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 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 carisoprodal [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.[1] 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

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.

[1] 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.

supplements thereto may be excluded at the hearing." *Id.*

Pursuant to my authority under 21 U.S.C. 824(d), on November 10, 2009, I further ordered that Respondent's registration be suspended immediately because its "continued registration * * * constitutes an imminent danger to the public health and safety." ALJ Ex. 8, at 1. The Immediate Suspension Order incorporated by reference the allegations of the Order to Show Cause and cited the additional allegations that Respondent had recently filled more prescriptions for controlled substances for two persons who were travelling substantial distances to obtain the drugs. *Id.* at 1–2.

More specifically, the Immediate Suspension Order alleged that on October 2, 2009, L.D.C., a resident of Portsmouth, Ohio obtained from a physician practicing in Wheelersburg, Ohio, prescriptions for 90 tablets of oxycodone 30 mg. and 60 tablets of carisoprodol (a non-controlled but highly abused drug which metabolizes into meprobamate, a Schedule IV depressant), and that she then travelled "approximately 100 miles from Wheelersburg to Columbus" and filled the prescriptions at Respondent. *Id.* at 2. The Order alleged that the next morning, L.D.C. "was found dead at her residence * * * with a prescription vial identifying [Respondent] as the dispensing pharmacy and several scattered oxycodone tablets * * * next to her body," and that the Coroner's Office had preliminarily determined that she "died from the * * * 'probable toxic effects of drugs (oxycodone, carisoprodol and others).'" *Id.*

The Immediate Suspension Order also alleged that on various dates including July 3, September 1, and October 1, 2009, Respondent had filled various prescriptions for oxycodone issued to S.J.P., of Waverly, Ohio. *Id.* The Order alleged that Waverly, Ohio is "approximately 64 miles from Columbus" and that the prescriptions were issued by physicians who practiced "in Lees [sic] Summit, Missouri," as well as in Dayton and Portsmouth, Ohio, which are 78 and 92 miles, respectively, from Respondent. *Id.*

The Order thus alleged that Respondent "knew or should have known that the above dispensed controlled substances were likely to be diverted or used for other than legitimate medical purposes" and that "[b]y dispensing such prescriptions, [Respondent] failed to fulfill its corresponding responsibility for the proper dispensing of controlled substances." *Id.* at 3. Based on the above, I concluded that there was a "substantial likelihood that [Respondent] will continue to violate its corresponding responsibility to properly dispense controlled substances" and that Respondent's continued registration during the pendency of the proceeding "would constitute an imminent danger to the public health and safety." *Id.* I, therefore, ordered that Respondent's registration be suspended.

On November 18–19, 2009, as well as on March 23–25, 2010, the ALJ conducted a hearing in Columbus, Ohio.[2] At the hearing, both parties elicited testimony from witnesses and submitted documentary evidence into the record. Following the hearing, both parties filed briefs containing their proposed findings of fact, conclusions of law, and argument.

On May 18, 2010, the ALJ issued her Recommended Decision. Applying the public interest factors, *see* 21 U.S.C. 823(f), the ALJ concluded that the "record demonstrates that it is against the public interest for the Respondent to retain its controlled substances registration" and recommended that "Respondent's registration be revoked and any pending applications for renewal be denied." ALJ at 54.

Under the first factor—the recommendation of the appropriate State licensing board or professional disciplinary authority—the ALJ found that "the Ohio Board of Pharmacy has not made a recommendation in this proceeding." *Id.* at 45. The ALJ further found, however, that on March 5, 2009, the Board had fined Mr. Fletcher and placed his license on probation because he "did not ensure, on three separate occasions, that a qualified person was at * * * Respondent to receive deliveries of controlled substances," which "were left at unsecure locations pending his arrival at the Respondent. " *Id.* The ALJ concluded that this "security violation weighs in favor of revocation" of Respondent's registration. *Id.*

As to the second factor—Respondent's experience in dispensing controlled substances—the ALJ found that "Respondent ignored numerous 'red flags' when dispensing controlled substances to Dr. Volkman's patients." *Id.* at 46. In particular, the ALJ relied on the testimony and report of the Government's Expert that various patients of Volkman:

> (1) were driving long distances to have their prescriptions filled, (2) were receiving large volumes of controlled substances in the highest strength in each prescription, (3) were not receiving individualized therapy, for 75% of these patients received the same four drug 'cocktail,' (4) were paying large amounts of cash for their prescriptions, and (5) were receiving multiple narcotic pain killers on the same day.

Id.

Noting Agency precedent 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 prescriptions,'" *id.* at 47 (quoting *Ralph J. Bertolino,* 55 FR 4729, 4730 (1990)), the ALJ concluded that Respondent "clos[ed] a blind eye to these obvious red flags," and accordingly, "was not taking seriously its corresponding responsibility for these prescriptions" to

[2] On February 4, 2010, the Government filed a motion in limine to exclude the testimony of various witnesses for Respondent on the ground that their names and an adequate summary of their testimony had not been previously disclosed as required by the ALJ's Order for Pre-Hearing Statements. ALJ Ex. 20. At the hearing on March 23, the Government renewed its motion. The ALJ found that Respondent's Counsel had violated her Order because "the Summary of Witnesses [sic] testimonies was not provided by the deadlines, and the summary that was provided is topical in nature, and not specific" and did not provide "full disclosure of proposed witness testimony." Tr. 786–87. While deeming "such conduct abhorrent" and acknowledging that the Government's Motion "in all [of] parameters should be granted," she nonetheless allowed Respondent to call all of its witnesses even though the Government was "being prejudiced" by the inadequacy of the disclosure. *Id.* at 786–88. This was because the ALJ understood that she has "a responsibility to develop a record." *Id.* at 787.

The ALJ's comments reflect a clear misunderstanding of her role. Proceedings under sections 303 and 304 of the Controlled Substances Act are adversarial and not inquisitorial in nature. As such, it is not the ALJ's role but rather that of the parties to develop the record; the ALJ's role is to ensure that the parties do so in accordance with the Agency's rules of procedure and the Administrative Procedure Act and that the proceeding is conducted with due regard for the Respondent's rights under the Due Process Clause.

Equally troubling is the ALJ's failure to resolve the issues raised by the Government's motion prior to the second phase of the hearing, which did not reconvene until March 23, 2010. Notably, Respondent filed its response to the Government's motion and its second supplemental pre-hearing statement on February 12, 2010; surely, at some point during this nearly six-week-long period and prior to the hearing, the ALJ could have ruled on the motion and issued an appropriate order.

However, while I find the ALJ's delay in handling the motion and her ruling disturbing, much (if not most) of the evidence presented in this matter (including that presented by the Government) is not probative of the issue of whether Respondent violated 21 CFR 1306.04(a). Moreover, many of Respondent's witnesses testified as to the character/reputation of its owner; while disclosure regarding these witnesses should have been more detailed, the prejudice to the Government was minimal.

As to the remaining witnesses, only three of them (Mark Aalyson, Catherine Smith, and Carisa Cole) offered any testimony that is arguably relevant to, and probative of, the central issue. Notably, in its post-hearing brief, the Government does not contend that it was prejudiced by inadequate disclosure of the testimony of these witnesses. I therefore conclude that Government has not preserved its objection.

these patients. *Id.* (citing 21 CFR 1306.04(a)).

The ALJ also noted that "[m]any of Dr. Volkman's patients had told [Respondent's owner] that other pharmacies would not fill Dr. Volkman's prescriptions" and yet Respondent's owner did not call these other pharmacies to ask why. *Id.* She also noted that Respondent had an "unconventional" relationship with Volkman in that Volkman referred his patients to Respondent, that Mr. Fletcher and Volkman's office would coordinate keeping Respondent "open late in the evenings" so that Volkman's patients could fill their controlled substance prescriptions, and that it "kept large quantities of controlled substances on hand to fill these large prescriptions." *Id.* at 48. Relatedly, the ALJ found that one of Volkman's patients credibly testified that she had filled prescriptions at Respondent "while exhibiting 'high' behavior such as slurred speech, stumbling walk, and probably 'drooling.'" *Id.* at 49.

The ALJ further found that "a number of Dr. Volkman's patients died from drug overdoses after having prescriptions filled at the Respondent" and that while "these patients were often drug addicts who did not take the prescription drugs in the manner prescribed," the quantities Respondent dispensed "provided these patients with the means to ingest such quantities as to cause an overdose death." *Id.* at 47. The ALJ also found that the quantities Respondent dispensed were large enough not only to support various Volkman patients' "own addiction, but to also sell the extra controlled substances to provide the income needed for the next prescriptions, or to sponsor someone else in their quest for the drugs needed to feed their addiction." *Id.* at 48.

While noting that Respondent's owner had called Dr. Volkman "to verify his legitimacy," as well as "a local attorney to inquire about Dr. Volkman's reputation in the community," that he had called other prescribing physicians to verify prescriptions, and that he required customers to show identification prior to dispensing controlled substances and had no security issues beyond those for which he was cited by the Ohio Board, the ALJ concluded that "Respondent's failure to react to the 'red flags' raised by the conduct of Dr. Volkman's patients and the dispensing patterns the Respondent used for these patients weigh in favor of revocation." *Id.* at 49–50.

As to the third factor—Respondent's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances—the ALJ found that the record "contains no evidence of a conviction of * * * Respondent or Mr. Fletcher related to the dispensing of controlled substances." ALJ at 50.

As to the fourth factor—Respondent's compliance with applicable State, Federal, or local laws relating to controlled substances—the ALJ found that "Respondent violated recordkeeping requirements by failing to have readily retrievable biennial inventories" and thus violated 21 U.S.C. 827(a)(1) and 21 CFR 1304.11(c). *Id.* The ALJ also found that "Mr. Fletcher failed to do drug utilization reviews prior to dispensing controlled substances." *Id.* at 51.

Next, the ALJ found that "in 2008 and 2009, [Mr. Fletcher] conducted searches on the OARRS [3] database" for "individuals who had predeceased the search" and thus "violat[ed] the requirement that he only search this database for current customers." *Id.* She also found that "Respondent's banking conduct related to its dispensing business violated bank structuring laws and regulations" because "Mr. Fletcher made deposits just short of $10,000, thus avoiding the reporting requirement of the Bank Secrecy Act." *Id.*

Finally, the ALJ reiterated her previous findings that Respondent had ignored the "red flags" indicating that Dr. Volkman's prescriptions were illegal. *Id.* Noting "the lack of individual therapy, the quantities and strength of the medications, and the other behavior patterns demonstrated by" the Volkman patients, the ALJ concluded that Respondent had "adequate evidence to determine that the prescriptions were not written for a legitimate medical purpose," and that its violation of its "corresponding responsibility weights greatly in favor of revocation in this matter." *Id.* at 51–52.

As for the fifth factor—such other conduct which may threaten the public health and safety—the ALJ noted that Mr. Fletcher did not testify in the proceeding. *Id.* at 52. While she acknowledged the settled case law that notwithstanding the Fifth Amendment privilege, an adverse inference may be drawn in a civil matter based on a party's failure to testify, the ALJ nevertheless declined to "draw an adverse inference" even though she found Mr. Fletcher's "inconsistent handling of controlled substances" to be "most troubling." *Id.* (citing, *inter alia, Baxter* v. *Palmigiano,* 425 U.S. 308, 318 (1976)). More specifically, the ALJ observed that Mr. Fletcher "clearly knew the questions to ask when dispensing controlled substances to a customer" but that "in six months he filled over 4,900 prescriptions without seeming to consistently engage in such conversations with Dr. Volkman's patients" and that, even "when they demonstrated their addictive behavior before him, he filled [their] prescriptions anyway." *Id.* The ALJ concluded that this conduct was "adverse to the public health" and supported revocation. *Id.* at 53. The ALJ further noted that Mr. Fletcher had failed to provide assurances that he will not engage in future misconduct. *Id.* (citing numerous Agency cases).[4]

The ALJ thus concluded that the Government had "met its burden of proof" and demonstrated that Respondent's continued registration is inconsistent with "the public interest." *Id.* at 54. She therefore recommended that "Respondent's registration be revoked and [that] any pending applications for renewal be denied." *Id.*

On June 17, 2010, Respondent timely filed Exceptions to the ALJ's Decision; its Exceptions have been considered in my review of this matter. Having reviewed the record in its entirety, I agree with the ALJ's ultimate finding that Respondent's continued registration is inconsistent with the public interest. However, because Respondent's registration has expired and it has not filed a renewal application, there is neither a registration to revoke nor a renewal application to deny.

As noted above, Respondent's registration was suspended prior to the hearing pursuant to my authority under 21 U.S.C. 824(d). I, therefore, conclude that this case is not moot and uphold the suspension order. As the ultimate finder of fact, I make the following findings.

[3] Ohio Automated Rx Reporting System. The law allowing the Ohio Board of Pharmacy (BOP) to develop its prescription monitoring program (OARRS) became effective May 18, 2005; the rules implementing the law went into effect on January 1, 2006. GX 18, at 2 (Ohio Automated Rx Reporting System Handbook). These rules require every pharmacy (including out-of-State pharmacies) that "services outpatients and dispenses to an Ohio residence any controlled substance or any product containing tramadol or carisoprodol" "to submit the dispensing information to the BOP." *Id.*

[4] Based on the testimony of Respondent's character witnesses (which included some of his customers), the ALJ concluded that this "evidence demonstrates that the Respondent acts responsively in many of his dealings with others." ALJ at 54. The ALJ concluded, however, this evidence does "not negate the fact that at least between September 2005 and February of 2006, Mr. Fletcher chose to turn a blind eye to the conduct of Dr. Volkman's patients and to dispense controlled substances irresponsibly." *Id.*

Findings

Respondent previously held DEA Certificate of Registration, BE5902615, under which it was authorized to dispense controlled substance in Schedules II through V at the registered location of 1336 East Main Street, Columbus, Ohio 43205. GXs 1 & 2. Respondent last renewed its registration on August 27, 2007; its registration expired on August 31, 2010. *Id.* According to the records of the Agency, of which I take official notice, Respondent has not filed a renewal application.[5]

Respondent is owned by Eugene H. Fletcher, who is also its sole pharmacist.[6] ALJ Ex. 3, at 2. Respondent sells only prescription pharmaceuticals. Tr. 863.

