]he term 'valid prescription' [to] mean[] a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by * * * a practitioner who has conducted at least 1 in-person medical evaluation of the patient.'' 122 Stat. 4820. Section 2 further defines ''[t]he term 'in-person medical evaluation' [to] mean[] a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.'' *Id.* These provisions do not, however, apply to Respondent's conduct.

[27] 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).

[28] I acknowledge that in Gonzales, the Supreme Court stated that ''[a]s for the federal law factor, though it does require the Attorney General to decide '[c]ompliance' with the law, it does not suggest he may decide what the law says. Were it otherwise, the Attorney General could

In his brief, Respondent also contends that New Jersey's exception ''[f]or a patient examined by a healthcare professional who is in collaborative practice with the practitioner'' also applies. *Id.* § 13:35–7.1A(b)(5); *see* Resp. Prop. Findings 52. However, with respect to this exception, Respondent testified that ''I don't know what collaborative means there,'' Tr. 589, and in any event, there is no credible evidence that Respondent collaborated with any of the practitioners who may have previously examined the Liberty patients. *Id.* at 573 & 614.

Respondent thus failed to establish a legitimate doctor-patient relationship under the New Jersey regulation. I therefore further hold that Respondent's prescriptions to the Liberty patients were not ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice,'' 21 CFR 1306.04(a) and thus violated the CSA as well.

Respondent's prescriptions also violated numerous laws of the States where the patients were located. Respondent prescribed controlled substances to two residents of Georgia, A.B. and D.C. Under the rules of the Georgia Composite State Board of Medical Examiners, it is ''unprofessional conduct'' to ''[p]rovid[e] treatment and/or consultation recommendations via electronic or other means unless the licensee has performed a history and physical examination of the patient adequate to establish differential diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended.'' Ga. Comp. R. & Regs. 360–3.02(6).[29] Moreover, Respondent violated Georgia law because he engaged in the unlicensed practice of medicine. *See* Ga. Code Ann. § 43–34–31.1.[30]

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

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

Respondent prescribed a controlled substance to R.Z., a Massachusetts resident. Massachusetts law follows nearly verbatim the CSA's prescription requirement. *Compare* Mass. Gen. Laws ch. 94C, § 19(a), *with* 21 CFR 1306.04(a). In December 2003, the Massachusetts Board of Registration in Medicine issued the following interpretation of the State's prescription law:

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

Commonwealth of Massachusetts, Board of Registration in Medicine, *Policy 03–06 INTERNET PRESCRIBING* (Adopted Dec. 17, 2003).[31] As the Board's interpretation makes plain, Respondent acted outside of the usual course of professional practice when he prescribed a controlled substance to R.Z., and therefore violated both Massachusetts law and the CSA.[32]

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authoritatively interpret 'State' and 'local laws,' which are also included in 21 U.S.C. 823(f), despite the obvious constitutional problems in his doing so.'' 546 U.S. at 264.

In determining whether Respondent established a legitimate doctor-patient relationship with the Liberty patients, this Agency must necessarily examine state law. Moreover, the requirement that a practitioner must generally perform a physical exam in order to properly diagnose a patient is one which is universally accepted throughout the medical community and by state medical boards. *See* American Medical Association, *Guidance for Physicians on Internet Prescribing* (GX 8); *see also* Federation of State Medical Boards, *Internet Prescribing Language By State* (available at *http://www.fsmb.org/ncip_resources.html/*).

Notably, Respondent cites no decision of either the New Jersey Board of Medical Examiners or the New Jersey courts holding that conduct similar to his internet prescribing was lawful under the exceptions which he contended ''could apply.'' Tr. 589. If Respondent had, this Agency would, of course, respect that decision.

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

[30] This statute provides:

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

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

[31] The ALJ also noted that Respondent was required to be licensed to practice medicine in Massachusetts and that ''[o]nly a practitioner who is authorized to prescribe controlled substances may do so.'' ALJ at 39 (citing Mass. Gen. Laws. ch. 94C, § 18(a)). In light of the Massachusetts' Board clear interpretation as set forth in its policy on Internet Prescribing, I conclude that it is unnecessary to address whether Respondent also violated the State's provisions requiring a license and controlled substance registration which appear to allow an out-of-state practitioner to issue a prescription to a state resident in some instances. *Id.* § 18(c).

