	Number of annual respondents	Average time per response	Total annual hours
DEA–224 (paper)	5,867	0.2 hours (12 minutes)	1,173.4
DEA–224 (electronic)	79,057	0.13 hours (8 minutes)	10,540.9
DEA–224a (paper)	66,200	0.2 hours (12 minutes)	13,240
DEA–224a (electronic)	323,758	0.07 hours (4 minutes)	21,583.8
DEA–224b (chain renewal)*	32	5 hours	160
DEA–224c	0	0.25 hours (15 minutes)	0
Total	474,914		46,698.1

* In total, 64 chain pharmacies represent 36,660 individual pharmacy registrants. Pharmacies register for a three-year registration period. In calendar year 2011, the year for which estimates are calculated, 32 chains registered 6,472 individual pharmacies.

(6) *An estimate of the total public burden (in hours) associated with the collection:* It is estimated that there are 46,698 annual burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, 145 N Street NE., Suite 2E–508, Washington, DC 20530.

Dated: August 1, 2012.

Jerri Murray,

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

[FR Doc. 2012–19228 Filed 8–6–12; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–52]

Physicians Pharmacy, L.L.C.; Decision and Order

On December 15, 2011, Administrative Law Judge Timothy D. Wing issued the attached recommended decision.[1] Thereafter, the Government filed Exceptions to the ALJ's decision.

Having carefully considered the ALJ's recommended decision and the record in light of the Government's Exceptions, I have decided to adopt the ALJ's rulings, findings of fact, and conclusions of law except as discussed below.[2] Accordingly, I will order that Respondent's application be granted.

The Government's Exceptions

The Government's principal contention is that Mr. Lawrence James, Respondent's pharmacist-in-charge, ''will not adequately fulfill his corresponding responsibility to prevent drug diversion.'' Exceptions at 1. Ignoring that Mr. James has nearly forty years of experience as a registered pharmacist and has never been cited for any violation of state or federal laws, the Government argues that various portions of Mr. James' testimony support its contention.

First, the Government's argues that ''[i]n testifying how he would prevent diversion and fraud, [its pharmacist-in-charge's] testimony focused on fraudulent prescriptions, including prescriptions that had been altered, stolen or forged by the prospective patient.'' *Id.* at 1–2 (citing Tr. 51). Continuing, the Government argues that ''Mr. James did not address the significant diversion problem that exists with pill-pushing physicians and [which] is the exact type of pernicious drug diversion that plagues southern Ohio and surrounding areas.'' *Id.* at 2. The Government based this contention on the following colloquy:

> Q [by Government Counsel]: Are you aware of any diversion schemes where the doctor was in cahoots with the patient to issue a prescription that wasn't for a legitimate medical purpose?
>
> A That question is also very tough because it relies upon basically the equivalent of hearsay evidence. I have heard of and been told of some of those things, but at the same difference—and I am sure somewhere in Ohio, somewhere in the United States, there probably are doctors, like down in Florida, that will have an arrangement with a patient where they will supposedly—the doctor will write them a prescription, they'll get it filled, and the doctor either gets a cut of the pills or whatever. Have I ever actually seen any of that or am I totally aware of like any specifics? No, I am not.

Tr. 52.

While the Government finds this testimony remarkable in light of Mr. James' extensive experience as a Registered Pharmacist and the scope of the diversion problem in southern Ohio, it did not ask Mr. James any further questions regarding his awareness of doctors writing unlawful prescriptions. Nor did the Government pose to Mr. James any hypothetical questions regarding how he would handle prescriptions which raise red flags due to the quantity and strength of the drug or combination of drugs prescribed, as well as other relevant circumstances. Thus, to the extent Mr. James did not address to the Government's satisfaction the problems posed by prescriptions issued by pill-pushing physicians, the Government ignores that it (and not Respondent) had the burden of proof in this proceeding, *see* 21 CFR 1301.44(d), and that Mr. James was only required to

[1] All citations to the ALJ's opinion are to the slip opinion as originally issued.

[2] I do not, however, adopt footnote 20 of the ALJ's opinion. *See Kwan Bo Jin,* 77 FR 35021, 35021 n.2 (2012). Moreover, to the extent the ALJ's decision suggests that a practitioner does not have an obligation to maintain effective controls against diversion of controlled substances because this is not a statutory factor under the public interest standard of section 823(f), *see* ALJ at 25–26, it should be noted that factor four authorizes the Agency to consider an applicant's compliance with applicable federal and state laws ''relating to controlled substances'' and DEA regulations require that an applicant or registrant ''provide effective controls and procedures to guard against theft and diversion of controlled substances.'' 21 CFR 1301.71(a).

However, I agree with the ALJ's rejection of the Government's contention that ''in assessing the public interest, the nature and amount of diversion of controlled substances in a geographical area is a legitimate area of inquiry and concern when determining whether an applicant should be granted a DEA registration.'' ALJ at 25 (quoting Gov. Br. 4). Contrary to the Government's understanding, DEA has held that the public interest inquiry is not a free-wheeling inquiry but is guided by the specific factors set forth by Congress for the applicable category of registration. *Gregory D. Owens,* 74 FR 36751, 36757 (2009). With respect to a practitioner (which includes a pharmacy), *see* 21 U.S.C. 823(f), these factors primarily focus on an applicant's past conduct and the likelihood of future compliance. Nothing in the texts of any of the five factors set forth in section 823(f) remotely suggests that Congress granted the Agency the authority to deny an application based on its assessment of ''the nature and amount of diversion of controlled substances in a geographical area.'' Gov. Br. 4.

Indeed, this is simply the other side of the community impact coin. However, in multiple cases, DEA has held that such evidence is not relevant to any of the public interest factors and further noted that a rule which takes into account the impact on the community caused by not registering (or de-registering through a revocation proceeding) a particular practitioner is completely unworkable. *See Linda Sue Cheek,* 76 FR 66972, 66973 n.4 (2011) (quoting *Owens,* 74 FR at 36757) (''the ALJ's reasoning begs the question of how many patients from underserved areas would a practitioner have to treat to claim the benefit of the rule'').

answer those questions posed by the Government.[3]

The Government also argues that ''Mr. James testified that, in his view, the corresponding responsibility requirement [of 21 CFR 1306.04(a)] exists so the Government can 'nail pharmacists and not go after doctors.''' *Id.* While that is true, Mr. James then acknowledged that this ''may be incorrect assumption'' but that it seemed to him ''that they are much harder on pharmacists than they ever are on doctors until very recently.'' Tr. 53. Contrary to the Government's view, Mr. James' expression of opinion, whether correct or not, is not probative of whether he is likely to violate federal law.

The Government further contends that Mr. James ''testified that he would fill any prescription written by a properly licensed physician unless he had a 'personal reason' not to do so.'' *Id.* (citing Tr. 52). No such statement occurs at the cited portion of the transcript and the Government ignores the following answer Mr. James gave when asked to describe the responsibilities and duties of a pharmacist:

> A pharmacist's duties and responsibilities are to fill all legitimate and legal prescriptions. We are allowed at any point to refuse to fill any prescriptions that our own personal conscience thinks is not correct * * * we don't even really have to have a reason. I think I've only turned down two in my life for personal purposes. But to verify that the prescription is legal, legitimate for lawful use, and then to fill the prescriptions, counsel the patient, make sure they understand what they're taken for, answer any questions they may have. That's the rough idea.

Tr. 36.

Indeed, the only evidence that supports the contention that Mr. James would fill any prescription as long as it was written by a licensed physician, was the testimony of a DI regarding a round-table discussion he had with the various principals of Respondent:

> Throughout the discussions, we talked heavily about diversion. I talked to Mr. James or asked Mr. James with regards to his opinion of the diversion problem in southern Ohio, and he alluded basically that he didn't think there was a diversion problem. I asked him about other pharmacists not filling prescriptions for pain management clinics that were located in southern Ohio. Mr. James was clear that he thought that was totally wrong of the pharmacist to even turn down the prescriptions as it's a legitimate prescription and pharmacists need not to turn those away.

Id. at 138–39.

The DI offered no further testimony to the effect that he discussed with Mr. James the nature of the prescriptions that were being issued by the pain management clinics (the drugs, strength, and quantities, as well as other relevant circumstances which support a finding that the prescriptions were not legitimate) and which pharmacists were refusing to fill.[4] Thus, this testimony does not support a finding that Mr. James will fill prescriptions even when he has reason to know that they have not been issued for a legitimate medical purpose.

While in determining the public interest, DEA is entitled to consider the likelihood of an applicant's future compliance with federal and state laws related to controlled substances, *see* 21 U.S.C. 823(f)(4), federal law requires that the finding be based ''on consideration *of the whole record''* and ''supported by * * * the reliable, probative, and substantial evidence.'' 5 U.S.C. 556(d) (emphasis added). The Government's Exceptions do not provide a persuasive reason to reject the ALJ's credibility findings with respect to Mr. James or his conclusion that Mr. James ''demonstrate[d] a sufficient understanding of a pharmacist's corresponding duties'' under 21 CFR 1306.04.[5] Accordingly, I adopt the ALJ's ultimate conclusion that the Government has not proved ''by substantial evidence that Respondent's registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f),'' ALJ at 29, and will order that Respondent's application for a DEA Certificate of Registration as a retail pharmacy be granted.[6]

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Physicians Pharmacy, L.L.C., for a DEA Certificate of Registration as a retail pharmacy, be, and it hereby is, granted. This Order is effective immediately.