In 2003, Dr. Paul Volkman, a physician who was unable to obtain malpractice insurance because of several large malpractice settlements and judgments, commenced working at a Portsmouth, Ohio pain clinic owned by one Denise Huffman. GX 6, at 2. As previously found by the Agency (and as upheld by the United States Court of Appeals for the Sixth Circuit), Volkman frequently prescribed large quantities of multiple controlled substances including narcotics containing oxycodone[7] and hydrocodone,[8] benzodiazepines such as Xanax (alprazolam) and Valium (diazepam),[9] as well as the currently non-controlled drug Soma (carisoprodol) which is nonetheless popular with drug abusers, without a legitimate medical purpose and outside of the usual course of professional practice. GX 6, at 2–3; *Paul H. Volkman,* 73 FR 30630, 30633–34, 30639 (2008), *pet. for rev. denied, Volkman* v. *DEA,* 567 F.3d 1215 (6th Cir. 2009). In plain English, the record in the Agency proceeding involving Dr. Volkman conclusively established that he was a drug dealer.

On September 9, 2005 (several months after DEA executed a search warrant at Huffman's clinic), Volkman left the clinic; three days later, he started seeing patients out of his residence at 1310 Center St. in Portsmouth.[10] GX 6, at 4; 73 FR at 30635. However, Volkman's patients encountered problems filling his prescriptions. GX 39, at 1. D.S., one of Volkman's patients, helped Volkman by going on the Internet to search for pharmacies that would fill his prescriptions; according to D.S., she would call and ask the pharmacists if they "would fill prescriptions for oxycodone 30 mg., hydrocodone 10 mg., Xanax 2mg., [and] Soma 350 mg., and if they had the drugs on hand."[11] Id. While the pharmacists at other pharmacies "either said they did not have the medications in stock or would not fill prescriptions for Dr. Volkman," Mr. Fletcher said that he had the "drugs in stock" and that "he would fill the prescriptions." *Id.* at 2.

Thereafter, D.S. posted a notice on a bulletin board in Volkman's office which provided Respondent's name, address, and phone number. *Id.; see also* GX 15. Directions were also provided from Volkman's residence to Respondent.[12] *See* GX 15, at 1, 2, 4, 5. Moreover, when, in October 2005, Volkman moved to Chillicothe, Ohio, he posted similar notices with directions to Respondent. The distance from Volkman's Portsmouth residence to Respondent was approximately 94 miles, *see* GX 15, at 2; the distance from his Chillicothe office to Respondent was 56 miles. GX 9, at 23.

According to Dr. Volkman's former security guard, "Volkman instructed his employees to send all his patients to [Respondent] to have their prescriptions filled." GX 22, at 2; *see also* GX 23, at 1. Moreover, "just about every day, a call was made from [Volkman's] clinic to [Respondent] or from the [Respondent] to the clinic" during which Mr. Fletcher was told when Volkman's "last patient had been seen" so that he would know how late to keep the pharmacy open to fill the prescriptions Volkman issued. GX 22, at 2. At times, patients would show up at Respondent and fill their prescriptions as late as midnight. GX 24, at 3; *see also* GX 23, at 2 (L.W. relating that she filled prescriptions at Respondent as late as 9 or 10 p.m.). Volkman's ex-security guard stated that the patients "did not appear to be in pain" and that he believed that "about 60% of [them] were pill patients and not pain patients." GX 22, at 3. *See also* GX 24, at 6 (affidavit of A.S.; "[t]here were some legitimate patients, but most of Dr. Volkman's patients were not legitimate. They were going to Dr. Volkman and [Respondent] for drugs to abuse and to sell."); GX 9, at 11 (photographs of patients waiting to see Volkman taken on date Portsmouth P.D. executed search warrant at his practice).

As part of the investigation, DEA Diversion Investigators (DIs) obtained data from the Agency's ARCOS system showing Respondent's purchases of oxycodone and hydrocodone combination drugs; these drugs are Schedule II and III narcotics, respectively. Tr. 533–34. The oxycodone data showed that in 2004, Respondent had purchased 96,000 dosage units. GX 9, at 33. However, during 2005, Respondent purchased 495,000 dosage units; of this amount, approximately 400,000 dosage units were purchased between September and December. *Id.* Likewise, in 2004, Respondent purchased 88,000 dosage units of hydrocodone. *Id.* at 34. In 2005, Respondent purchased 328,000 dosage units; of this amount, more than 200,000 were purchased between September and December.[13] *Id.* While in 2004, Respondent was only the 300th largest pharmacy purchaser of oxycodone in Ohio; in 2005, it was the eleventh largest purchaser, and in 2006, it was the seventh largest. *Id.*

On February 10, 2006, a search warrant was executed at Respondent and its dispensing records were seized.[14] Tr. 523. The records showed that between September 1, 2005 and February 10, 2006, Respondent dispensed a total of 6,619 controlled-

[5] An agency "may take official notice of facts at any stage in a proceeding-even in the final decision." U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947). In accordance with the Administrative Procedure Act and DEA's regulation, Respondent is "entitled on timely request to an opportunity to show to the contrary." 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). Accordingly, Respondent may file a motion for reconsideration of this fact within fifteen days of service of this Order which shall commence with the mailing of the Order.

[6] Mr. Fletcher additionally owns and operates a dumpster business and owns and manages both commercial and residential rental properties. *Id.* at 866, 1598.

[7] Oxycodone is a schedule II controlled substance. 21 CFR 1308.12(b)(1)(xiii).

[8] Hydrocodone, when combined with another non-narcotic therapeutic ingredient such as acetaminophen, is a schedule III controlled substance. 21 CFR 1308.13(e)(1).

[9] Alprazolam and diazepam are benzodiazepines and are schedule IV depressants. 21 CFR 1308.14(c).

[10] According to a Diversion Investigator (DI), Volkman started writing prescriptions out of his residence on September 12, 2005. GX 9, at 9.

[11] It is acknowledged that D.S.'s affidavit stated that in September 2005, she had started taking people to Respondent to fill prescriptions. GX 39, at 3. D.S. further stated that she had taken her friend C.R. to Respondent to fill prescriptions and that C.R. overdosed and died the same day as her first trip to Respondent. *Id.* at 5. Subsequently, the Government acknowledged that C.R. had died on March 9, 2004. Letter of Government Counsel to ALJ, at 1. (May 10, 2010).

Notwithstanding D.S.'s misrepresentation, there is substantial circumstantial evidence establishing the relationship between Respondent and Volkman. I therefor find credible D.S.'s statement regarding how she found Respondent.

[12] In October 2005, the Portsmouth Police executed a search warrant at Volkman's residence. GX 6, at 4. While no charges were filed, Volkman was issued a condemnation notice. *Id.* Shortly thereafter, Volkman moved to Chillicothe, Ohio. *Id.*

[13] The data also showed that in 2006, Respondent purchased 820,000 dosage units of oxycodone and 224,000 dosage units of hydrocodone. GX 9, at 33–34.

[14] On the same day, a search warrant was also executed at Dr. Volkman's Chillicothe office and his registration was suspended. GX 9, at 13.

substance prescriptions; 4,979 of the prescriptions (75%) had been issued by Dr. Volkman.[15] GX 9, at 62. Corresponding with Mr. Fletcher's agreeing to fill Volkman's prescriptions, Respondent experienced multi-fold increases in the amounts of prescriptions it filled for oxycodone, hydrocodone, diazepam and alprazolam. Tr. 526; GX 9, at 29.

Nearly ninety-nine percent of the persons who obtained controlled-substance prescriptions from Volkman and filled them at Respondent did not live in Columbus, Ohio. GX 9, at 24; Tr. 522. Approximately half of the patients were from Kentucky, with some of the patients driving three to four hours to obtain the drugs;[16] many other patients were from the Portsmouth, Ohio area.[17] *See* GX 14; Tr. 571–72. From Portsmouth to Respondent there were 40 other pharmacies along the route. GX 34, at 2. Moreover, the dispensing records showed that 87 percent of Respondent's customers paid cash for their prescriptions; by contrast, according to the Government's Expert, "the national average of cash paying customers for prescriptions [was] 11.4% in 2005 and 10% in 2006."[18] GX 20, at 2; Tr. 534–35. Only five percent of the customers paid with insurance, and eight percent paid with a combination of insurance and cash. Tr. 534–35; GX 9, at 41.

L.W., a resident of Quincy, Kentucky, and A.S., a resident of Portsmouth, were among those persons who obtained controlled-substance prescriptions from Volkman and filled them at Respondent. *See* GXs 23 & 24; Tr. 272. On October 10, 2005, L.W. filled at Respondent prescriptions for 270 tablets of oxycodone 30 mg., 240 tablets of hydrocodone/apap (10/500),[19] 90 tablets of alprazolam 2 mg. (generic for Xanax), and 180 tablets of carisoprodol 350 mg. GX 12, at 2. On November 7, L.W. obtained from Respondent an additional 270 tablets of oxycodone 30 mg., 240 hydrocodone 10/500, 90 alprazolam 2 mg., and 240 tablets of carisoprodol; on December 6, she obtained the same four drugs and quantities, the sole difference being that she received only 180 oxycodone 30 mg. *Id.* Finally, on February 3, 2006, L.W. obtained from Respondent 360 tablets of oxycodone 30 mg., 360 tablets of hydrocodone 10/325, 90 tablets of alprazolam 2 mg., and 240 carisoprodol. *Id.*

In an affidavit, L.W. stated that while she initially needed to take pain medication following two accidents, the last of which occurred in February 2004, at the time she was seeing Dr. Volkman and filling the prescriptions at Respondent, she was both selling the drugs and taking them "to get high." GX 23, at 4. She stated that on those occasions when she spoke with Mr. Fletcher at Respondent, he "never asked me about my medical condition but would just make small talk." *Id.*[20] She further stated that she "was high on drugs several times when having prescriptions filled at [Respondent] and at times was high when [she] spoke with" Mr. Fletcher. *Id.* at 3–4. L.W. further stated that on her last visit to Respondent, she was "so high" that her "slurred speech and unsteady walk would have been very noticeable" and that her "head was hanging down and [she] was probably drooling." *Id.* at 4.

Respondent filled A.S.'s prescriptions, which she obtained from Dr. Volkman, for oxycodone, hydrocodone, diazepam, alprazolam, and carisoprodol on seven occasions between September 13, 2005 and February 1, 2006. GX 12, at 1. More specifically, on September 13, Respondent dispensed to her 240 oxycodone 30 mg., 180 hydrocodone/apap 10/650, 90 diazepam 10 mg., and 90 carisoprodol 350 mg. *Id.* Respondent made additional dispensings of Volkman's prescriptions as follows: On October 10, 330 oxycodone 30 mg., 240 hydrocodone 10/500, 90 alprazolam 2 mg., and 180 carisoprodol 350 mg.;[21] on November 8, 165 oxycodone 30 mg., 120 hydrocodone, 45 alprazolam, and 90 carisoprodol; on December 2, 180 oxycodone 5 mg., 240 hydrocodone, 90 alprazolam, and 180 carisoprodol; on December 20, 90 oxycodone 5 mg., 120 hydrocodone, 45 alprazolam, and 90 carisoprodol; on January 2, 2006, 240 oxycodone 15 mg., 240 hydrocodone, 90 alprazolam, and 180 carisoprodol; and on February 1, 240 oxycodone 30 mg., 240 hydrocodone, 90 alprazolam, and 180 carisoprodol. *Id.*

A.S. testified at the hearing. While the ALJ found portions of her testimony not credible because "she became vague, and contradicted herself," ALJ at 23 n.6, the ALJ found credible her testimony that her sister-in-law told her about Dr. Volkman and sponsored her by giving her the money to pay for her office visit and to fill the prescriptions she obtained. *Id.* at 22 n.5; Tr. 264. The ALJ further found credible A.S.'s testimony that she gave her sister-in-law "half of the pills," which her sister-in-law then sold to raise money to sponsor someone else. ALJ at 22 & n.5. (citing Tr. 266, 276, 283.) A.S. testified that her sister-in-law "would take several people to the doctor" and that they would go to Respondent to fill the prescriptions. Tr. 283. A.S.'s sister-in-law would pay for everything and receive "half [of] the medication." *Id.* A.S. testified that Volkman gave her combination prescriptions and that Volkman's office told her to go to Respondent, which was a two-hour drive (one-way) from Portsmouth. *Id.* at 274–75. A.S. also admitted that she was addicted to oxycodone and had been at the time she obtained prescriptions from Dr. Volkman and filled them at Respondent.[22] *Id.* at 253 & 336.

[15] During this period, Respondent filled a total of 5,206 prescriptions issued by Volkman. GX 9, at 24, 28.

[16] Several persons drove to Respondent from Paintsville, Kentucky, a distance of 182 miles; according to a DI, there were 96 pharmacies enroute. GX 34, at 3.

