

## Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Identification of Explosive Materials.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: None. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: None. The regulations of 27 CFR 55.109 require that manufacturers of explosive materials place marks of identification on the materials manufactured. Marking of explosives enables law enforcement entities to more effectively trace explosives from the manufacturer through the distribution chain to the end purchaser. This process is used as a tool in criminal enforcement activities.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 1,563 respondents will respond to this information collection. Estimated time for a respondent to respond is none. Because the manufacturers are required to place markings on explosives, the burden hours are considered usual and customary. 5 CFR 1320.3(b)(2) states, there is no burden when the collection of information is usual and customary.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual total burden hours associated with this collection is 1 hour.

*If additional information is required contact:* Lynn Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, Room 2E-502, 145 N Street NE., Washington, DC 20530.

Dated: October 21, 2010.

**Lynn Murray,**

*Department Clearance Officer, PRA, U.S. Department of Justice.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 06-8]

#### George Mathew, M.D.; Denial of Application

On September 19, 2005, I, the Deputy Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration to George Mathew, M.D. (Respondent), of Seattle, Washington. The Order proposed the revocation of Respondent's DEA Certificate of Registration, BM5009065, which authorized him to dispense controlled substances in schedules II through V as a practitioner, and the denial of any pending applications to renew or modify his registration on the ground that his "continued registration is inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f) and 824(a)(4)." Show Cause Order at 1.

The Show Cause Order alleged that Respondent had participated in a criminal scheme run by Johar Saran, the owner of Carrington Healthcare Systems/Infiniti Services Group (CHS/ISG) of Arlington, Texas, which used numerous pharmacies owned by "sham corporations" to obtain the DEA registrations necessary to "purchase and dispense large quantities of controlled substances via the Internet." *Id.* at 5. As for Respondent's involvement, the Order alleged that between May 1, 2005 and June 17, 2005, Respondent, who was licensed in the State of Washington, had authorized 136 prescriptions for residents of "at least 27 different states" and that "[n]inety-three percent of the [prescriptions] were for hydrocodone," a schedule III controlled substance. *Id.* at 6. The Order further alleged that Respondent "did not see [the] 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 [the] drug orders was the customer's online questionnaire." *Id.* The Order thus alleged that Respondent "participated" in a scheme to "facilitate [the] circumvention of legitimate medical practice" by "prescribing controlled substances to Internet customers despite never establishing a genuine doctor-patient relationship with the Internet customer." *Id.* at 5.

Next, the Show Cause Order alleged that a DEA Diversion Investigator (DI) had accessed a Web site, <http://www.heynowmeds.com>, and, after

providing his name, address, phone number, date of birth, gender, and filling out a brief medical questionnaire, purchased hydrocodone. *Id.* at 6. The Order further alleged that the DI received the drug three days later, that he had not been contacted by any one affiliated with the Web site, and that the bottle's label listed Respondent as the prescriber and Southwest Fusion, an entity in Fort Worth, Texas, as the dispensing pharmacy. *Id.*

The Show Cause Order thus alleged that Respondent "did not establish legitimate physician-patient relationships with the Internet customers to whom [he] prescribed controlled substances" and that "such prescriptions [were] not [issued] for a legitimate medical purpose in the usual course of professional practice." *Id.* at 7. The Order thus alleged that the prescriptions violated 21 CFR 1306.04(a).<sup>1</sup>

On September 22, 2005, Respondent requested a hearing on the allegations, which he denied, maintaining that he had been the victim of identity theft, ALJ Ex. 2; the matter was then placed on the docket of the Agency's Administrative Law Judges (ALJ). Moreover, on October 7, 2005, Respondent requested a stay of the immediate suspension based on his contention of identity theft. *See ALJ Ex. 4.* On October 14, 2005, I stayed the suspension pending resolution of his claim. *Id.*

Thereafter, on October 19, 2005, the parties filed a Joint Motion to Stay the Proceedings, ALJ Ex. 3, and on October 26, 2005, the ALJ granted a stay. ALJ Ex. 5. On December 4, 2006, the parties filed a joint status report. ALJ Ex. 6. Therein, the parties notified the ALJ of their inability to reach a resolution of the matter and requested that the stay of the proceedings be lifted and that the hearing be held as soon as possible. *Id.*

In its prehearing statement of January 5, 2007, the Government notified Respondent that it also intended to present evidence regarding statements he made during an interview with DEA Investigators on September 22, 2005. Gov. Prehearing Statement at 7. More specifically, the Government alleged that Respondent had contracted with EDrugs, an entity which operated a Web site (<http://www.eDrugstore.com>), and that "on a daily basis" "for about 6

<sup>1</sup> While I also immediately suspended Respondent's registration based on my conclusion that his continued registration during the pendency of the proceeding "would constitute an immediate danger to public health and safety," Show Cause Order at 7, on October 14, 2005, I subsequently stayed the suspension after Respondent maintained that he was the victim of identity theft. ALJ Ex. 4.

months between July 2003 and February 2004,” he would go to the “company webpage and review a list” which “contain[ed] patient names and suggested prescription drugs.” *Id.* at 7–8. The Government also alleged that Respondent “stated that he approved prescriptions for non-controlled substances and diet medications,” that “[h]e was paid \$3.00 for each non-controlled prescription and \$10.00 for each diet prescription,” and that he “received approximately \$30,000 from EDrugs for his services.” *Id.* at 8.

After delays authorized by the ALJ, a hearing was held in Seattle, Washington on July 24–26, 2007. At the hearing, both parties called witnesses to testify and introduced documentary evidence. After the hearing, both parties submitted Proposed Findings of Fact, Conclusions of Law and Arguments.

On September 22, 2008, the parties filed a Joint Motion to Stay the Administrative Proceedings until March 31, 2009. ALJ Ex. 12. The basis of the motion was that on July 8, 2008, the Washington Medical Quality Assurance Commission (MQAC) had summarily suspended Respondent’s State medical license and that his hearing on that matter was not scheduled until March 6, 2009. ALJ Ex. 12. On September 26, 2008, the ALJ granted the motion and directed the parties to file a joint status report by March 31, 2009. ALJ Ex. 13.

On March 30, 2009, the parties filed a Joint Status Report, Motion to Lift Stay of Proceedings and Motion to Reopen the Record. ALJ Ex. 15. Therein, the parties noted that the MQAC had entered an Agreed Order which allowed Respondent to resume practicing medicine provided he satisfied various terms and conditions set forth therein; the parties also sought to supplement the record with various documents related to the MQAC proceeding and to file supplemental briefs. *Id.* On April 1, 2009, the ALJ lifted the stay, reopened the record to admit the MQAC documents, granted the parties additional time to file supplemental post-hearing briefs, and then closed the record. ALJ Ex. 16. On July 22, 2009, the ALJ also reopened the record on Respondent’s motion to admit an exhibit and then closed the record again. ALJ Ex. 18. Finally, on July 29, 2009, the ALJ reopened the record *sua sponte* to admit various documents related to the matter’s procedural history and then finally closed the record. ALJ Ex. 17.

On October 2, 2009, the ALJ issued her recommended decision (ALJ). Therein, the ALJ concluded that the Government had made a *prima facie* showing that Respondent had

committed acts which render his registration inconsistent with the public interest, finding that the evidence under factors two (Respondent’s experience in dispensing controlled substances) and four (Respondent’s compliance with State and Federal laws related to controlled substances) supported the revocation of Respondent’s registration. ALJ at 29 & 31.

The ALJ found that Respondent had contracted with eDrugstore, an internet pharmacy, and that from July 2003 through early 2004, Respondent had issued over 300 controlled substance prescriptions. *Id.* at 26. The ALJ also found that Respondent had issued prescriptions after reviewing online questionnaires and that he did not keep any medical records for the individuals to whom he prescribed the controlled substances. *Id.*

With respect to these prescriptions, she further found that Respondent, who is only licensed to practice medicine in Washington, “prescribed controlled substances to individuals in other states, to include California, Indiana, Massachusetts, Texas, and Virginia,” which require a physician to be licensed by them prior to issuing prescriptions to a State resident, and that this conduct violated the Controlled Substances Act (CSA) because he engaged in the unauthorized practice of medicine and thus acted outside of the usual course of professional practice. *Id.* at 27, 28 (collecting cases). She also concluded that Respondent violated the CSA in issuing these prescriptions because he did not have “a face-to-face meeting” with the patient and “violat[e] the standard of care \* \* \* for prescribing controlled substances” and thus did not establish “a valid doctor-patient relationship.” *Id.* at 29.

Based on an undercover purchase, the ALJ found that “Respondent’s name and DEA number were used to authorize prescriptions through the Heynowmeds website.” *Id.* While the ALJ acknowledged Respondent’s contention that he did not issue prescriptions for this Web site, she concluded that because Respondent had “allow[ed] such a website to gain access and to use his DEA registration number,” he “remains responsible for the outcome of that use.” *Id.* She further reasoned that Respondent’s failure to safeguard his registration from unauthorized use “create[d] a risk of diversion” and “a risk to the public health and safety” because it allowed persons “without a legitimate need for \* \* \* controlled substances” to obtain them and thus was relevant conduct under factor five (such other

conduct which may threaten public health and safety).<sup>2</sup> *Id.* at 30.