Dated: July 25, 2012.

Michele M. Leonhart,

Administrator.

Paul E. Soeffing, Esq.,
D. Linden Barber, Esq., for the Government

Steven E. Hillman, Esq., for the Respondent

Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge

I. Introduction

This proceeding is an adjudication pursuant to the Administrative Procedure Act, 5 U.S.C. 551 et seq., to

[3] However, it is also noted that prior to this colloquy, Mr. James testified that he believed that diversion of controlled substances is ''a major problem'' in both Ohio and nationally. Tr. 44. Mr. James then explained: ''[j]ust look at the state of Florida where they have six doctors who basically from what I understand work out of the back of their house, back of their car, writing prescriptions for anybody who has $200 to give them whatever they want.'' *Id.* This testimony would seem to address the problem of pill-pushing physicians.

[4] In its Exceptions, the Government argues that the DI ''provided an example of this model of drug diversion by one particular doctor in Ohio who prescribed large amounts of oxycodone and other controlled substances to individuals that resulted in numerous deaths.'' Exceptions at 3 (Tr. 130–31). Continuing, the Government argues ''[t]hese are the types of the prescriptions that Mr. James indicated that he would fill when he was interviewed by [the] DI.'' *Id.* (citing Tr. 138–39).

It is true that the DI testified regarding the prescribing practices of Dr. Paul Volkman, an ex-registrant and now-convicted federal drug felon. However, the DI offered no testimony that he even discussed the type of prescriptions Volkman wrote with Mr. James, Tr. 130–31, let alone that Mr. James said he would fill such prescriptions. *See id.* at 138–39. Accordingly, there is no basis in the record to support the Government's contention.

[5] The Government also takes exception to the ALJ's finding that Mr. Hillman, one of Respondent's owners ''was generally credible.'' Exceptions at 4. It argues that there are ''inconsistencies between Mr. Hillman's answers to DEA's written questions * * * and his testimony at the hearing.'' *Id.* More specifically, the Government argues that while Mr. Hillman answered ''no'' to a written question as to whether he had ''any interest, either personally or professionally'' in one of nine listed pain clinics, he testified at the hearing ''that he had a professional relationship with several clinics as their attorney.'' *Id.* (citing GX 2, at 4; GX 3, at 4; Tr. 123). Even ignoring that the written question is laced with ambiguity, on the questionnaire, Mr. Hillman answered ''yes'' to the question of whether he had ''ever represented owners and/or physicians in the above list in any civil or criminal procedures.'' *See* GX 2, at 5; GX 3, at 4.

Furthermore, the Government offers no explanation as to why Mr. Hillman's representation of pain clinics in legal proceedings is relevant under any of the public interest factors.

[6] The Government takes exception to the ALJ's exclusion of a video recording on the ground that the Government failed to provide a written transcript of the recording as required by the ALJ's pre-hearing ruling. Exceptions at 6. The Government contends that ''[t]here is no statutory or regulatory requirement that a written transcript be provided.'' *Id.* However, under the Administrative Procedure Act, the ALJ is authorized to ''regulate the course of the hearing,'' 5 U.S.C. 556(c), and requiring the production of a transcript for a recording which a party seeks to admit into the record, clearly falls within this power. While it appears that this case was reassigned to the lawyer who tried it, the pre-hearing ruling was issued more than three months before the hearing, and thus, the Government had ample time to comply with the Judge's ruling. Moreover, while the Government noted that Respondent stipulated to the admission of the exhibit, it is the Judge (and not the parties) who runs the proceeding.

Nor is it clear why the video, which according to the Government is of a meeting between Mr. Hillman and members of the community during which the latter expressed their concerns about diversion, is relevant to any of the public interest factors. In any event, the DVD was corrupted and could not be played. I therefore reject this exception.

determine whether the Drug Enforcement Administration (DEA, Agency or Government) should deny an application for a DEA Certificate of Registration (COR) as a retail pharmacy, pursuant to 21 U.S.C. 823(f) and 824(a)(4), on the grounds that such registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f). Without this registration, the applicant, Physicians Pharmacy, LLC (Respondent) of Piketon, Ohio, will be unable to lawfully distribute, dispense or otherwise handle controlled substances.

On May 11, 2011, the Deputy Assistant Administrator, DEA, issued an Order to Show Cause (OSC) to Respondent. The OSC provided notice to Respondent of an opportunity to show cause as to why the DEA should not deny Respondent's application for a DEA COR as a pharmacy, pursuant to 21 U.S.C. 824(a)(4), alleging that such registration would be inconsistent with the public interest as that term is defined in 21 U.S.C. 823(f). (ALJ Ex. 1, at 1.) The OSC alleged [1] as a basis the following:

1. On January 12, 2011, [Respondent] applied to be registered with DEA as a pharmacy with a registered location of 727 Second Street, Piketon, Ohio.

2. The owners and corporate officers of the pharmacy have no experience owning or operating a pharmacy.

3. On behalf of [Respondent], corporate officer Steven Hillman told the mayor of Piketon and members of the public that prescriptions presented to the pharmacy will be filled so long as they contain a diagnostic code from the physician and match a facsimile or electronic version of the prescription that will be sent to the pharmacy by the physician. This statement fails to acknowledge the full scope of the ''corresponding responsibility'' of the pharmacist. *See* 21 CFR 1306.04(a).

4. On behalf of [Respondent], corporate officer Steven Hillman, in response to DEA's request to explain the owners' understanding of diversion in the Piketon region, stated, ''I never have been told.'' The remainder of his response was not relevant to the question. The corporate officers were either deceptively avoiding answering the question or were willfully ignorant of the rampant pharmaceutical drug abuse problem in southern Ohio. The response by Mr. Hillman on behalf of [Respondent] evinces a likelihood that [Respondent] will ignore signs of diversion and abuse.

5. [Respondent]'s pharmacist, Lawrence James, in response to DEA's asking if he was aware of the diversion of controlled substances in southern Ohio, stated that much of the problem stems from pharmacies not filling prescriptions from pain clinics. Mr. James stated that prescriptions from pain clinics were valid and should be filled.

6. On behalf of [Respondent], corporate officer William Caserta advised DEA that [Respondent] would serve clinics south of Columbus, Ohio. Columbus is approximately 67 miles from Piketon. When asked if there were concerns over chronic pain patients travelling from significant distances to obtain controlled substances, corporate officer Don Wolery asserted that the problem was local pharmacies refusing to fill prescriptions because pharmacists believe that the some [sic] prescriptions are not for legitimate medical problems.

7. The statements made by the corporate officers and pharmacist demonstrate a lack of understanding about the diversion and illicit use of pharmaceutical controlled substances. The statements indicate that [Respondent] will fill prescriptions issued by individual practitioners under circumstances that are indicative that the prescriptions are not issued in the usual course of professional practice or for a legitimate medical purpose.

Following prehearing procedures, a hearing was held in Cincinnati, Ohio on October 4, 2011, with both parties represented by counsel.[2] The Government called five witnesses and introduced documentary evidence. Respondent did not put on any evidence. After the hearing, both parties filed proposed findings of fact, conclusions of law, and argument. All of the evidence and post-hearing submissions have been considered, and to the extent the parties' proposed findings of fact have been adopted, they are substantively incorporated into those set forth below.

II. Issue

Whether the record establishes that Respondent's application for a DEA COR as a retail pharmacy should be denied on the grounds that such registration would be inconsistent with the public interest pursuant to 21 U.S.C. 824(a)(4) and 823(f).

III. Evidence and Incorporated Findings of Fact [3]

I find, by a preponderance of the evidence, the following facts:

A. Background

with a registered address of 727 Second Street, Piketon, Ohio 45661. (Tr. 136; Gov't Ex. 1.) The application contains Mr. Hillman's e-signature and lists Mr. Caserta as the Respondent is a Limited Liability Company (LLC) that was initially formed in or about 2010 with three members, Don Wolery (Mr. Wolery), Steven Hillman (Mr. Hillman), and William Caserta (Mr. Caserta). (Tr. 14, 25–26, 96–97.) Respondent currently has two members, Mr. Hillman and Mr. Caserta, who each hold a one-half ownership interest. (Tr. 26, 97.) Respondent is currently licensed as a retail pharmacy with the Ohio State Board of Pharmacy.[4] (Tr. 123; ALJ Ex. 2, at 4.) Lawrence James (Mr. James) is listed on Respondent's state pharmacy license as the ''Responsible Person.'' (Tr. 40–41; ALJ Ex. 2, at 4.) On January 12, 2011, Respondent submitted an electronic application for a DEA COR as a retail pharmacy in Schedules II through V, contact person. (Tr. 136; Gov't Ex. 1.)