[17] According to the testimony of Lisa Roberts, R.N., who works for the Portsmouth Health Department and who is a member of the Ohio Department of Health Poison Action Group, Tr. 26, Scioto County (where Portsmouth is located) "showed a 360 percent increase in unintentional prescription drug overdoses" from 1999 to 2009. *Id.* at 32. In a Community Health Assessment she prepared for the City of Portsmouth, Ms. Roberts wrote that "Scioto County has long been the target of lucrative 'Pill Mills' [which] prescribe powerful prescription drugs to individuals without proof of chronic pain." GX 8, at 6. Continuing, Ms. Roberts noted that "[m]any people have become addicted as a result of these establishments" and that "much of the pills distributed there end up being illegally diverted to the public, including [to] high school students." *Id.* She also noted that "[p]eople come from other states as well to patronize these establishments." *Id.* Ms. Roberts testified that she "knew people that went to [Dr. Volkman] to get drugs to sell," as well as about the practice of sponsoring, by which an abuser or drug dealer recruits another person and fronts the person the money needed to pay for a doctor visit and to fill the prescriptions; the sponsor then receives half the pills back which can then be sold. Tr. 43, 62–63. *See also* Tr. 264, 266, 276, 283.

[18] Payment information was taken from the seized prescriptions. Tr. 570.

[19] Apap is the abbreviation for acetaminophen.

[20] *Cf.* GX 22, at 3 (affidavit of Delbert Evans, Dr. Volkman's security guard; "Some calls by Eugene were to speak with Dr. Volkman but the majority of the calls were to determine how late he should stay open to fill Dr. Volkman's prescriptions.").

[21] After this date, each of the hydrocodone dispensings was for the 10 mg. strength (which is the strongest formulation); the alprazolam dispensings were for the 2 mg. strength, and the carisoprodol was for the 350 mg. strength. *See* GX 12, at 1.

[22] On cross-examination, A.S. admitted that she never told Mr. Fletcher that she was addicted or that she was giving half of her drugs to her sister-in-law. Tr. 312. However, one would hardly expect a drug abuser or diverter to tell a pharmacist why she was seeking the drugs. A.S. also testified on cross-examination that she presented valid prescriptions to Mr. Fletcher. *Id.* at 314. However, Respondent's counsel did not clarify what he meant by the term "valid," which can mean one of several things such as that the prescriptions were not fraudulent or forged, that they were issued for a legitimate medical purpose, or that they were in proper form and contained the required information.

A.S. also testified that she had been in constant pain since a 1996 car accident, that she was in pain when she testified in this proceeding, and that she

Continued

S.L.J. was a confidential informant for the Portsmouth Police Department (PPD). GX 4, at 744. On September 16, 2005, the PPD sent S.L.J. to see Dr. Volkman and to obtain controlled-substance prescriptions. *Id.* Dr. Volkman wrote her prescriptions for oxycodone 30 mg. and Percocet,[23] which S.L.J. turned over to the police. *Id.* On September 26, S.L.J., who was an addict, returned to Dr. Volkman's office on her own initiative and without the PPD's knowledge; she obtained prescriptions for 135 tablets of Percocet 5/325 mg. and 135 tablets of oxycodone 30 mg. *Id.* at 745–46. The same day, S.L.J. filled those prescriptions at Respondent. *Id.* at 746. On September 29, 2005, S.L.J. was found dead; the coroner determined that the cause of death was "multiple drug intoxication." *Id.* The Government did not, however, submit the coroner's report or a police report and thus did not establish that Respondent dispensed the drugs on which S.L.J. overdosed.[24]

E.R. lived in Grayson, Kentucky and went to Dr. Volkman at his Chillicothe, Ohio clinic on just one occasion. GX 4, at 749 & 750; Tr. 407. He had planned to obtain prescriptions for controlled substances, fill them, and then sell the drugs on the street to get out of debt. Tr. 405–07, 409–10. E.R., who had heard from friends that Volkman would write large-volume controlled-substance prescriptions, drove for several hours with a friend to see Volkman. *Id.* at 406, 410. E.R. obtained from Volkman prescriptions for 240 oxycodone 30 mg., 240 hydrocodone/apap 10/500, 90 alprazolam 2 mg., and 90 Soma 350 mg. *Id.* at 408; GX 4, at 750. The following day, E.R. drove with his wife to Respondent and filled the prescriptions. *Id.* at 409–12.

Immediately after he obtained the drugs, E.R. entered his car and proceeded to crush and snort two oxycodone tablets. *Id.* at 412. On the return trip, "he also took a couple of Xanax." *Id.* Following a stop at the local WalMart, E.R. and wife went to see a friend who sold controlled substances and E.R. offered to sell him some of the hydrocodone. *Id.* at 413. However, the drug dealer was having a domestic dispute so E.R. and his wife returned to their home. *Id.*

Later that evening, the drug dealer came to E.R.'s house and "partied with" E.R. for several hours. *Id.* The following morning, E.R. was found dead. *Id.* at 413–14. However, once again, the Government did not introduce into evidence the coroner's report or a police report and thus has not established in this case that E.R. overdosed on the drugs he obtained at Respondent.

The evidence also showed that in October 2005, and shortly after Respondent started dispensing the Volkman prescriptions, Mr. Fletcher phoned Robin Padolik, who was then employed as an Automated Clearing House Coordinator for the Commerce National Bank (CNB), where he held various accounts. GX 25, at 1, 3. According to Ms. Padolik, beginning around September 2005, CNB personnel began noticing an increase in the amounts of Mr. Fletcher's cash deposits and placed him on CNB's "Watch List." *Id.* The same month, Mr. Fletcher's transfers to his outside accounts became more frequent, and in mid-October, Mr. Fletched called and asked Ms. Padolik "at what point the bank would be required to file a form when he made a cash deposit; how a deposit would [be] process[ed]"; and, if making deposits into two "separate accounts [would] prevent a form submission." *Id.* at 3. Ms. Padolik specifically related that on October 13, 2005, Mr. Fletcher called and asked whether "if he deposited $6,000 in one account and $4,000 in another account," the bank would be required "to submit 'that report.' " *Id.* Based on Mr. Fletcher's question, Ms. Padolik, who had been trained in the Bank Secrecy Act and the recognition of money-laundering, concluded that Mr. Fletcher "apparently knew [that] the threshold for reporting was any amount over $10,000, but did not know the name of the form the bank was required to file." *Id.* Ms. Padolik ducked Mr. Fletcher's question. *Id.*

On October 18, Mr. Fletcher called Ms. Padolik and asked if "account deposit amounts were associated with the Taxpayer Identification Number (TIN)." *Id.* at 4. He also asked "how he could change his TIN" for the accounts he maintained for Respondent and for his other business ventures. *Id.* Ms. Padolik again ducked Mr. Fletcher's questions and reported him to Andrew Reardon, CNB's Compliance Manager. *Id.*

As Ms. Padolik testified, "it was really a big red flag when he started asking questions about dollar amounts * * * so it looked like he was really fishing for information on how he can [sic] get around BSA reporting." Tr. 167. Ms. Padolik explained that "[d]eposit structuring * * * is a break-up of cash deposits that are turned into other financial transactions * * * it's cash that is taken from its criminal origin and passed through the system with many transactions * * * Structuring is a way to take cash from an illegal source and make it look more legal by passing it through the financial system." Tr. 157–58.

Ms. Padolik specifically identified six transactions by Mr. Fletcher which raised her suspicion that he was engaged in structuring to avoid the bank's filing of a Currency Transaction Report (CTR). GX 25, at 4; *see also* Tr. 166; 31 CFR 103.11. These included deposits of $9,900 on October 11, a check for $41,000 issued to an investment company on October 15, a deposit of $9,980 on October 17, a deposit of $8,380 on October 18, a deposit of $9,950 on October 19, and a deposit of $9,900 on October 20, 2005. GX 25, at 4. Following a review of his transactions by the CNB's High Risk Committee, the Bank concluded that Mr. Fletcher had engaged in structuring in violation of Federal banking regulations and closed his accounts. Tr. 207–08; GX 28.[25] A DI further found that Mr. Fletcher's "net profit from dispensing for Dr. Volkman [was] almost $500,000." Tr. 620.

DEA Investigators interviewed Mr. Fletcher regarding the Volkman prescriptions on two occasions, February 10, 2006 and November 27, 2007. Tr. 600. According to the DI who conducted the latter interview, Mr. Fletcher said that "he had questions about" Dr. Volkman. *Id.* at 606. Mr. Fletcher maintained that he had called Dr. Volkman, who told him that "he did an MRI, and blood tests."[26] *Id.* Mr. Fletcher also maintained that Volkman's prescriptions were valid because "the physician was licensed in Ohio and [the prescription] was written to the person

had pain at the level of an eight on the scale of one to ten. *Id.* at 258–60.

[23] Percocet is a brand-name product containing oxycodone and acetaminophen and is a schedule II controlled substance. ALJ Ex. 5, at 1.

[24] While I previously found in the *Volkman* decision that S.L.J. had died of multiple drug intoxication and had both oxycodone and alprazolam in her system, *see* 73 FR 30636 n.23, Respondent was not a party to that proceeding. The Government was thus required to prove this fact anew, which it failed to do because the DI testified that he was unsure of, and did not recall the cause of S.L.J.'s death. Accordingly, I conclude that the Government has not proved that S.L.J.'s death was caused by the prescriptions she filled at Respondent.

[25] To refute this evidence, Respondent put on the testimony of his accountant, who maintained that Mr. Fletcher "more than likely" was of "low sophistication" in regards to banking regulations. Tr. 1602. However, I find credible Ms. Padolik's testimony (both at the hearing and in her affidavit) regarding the questions Mr. Fletcher asked regarding the bank's reporting obligations and conclude that he clearly knew what he was doing and was engaged in structuring.

[26] There was also testimony that Volkman's patients complained to Respondent's employees of having to pay extra for drug tests. Tr. 1265–67; 1713–14.

presenting" it. *Id.* He stated the prescriptions were not forged. *Id.*

However, twice in the interview, Mr. Fletcher admitted that his customers had told him that "'other pharmacists would not fill Dr. Volkman's prescriptions.'" *Id.* at 622 & 624. The DI then asked Mr. Fletcher if he had "call[ed] the other pharmacists and asked them why they were not filling Dr. Volkman's scripts." *Id.* at 622. Mr. Fletcher answered: "I don't communicate with other pharmacists." *Id.*

The DI also asked Mr. Fletcher if he ever felt that Dr. Volkman's patients were addicted to drugs; Mr. Fletcher answered that it was "'hard to say.'" *Id.* at 606. Mr. Fletcher told the DI that sometimes Dr. Volkman's patients would ask him to sell them extra pills; Mr. Fletcher stated that he had refused to do so. *Id.* He also stated that he did "not get into" the "personal life" of his customers to determine their medical conditions. GX 9, at 69.

When the DI asked Mr. Fletcher about his "corresponding responsibility," he acknowledged that a physician must prescribe "for a legitimate ailment, and [that] the dose must be correct." GX 9, at 68. However, Mr. Fletcher maintained that "what to prescribe and the quantities" was for the physician to decide and that it was "not his job to question a physician." *Id.* He further asserted that he did not find it suspicious that the customers were traveling long distances, paying cash, obtaining combinations of controlled substances, and that other pharmacies had refused to fill the prescriptions. *Id.* at 69.

The Government introduced evidence showing that Respondent's purchases and dispensings of controlled substances were substantially greater than that of a single CVS pharmacy which was located 1.6 miles from it. GX 9, at 30–39. It also introduced evidence comparing the prices Respondent and four other independent pharmacies (two of which were located in Columbus, two of which were located in Portsmouth) paid their suppliers for various controlled substances as well as what they charged their customers; the Government asserts that this evidence shows that these four pharmacies sold controlled substances at an average price 37% cheaper than that charged by Respondent. GX 9, at 55–56.

It is obvious, however, that neither strand of evidence rises to the level of substantial evidence because neither is based on a statistically valid sample. Indeed, to compare Respondent's controlled-substance dispensings to that of a single CVS located 1.6 miles away ignores that the two stores may serve communities with substantially different demographics such as the age of the residents and the presence of competitors. So too, comparing Respondent's prices with those charged by four other pharmacies (out of likely thousands of pharmacies in the State of Ohio including hundreds of independents) and which do not even appear to have been selected at random, is manifestly inadequate to prove that Respondent charged more because it was selling to an illicit market.

The Government also put on extensive evidence to the effect that Respondent was located in a bad/high-crime neighborhood and that Mr. Fletcher carried a gun while at his business. As for the character of Respondent's neighborhood, the principal issue in this case was whether Respondent was dispensing controlled-substance prescriptions which it either knew or had reason to know lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. *See* ALJ Ex. 1, at 1–2 (citing 21 CFR 1306.04(a)). Whether Respondent is located in a bad neighborhood is of no relevance in determining whether Mr. Fletcher violated his corresponding responsibility under the CSA. While there is evidence (discussed below) that Respondent and Mr. Fletcher were found by the Ohio Board of Pharmacy to have violated State law because he was not present on three occasions when controlled substances were delivered and the drugs were not properly stored, GX 16, at 2, presumably, this would have been a violation even if Respondent had been located in the safest neighborhood in the State of Ohio. So too, the evidence that Mr. Fletcher carried a gun is entirely irrelevant.[27]

Evidence Regarding Respondent's Practices After February 10, 2006

The Government also obtained data from OARRS, the Ohio prescription monitoring program, showing controlled-substance prescriptions that were issued by Florida-based physicians and filled by Respondent. Tr. 476; GXs 10 & 11. The Government submitted a spreadsheet showing more than fifty prescriptions for drugs such as oxycodone in 15 mg. and 30 mg. strength and alprazolam, which Respondent filled between September 4, 2007 and September 2, 2008. *See* GX 10. At least seventeen of the persons listed as having filled prescriptions at Respondent were residents of Kentucky; several individuals filled multiple prescriptions for oxycodone on the same day. *See id.* For example, on April 25, 2008, A.B., a resident of Denton, Kentucky (143 miles from Respondent), filled prescriptions for 180 oxycodone 30 mg., 120 oxycodone 15 mg., and 90 alprazolam 2 mg.; on July 23, 2008, C.W., a resident of Ashland, Kentucky (123 miles from Respondent), filled prescriptions for 240 oxycodone 30 mg., 60 oxycodone 15 mg., and also 60 alprazolam 2 mg.; and on August 11, 2008, N.W., a resident of Flatwoods, Kentucky (118 miles from Respondent), filled prescriptions for 240 oxycodone 30 mg., 90 oxycodone 15 mg., and also 60 alprazolam 2 mg. GX 10, at 1–2. Moreover, on August 25, 2008, C.L. filled prescriptions for 90 diazepam 10 mg. and 60 alprazolam 2 mg.[28] *Id.* at 1.

