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## Department of Justice

Drug Enforcement Administration

Grider Drug #1 & Grider Drug #2; Decision and Order; Notice

## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

**[Docket No. 08–19]**

### Grider Drug #1 & Grider Drug #2; Decision and Order

On October 30, 2007, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Grider Drug #1, the holder of DEA Certificate of Registration No. AG3498347, and Grider Drug #2, the holder of DEA Certificate of Registration No. AG9715751, (hereinafter, Respondent or Respondents), of Russell Springs, Kentucky.[1] ALJ Ex. 1, at 1. The Show Cause Order proposed the revocation of each Respondent's retail pharmacy registration, as well as the denial of any pending applications to renew or modify each registration, on the ground that the Respondents' ''continued registrations are inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 823(f); 824(a)). The Show Cause Order alleged that each Respondent had committed numerous violations of federal regulations, as well as that Leon Grider, the owner of Respondents, had been indicted on state law charges of trafficking in controlled substances and bribing a witness.[2] *Id.* at 4.

Subsequently, on June 22, 2010, the Government raised additional allegations that Respondents were dispensing prescriptions to six persons engaged in doctor-shopping and that ''Respondents 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 they ''failed to fulfill their corresponding responsibility for the proper dispensing of controlled substances.'' GX 21, at 1–3. Based on the allegations that this conduct had continued through early May 2010, I concluded that there was a ''substantial likelihood'' that it would continue. *Id.* at 3. Accordingly, I concluded that Respondents' continued registration during the pendency of the proceedings ''would constitute an imminent danger to the public health and safety'' and authorized the immediate suspension of each Respondent's registration.[3] *Id.* at 3–4.

Following service of the initial Show Cause Order, Respondents requested a hearing on the allegations and the matter was placed on the docket of the Agency's Office of Administrative Law Judges (ALJ) and assigned to an ALJ, who proceeded to conduct pre-hearing procedures. On June 6, 2008, the ALJ granted Respondents' motion to stay the proceedings pending the conclusion of a state-court criminal case against their owner Leon Grider, which was scheduled to conclude on October 10, 2008, noting that ''the parties believe that the presentation of evidence in the above-captioned matter will be facilitated.'' Order Granting Stay of Proceedings, at 1. However, nine months later, after further delays in the state proceeding, the ALJ terminated the stay, and finally, in August 2009, the ALJ commenced the hearing.[4]

Giving new force to Justice Douglas's dissenting opinion in *Sierra Club* v. *Morton,*[5] the parties proceeded to take twenty-seven days of testimony over the ensuing twenty months and create a record comprised of more than 6200 pages of transcript as well as several thousand pages more of various exhibits, with much of the record devoted to litigating issues which are plainly irrelevant. Primary responsibility for the state of the record lies with the ALJ, who failed to exercise anything more than minimal control over the parties' respective presentations.

After the hearing, both parties submitted briefs containing their proposed findings of fact, legal conclusions and argument.[6] Thereafter, on September 23, 2011, the ALJ issued her recommended decision.

With respect to factors two (Respondents' experience in dispensing controlled substances) and four (Respondents' compliance with applicable laws related to controlled substances), the ALJ found, *inter alia,* that Respondents' owner, Leon Grider, had, on various occasions, distributed controlled substances to several persons without a prescription. ALJ at 85–85. Based on audits which Respondents paid an accounting firm to conduct on themselves, the ALJ further found that Respondents could not ''account for a substantial number of dosage units of controlled substances'' including hydrocodone and methadone. *Id.* at 85–86. In addition, the ALJ found that Respondents did not report various thefts of controlled substances and failed to reduce to writing and maintain called-in prescriptions. *Id.* at 87.

The ALJ further found that Respondents had violated their corresponding responsibility under 21 CFR 1306.04(a) by dispensing to the six persons (as alleged in the Immediate Suspension Order) controlled-substance prescriptions which lacked a legitimate medical purpose and that Respondents' pharmacists ignored various red flags indicative that the patients were engaged in drug abuse or diversion. *Id.* at 89–90.

Next, the ALJ rejected various allegations of violations that were based on data from the State of Kentucky's Prescription Monitoring Program (KASPER) on the ground that the Government had not obtained a court order as required by state law to render these reports and the underlying data contained in them admissible in this proceeding. ALJ at 91. However, the ALJ found that Respondents had violated federal regulations by dispensing schedule II controlled substances without retaining the hard copy of the prescription, as well as by dispensing prescriptions ''that were never called-in or authorized by the prescribing physicians.'' *Id.* at 92.

As for factor five—such other conduct which may threaten public health and safety—the ALJ found that Respondents' pharmacists had improperly billed Medicaid for medications (including controlled substances) by billing for one medication while actually dispensing another and that this conduct circumvented ''the prescription check and balance such Medicaid reporting creates.'' ALJ at 94. In addition, the ALJ found that Leon Grider had ''inaccurately'' labeled prescription bottles as well as placed false prescription labels on bottles he provided to a confidential informant. *Id.*

Based on her findings under factors two, four, and five, the ALJ thus concluded that the Government had satisfied its *prima facie* case by showing that Respondent had committed acts inconsistent with the public interest. *Id.* at 95. The ALJ then held that

[1] The Order also sought the revocation of the registration issued to a third pharmacy, Grider Drug Key Village. ALJ Ex. 1, at 1. However, this store discontinued selling pharmaceuticals in November 2008 and the proceeding was subsequently terminated with respect to it. ALJ Ex. 5.