B. The Government's Evidence

The Government's evidence included testimony from five witnesses: Mr. Wolery; Mr. Caserta; Mr. James; Mr. Hillman; and DEA Diversion Investigator (DI) Christopher Kresnak (DI Kresnak). In addition to testimonial evidence, the Government also introduced various documentary exhibits, to include: Respondent's master information for electronic application; [5] correspondence between DEA and Respondent; [6] an agenda and sign-in sheet for a regional meeting on prescription drug overdoses; [7] Mr. James's work history; [8] and three documents produced by Mr. James for use by Respondent, including a note to its customers, its mission statement, and information for physicians with pain patients.[9]

Mr. Wolery testified that he is an attorney, and that he and Mr. Hillman came up with the concept of opening a pharmacy. (Tr. 14.) He decided to become a member of Respondent because he wanted to make money and thought ''[i]t was a good business idea.'' (Tr. 14, 15.) Mr. Wolery testified that he contributed $1,330 to the business. (Tr. 18.) Mr. Wolery testified that he has no experience as a pharmacist, nor has he ever owned or operated a pharmacy. (Tr. 16.) He testified that he had no intentions of running the pharmacy: ''Mr. James had been chosen as a pharmacist to run it and had been given the latitude to run it as he saw fit, and given his experience in this matter, we felt that he was a good choice to run this operation in a lawful manner.'' (*Id.*)

[1] Represented to be a ''non-exhaustive summary of facts and law'' in support of the OSC. ALJ Ex.1, at 1.

[2] Respondent was represented by Steven Hillman, a member of Respondent with a fifty percent ownership interest. Mr. Hillman also testified in this matter.

[3] In addition to the evidence discussed in this Section, additional evidence and findings of fact are discussed in later Sections of this Recommended Decision.

[4] Respondent's state pharmacy license was issued in or about February 2011. (Tr. 123–24.)

[5] Gov't Ex. 1.

[6] Gov't Exs. 2–4.

[7] Gov't Ex. 6.

[8] Gov't Ex. 7.

[9] Gov't Exs. 8–10.

Rather, Mr. Wolery's role in the business was ''helping set it up. I met with the Ohio Pharmacy Board to make sure that plans and specifications * * * met with their [sic] approval.'' (Tr. 16–17, 18.) In speaking with representatives at the Ohio Pharmacy Board, Mr. Wolery testified that he asked them

> what they would require for a pharmacy, what they would like to see as far as security for the pharmacy, the type of safe and things like that, show them the potential schematic of what it would look like and ask them if there was anything that they would like to see in order for this pharmacy to be licensed, * * *

(Tr. 23.)

Mr. Wolery testified that he ended his membership on March 16, 2011, for personal reasons, and expressly stated that he did not leave the business for financial reasons. (Tr. 15–16.) Mr. Wolery provided a resignation letter and walked away without getting any of his initial investment back. (Tr. 17–18.) Mr. Wolery testified that he told Mr. Hillman that if Respondent gets a DEA COR and eventually makes a profit, he'd like to get his $1,330 investment back. (Tr. 18.) Although Mr. Wolery stated that he would not become a member should Respondent be granted a DEA COR, he testified that he believes the business will be profitable because ''there's a need for it. * * * People can't get scripts filled, even those that deserve them. So there's a need and I think the pharmacy will meet that need, as any pharmacy.'' (Tr. 18.)

Mr. Caserta testified that he has no experience as a pharmacist and has never owned or operated a pharmacy, but he became a member of Respondent after he was approached by Mr. Wolery and Mr. Hillman. (Tr. 25–26.) He did not make an initial investment, but he currently owns a fifty-percent share and serves as a managing partner. (*Id.*) Mr. Caserta testified that part of his job with Respondent included interviewing applicants to serve as Respondent's pharmacist. (Tr. 29.) After interviewing several applicants, Mr. Caserta and the other members hired Mr. James ''because of his work record, it was impeccable. His background was very good. And he had a lot of experience in managing a pharmacy, * * *'' (*Id.*)

Mr. Caserta testified that he spoke to the chief of police, the planning board, the zoning board, and the ''Assistant—to the County Attorney, the City Attorney'' for Piketon to ensure that they had no objections to Respondent opening in Piketon. (Tr. 30.) He testified that the chief of police told Mr. Caserta that if Respondent was not going to have a doctor and it was simply going to be an apothecary, then he had no objections. Similarly, none of the other people who Mr. Caserta spoke to had any objections. (*Id.*) Mr. Caserta testified that if Respondent receives a DEA COR, it will fill both non-controlled and controlled substance prescriptions for customers between an eighteen and forty-mile radius. (Tr. 27–28.) Mr. Caserta testified that the Kentucky border is approximately thirty miles away, but he ''ha[s] no idea'' if Respondent will get customers from Kentucky. (Tr. 28.)

Mr. James testified that he completed two years of pre-pharmacy studies at Ohio Dominican College and then earned a Bachelor of Science degree in pharmacy from Ohio State University. (Tr. 32.) He graduated in June 1975, and has been a registered pharmacist in Ohio since August 2, 1975. (*Id.*) Mr. James has worked continuously as a pharmacist in Ohio since he was registered, with the exception of ''no more than three weeks' break between any jobs.'' (Tr. 33; *see* Gov't Ex. 7.[10]) Mr. James has worked at seven retail pharmacies, one in-house pharmacy organization that filled prescriptions for patients released from the James Cancer Center, and one community hospital as the staff pharmacist. (Tr. 35; Gov't Ex. 7.) Mr. James has also worked for a company called HealthPro Staffing Agency, where he was given a nine-month assignment to the Ohio Department of Mental Health, filling prescriptions for twenty-three prisons in central and south-central Ohio. (Tr. 43, 44.)

Mr. James testified that he was put in touch with Mr. Caserta through an employment agent. (Tr. 38.) After speaking to Mr. Caserta and going to see Respondent's location, Mr. James agreed to work as the main pharmacist. (*Id.*) Mr. James testified that Respondent is located in an old brick building in Piketon, Ohio. (Tr. 48.) He believes there are approximately four other pharmacies within five or ten miles of Respondent's location. (Tr. 42.) None of the pharmacies in the area, however, are set up as ''strictly an apothecary-type business,'' as Respondent, but are all ''traditional pharmacies, including over-the-counter drugs, * * * greeting cards, * * * deodorants and other things.'' (Tr. 91–92.) Although Mr. James is not involved in the business plan since he is not an owner, (Tr. 85), Mr. James testified that when he was hired, he understood that decisions as to how the pharmacy will operate will have to be approved by Mr. Hillman and Mr. Caserta. (Tr. 84, 92–93.) He testified, however, that ''nothing has yet been turned down by either'' of them. (Tr. 93.)

Mr. James testified that Respondent currently has one other employee, Theresa Putnam (Ms. Putnam), but that if Respondent obtains a DEA COR, Mr. James and Mr. Caserta will likely hire a pharmacy technician as well. (Tr. 41.) Mr. James explained that when he and Mr. Caserta were previously looking to hire a technician, they both interviewed the candidates. Mr. James then ''ranked them in the order that I felt the people would be of interest to us.'' (*Id.*) Mr. Caserta then ranked the candidates ''and then he made the decision ultimately of which one [they] would hire.'' (Tr. 41–42.)

Although Mr. James accepted the pharmacist position with Respondent in January 2011, he and Ms. Putnam have been furloughed since March 17, 2011, because Respondent is non-operational. (Tr. 39, 40–41.) Mr. James testified that although Respondent has a pharmacy license from the state, it is unable to operate even in non-controlled substances because the wholesaler does not want to sell just non-controlled substances to Respondent. (Tr. 67; 80.) The wholesaler ''didn't want to sell anything to us until we got all licenses taken care of, including the DEA license.'' (Tr. 67.) Mr. James testified that he was ready and willing to start working for Respondent, selling just non-controlled substances. (*Id.*) The last he spoke with the wholesaler, it was ready to sell to Respondent, but Mr. Caserta later informed Mr. James that the wholesaler would not sell any drugs until Respondent got its DEA registration. (Tr. 82.)

Mr. James testified that ''[a] pharmacist's duties and responsibilities are to fill all legitimate and legal prescriptions. We are allowed at any point to refuse to fill any prescription that our own personal conscience thinks is not correct according to—we don't even really have to have a reason.'' (Tr. 36.) Mr. James testified that he refused to fill two prescriptions during his career ''[f]or personal reasons.'' (Tr. 36.) He clarified later that he turned down two for ''personal purposes,'' but that he turned down ''many forged prescriptions * * * not for personal

[10] Mr. James testified that Government Exhibit 7 shows where he was working on September 15th of each year when he renewed his state pharmacy license. (Tr. 33.) Mr. James testified that the document accurately portrays his work history, with the following exceptions. First, ''for exactly one year to the day, I worked for a company called Ultimate Care Home Health Care, between Knox Community Hospital [in 1992] and Meijer [in 1993].'' (Tr. 34–35.) Second, Mr. James testified that he did not work at CVS Pharmacy in 2010. He actually worked for HealthPro Staffing Agency in 2010. (Tr. 43.)

purposes.'' (Tr. 60.) Mr. James explained that he turned down those prescriptions for ''legal purposes'' because he was confident that the prescriptions were fraudulent. (Tr. 60–61.)