Additional Evidence Regarding Patient Deaths

The Government also introduced evidence regarding two additional persons, L.D.C. and B.A., who obtained controlled substances from Respondent and died the following day. Both deaths occurred in the fall of 2009.

L.D.C., who was 34 years old at the time of her death, lived in West Portsmouth, Ohio. GX 29. On October 2, 2009, L.D.C. obtained prescriptions from Dr. Georgescu of Wheelersburg, Ohio for 90 tablets of oxycodone 30 mg. (90 dosage units) and 60 tablets of

[27] The Government also introduced evidence showing that Mr. Fletcher had violated the Ohio Board of Pharmacy's Acceptable Use Policy for the OARRS, because he obtained prescription information on two persons who had died. Tr. 930–31, 1803, 1808; GX 42, at 1. According to the Government's Expert, this violated the Board's policy because a pharmacy can only obtain information on a current customer. Tr. at 930–31. Notably, the Government's Expert did not testify that this conduct violated any State law or regulation.

While this may be an improper use of the database and a violation of the Board's policy, the matter is best left to the Board to resolve.

[28] On March 20, 2009, the Ohio Board of Pharmacy sent a notice to pharmacists explaining that it had observed "a significant volume of prescriptions from physicians in Florida" who were prescribing oxycodone, Xanax, Percocet and Soma for residents of Ohio and Kentucky who were "generally 20–55 years old and usually pay cash." GX 17. The Board further explained that "[i]n many of these cases, we are wondering how the term 'legitimate medical purpose' applies when a patient who is supposedly in severe pain can ride to Florida and back to receive treatment when we have excellent facilities in Ohio." *Id.* The Board requested pharmacists who had "already filled such prescriptions" to contact one of its Agents because the Board believed that "this may be a coordinated effort to obtain drugs and we are trying to develop a list of the people involved." *Id.*

There was also evidence that because of the effectiveness of the State of Kentucky's prescription monitoring program, drug dealers were sponsoring people to go to South Florida to obtain controlled-substance prescriptions and that some of these individuals would fill the prescriptions in Ohio. Tr. 429–34.

carisoprodol which she then filled at Respondent. GX 32, at 1, 4; GX 29, at 2; Tr. 629. These were the first and last prescriptions she filled at Respondent. GX 32, at 1.

According to the report filed by the Scioto Sheriff's Office, on October 3, L.D.C.'s boyfriend found her lying on the floor of the master bedroom near the footboard of their bed with blood coming from her nose and mouth. *Id.* On arriving at the scene, a Deputy Sheriff observed "38 white pills laying beside her and a pill bottle labeled oxycodone 30 mg. [which] was prescribed on October 2, 2009 and filled at" Respondent. GX 29, at 2. The officer also found that "on a dresser next to her [were] 10 oblong pills scored GG/2/4/9 and a pill bottle labeled Soma 350 mg. with 48 pills in it." *Id.* He also "saw a silver spoon with white residue on it and a needle with no cap on it." *Id.* at 4. A second officer made the same observations and reported that the pills labeled GG/2/4/9 were "believed to be Xanax." *Id.* at 5.

Thereafter, an autopsy was performed on L.D.C. On November 30, 2009, the Coroner issued her Opinion that the cause of L.D.C.'s death was the "[t]oxic effects of drugs" including "oxycodone, oxymorphone and others." GX 37, at 1. According to the toxicology report, oxycodone, oxymorphone, carisoprodol, and meprobamate were found in her blood. *Id.* at 2; GX 31.

On November 4, 2009, B.A., "a recovering drug addict" and resident of Morehead, Kentucky, "went to a doctor in Portsmouth[,] Ohio" and obtained four controlled-substance prescriptions, which he then filled at Respondent the same day. GX 38, at 1 & 7. The prescriptions were for 60 tablets of Roxicodone 30 mg. (oxycodone), 120 tablets of oxycodone 15 mg., 180 tablets of Roxicodone 30 mg. (oxycodone), and 30 alprazolam 1 mg. *Id.* at 7.

B.A. "went to bed at around 2300–2400 on Thursday November 4[,] 2009 and was high when he went to bed." *Id.* at 1. He was "found deceased the next morning by his room-mate." *Id.*

The next morning, a Detective went to B.A.'s trailer and interviewed B.A.'s roommate L.R., who reported that B.A. "appeared to be a little high last night before he went to bed" but because B.A. "had not been home all day yesterday * * * he did not know exactly what all [B.A.] had done." *Id.* at 4. L.R. further stated that B.A. "really didn't seem right," that he had been in the bathroom "for a long time," that when B.A. went to bed, he was "snoring really loud" but that when L.R. got up to use the bathroom at about 3:30 a.m., B.A. was no longer snoring. *Id.* at 5.

The Detective obtained L.R.'s consent to search the premises and found a key on B.A.'s car key ring which fit a safe in B.A.'s bedroom. *Id.* at 5. The Detective opened the safe and found six pill bottles, including the four prescriptions which B.A. had filled the day before at Respondent. *Id.* at 5–6.

With respect to these four prescriptions, the Detective found that there were no tablets left in the bottle which had contained 60 Roxicodone 30 mg., there were only fifty-two tablets left in the bottle which had contained 120 oxycodone 15 mg., there were only nineteen tablets left in the bottle which had contained 180 Roxicodone 30 mg., and there were only eight tablets left of the thirty alprazolam. *Id.* at 7.

The Detective also interviewed two persons who had accompanied B.A. on his trip to the doctor's office and to Respondent. *Id.* They stated that when B.A. emerged from the doctor's office, he had a "'mapquest' printout" with directions to Respondent; B.A. told them that the doctor's staff had said to fill his prescriptions at Respondent. *Id.* at 8.

Following L.D.C.'s death, Investigators conducted surveillance of Respondent during which they observed the license plates of its customers to determine where they were coming from. Tr. 592. One of the plates was traced to S.P., a resident of Waverly, Ohio. Tr. 593; GX 33. The Investigators then obtained an OARRS report on S.P. and prepared a spreadsheet listing the prescriptions she filled by date between November 6, 2007 and October 30, 2009, the dispensing pharmacy, and the prescriber. GX 33.

The report showed that S.P. had obtained oxycodone from Respondent on eighteen occasions during this period using prescriptions she had obtained from seven different doctors. *See* GX 33. Moreover, according to the OARRS report, the doctors were located in Waverly, Beavercreek, Dayton, Wheelersburg and Portsmouth; two of the Portsmouth doctors practiced at different clinics.[29] *Id.*

The prescriptions included ones for oxycodone issued by the following doctors: (1) On November 6 and December 4, 2007, as well as on January 9 and February 14, 2008, by Dr. B.B. of Waverly, Ohio; (2) on May 20, June 13 and 23, July 11, August 12, 2008 and January 6, 2009, by Dr. D.B. of Beavercreek, Ohio; (3) on September 10, October 1 and 27, and November 27, 2009, by Dr. M.G. of Portsmouth (Medical Solutions, L.L.C.); (4) on July 3, 2009, by Dr. J.D. of a different Portsmouth clinic (Complete Pain Management, L.L.C.); (5) on September 1, 2009, by Dr. P.C. of Dayton; (6) on October 1, 2009, by Dr. M.F. of Wheelersburg; and (7) on October 30, 2009, by Dr. J.C. of Portsmouth. *See* GX 33. The OARRS Report also contained controlled-substance prescriptions written by additional doctors which S.P. filled at other pharmacies. *See id.*

On November 6, 2009, DEA Investigators conducted an administrative inspection of Respondent. Tr. 610, 692. Investigators requested that Mr. Fletcher provide Respondent's biennial inventory of its controlled substances, but Respondent was unable to do so. *Id.* at 693–94. The lead DI further testified that Mr. Fletcher stated that he was unaware of the requirement of maintaining a biennial inventory. *Id.* at 694.

The Government's Expert Witness

The Government called Donald Sullivan, R.Ph. and PhD, as its expert witness. Dr. Sullivan, who holds active pharmacist licenses in Ohio and Florida, obtained a B.S. in Pharmacy from The Ohio State University, as well as both an M.S. and PhD in Pharmaceutical Administration, also from The Ohio State University. GX 19, at 1; Tr. 922. Between 1997 and 2006, Dr. Sullivan was an Associate Professor of Pharmacy Practice at Ohio Northern University. GX 19, at 1; Tr. 920. Thereafter, Dr. Sullivan was appointed to the rank of Full Professor and has been Chairman of the Department of Pharmacy at Ohio Northern University for the last four years. Tr. 920.

During graduate school, Dr. Sullivan worked as a Registered Pharmacist at both retail and mail order pharmacies. GX 19, at 2; Tr. 934. He testified that he has worked at "several different independents in the central Ohio area" and that he currently works part-time as a pharmacist for North Central Mental Health. *Id.* at 934–35. Dr. Sullivan was offered and accepted as an "expert witness * * * on standard pharmacy

[29] However, Drs. J.C. and M.G. appeared to have practiced at the same Portsmouth address. *See* GX 33, at 2; GX 38, at 7–8. There is, however, no evidence that J.C. and M.G. were at the clinic in the same time period.

In the Immediate Suspension Order, the Government alleged that Dr. M.F. was in Lee's Summit, Missouri. ALJ Ex. 8, at 2. On cross-examination, the DI conceded that the prescription issued by Dr. M.F. had indicated that he was in Wheelersburg, Ohio. Tr. 701.

During cross-examination of the DI, Respondent's counsel also suggested that Dr. P.C. was not practicing in Dayton but rather in Portsmouth when he wrote the prescriptions for S.P. *Id.* at 629–31. However, the DI said he did not have information that Dr. P.C. was practicing in Portsmouth and Respondent produced no evidence establishing this as a fact. *Id.* at 631.

practice and standards for dispensing controlled substances." *Id.* at 938.

Dr. Sullivan testified that the curriculum at pharmacy college includes courses in pharmacology and therapeutics, which cover "the actual pharmacology and pathophysiology of drug abuse," as well as in pharmacy law, which covers the subject of prescription drug abuse and prescription drug fraud. *Id.* at 925. He testified that the American Council of Pharmaceutical Education, which accredits schools of pharmacy, requires that these subject areas "be taught." *Id.* at 925–26. Dr. Sullivan has taught pharmacy law since his time as a teaching assistant in graduate school; in addition to his teaching at Ohio Northern University, he also teaches pharmacy law in continuing education programs and in review classes for the NAPLEX exam. *Id.* at 933.

Dr. Sullivan testified that under both Ohio and Federal law, there "is corresponding responsibility between the physician and the pharmacist." Tr. 939. He further explained that "[a] lot of pharmacists think that just because the physician wrote it, I have to fill it." *Id.* However, Dr. Sullivan stated that [t]here is nothing in Ohio law that says you have to fill any prescription." *Id.* at 939–40. He then explained that "one of the first things we try to get the students and pharmacist to understand is that under Ohio law, and federal law * * * 50 percent of the responsibility falls on the pharmacy, the pharmacist, 50 percent falls on the physician. Don't just fill it because the doctor wrote it." *Id.*

Similarly, in his report, Dr. Sullivan, after discussing the CSA's prescription requirement (21 CFR 1306.04(a)), explained that:

> The State of Ohio has similar language in its laws and regulations. Ohio Law states that: The pharmacist who fills any prescription has a corresponding responsibility with the physician to make sure that the prescription has been issued for a *Legitimate Medical Purpose.* The responsibility to ensure that a prescription is for a legitimate medical purpose in the usual course of a prescriber's professional practice is equal for both the physician and pharmacist. (Fifty percent of this responsibility is on the pharmacist and 50% is on the physician). The argument that "Just because a physician wrote the prescription, I can legally fill it" is no excuse.

GX 20, at 1 [30] (emphasis in original).

More importantly, Dr. Sullivan testified that a pharmacist is "[a]bsolutely" taught to question the legality of a prescription. Tr. 940. As examples of prescriptions he had refused to fill, Dr. Sullivan noted an instance where a physician had written for a combination of a narcotic, a benzodiazepine, a muscle relaxant, and a sleeping pill; there were "similar doses for everybody, [with] no individualization of therapy"; and "maximum doses for everyone." *Id.* at 940–41. Dr. Sullivan further testified that when he called the physician to determine what was wrong with the patients, "so we could document whether it is for a legitimate purpose," the physician never provided a "good answer" and he "stopped filling prescriptions for these patients." *Id.* at 941.