The ALJ then turned to other facts which she deemed relevant in the public interest determination. The ALJ found that “Respondent was cooperative and truthful” in his interview with DEA. *Id.* She also found significant the MQAC’s 2007 finding “that there was no evidence that the Respondent mishandled controlled substances during the Board’s” 2005 investigation. *Id.* at 30–31. She further found it “significant” that, under the most recent MQAC order, Respondent is being supervised by a mentoring physician who is required to report to the Board. *Id.*

While the ALJ concluded that the Government had made out its *prima facie* case, and that Respondent had violated both the CSA and State laws “in prescribing controlled substances over the Internet” and by his failure to safeguard his registration, she also noted that since the initiation of the proceedings, “Respondent has had approximately four years to handle controlled substances without any adverse action being taken or evidence being seized by the DEA” and that the “Medical Board is very diligent in monitoring [his] medical practice and will continue to do so in the future.” *Id.* at 31–32. Believing that “this proceeding has instilled in \* \* \* Respondent a grave respect for the authority and responsibilities which attach to his DEA registration,” the ALJ apparently recommended that I grant Respondent a new registration subject to the condition that he file his mentor’s reports with this Agency and that he take the additional medical education courses order by the MQAC. *Id.* at 32.

Neither party filed exceptions to the ALJ’s decision. Thereafter, on November 3, 2009, the ALJ forwarded the record to me for final agency action.

Having considered the record as a whole, I adopt the ALJ’s findings of fact

<sup>2</sup> With respect to factor one (the recommendation of the State board), the ALJ noted that the State Board “has not made a direct recommendation concerning [his] DEA registration.” ALJ at 25. The ALJ further found, however, that the State “Board has engaged in considerable oversight of the Respondent’s medical practice” which included summarily suspending his license after finding that his “continued practice of medicine constitute an immediate danger to the public health and safety” and that he had committed unprofessional conduct on two occasions (2007 and March 2009). *Id.* at 25–26. The ALJ did not, however, state whether this factor supported a finding that his continued registration is inconsistent with the public interest.

With respect to factor three (Respondent’s conviction record of offenses related to controlled substances), the ALJ found that there was “no evidence of [his] having a conviction record.” *Id.* at 30.

and legal conclusions except as noted herein. However, I further find that Respondent prescribed controlled substances for Heynowmeds.com. While I also agree with the ALJ that the Government made out a *prima facie* case for revocation, I reject the ALJ's conclusion that the other facts and circumstances support granting him a new registration. As explained below, the ALJ ignored the extensive Agency precedent which holds that an applicant is not entitled to be registered unless he accepts responsibility for his misconduct. Because Respondent did not testify in this proceeding and continues to maintain that "he ha[s] done nothing wrong," Tr. 645, he has not satisfied the Agency's rule for regaining his registration and his application must be denied. I make the following findings.

### Findings of Fact

#### *Respondent's Registration and License Status*

Respondent is a physician who previously held DEA Certificate of Registration, BM5009065, which authorized him to dispense controlled substances in schedules II through V as a practitioner; his registered location was in Seattle, Washington, and his registration expired on January 31, 2008. GX 1, at 1–2. Respondent did not, however, file a renewal application until January 24, 2008. ALJ Ex. 12, Appendix I, at 1 (Joint Stipulation). The parties also agree that Respondent's registration "did not continue in effect after January 31, 2008." *Id.* While Respondent no longer holds a registration, he does have an application for a new registration currently pending.

Respondent is board-certified in internal medicine and holds a medical license issued by the State of Washington. RX 4, at 1. While Respondent has a current license, he has been the subject of two recent disciplinary proceedings before the Washington Medical Quality Assurance Commission (MQAC).

On June 24, 2005, the MQAC filed a statement of charges which alleged that in July 2003, Respondent contracted with eDrugstore.md "to prescribe legend drugs to patients that were referred to him through the website," and was paid by the Web site and "not the patients." GX 27, at 1–2. The MQAC alleged that its "investigation included a portion of [his] prescriptions," and that "[f]rom August 2003, through approximately February 2004, Respondent authorized approximately 2,700 prescriptions in the sample obtained in the

investigation." *Id.* at 2. The MQAC further alleged that:

Respondent did not conduct a history and physical on any of these patients. He did not have face-to-face contact with any patient to evaluate them. Respondent did not have the patient's medical records available for review, and he did not have any way to verify any of the information provided to him via the online consultation form, nor did he attempt to do so. Respondent did not have a pre-existing physician-patient relationship with any of these patients. Respondent did not attempt to verify any pre-existing or underlying conditions, contraindications, or other medications that the patient was taking, other than via the online consultation form, filled out by the patient or through email. Nonetheless, Respondent undertook to provide diagnosis and treatment of every one of these patients.

*Id.* at 2.

In addition, the MQAC alleged that Respondent had prescribed controlled substances to three State residents and that he had no medical records for these persons. *Id.* at 3–4. More specifically, the MQAC alleged that "Respondent provided prescriptions for Percocet, Hydrocodone, and Amphetamine" to Patient 1, that he "prescribed Oxycodone and Alprazolam for Patient 2," and that he "prescribed Hydrocodone and Cyclobenzaprine for Patient 3." *Id.* at 3. With respect to each of these three patients, the MQAC also alleged that Respondent "has no record of a history and physical for this patient, and no information to explain this patient's diagnosis and treatment. There are no medical records, no test results, or documentation of any kind to support this patient's diagnosis and treatment." *Id.* at 3–4.

The MQAC thus alleged that Respondent's conduct with respect to both his prescribing over the Internet and his prescribing to the three patients constituted unprofessional conduct in violation of State law. *Id.* at 4. More specifically, the MQAC alleged that Respondent's prescribing violated Washington law prohibiting: (1) "[i]ncompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed," *id.* (quoting Wash. Rev. Code § 18.130.180(4)), and (2) "[t]he possession, use, prescription for use, or distribution of controlled substances or legend drugs in any way other than for legitimate or therapeutic purposes, diversion of controlled substances or legend drugs, the violation of any drug law, or prescribing controlled substances for oneself." *Id.* (quoting Wash. Rev. Code § 18.130.180(6)).

On January 18, 2007, following a hearing, the MQAC issued a Final Order

on the allegations. GX 28. Therein, the MQAC found proved the allegations that Respondent had contracted with eDrugstore.md "to prescribe legend drugs to patients that were referred to him through the web site" and that he "was compensated by eDrugstore.md [and] not by the patients." *Id.* at 5. The MQAC further found that Respondent used his DEA registration to prescribe medications and that "[f]rom August 2003 through March 2004, [he] authorized approximately 2,700 prescriptions." *Id.* at 6. The Board further found that:

The Respondent did not conduct a history and physical on any of these patients. He did not have a face-to-fac[e] contact with any patient to evaluate them. The Respondent did not have the patient's medical records available for review, and he did not have any way to verify any of the information provided to him via the online consultation form, nor did he attempt to do so. The Respondent did not have pre-existing or underlying conditions, contraindications, or other medications that the patient was taking, other than via the online consultation form filled out by the patient or through email. Nonetheless, Respondent undertook to provide diagnosis and treatment of every one of these patients.

*Id.*

The MQAC further found that, because "Respondent did not physically see, interview, or examine the patients he treated through eDrugstore.md, [he] could not verify their identity and could not establish a diagnosis through the use of accepted medical practices to justify prescribing medications" and that "[t]hrough eDrugstore.md, [he] prescribed [p]hentermine, a diet medication to treat obesity." *Id.* at 7. Continuing, the MQAC found that "[b]y prescribing" phentermine "over the Internet without proper counseling, follow up, and treatment plan, the Respondent failed to comply with standards of care from the perspective of managing obesity." *Id.* The MQAC also found that his prescribing of phentermine "over the Internet was negligent and such conduct created [an] unreasonable risk that the patients may be harmed." *Id.*

The MQAC further found that Respondent's internet prescribing "was contrary to [its] Guidelines for the Appropriate Use of the Internet in Medical Practice," which it had issued on October 11, 2002. *Id.* at 6. *See also* GX 24. The MQAC noted that the Guidelines:

Provide that treatment that is based solely on online questionnaires or online consultations do[es] not constitute an acceptable standard of care. Specifically, patient evaluation must be obtained prior to

providing treatment, including issuing prescriptions, electronically or otherwise. A patient evaluation includes a history and physical examination adequate to establish a diagnosis and to identify underlying conditions and/or contraindications to the treatment being recommended or provided.

GX 28, at 6; *see also* GX 24, at § 5.<sup>3</sup>

With respect to the three patients who were State residents, the MQAC found that Respondent had prescribed controlled substances to them and had “failed to keep any medical records for these patients.” GX 28, at 7. The MQAC also found that Respondent ha[d] no record of a history and physical exam for these patients and no information to explain the patients’ diagnosis and treatment. There are no medical records, no test results, or documentation of any kind to support the patient’s diagnosis and treatment.” *Id.* The MQAC further found that Respondent’s treatment of these patients “was below the standard of care for a physician in the state of Washington, and [that] his conduct created an unreasonable risk of harm.” *Id.* at 8.

The MQAC ultimately concluded that the State had “proved by clear and convincing evidence that \* \* \* Respondent’s conduct constituted unprofessional conduct in violation of” Wash. Rev. Code § 18.130.180(4). *Id.* at 9. However, apparently because the State produced no evidence showing that Respondent prescribed controlled substances “for use other than for therapeutic purposes,” *id.* at 8, the MQAC concluded that the State had “failed to prove by clear and convincing evidence that \* \* \* Respondent’s conduct constituted unprofessional

conduct in violation of” Wash. Rev. Code § 18.130.180(6).<sup>4</sup> *Id.* at 9.