[2] The specifics of the various allegations are discussed below.

[3] Apparently, the Government raised additional allegations in its pre-hearing statements.

[4] The ALJ also granted three continuances because of the medical condition of Respondent's counsel. Tr. 3005.

The proceeding also included an interlocutory appeal to this Office by Respondents of the ALJ's denial of their motion to stay the proceeding while they sought the return of numerous documents which were seized by the Kentucky Bureau of Investigation and the Medicaid Fraud Unit of the Kentucky's Attorney General's Office pursuant to a state criminal search warrant. *See* ALJ Ex. 10. I denied the interlocutory appeal. *See* ALJ Ex. 11.

[5] *See* 405 U.S. 727, 741 (1972) (citing Stone, 45 S. Cal. L. Rev. 450 (1972)).

[6] These submissions will be cited as Gov. Post-Hearing Br. and Resp. Post-Hearing Br., respectively.

Respondents had failed to rebut the Government's *prima facie* showing, noting that Respondents' owner did not testify and thus had not shown ''any remorse for the past failings of the Respondents or [that] he ha[s] implemented any procedures that would ensure such failings do not occur in the future.'' *Id.* In addition, the ALJ noted that Eric Grider (Respondents' owner's son and the pharmacist in charge at Grider #2) testified that ''Respondents had not implemented any operational or policy changes in response to this proceeding,'' and that even after the service of the first Show Cause Order, Respondents had continued to violate 21 CFR 1306.04(a) by failing to fulfill their corresponding responsibility to not dispense unlawful prescriptions. *Id.* at 95–96. Finally, the ALJ rejected Respondents' contentions that the violations proved by the Government were ''so minor and understandable in pharmacies doing extensive filling of controlled substances that those violations are insufficient * * * to justify suspension, revocation and/or denial of'' their registrations. *Id.* at 96. The ALJ thus recommended the revocation of Respondents' registrations and the denial of their pending applications. *Id.*

Respondents filed exceptions to the ALJ's decision.[7] Thereafter, the ALJ forwarded the record to me for final agency action.

Having considered the entire record, I adopt the ALJ's conclusions of law with respect to factors two and four, as well as her ultimate conclusion that Respondents have committed acts which render their registrations inconsistent with the public interest.[8] I also adopt the ALJ's legal conclusion that Respondents have not rebutted the Government's *prima facie* case. I therefore also adopt her recommended order. I make the following findings.

**Findings of Fact**

*Respondents' Registration and License Status*

Respondent Grider Drug #1 is the holder of DEA Certificate of Registration AG3498347, under which it was authorized to handle controlled substances at the registered location of 539 Main St., Russell Springs, Kentucky. GX 1. While this registration was due to expire on September 30, 2005, on August 23, 2005, Respondent filed a renewal application. GX 2. According to an affidavit of an official in charge of the DEA Registration Unit, upon filing this application, Respondent was authorized to continue dispensing controlled substances until the issuance of the immediate suspension order on June 22, 2010. *Id.* I therefore find that Grider Drug #1 has both a registration and an application currently pending before the Agency.

Respondent Grider Drug #2 formerly held DEA Certificate of Registration AG9715751, which authorized it to handle controlled substances at the registered location of 124 Dowell Rd., Russell Springs, Kentucky. GX 3. The expiration date of this registration was September 30, 2008, and Respondent did not file a renewal application until September 25, 2008. GX 4. According to an affidavit of the official in charge of the DEA Registration Unit, upon filing this application, Respondent was authorized to continue dispensing controlled substances until the issuance of the immediate suspension order on June 22, 2010. However, while the official's affidavit states that this was timely renewal application, *id.,* it was not because on October 30, 2007, the instant Order to Show Cause was issued to Grider #2, and under the Agency's regulation, when an Order to Show Cause has been issued to a registrant, the registrant must submit its renewal application ''at least 45 days before the date on which the existing registration is due to expire'' in order for its registration to be continued pending the issuance of the final order. 21 CFR 1301.36(i). Accordingly, I find that Respondent Grider Drug #2's registration expired on September 30, 2008. However, Respondent's Grider Drug #2's application is pending before the Agency. *See Paul H. Volkman,* 73 FR 30630, 30641 (2008), *pet. for rev. denied* 567 F.3d 215 (6th Cir. 2009).

The record contains evidence that Leon Grider, who is the pharmacist-in-charge at Grider Drug #1, owns both pharmacies. However, there is also some evidence that other Grider family members own shares in the pharmacies.

*The Substantive Allegations*

In the initial Show Cause Order, the Government raised a plethora of allegations. ALJ Ex. 1. These allegations included, *inter alia,* that:

(1) Grider #1 and #2 had refilled schedule II controlled substances seventeen and eight times respectively, in violation of 21 CFR 1306.12;

(2) Grider #1 and # 2 had refilled prescriptions for schedule III–V controlled substances without the prescribing physician's authorization fifty-seven and seventeen times respectively, in violation of 21 CFR 1306.21(a);

(3) Grider #1 and #2 filled prescriptions bearing invalid or expired DEA registration numbers 186 and 161 times respectively, in violation of 21 CFR 1306.05;

(4) Grider #1 refilled prescriptions for schedule III and IV controlled substances more than six months after the date of the original prescription, in violation of 21 CFR 1306.22(a);