[32] The ALJ also found that Respondent violated Minnesota law when he prescribed to P.G. because he lacked either a state medical license or a telemedicine registration. ALJ at 39–40 (citing Minn. Stat. § 147.081). The ALJ observed that Minnesota allows a physician to provide telemedicine services if four conditions are met including that the physician register with the State. ALJ at 40 (citing Minn. Stat. § 147.032 Subd. 1(a)). The Minnesota statute, however, exempts a physician who holds a valid license to practice in another state ''if * * * the services are provided on an irregular or infrequent basis,'' which is defined as ''if the person provides the services less than once a month or provides the services to fewer than ten patients annually.'' *Id.* Subd. 2(2).

The Government's evidence established that Respondent issued only a single prescription to P.G.; there is no evidence that he prescribed to any other Minnesota residents. While it may well be the

Continued

Respondent also issued a prescription for controlled substance to E.M., a New Hampshire resident. In April 2004, the New Hampshire Board of Medicine issued Guidelines on internet prescribing. In pertinent part, the Board stated:

> The members of the NH Board of Medicine have interpreted that a sufficient examination in the establishment of a valid physician-patient relationship cannot take place without an initial face-to-face encounter with the patient. It requires at a minimum: (1) Verifying the person requesting the medication is who they claim to be; (2) establishing a diagnosis through the use of acceptable medical practices, such as patient history, mental status exam, physical exam, and appropriate diagnostic and laboratory testing by the prescribing physician; (3) discussing with the patient the diagnosis and the evidence for it, and the risks and benefits of various treatment options; and (4) ensuring availability of the physician or coverage for the patient for appropriate follow-up care; (which usually includes a face-to-face encounter at least once a year and as often as is necessary to assure safe continuation of medication). Complete management of a patient by Internet, e-mail, or other forms of electronic communication is inappropriate.

New Hampshire Board of Medicine, *Guidelines for Physician Internet and Telephone Prescribing* (April 7, 2004).

Moreover, under New Hampshire law, ''[a]ny person shall be regarded as practicing medicine * * * who shall diagnose, treat * * * or prescribe any treatment of medicine for any disease or human ailment.'' N.H. Rev. Stat. § 329:1. Moreover, practicing medicine without a license or as ''otherwise authorized according to the law of'' the State constitutes the ''unlawful practice'' of medicine.[33] *Id.* § 329:24. I thus conclude that Respondent acted outside of the usual course of professional practice in prescribing a controlled substance to E.M. and violated both New Hampshire law and the CSA.

Respondent also prescribed a controlled substance to S.B., a South Carolina resident. In May 2001, the South Carolina Board of Medical Examiners promulgated its regulation on ''Contact with Patients before Prescribing.'' S.C. Code Regs. 81–28. This regulation declares that ''[i]t is unprofessional conduct for a physician to initially prescribe drugs to an individual without first establishing a proper physician-patient relationship.'' *Id.* Continuing, the regulation states that forming ''a proper relationship'' requires that a physician:

> (1) Personally perform an appropriate history and physical examination, make a diagnosis, and formulate a therapeutic plan. This process must be documented appropriately; and
>
> (2) Discuss with the patient the diagnosis and evidence for it, and the risks and benefits of various treatment options; and
>
> (3) Insure the availability of the physician or coverage for appropriate follow-up care.

Id.[34] Here too, Respondent failed to establish a valid doctor-patient relationship with S.B. under South Carolina law and thus violated the CSA when he prescribed a controlled substance to her. 21 CFR 1306.04(a).

Respondent also issued a prescription to K.B., a resident of Alabama. Under Alabama law, ''[t]he practice of medicine * * * across state lines means the practice of medicine * * * as defined in Section 34–24–50(1), as it applies to * * * [t]he rendering of treatment to a patient located within this state by a physician located outside this state as a result of transmission of individual patient data by electronic or other means from this state to such physician or his or her agent.'' Ala. Code § 34–24–501(a); *see also id.* § 34–24–50 (defining the ''practice of medicine'' as meaning ''[t]o diagnose, treat, correct, advise or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality''). Moreover, under Alabama law, ''[n]o person shall engage in the practice of medicine * * * across state lines in this state * * * unless he * * * has been issued a special purpose license to practice medicine * * * across state lines.'' *Id.* § 34–24–502(a).

