States on behalf of the United States **Environmental Protection Agency** ("EPA") for reimbursement of response costs incurred or to be incurred by EPA at the Halaco Superfund Site, located in Oxnard, California, from Debtor Commonwealth Aluminum Concast, Inc. ("Commonwealth Aluminum"). The United States alleged Commonwealth Aluminum is liable under Section 107(a)(3) of the Comprehensive **Environmental Response Compensation** and Liability Act, as amended ("CERCLA"), 42 U.S.C. 9607(a)(3), at the Halaco Site as a generator of hazardous wastes disposed of at the Site. Under the Settlement Agreement, the United States' claim will be allowed as an unsecured claim in the amount of \$2,672,800.00, to be paid as a Class 5 claim (General Unsecured Claims Other than Convenience Claims and Insured Claims) in accordance with the confirmed First Amended Joint Plan of Reorganization of Aleris International, Inc. and Its Affiliated Debtors, as Modified (the "Plan").

The proposed Settlement Agreement also resolves the United States' claims for civil penalties and punitive damages under Sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607, for any failure that occurred through the date of lodging of the Settlement Agreement with the Bankruptcy Court by Commonwealth Aluminum (as successor to Barmet Aluminum Corporation), without sufficient cause, to comply with a Unilateral Administrative Order for Remedial Design and Remedial Action at the Brantley Landfill Site, located in Island, McLean County, Kentucky, issued by EPA on March 31, 1995 (the "Brantley UAO"). In return for the resolution of these claims, Aleris Rolled Products, Inc. agrees to undertake on a going forward basis the obligations under the Brantley UAO.

Finally, the Settlement Agreement reflects the resolution of certain claims asserted by the United States, on behalf of EPA, against Debtors Aleris International, Inc. and Wabash Alloys, L.L.C., respectively, under the Clean Air Act, 42 U.S.C. 7401–767, and the Toxic Substances Control Act, 15 U.S.C. 2601–2697, by providing for the withdrawal of the proofs of claim asserting those

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Settlement Agreement. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to pubcomment-ees.enrd@usdoj.gov or

mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, and should refer to *In re: Old AII, Inc. (f/k/a Aleris International, Inc.) et al.*, Case No. 09–10478 (BLS), D.J. Ref. 90–5–2–1–08603/2.

During the public comment period, the proposed Settlement Agreement may also be examined on the following Department of Justice Web site: http://www.usdoj.gov/enrd/Consent Decrees.html.

A cop \overline{y} of the proposed Settlement Agreement may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044-7611 or by faxing or e-mailing a request to Tonia Fleetwood (tonia.fleetwood@usdoj.gov), fax no. (202) 514-0097, phone confirmation number (202) 514-1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of \$5.00 (25 cents per page reproduction cost) payable to the U.S. Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Henry Friedman,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2011–10464 Filed 4–29–11; 8:45 am] **BILLING CODE 4410–15–P**

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—ODVA, Inc.

Notice is hereby given that, on April 01, 2011, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 et seq. ("the Act"), ODVA, Inc. ("ODVA") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, TMG Technologie and Engineering GmbH, Karlsruhe, GERMANY; Tyco Electronics Corporation, Berwyn, PA; Rosemount Inc., Chanhassen, MN; Sencon Incorporated, Bedford Park, IL; ABOUNDI Inc., Nashua, NH; FACTS, Inc., Cuyahoga Falls, OH; STS Co., Ltd., Yongin-si, Gyeonggi-do, REPUBLIC OF KOREA; MagneMotion Inc., Devens,

MA; and ABT EndUstri Enerji Sistemleri Sanayi Tic. Ltd., Sti., Izmir, TURKEY, have been added as parties to this venture.

Also, Perry Slingsby Systems Ltd., North Yorkshire, UNITED KINGDOM; AC&T, Gyeonggi-do, REPUBLIC OF KOREA; F.A. Elec, Seoul, REPUBLIC OF KOREA; METRONIX Corp., Gunpo, Kyunggi-do, REPUBLIC OF KOREA; Trio Motion Technology Ltd., Gloucestershire, UNITED KINGDOM; TOKYO TRON CO., LTD.; TOKYO TRON CO., LTD., Tokyo-to, JAPAN; Alpha Wire, Elizabeth, NJ; and HanYang System, Kyunngido, REPUBLIC OF KOREA, have withdrawn as parties to this venture.

In addition, the following members have changed their names: Moeller GmbH to Eaton Industries GmbH, Bonn, GERMANY; Advanced Energy Japan K.K. to Hitachi Metals, Ltd., Tokyo, JAPAN; and Micro Innovation to Eaton Automation AG, St. Gallen, SWITZERLAND.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and ODVA intends to file additional written notifications disclosing all changes in membership.

On June 21, 1995, ODVA filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on February 15, 1996 (61 FR 6039).

The last notification was filed with the Department on November 15, 2010. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act December 17, 2010 (75 FR 79024).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2011–10466 Filed 4–29–11; 8:45 am] BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 10-18]

Sun & Lake Pharmacy, Inc.; D/B/A the Medicine Shoppe; Revocation of Registration

On October 19, 2009, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Sun & Lake Pharmacy, Inc., d/b/a The Medicine Shoppe (hereinafter, Respondent) of Lakeland, Florida. The Show Cause Order proposed the revocation of Respondent's Certificate of Registration, BS9433828, as a retail pharmacy, and the denial of any pending applications to renew or modify the registration, on the ground that its registration is "inconsistent with the public interest." ALJ Ex. 1, at 1 (citing 21 U.S.C. 823(f) & 824(a)(4)).

More specifically, the Show Cause Order alleged that Respondent had violated both federal and state laws by distributing controlled substances to persons throughout the United States "based on purported prescriptions issued to hundreds of customers through Internet websites * * * by physicians who were not licensed to practice medicine in the states in which the customers resided." Id. at 2 (citations omitted). The Show Cause Order also alleged that the prescriptions violated 21 CFR 1306.04(a) because the "physicians failed to establish a valid physician-patient relationship as required by multiple state laws" and were therefore issued "for other than a legitimate medical purpose and/or outside the usual course of professional practice." Id. at 3 (citations omitted).

Finally, the Order alleged that Respondent filled unlawful prescriptions issued by one Robert Reppy, D.O., because Reppy "issued prescriptions for controlled substances to customers throughout the United States even though he was licensed to practice medicine only in the State of Florida" and was therefore engaged in the unauthorized practice of medicine when he prescribed to persons outside of Florida. *Id.* The Order also alleged that Reppy violated Florida law by "issuing prescriptions via the Internet without a documented patient evaluation and discussion between [him] and [the] patient regarding treatment options." Id. (citations omitted).

On November 23, 2009, Respondent, through its counsel, requested a hearing on the allegations and the matter was placed on the docket of the DEA Administrative Law Judges (ALJs). ALJ Ex. 2. Following pre-hearing procedures, on February 24-25, 2010, an ALJ conducted a hearing in Tampa, Florida. At the hearing, the Government called witnesses to testify and introduced extensive documentary evidence; Respondent called no witnesses and introduced a single exhibit. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law and argument.

On April 8, 2010, the ALJ issued his Recommended Decision (also ALJ). As

to factor one-the recommendation of the state licensing authority—the ALI noted that there was no evidence that the State licensing authority had taken any action against Respondent's pharmacy license. ALJ at 28. The ALJ noted, however, that while state licensure is a necessary condition for holding a registration, Respondent's continued holding of its state license is not dispositive because DEA has an "independent responsibility to determine whether a registration is in the public interest." Id. (citations omitted). The ALJ thus concluded that Respondent's licensure status neither "weigh[s] for or against a determination" that its "continued registration * * * consistent with the public interest." Id.

As to factor three—Respondent's record of conviction of offenses related to the distribution or dispensing of controlled substances—the ALJ noted that while Respondent remains the subject of a criminal investigation, it has not been "convicted of any crime." Id. The ALJ reasoned, however, that "the probative value" of this finding "is somewhat diminished by the myriad of considerations that are factored into a decision to initiate, pursue, and dispose of criminal proceedings by" the prosecuting authorities. Id. at 28. The ALJ apparently concluded that this factor neither supported nor refuted the conclusion that Respondent's continued registration is inconsistent with the public interest. Id. at 29.

The ALJ considered the remaining factors—its experience in dispensing controlled substances (factor two), its compliance with applicable laws relating to controlled substances (factor four), and other conduct which may threaten public health and safety (factor five)—together. Id. at 29-48. With regard to these factors, the ALJ noted that there were two primary issues: (1) Whether Respondent complied with its "corresponding responsibility" under 21 CFR 1306.04(a) to not knowingly fill a prescription which has not been issued for a legitimate medical purpose, and (2) whether it "was authorized to dispense controlled substances to the ultimate user who received them where they were delivered." Id. at 32.