On July 3, 2008, the MQAC filed another Statement of Charges against Respondent, alleging that he had committed unprofessional conduct in providing treatment (or lack thereof) of four emergency room patients. ALJ Ex. 15, at 2; Jt. Ex. 1, at 1, 4. However, none of the allegations involved the prescribing of controlled substances. Five days later, on July 8, 2008, the Commission entered an Ex Parte Order of Summary Suspension. ALJ Ex. 15, at 2; Jt. Ex. 2, at 1, 3.

On March 5, 2009, Respondent entered into a Stipulated Findings of Fact, Conclusions of Law and Agreed Order with the Commission in which Respondent agreed that he had committed unprofessional conduct in his treatment of the patients in question in violation of Wash. Rev. Code § 18.130.180(4). The Commission permitted Respondent to return to the practice of medicine pursuant to terms and conditions of the Agreed Order. ALJ Ex. 15, at 2; Jt. Ex. 3, at 1, 3. On the same date, finding that the Agreed Order superseded and appropriately incorporated all the outstanding terms and conditions of the January 2007 Final Order, the Commission released Respondent from that Order. ALJ Ex. 15, at 2; Jt. Ex. 4, at 2.

Under the Agreed Order, which is to remain in effect for at least three years, Respondent is limited to “office-based family and internal medicine group practice.” Jt. Ex. 3, at 4. In addition to some continuing education and medical proficiency requirements, Respondent must “arrange for another physician to serve as a mentor at all times prior to termination of these practice conditions.” *Id.* at 5. Among other matters, under the Agreed Order, the mentor must make periodic reports to the Commission, exercise oversight of the office-based practice, and review all of Respondent’s charts and entries “until otherwise directed by the Commission.”<sup>5</sup> *Id.* at 5–6.

<sup>4</sup>Based on its findings that Respondent had committed unprofessional conduct, the MQAC imposed various sanctions on Respondent including a suspension (which was stayed), a restriction that he could only practice as an emergency medicine physician, and a fine of \$2500. *Id.* at 10–119. The MQAC also ordered him to complete an approved education and assessment course and six hours of continuing medical education in ethics and professionalism, to file a declaration each quarter stating that he was in compliance with the Order, and to appear before the Commission for compliance hearings. *Id.* at 11–12.

<sup>5</sup>By letter of June 15, 2009, Dr. David Lush indicated that he was Respondent’s mentor physician for purposes of the Agreed Order. RX 37, at 1. Dr. Lush further indicated that Respondent had

### The DEA Investigation of Respondent

In June 2004, DEA began investigating a criminal conspiracy run by Mr. Johar Saran and various associates, which among other crimes, unlawfully distributed controlled substances in violation of 21 U.S.C. 841(a)(1)(a) & (b)(1)(D), 846. *See generally* GX 23. More specifically, the Saran conspiracy controlled more than twenty corporate entities (including Carrington Health Services (CHS) and Infiniti Services Group (ISG)) which were used to fraudulently obtain the DEA pharmacy registrations that are legally necessary to purchase controlled substances from registered manufacturers and distributors. GX 24, Factual Resume at 5–6; Tr. 24–25. Saran and his co-conspirators purchased the controlled substances and then distributed them to customers who sought them through over 100 Web sites. GX 24, Factual Resume at 8. As Johar Saran admitted in his plea agreement, he and his co-conspirators “agreed to distribute and possess with the intent to distribute, controlled substances to Internet drug seeking customers without legitimate prescriptions. [He] knew that controlled substances would be distributed to Internet customers without the existence of a doctor patient relationship [and that] the Internet controlled substance distributions were outside the scope of professional practice and not for a legitimate medical purpose.” *Id.*

As part of the investigation, on December 9, 2004, DEA investigators conducted a “trash run” at CHS/ISG. Tr. 24. Among the evidence recovered were a dozen prescription labels for controlled substances (including phentermine, hydrocodone/apap, and alprazolam), which “appear[ed] to be the portion of a multi-part printout that should have been filed by the pharmacy as a record of the transaction or the prescription being filed.” *Id.* at 33–34; GX 37. The labels indicated that “George Mathew, M.D.” was the prescribing physician, gave his registered address in Seattle, Washington (albeit without the suite number and having a one-digit mistake in the zip code), and listed his DEA registration number. GXs 1 & 37. According to a DI, the pharmacy listed

commenced to work under his supervision at his community clinic in Raymond, Washington. *Id.* at 1, 2. Dr. Lush requested that “the DEA permit [Respondent] to hold a registration number so that he will be able to make the most constructive possible contribution to the operations of [the] clinic.” *Id.* at 2. He averred that, given the Commission’s restrictions on Respondent’s license, “there would be no danger to the public as a result of permitting [Respondent] to continue to hold a DEA registration number.” *Id.*

<sup>3</sup>On April 27, 2001, DEA published a guidance document, *Dispensing and Purchasing Controlled Substances over the Internet*, 66 FR 21181. Therein, the Agency explained that “Federal law requires that “[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice” and that “[u]nder Federal and state law, for a doctor to be acting in the usual course of professional practice, there must be a bona fide doctor/patient relationship.” *Id.* at 21182. The Agency further noted that “many state authorities” look to “four elements as an indication that a legitimate doctor/patient relationship has been established.” *Id.* These are: (1) “[a] patient has a medical complaint”; (2) “[a] medical history has been taken”; (3) “[a] physical examination has been performed”; and (4) “[s]ome logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.” *Id.* at 21182–83. The Document then noted that “[c]ompleting a questionnaire that is then reviewed by a doctor hired by the Internet pharmacy could not be considered the basis for a doctor/patient relationship. \* \* \* It is illegal to receive a prescription for a controlled substance without the establishment of a legitimate doctor/patient relationship, and it is unlikely for such a relationship to be formed through Internet correspondence alone.” *Id.* at 21183.

on the labels (Anchor Services, Inc. of Fort Worth, Texas) was a Saran-affiliated pharmacy; however, drug orders were not filled there but rather at the CHS location.<sup>6</sup> Tr. 36; see GX 22, at 3–4.

DEA Investigators also obtained a court order authorizing them to intercept electronic communications (including e-mail and downloads) to and from CHS/ISG from April 17, 2005 through the ensuing 90 days. Tr. 50–51; GX 36, at 2. The intercept yielded 136 prescriptions for controlled substances which were filled between May and June 17, 2005 by Southwest Infusion, one of Saran's sham pharmacies, and which bore Respondent's name as the prescribing doctor, his DEA number, and his signature. See generally GX 4. The prescriptions listed the same street address, suite number and city as Respondent's registered location but indicated the State as Massachusetts, rather than Washington, and a zip code of 98104, rather than 98121. See GXs 1 & 4.

The vast majority of the prescriptions were for schedule III controlled substances containing hydrocodone (typically containing 10 mg. of this controlled substance); other prescriptions were for the schedule IV controlled substances alprazolam and diazepam. See generally GX 4. The prescriptions were sent to patients throughout the United States (and outside of Washington State) and included the UPS shipping labels. *Id.*

DEA also executed search warrants for Saran's business and the residence of Ted Solomon, one of Saran's co-conspirators, who ran several of his own Web sites. Among the items seized at both CHS/ISG and at Solomon's home was a spreadsheet which listed persons who were identified as the "lead[s],"<sup>7</sup> the names of various companies and their Web sites, a contact for the companies, and various physician names. GX 33, at 3–4. Under the lead of "Heather," the spreadsheet listed several companies and their Web sites including Pacific Blue Rx (PacifcBlueRx.com) and FMS (rxmetro.com); the spreadsheet also listed Heynowmeds.com.<sup>8</sup> Tr. 98–100;

<sup>6</sup> The ALJ observed that the record contained no evidence that the medications reflected in the documents seized during the trash runs were actually sent to the individuals whose names appear on the seized documents. See also ALJ at 6. Ordinarily, a pharmacy would not go to the trouble of creating these documents unless it was dispensing a drug.

<sup>7</sup> The testimony established that the "lead" was an employee of Saran who managed various companies' accounts.

<sup>8</sup> The document does not, however, list a physician for heynowmeds.com. See GX 33, at 4.

GX 33, at 3–4. The spreadsheet listed Respondent as the Dr. for both PacificBlueRx and FMS. GX 33, at 3.

According to a DI, these three Web sites (as well as FMS) were owned by Michael Schwerdt, whose father-in-law was Abel Rodriguez.<sup>9</sup> Tr. 100 & 111. Heather Elliot managed their accounts for Saran. *Id.* at 102. According to the DI, Elliot would access the Internet and download approximately 50 prescriptions and print out their labels, which she then gave to people in the pharmacy who filled the vials and readied the drugs for shipping. *Id.* at 103. Elliot was eventually indicted and pled guilty to several Federal felony offenses. RX 27.

On May 23, 2005, a DI went to Heynowmeds.com, which he selected because it was one of the busier Web sites, to purchase hydrocodone. Tr. 67; GX 3, at 1. The Web site listed various types of medicine available, and the DI clicked on "pain relief." *Id.* at 73. The DI then ordered 90 tablets of hydrocodone/acetaminophen 10/325. *Id.* at 74. The DI selected this drug based on its popularity with drug abusers, which the DI explained was because "you can get the strongest strength of hydrocodone and the smallest strength of additives, like acetaminophen." *Id.*

While the Web site prompted the DI to provide some medical information, it did so only after asking for his contact and payment information. *Id.* at 77–78. The Web site also asked for contact information for his physician; the DI entered the name and cell phone of a DEA Special Agent. *Id.* at 79–80. The DI paid \$265.84 for the drugs using a money order.<sup>10</sup> GX 3, at 2 & 5.