Respondent did not hold either a medical license or a special purpose license to practice medicine across state lines as required by Alabama law. In issuing the prescription to K.B., Respondent not only violated Alabama law, he acted outside of the usual course of professional practice and thereby violated the CSA as well.

As the foregoing demonstrates, Respondent repeatedly violated both the CSA and various State laws in prescribing to Liberty's customers. Respondent nonetheless contends that the Supreme Court's decision in *Gonzales* ''indicates that the continuation of his registration should not turn on [this Agency's] determination of whether in fact he had satisfied the relevant standards for establishing a doctor-patient relationship.'' Resp. Br. at 51; *see also id.* at 52 (arguing that *Gonzales* ''militates against a determination by the agency, for purposes of determining whether [Respondent's] registration should be revoked, as to whether [his] practices with internet patients satisfied state * * * standards for effective medical practice'').

Contrary to Respondent's view, *Gonzales* expressly recognized that one of the core purposes of the prescription requirement was to ''ensure[] [that] patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse.'' 546 U.S. at 274. Respondent's internet prescribing practices beg the question of how he was supervising the persons to whom he prescribed, to prevent them from becoming addicted to, or engaging in recreational abuse of, the drugs.[35] Examining whether Respondent established legitimate doctor-patient relationships under state law with those to whom he prescribed, is thus a necessary incident of determining whether he violated the CSA.

Respondent further argues that the DEA 2001 Guidance ''does not require the doctor personally to take the history or perform the [physical] examination.'' Resp. Br. at 50. Relatedly, Respondent contends that ''in terms of the indicia'' of a legitimate doctor-patient relationship as stated in the Guidance, ''there is clearly room for a physician to issue a prescription premised in part upon an examination or history conducted by another professional.'' *Id.*

At the hearing, however, Respondent testified that he had not seen the Guidance prior to this proceeding, Tr.

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case that Respondent issued additional prescriptions to P.G. or other Minnesota residents, the Government has not proved that he engaged in the unauthorized practice of medicine within Minnesota.

[33] Respondent produced no evidence that his internet practice came within any of the exceptions to New Hampshire's licensing requirement. *See* N.H. Rev. Stat. § 329:21.

[34] Similar to other State's regulations (such as New Jersey's), the South Carolina rules recognizes several circumstances in which a physician can lawfully prescribe to a patient he had not personally examined. *See* S.C. Code of Regs. R. 81–28(B). Respondent has not, however, demonstrated that his prescribing to S.B. came within any of the exceptions that excuse a physician from personally examining his patient before prescribing.

[35] Respondent contends that his internet practice ''was not substantially different from the evaluation process he would perform when he was contacted by a nurse from [the hospital] while he was on call,'' in that ''without examining the patient directly, [he] would draw upon his substantial experience and expertise to get the information he needed * * * to determine what care the patient required.'' Response to Gov.'s Exceptions at 5. It does not require a degree in medicine, however, to recognize that there is a critical difference between the two situations. In the on-call situation, a nurse is personally observing the patient and likely relating the patient's vital signs and other information regarding the patient's symptoms/condition to the physician. In contrast, even when Respondent, in the course of his internet prescribing, reviewed the results of physical examinations, he had no current information available as to the patient's vital signs and other symptoms.

414–15; Respondent therefore could not have been induced into believing that his conduct was legal by the Guidance. Moreover, the Guidance made clear that its discussion of the criteria for establishing a legitimate doctor-patient relationship was based on a summary of the standards adopted by the various States. *See* 66 FR at 21182 (GX 6, at 4).[36]

As Respondent acknowledged, he did not conduct his own review of state laws or seek legal advice concerning the legality of prescribing through the Liberty website. At the time he commenced his contract with Liberty, numerous state medical boards had already issued either policy statements or regulations (including those States discussed above) which addressed the legality of a physician's prescribing to patients he had not personally examined. Moreover, at the time Respondent commenced his contract with Liberty, this Agency had published several final orders revoking practitioners' registrations based on their prescribing over the internet and without performing a physical examination.[37] *See, e.g., Marvin L. Gibbs, Jr., M.D.*, 69 FR 11658, 11661 (issued Mar. 11, 2004); *Mark Wade, M.D.*, 69 FR 7018, 7021–22 (issued Feb. 12, 2004); *Rick Joe Nelson, M.D.*, 66 FR 30752, 30753 (2001) (noting immediate suspension of practitioner's registration based on internet prescribing).