Continuing, Dr. Sullivan explained that "[m]ore is required" from a pharmacist than merely verifying the prescription with the doctor and that "[i]t is still [a pharmacist's] professional judgment to make the call * * * is it for a legitimate purpose or not?" *Id.* at 942. Dr. Sullivan emphasized that "just because the physician tells [a pharmacist] that, yes, it is for a legitimate medical purpose * * * [the pharmacist] still ha[s] that 50 percent corresponding liability to make [his] own judgment, is that for a legitimate medical purpose or not." *Id.*

Dr. Sullivan testified that there are "red flags" which pharmacists need to recognize and consider before they dispense a prescription. Tr. 936. As examples, he testified that pharmacists are "required to do drug utilization review on every prescription * * * before it is dispensed in the pharmacy" to determine whether "doses * * * are too high, duplicate therapy, potential use or misabuse [sic], [and prescriptions are] being filled too soon." [31] *Id.* Additional red flags include "[m]aximum doses being seen for every single patient, lack of individuation of therapy, certain patterns from physicians of potential abuse of seeing the same types of controlled substances over, and over, and over, again." *Id.* at 937. Moreover, other red flags involve "drug interactions [such as] [t]wo drugs being used for the same thing, three drugs being used for the same thing, three drugs in different classes[ ] that can cause the same side effects, such as respiratory [depression] where you might see a benzodiazepine, a muscle relaxer, and a narcotic pain killer." *Id.* at 937.

On cross-examination, Dr. Sullivan explained that "[t]here is no permanent physical checklist. [A pharmacist] should look for several different things, such as number of drugs being prescribed, quantities, types of drugs, patient profile, what is going on with that patient's drug therapy in the past, because you have to do prospective DUR. Where the patient lives, where they are coming from, and even method of payment." *Id.* at 993.

Dr. Sullivan further testified that it is "[a]bsolutely" important that pharmacists communicate with one another. Tr. 950–51. Dr. Sullivan explained that a pharmacist readily "develop[s] a pretty quick informal network among the pharmacists * * * within a five to ten mile radius" of his store because of the need to transfer prescriptions and that these informal networks also host such discussion as whether there is suspicious prescribing going on in various parts of the State. *Id.* at 951–52. Continuing, he testified that if a pharmacist is presented with a

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[30] While the Ohio courts may have interpreted State law as described above, as explained below, Dr. Sullivan's testimony that Federal law allocates fifty percent of the responsibility to the physician and fifty percent to the pharmacist is not a correct statement of the law, which has been amply explained in numerous decisions of the Federal courts and this Agency. To make clear, Federal law does not apportion the responsibility for dispensing unlawful prescriptions between a prescribing practitioner and a pharmacist. Rather, Federal law imposes separate and independent duties on the prescriber and the pharmacist.

More specifically, the prescriber must act within the usual course of professional practice and have a legitimate medical purpose to lawfully issue a controlled-substance prescription. 21 CFR 1306.04(a). As the Supreme Court and numerous Federal courts have made plain, to lawfully prescribe a controlled substance the physician must act "in accordance with a standard of medical practice generally recognized and accepted in the United States." *United States* v. *Moore,* 423 U.S. 122, 138–39 (1975); *see also United States* v. *Smith,* 573 F.3d 639, 647–48 (8th Cir. 2009); *United States* v. *Merrill,* 513 F.3d 1293, 1306 (11th Cir. 2008).

By contrast, a "pharmacist is not required to * * * practice medicine." *United States* v. *Hayes,* 595 F.2d 258, 261 (5th. Cir 1979). "What is required of [a pharmacist] is the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows [or has reason to know] that the issuing practitioner issued it outside the scope of medical practice." *Id.* at 261. As the Fifth Circuit has further explained, "a pharmacist can know that prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science." *Id* at 261 n.6; *see also United States* v. *Henry,* 727 F.2d 1373, 1379 (5th Cir. 1984) (applying "reason to believe" standard to pharmacist); *United States* v. *Seeling,* 622 F.2d 207, 213 (6th Cir. 1980) (upholding use of deliberate ignorance instruction in prosecution of pharmacist).

However, Dr. Sullivan's statements that: (1) A pharmacist is not required to fill any prescription, and (2) it is not an excuse that because a doctor wrote the prescription, it can be legally filled, are consistent with Federal law.

[31] According to Dr. Sullivan, as part of the prospective drug utilization review, a pharmacist is required to check a patient's profile for the following: "(a) *over-utilization or under-utilization*[;] (b) *therapeutic duplication*[;] (c) drug-disease state contraindications[;] (d) drug-drug interactions[;] (e) *incorrect drug dose or duration of treatment*[;] (f) drug-allergy interaction[;] (g) *abuse/misuse*[;] (h) inappropriate duration of treatment[; and] (i) documented good/nutritional supplements-drug interactions." GX 20, at 3–4 (emphasis in original).

prescription which another pharmacy had refused to fill, "there had better be a lot of documentation, a lot of conversation with the physician, and a very, very good explanation * * * professionally as to why that patient needs that prescription filled" before the pharmacist "risk[s] [his] license and fill[s] that prescription." *Id.* at 953.

Dr. Sullivan explained that were a patient to tell him that another pharmacy had refused to fill the prescription, he would first call that pharmacist and ask why he refused to fill the prescription and why he suspected that the prescription was not "for a legitimate medical purpose." *Id.* Dr. Sullivan also explained that it was "[a]bsolutely" important that a pharmacist maintain an open line of communication with a prescribing physician. *Id.* at 954.

Dr. Sullivan reviewed the prescriptions issued to fifty-five patients by Dr. Volkman which were filled by Respondent between September 13, 2005 and February 9, 2006. *Id.* at 948, 991, 1011; GX 20.[32] He subsequently prepared a report which was submitted into the record. GX 20.

At the outset of his report, Dr. Sullivan observed that "all these patients were from extreme southern Ohio and northern Kentucky" and were "driving 2+ hours to Columbus to have their prescriptions filled." *Id.* at 1. Dr. Sullivan noted that the customers "would have bypassed [dozens of other] pharmacies en route to Columbus." *Id.;* Tr. 960. Dr. Sullivan opined that "[t]his would be a major red flag to any pharmacist" and that "a reasonable pharmacist would seriously question why these patients were driving such a long distance to have their prescriptions filled." GX 20, at 1. At the hearing, Dr. Sullivan further explained that according to the Shearing Report, which "looks at why consumers shop at certain community pharmacies," in "at least 28 out of the last 30 years, the number one reason is proximity to where they live." Tr. 959. Dr. Sullivan thus observed that "[t]his pattern of patients traveling long distances from the location of their home and physician is extremely unusual and very suspicious." GX 20, at 2.

In addition, Dr. Sullivan noted that forty of the fifty-five patients (73%) had paid cash for their prescriptions" and that "the national average of cash paying customers for prescriptions [was] 11.4% in 2005 and 10% in 2006."[33] *Id.* Explaining that "profit margins on cash prescriptions are 30% higher than insurance prescriptions for brand-name[] drugs and 100% to 500% higher than insurance prescriptions for generics," he concluded that this "is an obvious example of a pharmacy profiting from drugs that are most likely being abused or diverted for sale on the street" and that "[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect." *Id.*

In his report, Dr. Sullivan stated that in all of his "years of practice and teaching, I have never seen such an abuse of controlled substances dispensing by one pharmacy, especially in schedule II controlled substances."[34] GX 20, at 1. Dr. Sullivan also found "extremely surprising the volume of controlled substances this one doctor [wrote], especially for schedule II drugs." GX 20, at 1–2. According to Dr. Sullivan, this "should have been a major red flag for any reasonable pharmacist that this physician is nothing more than a controlled substance prescription mill for patients who are diverting and abusing narcotic drugs." *Id.* at 2.

Dr. Sullivan further observed that "75% of the [Volkman] patients received the same four drug cocktail, which included a benzodiazepine, two narcotic pain killers and Soma (a muscle relaxer known to be highly abused)." *Id.* at 3. According to Dr. Sullivan, "[i]t is well known in the pharmacy profession [that] the combination of a benzodiazepine, narcotic pain killer, and Soma [is] being used by patients abusing prescription drugs." *Id.* Dr. Sullivan then noted that Dr. Volkman "took this to another level by prescribing two narcotic pain killers at the same time." *Id.*

In his testimony, Dr. Sullivan explained that pharmacists refer to the combination of "the benzodiazepine, the narcotic * * * pain killer, and the sleeping pill" as "[t]he triple," and that when Soma (carisoprodol) is added, the combination is known as the "homerun." Tr. 956. Noting that Volkman was issuing duplicate prescriptions for schedule II narcotics, Dr. Sullivan testified that he had never seen two schedule II narcotics prescribed together other than for treatment of cancer or hospice patients. *Id.* at 956–57, 1027–28.[35] He further observed that "41 of the 55 [patients] (75%) received two narcotic pain killers on the same day," and that this happened "68 different times for these 41 patients." GX 20, at 3. He then reiterated that "[t]o have two schedule II controlled substances, or two narcotics, a schedule II, and a schedule III * * * like * * * a Vicodin * * * or a Lortab * * * combined together * * * was something [he] had never seen to this extent before these prescriptions." *Id.* at 957.

Noting that a pharmacist's primary obligation is to take care of the patient, Dr. Sullivan stated that if he saw two prescriptions for two narcotic pain killers for one patient, he would worry about the potential central nervous system (CNS) effects or "the respiratory depression that might occur with this patient." *Id.* at 957. Observing that "a lot of these drugs" have a "synergistic effect on respiratory depression," he explained that "[i]t is not two narcotics equal twice the respiratory depression, it is one plus one equals three or four times the respiratory depression." *Id.* Moreover, when a benzodiazepine and a muscle relaxant are added "on top of that," there is a concern as to whether "the patient

[32] While the ALJ found that "Dr. Sullivan was provided 55 prescriptions," ALJ at 30, his subsequent testimony made clear that he had actually reviewed hundreds of prescriptions. Tr. 1011 ("There were 55 patients, there were hundreds of prescriptions that I looked at.").

Respondent's Counsel also took issue with Dr. Sullivan's statement that he had reviewed a "random" sample. *See* Tr. 992 ("So you would agree with me that this isn't really a random sample, wouldn't you?"). Dr. Sullivan testified that the sample represented ten percent of the prescriptions seized from Respondent by DEA and that the selection of that ten percent was "based on a statistical formula" that he obtained from a statistics Web site and had later validated, but he did not include the formula in his report. *Id.* at 992.

However, it is immaterial whether the sample Dr. Sullivan reviewed was randomly selected as Mr. Fletcher's obligation under 21 CFR 1306.04(a) applies to every prescription he dispensed.

[33] The ALJ found that Dr. Sullivan "credibly" testified that "nationwide[ ] only 10% of prescriptions [are] paid for in cash." ALJ at 31 (citing Tr. 961). Dr. Sullivan further testified that IMS Health, "the number one data collection firm for basically all prescription drug prescribing, dispensing, and pricing," was the source of this data. Tr. 961.

[34] In his testimony, Dr. Sullivan elaborated that he had "almost never seen" cases where physicians were "abusing the prescribing of controlled substances" by issuing prescriptions for schedule II drugs and that most cases typically involved schedule III and IV drugs. Tr. 955–56. On cross-examination, Dr. Sullivan admitted that he had probably not filled a pain medication prescription in approximately twelve years, *id.* at 977, and that this report represented his first determination that "a pharmacy is abusing controlled substances." *Id.* at 990. However, he had previously filled "probably 1,000" prescriptions for oxycodone and thousands of prescriptions for alprazolam. *Id.* at 980–981.

[35] When asked on cross-examination if he knew what break-through pain is and whether he was aware that Dr. Volkman "practiced pain break-through type treatment," Dr. Sullivan explained that there is no such separate specialty in pain management and that this "is when a patient is on a dose of medication, and they are having flare-ups in pain, then another drug is given to help on a temporary acute basis to take care of that pain flare." Tr. 1027. He further stated that such treatment regimens were sometimes seen "in hospice patients and cancer patients." *Id.* at 1028. Respondent did not establish that Volkman was legitimately prescribing multiple drugs for this purpose.

[is] going to be able to safely take these medications together." *Id.* He then testified that looking at the quantities, doses, and that multiple drugs were being prescribed for a single patient, he would ask himself "how could this possibly be for a legitimate medical purpose." Tr. 958.

In his report, Dr. Sullivan further noted that there were three patients who "received three narcotic pain killers on the same day" and that "[t]here is no logical reason why the patient would be on two or three narcotic pain killers at the same time." GX 20, at 3. Continuing, he explained that this is "a major red flag" which is strongly suggestive of abuse and that "[n]o reasonable pharmacist would fill two or three of these prescriptions on the same day." *Id. See also id.* at 5 (discussing M.C., who on the same day received prescriptions for Percocet 10/325, Norco 10/325,[36] and oxycodone 30 mg.).

With regard to the narcotic pain killers Respondent dispensed, Dr. Sullivan explained that the "normal dose of oxycodone" is "5 mg. to 10 mg. every four hours," but that "80% of the patients in the sample were prescribed 15 mg. to 60 mg. every two or three hours." GX 20, at 4. Dr. Sullivan explained that "a reasonable pharmacist would recognize this as a problem and a marker of drug abuse and addiction." *Id.*

As to the prescriptions for schedule III hydrocodone/apap drugs, Dr. Sullivan noted that "100% (89/89) were for the highest strength available, which is 10 mg. of hydrocodone." *Id.* Observing that it was "clinically impossible that all the patients in the sample would always need the highest possible dose of hydrocodone with acetaminophen," Dr. Sullivan thus concluded that there was "no individualization of dosing based on pain in these patients, which should have been a major red flag for any pharmacist." *Id.* Moreover, "[a]ny pharmacist would have known that this was a problem and a strong indicator of a doctor operating a controlled substance prescribing mill." *Id.*[37]

With respect to the Xanax (alprazolam) prescriptions, "one of the most highly abused benzodiazepines on the market" and a drug "in high demand on the street," Dr. Sullivan observed that all sixty prescriptions were for the maximum strength of the drug. *Id.* Moreover, ninety-three percent of the prescriptions "exceeded the FDA approved maximum daily dosage of 4 mg. per day" and thirty-two percent "exceeded the FDA approved dosing schedule of three times a day." *Id.* At the hearing, Dr. Sullivan explained that Xanax 2 mg. is generally only prescribed to patients with post-traumatic stress disorder. Tr. 970.