(5) Grider #1 and Grider #2 engaged in the unauthorized transfer of prescriptions and prescription refills from Grider Drug Key Village 289 and 40 times respectively, in violation of 21 CFR 1306.25(a); [9]

(6) data from the Kentucky All-Schedule Prescriptions Electronic Reporting System (hereinafter, KASPER) show that Grider #1 had filled schedule III–V prescriptions for which it could not produce the actual prescription in nine instances, in violation of 21 CFR 1306.21(a);

(7) Grider #1 and #2 failed to take and maintain a biennial inventory, as required by 21 CFR 1304.11(c);

(8) ''[a]n accountability audit of 50 controlled substances covering [the] period of May 31, 2003 to August 19, 2004, revealed a shortage of 22,219 dosage units of controlled substances'' at Grider #1 and 105,913 dosage units at Grider #2;

(9) Grider Drug #1 ''filled four controlled-substance prescriptions which incorrectly listed Grider Drug #2 as the 'issuing physician' and that Grider #2 filled several schedule II controlled-substance prescriptions which listed itself as the physician, in violation of 21 CFR 1306.05(a); and

(10) Grider Drug #1 and Grider Drug #2 engaged in 133 unauthorized

[7] Respondent's Exceptions have been thoroughly considered and are discussed throughout this decision.

[8] The ALJ's factual findings comprise 270 paragraphs, many of which contain multiple findings. As explained below, I adopt some of the findings and reject others for a variety of reasons. For example, the ALJ made extensive findings based on KASPER data and reports only to ultimately conclude that the KASPER data and reports were not admissible. *Compare* ALJ at 49–54, *with id. at* 91–92. However, because I conclude that the ALJ correctly held that the KASPER data were not admissible, and cannot be disclosed other than in accordance with the KASPER statute, she should not have made these findings. The ALJ also made extensive findings as to the result of a Government audit of Respondents' handling of controlled substances which was performed by a new Diversion Investigator. *Id.* at 59–63. However, the Government did not rely on this audit, and its lead witness candidly acknowledged that the audit was flawed. Because these findings are not probative of any issue in the case, they should not have been made. Other findings of the ALJ are discussed throughout this opinion.

[9] The Show Cause Order also alleged that Grider Drug Key Village engaged in 139 unauthorized transfers of controlled substance prescriptions and refills from Grider Drug #1 to Grider Drug Key Village and 150 unauthorized transfers of prescriptions and refills from Grider #2 to Grider Drug Key Village. ALJ Ex. 1, at 3–4.

transfers of prescriptions and prescription refills between themselves, in violation of 21 CFR 1306.25(a). *Id.* The Government raised additional allegations in its Pre-Hearing Statements, as well as in the Immediate Suspension Order. ALJ 21.

*The Admissibility of KASPER Data*

With respect to most of these allegations, a principal component of the Government's proof was reports and/or data contained in reports which were obtained by law enforcement personnel from the State of Kentucky's KASPER system. Notwithstanding Respondents' repeated objection to the use of this data on various grounds, the ALJ relied on it to make numerous findings regarding the allegations that Respondents had filled prescriptions under expired, invalid, or surrendered DEA numbers, that Respondents listed themselves as the prescribing physician in numerous instances, that Respondents refilled schedule II controlled substance prescriptions, that Respondent dispensed prescriptions without retaining a hard copy of them, and that Respondents dispensed refills of prescriptions for schedule III–V drugs which were not authorized. ALJ at 49–54. However, in her conclusions of law, the ALJ noted that Respondents also challenged the admissibility of the KASPER reports, and held that under Kentucky law, a court order is required for the reports and the data contained therein to be admissible in this proceeding. ALJ at 91 & n.46 (citing Ky. Rev. Stat. § 218A.202(8); *Sangster* v. *Kentucky Bd. of Med. Lic.,* 2010 WL 4294213 (Ky. Ct. App. 2010)).[10]

In its post-hearing brief, the Government argued that in several previous proceedings, the Agency's final orders had relied on KASPER data in making various findings. Gov. Br., at 101. *See Paul Volkman,* 73 FR 30630, 30633 (2008). However, as the ALJ recognized, the admissibility of KASPER reports and data has not been previously challenged in a DEA proceeding.

Under Kentucky law, KASPER data may only be disclosed ''to persons and entities authorized to receive that data under this section. Disclosure to any other person or entity, including disclosure in the context of a civil action where the disclosure is sought either for the purpose of discovery or for evidence, is prohibited unless specifically authorized by this section.'' Ky. Rev. Stat. § 218A.202(6). The statute authorizes disclosure of KASPER data to eight categories of persons or entities, including: (1) ''[a] designated representative of a board responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other person authorized to prescribe, administer, or dispense controlled substances and who is involved in a bona fide specific investigation involving a designated person''; and (2) a certified peace officer of a State, ''or a federal peace officer whose duty is to enforce the laws of this Commonwealth, of another state, or of the United States relating to drugs and who is engaged in a bona fide specific investigation involving a designated person.'' *Id.*

However, ''[a]uthorized users must apply for an account'' and provide appropriate proof of their identity and credentials. RX 42, at 20. Most significantly, applicants must also execute an account use agreement pursuant to which they agree that access to KASPER ''is granted only with the authority and rights allowed under KRS 218A.202,'' as well as ''to use the reports only in manners set forth under KRS 218A.202.'' RX 52, at 1. *See also* Tr. 179 (testimony of supervisory DI: ''We have an account with KASPER and in order to get that account we had to apply to KASPER and get all our information notarized and then approved by the Cabinet for Health Services.'').