In his response to the Government's Exceptions, Respondent contends that because of Boswell's ''attentiveness to regulatory and compliance issues,'' he was ''led * * * to believe that his internet practice would be proper.'' Response to Gov.'s Exceptions 7. This is not a persuasive argument. Indeed, one would think that a licensed professional and the holder of an appointment as a clinical professor would be well aware of such state laws and regulations as those prohibiting the unauthorized practice medicine and those defining something as fundamental to the practice of medicine as the steps necessary to establish a legitimate doctor-patient relationship. As the California Court of Appeal has explained:

> [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).

Respondent further contends that his case is distinguishable from other Agency cases involving internet prescribers. *See* Resp. Br. at 43–46. More specifically, Respondent contends that in contrast to other internet prescribers, he ''issued no more than a handful of prescriptions a day,'' that he prescribed ''only after reviewing the patient's medical record and conducting a searching personal interview,'' that he ''only prescribed medications that were pertinent to his area of medical expertise,'' and that he ''rejected many requests for medication that he deemed inappropriate.'' *Id.* at 43. Relatedly, Respondent contends that Liberty attempted to identify persons who were obtaining drugs from multiple sources and that it verified medical records. *Id.* at 45. He also contends that ''[h]e genuinely made a good faith effort'' to practice ''medicine properly and effectively.'' Resp. to Gov.'s Exceptions at 10.

As to these contentions, the evidence is mixed. While there is no evidence rebutting his contention that he issued only a small number of prescriptions each day, by his own admission he consulted for Liberty for approximately one year during which he issued between 800 and 1200 prescriptions. However, the record does not establish the extent to which these prescriptions were for controlled substances. Moreover, he continued to prescribe for three months after being served with the Order to Show Cause.[38] While it seems likely that he prescribed controlled substances during this period, the Government did not establish the scope of his controlled substance prescribing activity after he was served with the Order.

Moreover, notwithstanding his contention that he prescribed only after reviewing a patient's medical record and ''conducting a searching'' interview, the evidence establishes that in some instances (R.Z. and S.K.) he prescribed before Liberty even obtained the records, and that in other instances he relied on records that—according to his own testimony—were outdated (P.G) and even indicated that narcotics were not in the patient's best interest. Relatedly, as the ALJ noted, other evidence casts serious doubt as to his assertions that he always conducted a consultation with the patients, let alone a searching interview of them. ALJ at 12. (FoF 36).

On the other hand, there is some evidence that Liberty rejected patients who were seeking drugs from multiple sources, or who were seeking drugs to give to others. There is also evidence that in some instances, Liberty verified a patient's records with the patient's original physicians although it is unclear what this process involved and how often it was undertaken.[39] Relatedly, even though the patient files typically included photocopies of a driver's license, there is no guarantee that the drugs were actually going to these persons.

Moreover, the ALJ found that Respondent ''declined to prescribe medications in many instances where Liberty customers were directed to him.'' ALJ at 17 (FoF 52). The Government produced no evidence to rebut Respondent's contention as to the frequency of his refusals to prescribe. Relatedly, there is also evidence that Respondent rejected a request for drugs when he thought the person would divert or was seeking drugs from multiple sources. Moreover, there is evidence that Respondent refused to prescribe because a person's complaint (and the supporting records) had not been verified.

[36] The Guidance is not a regulation and thus does not have the force and effect of law. Rather, it is a Notice which simply provides guidance.

[37] Respondent also contends that his shortfalls were of one ''seeking to practice in an area where the technical requirements are both widely dispersed and in flux.'' Resp. Br. 46; *see also id.* at 52. However, at the time he commenced his contract with Liberty, each of the States discussed above had already either enacted laws, or issued regulations or policy statements, addressing the propriety of this activity. And in any event, Respondent cannot credibly argue that his conduct should be excused because the legal requirements were in flux when he made no inquiry as to what the requirements were.