Two days later, on May 25, the DI received the hydrocodone that he had ordered. *Id.* at 82. The label indicated that the filling pharmacy was SouthWest Infusion, one of Saran's pharmacies;<sup>11</sup> the prescriber was listed

<sup>9</sup> A July 6, 2005, "Affidavit for Arrest" for Abel Rodriguez identified Michael Schwerdt as Abel Rodriguez's son-in-law. RX 22, at 28. It also indicated that documents printed from Florida Corporations Online and seized at the time of a search warrant for certain business properties listed Abel Rodriguez as the registered agent for La Familia Pharmacy III, Inc. *Id.* at 32.

<sup>10</sup> The instructions sent to the DI about payment for the shipment indicated that he should make his money order payable to Adserv, but the DI made the money order payable to SouthWest Infusion in order to track the payment back to the "fill" pharmacy. Tr. 86–87. Adserv employed Craig Schwerdt, the brother of Michael Schwerdt; the latter sent the former to Saran's headquarters "to make sure that [Heynowmeds'] orders were going out in a timely fashion." *Id.* at 104; see also *id.* at 137; RX 24, at 47.

<sup>11</sup> The DI testified that "at one point" Johar Saran had "23 pharmacies" but that the number "dwindled down to 19 by the end." Tr. at 61.

as "George Mathew, M.D." *Id.* at 61; GX 3, at 3.

The DI testified that Respondent was "the contracting physician" for Heynowmeds, PacificBlueRx, and Rx Metro, Tr. 100, in that he was "the physician that [wa]s approving the drug orders and [wa]s being compensated by these websites for doing so." *Id.* at 102–03. The DI also testified that while he had "no knowledge" as to whether Respondent had personally approved his order for hydrocodone, *id.* at 110, Respondent had "entered into a contract with Abel Rodriguez" and made both his DEA registration and his State license available to Rodriguez. *Id.* at 111.

The DI then admitted that he had not found any contract between Respondent and the three Web sites. *Id.* at 114. Moreover, the DI further testified that during the Title III search, the Investigators found no evidence of personal contact between Respondent and the Saran pharmacies. *Id.* at 62–63. The DI explained, however, that "when a physician enters into a contract with a Web site owner, the Web site owner arranges for the fill pharmacy" and there is "no reason for the physician to contact that fill pharmacy unless he's \* \* \* following up on any questions or concerns that there might be about the drugs." *Id.* at 63. The DI further testified that because Respondent's case was an "administrative" matter, the Investigators "did not follow the money trail" with respect to him. *Id.* Moreover, the Investigators did not have evidence of e-mails which Respondent may have sent to the three Web sites and which the Web sites may have sent to him.<sup>12</sup> *Id.* at 158 & 164.

On September 20, 2005, a Grand Jury indicted Johar Saran, 18 of his co-conspirators, and Saran's corporations for multiple felony offenses under Federal law. GX 22; Tr. 26. Thereafter, on September 22, 2005, DEA Investigators from the Seattle Division Office served the Order to Show Cause and Immediate Suspension on Respondent. Tr. 147, 149, 595, 597–98.

Later that day, the DIs met with Respondent and his attorney at the latter's office. *Id.* at 598. According to one of the DIs, during the interview Respondent told the DIs that "everything" in the Show Cause Order

<sup>12</sup> The ALJ noted that Government did not produce any testimony or statements from individuals associated with Saran including Johar Saran (and Heather Elliot) implicating Respondent. See ALJ at 5. However, this is hardly dispositive given that the Government did not allege that Respondent worked directly for a Saran-owned Web site. Moreover, given that this was a blatantly criminal scheme, it is not clear why Ms. Elliot would have needed to speak with Respondent rather than the Web site owners.

was “false.” *Id.* at 599. Respondent admitted, however, that “he had at one time \* \* \* authorized some prescriptions on the Internet,” which was between “July 2003 and early 2004,” when he had a “contract with a company called eDrugs or eDrugstore.” *Id.* at 599, 600.

Respondent told Investigators that he approved drug orders for eDrugstore by reviewing an online questionnaire and a drug recommendation; if he agreed with the recommendation, he would authorize the drug order. *Id.* at 609. He further stated that the prescriptions he authorized were for “mainly non-controlled substances” and that, while he had authorized some prescriptions for “diet medications,” he “had not authorized any narcotic controlled substances.” *Id.* at 599. Respondent further maintained “that the quantity of the controlled substance prescriptions versus the non-controlled substance prescriptions was very small.” *Id.* at 606. Respondent did not have medical records pertinent to his prescribing for eDrugstore. *Id.* at 606–07.

Respondent told the DIs that he had been paid \$30,000 by eDrugstore during the six-month period he prescribed for it. *Id.* at 599–600, 605–06. He also stated that he was paid \$3 for non-controlled substances and \$10 for the diet drugs, which he admitted were controlled substances. *Id.* at 606. While Respondent further told the DIs that he would provide them with bank records regarding the payments he received from eDrugstore, he never did. *Id.* at 606–07.

However, his contention that he wrote only a “very small” number of controlled substance prescriptions cannot be reconciled with the MQAC’s finding that Respondent authorized 2,700 prescriptions for eDrugstore, the total amount of the compensation (\$30,000) he admitted to having received from eDrugstore, and the respective amounts eDrugstore paid him for the controlled (\$10) and non-controlled prescriptions (\$3). Indeed, this evidence suggests that the great majority of the prescriptions he wrote for eDrugstore were for controlled substances.<sup>13</sup>

With respect to the allegations of the Show Cause Order, Respondent stated that while he was prescribing for

<sup>13</sup> To demonstrate, even if half of the 2,700 prescriptions (1,350) were for controlled substances, he would have earned less than \$18,000 based on the amounts he received for the controlled (\$10) and non-controlled (\$3) prescriptions. Given the number of prescriptions, the only way that Respondent would have earned \$30,000 was if nearly all the prescriptions were for controlled substances.

eDrugstore, he received a telephone call from Abel Rodriguez, who “had obtained his name from a faxed prescription that he had received from eDrugstore.” *Id.* at 602. Respondent told the DIs that eDrugstore used Rodriguez’s pharmacy, La Familia Pharmacy, to fill some of its prescriptions, and that that was how Rodriguez received the prescription (which contained his DEA registration number).<sup>14</sup> *Id.* at 624, 629. Rodriguez solicited Respondent to write prescriptions for his Web site; Respondent told the DIs that Rodriguez offered to pay him \$30 to \$35 for each controlled substance prescription. *Id.* at 611. After the phone call, Respondent went to Florida to visit Rodriguez and his pharmacy because he did not know Rodriguez, and Rodriguez came to Seattle. *Id.* at 612.

During the interview, Respondent maintained that he had written only about 100 prescriptions for non-controlled substances for Rodriguez’s Web site. *Id.* at 614. He also denied having written any controlled substance prescriptions for him. *Id.* He denied receiving any money from Johar Saran. *Id.* at 601. He also denied knowing any of the individuals or entities listed in the Order to Show Cause and “said that someone else had provided [his] DEA number to them because he had not provided anything to any of these people” because he did not “know any of these people.” *Id.* at 604.

The Supervisory DI present at Respondent’s interview testified that Respondent was cooperative, supportive of the DEA, and that “[h]e appeared truthful.” *Id.* at 604, 628. In a report submitted to the DEA Fort Worth office, she described Respondent’s demeanor during the interview as candid and cooperative. *Id.* at 150.

In support of his contention that Rodriguez had used his registration number without his permission, Respondent offered into evidence an affidavit prepared by Special Agents of the Florida Department of Law Enforcement in support of an application for a warrant to arrest Rodriguez. RX 22, at 12 *et seq.* According to Respondent, the affidavit stated that “Rodriguez had forged the name of a physician, Miguel Mora, by ‘rubber-stamping’ Dr. Mora’s name to prescriptions filled by the La Familia group, even though he was not actually involved in prescribing the medications.” Resp. Br. at 17 (quoting RX 22, at 49). However, the affidavit does not identify Respondent as a physician whose name and registration

<sup>14</sup> Respondent denied having provided Rodriguez with his DEA number. *Id.* at 628.

were used to prescribe controlled substances without his authorization.<sup>15</sup> See generally RX 22.

Respondent did not testify in this proceeding. Instead, to bolster the credibility of his statement to the investigators that he did not authorize controlled prescriptions pursuant to his arrangement with Abel Rodriguez, he offered evidence that, in May 2007, he took and passed a polygraph examination which was arranged by his attorney. Tr. 505–07; RXs 6 & 33. The ALJ admitted this evidence over the objection of the Government. Tr. 641.

In *United States v. Scheffer*, 523 U.S. 303 (1998), the Supreme Court upheld a rule of evidence, which renders polygraph evidence inadmissible in a criminal proceeding, against a constitutional challenge. Fundamental to the Court’s holding was its conclusion that polygraph evidence is not reliable. As the Court explained, “there is simply no consensus that polygraph evidence is reliable,” and “[t]o this day, the scientific community remains extremely polarized about the reliability of polygraph techniques.” *Scheffer*, 523 U.S. at 309 (citations omitted).