The KASPER statute further provides that ''[a] person who receives data or any report of the system from the cabinet shall not provide it to any other person or entity except by order of a court of competent jurisdiction and only to a person or entity authorized to receive the data or the report under this section, except'' when done pursuant to three exceptions, none of which apply here. KRS § 218A.202(8). While one of these exceptions provides that ''[t]he Department for Medicaid Services may submit the data as evidence in an administrative hearing held in accordance with KRS Chapter 13B,'' an Opinion of the Kentucky Attorney General explains that:

> The fact that the General Assembly deemed it necessary to make a special exception for Medicaid hearings indicates that administrative hearings, in general, were not contemplated as a permissible forum for disclosure of KASPER data. We must therefore conclude that data from the KASPER system cannot, without a court order, be used as either documentary or testimonial evidence in an administrative hearing before the Board of Medical Licensure. Any drug transactions at issue in the hearing must be proved from other sources.

5 Op. Ky. Att'y Gen. 7, at 6 (2005). However, as the Kentucky Attorney General further explained, ''there is no 'fruit of the poisonous tree' doctrine associated with KRS 218A.202, which would make the use of the KASPER information as a starting point for seeking confirming evidence into the equivalent of a 'disclosure.' '' *Id.* at 7.

More recently, the Supreme Court of Kentucky has held that the KASPER statute creates an evidentiary privilege, which fosters important objectives, even if it is not absolute. *Commonwealth Cabinet for Health and Family Services* v. *Chauvin,* 316 SW.3d 279, 288 (Ky. 2010). In *Chauvin,* the Kentucky Supreme Court further explained that the statute's exceptions which permit disclosure ''are rather limited and do not undermine the general prohibition on disclosure.'' *Id.*[11]

Here, while there is no argument that DEA Investigators were authorized to obtain KASPER data to pursue their investigation, they agreed, as a condition of obtaining this data, to use the reports only in the manners permitted under Kentucky law. However, as explained above, with the exception of a state Medicaid proceeding, Kentucky law does not authorize disclosure of this information in an administrative proceeding without a court order. Because DEA Investigators did not obtain a court order authorizing the use of the KASPER data in this proceeding and agreed to use the reports and data only as authorized by Kentucky law, the reports and data contained therein were not admissible.

Accordingly, the ALJ should not have made any findings based on them. However, where DEA Investigators merely used the KASPER reports and data as an investigative tool to facilitate the search for other evidence which establishes violations on the part of Respondents, that other evidence is admissible. Accordingly, I turn to whether the various allegations set forth above are supported by substantial evidence.[12]

[10] Given the ALJ's conclusion that this evidence was not admissible, it is perplexing that the ALJ made numerous factual findings relying on this evidence.

[11] Under 21 U.S.C. 876(a), the Attorney General is authorized to ''require the production of any records * * * which the Attorney General finds relevant or material to'' an investigation under the CSA. This case does not, however, present any question as to whether the CSA preempts the KASPER statute's prohibition against disclosure in a proceeding under 21 U.S.C. 824(a).

[12] The Government also introduced data from the DEA ARCOS system to show Respondents' purchases of oxycodone and hydrocodone in various years and compare them with the average purchases of pharmacies in the local area, the State of Kentucky, and United States. However, while some of the figures show that Respondents were purchasing greater quantities than the average of the pharmacies in these categories, some of the data shows the opposite. And while the hydrocodone

*Allegation One—Refilling Schedule II Controlled Substances*

The Controlled Substances Act explicitly prohibits the refilling of a schedule II controlled substance. *See* 21 U.S.C. 829(a).[13] With respect to Grider #1, the Government produced copies of fifteen schedule II prescriptions which it alleged were refilled. GX 13. However, with respect to many of these prescriptions, the DI testified (and/or the copies of the prescriptions include a handwritten notation) that his finding was based on his review of the KASPER report. Tr. 357–371; GX 13, at 3, 7, 9, 15, 17, 19. In another instance, the DI identified two prescriptions for OxyContin issued to a patient on December 20, 2002 (with a fill date of 1/30/03) and February 13, 2003. GX 13, at 5–6; Tr. 361. However, when questioned regarding these prescriptions, the DI testified that ''I made no annotations. I don't think I saw anything really wrong with these two.'' Tr. 361. And with respect to other prescriptions in this exhibit (*See* GX 13, at 11–14), the DI offered no explanation at all as to why they were included. Tr. 364–65.

The Government's Exhibit with respect to Grider #2's refilling of schedule II drugs contained thirteen prescriptions (two of which were actually for Lortab, a schedule III drug, and Xanax, a schedule IV drug). *See* GX 15. Here again, the Government's contention that Grider #2 refilled the schedule II prescriptions was based on inadmissible KASPER data. Tr. 418–35 (DI's testimony at Tr. 427: ''[a]ll the prescriptions and the annotations [in GX 15] were done in comparing and contrasting with KASPER.''). In addition, with respect to the first prescription contained in this exhibit (which was for a schedule II drug), the DI acknowledged that the prescription had not been refilled. *Id.* at 420. Instead, the DI's concern was prompted by the fact that the KASPER report indicated that it had been filled on a Sunday, when the pharmacy was closed. *Id.* Even if this fact was adduced by admissible evidence, by itself, it would not constitute substantial evidence of any violation of the CSA.