Again, Dr. Sullivan noted that there was "no individualization of therapy" and that "[e]very patient was prescribed the same strength at extremely high doses." GX 20, at 4. He further opined that "[a]ny pharmacist would have known that this was a problem and a strong indicator of a doctor operating a controlled substance prescribing mill." *Id.*

With regard to the Valium (diazepam), which is also "a highly abused benzodiazepine in high demand on the street," Dr. Sullivan noted that all of the forty-two prescriptions he reviewed were for the highest strength available, 10 mg. GX 20, at 4. He then noted that Patient K.D. "was prescribed Valium 20 mg. at bedtime, twice the maximum dose," and "[a]t least 50% of the prescriptions were written for a maximum dose of four times daily." *Id.* at 5. Dr. Sullivan again explained that "[a]ny pharmacist would have known that this was a problem and a strong indicator of a doctor operating a controlled substance prescribing mill." *Id.*

After noting that over the period of September 2005 through January 2006, Dr. Volkman "seemed to be writ[ing] larger doses and higher quantities as time went on" and that this was "definitely a sign of drug abuse" which "a reasonable pharmacist[38] would have caught," Dr. Sullivan discussed "a few of the most blatant examples of abuse and diversion." *Id.* These included instances in which Respondent provided early refills such as for L.B., who on December 28, 2005, received a Xanax prescription two weeks early; and S.K., who, on September 13, 2005, received a prescription for 240 tablets of oxycodone 15 mg., with eight tablets to be taken per day (thus being a thirty-day supply), and who, one week later, obtained an additional 168 tablets of the same drug. *Id.* at 5–6. Moreover, M.P. filled two prescriptions for Percocet 5/325 on the same day, and L.A.T. filled two prescriptions for oxycodone on the same day. *Id.* at 6.

Dr. Sullivan further observed that J.C. had received a prescription for 720 tablets of oxycodone 15 mg. with a dosing of two tablets every two hours (or twenty-four tablets per day), as well as for twelve tablets per day of hydrocodone/apap 10 mg./325 mg.; according to Dr. Sullivan, "[n]o patient could take this much narcotic in one day and not overdose." *Id.* at 5. He also noted that M.C. had received three different narcotics on the same day including 180 Percocet 10/325, 180 Norco 10/325, and 240 oxycodone 30 mg., and observed that "[a]t these doses[,] this patient [was] taking 300 mg. of oxycodone per day along with 60 mg. of hydrocodone" and that "[n]o patient could take this much narcotic in one day and not overdose." *Id.* Finally, with respect to J.C. (a resident of Grayson, Ky.) and M.C. (a resident of Flatwoods, Ky.), Dr. Sullivan explained that "[a] reasonable pharmacist would notice [the amounts being taken] as a problem" and that the amounts were a marker of drug abuse or diversion such that a reasonable pharmacist would not have filled the prescriptions. *Id.*

Dr. Sullivan concluded his report as follows:

> A pharmacist might act in the best interest of the patient and fill an occasion[al] prescription for a high dose or large quantity. However, the evidence presented above is overwhelming and shows a pattern of dispensing controlled substances to patients who are known drug abusers[39] or are diverting prescription drugs for illegal purposes. There are dozens of patients with the same drugs on their profile[s] and all at maximum doses and beyond. There is no medically sound reason why patients should be treated with two or three drugs in the same class for the same thing as these patients are. Any reasonable pharmacist would notice this as a problem very quickly and easily. In addition, these drugs when combined cause CNS (central nervous system) depression and can easily lead to overdose. Any reasonable pharmacist would recognize this danger and would not dispense these medications (duplicate therapy) together. These are all textbook examples of drug abuse and/or drug diversion. Any reasonable pharmacist would quickly recognize this based on their education and training. In all my years of practicing and teaching, I have never seen such an abuse of controlled substance

[36] Norco is a brand name drug containing hydrocodone bitartrate and acetaminophen, and a schedule III controlled substance pursuant to 21 CFR 1308.13(e)(1). ALJ Ex. 5, at 2.

[37] Dr. Sullivan also observed that "[m]any of the narcotic prescriptions had the words 'severe LBP' on them," which "most likely stands for 'Severe Low Back Pain.'" GX 20, at 5. Explaining that "[l]ower back pain is viewed in the medical field as the 'biggest scam to obtain controlled substances' because it is the hardest to disprove due to the lack of definitive clinical measures," he reported that "[i]t is very unusual that all these patients had the same diagnosis and they all had to be on the maximum doses of these controlled substances including Soma." *Id.*

[38] On cross-examination Dr. Sullivan elaborated that "a reasonable pharmacist" is "[a] pharmacist who looks out for the best interest of their patients, takes care of their patients, within the legal requirements of the law." Tr. 1025.

[39] On cross-examination, Dr. Sullivan clarified that he described the patients as "known drug abusers" because "[t]hat is my professional opinion based on what I saw in the prescriptions." Tr. 1032–33.

dispensing by one pharmacy, especially in schedule II controlled substances.

Id. at 6.

On cross-examination, Dr. Sullivan conceded that he "would not have turn[ed] away every one of" the customers whose prescriptions were reviewed in his report but that after he had "seen a pattern," he "would have started to make phone calls and then started to not fill them." Tr. 1009. Moreover, "based on the large quantities" and "the safety of the patient," there were some prescriptions, including those "for three narcotic pain killers" that he "would not have filled" at all. *Id.* at 1010. Dr. Sullivan further explained that in determining which prescriptions he would have filled, he would "had to have looked at the patient history, and [considered] the conversation of the physician." *Id.* at 1011. Clarifying his testimony, Dr. Sullivan explained that while it might have required time to detect a pattern with respect to some of the prescriptions, others should not have been filled at all "just looking blatantly at the doses, the combinations, that would have been, definitely, harmful to that patient, taking those drugs in those doses." *Id.* at 1012–13. Dr. Sullivan then explained that part of the reason for his equivocation with respect to whether he would have filled some of the prescriptions is that when he reviewed them, he did not "know how long [Mr. Fletcher] had been treating those patients." *Id.* at 1013.

Dr. Sullivan also acknowledged that he does not have actual knowledge of whether the Volkman patients were abusing or diverting the drugs. *Id.* at 1019. However, he reiterated his opinion that based on the quantities and doses that Volkman was prescribing, the drugs were either being abused or diverted because the patients would be dead if they took the amounts that were prescribed. *Id.* at 1032. Notably, the ALJ found that Dr. Sullivan "rationally and credibly concluded that these patients abused the drugs, diverted the drugs, or [if they had] consumed them * * * would be dead." ALJ at 35 (citing Tr. 1032); Tr. 1019.

The State Board Proceeding

On March 5, 2009, the Ohio State Board of Pharmacy (Board) found that on three occasions between August 29, 2006 and November 27, 2007, deliveries of controlled substances were made to Respondent when a pharmacist was not on duty and that the drugs were not properly secured. GX 16, at 2–3 & 4; Tr. 1066. In the first instance, the delivery was placed in a hallway closet outside of Respondent; in both the second and third instances, the drugs were placed in a pharmacy technician's automobile, which was parked in Respondent's parking lot. GX 16, at 2. Based on these incidents, the Board found that Respondent violated Ohio law. *Id.* at 2–3 (citing Ohio Rev. Code § 4729.55). The Board fined Respondent $1,000.00, *id.* at 3, and Mr. Fletcher $1,500.00. Tr. 1073. In addition, the Board placed Mr. Fletcher's pharmacist's license on probation for two years and suspended it for twelve weeks, but then waived ten weeks of the suspension.[40] Tr. 1074. According to the Board's Order in the case against Respondent, it had the right to appeal to the State courts. GX 16, at 3.

Respondent's Evidence

Respondent called fifteen witnesses, half of whom testified regarding the Government's various excursions into such issues as the character of the neighborhood, Mr. Fletcher's practice of carrying a gun at work, and his prices. Having concluded that the character of the neighborhood and Mr. Fletcher's carrying of a gun are not relevant in assessing his compliance with 21 CFR 1306.04(a) and that the Government has not proved with substantial evidence that Respondent charged higher prices than similar pharmacies, it is not necessary to discuss the testimony of those witnesses Respondent called to refute these contentions.[41] Accordingly, only four witnesses offered testimony arguably relevant to the issues in this proceeding.

Mark Aalyson testified that he had practiced law in Portsmouth, Ohio, that his "practice was devoted exclusively" to representing injured workers before the Industrial Commission of Ohio, and that he knew most of the doctors who practiced in Scioto County. Tr. 1156. Mr. Aalyson testified that in the "early fall of 2006," Mr. Fletcher called him and asked whether he "had ever heard of a Dr. Paul Volkman."[42] *Id.* According to Mr. Aaylson, Mr. Fletcher told him that he was getting patients from the Scioto County area who were getting prescriptions for pain medication from Dr. Volkman. *Id.* at 1157. Mr. Aalyson testified that he told Mr. Fletcher that he did not know who Volkman was and was "not sure how long he has been around." *Id.* at 1158–59. Mr. Aalyson then asked Mr. Fletcher "what is the problem?" *Id.* Mr. Fletcher answered: "I'm getting a lot of people coming in, and I'm beginning to wonder if the guy is legitimate." *Id.* at 1159.

Julie Fuller worked as a sales representative for AmeriSource Bergen, a major drug distributor, from December 2003 until January 2007. Tr. 1550. She testified that during her visits to Respondent, she saw Mr. Fletcher check for early refills and for drug interactions. *Id.* at 1567–68. However, she acknowledged that the purpose of her visits was not "to observe him" in the practice of pharmacy but to get his business. *Id.* at 1584. Moreover, Ms. Fuller testified that she believed that Respondent closed at 6 p.m. and that her visits occurred "[s]omewhere between 10 and 5," Tr. 1582; she did not testify that she observed Mr. Fletcher filling any of Dr. Volkman's controlled-substance prescriptions. Her testimony is therefore of no probative value.

Respondent also called Mr. Fletcher's cousin, Carisa Cole, who worked at Respondent between December 2004 and October 2009. *Id.* at 1704–05. In her testimony, Ms. Cole maintained that she never saw anyone who appeared under the influence of either drugs or alcohol and that Mr. Fletcher would not serve persons who appeared under the influence (although it is not clear how she would know that Mr. Fletcher would not serve such persons if she never saw any one who appeared under the influence). *Id.* at 1708. However, on cross-examination, she testified that she could not recall that any of the patients Mr. Fletcher refused to dispense to for this reason were patients of Dr.

[40] Regarding the Ohio Board proceedings, the ALJ allowed Respondent to elicit the testimony of Barton Kaderly, who had previously been a citizen member of the Board; Mr. Kaderly testified as to his being "appalled" over the decision of his fellow board members to fine Respondent and Mr. Fletcher. Tr. 1064, 1074–75. Beyond the fact that Mr. Kaderly's personal opinion is irrelevant and should have been excluded, the ALJ apparently forgot that DEA has held that a registrant cannot collaterally attack the results of a State board proceeding in proceedings under 21 U.S.C. 823 & 824. *See Hicham K. Riba,* 73 FR 75773, 75774 (2008). I therefore give no weight to his testimony.

[41] These witnesses include Ms. Adkins, Ms. Berring, Mr. Gordon, Mr. Cates, Dr. Will, Mr. Macke, and Mr. Kimbler. I have, however, considered the testimony of these individuals (as well as that of Ms. Banks and Ms. Del Guzzo) to the extent they testified as to Mr. Fletcher's reputation and character.

As previously discussed, I have considered the testimony of Mr. Newman, Respondent's CPA, in making my findings regarding Respondent's structuring activities as well as that of Mr. Kaderly.

[42] Respondent's counsel asked Mr. Aalyson six times when this conversation occurred, going so far as to suggest that "you are not sure of the year, you don't have a telephone record, or anything, to show what year it would have been, it could have been 2005?" *See* Tr. 1156, 1166. While Mr. Aalyson answered this last question: "I can't remember, I'm sorry," he had previously testified repeatedly that the conversation had occurred around the time he entered into the agreement by which he sold his law practice and that this happened in October 2006. Tr. 1156, 1166.

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Volkman. *Id.* at 1741. She also stated that he turned away a person who presented a prescription issued by a Florida-based doctor but could not recall when this happened. *Id.* at 1712. Finally, she testified that he also sometimes turned people away because they did not have a photo ID. *Id.* at 1747.

Ms. Cole maintained that she was present when Dr. Volkman's patients came to the pharmacy and that "a lot of them complained of having blood taken too often" to "make sure that they were actually taking their medication." *Id.* at 1713. She also testified that while Respondent's hours were "until 5:30," "[t]here were a few times" that Mr. Fletcher would stay open later because he knew that Volkman's patients were coming. *Id.* at 1716, 1720. However, Ms. Cole never talked with either Dr. Volkman or his security guard. *Id.* at 1721.

On cross-examination, Ms. Cole stated that she would typically leave Respondent at "[a]bout 5:30," but that sometimes she would stay past 5:30 two or three times per week for the Volkman patients, and had stayed as late as 9:30 for a Volkman patient. *Id.* at 1733. However, she acknowledged that she would not typically be at the pharmacy after nine o'clock because she has "three children" and "child care issues." *Id.* at 1743–44. Moreover, she did not work at Respondent on Saturdays. *Id.* at 1740.