Under the Administrative Procedure Act (APA), the Agency’s order must be “supported by and in accordance with *the reliable*, probative, and substantial evidence.” 5 U.S.C. 556(d) (emphasis added). Respondent has made no showing that the scientific community and the courts consider this evidence any more reliable today than they did when *Scheffer* was decided. While Respondent argues that several Agencies (including this one) use polygraphs for a variety of administrative and investigatory purposes, the *Scheffer* Court rejected the same argument, noting, most significantly, that these uses “do not establish the reliability of polygraphs as trial evidence.” 523 U.S. at 312 n.8.<sup>16</sup> Accordingly, I conclude

<sup>15</sup> Earlier, the affidavit noted that during a search, officers had found in a personnel file of one of Abel Rodriguez’s associates “[a]n entry labeled ‘George Matthew, 121 Vine St, Seattle WA, 98122,’ which also included his DEA number). RX 22, at 38. In parentheses, the affidavit stated that Respondent “has previously been identified as a doctor writing prescriptions for the internet pharmacy operation.” *Id.*

<sup>16</sup> Even were I to hold Respondent’s polygraph evidence admissible, I would give it no weight as each of the questions was compounded. More specifically, the examiner asked Respondent if he had: (1) “ever done business with Johar Saran, CHS/HIS [sic], or <http://www.heynowmeds.com>,” (2) “ever personally prescribed controlled substances for customers of Johar Saran, CHS/HIS [sic], or <http://www.heynowmeds.com>, and (3) “ever received any payment and/or money from Johar Saran, CHS/ISH [sic] or <http://www.heynowmeds.com>.” Tr. 506–07.

that the evidence should not have been admitted and I decline to rely on it.<sup>17</sup>

The Government also called Dr. George Van Komen, who was qualified as an expert witness in the prescribing of controlled substances including prescribing over the Internet. Tr. 284. Dr. Van Komen holds board certification in internal medicine, is a fellow of the American College of Physicians, and is an assistant professor of clinical medicine at the University of Utah School of Medicine, where he teaches a course in medical ethics and professionalism. GX 10, at 1; Tr. 261–63. Previously, Dr. Van Komen was a member and chairman of the Utah Physicians Licensing Board as well as a member of the Board of Directors and President of the Federation of State Medical Boards (FSMB); currently, he is the chairman of the Utah Medical Association's Committee for Controlled Substances. GX 10, at 2–3. Dr. Van Komen was also a member of the committee which drafted the FSMB's *Model Guidelines for the Appropriate Use of the Internet in Medical Practice* (2002). Tr. 290; see also GX 18.

Dr. Van Komen testified that there is "a well defined standard of care" for prescribing controlled substances and establishing a legitimate doctor patient relationship. Tr. 295. He further noted that the standards for Internet prescribing adopted by the MQAC (GX 24), closely follow the FSMB's guidelines and "outline for physicians in very clear language what's appropriate and what's not appropriate." Tr. 297. Dr. Van Komen then testified

After the hearing, the Government submitted an affidavit by a DEA Supervisory Special Agent (SSA) who was also the Polygraph Staff Coordinator. GX 38. The SSA reviewed the testimony of Respondent's polygraph examiner as well as Respondent's Exhibits 33 (pre-polygraph interview notes), 34 (Polygraph examination agreement), and 35 (Backster Zone Comparison Test Variations). *Id.* at 2. The SSA concluded that all three target questions in the polygraph exam were compounded, which "could substantially diminish the accuracy of" the exam results, as the questions could have been truthfully answered either yes or no. *Id.* (emphasis in original). To avoid this result, the questions should have been asked individually as to Johar Saran, CHS/ISG, and <http://www.heynewmeds.com>. *Id.* The SSA further stated that the Respondent's exam would be deemed an "Administrative Opinion," because the results were not based upon the physiological responses to applied stimuli. *Id.* at 3.

<sup>17</sup> Respondent also called an expert witness in information technology, who attempted to trace the source and destination Internet Protocol addresses identified in the intercepted prescriptions to show that Respondent did not have a connection with, or own, the addresses. Tr. 397–405. The witness, however, acknowledged that his "research was inconclusive." *Id.* at 405; see also *id.* at 413. He further acknowledged that he was not asked to research whether Respondent had accessed the IP addresses and that his research did not establish that Respondent had not accessed them. *Id.* at 422.

that the standard of care for prescribing a controlled substance requires that a doctor-patient relationship be established. *Id.* at 304–05. More specifically, Dr. Van Komen testified that this begins with the patient presenting with an ailment or medical problem and that the physician must then: (1) Meet the patient face-to-face to take a history and perform a physical examination; (2) order appropriate tests to confirm or eliminate a potential diagnosis; (3) make a diagnosis; (4) discuss the diagnosis and treatment options with the patient; and (5) discuss the risks and benefits of specific treatment choices. *Id.* at 304–06. The standard of care for prescribing a controlled substance also requires that the physician maintain patient files documenting "what has occurred in the doctor/patient relationship" and following up with the patient to make sure that the treatment is having the intended effect and not causing side effects. *Id.* at 307–08, 344.

Dr. Van Komen subsequently explained that reviewing an online questionnaire or engaging in a telephone consultation does not provide "the same information" regarding a patient's potential drug dependency as does "a face-to-face meeting." Tr. 334–35. Moreover, after writing a prescription, a doctor can reassess the patient when he comes back to the office. *Id.* at 334.

Based on his review of the MQAC's 2005 Statement of Charges (GX 27) and its 2007 Final Order (GX 28), Dr. Van Komen opined that Respondent "prescribe[d] outside the standard of care usually accepted or as is accepted by the medical community." Tr. 328. He also opined that the DVD which showed how the DI obtained hydrocodone through the Heynowmeds Web site, as well as the prescriptions that were listed on the spreadsheet of intercepted data, supported his conclusion. *Id.* at 329–30.

The Government then asked Dr. Van Komen whether he had an opinion as to whether Respondent's prescriptions were issued for "a legitimate medical purpose." *Id.* at 330. Dr. Van Komen explained that there was no "way of knowing if any of the prescriptions are for a legitimate medical purpose because there's no contemporaneous medical records on any of the patients." *Id.* Continuing, Dr. Van Komen explained that the failure to maintain medical records is "a huge breach of the responsibility of a physician when he's prescribing any medication \* \* \* especially with controlled drugs." *Id.*

As for the MQAC's finding that Respondent had violated State law in prescribing phentermine, Dr. Van Komen testified that this drug is a

schedule IV controlled substance which "can be abused and that the physician needs to [engage in] very close monitoring of patients," and that "it makes no sense at all to prescribe phentermine without a doctor/patient relationship." *Id.* at 331. He further testified that phentermine is a stimulant, and that "[o]f all of the drugs that we prescribe, stimulants are by far the most addictive." *Id.* at 343.

With respect to hydrocodone, Dr. Van Komen testified that a physician has to have "a real interaction" with "the patient before" deciding to "use opioid medication in the treatment of [the patient's] pain" and that once the physician prescribes the drug, he has to "have the patient come back" to "make sure that [the patient is] using the medication appropriately." *Id.* at 337. Dr. Van Komen also explained that hydrocodone is "very abused" and is "one of the leading cause[s] of drug overdose deaths in the United States." *Id.* at 338.

On cross-examination, Dr. Van Komen further explained that even if he did not consider the evidence that the Government obtained in the Saran investigation, his "opinion" regarding the medical propriety of Respondent's prescribing "would be the same as the [MQAC] found." *Id.* at 360. Continuing, Dr. Van Komen opined that Respondent "abuse[d] his authority as a physician by prescribing on the Internet without bonafide doctor/patient relationships." *Id.* at 360–61. He further noted that Respondent "did allow his DEA number and his medical license to remain with the Internet company" and "[h]e did very little after his initial stopping of prescribing in 2004 to try and get back the information from the Internet company." *Id.* at 361.

## Discussion

Pursuant to Section 303(f) of the Controlled Substances Act (CSA), "[t]he Attorney General may deny an application for [a practitioner's] registration if he determines that the issuance of such registration would be inconsistent with the public interest." *Id.* § 823(f). 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.* § 823(f).

“These 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 to deny an application or revoke an existing registration. *Id.* Moreover, I am “not required to make findings as to all of the factors.” *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall v. DEA*, 412 F.3d 165, 173–74 (DC Cir. 2005).

With respect to a practitioner’s registration, the Government bears the burden of proving (by a preponderance of the evidence) that granting the application would be inconsistent with the public interest. 21 CFR 1301.44(d). However, where the Government satisfies its *prima facie* burden, as for example, by showing that an applicant, who was previously registered, committed acts which are inconsistent with the public interest, the burden then shifts to the applicant to demonstrate why he can be entrusted with a registration.

In this matter, I agree with the ALJ that the Government has satisfied its *prima facie* burden by showing that Respondent committed acts which render his registration inconsistent with the public interest. *See* ALJ at 31 (“The Government clearly met its burden of proving that justification exists for revoking the Respondent’s DEA registration.”). However, I reject the ALJ’s implicit conclusion that Respondent has rebutted the Government’s *prima facie* case and her recommendation that Respondent “be given an opportunity to demonstrate,” while he is being mentored, “his continuing ability and willingness to comply with the statutory and regulatory provisions that adhere to a DEA registration.” *Id.* at 32.