However, another document in this exhibit is a copy of a label for a hydrocodone prescription. GX 15, at 4. Consistent with the annotation on this document, the DI testified that during a 2004 search of Respondents, Investigators did not find either a hard copy (*i.e.,* a prescription signed by the prescriber) or a called-in prescription. Tr. 422. Rather, the only document found by the Investigators was the label. *Id. See also* Tr. 468–74 and GX 39, at 4 (dispensings for Duragesic (fentanyl) and Roxicet filled on April 8, 2003 to patient LC). As explained more fully below, this evidence does constitute substantial evidence of a violation of the CSA, which prohibits the dispensing of controlled substances by a pharmacist without a prescription. *See* 21 U.S.C. 829(a) (schedule II) & (b) (schedules III & IV).

The DI also testified to a split distribution of a prescription for 15 Duragesic patches, noting that ten of the patches had been dispensed initially and the remaining five had been dispensed eight days later and that this was ''an instance where it seems the pharmacy didn't have enough in stock.'' Tr. 426. However, once again, this allegation was based on inadmissible KASPER data and no other evidence establishes that the prescription was dispensed in this manner.

*Allegation Two—Refilling Schedule III Through V Prescriptions Without Authorization of the Prescriber*

As noted above, the Government alleged that both Respondents dispensed numerous unauthorized refills of schedule III through V controlled substances. However, the documentary evidence with respect to Grider #1 included only four prescriptions (two for hydrocodone combination drugs, and two for Ambien (zolpidem)); with respect to Grider #2, the evidence included only six prescriptions (three for Xanax, one for diazepam, and two for Lorcet (hydrocodone)). *See* GXs 14 & 16. In addition, the Government offered the testimony of its lead DI and Dr. CS and two exhibits regarding Grider #1's dispensing of multiple refills for Dr. CS's patient BW. *See* GXs 30 & 31.

As for the prescriptions contained in GX 14 (Grider #1), once again the DI relied on the KASPER data in concluding that Grider #1 had dispensed unauthorized refills. GX 14, at 1–2. As for the Grider #2 prescriptions, the first prescription found in GX 16 (a Xanax prescription to BP, which authorized no refills) was the subject of the DI's concern because while both the prescription and the label were dated June 5, 2003, KASPER data indicated that it was filled eighteen days later. GX 16, at 1–2. However, there is no contention that the KASPER data shows that the prescription was filled on both dates, and thus, even if this data was admissible, it would not establish that this was an unauthorized refill as there is otherwise no indication that this prescription was filled more than once.

The DI further asserted that per KASPER records, a June 18, 2003 prescription for Xanax issued to JB, which authorized no refills, was filled on both June 18 and June 19, 2003. *Id.* at 3. Once again, the Government produced no other evidence to prove its allegation.[14] However, the Government did produce a copy of a label for a Xanax prescription which was dispensed on March 12, 2003 to JB. *Id.* at 6. According to the DI's testimony (and a notation on the copy), Investigators could not find either the original signed prescription or a called-in prescription for this dispensing. *Id.;* Tr. 442.

Also included in this exhibit were two prescriptions for 30 Lorcet (TID, a 10-day supply), with no refills, which were dated December 24, 2002, and January 3, 2003, as well as labels indicating that the prescriptions were filled on December 31, 2002 and January 6, 2003. GX 16, at 7–8. Next to the signed prescription which is dated January 3, 2003, is the handwritten notation: ''Script filled 1–6–2003, just one (1) day after refilling script above!'' *Id.* at 7. However, the Government elicited no testimony from the DI explaining the basis for this statement. Tr. 441–44. Here again, this does not constitute substantial evidence of the allegation.

However, the evidence also shows that on June 6, 2007, Dr. CS issued a prescription for 91 Lortab 7.5/500 to BW, with no refills, with instructions to take a decreasing dose of the medicine at two-week intervals and then stop. GX 30, at 1. The evidence further shows

data generally shows that Respondents purchased more than the average pharmacy in each of the three categories, no further evidence was offered to explain the statistical significance of Respondents' purchases. Moreover, in its brief, the Government offered no further explanation as to what this evidence proved.

[13] However, under a DEA regulation promulgated several years after the prescriptions at issue here, a practitioner ''may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substances provided'' that several ''conditions are met,'' including that the ''practitioner provides written instruction on each prescription * * * indicating the earliest date on which a pharmacy may fill each prescription.'' 21 CFR 1306.12(a).

[14] This page of GX 16 also includes a March 26, 2003 prescription for Xanax with no refills issued by the same physician to JB and a copy of the prescription label which bears the date ''03/26/03.'' GX 16, at 3–4. No contention was made that this prescription was improperly refilled. In addition, the exhibit contains an August 14, 2003 prescription for diazepam issued by a Dr. JE with two refills, and a label for the dispensing which is dated ''09/16/03.'' *Id.* at 5–6. Here again, no contention was raised that this prescription was improperly refilled.

that the prescription was dispensed on the date of issuance. *Id.*

Dr. CS testified that in 2006, she instituted a policy that her staff was not authorized to call in refills because she had received two phone calls from pharmacies that patients were ''masquerading as [her] office staff, trying to obtain * * * Lortab.'' Tr. 3031–32. Dr. CS further testified that on June 6, 2007, BW had wanted to get off of Lortab and that the prescription she wrote was to taper BW off of the drug. Tr. 3050–52, 3056.