Mr. James testified that diversion is ''a major problem'' not only in southeastern Ohio, but across the entire country. (Tr. 44.) In addition to testifying that some patients try to alter prescriptions or bring in forged prescriptions, (Tr. 51), Mr. James testified that in Florida, for instance, ''they have six doctors who basically * * * work out of the back of their house, back of their car, writing prescriptions for anybody who has $200 to give them whatever they want, and then those people wind up coming all over the United States trying to get them filled.'' (Tr. 44–45.) Mr. James also testified that he is aware that there are some doctors who ''will have an arrangement with the patient where they will supposedly—the doctor will write them a prescription, they'll get it filled, and the doctor either gets a cut of the pills or whatever.'' (Tr. 52.) Mr. James has never ''actually seen any of that,'' nor is he ''totally aware of * * * any specifics.'' (*Id.*)

Mr. James testified that he is aware of a pharmacist's corresponding responsibility under 21 CFR 1306.05. (Tr. 53.) He testified, however, that he does not believe that certain pharmacists are more diligent than others in checking prescriptions. (Tr. 77.) He agreed that some pharmacists are more fearful of the inspectors from the State Board of Pharmacy than others. (Tr. 77–78.) Mr. James later testified that ''I believe there are good pharmacists, I believe there are also bad pharmacists. I believe that people get themselves into situations that they sometimes think they can't control even though they really can control them.'' (Tr. 79.) He also testified that he ''absolutely'' believes that some pharmacists fill bad prescriptions. (*Id.*) The Government attempted to clarify with the following colloquy:

> Q But you wouldn't characterize them as being less diligent than any other pharmacist?
>
> A In one case, he was more fearful that his supervisor would find out that he didn't fill it, and the supervisor would raise Cain for, ''Why didn't you fill this prescription?'' It didn't matter that it was a very questionable prescription for a very questionable quantity.
>
> The field of pharmacy is not a pretty field anymore. It has changed so much since the DEA laws of 1976 and what insurances did around that time that it's a whole different ballgame than it was back in my early years.

(Tr. 79–80.)

Mr. James testified that he fulfills his corresponding responsibility by verifying that each prescription contains the customer's name and address, and by asking each customer for a valid phone number even though the law does not require that information. (Tr. 54–55.) Mr. James testified that he also observes each prescription to see what drug the customer is getting, and ''[s]ometimes I'll ask the person questions like as to what they got this prescription for on controlled substances, * * * .'' (Tr. 55.) He explained: '' 'It's my license,' I keep telling everybody. I don't care what these companies say to keep doing, it's my rear end that's on the line here. If my license gets suspended, it's my job. * * * I want guidelines for the actual pharmacist to be able to have honest input so he can decide whether this is really a legitimate prescription, * * * .'' (Tr. 53–54.)

Mr. James testified that he would like to employ five additional safeguards as the pharmacist for Respondent. First, he would like to ask the prescribing physicians to provide an IDC–9 diagnosis code for each prescription so that Mr. James can ''verify that the prescription was indeed for a legal, legitimate purpose, which has always been a problem.'' (Tr. 46.) Mr. James testified that the IDC–9 code is typically used by insurance companies for billing purposes, and he has never seen it used by a pharmacy. (Tr. 47–48.) He explained, however, that he thinks it will be useful to pharmacists. (Tr. 47.) Although none of the pharmacies that Mr. James previously worked for implemented his idea, he testified that Mr. Hillman responded, ''You're the boss of the pharmacy, and if you think we need it, then we need it basically.'' (Tr. 86–87.)

Second, Mr. James testified that he would like to request that the prescribing physicians fax a copy of each prescription directly to the pharmacy so that Mr. James can verify that nothing has been changed on the prescription carried into the pharmacy by the customer. (Tr. 47, 87.) Mr. James testified that Mr. Hillman and Mr. Caserta agreed to implement this policy as well. (Tr. 87.)

Third, Mr. James testified that he would like to use OARRS [11] to help him determine if a prescription is valid by checking OARRS to see if the customer has had other controlled substances prescriptions issued and filled. (Tr. 90.) According to Mr. James, Mr. Hillman and Mr. Caserta liked this idea as well. (Tr. 91.) Mr. James testified that OARRS hasn't typically been used in this fashion, explaining that some of his colleagues think his idea is ''blasphemous'' and that he's ''gotten some indication from the State Board of Pharmacy that they didn't like the idea that I was going to be checking with OARRS.'' (Tr. 90–91.)

Fourth, Mr. James testified that he would like to require that each customer provide a valid state-issued license or ID when picking up a prescription that Mr. James can keep on file. (Tr. 46.) He further explained that if a customer is unable to pick up a prescription, the customer will have to notify Respondent that another person will pick up the prescription on the customer's behalf and that person will have to provide a valid form of identification. (Tr. 46–47.) Mr. James will keep a copy of that identification in the customer's file, and testified that there were copiers for him to do that. (Tr. 87.)

Finally, Mr. James testified that in addition to keeping a log of all Schedule II drugs, he would also like to keep a log of all other controlled substances, so that ''[a]ll controlled substances would have an exact inventory at all times.'' (Tr. 47, 88.)

Mr. James also testified that in late February 2009, he prepared three documents for potential use by Respondent. (Tr. 57–58, 70–71, 71–72.) Mr. James testified that he gave the documents to Mr. Caserta and Mr. Hillman to consider, but he did not think the documents had been approved for use, stating that ''until the other day when I saw these things inside the folder, as far as I was concerned, they were thrown away.'' (Tr. 58.)

First, Mr. James created a document entitled ''Note to Our Customers with Pain'' that he would like to give to pain medication customers so that the customers ''understand exactly what were [sic] going to do to verify that their prescriptions were legitimate, legal, valid and under what circumstances I possibly would tell them, 'Sorry, I cannot fill your prescription.' '' (Tr. 58; *see* Gov't Ex. 8.) Mr. James testified that the document informs customers that they need to fill all of their prescriptions with Respondent, not just their controlled substances prescriptions. (Tr. 58; *see also* Gov't Ex. 8.) He explained that this will help him identify any potential drug interactions and also demonstrates that he is not operating a pill mill. (Tr. 63.) He also testified that the document informs customers that if the insurance company ''rejects the claim as too early, we will not fill the

[11] OARRS refers to the Ohio Automated Rx Reporting System, a drug database established and maintained pursuant to Ohio law. Ohio Admin. Code R. 4731–11–11 (2011).

prescription until the proper time. Do not think that you can just pay cash and get it filled.'' (Tr. 65–66.) He also testified that the document informs customers that the prescribing physicians ''can speed up the process by faxing all prescriptions in advance to the pharmacy, along with the proper IDC–9 diagnosis code.'' (Tr. 68; *see also* Gov't Ex. 8.) He explained that this will save time for the customers because otherwise he will have to contact the prescribing physician after the customer comes into the pharmacy. (Tr. 68.) Mr. James testified that he assumes some form of this document will be used. (Tr. 59.)

Second, Mr. James testified that he created a document entitled ''Our Mission Statement.'' (Tr. 70–71; *see* Gov't Ex. 9.) Mr. James proposed that Respondent provide the mission statement to customers ''to indicate to people what our business was, what we were and what we hoped to do.'' (Tr. 71.) The document informs customers that Respondent wants to be their ''local pharmacy for all of your prescription needs.'' (Gov't Ex. 9.) It also informs customers that Respondent does not offer over-the-counter medications and does not have a doctor on staff. (*Id.*)

Third, Mr. James testified that he created a document entitled ''Information for Doctors with Pain Customers.'' (Tr. 71–72; *see* Gov't Ex. 10.) Mr. James testified that this document was not approved for use yet. The draft document sets forth the security measures that Mr. James ''would like to put into place to protect the doctor, the patient and myself[.]'' (Tr. 73; *see* Gov't Ex. 10.)

Mr. James also testified to the physical security measures implemented by Respondent. He testified that the main gate to the building has a ''good major gated lock, so it's harder to get into[.]'' (Tr. 48.) Once inside, the pharmacy department is to the right and the waiting area is to the left. (*Id.*) Mr. James testified that the ''pharmacy has a thick door which has an opening, which has * * * bulletproof glass. * * * The windows into the pharmacy also have bars which I believe were actually requested by the State Board of Pharmacy.'' (Tr. 49.) Mr. James also testified that there is a walk-in safe in the pharmacy, approximately three feet deep, six or seven feet wide and tall enough for him to stand inside without ducking his head. He stated that it is the ''biggest safe I've ever seen inside a pharmacy.'' (*Id.*) Mr. James testified that this is the ''best security I've ever seen'' at a pharmacy. (Tr. 50.) He testified that when the inspector from the State Board of Pharmacy observed the safe, he made no negative comments, but simply said '' 'Yes, that will do,' or something to that effect.'' (Tr. 88–89.)