As explained below, the ALJ disregarded the extensive body of Agency precedent holding that an applicant must acknowledge his prior misconduct and accept responsibility for it. *See, e.g., Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (collecting cases). Respondent did not testify in this proceeding and continues to assert that he has “done nothing wrong.” Tr. 645 (closing argument); *see also* Resp. Br. at 46. Accordingly, Respondent has not shown that he is entitled to a new registration.

#### Factor One—The Recommendation of the State Licensing Board

Respondent has twice been subjected to disciplinary proceedings brought by the MQAC. The latter MQAC case, which included a summary suspension for his failure to properly treat emergency room patients, did not involve his prescribing of controlled substances.

However, the first case was based on his internet prescribing of phentermine to patients he never physically examined, as well as his prescribing of controlled substances to three other patients on whom he did not maintain medical records. Based on this conduct, the MQAC found Respondent guilty of unprofessional conduct and imposed a suspension, which it stayed, as well as restrictions on his practice.

Notably, in this matter, the MQAC has not made a recommendation that he retain his DEA registration. Respondent nonetheless argues that its decision reflects its conclusion that permitting him to continue to practice “would not create a danger to public health and safety.” Resp. Br. at 29. In his closing argument, Respondent further maintained that this Agency is required to defer to the MQAC’s decision allowing him to continue to practice under conditions. Tr. 655.

While the MQAC’s reinstatement of his medical license (following the second proceeding) now makes him eligible to hold a DEA registration, *see* 21 U.S.C. 823(f), this Agency has repeatedly held that possessing a valid State license is not dispositive of the public interest inquiry. *See Patrick W. Stodola*, 74 FR 20727, 20730 n.16 (2009); *Robert A. Leslie*, 68 FR at 15230. DEA has long held that “the Controlled Substances Act requires that the Administrator \* \* \* make an independent determination as to whether the granting of controlled substances privileges would be in the public interest.” *Mortimer Levin*, 57 FR 8680, 8681 (1992).<sup>18</sup> Accordingly, I am not required to defer to the MQAC’s decision to allow Respondent to practice medicine, and I conclude that this factor is not dispositive either for, or against, granting Respondent’s application.

<sup>18</sup> For reasons explained in my discussion of the sanction, I conclude that the conditions imposed by the MQAC do not adequately protect the public interest.

#### Factors Two and Four—Respondent’s Experience in Dispensing Controlled Substances and His Record of Compliance With Laws Related to Controlled Substances

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 related to controlled substances.” *Id.* *See also* 21 U.S.C. 802(10) (defining the term “dispense” as meaning “to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance”) (emphasis added).

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, 143 (1975)).

Under the CSA, it is fundamental that a practitioner must establish and maintain 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.” *Laurence T. McKinney*, 73 FR 43260, 43265 n.22 (2008); *see also Moore*, 423 U.S. at 142–43 (noting that evidence established that physician “exceeded the bounds of ‘professional practice,’” when “he gave inadequate physical examinations or none at all,” “ignored the results of the tests he did make,” and “took no precautions against \* \* \* misuse and diversion”). At the time of the events at issue here, the CSA generally looked to State law to determine whether a doctor and patient had established a bonafide doctor-patient relationship. *See Kamir Garcés-Mejías*, 72 FR 54931, 54935 (2007); *United Prescription Services, Inc.*, 72 FR 50397, 50407 (2007).<sup>19</sup>

<sup>19</sup> On October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer



It is undisputed that Respondent prescribed for the eDrugstore Web site and issued numerous prescriptions for phentermine, a schedule IV controlled substance, to persons located throughout the United States. As the MQAC found, Respondent did not take a medical history on any of these persons and did not perform physical examinations of them. As the MQAC further found, he did not obtain each person's medical records and did not attempt to verify (and had no way to verify) the information which these persons provided. Yet as the MQAC found, he diagnosed each person and prescribed to them. As the MQAC found, and as Dr. Van Komen testified, Respondent failed to comply with the standard of care for prescribing phentermine.<sup>20</sup>

Protection Act of 2008, Public Law 110-425, 122 Stat. 4820 (2008). Section 2 of the Act prohibits the dispensing of a prescription controlled substance "by means of the Internet without a valid prescription," and defines, in relevant part, "[t]he term 'valid prescription' [to] mean[] a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by \* \* \* a practitioner who has conducted at least 1 in-person medical evaluation of the patient." 122 Stat. 4820 (codified at 21 U.S.C. 829(e)(1) & (2)). Section 2 further defines "[t]he term 'in-person medical evaluation' [to] mean[] a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals." *Id.* (codified at 21 U.S.C. 829(e)(2)(B)). These provisions do not, however, apply to Respondent's conduct.

<sup>20</sup> At the hearing, Respondent contended that the Government violated his right to Due Process by introducing the evidence regarding the MQAC's 2005 statement of charges and its 2007 order because the Government did not make any allegations in the Show Cause Order regarding the first MQAC proceeding, Tr. 322. Respondent did not dispute, however, that the documents were noticed in the Government's pre-hearing statement and that they were timely exchanged. *Id.* at 324-25. The ALJ properly overruled Respondent's objection in holding that the Government had complied with due process.

One of the fundamental tenets of Due Process is that the Agency must provide a respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action. See *NLRB v. I.W.G., Inc.*, 144 F.3d 685, 688-89 (10th Cir. 1998); *Pergament United Sales, Inc. v. NLRB*, 920 F.2d 130, 134 (2d Cir. 1990). See also 5 U.S.C. 554(b) ("Persons entitled to notice of an agency hearing shall be timely informed of \* \* \* the matters of fact and law asserted.").

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

It is acknowledged that the MQAC found that there was no evidence that Respondent "diverted controlled substances \* \* \* for illegitimate purpose in violation of any drug law." GX 28, at 8. However, the MQAC did not explain what legal standard it applied in making this finding. While the State of Washington can, of course, apply any standard it chooses in defining diversion for purposes of State law, the State has no authority to definitively interpret the CSA and determine what constitutes diversion under Federal law.

Several Federal courts of appeals have held that conduct similar to what the MQAC found Respondent to have engaged in by prescribing phentermine over the Internet violates the prescription requirement of Federal law and constitutes an unlawful distribution under 21 U.S.C. 841(a). See *United States v. Nelson*, 383 F.3d 1227, 1231-32 (10th Cir. 2004) (upholding physician's conviction for conspiracy to distribute prescription controlled substances "outside the usual course of professional practice" through internet scheme when physician approved "prescription drug requests \* \* \* without ever examining his purported patient"); see also *United States v. Smith*, 573 F.3d 639, 657-58 (8th Cir. 2009) (upholding conviction of operator of internet drug distribution scheme for violations of 21 U.S.C. 841(a)(1) where "[t]here was never an established doctor/patient relationship. There was never a face-to-face examination. There was never a history. There was no physical examination." (citation omitted)); *United States v. Fuchs*, 467 F.3d 889 (5th Cir. 2006) (rejecting pharmacist's challenge to convictions for dispensing controlled substance "not in the usual course of professional practice in violation of 21 U.S.C. 841(a);" scheme involved customers

disclose an allegation in the Order to Show Cause is not dispositive, and an issue can be litigated if the Government otherwise timely notifies a respondent of its intent to litigate the issue.

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

going to pharmacist's Web site, completing an online profile and requesting medication, which was then forwarded to physician who "reviewed the patient's profile and approved and signed the prescription without communicating with the patient either face to face or over the telephone".

As these decisions make plain, a physician acts outside of the usual course of professional practice and lacks a legitimate medical purpose when he issues a controlled substance prescription to a person with whom he has not established a legitimate doctor-patient relationship. As the MQAC's finding makes clear—and as Dr. Van Komen's testimony corroborates—by failing to take a medical history, review medical records and perform physical examinations, Respondent did not establish a legitimate doctor-patient relationship with any of the persons he prescribed phentermine to through eDrugstore. Tr. 330 & 360-61.

Respondent's conduct was not simply "malpractice, or even intentional malpractice." *United States v. Feingold*, 454 F.3d 1001, 1010 (9th Cir. 2006). Rather, he "wantonly ignored the basic protocols of the medical profession" and "his actions completely betrayed any semblance of legitimate medical treatment." *Id.* Accordingly, I hold that Respondent, in issuing phentermine prescriptions for eDrugstore, acted outside of the usual course of professional practice and lacked a legitimate medical purpose and therefore violated Federal law. 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a). And to make clear for purposes of Federal law, where, as here, a physician violates the CSA's prescription requirement, the drug is deemed diverted.<sup>21</sup>

I further find that the Government has proved by a preponderance of the

<sup>21</sup> The MQAC also found that Respondent had prescribed controlled substances to three State residents and yet had "failed to keep any medical records for these patients" and thus lacked documentation of having taken the patient's history, physical exam, and had no "documentation of any kind to support the patient's diagnosis and treatment." GX 28, at 7. Here again, the MQAC found that Respondent had committed unprofessional conduct and violated the standard of care applicable under Washington law. *Id.* However, the MQAC found that the State had failed to prove that Respondent lacked a therapeutic purpose in issuing these prescriptions.