[38] With respect to his prescribing following the service of the Show Cause Order, Respondent does not maintain that he did not prescribe controlled substances in this period. Rather, he argues that I should consider the fact that the Order alleged that he ''improperly prescribed drugs [phentermine and phendimetrazine] that he never in fact prescribed.'' Response to Gov.'s Exceptions at 11. Respondent ignores, however, that the Show Cause Order also quoted the prescription requirement of 21 CFR 1306.04(a), and the New Jersey regulation setting forth the requirements for prescribing a drug including that a ''practitioner shall * * * perform an appropriate history and physical examination.'' Show Cause Order at 1 & 3. Moreover, the Show Cause Order alleged that Respondent was prescribing to persons that he was not physically examining and had no prior doctor-patient relationship with, and was thus violating 21 CFR 1306.04. *Id.* at 6. The Show Cause Order thus provided Respondent with fair warning as to the illegality of his conduct.

[39] For example, did Liberty's employees simply ask whether a person had been a patient? Did they ask whether the patient was still being treated by the physician? Did they ask what the physician's diagnosis was? And did they ask if there was any evidence that the patient had engaged in drug seeking behavior? Moreover, in some instances, Respondent prescribed before the records were even sent to Liberty. Finally, in at least one case (patient L.F.), it appeared that some of the records were fraudulent.

While the record as a whole may not conclusively show that Respondent knowingly diverted, at the very least it establishes that Respondent acted with reckless disregard for his obligations as a practitioner under both the CSA and numerous state laws. Moreover, Respondent acknowledged that he prescribed schedule II drugs and authorized refills of these prescriptions, in violation of federal law. *See* 21 U.S.C. 829(a).[40] The Government has therefore proved that Respondent has committed acts that render his registration ''inconsistent with the public interest.'' *Id.* § 824(a)(4).

Sanction

Under Agency precedent, where, as here, ''the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must '' 'present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.' '' *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988)). ''Moreover, because 'past performance is the best predictor of future performance,' *ALRA Labs, Inc.* v. *DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.'' *Medicine Shoppe*, 73 FR at 387; *see also Jackson*, 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Prince George Daniels*, 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA*, 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).

The ALJ acknowledged that the Government had ''clearly demonstrated'' that Respondent's internet prescribing practices violated the CSA. ALJ at 43. While the ALJ recognized that Respondent's internet prescribing was ''egregious conduct,'' *id.*, that he ''fail[ed] to be totally truthful during his testimony,'' *id.* at 44, and that he ''demonstrated a lack of sound judgment'' in continuing his internet prescribing for three months following the service of the Show Cause Order, *id.*, she also noted that he ''is clearly a very educated, dedicated and talented physician,'' *id.*; that he had been practicing medicine for eleven years, and that ''the only instances of [his] improper handling of controlled substances were related to his'' internet prescribing. *Id.* Balancing Respondent's misconduct against his overall practice, the ALJ recommended that I continue his registration, subject only to the condition that he not prescribe over the internet. *Id.*

As explained above, this Agency has repeatedly held that accepting responsibility for one's misconduct is an ''important factor'' in the public interest determination. *See Hoxie*, 419 F.3d at 483 (upholding Agency's consideration of whether registrant/applicant has admitted fault); *Jackson*, 72 FR at 23853; *Kennedy*, 71 FR at 35709; *Daniels*, 60 FR at 62887. The ALJ, however, made no finding as to whether Respondent had accepted responsibility for his misconduct.

While Respondent testified that it was not his ''present intention'' to resume internet prescribing,[41] the record as a whole does not establish that he has accepted responsibility for his misconduct. I acknowledge that the DI who served Respondent with the Show Cause Order described him as cooperative, and that Respondent admitted that his internet prescribing was even more extensive than that shown by the Government. In his testimony, however, Respondent continued to maintain that his prescribing without performing a physical exam was lawful under New Jersey's regulation. Moreover, Respondent did not acknowledge that he violated either the CSA, or any other state laws and regulations, whether they related to the standards for establishing a legitimate doctor-patient relationship or addressed the unauthorized practice of medicine. Respondent's failure to acknowledge the illegality of his conduct does not inspire confidence that he will refrain from engaging in similar acts in the future.