According to the evidence, another doctor had run a KASPER on BW and upon noticing that she was getting Lortab refills, contacted Dr. CS regarding the refills. GX 30, at 2. On November 9, 2007, Dr. CS's Office Manager (LBB) then called Grider #1 and spoke with Leon Grider regarding the refills and documented this conversation in BW's medical record. Tr. 3040, 3054–55. According to the note:

He [Leon Grider] stated that the DEA has the original prescription and he would contact them to fax it to us. He also stated that Richard Potters filled the original prescription and it showed 0 refills. He said someone from our office must have called in refills. The last one filled was on 10/18/07. I informed him that we do not call in controlled's-which is stated in our policy. We also discussed that controlled's prescribed from our office are not to be refilled earlier than one day.—lbb

GX 70.[15] Dr. CS further testified that no one from her office had called in refills for BW. Tr. 3055–56. Dr. CS subsequently filed a complaint with the State Attorney General regarding the refills.[16] *Id.* at 3056.

While the note recorded by Dr. CS's Office Manager is hearsay, I conclude that it is sufficiently reliable to constitute substantial evidence. Leon Grider's statements establish that he did in fact refill Dr. CS's prescription and constitute an admission. While that statement was made to Dr. CS's Office Manager, it was recorded in the patient's medical record, a source of evidence which the Supreme Court has long recognized as inherently reliable. *See Richardson* v. *Perales,* 402 U.S. 389 (1971). Moreover, Leon Grider did not testify and refute this evidence. Thus, this allegation is proved without resort to the KASPER data.[17]

[15] Dr. CS testified that GX 70 ''are notes that I made from my chart records concerning the patient who had brought complaints to me about discrepancies or discrepancies that we found during their visits, and also [a] note about one patient who actually had unauthorized refills.'' Tr. 3040.

[16] Respondent's star witness was James Faller, a federally convicted swindler and money launderer, *see* GXs 79 (judgment of conviction) & 80 (opinion of the Eleventh Circuit denying appeal), who was allowed to sit in on the entire proceeding as a representative of Respondents and then testify regarding the various allegations. Faller asserted that Dr. CS ''was in some kind of trouble'' and ''was under some kind of investigation'' because her prescription pads had been stolen and that these were used to obtain controlled substances which were used by employees of the call center Faller ran. Tr. 5508. He then maintained that he had evidence to contradict Dr. CS's testimony, stating ''we have the records of what actually took place, not only the state's records, and her records and the pharmacy records. And they contradict that.'' *Id.* at 5509. As was typically the case throughout his testimony, Faller's bark was stronger than his bite, as notwithstanding his statement, Respondents produced no such records.

While Faller's felony conviction does not render him incompetent to testify, there is ample reason to reject nearly all (if not all) of his testimony as incredible. According to Faller, his legal troubles which led to the federal convictions began back in 1993, when he had ''blown the whistle'' on his boss, who was purportedly stealing from various people to fund the PKK, a terrorist organization, and that his boss was doing this ''on behalf of the United States Government.'' *Id.* at 5519. Faller claimed that following this, threats were made on the lives of his attorneys; that he was falsely incarcerated; that shortly before he was indicted on the money laundering and fraud charges, an FBI agent had ''contacted my attorneys and I [sic] * * * and said [that] if I wouldn't shut up and go away, if I wouldn't pay him money he would destroy my life.'' *Id.* at 5521. According to Faller, following this, the FBI ''had [his] car stolen in Europe''; caused his daughter to be ''sexually assaulted,'' by tampering with a custody dispute he had with his ex-wife, *id.* at 5523 & 5540; ''threatened to rape and murder my wife and cut the baby out of her stomach,'' *id.* at 5523; then ''were going to try to shoot'' him; and tried to kill his attorney and her husband by running them off the road. *Id.* at 5526–27.

Faller also alleged that upon moving to Russell Springs in April 2001 to run a call center, he developed new legal troubles because both the Police Chief and the Commonwealth Attorney ''wanted me out because we were knocking down * * * drug problems'' by ''start[ing] mandatory drug testing for all the employees.'' *Id.* at 5011. Faller then claimed that the Police Chief and Commonwealth Attorney had interfered with his efforts to address Russell Spring's drug problem because the Police Chief was ''a part of it.'' *Id.* at 5569. As for why the Commonwealth Attorney also ''wanted [him] out,'' Faller stated this was because he had ''raised so much cane all across the board'' with the Commonwealth Attorney, *id.,* even though he had only recently moved to Russell Springs.