Ms. Cole acknowledged that Volkman's patients were typically not from the Columbus area and were coming from Portsmouth and Southern Ohio, as well as Kentucky and West Virginia. *Id.* at 1723. Ms. Cole also stated that Mr. Fletcher had asked these patients why they were filling their prescriptions at his pharmacy and that the patients had stated that other pharmacies did not have the medication or had run out. *Id.* at 1724. When then asked whether she knew if Mr. Fletcher had ever asked the patients "why they never filled their prescriptions at any pharmacies in between Portsmouth and Columbus," she answered that she did not know if there were any pharmacies between these cities even though she acknowledged that it was a two hour drive. *Id.* at 1726–27.

Ms. Cole also maintained that Mr. Fletcher had tried calling some of the pharmacies but then acknowledged that she was "not real sure" if she was present when any of these calls were made. *Id.* at 1725. Moreover, as found above, during an interview with a DEA Investigator, Mr. Fletcher stated that he did not call other pharmacies regarding the Volkman prescriptions. *Id.*

Ms. Cole also acknowledged that the Volkman prescriptions would include at least one schedule II drug, that being oxycodone, which would be prescribed in combination with Soma and alprazolam. *Id.* at 1732. She further acknowledged that Volkman patients would typically present their prescriptions at the same time and that they "typically had the same prescriptions." *Id.* at 1736.

Subsequently, Ms. Cole testified that "every time we got a prescription from Florida, or anywhere out of the State of Ohio, [or] even within the State of Ohio [but from outside of Columbus] * * * that we would call and verify the prescriptions," which Ms. Cole stated, would be done on "[t]he business line." Tr. 1747–48, 1753. Ms. Cole's recollection is patently erroneous as shown by the evidence that Respondent filled 4,900 controlled-substance prescriptions for Volkman's patients and the phone records Respondent submitted, which establish that during the five-month period in which it filled Volkman's prescriptions, it never made more than ninety-seven long distance phone calls in a month.[43] *See* RX 19. Ms. Cole also testified that she remembered D.S. (who had sponsored A.S.) bringing other people to Respondent to have her prescriptions filled. Tr. 1757.

Ms. Cole further testified that Mr. Fletcher questioned those persons who obtained controlled-substance prescriptions from Florida doctors, and that they claimed that they had recently moved to either Kentucky or Ohio or were working in Columbus and couldn't go home. *Id.* at 1749. Ms. Cole stated that she was "skeptical" of the people presenting these prescriptions because of the distances involved. *Id.* With the exception of her testimony as to her skepticism, the remainder of this testimony is absurd on its face—if a person had in fact recently moved to Kentucky or Southern Ohio, this fact would have been verifiable by simply looking at his/her driver's license as Ms. Cole claimed Mr. Fletcher always did. Moreover, if a person had recently moved to these areas, one must wonder how they would find out so quickly that only Respondent would fill their prescriptions. As for those persons who claimed they were working in Columbus and could not go home, it is odd that they could travel to South Florida to obtain the prescriptions in the first place.

[43] This also assumes that every single phone call was made to Dr. Volkman even though Respondent's phone bills show calls to numerous cities in Ohio where there is no evidence that Volkman worked or lived, as well as to cities in other States.

Respondent also called Catherine Smith, who worked as a pharmacy technician at Respondent and who considered Mr. Fletcher to be her "best friend." *Id.* at 1235.[44] Ms. Smith testified that her duties involved a variety of functions including working at the front window and "talk[ing] to [the] patients," "look[ing] at prescriptions," and also "fill[ing] prescriptions." *Id.* Ms. Smith testified that she saw the prescriptions "first," and that if one did not "look legit" (meaning forged), she would "present it to Mr. Fletcher." *Id.* at 1425. Ms. Smith also testified that she was the person who "counted the medicine" and "put [it] in a bottle" and that she "explained it to the patients." *Id.* at 1429–30. According to Ms. Smith, Mr. Fletcher would enter the prescription information into the pharmacy computer and print out the labels. *Id.* at 1430.

Ms. Smith further maintained that if a patient did not seem right to her, she would mention it to Mr. Fletcher, who would then question the patient and not fill the script if the patient was showing symptoms of being under the influence. *Id.* at 1238. She also claimed that Mr. Fletcher would ask Respondent's customers why they were taking the pain medicine; he would also tell the patients "this is a large quantity of pills you are taking here" and ask them "can you work without the medicine?" *Id.* at 1253–54. Ms. Smith further maintained that Mr. Fletcher would tell the patients "be careful of the way you take it, take it the way you are supposed to take it, the way they prescribe it" and that he would "tell them some of the cautions to take with it." *Id.* at 1254. She maintained that Mr. Fletcher "talked to everybody about their prescriptions." *Id.* at 1281.

On cross-examination, however, Ms. Smith then qualified her testimony, stating: "I'm not saying he talks to everybody, but the majority of them * * * that is on that kind of pain medicine." *Id.* at 1423. Moreover, when DEA Investigators interviewed numerous patients of Dr. Volkman, most of them stated that Mr. Fletcher did not ask about their medical conditions. GX 9, at 86; *see also* GX 23, at 3 (affidavit of L.W., "When having prescriptions filled at [Respondent], most of the time I spoke with Eugene's assistants but I did speak with Eugene several times also. When we spoke together, Eugene never asked me about my medical

[44] Ms. Smith testified that she did not work Saturdays and that only Mr. Fletcher worked then. Tr. 1240.

condition but would just make small talk.").

Ms. Smith also maintained that Mr. Fletcher would call the doctors "and make sure that the script is legit." *Id.* at 1264. However, while Mr. Fletcher may have spoken with Dr. Volkman on some occasions, according to Volkman's former security guard, the majority of the calls Mr. Fletcher made to Volkman's office "were to determine how late he should stay open to fill Dr. Volkman's prescriptions." GX 22, at 1–2. Moreover, in the calls the security guard answered, "Eugene never asked about the medical condition of any patients and I never recall hearing any other staff members discuss with Eugene any patient's medical condition or anything else other than to arrange pharmacy hours." *Id.* at 3. And as noted above, Respondent's phone records suggest that Respondent filled numerous prescriptions without calling Dr. Volkman.[45] Moreover, neither Ms. Smith nor Ms. Cole testified as to any specific instances in which Mr. Fletcher had refused to fill prescriptions presented by Volkman's patients on the ground that the prescriptions lacked a legitimate medical purpose.[46]

Finally, notwithstanding the substantial probative evidence offered against him, Mr. Fletcher did not testify in this proceeding.

Discussion

Section 304(a) of the Controlled Substances Act provides that "[a] registration * * * to * * * dispense a controlled substance * * * may be suspended or revoked by the Attorney General upon a finding that the registrant * * * has committed such acts as would render [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 following factors be considered:

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

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

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id. § 823(f).

"[T]hese factors are * * * considered in the disjunctive." *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether a registrant has committed acts which render its registration inconsistent with the public interest. *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 by a preponderance of the evidence 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 Respondent to either refute the Government's case or to " 'present[] sufficient mitigating evidence' " to show why, notwithstanding that it has committed acts which render its registration inconsistent with the public interest, 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))), *pet. for rev. denied, Medicine Shoppe-Jonesborough* v. *DEA,* 2008 WL 4899525 (6th Cir.). "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."[47] 21 U.S.C. 824(a)(4). I further conclude that Respondent has not rebutted the Government's *prima facie* case. Accordingly, I affirm the order of immediate suspension.[48]

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

[45] Respondent also asked Ms. Smith, who formerly held a license as a registered nurse, a series of questions about the proper dosing of pain medications. Tr. 1279–80. Ms. Smith has not, however, maintained her license and did not testify as to having any expertise in the treatment of chronic pain patients. *Id.* at 1280.

[46] It is acknowledged that the ALJ found that Ms. Cole credibly testified that Mr. Fletcher refused to fill a prescription for a patient because the "patient may have been trying to fill a schedule II prescription too early." ALJ at 20 (quoting Tr. 1737). She did not, however, recall the name of the patient, and her testimony suggests that this was a one-time occurrence as she did not assert that this had happened on more than one occasion. Tr. 1737. Most significantly, she did not testify that he refused to fill the prescription because it lacked a legitimate medical purpose and the great weight of the evidence (including the volume of prescriptions, the type and quantity of the drugs, and Mr. Fletcher's statements to Investigators), supports the conclusion that he never refused to fill a prescription issued by Volkman because it lacked a legitimate medical purpose.

[47] As to factor one, the Ohio Board of Pharmacy has not made a recommendation in this matter. *See* 21 U.S.C. 823(f)(1). Moreover, while there is no evidence that the State Board has revoked either Respondent's or Mr. Fletcher's license, DEA has held repeatedly that a registrant's 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. As DEA has long held, "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).

It is likewise noted that there is no evidence that either Respondent or Mr. Fletcher has been convicted of any offenses under Federal or State laws related to the distribution or dispensing of controlled substances. 21 U.S.C. 823(f)(3). However, there are multiple reasons why even serious misconduct may not be the subject of a criminal prosecution. Thus, DEA has recognized that the lack of any criminal convictions related to controlled substances is not dispositive. *See Edmund Chein,* 72 FR 6580, 6593 n.22 (2007).

Accordingly, that Respondent may still hold its Ohio pharmacy license and that neither it, nor Mr. Fletcher, has been convicted of a criminal offense is not dispositive.

[48] While Respondent allowed his registration to expire and has not submitted a renewal application, there is no evidence that Mr. Fletcher has surrendered Respondent's pharmacy license and his pharmacist's license, and neither party argues that this case is moot. Moreover, Respondent's registration was immediately suspended at which time its controlled substances were seized. Under the CSA, "[a]ll right, title, and interest in" any controlled substances seized pursuant to a suspension order "vest in the United States upon a revocation order becoming final" and "shall be forfeited to the United States." 21 U.S.C. 824(f). DEA has previously held that "a litigant cannot defeat the effect of this provision by simply allowing its registration to expire." *Meetinghouse Community Pharmacy, Inc.,* 784 FR 10073, 10074 n.5 (2009). Accordingly, there are collateral consequences which preclude a finding of mootness. *See id.; Trinity Health Care Corp.,* 72 FR 30849, 30853–54 (2007).

practice." 21 CFR 1306.04(a). This 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."[49] *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).

Respondent contends that "[t]he [G]overnment can point to no specific violation of a known rule, but merely relies upon the general and vague allegation that Respondent did not satisfy a 'corresponding duty' to ensure that [it] dispenses controlled substances for a legitimate medical purpose." Resp. Exceptions, at 1. It further contends that it "has been held to an unknown and ambiguous standard, [which is] higher than any standard previously imposed on any pharmacist." *Id.* at 6. Contrary to Respondent's contention, the Federal courts have had little problem applying the regulation and long ago expressly rejected the argument that the regulation is unconstitutionally vague and does not provide fair notice of what conduct is prohibited. *See, e.g., United States* v. *Hayes,* 595 F.2d 258, 260 (5th Cir. 1979) ("The regulation gives fair notice that certain conduct is proscribed.") (int. quotations and citations omitted).

Most significantly, the great weight of the evidence establishes that Mr. Fletcher filled numerous controlled-substance prescriptions which he had reason to know were not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. Indeed, Mr. Fletcher knew from the outset that Dr. Volkman's prescriptions lacked a legitimate medical purpose. As found above, Mr. Fletcher was specifically asked in a phone call by one of Dr. Volkman's patients if he would fill prescriptions written by Volkman for multiple drugs including oxycodone 30 mg. and hydrocodone 10 mg., which are schedule II and III narcotics respectively, Xanax 2 mg., a schedule IV benzodiazepine, and Soma (carisoprodol), a muscle relaxant which is currently a non-scheduled drug but which is nonetheless popular with drug abusers and which metabolizes into meprobamate, a schedule IV drug.[50]

As the Government's Expert explained, the combination of a benzodiazepine, a narcotic and carisoprodol is "well known in the pharmacy profession" as being used "by patients abusing prescription drugs." GX 20, at 3. Moreover, as the Government's Expert elaborated, Dr. Volkman took this "to another level" by prescribing two narcotics in addition to a benzodiazepine and carisoprodol, thus distributing a schedule II narcotic, a schedule III narcotic, a schedule IV depressant, and carisoprodol, for a total of four drugs at the same time. *Id.*

The Government's Expert further explained that the combination of these two narcotics, a benzodiazepine, and a muscle relaxant would have a "synergistic effect" on a patient's central nervous system and cause respiratory depression thus posing a substantial risk to any patient actually taking the drugs as prescribed. Thus, from the time Mr. Fletcher agreed to fill the prescriptions, he had reason to know that Volkman's prescriptions lacked "a legitimate medical purpose." 21 CFR 1306.04(a).

Notwithstanding this, there is ample evidence showing that Respondent repeatedly dispensed cocktail prescriptions for oxycodone, hydrocodone, alprazolam, and carisoprodol. *See* GX 12 (spreadsheet of prescriptions dispensed to A.S. and L.W.); GX 20, at 3 (Gov. Expert's report noting that "75% of the patients received the same four drug cocktail which included a benzodiazepine, two narcotic pain killers and Soma"). With respect to A.S.[51] and L.W., many of the oxycodone prescriptions were for 30 mg. and were for quantities which would provide a daily dose multiple times the amount that the Government's Expert—whose testimony was unrefuted—stated was the "normal dose of oxycodone" and thus indicated that Volkman was running a pill mill. Likewise, the prescriptions for hydrocodone and alprazolam were always for the strongest formulations of the drug; with respect to the alprazolam, the Government's Expert explained that ninety-three percent of the prescriptions he reviewed exceeded the FDA-approved maximum daily dosage and that the two-milligram strength of the drug is generally only prescribed for a patient with post-traumatic stress disorder.