As to the first issue, the ALJ explained that a "pharmacy registrant must understand the requirements attendant upon the issuance of an effective prescription under the regulations." *Id.* at 33. The ALJ further noted that under the Controlled Substances Act, "it is fundamental that a physician practitioner must have established a bona fide doctor-patient relationship in order to act 'in the usual course of professional practice' and to issue a

prescription 'for a legitimate medical purpose," and that at the time of the conduct at issue, "the CSA generally looked to state law to determine whether a bona fide doctor patient relationship existed." Id. at 33-34 (citations omitted). The ALJ also explained that under agency precedent, "'an entity which voluntarily engages in commerce by shipping controlled substances to persons located in other States is properly charged with knowledge of the laws regarding both the practice of medicine and pharmacy in those States," and this obligation includes "'determin[ing] whether the physicians were in compliance with the States' licensure requirements and specific standards for issuing treatment recommendations and prescribing controlled substances.'" Id. at 38 (quoting Bob's Pharmacv & Diabetic Supplies, 74 FR 19599, 19601 (2009); United Prescriptions Servs., Inc., 72 FR 50397, 50408 (2007)). Moreover, the ALJ also cited Agency precedent that, under the CSA, "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 or other authority required to practice medicine within a State is therefore unlawful under the CSA." Id. (citations omitted).

The ALJ also concluded that Respondent had ignored evidence that the prescriptions were not issued pursuant to a valid doctor-patient relationship. The ALJ noted that a DEA Diversion Investigator (DI) had provided Respondent with various documents including a Guidance Document on Dispensing and Purchasing Controlled Substances Over the Internet, 66 FR 21181 (2001), which explained four widely accepted elements for establishing a bona fide doctor-patient relationship (including, inter alia, that a medical history be taken and a physical examination be performed) and the DEA Pharmacist's Manual. ALJ at 34-35. The ALJ also found that Respondent's owner had expressed to the DI that it had been solicited to distribute drugs for an internet prescribing scheme but that he declined to do so because he did not believe there would be adequate doctorpatient relationships to support the prescriptions and thus he "expressed actual understanding" that "where doctor and patient are geographically isolated from each other, it increases the risk that the requisite doctor-patient relationship does not exist." Id. at 35.

Noting that Respondent had filled several prescriptions which were

shipped to Alabama residents and which were authorized by a Dr. Flynn, who was located in Pennsylvania, and Dr. De LaGuardia, who was located Kansas, the ALJ reasoned that "[t]he fact that the prescriptions were authorized by practitioners geographically isolated from Alabama made it unlikely that the issuing physician had the requisite doctor-patient relationship with the ultimate user"; he then found that Respondent "took no steps to resolve these red flags prior to dispensing controlled substances" and thus violated "its corresponding responsibility" under Federal law. Id. at 40. The ALJ further noted that Respondent "had * ignored similar obligations to resolve anomalies attendant upon remote doctor and patient locations prior to dispensing controlled substances prescribed by [these two doctors] to customers in states including, inter alia, California, Georgia, Illinois, Louisiana, Mississippi, North Carolina, and South Carolina." Id. at 40-41. (citing numerous State laws).

The ALJ also noted that "apart from the geographic separation between Dr. Flynn and his nationwide ultimate-user base, * * * Respondent * * * possess[ed] * * * documents that reflected that on single days, this physician issued 837, 347, 344 and 314 prescriptions, [and this] should have resulted in great concern [on its part] that this number of individuals was not being examined and treated on a daily basis by" Flynn, who was "one of [its] regular prescribing physicians." Id. at 44–45. Similarly, the ALJ noted that "on several days Dr. De La Guardia, another regular prescriber, issued over 100 prescriptions." Id. at 45. Because Respondent ignored both the geographic separation between the patients and prescribers as well as the high volume of their prescriptions, the ALJ concluded that it violated Federal and state laws related to controlled substances and "its obligations as a DEA registrant" and that this "militate[s] strongly in favor of revocation." Id. at

The ALJ further noted that "these prescriptions were issued by physicians not licensed to practice in the states in which the customers resided" and that this issue "needed to be resolved [by Respondent] prior to the dispensing of a single controlled substance" pursuant to these prescriptions. *Id.* at 41.

Next the ALJ noted that "[t]he CSA requires that a practitioner * * * be currently authorized to handle controlled substances in 'the jurisdiction in which he practices' in order to maintain a DEA registration." *Id.* at 42 (citing 21 U.S.C. 802(21) & 823(f)). Reasoning that "state

authorization of the pharmacy registrant to dispense in the state where the controlled substance is ultimately dispensed stands as a fundamental condition precedent to establishing that a prescription has been lawfully filled," the ALJ, citing numerous state laws requiring that a pharmacy be licensed in the State to deliver drugs to one of its residents, concluded that Respondent's "filling and shipping of * * * controlled substances was done in direct violation of state laws relating to controlled substances." *Id.* at 43–44.

Finally, the ALJ noted that Mr. Fosu "elected not to testify" and that Mrs. Fosu, who was also involved in Respondent's operations, had invoked the Fifth Amendment when called to testify. Id. at 47. Noting the Agency rule that where the Government makes out a prima facie case, the Respondent must accept responsibility for its misconduct, the ALI concluded that the Fosus had failed "to accept any responsibility for any of [Respondent's] prescription filling practices" and that this "militates strongly in favor of revocation." Id. at 48. The ALJ thus concluded that Respondent had not rebutted the Government's prima facie case and recommended that Respondent's registration be revoked and any pending applications be denied. Id. at 48-49.

Neither party filed exceptions to the ALJ's decision. Thereafter, the record was forwarded to me for final agency action.

Having considered the entire record in this matter, I adopt the ALJ's findings of fact and conclusions of law except as specifically noted herein. I further adopt the ALJ's recommended sanction that Respondent's registration be revoked and its pending application be denied. I make the following findings.

Findings

Respondent is a Florida corporation which owns and operates a retail pharmacy doing business under the name of The Medicine Shoppe. GX 2. Respondent, which first became registered on September 1, 2005, holds DEA Certificate of Registration BS9433828, which authorizes it to dispense controlled substances in schedules II through V as a retail pharmacy at the registered location of 1231 Lakeland Hills Blvd., Lakeland, Florida. *Id.* Respondent's registration was last renewed on February 15, 2008 and was not due to expire until February 28, 2011. Id. According to the registration records of the Agency, of which I take official notice, see 5 U.S.C. 556(e); on January 12, 2011, Respondent submitted a renewal application. I therefore find that Respondent's

registration has remained in effect pending the issuance of this Decision and Final Order.¹ See 5 U.S.C. 558(c); 21 CFR 1301.36(i).

Kwame Fosu, who is a registered pharmacist, is the director, registered agent, and owner of Respondent. ALJ Ex. 6, at 2 (stipulated facts); GX 7. Patricia Fosu, who is Mr. Fosu's wife, Tr. 184, is also a registered pharmacist in Florida. *Id.* at 317.

Sometime in early 2005, DEA Investigators (DIs) with the Tampa Field Division started receiving a large volume of complaints about various Florida pharmacies from persons who had ordered drugs through Web sites. Id. at 29, 31. Using an agency database, the DIs determined that there were "a lot of small pharmacies" in the Tampa Bay area that were purchasing "large amounts of hydrocodone," (a schedule III controlled substance as it is usually dispensed to patients), including some that were purchasing "over a million dosage units" and these quantities were at least twice as great as those being purchased by large chain drugstores such as Walgreens or CVS.2 Id. at 33. The DIs also noticed that the largest purchasers were usually pharmacies that had recently obtained DEA registrations. Id. at 35.

With this information, the Tampa DIs commenced visiting these pharmacies to determine what was going on and to educate them about DEA's position on the lawfulness of prescriptions originating through the Internet. *Id.* at 36 & 40. The Tampa Office also decided that every time they received a new application for a pharmacy registration, they would "be proactive" and visit the pharmacies and explain to them that prescriptions that were not issued based on "a doctor-patient relationship" were not legal and that, if the doctor was located in a State other than where the patient resides, "there is no way there could be a doctor-patient relationship." 3 Id. at 41-42.

¹Under the Administative Procedure Act (APA), and agency "may take official notice of facts at ay stage in a proceeding-even in the final decision." U.S. Dept. of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is "entitled on timely request, to an opportunity to show to the contrary." 5 U.S.C. 556(e); see also 21 CFR 1316.59(e). Respondent can dispute the fact of which I take oficial notice by filing a properly supported motion for reconsideration within twenty days of service of this Order, which shall begin on the date it is mailed.