Mr. James did not know if the size of the safe was indicative of the volume of controlled substances that will be kept on hand. (Tr. 50.) He did indicate, however, that he will keep all of the controlled substances, rather than just the Schedule II controlled substances, in the safe. (*Id.*) Mr. James testified that he does ''not really'' know what the percentage breakdown will be for controlled and non-controlled substances filled by Respondent once it opens for business. (Tr. 73.) Although Mr. James testified that he hopes the percentage is acceptable, he indicated that it has been ''rather confusing'' to determine what an acceptable percentage might be. (Tr. 73, 74.) For instance, he testified that the State Board of Pharmacy suggested that no more than twenty-five percent of all prescriptions filled by Respondent should be for controlled substances, but the wholesaler indicated that no more than thirty or thirty-five percent should be for controlled substances. Then, when Mr. James spoke to DI Kresnak, he got ''a different percentage.'' (Tr. 74.)

Mr. Hillman testified that on October 21, 2009, he attended a regional meeting in Scioto County, Ohio entitled ''Epidemic of Prescription Drug Overdoses: A Call to Action.'' (Tr. 109–10; Gov't Ex. 6.) Mr. Hillman explained that the meeting ''was mostly political. * * * And they talked about * * * having to get better control over the prescription drugs.'' (Tr. 110.) Mr. Hillman testified that he did not find the meeting to be educational, explaining that ''I don't know a lot about drugs, but the people who were speaking knew less than I did.'' (Tr. 111.) Mr. Hillman initially planned to attend the meeting because ''somebody has to be blind not to understand that there's some serious drug problems,'' so he wanted to get involved. (*Id.*) Mr. Hillman explained that he wanted to get involved by talking with various officials about the fact that there were no laws in place at the time regarding licensing for businesses that treated pain patients. (Tr. 111–12.) He also informed the officials that he believed OARRS was inadequate, suggesting that it should be interactive so that pharmacists can enter a patient's personal information to determine what other prescriptions the patient has had filled with other pharmacies. (Tr. 112–13.) Mr. Hillman eventually started to work with a state representative who ''wound up sponsoring the bill,'' [12] but the representative eventually stopped returning Mr. Hillman's calls. (Tr. 113–14.) Mr. Hillman testified that he was not contemplating opening a pharmacy at the time of the town meeting. (Tr. 114.)

Mr. Hillman further testified that he has no experience as a pharmacist and has never owned or operated a pharmacy. (Tr. 98.) Mr. Hillman also testified that he is not familiar with DEA's Controlled Substance Ordering System (CSOS), explaining that he ''would never order controlled substances,'' so he has ''[n]o reason to become familiar.'' (Tr. 98–99.) Mr. Hillman explained that he will have ''very little'' to do with running the pharmacy. (Tr. 97.) Rather, Mr. James will be the pharmacist in charge and that he ''will be 100 percent in control'' of verifying prescriptions. (Tr. 99.)

Mr. Hillman testified that he was aware of pain management clinics in southern Ohio, but that all except for one of the clinics have closed. (Tr. 103–04.) The pain management clinic that Mr. Hillman believes is still open is located about forty or fifty miles from Respondent. (Tr. 104.) Mr. Hillman does not know if Respondent will get customers from that pain management clinic, but he testified that Respondent will not advertise in that area. (*Id.*) Mr. Hillman testified that he does not know where the patients of the other pain clinics now receive medical care; nor does he know where the patients of those clinics filled their prescriptions before the pain clinics closed. (Tr. 105.)

Mr. Hillman testified that Respondent is located in ''a 160-year old farmhouse'' that has two rooms on the first floor and two rooms on the second floor. (Tr. 101.) Upon entering the front door, there is a room to the right, which will be the actual pharmacy, and a room to the left, which will be the waiting area. (Tr. 101.) Mr. Hillman testified that he contacted the City Attorney for Piketon and invited him to look around the pharmacy and ask any questions. (Tr. 116–17.) The City Attorney accepted the invitation, and went to the pharmacy with the chief of police, the mayor, some city council members, as well as some citizens.[13] (Tr. 118.)

[12] While not entirely clear from the record which ''bill'' Mr. Hillman is referring to, his testimony is consistent with a 2011 Ohio House Bill Number 93, which is now codified at Ohio Rev. Code Ann. § 4729.51 (2011).

[13] The Government offered a video recording of the meeting, obtained from the Internet, arguing that the recording was relevant to show ''the diversion problems in southern Ohio, concerns expressed by the community and the knowledge * * * of Mr. Hillman and the steps that he had

Continued

Mr. Hillman testified that Respondent has been licensed by the Ohio Board of Pharmacy since early 2011. (Tr. 123–24.) Respondent has not opened for business yet, however, because the wholesaler will not even supply Respondent with the non-controlled drugs until it obtains its DEA COR. (Tr. 124.) If Respondent obtains a DEA COR, Mr. Hillman testified that, at the outset, Respondent will not sell anything other than prescription drugs. (Tr. 100.) If, however, Mr. James determines that there is a need for any over-the-counter medications, then Respondent may start to sell those medications. (Tr. 100–01.) Mr. Hillman testified that all of the medication will still be kept behind the glass with Mr. James, and there will be no displays in the waiting area. (Tr. 101.)

Mr. Hillman testified that ''if 'diversion' is controlled substances going to someplace they shouldn't be,'' then he believes it exists in southern Ohio, citing a 2008 case where twenty-two people died from prescription drug overdoses even though none of them had a lawful prescription. (Tr. 106, 107–08.) Mr. Hillman was not aware of any other specific incidents, claiming that ''[o]nce Scioto County gave me that information, they stopped giving me any additional information.'' (Tr. 108.) He stated, however, that ''when people walk into our pharmacy, those people that the medications are sold to will be sold to appropriate people, period. If the pharmacist believes for one second that there's something wrong, he'll deal with it.'' (*Id.*) Mr. Hillman also testified that to prevent diversion, he would like Respondent to maintain contact with the prescribing physicians. (Tr. 100.) He also stated that Respondent has ''adopted'' all of Mr. James's suggestions, including requiring prescribing physicians to fax a copy of all prescriptions to the pharmacy and requiring customers to present photo identification before obtaining their medications. (*Id.*)

DI Kresnak [14] testified that southern Ohio, northeastern Kentucky, and West Virginia, were formerly ''thriving'' with labor-intense jobs, leading to a population of coal miners, railroad workers, and steel workers. (Tr. 130.) According to DI Kresnak, these industries have left the area over the past couple of decades, and ''a population of drug dealers moved in the area.'' (*Id.*) Many of the drug dealers are supplied by questionable doctors in the area. (*Id.*) DI Kresnak testified that he obtained information from local coroners and law enforcement officials indicating that ''Kentucky is averaging almost three bodies a day for prescription drug overdose. The State of Ohio has indicated they're close to that number for prescription overdose.'' (Tr. 131–32.) DI Kresnak also testified that from approximately 2005 to 2008, southern Ohio had an increase of prescription drug overdoses of approximately 280 percent. (Tr. 132.)

In addressing Mr. Hillman's testimony that most of the pain clinics in the area had closed, DI Kresnak explained that prior to summer 2011, when House Bill 93 was enacted by the Ohio Legislature, the majority of the pain clinics in southern Ohio were owned by convicted felons who would bring in physicians who had previously faced disciplinary action. (Tr. 132–33.) House Bill 93, however, required that ''if you were a pain clinic, you had to be a licensed practitioner. I believe you had to be associated with a hospital. There were several other caveats to the law that I'm not familiar with.'' (Tr. 132.) DI Kresnak explained now that ''there are individuals trying to undermine the current law.'' [15] (Tr. 132.)

DI Kresnak testified that he became familiar with Respondent's application for a DEA COR, which was filled out by Mr. Hillman. (Tr. 135; *see* Gov't Ex. 1.) Although DI Kresnak does not typically conduct an on-site visit for a new retail pharmacy application, he did conduct one in this case. (Tr. 136–37.) DI Kresnak contacted Mr. James and went to the pharmacy in February 2011. (Tr. 137.) DI Kresnak had a round-table discussion with Mr. James, Mr. Caserta, Mr. Wolery, and Ms. Putnam. (*Id.*) He did not interview them individually, but instead discussed as a group ''why the pharmacy was going to be open, the need for the pharmacy in the area.'' (Tr. 138.) They also talked about diversion, and according to DI Kresnak, Mr. James ''alluded basically that he didn't think there was a diversion problem.'' DI Kresnak testified that Mr. James thought it was wrong that other pharmacists would not fill prescriptions for pain management clinics located in southern Ohio. (*Id.*)

DI Kresnak testified that he discussed the procedures that Mr. James would implement at the pharmacy, including ''the need for doctors to fax the prescriptions over to verify correctness and accuracy.'' (Tr. 139.) DI Kresnak testified that Mr. James also wants to request IDC–9 codes from prescribing physicians. (Tr. 148.) DI Kresnak refused to ''comment on'' whether he thought it was a good idea ''because it's above what DEA requires.'' (*Id.*) DI Kresnak also refused to comment on whether it was a good idea to have the prescribing physician fax the prescription to Mr. James to compare to the prescription brought in by the customer, stating ''I'm not a pharmacist. I don't run pharmacies.'' (*Id.*) He agreed, however, that this would ''help get the ultimate user the prescription.'' (Tr. 148–49.)