Respondent also filled prescriptions issued to a single patient for multiple schedule II drugs on the same day, as well as three narcotic controlled substances on a single day. Moreover, in the prescriptions he reviewed, the Government Expert observed that there was "no individualization of dosing based on pain in these patients" with respect to the hydrocodone and alprazolam prescriptions and that "[a]ny pharmacist would have known that this was a problem and a strong indicator of a doctor operating a controlled substance prescribing mill." The Government's Expert also noted various instances of Respondent dispensing refills that were weeks early.

In addition, the fact that Mr. Fletcher had been called by D.S., who lived in Southern Ohio and was seeing a doctor whose office was nearly 100 miles away from his pharmacy, and yet, was obviously having problems filling her prescriptions, provided further reason to know that the prescriptions were not legitimate. While Mr. Fletcher did not ask where D.S. and Dr. Volkman were from and thus may not have had actual knowledge at the time of the initial phone call where Volkman and the patients were from, *see* GX 39, at 2; under a DEA regulation, each controlled-substance prescription must include the name and address of both

[49] 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)).

[50] Because of its potential for abuse, DEA has, however, initiated a proceeding to place carisoprodol into schedule IV of the Controlled Substances Act. *See* 74 FR 59108, 59109 (2009).

[51] While A.S. testified that she had been in pain caused by an auto accident, she also testified that she diverted drugs. Moreover, while A.S.'s pain may have justified the prescribing of a controlled substance, Respondent offered no evidence refuting the Government Expert's testimony that the four-drug cocktail of oxycodone, hydrocodone, alprazolam, and carisoprodol, which Volkman repeatedly prescribed to her, does not have a legitimate medical purpose.

the patient and prescriber. 21 CFR 1306.05(a).

Thus, the first time one of Volkman's patients presented a prescription to him, Mr. Fletcher knew that Volkman was practicing in Portsmouth, approximately 90 miles from Columbus, as well as the location of the patient's residence; he also knew with each successive prescription he received from a Volkman patient that they were travelling great distances to fill their prescriptions.

As the evidence shows, only a few of Volkman's patients lived in the Columbus area, and most of them were travelling great distances (and sometimes with others) to get their prescriptions filled at Respondent, with approximately half of them coming from Kentucky (more than two hours away) and many others coming from the Portsmouth area. Notwithstanding that many of the patients were travelling for hours to fill their prescriptions at Respondent, Volkman's controlled-substance prescriptions accounted for seventy-five percent of the total amount of controlled-substance prescriptions dispensed by Respondent, and controlled substances accounted for approximately ninety-five percent of Volkman's prescriptions. As the Government's Expert testified, the fact that the patients were driving so far to get their prescriptions filled "would be a major red flag to any pharmacist."

Indeed, Mr. Fletcher admitted in an interview that he had been told by Volkman's patients that no other pharmacists would fill the prescriptions. Yet, even when presented with this fact, he did not call any pharmacists to determine why. He also admitted in an interview that some of Volkman's patients had asked him to sell them extra pills, a clear indication that Volkman's patients were either abusing and/or selling the drugs. Yet he continued to fill Volkman's prescriptions.

Moreover, in substantial contrast to the national average of cash-paying customers which is approximately ten to eleven percent, nearly eighty-seven percent of the Volkman patients paid cash for their prescriptions. This, too, was a red flag as "[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect."

The evidence further shows that Respondent and Dr. Volkman's clinic would call each other on a daily basis to discuss when Volkman had seen his last patient so that Mr. Fletcher would know how late to stay open and that he stayed open as late as midnight to await the arrival of Volkman's patients and to fill their prescriptions. Relatedly, the evidence shows that Volkman directed his patients to go to Respondent and even provided driving directions to it. And the evidence also showed that Volkman's patients would travel to Respondent in groups.

Moreover, in early October 2005, Volkman, following a raid by the Portsmouth P.D., moved his "practice" to Chillicothe. Mr. Fletcher knew that Volkman had moved to Chillicothe because he called Volkman at this clinic. GX 22. This begs the question of whether Mr. Fletcher asked Volkman why he had moved his practice, which, like all of the other questions raised by his conduct, Mr. Fletcher has failed to address because he did not testify.[52] *See, e.g., Baxter* v. *Palmigiano,* 425 U.S. 308, 316 (1976). In light of the substantial probative evidence offered against Respondent and Mr. Fletcher, Mr. Fletcher's failure to testify supports the drawing of an adverse inference against Respondent and Mr. Fletcher. I therefore conclude that Mr. Fletcher knew that Volkman's prescriptions lacked "a legitimate medical purpose" and thus violated Federal law.

Against this evidence, Respondent elicited the testimony of his two employees. Ms. Smith testified that Mr. Fletcher would question his customers as to why they were taking the medicine, tell them that they were taking a large quantity of pills, and ask them if they could work without the drugs. She further maintained on direct examination that Mr. Fletcher "talked to everybody about their prescriptions" but then retreated from this testimony, stating that he did not talk "to everybody" but only "the majority of them." Moreover, earlier in her testimony, she had stated that she explained the medications to the patients and most of the patients interviewed by DEA Investigators stated that Mr. Fletcher did not ask them about their medical condition.

As for Ms. Cole, much of her testimony is of dubious credibility. For example, Ms. Cole testified that Mr. Fletcher had tried calling some of the pharmacies which had refused to fill Volkman's prescriptions. Yet, when interviewed by a DEA Investigator, Mr. Fletcher stated that he did not talk to other pharmacists. Ms. Cole also testified that every time Mr. Fletcher received prescriptions from outside of the Columbus area, he would call to verify the prescriptions. However, Respondent's phone records show otherwise.

Regardless, even if Mr. Fletcher had called to verify each and every prescription that Dr. Volkman issued, the evidence would still support the conclusion that he repeatedly violated his corresponding responsibility under Federal law because many of the Volkman prescriptions patently served no legitimate medical purpose. *See United States* v. *Hayes,* 595 F.2d at 260 ("[A] pharmacist may not fill a written order from a practitioner, appearing on its face to be a prescription, if he knows the practitioner issued it in other than the usual course of medical treatment.").

As the Fifth Circuit has explained, while "[v]erification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice[,] * * * it is not an insurance policy against a fact finder's concluding that the pharmacist had the requisite knowledge despite a purported but false verification." *Id.* at 261. A pharmacist has "the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the [CSA] because he knows that the issuing practitioner issued it outside the scope of medical practice." *Id.*

In an interview with a DEA Investigator, Mr. Fletcher admitted that "he had questions about" Dr. Volkman but that he was satisfied because Volkman told him that he did an MRI and blood tests.[53] However, as found above, Respondent repeatedly dispensed drug cocktails for multiple controlled substances including oxycodone, hydrocodone, and alprazolam, as well as carisoprodol, a combination which is widely known in the pharmacy profession as being popular with drug abusers, and it did so in such quantities that any reasonable pharmacist would have asked how the prescriptions could possibly serve a legitimate medical purpose. The Government's Expert also explained that these cocktails would have a synergistic effect on a person's central nervous system and could cause respiratory

[52] The evidence also shows that in October 2005, shortly after he had commenced filling Volkman's prescriptions, Mr. Fletcher was aware of the $10,000 threshold which triggers a bank's obligation to report a cash deposit under the Bank Secrecy Act and that he then structured multiple bank deposits in an attempt to avoid his bank's filing of Currency Transaction Reports, which would draw attention to his activities. This evidence further supports the conclusion that Mr. Fletcher clearly knew that by filling the Volkman prescriptions, he was engaging in illegal activity.

[53] Respondent's employees also testified that some of Volkman's patients complained that he was requiring them to undergo blood or urine tests. This sliver of evidence provides no reason to ignore the overwhelming evidence against Respondent.

depression. Accordingly, even if Volkman told Mr. Fletcher that he did blood tests and MRIs, this would not make the prescriptions any more legitimate.[54]

This alone supports the conclusion that Mr. Fletcher violated Federal law in dispensing the Volkman prescriptions. 21 CFR 1306.04(a). The other evidence—such as that related to the quantities of the various drugs being prescribed, the dosing, and lack of individualization of therapy; the distances the patients were travelling and the typical method of payment; the fact that Mr. Fletcher knew that other pharmacists had refused to fill Volkman's prescriptions; the percentage and number of Volkman's prescriptions that were for controlled substances—is simply icing on the cake.

Moreover, even after a DEA Investigator had interviewed Mr. Fletcher and asked him if he found it suspicious that Volkman's patients were travelling long distances to fill their prescriptions, Mr. Fletcher proceeded to fill numerous oxycodone and alprazolam prescriptions for residents of Kentucky who had travelled to South Florida to obtain the prescriptions. Indeed, even one of Respondent's employees was "skeptical" as to whether these were legitimate prescriptions. While Respondent contends that Mr. Fletcher stopped filling prescriptions issued by Florida pain-clinic physicians after he received the Ohio Board of Pharmacy's Notice, Mr. Fletcher did not testify in this proceeding and so has failed to offer any explanation as to why he filled the prescriptions in the first place. Furthermore, a responsible DEA registrant should be able to make these determinations without the authorities having to provide the information to him on a silver platter.

Nor was this the end of Respondent's abysmal experience in dispensing controlled substances. On November 4, 2009, Respondent dispensed to B.A., a recovering drug addict who lived in Morehead, Kentucky, four controlled-substance prescriptions issued by a Portsmouth physician, including two for Roxicodone 30 mg. (totaling 240 tablets), one for 120 oxycodone 15 mg., and one for 30 alprazolam; B.A. had been directed by the doctor's staff to fill his prescriptions at Respondent. Later that day, B.A. got high, and the next morning, he was found dead; the detective who found the prescription vials noted that there were only nineteen tablets left out of the total of 240 Roxicodone 30 mg., there were only fifty-two tablets left out of the 120 oxycodone 15 mg., and only eight tablets out of the 30 alprazolam. The quantity of oxycodone provided by these prescriptions totaled 300 mg. per day, an amount which was five to ten times the normal daily dose of oxycodone (5 to 10 mg. every four hours) as testified to by the Government's Expert. Moreover, on this single day, Respondent dispensed three prescriptions for the same schedule II narcotic. According to the Government's Expert, both the multiple prescriptions which B.A. presented and the large quantities prescribed were "red flags" which are suggestive of abuse and "no reasonable pharmacist would fill" the prescriptions. Here again, however, Mr. Fletcher failed to testify and thus offered no explanation as to why he did so.

DEA Investigators also obtained an OARRS report which showed that on eighteen different occasions between November 6, 2007 and October 30, 2009, Respondent had dispensed oxycodone to S.P. based on prescriptions she obtained from seven different doctors; most of the doctors practiced in different cities (Waverly, Beavercreek, Dayton and Wheelersburg), and while three of the doctors practiced in Portsmouth, two of them practiced at different clinics. Notwithstanding that its own dispensing records should have shown that S.P. was a doctor shopper (indeed, there was no need for Mr. Fletcher to check the OARRS to make this determination), Respondent repeatedly dispensed this highly abused schedule II controlled substance to her. Here again, Mr. Fletcher did not testify and thus has failed to explain why he ignored the information in his own records.

Respondent and Mr. Fletcher also violated the CSA and DEA regulations because during the November 6, 2009 inspection, it could not produce the biennial inventory of controlled substances which it is required to maintain. *See* 21 U.S.C. 827(a)(1) ("every registrant * * * shall * * * as soon * * * as such registrant first engages in the * * * dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand"); *see also* 21 CFR 1304.11. Moreover, Mr. Fletcher was unaware that there is such a requirement. Finally, as found by the Ohio Board of Pharmacy, Mr. Fletcher and Respondent violated Ohio law on three occasions because Mr. Fletcher, as "the responsible pharmacist[,] failed to maintain supervision and control over the custody and possession of dangerous drugs" which had been delivered to the pharmacy.

I therefore conclude that the evidence relevant to Respondent's experience in dispensing controlled substances and its record of compliance with applicable Federal and State laws related to controlled substances shows that it has committed acts which render its continued registration inconsistent with the public interest and which justified the suspension of its registration. Notably, Mr. Fletcher failed to testify in this proceeding; Respondent therefore has not rebutted the Government's *prima facie* case. While there is only the suspension order to review (because Respondent allowed its registration to expire), which I affirm, had Respondent filed a renewal application, I would have denied it.

Order

Pursuant to the authority vested in me by 21 U.S.C. 824, as well as by 28 CFR 0.100(b) and 0.104, I hereby affirm my order which immediately suspended the now-expired DEA Certificate of Registration, BE5902615, issued to East Main Street Pharmacy. This Order is effective immediately.

Dated: October 15, 2010.

Michele M. Leonhart,

Deputy Administrator.

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[54] Respondent also elicited the testimony of Mr. Aalyson, a lawyer who practiced workers compensation law in Portsmouth and who knew most of the local doctors, that Mr. Fletcher had called and asked him if knew whether Dr. Volkman was a legitimate doctor. Tr. 1159. Mr. Aalyson testified that the phone call occurred in October 2006, more than a year after Mr. Fletcher started filling Volkman's prescriptions and eight months after DEA suspended Volkman's registration and thus could no longer prescribe.

To the extent this testimony was offered to support the contention that Mr. Fletcher tried to do due diligence, it provides no comfort to him as the conversation occurred more than a year after he started filling Volkman's prescriptions. Moreover, even if the conversation had occurred shortly after Mr. Fletcher started filling Volkman's prescriptions (the apparent point of Respondent's repeated questioning of Mr. Aalyson regarding when the conversation occurred), his testimony that Mr. Fletcher stated that he was "getting a lot of people coming in, and I'm beginning to wonder if the guy is legitimate," Tr. 1159, would actually support the Government's case that Mr. Fletcher knew Volkman's prescriptions were not legitimate.

OFFICE OF MANAGEMENT AND BUDGET

Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Office of Management and Budget, Office of Federal Financial Management.

ACTION: Notice; request for comments.