² The DI did not clarify te time period during which these purchases occurred.

³ The DI also testified that while some of the pharmacists they encountered claimed that they were just doing mail order they were not because

Pursuant to this policy, on December 5, 2005, two DIs went to Respondent and met with Mr. Fosu.⁴ The DIs gave Mr. Fosu a package of documents which included the DEA Pharmacist's Manual, the Agency's 2001 Guidance Document entitled Dispensing and Purchasing Controlled Substances over the Internet 5 along with a one page document summarizing some of the critical points of the Guidance Document, as well as documents containing Frequently Asked Questions regarding the dispensing and purchasing of controlled substances over the internet, and provisions of Florida law setting forth grounds for disciplinary action against a pharmacist's license (including where a pharmacist dispenses a drug either knowing or having reason to know that a prescription is not based upon a valid practitioner-patient relationship). GX 7. During their discussion of the use of the internet, the DI told Mr. Fosu that internet prescribing was illegal as were prescriptions that were digitally signed. Tr. 150-51, 153. Mr. Fosu told the DI "that he was aware of the internet situation because he had been approached by an individual" about filling prescriptions for an internet site, but "he had informed that individual that he wasn't interested in doing internet because he did no see the doctor-patient relationship and he didn't want to have any trouble [and]

Id. at 21182-83.

wasn't going to be doing [the] internet." Tr. 49; see also id. at 45.

The DI further testified that she had given Mr. Fosu her business card and that she asked him to call her if he was ever approached again by someone about filling internet prescriptions and to obtain as much information as he could to identify the person. Id. at 50 & 102. The DI was never subsequently contacted by Mr. Fosu. Id.

In late January or early February 2007, another DI, who was assigned to the Pittsburgh, Pennsylvania Resident Office, received a phone call from a pharmacy owner who reported that he had been called by a person who represented that he worked for an entity known as Coralpines and who had solicited him to fill prescriptions that were issued over the internet. Id. at 332 & 337. The pharmacy owner stated that the Coralpines' representative had told him that if he agreed to do so, he would be given a user name and password so that he could access a Web site and download prescriptions which he was to fill. Id. at 332-33. When the pharmacy owner "expressed [his] reservations" to Coralpines' representative, it wired "a significant amount of money" to him to show its "good faith." *Id.* at 333.

Thereafter, the pharmacy owner accessed Coralpines' Web site and downloaded hundred of prescriptions that it wanted his pharmacy to fill. Id. Upon printing out the prescriptions, which totaled about 200, the pharmacy owner noted that they were issued by "mainly three doctors" and yet were for persons located throughout the country. *Id.* More specifically, the prescribing doctors were Michael Flynn, who was located in Wallingford, Pennsylvania; Alfredo Valdivieso, who was located in Puerto Rico; and Enrique De La Guardia, who was located in Ft. Leavenworth, Kansas. Id. at 337-38. With the exceptions of Dr. De La Guardia, who was licensed in both Kansas and Nebraska, the other doctors were licensed only in the States where they were located. Id. at 338-39.

Apparently because all of the prescriptions were for controlled substances, the pharmacy owner decided not to do business with Coralpines and turned over the prescriptions to the DI. Id. at 333. According to the DI, the prescriptions were primarily for phentermine, diazepam, and alprazolam, all of which are schedule IV controlled substances. Id. at 335; see also 21 CFR 1308.14(c) &

According to the DI, the prescription forms were divided into three sections; one section contained prescription

information such as the customer's name, address, drug, quantity, date, and a physician's signature; another section contained the label that goes on the prescription vial, and the third section contained either a UPS or Fed Ex shipping label with an account number, the pharmacy's name, and the patient's name. Id. at 334-36.

Each prescription form also included the name of the Web site which the customer had accessed to order the drugs. Id. at 339-40. There were approximately 30 Web sites including pillforce.com, pillpush.com and pillroyal.com; the DI later determined that crownpills.com was also affiliated with Coralpines. Id. at 340-41 & 349. The DI also determined that Coralpines was located in Durban, South Africa. Id. at 340.

On February 15, 2007, the DI, using an undercover name, visited pillpush.com and purchased alprazolam. Id. at 350 & 354. In additional to providing his name and address, the DI was directed to complete a ten-question questionnaire. Id. at 351. The DI gave a false height and weight, and when asked why he wanted the drug, wrote "anxiety." Id. The DI then provided his credit card information and placed his order. Id.

A week later, the DI received a package containing a drug vial which contained 60 tablets of alprazolam.⁶ Id. The vial label indicated that the prescription had been filled by Respondent and that the prescribing physician was Dr. Flynn. Id. at 351–52. Prior to the issuance of the prescription, the DI neither saw nor spoke with Dr. Flynn. Id. at 352. Nor, prior to his receiving the prescription, did he speak with anyone at Respondent. Id. at 354.

Thereafter, a subpoena was issued to UPS for shipping records for the account number (which was the same number as had been on the 200 prescriptions that were turned over to DEA by the western Pa. pharmacy owner) under which the alprazolam had been shipped. Id. at 354-55. UPS turned over the records which showed that in a one to one-and-a-half-month time period, Respondent had made 1600 shipments to persons located throughout the country. Id. at 355.

Using the UPS records, the DI contacted several persons who lived near Pittsburgh. Id. at 359. The DI (accompanied by another DI) interviewed B.F. at her residence; B.F. told them that she had ordered

in "[m]ail order, the doctor sees the patient, the patient gets the prescription [and] mails the prescription into their pharmacy * [internet prescribing] was done completely different." Tr. 42.

 $^{^4\,\}mathrm{The}$ DI had previously gone to Respondent in October but was informed that Mr. Fosu was out of the country. Tr, 43. Because the DI wanted to discuss these issues with Mr. Fosu, she decided that she would revisit Respondent when he returned. Id.

⁵ This document had previously been pubished in the Federal Register at 66 FR 21181. GX 8, at 2. The Guidance Document specifically stated 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 action in the usual course of his professional practice.'" 66 FR at 21182 (quoting 21 CFR 1306.04(a)). The Guidance explained that "[e]very state separately imposes the same requirement under its laws" 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. Continuing, the Gudance exlained that "[f]or purposes of state law, many state authorities, with the endorsement of medical societies, consider the existence of the following four elements as an indication that a legitimate doctor patient relationship has been established:

A patient has a medical complaint: A medical history has been taken;

A physical; examination has been performed; and

Some logical connection exists between the medical complaint, the medical history, the physical examination, and the drug prescribed.

⁶ The DI subsequently testified that he received the drugs on February 23, 2007. Tr. 353. The DI also testified that the drugs were tested by a DEA laboratory and found to be alprazolam. Id.

alprazolam through a Web site (pillroyal.com), which was one of those known to be an affiliate of Coralpines. Id. at 359–60; GX 16, at 1. While B.F. related as to how she had filled out a questionnaire and provided credit card information, she also stated that she did not have to provide medical records and neither was examined by, nor spoke with a physician. Tr. 361. Shortly thereafter, B.F. received a bottle of alprazolam; its label indicated that the prescription had been filled by Respondent and listed Dr. Flynn as the prescribing physician. Id. at 361-62. B.F. also printed out copies of e-mail correspondence (which she gave to the DIs) which had confirmed her order and the subsequent shipment of it. GX 16, at 1-3. The DIs subsequently confirmed that the e-mail address of the sender was the same as had been used by representatives of Coralpines in contacting the pharmacy owner who had declined to fill prescriptions for it. Tr. 362-63.

The DI also interviewed C.S. *Id.* at 369. C.S. also related that he had gone to a Web site that the DIs had identified as being affiliated with Coralpines and ordered 90 tablets of diazepam "merely through" completing a questionnaire and providing credit card information. Id. at 370. C.S. "did not have to provide any additional records" and was neither examined by nor spoke "with a doctor." Id. at 371 & 373. C.S. subsequently received a prescription which had been issued by Dr. Flynn and filled by Respondent. Id.; see also GX 18 (copy of March 26, 2007 prescription for 90 tablets of diazepam 10 mg.).7

On June 12, 2007, a search warrant was executed at Respondent. During the search, the authorities seized hard copies of the controlled substance prescriptions Respondent had dispensed; Respondent's purchasing, dispensing records, and shipping documents; and various notes that related to the investigation of Coralpines. Tr. 381. Moreover, computer forensic examiners imaged the hard drives of Respondent's computers. *Id.* at 381–82.