DI Kresnak also testified that Mr. Caserta informed him that Respondent would fill prescriptions for ''anything south of Columbus.'' (Tr. 139.) When DI Kresnak asked how they would feel about pain patients traveling so far to have their prescriptions filled, ''Mr. Wolery stated that he felt that it was a shame that they had to travel that far, that they were legitimate prescriptions and that it's just a darned shame they have to travel that far.'' (*Id.*) This concerned DI Kresnak because ''there isn't a pharmacist that is filling for these pain clinics with exception to one or two, and the ones that were filling for the one or two, people were traveling great distances. * * * These customers all of a sudden weren't going to have to be traveling much longer because there was going to be a pharmacy opening up in the area.'' (Tr. 140.)

DI Kresnak testified that he is not aware of a guideline setting forth the percentage of controlled substances that should be sold out of a pharmacy. (Tr. 149.) He testified that ''the DEA is not going to put limits or percentages within a business.'' (Tr. 150.) DI Kresnak explained security measures in place at Respondent, based on his inspection of the building. (Tr. 138, 141.) DI Kresnak testified that there are numerous cameras on the outside of the building, pointing in all directions. (Tr. 141.) The windows of the building are secured by iron bars on the inside. (Tr. 143.) DI Kresnak testified, however, that having bars on the windows does not ''bother[] me.'' (Tr. 156.) The front door to the

proposed to take to remain in compliance with the requirements of DEA in stemming diversion and satisfying the local community.'' (Tr. 119–20.) I excluded the exhibit as both irrelevant and noncompliant with the June 28, 2011 Prehearing Ruling, (Tr. 120), which required that ''[a]ny audio or video recordings must include a written transcript.'' (ALJ Ex. 6, at 2 n.3.)

[14] DI Kresnak has been a DI with DEA for approximately eight-and-one-half years in Cincinnati. (Tr. 127–28.) Prior to working with the DEA, DI Kresnak received a four-year degree in management from Park University, and then completed work in a master's program at Central Michigan University. (Tr. 128.) DI Kresnak also spent twenty-two years in the United States Marine Corps, where he retired as a Master Sergeant. (*Id.*)

[15] Respondent's counsel questioned DI Kresnak what he meant by that statement, asking whether DI Kresnak meant these individuals were actually violating the law ''or just that they're obeying it to the extent that you don't like it?'' (Tr. 151–52.) DI Kresnak testified that ''it's not a matter of I don't like it. There's probably more to that answer that I'm not at liberty to say at this time, sir.'' (Tr. 152.)

building is ''gated with an iron gate with a padlock.'' (Tr. 141.) Once inside the building, DI Kresnak testified that the pharmacy is to the right, and the waiting room is to the left. Beyond the waiting room is an office where Ms. Putnam ''would be accepting the prescriptions and payment.'' (*Id.*) DI Kresnak testified that there is a door and ''heavily fortified, very thick, almost bulletproof glass with a sliding drawer to allow the payment and the prescription to come through.'' (Tr. 141.) DI Kresnak testified that there is another ''heavily fortified'' door with several glass windows leading to the pharmacy section. (*Id.*) The door contains a speaker hole so the pharmacist can communicate with customers, as well as a four-inch hole where the pharmacist pushes the medication through to a basket on the customer's side of the door. (Tr. 142.)

DI Kresnak testified that inside of the pharmacy area, there is a very large vault, approximately ''eight feet wide and four feet deep [with] a Class V door on it, which is a very heavy steel door with a combination lock on it.'' (Tr. 142.) DI Kresnak testified that he's never seen a vault in a pharmacy; he's only seen safes in pharmacies. (Tr. 143.) He added, ''This is a distributor's vault. This is something that a small mom and pop distributor would have for their Schedule II narcotics.'' (*Id.*) ''[P]harmacies typically have ''3x3 combination safes with a door on the front.'' (Tr. 144.) DI Kresnak testified, however, that with regards to diversion, ''[t]here's nothing wrong with being cautious, * * * .'' (Tr. 147.) He also testified that there is nothing wrong with having that kind of security. (Tr. 156.)

DI Kresnak testified that Mr. Hillman was not present when he conducted the roundtable and site inspection of Respondent's location. (Tr. 152–53.) DI Kresnak arranged to meet Mr. Hillman in person, but DI Kresnak did not show up. (Tr. 155.) As a result, DI Kresnak submitted written questions to Mr. Hillman. (Tr. 152; *see also* Gov't Ex. 2.) On March 7, 2011, Mr. Hillman submitted his responses to DI Kresnak. (Gov't Ex. 3.) [16]

Notably, when Government counsel asked DI Kresnak if he believed granting a DEA COR to Respondent will threaten the public health and safety, DI Kresnak responded:

> I worked in an area which diversion—I claim it as a pandemic when it comes to prescription drugs. I have seen what it's done to families. We talked about the history of Portsmouth in regards to when industry was there. That was a town that you could leave your bicycle on the sidewalks. It was a town where everybody knew everybody. It's a ghost town when it comes to neighborly love anymore because you have to lock everything up. You cannot leave anything out.
>
> The diversion problem is so bad. It's an underground economy, sir. The underground economy is that of pills. When people have to make their mortgage payment or their rent payment or their utility payments and they're short, they know they can trade their medicines for cash, for something that will help them continue to survive until the next payday.
>
> There is just countless numbers of incidents that I've been involved in. I've sat at the tables and talked to the family members of overdose victims, and yes, they'll all say that, ''Yes, they took their pills.'' But the physicians and the pharmacists that filled those, two of them are in prison right now. It is a major problem in that area.
>
> It was a long answer to your question sir. It is not in the—I've talked to civic leaders, I've talked to the police chief. They don't want this, they feel that it is not in the best public interest to have this apothecary in their community.

(Tr. 144–45.) After Respondent's counsel interposed a relevance objection, stating that ''this has absolutely nothing to do with Physicians Pharmacy in Piketon, Ohio,'' (Tr. 145), Government counsel effectively conceded the point and again asked DI Kresnak specifically, ''why will giving a registration to Physicians Pharmacy, this specific pharmacy, in your opinion, why would that pose a threat to the public health and safety?'' (Tr. 146.) DI Kresnak stated, ''I know from the addicts I've talked to, they can't wait for it to open.'' (*Id.*)

C. Respondent's Evidence

As noted above, Respondent did not produce any testimonial or documentary evidence at the hearing, relying instead on the testimony and evidence introduced during the Government's presentation of its case, the majority of which involved testimony by witnesses affiliated with Respondent.

IV. Discussion

A. The Applicable Statutory and Regulatory Provisions

The Controlled Substances Act (CSA) provides that any person who dispenses a controlled substance must obtain a registration issued by the DEA in accordance with applicable rules and regulations.[17] The CSA further provides that the ''Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances * * * if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices.'' [18] An application for registration may be denied if the ''Attorney General determines that the issuance of such registration * * * would be inconsistent with the public interest.'' [19]

B. The Public Interest Standard

The CSA, at 21 U.S.C. 824(a)(4), provides, insofar as pertinent to this proceeding, that the Administrator may deny an application for a COR if she finds that an applicant has committed such acts as would render his registration inconsistent with the public interest as that term is used in 21 U.S.C. 823(f). Pursuant to 21 U.S.C. 823(f), the Administrator may deny an application for a DEA COR if she determines that such registration would be inconsistent with the public interest. In determining the public interest, the Administrator is required to consider the following factors:

> (1) The recommendation of the appropriate state licensing board or professional disciplinary authority.
>
> (2) The applicant's experience in dispensing or conducting research with respect to 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.[20]

As a threshold matter, the factors specified in Section 823(f) are to be considered in the disjunctive: The Administrator may properly rely on any one or a combination of those factors, and give each factor the weight she deems appropriate, in determining whether a registration should be revoked or an application for registration denied. *See David H. Gillis, M.D.,* 58 FR 37,507, 37,508 (DEA 1993); *see also D & S Sales,* 71 FR 37,607,

[16] Although Government Exhibits 2 and 3 were admitted into evidence by stipulation, (Tr. 7), the Government offered no testimony pertaining to these exhibits. Nor are they addressed in the Government's post-hearing brief. I find these exhibits generally consistent with other evidence of record.

[17] 21 U.S.C. 802(10), 822(a)(2).

[18] 21 U.S.C. 823(f).

[19] *Id.* The Attorney General has delegated this authority by regulation to the Administrator of the Drug Enforcement Administration. 28 C.F.R. § 0.100(b). *See e.g. Lawrence Lerner, M.D.,* 54 FR 8,014, 8,015 (DEA 1989).

[20] I conclude that the reference to ''other conduct which may threaten the public health and safety'' would as a matter of statutory interpretation logically encompass the factors listed in § 824(a). *See Kuen H. Chen, M.D.,* 58 FR 65,401, 65,402 (DEA 1993).