Faller further testified he had filed a lawsuit alleging public corruption against the Police Chief, the State Police Detective who investigated the Respondents, and other officials of Russell Springs, and ''got the grand jury fired up,'' but that the grand jury ''actually had convicted drug dealers on'' it and that ''[i]t was incredible what they did to tamper with'' it. *Id.* at 5570. He then claimed that ''there would have been indictments,'' but that the State of Kentucky moved to stop them by bringing in a KBI [Kentucky Bureau of Investigation] Agent (Agent Dudinsky), who had assisted in executing the 2007 state search warrants at Respondents; he also claimed that ''[t]hey immediately removed the foreperson of the grand jury'' and replaced him/her with DB, who he alleged was a drug dealer associated with the Police Chief. Faller asserted that the Police Chief and the KBI agent ''were using a cell phone to eavesdrop on the grand jury,'' *id.* at 5574, and that he was going to be held in contempt by the state judge, R. Cletus Maricle, who was supervising the grand jury, because he found this out, but that the FBI arrested Judge Maricle and charged the Judge with various crimes of which he was eventually convicted. *Id.*

However, a report issued by the Grand Jury states that it believed that the KBI Agent ''ha[d] very efficiently carried out our instructions in investigating the matter we have asked him to investigate,'' that he had provided ''able assistance,'' and that he ''ha[d] been unfairly vilified for simply doing his job.'' GX 85, at 2–3. The Grand Jury further stated that the original foreperson ''was excused due to illness.'' *Id.* Moreover, the Grand Jury report was signed by its foreperson, whose name was not DB. *Id.* at 3. Apparently the Grand Jury did not return any indictments as, in Faller's words, ''[i]t was another one of these whitewashing grand juries.'' Tr. 5104. Faller further claimed that he had been asked by the FBI and U.S. Attorney to prepare ''an aid in sentencing Judge Maricle, which [he] did,'' (which seems rather strange given his past history with the FBI) and that he said ''in the sentencing memorandum'' that Judge Maricle ''was involved in the same exact conduct in Russell County to protect Chief Irvin'' as the conduct which led to his conviction. Tr. 5577.

Faller asserted the existence of still other conspiratorial acts on the part of various governmental entities. These included the Kentucky Attorney General, who ''somehow managed to get the Department of Defense * * * to ask Express Scripts to cut off Grider Drug and all insurance carriers,'' Tr. 5456; that during the 2007 search, KBI Agent Dudinsky had planted drugs in Leon Grider's office, which Faller purportedly based on a videotape he viewed but which was not presented at the hearing, *id.* at 5448–53; and then the IRS, which had recently searched Faller's home (for reasons unclear on the record), and which, following the search, ''accidentally turned over'' files that Faller had been working on for the Griders which Faller alleged had been stolen during a break-in of his home ''years ago.'' *Id.* at 5436–38.

It is further noted that much of Faller's testimony, which went on for nearly three days, was plainly irrelevant, and even when he testified regarding one of the Government's allegations, it was typically clear that he lacked personal knowledge of the allegation. *See* Tr. 5018 (Faller's testimony that he was first contacted by Leon Grider in April 2006). The ALJ ultimately ignored nearly all (but not all) of Faller's testimony, which was typically provided in a rambling narrative even when questioned by Respondents' counsel (notwithstanding the Government's objections and the ALJ's instructions), and did not even address whether she found it credible. It is perplexing that the ALJ did not exercise more control over Faller's typically irrelevant and ludicrous testimony.

[17] In his affidavit, the supervisory DI also stated that a review of the prescriptions (which was completed by November 1, 2004) issued at Grider Drug #2 and seized during the August 2004 search showed ''sixteen (16) instances of refilling a schedule III–V controlled substances [sic] prescription without authorization in violation of 21 U.S.C. 829(b) and 21 CFR 1306.21 and 1306.22.'' GX 9, at 16. These provisions require that any controlled substance, which is a prescription drug, may only be dispensed pursuant to a prescription and that ''[s]uch prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner.'' *See* 21 U.S.C. 829(b).

Noting the above statement, Government Counsel then asked the supervisory DI: ''With regard to this particular paragraph, during the course of your investigation did you come across a physician by the name of Robert Shipp.'' Tr. 436. The DI answered ''[y]es,'' and then explained that ''[i]n July of 2004, Dr. Shipp surrendered his DEA registration to us as a result of an investigation that we conducted of his medical clinic in Columbia, Kentucky, which is about a 30 minute drive from Russell Springs.'' *Id.* at 437. According to the DI,

*Allegation Three—Respondents Filled Prescriptions Bearing Invalid or Expired DEA Numbers*

Next, the Government alleged that Respondent filled numerous prescriptions that bore invalid or expired DEA numbers. While the Government submitted copies of various prescriptions which Respondent filled, *see* GXs 23 & 26; it produced no evidence that any of the DEA numbers on the prescriptions themselves were either expired or invalid. Rather, the Government's proof was based on KASPER reports submitted by Respondents which listed DEA numbers which differed from those on the actual prescriptions. *See id; see also* GX 9; Tr. 316, 321. Here again, the Government relied on inadmissible evidence to prove the violations. Accordingly, the allegation is not supported by substantial evidence.

There is, however, evidence that Respondents violated DEA regulations because, in some instances, the labels they affixed to prescriptions contained the wrong physician's name. *See* GX 26, at 1–2; 7–8; 9–10.

*Allegation Four—Grider #1 Refilled Prescriptions More Than Six Months After the Date of the Original Prescription*

In support of this allegation, the DI asserted that on four occasions between January 2003 and August 2004, Grider filled schedule III and IV controlled substance prescriptions that had been issued more than six months earlier. GX 9, at 14. With respect to Grider #1, the Government's proof was limited to the bare assertion by the DI that he had ''reviewed prescriptions seized from Grider #1, and compared and contrasted these prescriptions with prescription logs, transfer records, and KASPER reports.'' [18] *Id.* No further evidence was offered specifically identifying the prescriptions, their date of issuance, and the date on which they were refilled. Moreover, here again, it appears that this allegation was based on KASPER data.