During the search, members of the search party (including the Pittsburghbased DI) interviewed Patricia Fosu. *Id.* at 385. Ms. Fosu stated that her husband had purchased Respondent in 2005 and that she had initially worked there on a part-time basis; however, her hours had increased in the months before the warrant was executed (which corresponds with the period in which

Respondent commenced filling prescriptions for Coralpines). *Id.* at 385–86.

Ms. Fosu further stated that in November 2006, she and her husband were approached by one Gerald Wright, who identified himself as a pharmacist, and who solicited them to fill prescriptions issued by doctors who worked for Coralpines. Id. at 390. Wright, who practiced at CRJ Pharmacy, told the Fosus that he was personally filling prescriptions for Coralpines.⁸ Id. According to Ms. Fosu, while she and her husband had expressed their concern to Wright that the Coralpines' physicians were not seeing the patients, Wright stated that they had nothing "to worry about because other pharmacies across the country" were also filling prescriptions that were issued "in a similar manner." Id. at 397.

During the interview, Ms. Fosu identified Drs. Flynn and De La Guardia as the prescribers of the prescriptions which Respondent filled for Coralpines. Id. at 396. While Ms. Fosu related that she had initially made a few phone calls to Dr. De La Guardia to verify that he had issued the prescriptions, she was never able to speak with Dr. Flynn, whose prescribing practices raised her concern because of the large number of prescriptions he was issuing. Id. Ms. Fosu further asserted that she and her husband became concerned that most of the Coralpines prescriptions were for controlled substances. Id. at 397–98. She further maintained that she and her husband had decided in April 2007 to stop filling prescriptions for Coralpines because they did not believe that there was "a legitimate doctorpatient relationship" between the patients and Drs. Flynn or De La Guardia. Id. at 398.

Ms. Fosu also related that in January 2007, she and her husband had been visited by Dr. Robert Reppy, a Tampaarea physician, who solicited Respondent to fill prescriptions that he would be writing for persons who were located throughout the United States. *Id.* at 399. Reppy "assured" the Fosus that "his patients would be flying in from all across the country to be seen by [him] at his" Tampa office. *Id.*

The Fosus agreed to fill Reppy's prescriptions and shortly thereafter started receiving faxed prescriptions which were "mainly for hydrocodone," which is a schedule III narcotic. *Id.*; see also 21 CFR 1308.13(e). Ms. Fosu further stated that because she and her

husband "were concerned about whether [Reppy] was actually seeing these patients," they made an unannounced visit to his office. Tr. 399. Reppy assured the Fosus that "he was actually seeing these patients." *Id.* at 400.

During the course of executing the warrant, Respondent received six prescriptions via fax from Reppy's office. *Id.* The prescriptions were for patients who did not reside in Florida. *Id.* at 403. The DI did not, however, have any information linking Reppy to Coralpines and did not know if Reppy was issuing prescriptions through any other internet sites. *Id.* at 401.

Later that morning, Mr. Fosu arrived at Respondent and agreed to be interviewed. Id. at 413-14. Mr. Fosu related that, in the summer of 2006, he had received a phone call from a woman working for Coralpines who solicited him to fill prescriptions for it. Id. at 414-15. Mr. Fosu maintained that he was not comfortable with Coralpines' proposal because he "didn't believe that the doctors would actually be seeing the patients" and believed that there would not be "a legitimate doctor-patient relationship." Id. at 415. Mr. Fosu claimed that he had called the DEA Tampa office and was told to contact the Florida Board of Pharmacy. Id. at 415-16. Mr. Fosu spoke with a representative of the Board to inquire about the legality of filling prescriptions for doctors who were not in the same area as their patients. Id. at 416. The Board's representative told Mr. Fosu not to fill the prescriptions if they "were not based on a legitimate doctor-patient relationship." Id. at 416-17. Mr. Fosu then questioned the Board representative as to what constitutes a doctor-patient relationship and was advised to contact the Florida Board of Medicine for further guidance. Id. at

During the interview, Mr. Fosu corroborated that in November 2006, he was approached by Wright, who solicited him to fill prescriptions for doctors affiliated with the Pitcairn Group. Id. at 417. Wright told Fosu that he was filling prescriptions for Pitcairn and asked him if he was

⁷The prescription was seized from Respondent in June 2007 during the execution of a search warrant. See GX17

⁸ In February 2007, I ordered that CRJ Pharmacy's DEA registration be immediately suspended. See 72 FR 30846 (2007). Subsequently, CRJ surrendered its state license and went out of business. Id. at 30847

⁹While in this portion of his testimony, the DI referred to the Pitcairn Group, the evidence suggests that Pitcairn either changed its name to Coralpines, Tr. 420, was an entity that was controlled by Coralpines, or was taken over by it. GX 15, at 4 (Jan. 30, 2007 e-mail from Coralpines Support to "Kwamen and Pat" stating in part: "Pitcairn has a credit balance with Sunlake for 8k. We will deduct this of [sic] next weeks report. Thanks, Coralpines Support."); *id.* at 6 (Jan. 10, 2007 e-mail with subject line of "Pitcairn migrating to Coralpines," and stating: "My name is Justin, I will be taking over for Pitcairn as Juan has gone on leave.").

interested in doing so. *Id.* at 417–18. Fosu maintained that he questioned Wright about whether the prescriptions were based on legitimate doctor-patient relationships and that Wright had told him not worry because other pharmacies were filling prescriptions for Pitcairn. *Id.* at 418.

In the interview, Mr. Fosu maintained that during the course of his relationship with Coralpines, he had become "increasing[ly] concerned" that the prescriptions were only for controlled substances such as hydrocodone and alprazolam and that when he raised this issue with Coralpines, he was told that he would start seeing a "mix of prescriptions." Id. at 420. However, Coralpines continued to send him alprazolam prescriptions. Id. Mr. Fosu further related that he had worked for Coralpines from November 2006 through April 2007, that Coralpines paid him \$20 per prescription, and that Coralpines had paid him a total of between \$150,000 to \$250,000 for Respondent's services. 10 Id. at 421. These payments came from foreign sources and according to Mr. Fosu, further raised his concern. Id.

Mr. Fosu also admitted that he was concerned about Dr. Reppy's prescriptions and that this had prompted the visit to Reppy's office, which had occurred approximately one month before the warrant was executed. *Id.* at 422. After the visit, Respondent continued to fill Reppy's prescriptions. *Id.* at 423. However, during his interview, Mr. Fosu announced that from that "day forward, [he] would no longer fill these prescriptions because [he] did not believe that Dr. Reppy was ever seeing these patients from out of state." *Id.*

The day after the interview, Mr. Fosu called the DI and asked him whether he should fill the hydrocodone refills which Reppy had authorized on his prescriptions. *Id.* at 428. The DI instructed Fosu "to use his best judgment as a pharmacist" and, if he did "not believe that these prescriptions were issued for a legitimate medical purpose, then [he] shouldn't be refilling the prescriptions." *Id.* The DI further explained that if Reppy "was not seeing these patients," then "there was no doctor-patient relationship" and he should not refill the prescriptions. *Id.*

Mr. Fosu then told the DI that he would not refill Reppy's prescriptions. *Id.* at 428–29.

As found above, during the search, the hard drives of Respondent's computers were imaged and subsequently analyzed by the National Drug Intelligence Center. *Id.* at 423–24. According to the DI, the analysis showed that between January and the June 2007, Respondent had filled 2,400 prescriptions issued by Reppy, which were primarily for hydrocodone, and that the prescriptions had been sent to residents of 46 different States. Id. at 425. However, the Government did not submit any report or summary providing further detail as to Reppy's prescribing practices. Nor did the Government submit copies of any of Reppy's prescriptions.

As found above, the search party also seized numerous hard copy prescriptions that Respondent had filled which were issued by Drs. Flynn and De La Guardia. *Id.* at 447. The DI (along with other DEA employees) prepared a spreadsheet listing each doctor's prescriptions by date of issuance and drug prescribed; the spreadsheet also provided a daily total of the prescriptions. *Id.*; see also GXs 12 & 13.

The Government also submitted representative samples of the controlled substance prescriptions issued by Drs. Flynn and De La Guardia which were filled by Respondent. With respect to Dr. Flynn, the exhibits included copies of 97 controlled substance prescriptions, see GX 10; with respect to Dr. De La Guardia, the exhibit included copies of 94 controlled substance prescriptions. See GX 11. Both of these exhibits included a cover page which listed the number of prescriptions by State of the patient. GX 10, at 1; GX 11, at 1.