37,610 (DEA 2006); *Joy's Ideas,* 70 FR 33,195, 33,197 (DEA 2005); *Henry J. Schwarz, Jr., M.D.,* 54 FR 16,422, 16,424 (DEA 1989). Application of the public interest factors requires an individualized determination and assessment ''tethered securely to state law * * * and federal regulations.'' *Volkman* v. *DEA,* 567 F.3d 215, 223 (6th Cir. 2009). Additionally, in an action to deny a practitioner-registrant's[21] application for a COR, the DEA has the burden of proving that the requirements for denial are satisfied.[22] The burden of proof shifts to a respondent once the Government has made its prima facie case.[23]

D. The Factors To Be Considered

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution or Dispensing of Controlled Substances

In this case, regarding Factor One, it is undisputed that Respondent currently holds a valid unrestricted pharmacy license in Ohio. (Tr. 123.) Although not dispositive, Respondent's possession of a valid retail pharmacy license in Ohio weighs against a finding that Respondent's registration would be inconsistent with the public interest. *See Robert A. Leslie, M.D.,* 68 FR 15,227, 15,230 (DEA 2003) (state license is a necessary, but not a sufficient condition for registration, and therefore, this factor is not dispositive).

Regarding Factor Three, there is no evidence that any of the members of Respondent, including Respondent's Ohio-licensed pharmacist, have ever been convicted under any federal or state law relating to the manufacture, distribution or dispensing of controlled substances. I therefore find that this factor, although not dispositive, *see Leslie,* 68 FR at 15,230, weighs against a finding that Respondent's registration would be inconsistent with the public interest.

Factors 2, 4 and 5: Respondent's Experience in Handling Controlled Substances; Compliance With Applicable State, Federal or Local Laws Relating to Controlled Substances; and Such Other Conduct Which May Threaten the Public Health and Safety

Regarding Factors Two and Four, the Government argues in substance that Respondent's application for registration is inconsistent with the public interest because Respondent's owners do not have ''experience as a pharmacist or as the owner or operator of a pharmacy,'' further arguing that they have ''demonstrated a limited knowledge of diversion and the issues surrounding diversion.'' [24] (Gov't Br. at 4.) Additionally, while facially acknowledging that Respondent's pharmacist ''does have experience,'' the Government argues in substance that his testimony at hearing ''did not address the significant diversion problem that exists with pill-pushing physicians,'' nor did he have sufficient experience with refusing to fill prescriptions from ''unscrupulous physicians'' over his thirty-six-year career. (*Id.*)

The credible evidence of record with regard to Respondent's ownership, operation, and employees, as it pertains to experience in handling controlled substances, does not support a finding by a preponderance of the evidence that registration would be inconsistent with the public interest. As an initial factual matter, it is undisputed that Respondent is licensed by the State of Ohio as a retail pharmacy, and Respondent's pharmacist-in-charge, Mr. James, has been a registered pharmacist in Ohio since 1975. (Tr. 32, 67, 80.)

Agency precedent establishes the relevant parameters of assessing the conduct of individuals associated with a pharmacy-applicant. ''DEA has consistently held that a pharmacy operates under the control of owners, stockholders, pharmacists, or other employees, and the conduct of these individuals is relevant in evaluating a pharmacy's fitness to be registered with DEA.'' *Bradford's Pharmacy Conditional Grant of Registration,* 63 FR 58,418, 58,420 (DEA 1998) (pharmacist-owner convicted of felony conduct). For example, DEA has consistently held that a corporate registration may be revoked or denied where ''a natural person who is an owner, officer, or key employee, or who has some responsibility for the operation of the registrant's controlled substance business, has been convicted of a felony offense relating to controlled substances.'' *Spoon's Pharmacy,* 50 FR 46,520, 46,520–21 (DEA 1985).

The evidence of record pertaining to Respondent's LLC members and key personnel is undisputed. One former member, Mr. Wolery, credibly testified that he is an attorney but ended his relationship with Respondent in March 2011, but had no intention of having an active role in the operation of Respondent. (Tr. 16.) With regard to the operation of the pharmacy, Mr. Wolery testified in pertinent part:

> Mr. James had been chosen as a pharmacist to run [Respondent] and had been given the latitude to run it as he saw fit, and given his experience in this matter, we felt that he was a good choice to run this operation in a lawful manner. He had no dings, he had no problems. He had been a manager of a pharmacy. He knew all the ins and outs. He knew everything that needed to be known in a pharmacy, and so we felt that he would be the right person to run it. We're not pharmacists. We had no intentions of running the pharmacy or telling him how to do his job.

(Tr. 16.)

A second member of the LLC, Mr. Caserta, credibly testified that he is a retired pilot and businessman, and currently owns a fifty-percent share in Respondent, serving as a managing partner. (Tr. 24–26.) A third member, Mr. Hillman, credibly testified that he is a self-employed attorney, and a current member of Respondent, having half-ownership along with Mr. Caserta. (Tr. 97.) The testimony by Mr. Caserta and Mr. Hillman unequivocally and credibly maintained that Mr. James, Respondent's pharmacist, will be responsible for the handling of all controlled substances. Testimony by Mr. James was fully consistent. (Tr. 86–87, 92–93.) There is simply no evidence of record of any misconduct or other ''acts'' by any past or current member-owner of Respondent, or employee that is inconsistent with the public interest. *See* 21 U.S.C. 824(a)(4). Nor is there any evidence that anyone other than Respondent's pharmacist will have an active role in the handling of controlled substances, unless under the direct supervision of the pharmacist.

The Government correctly acknowledges the extensive experience of Respondent's pharmacist, Mr. James, which spans over three decades. I find the Government's argument that Mr. James did not adequately address in testimony the ''significant diversion problem that exists with pill-pushing physicians'' or demonstrate a sufficient understanding of a pharmacist's

[21] The term ''practitioner'' includes pharmacy. 21 U.S.C. 802(21).

[22] *See* 21 CFR 1301.44(d). ''The Government has the burden of proof in a hearing for the denial of an application for registration by a practitioner.'' (Gov't Br. at 3.)

[23] *See Medicine Shoppe—Jonesborough,* 73 FR 364, 380 (DEA 2008); *see also Thomas E. Johnston,* 45 FR 72,311, 72,311 (DEA 1980).

[24] The Government conceded at hearing that the relevant consideration under Factor Two would be the experience of the pharmacist rather than the experience of owners or members who have no expected operational role in the handling of controlled substances. (Tr. 161.)

corresponding duties pursuant to 21 CFR 1301.04, (Gov't Br. at 4), to be both legally and factually unpersuasive, given the evidence of record. Of significance, it is the Government that bears the initial burden of proof in this proceeding, not Respondent. 21 CFR 1301.44(d).

Mr. James credibly and consistently testified at hearing that diversion is a major problem not only in southeastern Ohio, but across the entire country. (Tr. 44.) Mr. James further testified that over his career he has turned down two prescriptions for ''personal reasons,'' explaining that to mean a refusal ''to fill any prescription that our own personal conscience thinks is not correct.'' (Tr. 36.) Of significance, Mr. James further testified that over the course of his career he has turned down many prescriptions for legal reasons, such as forged prescriptions. (Tr. 60–61.) With regard to his corresponding duty as a pharmacist, Mr. James credibly testified that he fully understands the parameters of applicable regulations. (*See e.g.* Tr. 53–60, 69–70, 85–94.) In addition to the required safeguards, Mr. James also explained in detail his intent to employ five additional safeguards to ''verify that the prescription was indeed for a legal, legitimate purpose, which has always been a problem.'' (Tr. 46.)

In addition to the foregoing testimony, the record also reflects that Mr. James has extensive experience as a pharmacist in Ohio, to include recent employment as a pharmacist at CVS Pharmacy, Columbus, Ohio, from 2003 to 2009.[25] (Gov't Ex. 7.) The record is devoid of any evidence that Mr. James has had any issues pertaining to his professional qualifications or practice as a pharmacist in Ohio from 1975 to present. Mr. James presented his testimony in a serious and professional manner. His testimony was internally consistent and consistent with other credible evidence of record. I find Mr. James's testimony fully credible and in accord with his over thirty-year, unblemished record as a licensed pharmacist in Ohio.

The Government also argues with regard to Factors Two and Five that ''in assessing the public interest, the nature and amount of diversion of controlled substances in a geographical area is a legitimate area of inquiry and concern when determining whether an applicant should be granted a DEA registration,''[26] citing by analogy *Southwood Pharmaceuticals, Inc.,* 72 FR 36,487, 36,491 (DEA 2007) (requirement for manufacturer of controlled substances to manifest due diligence in approving new customer). While not addressed in the Government's brief, the statutory requirements for a manufacturer with regard to ''due diligence for new customers'' differ markedly from those imposed on a practitioner-applicant. For example, in the case of manufacturers of controlled substances in Schedules III through V, the public interest factors include consideration of ''maintenance of effective controls against diversion of particular controlled substances * * * [and] the existence in the establishment of effective controls against diversion.'' 21 U.S.C. 823(d)(1) and (5). In addition to the statutory differences, there are numerous material regulatory differences in the treatment of different categories of registrants.[27] Finally, unlike a practitioner-applicant, ''[a]t any hearing on an application to manufacture any controlled substance listed in Schedule I or II, the applicant shall have the burden of proving that the requirements of such registration * * * are satisfied.'' 21 CFR 1301.44(a).