While the ALJ's opinion erroneously suggests that the CSA requires that a physician maintain patient records, see ALJ at 26-27, the CSA requires only that a doctor maintain records showing the disposition of controlled substances which are dispensed and administered (but not prescribed) as a regular part of his professional practice. See 21 CFR 1304.04(d). However, a practitioner's failure to maintain records required under State law which relate to the prescribing of controlled substances is properly considered by the Agency under factors two, four, and five of the public interest standard.

evidence that Respondent also wrote the prescriptions which were identified as having been ordered through the Heynowmeds Web site and which were filled by the Saran pharmacies. See GXs 2–5. Relatedly, I reject Respondent's affirmative defense that his name, signature and DEA registration number were "stole[n] and misused" by Abel Rodriguez.

As found above, Respondent's name, registration number, and signature were found on more than 130 controlled substance prescriptions which were intercepted by the Government in its investigation of the Saran conspiracy;<sup>22</sup> these prescriptions were clearly distributed as evidenced by the attached shipping labels. GX 3. The presence of Respondent's name, registration number, and signature on these prescriptions creates a rebuttable presumption that he authorized them. Moreover, during the execution of search warrants at both CHS/ISG and the home of one of Saran's co-conspirators, Investigators seized a document which listed Respondent as the prescribing physician for several Web sites whose prescriptions were filled at Saran's pharmacies. Finally, in an interview with investigators, Respondent admitted that he had travelled from Washington State to Florida to meet Abel Rodriguez and that he had written prescriptions for Rodriguez (although he denied writing controlled substance prescriptions for his Web site).

Respondent did not testify in this proceeding. Instead, to support his defense, he put forward: (1) The results of a polygraph examination; (2) an affidavit submitted by Florida law enforcement officers in support of an arrest warrant for Abel Rodriguez, which stated that another physician's signature was used by an associate of Rodriguez to authorize prescriptions even though the physician was not involved in prescribing the drugs; and (3) the testimony of a DI who served the Show Cause Order and interviewed him later the same day during which he denied having written prescriptions for Heynowmeds.

Respondent's evidence is not sufficient to rebut the presumption that he wrote the prescriptions. With respect to the polygraph evidence, even putting aside the criticism of the Government's expert regarding the manner in which the test was administered, there is no consensus among the scientific

community and the courts that polygraph evidence is reliable. See *United States v. Scheffer*, 523 U.S. at 309. As explained above, this evidence does not meet the standard of reliability imposed by the APA.

As for the affidavit's statement (which was based on the statement of one of Rodriguez's associates) that another physician's signature was used without his authority, all this establishes is that that physician's signature was misused. It does not prove that Respondent's registration was misused in writing the prescriptions.

Finally, Respondent relies on his statement to the DIs in which he denied that he wrote the controlled substance prescriptions identified in the Order to Show Cause. Respondent also points to the testimony of the DI that she found him to be credible.

However, Respondent's interview was not sworn. Moreover, the DI who did the interview was based in Seattle, had no previous role in the Saran investigation which was run by the Fort Worth, Texas office, and thus was not familiar with what the investigation had uncovered. Accordingly, the DI did not have the underlying knowledge of the facts of the investigation necessary to probe Respondent's story and to evaluate his credibility.

Beyond this, there is no reason to give dispositive weight to this statement when Respondent could have testified (and subjected himself to cross-examination) at his hearing but chose not to. It is well established that the Agency can draw an adverse inference from a respondent's failure "to testify in response to probative evidence offered against" him. See *Baxter v. Palmigiano*, 425 U.S. 308, 316 (1976); see also *United States v. Solano-Godines*, 120 F.3d 957, 962 (9th Cir. 1997) ("In civil proceedings \* \* \* the Fifth Amendment does not forbid fact finders from drawing adverse inferences against a party who refuses to testify."). It is appropriate to draw an adverse inference here, where the Government produced evidence showing that his name, registration number and signature were used to authorize controlled substance prescriptions and Respondent failed to testify.<sup>23</sup>

<sup>23</sup> In his brief, Respondent argues that the Government has not met its evidentiary burden because it did not present additional evidence establishing his involvement with Heynowmeds such as "proof of payments" to him from Heynowmeds or "testimony from an undercover officer or from bona fide drug-seeking customers about direct contacts with" him. Resp. Br. at 34–36. Respondent's position would have some merit if he had presented substantial, reliable and probative evidence that he was not involved with Heynowmeds. He did not.

I thus find that Respondent authorized the intercepted prescriptions. And for the same reasons that I found that the phentermine prescriptions violated Federal law (*i.e.*, he did not establish a legitimate doctor/patient relationship with those he prescribed for), I conclude that these prescriptions were also issued outside of the usual course of professional practice and lacked a legitimate medical purpose and thus violated Federal law. See 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a).

The prescriptions violated Federal law for a further reason. As the Supreme Court explained shortly after the CSA's enactment, "[i]n the case of a physician[,] [the Act] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice." *United States v. Moore*, 423 U.S. at 140–41. See also 21 U.S.C. 802(21) (defining "[t]he term 'practitioner' [to] mean[] a physician \* \* \* or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices \* \* \* to dispense \* \* \* a controlled substance in the course of professional practice."). Accordingly, DEA has held that "[a] physician who engages in the unauthorized practice of medicine under state law is not a 'practitioner acting in the usual course of \* \* \* professional practice,'" and that "[a] controlled-substance prescription issued by a physician who lacks the license necessary to practice medicine within a State is therefore unlawful under the CSA." *United Prescription Services, Inc.*, 72 FR at 50407 (quoting 21 CFR 1306.04(a)). Likewise, the MQAC's 2002 Guidelines clearly stated that "[p]hysicians who treat or prescribe through Internet Web sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients reside." GX 24, at 6. Because Respondent was licensed only in Washington State, the prescriptions identified in Government Exhibits 2–5 were unlawful under both Federal law and the laws of numerous States for this reason as well. See, *e.g.*, Ala. Code § 34–24–502 (2005); *id.* § 34–24–51; Cal. Bus. & Prof. Code § 2052 (2005)<sup>24</sup>; N.C. Gen.

I further note that while Respondent promised to turn over his bank records, he never did.

<sup>24</sup> See also *Hageseth v. Superior Court*, 59 Cal. Rptr. 3d 385 (Ct. App. 2007) (upholding prosecution of out-of-State and unlicensed physician who prescribed drug to State resident over the Internet for the unauthorized practice of medicine); *United Prescription Services*, 72 FR at 50401 n.10 (discussing actions brought by Medical

<sup>22</sup> The act of writing a prescription, by itself, constitutes the delivery of a controlled substance under Federal law even if the prescription is never dispensed by a pharmacy.

Stat. § 90–18; Tenn. Code Ann. § 63–6–201; Tenn. Comp. R. & Regs. 0880–2.16; Tex. Occ. Code Ann. §§ 151.056 & 155.001.

As the forgoing demonstrates, Respondent issued numerous controlled substance prescriptions in violation of both Federal and State laws. He also lacked the records required under Washington law to justify his prescribing of controlled substances. Accordingly, I conclude that the evidence presented by the Government on factors two and four satisfies its *prima facie* burden of showing that granting Respondent's application "would be inconsistent with the public interest." 21 U.S.C. 823(f).

### Sanction

Under Agency precedent, where, as here, "the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must "present[] sufficient mitigating evidence to assure the Administrator that [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); *Cuong Tron Tran*, 63 FR 64280, 62483 (1998); *Prince George Daniels*, 60 FR 62884, 62887 (1995). *See also Hoxie v. DEA*, 419 F.3d at 483 ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[]") in the public interest determination).

The ALJ did not acknowledge any of these cases in her recommended decision. *See* ALJ at 30–32. Instead, she noted that it was "appropriate to consider all of the facts and circumstances" which, in her view, include that he "was cooperative and truthful when working with DEA personnel," the Medical Board's 2007 finding that "there was no evidence that [he] mishandled controlled substances during the MQAC's" June's 2005 investigation, and "most significant[ly],"

that under the MQAC's 2009 Order, Respondent is now being supervised by another physician. *Id.* Apparently, the ALJ also deemed it significant that since the institution of the proceeding, the Agency had not found any evidence of Respondent's mishandling of controlled substances. *Id.* at 31–32. Expressing her belief that "this proceeding has instilled in the Respondent a grave respect for the authority and responsibilities which attach to his DEA registration," the ALJ recommended that Respondent "be given an opportunity to demonstrate, during his mentorship, his continuing ability and willingness to comply with the statutory and regulatory provisions that adhere to a \* \* \* registration." *Id.* at 32.

The ALJ's reasoning is unpersuasive. While it is true that the MQAC found no diversion in its 2005 investigation, as explained above, under Federal law, when prescriptions are issued outside of the usual course of professional practice and lack a legitimate medical purpose, 21 CFR 1306.04(a), the drugs are deemed to have been diverted. Indeed, in other decisions involving practitioners who prescribed over the Internet, DEA has noted the egregious nature of this misconduct and the serious threat it poses to public health and safety. *See William R. Lockridge*, 71 FR 77791, 77800 (2006) (noting that internet prescriber "was a drug dealer" and that conduct created "imminent danger to public health and safety"); *Mario Avello*, 70 FR 11695, 11697 (2005); *cf. Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36504 (2007) (discussing increase in the rates of prescription drug abuse and the Internet's "role in facilitating the growth of prescription drug abuse"); *see also* National Center on Addiction and Substance Abuse, "You've Got Drugs?" *IV: Prescription Drug Pushers on the Internet* (2007), at 11 ("[T]he wide availability of dangerous and addictive drugs on the Internet reveals a wide-open channel of distribution. This easy availability has enormous implications for public health, particularly the health of our children, since research has documented the tight connection between availability of drugs to young people and substance abuse and addiction.") (GX 32).