Upon reviewing Dr. Flynn's prescriptions, the DI found that on numerous days, Flynn had issued an extraordinary number of prescriptions. More specifically, on February 2, 2007, Flynn had issued 344 prescriptions including 235 for alprazolam, 86 for diazepam, 4 for lorazepam, and 12 for clonazepam. GX 12, at 1. Moreover, on February 19, 2007, Flynn had issued 837 prescriptions including 581 for alprazolam, 183 for diazepam, 1 for lorazepam, and 37 for clonazepam. Id. In addition, on February 23, Flynn issued 314 prescriptions; on February 28, 338 prescriptions; on March 26, 347 prescriptions, and on April 3, 267 prescriptions.¹¹ Id. at 1–2. In addition,

on February 14 and 15, he issued 195 and 247 prescriptions respectively; ¹² there were also multiple other days on which he issued between 100 and 200 prescriptions. *Id.* In each instance, the great majority of the prescriptions were for controlled substances. Between January 31 and April 5, Dr. Flynn wrote a total of 3,227 alprazolam prescriptions, 1,310 diazepam prescriptions, 415 lorazepam prescriptions, and 195 clonazepam prescriptions. ¹³ *Id.* at 2.

As for Dr. De La Guardia, the evidence showed that between November 30, 2006 and February 6, 2007, Respondent filled 1,366 alprazolam prescriptions, 628 diazepam prescriptions, 187 lorazepam prescriptions, 58 clonazepam prescriptions, and 64 phentermine prescriptions which he had issued. GX 14, at 2. While De La Guardia generally did not issue prescriptions at the same rate as Flynn, there were numerous days on which he wrote more than 50 controlled substance prescriptions and several days on which he wrote more than 100. *Id*.

In September 2007, Mr. Fosu called the DI, who had since returned to the Pittsburgh office. *Id.* at 430. Mr. Fosu reported that he had been solicited by another entity to fill more internet prescriptions for hydrocodone, which were issued by a physician in Puerto Rico, and that he had been sent copies of two prescriptions, one of which was for a Pennsylvania resident. *Id.* at 430–

¹⁰ Various e-mails suggest that this amount was Respondent's compensation for filling the prescriptions and that it was also reimbursed for its drug costs. GX 15, at 3–14 (stating "your estimated cost for my totals for week 4 & 5 was about \$31,000 that is only my cost of drugs. My service fee is about 13,180 for 670 script[s] filed"); *id.* at 17 (stating that in the "week ending 02/09/2007 I did 579 prescriptions my service fee is 11,580,000 [and my] drug cost is obout [sic] \$12,000").

¹¹ Flynn's February 23rd prescriptions included 84 alprazolam, 30 for diazepam, 176 for lorazepam, and 12 for clonazepam; his February 28 prescriptions included 222 for alprazolam, 54 for

diazepam, 9 for lorazepam, and 14 for clonazepam; his March 26 prescriptions included 137 for alprazolam and 210 for diazepam, and his April 3 prescriptions included 136 alprazolam, 76 for diazepam, 34 for lorazepam and 21 for clonazepam. GX12, at 1–2.

¹²His February 14 prescriptions included 136 for alprazolam and 58 for diazepam; his February 15 included 181 for alprazolam and 64 diazepam. GX 12. at 1.

¹³ Based on this information, in July 2007, DEA personnel obtained a warrant to search Dr. Flynn's registered location, which was also his home. Tr. 461. While Dr. Flynn was not home when the warrant was executed, he returned the following day and was interviewed by the DI and others. Id. at 463. During his interview, Flynn admitted that he worked for Coralpines; he further admitted that he would go to its website and see "hundreds of questionnaires," that he issued prescriptions without talking to any of the customers by phone [and] without reviewing any other medical records." Id. at 464. He further admitted that "in most cases * he didn't even review the questionnaires,' that "[h]e viewed this as an easy way to make money, and that this "was not a legitimate medical practice." Id. at 464. Flynn also stated that "he was never contacted by any pharmacy to verify [his] prescriptions" and was "never questioned about" the legitimacy of the prescriptions. Id. On July 30, 2007, Dr. Flynn surrendered his registration and eventually pled guilty to violating 21 U.S.C. 846 Tr. 465; GXs 4 & 23.

As for Dr. De La Guardia, the record shows that he surrendered his registration on August 1, 2007. GX 5.

31. Mr. Fosu stated that he did not feel comfortable with the proposal and that he wanted to provide this information to the DI. *Id.* at 431.

Mr. Fosu then told the DI that he had since met again with Dr. Reppy, who told him that he had "weeded out the bad people" and that Reppy had asked him to continue to fill his prescriptions. Id. Mr. Fosu maintained that Reppy had assured him that he was actually seeing the patients and that he was requiring them to provide some form of identification. Id. at 432. Mr. Fosu then stated that he planned on filling these prescriptions "if he had some sort of identification for the patient to [show] that the patient was who they said they were" and that "would match what was on the" prescription. Id.

However, on cross-examination, the DI admitted that he did not know whether Reppy's patients were actually coming in to see him. Id. at 541. Moreover, the Government offered no other evidence probative of whether Reppy's patients were actually seeing him. Id. The DI also acknowledged that he did not know whether there was anything wrong with Reppy's prescriptions, none of which were entered into evidence. Id. Indeed, the DI acknowledged that he did not know whether Respondent had filled any prescriptions issued by Reppy and that it was "possible" that Respondent had not even filled Reppy's prescriptions. Id. at 543.

During their respective interviews, both Mr. and Mrs. Fosu acknowledged that Respondent had actually dispensed the Coralpines prescriptions, which had been placed in several boxes found in one of Respondent's back rooms. *Id.* 493–95, 497–500, 545. I thus find that Respondent filled and distributed the prescriptions identified in Government Exhibits 10 and 11. ¹⁴ I further find that

Government Exhibits 12 & 13 accurately reflect prescriptions that Drs. Flynn and De La Guardia issued on various dates and which were eventually filled by Respondent.

The Government also introduced into evidence various e-mails that were sent from the Fosus to Coralpines and vice versa. See GX 15. Among these is a February 13, 2007 e-mail from "Kwamen and Pat" to "Coralpines Support" with the subject line of "sun&lake costs." *Id.* at 20. In this e-mail, Pat Fosu wrote:

The volume is NOT the problem but rather your erratic payments. Do you know the amount of drugs and boxes upon boxes of UPS bags that we ordered just to service your company? Do you know the risk that we have to take to order enough narcotic or control [sic] medications just to meet your client needs?

I have gone out of my way to order huge inventory of narcotics plus hire additional labor to take care of your needs only to experince [sic] your erratic, sluggish, and when-you-like payment attitude.

Just last week, the DEA confiscated all the narcotics or control medications in another pharmacy and I stand to lose these meds if they should come to my pharmacy. But you don't have anything to lose! And when I go through all these headaches to satisfy your needs then I have to put up with your PAYMENT PLAN!

Id.

As part of its investigation, a DI sent administrative subpoenas to the boards of pharmacy of each State (except for Florida) and the District of Columbia to determine whether Respondent or each of the Fosus held the requisite pharmacy license. Tr. 204. The DI received a response from all but four States; these responses were submitted into the record as Government Exhibit 6. Id. at 205. According to the DI, neither of the Fosus was licensed in these States. Id. at 205-06. However, the Government did not submit a copy of the subpoenas it issued, and the ALJ found that the responses from the States of Delaware, Kansas, Missouri, New Hampshire, South Carolina, and Wyoming did not adequately establish "what inquiry was made and answered or why the author possesses the requisite competence to provide the information contained therein" and were therefore unreliable. ALJ at 9 n.15. I agree with the ALJ's findings. I further agree with the ALJ's findings that Respondent did not have a state license in the remaining States.

linking Romain to either Coralpines or any other internet facilitator. Tr. 407. Moreover, the Government did not produce any other evidence probative of whether the single Romain prescription laced a legitimate medical purpose and was issued outside of the usual course of professional practice.

Respondent did not call any witnesses to testify on its behalf. It introduced but a single exhibit, which was comprised of photographs showing both the exterior and interior of its premises. *See* RX 11.

Discussion

Section 304(a) of the Controlled Substances Act (CSA) provides that "[a] registration * * * to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render [its] registration under section 823 of this title inconsistent with the public interest as determined under such section." 21 U.S.C. 824(a)(4). In determining the public interest in the case of a practitioner, the Act directs that the Attorney General consider the following factors:

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

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

- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Id. § 823(f).

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

The Government has the burden of proving that the Respondent has committed acts which render its registration inconsistent with the public interest. 21 CFR 1301.44(d) & (e). However, where the Government has made out a *prima facie* case, the burden shifts to the applicant to "present[] sufficient mitigating evidence" to show why it can be entrusted with a new 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))), aff'd, Medicine Shoppe-Jonesborough v.