Moreover, while a registrant must accept responsibility and demonstrate that he will not engage in future misconduct in order to establish that his/her continued registration is consistent with the public interest, these are not the only factors that are relevant in determining the appropriate sanction. As I have previously noted, ''[n]either *Jackson* nor any other agency decision holds * * * that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked.'' *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36504 (2007).[42]

In *Southwood*, I explained that ''even when a proceeding serves a remedial purpose, an administrative agency can properly consider the need to deter others from engaging in similar acts.'' *Id.* (citing *Butz* v. *Glover Livestock Commission Co., Inc.*, 411 U.S. 182, 187–88 (1973)). I further noted that the ''[c]onsideration of the deterrent effect of a potential sanction is supported by the CSA's purpose of protecting the public interest, *see* 21 U.S.C. 801, and the broad grant of authority conveyed in the statutory text, which authorizes the [suspension or] revocation of a registration when a registrant 'has committed such acts as would render [his] registration * * * inconsistent with the public interest,' *id.* section 824(a)(4), and [which] specifically directs the Attorney General to consider ['such other conduct which may threaten public health and safety,' *id.* section 823(f)].'' *Southwood*, 72 FR at 36504.

I acknowledge that Respondent has impressive credentials, and that except for his internet prescribing, there is no evidence that he violated the CSA or state laws in his years of practice as an anesthesiologist and pain management specialist. However, under any circumstance, Respondent's conduct as an internet prescriber would be disturbing. That he holds an appointment as a clinical professor renders his conduct even more so. Relatedly, Respondent's testimony as to why he believed that his Internet prescribing was lawful and failed to perform his own inquiries into the legality of this practice is especially unpersuasive and does not excuse his failure to obey the law.

Moreover, Respondent's Internet prescribing was not a brief sojourn into illegality. Rather, he engaged in his

[40] Respondent also provided Liberty with an electronic copy of his signature. Tr. 511 & 570. While Respondent credibly testified that he had no reason to suspect that Liberty was using his signature to authorize prescriptions which he had not approved, he acknowledged that he had no way of determining whether Liberty was misusing his signature. *Id.* at 570. This Agency has previously held that failing to safeguard one's signature constitutes conduct inconsistent with the public interest. *See Robert G. Hallermeier, M.D.*, 62 FR 26818, 26820 (1997).

[41] Notably, while the ALJ credited this testimony, she was less than impressed with Respondent's testimony that he did not intend to resume internet prescribing. *See* ALJ 15 n.4 (''Although [Respondent] appeared to be credible when he testified here to his intent, I do question how he resolves this intent with his continued interest in telemedicine.''). Indeed, intentions can change, and Respondent's statement is hardly an unequivocal statement that he will not resume such conduct in the future.

[42] Southwood was decided before the ALJ issued her recommended decision in this matter. The ALJ did not, however, even acknowledge the decision.

misconduct for a year, during which time he likely issued between 800 to 1,200 prescriptions. Yet the record does not establish the extent to which these prescriptions were for controlled substances.[43]

I acknowledge that proceedings under Section 304 are non-punitive. But even were I to ignore that Respondent has not accepted responsibility for his misconduct, and credit his testimony that he did not intend to resume his internet practice, I would still conclude that a lengthy suspension of his registration is warranted.

As found above, the diversion and abuse of prescription drugs has increased dramatically, with the number of people admitting to such abuse (approximately 15.1 million) exceeding by twenty-three percent, the number who abuse cocaine, hallucinogens, inhalants and heroin combined. Moreover, the growth rate of prescription drug abuse is twice the growth rate of marijuana abuse and five times the growth rate of cocaine abuse; between 1992 and 2002, the growth in prescription opioid abuse among teenagers grew by 542 percent.

The use of the internet and telephone to prescribe to individuals with whom a physician has not established a bona fide doctor-patient relationship is one of the primary means by which controlled substances are being diverted and obtained for recreational abuse. The growth of this means of diversion represents a grave threat to public health and safety. Accordingly, this Agency has repeatedly revoked the registrations of numerous practitioners who have committed similar acts by prescribing over the internet without establishing legitimate doctor-patient relationships. *See, e.g., Kamir Garces-Mejias*, 72 FR 54931 (2007); *William Lockridge*, 71 FR 77791 (2006); *Mario Diaz*, 71 FR 70788 (2006). The ALJ did not, however, even acknowledge any of the numerous Agency decisions to this effect.