For the foregoing reasons, I decline to apply public interest factors applicable to other categories of registrants by analogy or otherwise, since to do so would conflict with the clear and unambiguous statutory language that sets forth specific public interest factors that Congress directed be considered for distinct categories of registrants.[28] *Robinson* v. *Shell Oil Co.,* 519 U.S. 337, 340 (1997) (''[I]nquiry must cease if the statutory language is unambiguous and 'the statutory scheme is coherent and consistent.''' (citation omitted)).

In light of the foregoing, I have carefully considered the Government's various arguments along with the evidence of record pursuant to the applicable factors under 21 U.S.C. 823(f). In so doing, the paucity of evidence in support of the OSC's allegations that Respondent's registration is inconsistent with the public interest was striking. The only Government witness called to testify in support of the allegations contained within the OSC was DI Kresnak, who testified in substance that he was the investigator that handled Respondent's application for a DEA registration as a pharmacy.[29] (Tr. 134–35.) While generally credible, DI Kresnak offered little to no substantive evidence as to why Respondent's registration would be inconsistent with the public interest. On direct examination, Government counsel asked DI Kresnak in substance why Respondent posed a threat to the public health and safety. Initially, DI Kresnak provided a lengthy and non-responsive answer, essentially concluding that members of the community informed him ''they don't want this.''[30] (Tr. 144–45.) Government counsel again asked DI Kresnak to explain specifically why Respondent posed a threat to the public health and safety, to which DI Kresnak responded: ''I know from the addicts I've talked to, they can't wait for it to open.''[31] (Tr. 146.)

DI Kresnak's testimony demonstrates a remarkable lack of evidence of any articulable reason to support a finding that Respondent's application for registration may be inconsistent with the public interest. DI Kresnak's reference to statements by ''addicts'' was devoid of context or any evidence to support the basis, let alone credibility, for such vague hearsay statements. On cross-examination, DI Kresnak offered little more in the way of substantive testimony other than to suggest there might be other evidence that he was not at liberty to share at hearing. (Tr. 152.) While DI Kresnak credibly testified to a serious drug abuse and diversion problem in Ohio, not unlike other regions of the United States, he offered no testimony linking that issue specifically to Respondent or anyone associated with Respondent. Nor did the testimony substantively address the fact that Respondent possesses all requisite state authority to operate as a pharmacy in Ohio.

The Government's public interest argument relative to illicit drug abuse and diversion problems within a given

[25] In 2010, Mr. James worked as a pharmacist at HealthPro Staffing Agency. *See supra* note 10.

[26] Gov't Br. at 4.

[27] *Compare, e.g.,* 21 CFR 1301.74(a) and (b), with § 1301.75.

[28] *Cf. Cynthia M. Cadet, M.D.,* 76 FR 19,450, 19,450 n.3 (DEA 2011).

[29] Presumably, DI Kresnak's investigative findings would have informed the Agency's initial decision not to approve Respondent's application for registration, but rather to issue an OSC ''as to why DEA should not deny [Respondent's] application for a DEA registration.'' (ALJ Ex. 1, at 1.)

[30] Notably, other credible evidence of record establishes that local community leaders were consulted in advance by Respondent but apparently voiced no significant objections. (Tr. 29–30.) Of greater relevance, Respondent is actively licensed by the Ohio Board of Pharmacy, and also has obtained all requisite local permits. (Tr. 30, 123.) Testimony at hearing also revealed that some of the security measures employed by Respondent, including the vault, were put in place at the specific direction of the Ohio Board of Pharmacy, prior to granting Respondent a license. (Tr. 16–17; 23; 49–50.) (''From what I've been told, State Board of Pharmacy said that they wanted a certain kind of safe, and that's the one they bought.'' Tr. 50.) The Government did not call any local or state officials from Ohio to testify at hearing.

[31] This served as DI Kresnak's full answer to the serious and very relevant question asked by Government counsel, which was not posed a third time. (Tr. 146, 157.)

community, without linkage to specific conduct by a proposed registrant, is also at odds with analogous Agency precedent. For example, in *East Main Street Pharmacy,* 75 FR 66,149 (DEA 2010), the Agency rejected as irrelevant evidence that the respondent was located in a high crime area to include the fact that the owner-pharmacist carried a gun. The ''principle issue * * * was whether [the r]espondent was dispensing controlled-substance prescriptions which it either knew or had reason to know lacked a legitimate medical purpose and were issued outside the usual course of professional practice.'' *Id.* at 66,155. In other contexts, the Agency has also rejected an expansive reading of the public interest factors, focusing instead on specific conduct or acts by the registrant. ''The public interest standard of 21 U.S.C. [§] 823(f) is not a freewheeling inquiry but is guided by the five specific factors which Congress directed the Attorney General to consider * * * which focus primarily on the acts committed by a practitioner.'' *Gregory D. Owens, D.D.S.* 74 FR 36,751, 36,757 (DEA 2009).

In the instant case, the Government's evidence of a serious diversion problem in Ohio was credibly established through the testimony of DI Kresnak, but there is simply no credible evidence of record establishing that Respondent will be a contributing source of drug diversion through any acts or omissions by any owner-member or employee of Respondent. As the record evidence reveals, Respondent's Ohio-licensed pharmacist-in-charge has over thirty years of unblemished experience and expects to adhere to standards of dispensing above those required by existing law and regulation.

The Government's further argument that the size of the ''walk-in vault'' alone supports a finding by a preponderance of the evidence ''that the pharmacy intends to do a large business in controlled substances and this, coupled with the diversion problem that exists in southern Ohio, would not be in the public interest'' [32] is equally unpersuasive. The credible testimony at hearing from Respondent's pharmacist, Mr. James, established that he did not know the volume of controlled substances that would be kept at the pharmacy, since there was no way to know that until the pharmacy was operational. (Tr. 50.) Similarly, Mr. Hillman testified that he did not know the volume of expected sales of controlled substances until the business was operational. (Tr. 100.) He credibly explained that he believed there was enough business in the area for the pharmacy to be successful, noting that if ''there's not enough business, I'll go broke.'' (Tr. 122.)

Although Respondent did not establish a specific quantity of controlled substances expected to be sold once operational, it had no burden to do so. 21 CFR 1301.44(d). The Government's argument that a walk-in vault constitutes de facto evidence of the volume of controlled substances Respondent will handle, and further proof that this will contribute to the diversion problem in southern Ohio is at best speculative. ''Speculation is, of course, no substitute for evidence, and a decision based on speculation is not supported by substantial evidence.'' *White ex rel. Smith* v. *Apfel,* 167 F.3d 369, 375 (7th Cir. 1999) (citing *Erhardt* v. *Sec'y, DHS,* 969 F.2d 534, 538 (7th Cir. 1992)). More importantly, the Government did not prove by a preponderance of evidence at hearing that Respondent's handling of controlled substances, whether in a large volume or small, would be contrary to applicable state and federal law. In fact, testimony from DI Kresnak pertaining to various precautions Respondent's pharmacist intended to take to prevent the diversion of controlled substances were ''above what DEA requires.'' (Tr. 148.) DI Kresnak also testified that there was nothing wrong with the kind of security measures taken by Respondent to protect against diversion. (Tr. 147.)

After careful consideration of the entire record, I find that the Government has failed to establish by a preponderance of the evidence any acts or demonstrable conduct by any member or employee of Respondent, that would support a finding by substantial evidence that Respondent's registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 823(f). I therefore find that Respondent's registration under Factors Two, Four, and Five would not be inconsistent with the public interest.

V. Conclusion and Recommendation

I find that the Government has not established by substantial evidence a prima facie case in support of denying Respondent's application for a DEA COR as a retail pharmacy. The Government has failed to demonstrate by a preponderance of the evidence that such registration would be inconsistent with the public interest as that term is used in 21 U.S.C. 824(a)(4) and 823(f). Accordingly, I recommend approval of Respondent's application for a DEA COR as a retail pharmacy pursuant to 21 U.S.C. 823(f).

Dated: December 15, 2011.

Timothy D. Wing,
Administrative Law Judge.

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[32] Gov't Br. at 5.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application; SA INTL GMBH C/O., Sigma Aldrich Co. LLC

Pursuant to Title 21 Code of Federal Regulations 1301.34 (a), this is notice that on May 2, 2012, SA INTL GMBH C/O., Sigma Aldrich Co. LLC., 3500 Dekalb Street, St. Louis, Missouri 63118, made application by renewal to the Drug Enforcement Administration (DEA) for registration as an importer of the following basic classes of controlled substances:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
Ethylamphetamine (1475)	I
Aminorex (1585)	I
Gamma Hydroxybutyric Acid (2010)	I
Methaqualone (2565)	I
Alpha-ethyltryptamine (7249)	I
Ibogaine (7260)	I
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I