¹⁴ The Government also introduced a single prescription for alprazolam which was written by Dr. Shabir Bhimji of Austin, Texas for a patient in Boulder, Colorado, and a single prescription written by Dr. Gerard Romain of Tampa, Florida for a patient in Boston, Massachusetts. GXs 19 & 21. With respect to Dr. Bhimji, the DI testified that he had written 100 prescriptions on a signle day in April 2007. Tr. 458. However, other thant the single alprazolam prescription, the record does not establish that any of the other prescriptions were for controlled substances.

As for the prescription issued by Dr. Romain, while the DI testified "that there were a number of other prescriptions from other physicians not previously identified as being affiliated with Coralpines" and named Dr. Romain as someone who was "allegedly issuing prescriptions for patients all across the United States," and that an "examination of prescriptions [Respondent] filled * * * showed that there were patients all across the United States receiving these prescriptions," id. at 377–78, the DI subsequently admitted (on direct examination no less) that he had no information

DEA, 2008 WL 4899525 (6th Cir. 2008). "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 Trong Tran, 63 FR 64280, 62483 (1998); Prince George Daniels, 60 FR 62884, 62887 (1995).

Having considered all of the factors, I conclude that the evidence pertinent to factors two and four makes out a *prima facie* showing that Respondent "has committed such acts as would render [its] registration * * * inconsistent with the public interest." ¹⁵ 21 U.S.C. 824(a)(4). I further hold that Respondent has not rebutted the Government's *prima facie* case. Accordingly, Respondent's registration will be revoked and any pending applications will be denied.

Factors Two and Four—Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Relating to Controlled Substances

Under a longstanding DEA regulation, a prescription for a controlled substance is unlawful unless it has been "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). The regulation further provides that while "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, * * * a corresponding responsibility rests with the pharmacist who fills the prescription." Id. (emphasis added). Continuing, the regulation states that "the person knowingly filling such a purported prescription, as well as the

person issuing it, [is] subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id*.

DEA has consistently interpreted this provision "as prohibiting a pharmacist from filling a prescription for a controlled substance when he either 'knows or has reason to know that the prescription was not written for a legitimate medical purpose.'" Medicine Shoppe-Jonesborough, 73 FR at 381 (quoting Medic-Aid Pharmacy, 55 FR 30043, 30044 (1990)); see also Frank's Corner Pharmacy, 60 FR 17574, 17576 (1995); Ralph J. Bertolino, 55 FR 4729, 4730 (1990); United States v. Seelig, 622 F.2d 207, 213 (6th Cir. 1980). This Agency has further held that "[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription." Bertolino, 55 FR at 4730 (citations omitted).16

Under the CSA, it is fundamental that "a practitioner must establish a bona fide doctor-patient relationship in order to act 'in the usual course of * professional practice' and to issue a prescription for a 'legitimate medical purpose.'" Patrick W. Stodola, 74 FR 20727, 20731 (2009) (citing Moore, 423 U.S. at 141-43). At the time of the events at issue here, the CSA generally looked to state law to determine whether a doctor has established a bona fide doctor-patient relationship with an individual.17 Stodola, 74 FR at 20731; see also Kamir Garces-Mejias, 72 FR 54931, 54935 (2007); United Prescription Servs., Inc., 72 FR 50397,

50407 (2007). As explained below, prior to the dispensings at issue here, numerous States had either enacted legislation or promulgated administrative rules which generally prohibited (except for in narrow circumstances not relevant here) a physician from prescribing a controlled substance to a person without having personally performed a physical examination.

In United Prescription Services, I further explained that "[a] physician who engages in the unauthorized practice of medicine is not a practitioner acting in the usual course of * * * professional practice.'" 72 FR at 50407 (citing 21 CFR 1306.04(a)). This rule derives from the text of the CSA, which defines the "[t]he term 'practitioner' [to] mean[] a physician * * licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices * * to * * * dispense * * * a controlled substance." 21 U.S.C. 802(21). See also 21 U.S.C. 823(f) ("The Attorney General shall register practitioners * * * to dispense * * * if the applicant is authorized to dispense * * * controlled substances under the laws of the State in which he practices.").

As the Supreme Court held shortly after the CSA's enactment: "In the case of a physician [the CSA] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connection with his professional practice." United States v. Moore, 423 U.S. 122, 140-41 (1975) (emphasis added). A controlled-substance prescription issued by a physician who lacks the license necessary to practice medicine within a State is therefore unlawful under the CSA. Cf. 21 CFR 1306.03(a)(1) ("A prescription for a controlled substance may be issued only by an individual practitioner who is * * * [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession[.]").

Finally, as I have previously explained, an entity which voluntarily engages in interstate commerce by shipping controlled substances to persons located in other States is properly charged with knowledge of the laws regarding both the practice of medicine and pharmacy in those States. United Prescription Servs., 72 FR at 50408; Bob's Pharmacy & Diabetic Supplies, 74 FR 19599, 19601 (2009); see also Hageseth v. Superior Court, 59 Cal. Rptr.3d 385, 403 (Ct. App. 2007) (noting that the "proscription of the unlicensed practice of medicine is neither an obscure nor an unusual state prohibition of which ignorance can

 $^{^{\}rm 15}\,\rm This$ Agency has repeatedly held that the possession of a valid state license is not dispositive of the public interest inquiry. See Patrick W. Stodola, 74 FR 20727, 20730 n.16 (2009); Robert A. Leslie, 68 FR at 15230. DEA has long held that "the Controlled Substances Act requires that the Administrator * * * make an independent determination as to whether the granting of controlled substances privileges would be in the public interest." Mortimer Levin, 57 FR 8680, 8681 1992). Nor is the lack of any criminal convictions related to controlled substances dispositive. Edmund Chein, 72 FR 6580, 6793 n.22 (2007), aff'd, Chein v. DEA, 533 F.3d 828 (D.C. Cir. 2008). Thus, the fact that Respondent may still hold its Florida pharmacy license and that neither it, not its owners, have been convicted of a criminal offense is not dispositive.

¹⁶ As the Supreme Court recently explained, "the prescription requirement * * * ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales* v. *Oregon*, 546 U.S. 243,274 (2006) (citing *United States* v. *Moore*, 423 U.S. 122, 135 (1975)).

¹⁷ On October 15, 2008, the President signed into law the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. 110-425, 122 Stat. 4820 (2008). Section 2 of the Act prohibits the dispensing of a prescription controlled substance "by means of the Internet without a valid prescription" and defines, in relevant part, the "[t]he $\,$ term 'valid prescription' [to] mean [] a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by * a practitioner who has conducted at least 1 inperson medical evaluation of the patient." 122 Stat. 4820 (codified at 21 U.S.C. 289(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.

reasonably be claimed, and certainly not by persons . . . who are licensed health care providers. Nor can such persons reasonably claim ignorance of the fact that authorization of a prescription pharmaceutical constitutes the practice of medicine.").¹⁸

The Fosus had ample reason to know that the prescriptions Respondent filled for Coralpines were issued outside of the course of professional practice and lacked a legitimate medical purpose for multiple reasons. 21 CFR 1306.04(a). First, the Fosus knew that Drs. Flynn and De La Guardia were prescribing controlled substances without establishing a valid doctor-patient relationship. Indeed, the evidence is clear that the Fosus knew from the outset of their agreement with Pitcairn/ Coralpines that Drs. Flynn and De La Guardia were issuing the prescriptions without having performed a physical examination of the persons who were seeking the drugs.

During the interviews they gave when the warrant was executed, both of the Fosus admitted they knew from the time they were approached by Mr. Wright that the Coralpines' scheme involved physicians issuing prescriptions for persons they never saw. Tr. 397 (DI's testimony regarding interview of Patricia Fosu) & 417–18 (DI's testimony regarding interview of Kwame Fosu). Moreover, certainly within days of agreeing to fill the prescriptions, the Fosus knew that, given the respective locations of Drs. Flynn (in Pennsylvania) and De La Guardia (Kansas) and the persons they were prescribing to, who were located throughout the country, neither doctor was performing physical examinations of these persons and establishing legitimate doctor-patient relationships with Coralpines' customers. Indeed, the Fosus admitted as much in their respective interviews. Id. at 396-97 & 419.

The volume of the prescriptions provided further reason to know—as if it was needed—that neither Dr. Flynn nor Dr. De La Guardia was physically examining these persons. As early as February 2, 2007, Dr. Flynn issued 344 prescriptions on a single day. Yet this did not lead the Fosus to stop filling the prescriptions. Indeed, on February 19, Flynn issued 837 prescriptions, a rate of nearly 35 prescriptions per hour had he worked around the clock.

Notwithstanding their knowledge of Flynn's assembly line rate of

prescribing, the Fosus continued to fill his prescriptions. While there were numerous other days on which Flynn wrote hundreds of prescriptions, Respondent continued to fill the prescriptions for several months thereafter.