Respondent maintains that his case is distinguishable from these and other reported decisions involving internet prescribers because he ''genuinely believed * * * that he was practicing medicine properly and effectively[,]'' and ''genuinely made a good faith effort to do so.'' Response to Gov.'s Exceptions at 10. He also contends that he ''is an extraordinarily dedicated and tireless physician who saw the internet as a way to care for more patients,'' and that while he ''can be faulted'' for ''having trusted colleagues and new business associates when he should have been more skeptical,'' ''the price should not be his career.'' *Id.* at 14.

It is true that in other Agency decisions revoking the registrations of internet prescribers, the evidence strongly supported the conclusion that the physicians were engaged in intentional acts of diversion. Here, by contrast, the evidence does not establish that he knowingly distributed controlled substances to those who were seeking the drugs to abuse them or to sell them to abusers. His conduct—which is extraordinary for its recklessness—nonetheless violated the CSA.

Continuing Respondent's registration, subject only to the condition that he refrain from prescribing over the Internet, is no sanction at all given the numerous state laws and new Federal law which prohibit this practice in the manner Respondent engaged in it. Adopting the ALJ's recommendation would not only ''ignore how irresponsibly [Respondent] acted,'' *Southwood*, 71 FR at 36503; it would also signal to others that one can ignore the law (and his obligation to determine what the law is) and yet incur no consequence for having done so. Given the extraordinary harm to public health and safety caused by internet prescribing, this is not the message that should be sent to those who contemplate prescribing controlled substances in this manner. Rather, such persons should understand that they are responsible for knowing the law and acting in conformity therewith, and that there will be serious consequences for those who fail to do so.

Accordingly, I conclude that Respondent's registration should be suspended for a period of one year. Moreover, Respondent's pending application for renewal of his registration will be held in abeyance during the course of the suspension. Upon completion of the suspension, his application will be approved provided that he fulfills the following condition. Because Respondent has not acknowledged that his internet prescribing practices violated the CSA, he must provide a sworn statement to this effect. If Respondent complies with this condition (and he commits no other acts which would warrant the denial of his application), the Agency will expeditiously grant his renewal application. If, however, if he fails to do so, his application will be denied.

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 the DEA Certificate of Registration issued to Joseph Gaudio, M.D., be, and it hereby is, suspended for a period of one year. I further order that Respondent's pending application to renew his registration be, and it hereby will be, held in abeyance pending the completion of the period of suspension and Respondent's providing to this Agency a sworn statement acknowledging that his internet prescribing activities violated the Controlled Substances Act and DEA regulations. This Order is effective April 8, 2009.[44]

Dated: February 26, 2009.

Michele M. Leonhart,

Deputy Administrator.

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[43] It is also noted that Respondent continued his internet prescribing for three months after he received the Show Cause Order, even though the Order put him on notice as to the requirements for a lawful prescription under both the CSA and state law. While Respondent did not dispute that he prescribed controlled substances during this period, I do not rely on this conduct in setting the sanction because the Government did not identify a single controlled substance prescription that he issued following the service of the Show Cause Order. If the Government had shown specific instances of Respondent's prescribing of controlled substances following service of the Order, I would have found that he knowingly diverted controlled substances and revoked his registration.

[44] Respondent can choose to commence serving his suspension earlier by tendering his Certificate of Registration and any order forms he has been issued to the nearest DEA office.

DEPARTMENT OF JUSTICE

Foreign Claims Settlement Commission

F.C.S.C. Meeting Notice No. 2–09

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR Part 504) and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of meetings for the transaction of Commission business and other matters specified, as follows:

Date and Time: Wednesday, March 18, 2009, at 10:30 a.m.

Subject Matter: Issuance of Proposed Decisions, Amended Proposed Decisions, Final Decisions and Orders in claims against Albania.

Status: Open.

All meetings are held at the Foreign Claims Settlement Commission, 600 E Street, NW., Washington, DC. Requests for information, or advance notices of intention to observe an open meeting, may be directed to: Administrative Officer, Foreign Claims Settlement Commission, 600 E Street, NW., Room