Moreover, as explained above, the Federal courts have recognized that prescribing controlled substances under these circumstances (*i.e.*, without taking medical history, physically examining the patient, and maintaining patient records) constitutes drug dealing. *See Nelson*, 383 F.3d at 1231–32 ("A practitioner has unlawfully distributed a controlled substance if she prescribes

the substance either outside the usual course of medical practice or without a legitimate medical purpose."); *United States v. Quinones*, 536 F.Supp.2d 267, 271 (E.D.N.Y. 2008) (rejecting motion to dismiss indictment under 21 U.S.C. 841; "[t]hat the moving defendants allegedly carried out their activities through the Internet is of no consequence. Two circuit courts have approved the application of the Federal drugs laws to the operation of Internet pharmacies.") (citing *Nelson*, 383 F.3d 1227, and *Fuchs*, 467 F.3d 889). Contrary to the ALJ's understanding, Respondent's internet prescribing does not involve minor regulatory violations, but rather egregious acts which go to the core of the CSA's statutory purpose of preventing diversion and abuse.

As noted above, the ALJ did not even acknowledge the extensive Agency case law which holds that where a registrant has committed acts which render his registration inconsistent with the public interest, he must do two things: (1) Accept responsibility for his actions, and (2) demonstrate that he will not engage in future misconduct. Accordingly, the ALJ made no finding as to whether Respondent has accepted responsibility for his misconduct.

However, the Agency is the ultimate fact finder so I do make a finding. Based on Respondent's failure to testify in this proceeding, as well as his maintaining that he has done nothing wrong, I find that he has not accepted responsibility for his misconduct. *See, e.g., Hoxie*, 419 F.3d at 483 ("admitting fault" is "properly considered" to be an "important factor"). Given the egregious nature of his misconduct, Respondent's failure to acknowledge his wrongdoing provides reason alone to hold that he has not rebutted the Government's *prima facie* case.<sup>25</sup> Accordingly,

<sup>25</sup> None of the other circumstances identified by the ALJ is sufficient to overcome Respondent's failure to acknowledge his misconduct, and only one of them—his being monitored by a mentor—would tend to establish that he can be entrusted with a new registration.

If Respondent had accepted responsibility, the MQAC's limitation of his practice to an office-based setting, which is supervised by another physician who must report to the MQAC, would be entitled to some weight. However, the gravamen of this case involved Respondent's misconduct in prescribing over the Internet and not his prescribing in a clinical setting. Thus, it is not clear that Respondent's mentor has either the authority or the capability to properly monitor him to ensure that he does not engage in internet prescribing. Respondent has therefore also failed to carry his burden with respect to showing that he can be entrusted with a new registration.

As for the ALJ's finding that he was "cooperative," this ignores that during his interview with the DIs he agreed to provide them with his bank records but never did. While the ALJ also noted that Respondent was "truthful," this finding was based

Respondent's application will be denied.

### Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that the pending application of George Mathew, M.D., for a DEA Certificate of Registration as a practitioner be, and it hereby is, denied. This Order is effective November 26, 2010.

Dated: October 17, 2010.

**Michele M. Leonhart,**

*Deputy Administrator.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. 09-48]

#### East Main Street Pharmacy; Affirmance of Suspension Order

On April 23, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to East Main Street Pharmacy ("Respondent"), of Columbus, Ohio. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BE5902615, as a retail pharmacy, as well as the denial of any pending applications to renew or modify its registration, "for reason that [Respondent's] continued registration is inconsistent with the public interest, as that term is used in

on an opinion of an Investigator who lacked adequate information to properly assess his credibility. Moreover, the inconsistency between Respondent's claim that in prescribing for eDrugstore he only wrote a "small minority" of controlled substance prescriptions and the evidence regarding the total number of prescriptions, the amounts he was paid for the respective types of prescriptions, and his compensation, provides further reason to question the ALJ's conclusion.

The ALJ also found it significant that the Agency had not produced any evidence that Respondent mishandled controlled substances since the institution of the proceeding. However, because Respondent failed to file a timely renewal application, thus allowing his registration to expire (and also had his State license suspended), he lacked authority to handle controlled substances for a substantial portion of this period. In addition, the weight to be given this circumstance is significantly diminished by the fact that he was then in the midst of a Show Cause Proceeding.

Finally, the ALJ did not cite any evidence to support her belief that "this proceeding has instilled in the Respondent a grave respect for the authority and responsibility which attach to his DEA registration." ALJ at 32. Given the egregious misconduct proved on this record, rather than take a leap of faith, I rely on the Agency's longstanding rule which requires that a registrant acknowledge his misconduct and the relevant evidence or, as in this case, the lack thereof.

21 U.S.C. 823(f) and 824(a)(4)." ALJ Ex. 1, at 1. More specifically, the Order alleged that Respondent had violated its corresponding responsibility under Federal regulations to not fill unlawful prescriptions. *Id.* at 2 (citing 21 CFR 1306.04(a)).

The Show Cause Order alleged that Respondent was owned by Eugene H. Fletcher, Respondent's sole pharmacist, and that from "September 2005 through February 2006" it "filled 6,619 controlled substance prescriptions" including 4,979 prescriptions issued by Dr. Paul Volkman of Portsmouth, Ohio. *Id.* at 1. The Show Cause Order further alleged that on February 10, 2006, DEA had immediately suspended Volkman's registration and that the Agency subsequently found that he had "repeatedly violated Federal law by prescribing controlled substances without a legitimate medical purpose and outside the course of professional practice." *Id.* (citing *Paul H. Volkman*, 73 FR 30630, 30642 (2008)). The Order also alleged that "Dr. Volkman directed his patients to have their prescriptions filled at" Respondent, who "filled them mostly in exchange for cash," and that "[n]inety-eight percent of Dr. Volkman's patients that filled their prescriptions at [Respondent] did not reside in the Columbus area." *Id.* Relatedly, the Order alleged that some of Volkman's patients travelled from Portsmouth and Chillicothe, Ohio to Respondent, a distance of 92 and 45 miles, respectively; that one of Volkman's patients had travelled from South Central Kentucky to Respondent to obtain his prescriptions, that many of Volkman's patients were obtaining prescriptions from other physicians, and that several of these persons died of overdoses. *Id.* at 2.

The Show Cause Order further alleged that Respondent "filled prescriptions for combinations of controlled substances and the non-controlled, but highly addictive drug carisoprodol [sic] (Soma), under circumstances indicating that the prescriptions were issued outside the usual course of professional practice." *Id.* at 2. More specifically, the Order alleged that Respondent filled for numerous patients of Volkman, "large quantity prescriptions" for a benzodiazepine, two narcotic pain medications, and Soma, and that "[t]hese drug combinations are generally known in the medical and pharmacy profession as being favored by drug-seeking individuals." *Id.* The Order also alleged that Respondent "filled several of the above combination prescriptions when the patients should have had two to three weeks' supply of medication from a previous prescription" and it

either "did not recognize, or ignored these indicators of drug diversion and abuse." *Id.*

Finally, the Order alleged that, with regard to Dr. Volkman's prescriptions, Mr. Fletcher had told a DEA Investigator "that it was 'not [his] job to question a physician.'" *Id.* Based on the above, the Order alleged that Respondent "knew, or should have known that [the] controlled substance prescriptions it filled for patients of Dr. Volkman were for no legitimate medical purpose." *Id.*

By letter of May 20, 2009, counsel for Respondent timely requested a hearing.<sup>1</sup> ALJ Ex. 2, at 1. The matter was then placed on the docket of the Agency's Administrative Law Judges (ALJs), and an ALJ proceeded to conduct pre-hearing procedures.

On May 26, 2009, the ALJ issued an Order for Pre-Hearing Statements. ALJ Ex. 14. The ALJ's order directed the parties to prepare a written statement, to be filed with the Hearing Clerk and served on opposing counsel, disclosing the "names and addresses of all witnesses whose testimony is to be presented." *Id.* at 2. The ALJ further ordered the parties to provide a:

[b]rief summary of the testimony of each witness, with the Government to indicate clearly each and every act, omission or occurrence upon which it relies in seeking to revoke Respondent's DEA Certificate of Registration, and the Respondent to indicate clearly each and every matter as to which it intends to introduce evidence in opposition thereto. The summaries are to state what the testimony will be, rather than merely listing the areas to be covered. The parties are reminded that testimony not disclosed in the prehearing statements or pursuant to subsequent filing is likely to be excluded at the hearing.

*Id.*

On July 31, 2009, the ALJ conducted a pre-hearing conference call with the parties and also issued a Prehearing Ruling. *See* ALJ Ex. 3. In her Prehearing Ruling, the ALJ ordered that "[i]f either party chooses to amend its witness list, it must file a supplement to its Prehearing Statement, noting any changes. The names of additional witnesses must be listed, along with a summary of the proposed testimony." *Id.* at 2. The ALJ further "reminded" the parties "that testimony not summarized in prehearing statements or

<sup>1</sup> Therein, Respondent denied the allegations maintaining that "Mr. Fletcher, based on his experience, training, and expertise, reasonably believed that all prescriptions filled were for a legitimate medical purpose" and that he "frequently exercised independent judgment to determine if the prescriptions were for legitimate medical purposes, and often refused to fill prescriptions written by licensed medical doctors, including Dr. Volkman." ALJ Ex. 2, at 2.