While at the time of the events at issue, the CSA did not explicitly require that a physician perform a physical examination prior to prescribing a controlled substance through the Internet, 19 as DEA explained in the 2001 Guidance Document (a copy of which was provided to the Fosus shortly after they obtained Respondent's registration and which was published in the **Federal** Register), most state medical boards considered that a doctor's performance of a physical examination (and the taking of a medical history) to be essential steps in establishing a legitimate doctor-patient relationship. See 66 FR at 21182-83. Moreover, prior to Respondent's agreeing to fill the Pitcairn/Coralpines prescriptions, most States had enacted legislation, promulgated administrative rules, or issued policy statements making clear that, except for in limited circumstances not relevant here, a physician must physically examine a patient before prescribing to him/her. As licensed health care providers and participants in interstate commerce, the Fosus "cannot reasonably claim ignorance" of state rules and standards of medical practice applicable to the issuance of treatment recommendations as well as those prohibiting the unauthorized practice of both medicine and pharmacy. See United Prescription Servs., 72 FR at 50408 (quoting Hageseth, 59 Cal. Rptr.3d at 403).

Since January 2001, California has prohibited the prescribing or dispensing of a dangerous drug "on the Internet for delivery to any person in this state, without an appropriate prior examination and medical indication therefore, except as authorized by Section 2242." Cal. Bus. & Prof. Code § 2242.1. In 2003, the Medical Board of California made clear that "[b]efore prescribing a dangerous drug, a physical examination must be performed" by the prescribing physician. In re Steven Opsahl, M.D., Decision and Order, at 3 (Med. Bd. Cal. 2003) (available by query at http://publicdocs.medbd.ca.gov/pdl/ mbc.aspx). Furthermore, the Medical Board of California determined that "[a] physician cannot do a good faith prior examination based on a history, a

review of medical records, responses to a questionnaire and a telephone conversation with the patient, without a physical examination of the patient." *Id.*

Moreover, well before Respondent commenced to dispense the prescriptions at issue here, the Medical Board of California had issued numerous Citation Orders to out-of-state physicians for prescribing over the Internet to California residents. These Orders invariably cited both the physicians' failure to perform a "good faith prior examination" and their lack of a "valid California Physician and Surgeon's License to practice medicine in California." Citation Order, Martin P. Feldman (August 15, 2003); see also Citation Order, Harry Hoff (June 17, 2003); Citation Order, Carlos Gustavo Levy (Jan. 28, 2003); Citation Order, Carlos Gustavo Levy (November 30, 2001).20 Respondent nonetheless dispensed controlled substance prescriptions issued by Drs. Flynn and De La Guardia to California residents and thus violated both the CSA and California law.

Similar to California, regulations adopted by the States of Ohio and Indiana require that a physician perform a physical examination of his/her patient prior to prescribing a controlled substance, except in limited circumstances not applicable here. 844 Ind. Admin. Code § 5–4–1(a); Ohio Admin. Code § 4731–11–09(A). The record shows that both Drs. Flynn and De La Guardia issued controlled substance prescriptions to residents of each State without performing physical examinations of them and thus violated the regulations of Indiana and Ohio.21 While Respondent clearly had reason to know that the prescriptions were issued outside of the usual course of professional practice and lacked a legitimate medical purpose, it nonetheless filled them. In doing so, Respondent violated the CSA. 21 CFR 1306.04(a).

Under Virginia law, a doctor must establish a bona fide practitioner-patient relationship prior to prescribing a controlled substance. Va. Code Ann. § 54.1–3303(A). Moreover, Virginia law expressly requires that a practitioner "perform or have performed an

¹⁸ In Hageseth, the California Court of Appeals upheld the State's jurisdiction to criminally prosecute an out-of-state physician who prescribed a drug to a California resident over the internet, for the unauthorized practice of medicine.

¹⁹ It now does. *See* Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Public Law 110–425, 122 Stat. 4820 (2008). These provisions are codified throughout the CSA.

²⁰ The Medical Board of California had also issued press releases announcing its position on the issuance of prescriptions by physicians who do not hold a California license. See Medical Board of California, Record Fines Issued by Medical Board to Physicians in Internet Prescribing Cases (News Release Feb. 10, 2003) available.http://www.mbc.ca.gov/NR_2003_02-10 Internetdrugs.htm>

²¹ There is no dispute that those persons who received prescriptions through Coralpines did not see either Dr. Flynn or Dr. De La Guardia.

appropriate examination of the patient, either physically or by use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically" and that "except for [in] medical emergencies, the examination shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription." *Id.* Both Drs. Flynn and De La Guardia issued controlled substance prescriptions to residents of Virginia without performing physical examination of them and thus failed to establish bona fide doctor-patient relationships with these persons. Respondent nonetheless dispensed these prescriptions and thus failed to comply with its "corresponding responsibility" under Federal law to dispense only lawful prescriptions. *Id.*

These are but a few representative examples of state medical practice standards that Drs. Flynn and De La Guardia violated and which rendered their prescriptions unlawful. See also ALJ at 39–41 (citing various state authorities). Yet the Fosus filled thousands of controlled substance prescriptions issued by them.²²

Many of the controlled substance prescriptions issued by Drs. Flynn and De La Guardia were unlawful for the further reason that both doctors prescribed to persons who resided in States where they were not licensed to practice medicine and where they were therefore engaged in the unauthorized practice of medicine. As noted above, a controlled substance prescription issued by a practitioner who is engaged in the unauthorized practice of medicine is not a prescription issued in the usual course of professional practice. *Moore*, 423 U.S. at 140–41; *United*, 72 FR at 50407.

For example, the evidence shows that both Drs. Flynn (who was licensed only in Pennsylvania) and De La Guardia (who was licensed only in Kansas and Nebraska) issued controlled substance prescriptions to residents of numerous States where they were not licensed to practice medicine including, *inter alia*, California, Georgia, Indiana, North Carolina, Ohio, Texas, and Virginia. *See* GX 10, at 1; GX 11, at 1. These prescriptions violated the laws of these States as well as the CSA. *See* Cal. Bus.

& Prof. Code §§ 2052 (criminalizing the practice of medicine without state license); Ga. Code Ann. §§ 43–34–26(a) (requiring license), 43–34–31 (requiring state license for medical treatment of individual in State by physician in another State); 43–34.31.1(a) (2007) (defining practice of medicine to include electronic prescribing by "[a] person who is physically located in another state" and requiring Georgia license); ²³ 225 Ill. Comp. Stat. Ann. § 60/3 (licensure requirement); id. § 60/ 3.5 (prohibiting unlicensed practice); id. § 60/49 (listing acts constituting holding oneself out to the public as a physician); id. § 60/49.5 (requiring persons engaged in telemedicine to hold Illinois license); Ind. Code Ann. §§ 25-22.5-8-1 (prohibiting the practice of medicine without a state license) & 25-22.5-1-1.1(a) (defining practice of medicine); N.C. Gen. Stat. Ann. § 90–18 (prohibiting practice of medicine across state lines unless licensed in state); Ohio Rev. Code Ann. §§ 4731.296 (prohibiting out-of-state practice of telemedicine without a special permit), 4731.41 (prohibiting practice of medicine without state license); Tex. Occup. Code Ann. §§ 155.001 (requiring license to practice medicine), 151.056(a) (making out-of-state treatment of individual in state the practice of medicine in state); Va. Code Ann. §§ 54.1-2902 (prohibiting practice of medicine without state licensure), 54.1-2903 (making prescribing the practice of medicine), 54.1–2929 (requiring license for the practice of medicine).²⁴ The Fosus nonetheless filled these prescriptions even though they were clearly illegal under both the respective State's law and the CSA.

Finally, as discussed at length in the ALJ's opinion, Respondent violated the laws of numerous States by engaging in the unauthorized practice of pharmacy. See ALJ at 43–44 & nn. 61–91 (citing numerous state laws). See also, e.g., Alaska Stat. § 08.80.158, GX 6 at 5, GX 10 at 2, GX 11 at 2–3; Ark. Code Ann. §§ 17–92–301 (prohibiting practice of pharmacy without a license) & 17–92–

302 (prohibiting filling of prescription by other than Arkansas-licensed pharmacist), GX 6 at 8-9, GX 10 at 5-6, GX 11, at 6-7; Cal. Bus. & Prof. Code § 4120 (requiring special permit for nonresident pharmacies), GX 6 at 10-15, GX 10 at 9-11, GX 11 at 11; Conn. Gen. Stat. Ann. § 20–627 (requiring registration of nonresident pharmacies), GX 6 at 17–18, GX 10 at 14–15, GX 11, at 14-15; La. Rev. Stat. Ann. § 37:1221 (requiring special permit for out-of-state pharmacies to provide pharmacy services to residents of the state), GX 6 at 27, GX 10 at 36-38, GX 11 at 36. Respondent dispensed prescriptions to residents of all of these States without holding the pharmacy licenses required to do so.²⁵ See GXs 10 & 11.

In its brief, Respondent contends that it filled the Internet prescriptions for only "a brief period of time" and that "[t]he vast majority of its business is, and always has been" retail 'walk-up' service and prescriptions deliveries to local nursing homes." Resp. Br. at 1. Contrary to Respondent's contention, its conduct in filling thousands of unlawful prescriptions over a period of five to six months was not a "brief" sojourn into illegality.

By itself, Respondent's (and the Fosus') conduct is egregious enough to conclude that its registration is inconsistent with the public interest. 21 U.S.C. 823(f). Indeed, the evidence shows that Respondent (and the Fosus) acted with flagrant and intentional disregard for both the CSA and state laws as demonstrated by the facts that: (1) Even though the Fosus had been previously advised by both DEA personnel (through both a briefing and written materials such as the 2001 Guidance Document) and by a representative of the Florida Board of Pharmacy that it was unlikely that internet prescriptions are issued in the course of a legitimate doctor-patient relationship, they knowingly filled the prescriptions; (2) Mr. Fosu's statement to the DIs during the December 2005 meeting that he had rejected a proposal to fill internet prescriptions because "he did not see the doctor-patient relationship," Tr. 49; as well as the Fosus' statements during their June 2007 interviews that they had raised similar questions when approached by Wright; and (3) Mrs. Fosu's Feb. 13, 2007 e-mail in which she asked Coralpines whether it "kn[ew] the risk that we have to take to order enough

²² For the reasons given by the ALJ, I also reject Respondent's argument that under Forlaw v. Fitzer, 456 So.2d 432, 435 (Fla. 1984), a physician's failure to conduct a physical examination is not a basis to conclude that a prescription is invalid. See ALJ at 36; Resp. Br. 18. I further note that even if this is an accurate statement of Florida law, Florida's standards for prescribing a controlled substance do not apply in other States.

 $^{^{23}}$ This provision was re-designated as Ga. Code Ann. \S 43–34–31 by Ga. L. 2009, p. 859, \S 1/HB509.

²⁴ In his opinion, the ALJ discussed at length various provisions of Alabama's law that require a special purpose license to practice medicine across state lines. ALJ at 39 (citing Ala Code. §§ 34–24–343, 34–24–501, 34–24–502(a); Ala. Admin. Code r. 540–x–16.03). However, as the ALJ noted, a physician is not required to obtain a special purpose license if he engages in such activity on an "irregular or infrequent basis" as defined by three different criteria. *Id.* (quoting Ala. Code § 34–24–505; Ala. Admin. Code r. 540–x–16.02). The record does not, however, establish that either Drs. Flynn or De La Guardia prescribed to Alabama residents at a frequency which required them to obtain an Alabama special purpose license.

²⁵ In light of the extensive evidence that Respondent violated Federal law in filling the Coralpines prescriptions, I deem it unnecessary to make any findings as to whether it failed to comply with its corresponding responsibility in filling Dr. Reppy's prescriptions.

narcotic or control medications just to meet your client needs" and noted that "[j]ust last week, the DEA confiscated all the narcotics or control medication in another pharmacy and I stand to lose these meds if they should come to my pharmacy." GX 16, at 20. In short, the Fosus clearly knew that in filling the Coralpines prescriptions, they were violating the CSA.

Under Agency precedent, where, as here, the Government has established its prima facie case, the burden shifts to the Respondent to demonstrate why the continuation of its registration is consistent with the public interest. See, e.g., Medicine Shoppe, 73 FR at 387. An essential element of this showing is that the registrant and its principals accept responsibility for their misconduct by acknowledging their wrongdoing. Id.; see also Jackson, 72 FR at 23853; Kennedy, 71 FR at 35709.

Here, however, Mr. Fosu did not testify and Mrs. Fosu invoked her Fifth Amendment privilege. I therefore hold that the Fosus (and Respondent) have failed to accept responsibility for their misconduct. Because Respondent has failed to rebut the Government's prima facie case, I further conclude that its registration should be revoked and that any pending application should be denied.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as by 28 CFR 0.100(b) and 0.104, I order that DEA Certificate of Registration, BS9433828, issued to Sun & Lake Pharmacy, Inc., be, and it hereby is, revoked. I further order that any pending applications of Sun & Lake Pharmacy, Inc., to renew or modify its registration, be, and they hereby are, denied. This Order is effective June 1, 2011.

Dated: April 22, 2011. Michele M. Leonhart,

Administrator.

[FR Doc. 2011-10506 Filed 4-29-11; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Federal Bureau of Prisons

Notice of Availability of the Environmental Assessment for the Short Term Sentences Acquisition Procurement

AGENCY: U.S. Department of Justice, Federal Bureau of Prisons. **ACTION:** Public Comment on

Environmental Assessment.

SUMMARY: The U.S. Department of Justice, Federal Bureau of Prisons (BOP) announces the availability of the Environmental Assessment (EA) prepared for the proposed contract to secure additional inmate bed space for the BOP's growing inmate population.

As part of this action, known as the Short Term Sentences Acquisition procurement, the BOP has identified a specific requirement to confine an aggregate population of approximately 3,000 low-security adult male inmates (with one year or less remaining to serve) that are primarily criminal aliens. The BOP is seeking to accommodate the growing federal inmate population by requesting additional contract beds.

In accordance with the National Environmental Policy Act (NEPA) of 1969, the Council of Environmental Quality Regulations (40 CFR parts 1500-1508), and the Department of Justice procedures for implementing NEPA (28 CFR 61), the BOP published an EA on January 28, 2011 which described the potential environmental and other impacts associated with the proposed action to award a contract to one or more private correctional contractors to house a population of approximately 3,000 federal, low-security, adult male inmates that are primarily criminal aliens with one year or less to serve on their sentences. Copies of the EA were distributed to federal, state, regional and local officials, agencies, organizations and the public. Publication of the EA initiated a public comment period lasting no less than 30 days and during that comment period, which ended on February 28, 2011, comments were received from several government agencies and a member of the public.

With the passage of time since the EA was first published, and following a thorough review of all public comments and environmental documentation amassed in support of the proposed action, the BOP determined that it was appropriate and in the best interests of the public to prepare a new EA. This new EA incorporates additional information prepared in response to public comments received by the BOP along with the most current information regarding the alternative facilities. The BOP's EA evaluates the potential environmental consequences of three action alternatives and the No Action Alternative. Natural, cultural, and socioeconomic resource impacts associated with the implementation of the proposed action at each of the alternative locations were analyzed to determine how these resources may be affected by the proposed action.

The alternatives considered in the EA include the use of the following

privately-owned and operated facilities:
Diamondback Correctional Center,
Watonga, Oklahoma; Great Plains
Correctional Facility, Hinton,
Oklahoma; and Willacy County
Processing Center, Raymondville, Texas.
The EA also includes information
concerning the BOP's preferred
alternative. Inmates housed in one or
more of these facilities would be
primarily criminal aliens who have less
than one year remaining to serve of their
sentences.

Request for Comments

The BOP invites your participation and is soliciting comments on the EA. The EA will be the subject of a 30-day comment period which begins May 2, 2011 and ends May 31, 2011. Comments concerning the EA and the proposed action must be received during this time to be assured consideration. All written comments received during this review period will be taken into consideration by the BOP. Copies of the EA are available for public viewing at: Watonga Public Library, 301 N. Prouty, Watonga, OK; Norman Smith Memorial Library, 115 E. Main Street, Hinton, OK; and Reber Memorial Library, 193 N. 4th Street, Raymondville, TX.

The EA is available upon request. To request a copy of the EA, please contact: Richard A. Cohn, Chief, or Issac J. Gaston, Site Selection Specialist, Capacity Planning and Site Selection Branch, Federal Bureau of Prisons, 320 First Street, NW., Washington, DC 20534 Tel: 202–514–6470, Fax: 202–616–6024/e-mail: racohn@bop.gov or igaston@bop.gov.

FOR FURTHER INFORMATION CONTACT:

Richard A. Cohn, or Issac J. Gaston, Federal Bureau of Prisons.

Dated: April 26, 2011.

Richard A. Cohn,

Chief, Capacity Planning and Site Selection Branch.

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DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Notice of Recurrence

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the revised Office of Workers' Compensation Programs sponsored information collection