The Government did submit an exhibit which purports to show that Grider Key Village engaged in the same practice. GX 24. Although this allegation is properly considered given the common ownership of the three pharmacies, the documentary evidence, which includes four prescriptions and four labels for refills, does not support the allegation as the dates of the refills are all well within six months of the date of the original prescriptions. *See id.* And while the exhibit contains various handwritten comments asserting that refills occurred more than six months after the original prescription was issued (two were allegedly refilled one day late), when asked by the ALJ what was the source of the information as to the refill dates, the DI testified that it came from the KASPER report. Tr. 308. Here again, the Government's reliance on inadmissible KASPER data precludes a finding that the allegation is supported by substantial evidence.

*Allegations Five and Ten—Grider #1 and Grider #2 Engaged In the Unauthorized Transfer of Prescriptions and Refills To and From Grider Key Village, as Well as To and From Each Other*

In his affidavit, the supervisory DI stated that his review of Grider #1's ''prescription logs, transfer records, and KASPER reports'' showed that there were 289 ''instances of unauthorized transfer of controlled substances [sic] prescriptions and/or prescription refills from Grider Drug-Key Village to Grider Drug #1,'' and 453 ''instances of unauthorized transfer of controlled substances [sic] prescriptions and/or prescription refills from Grider Drug #2 to Grider Drug #1.'' GX 9, at 14. The supervisory DI further testified that during the August 2004 search of the pharmacies, one of his investigators relayed information to him regarding the existence of logbooks listing prescriptions which were transferred between the pharmacies. Tr. 695–96. The supervisory DI testified that ''[t]here were two logs,'' which were provided to DEA by either Mr. Grider or another employee, and which bore on their cover, the titles of either ''Grider-Key Village transfers or Grider Drug #2 transfers.'' *Id.* at 696–97.

The DI further testified that the logs contained ''the date and the prescription that was being or had been courtesy filled.'' *Id.* at 697. Explaining the term ''courtesy fill,'' the DI gave the example of where ''the prescription was originally brought * * * to Grider #2, but for some reason or other it was * * * actually filled at Grider #1, but the records and the distribution of that filling, when you look at the KASPER and you get the actual prescriptions, is at Grider Drug #2.'' *Id.* The DI subsequently testified that the only information in the log was ''the date and the prescription number,'' and acknowledged that he determined that the prescriptions had been filled at the other pharmacy by looking at KASPER data. *Id.* at 699. However, the DI then explained that pharmacy's employees had told the Investigators that the log was used to list prescriptions that were actually filled by other pharmacies. *Id.*

The DI then added that this was not permitted under the law because while ''you can transfer a prescription from one pharmacy to the other * * * once you transfer that prescription, you can't transfer that prescription back.'' *Id.* at 701. Continuing, the DI explained that this ''is a violation'' of regulations requiring the pharmacy ''to maintain complete and accurate records of receipt and distribution'' and that this is ''what causes the skewage'' in ''the audit figures'' with one pharmacy being short of a drug and the other pharmacy having an overage.[19] *Id.* at 701–02.

*Allegation Six—KASPER Data Shows That Grider #1 Filled Nine Schedule III—V Prescriptions for Which It Could Not Produce the Actual Prescriptions*

On its face, proof of this allegation requires KASPER data for which the Government did not obtain the required court order. Accordingly, the allegation is not supported by substantial evidence.

*Allegation Seven—Grider #1 and Grider #2 Failed to Take and Maintain a Biennial Inventory, as Required by 21 CFR 1304.11(c)*

As evidence of this violation, the Government submitted the DI's affidavit. GX 9. Therein, the DI stated that he ''developed further information

''[t]he case was well publicized'' and that ''Dr. Shipp is very well known, or was very well known in the area.'' *Id.* The DI then explained that in July 2008, he had obtained a further KASPER report on the Respondents for the period of January 1, 2005 through July 7, 2008, and found that several prescriptions had been dispensed by Grider #2 under the registration number of Dr. Shipp after he had surrendered his registration. GX 18.

When the Government moved for the admission of the KASPER report (GX 18), the Respondent objected to the admission of this exhibit both because it was a KASPER report and on grounds of relevancy. Tr. 440. However, the ALJ admitted the exhibit. Even if this evidence was relevant to prove the allegation (which does not appear to have been made in either the Show Cause Order or the Government's various pre-hearing statements), here again, the Government's proof of the dispensings was based solely on an inadmissible KASPER report. The allegation is therefore not supported by substantial evidence.

[18] This statement was made in support of six different allegations which the DI raised in his affidavit. *See* GX 9, at 14.

[19] This allegation might well have been proved without introducing KASPER data (given the testimony that pharmacy employees had stated what the logs documented). However, the Government did not introduce the logbooks into the record and thus there is a lack of evidence to substantiate the number of instances in which the prescriptions were transferred.

during the execution of the * * * search warrants [on August 19, 2004] that each of the three Grider Drug locations failed to take and complete a biennial inventory as required by 21 U.S.C. 827(a) and 21 CFR 1301.11(c).'' [20] *Id.* at 13.

However, less than a month after executing his affidavit, the DI testified that he had done an audit of the three pharmacies' handling of certain drugs. Tr. 606–13. Contradicting the statement in his affidavit, the DI testified that in performing the audit, he had used Grider #1's and Grider #2's biennial inventories of May 31, 2003 as the initial inventories, and that there was no biennial inventory for Grider Drug—Key Village, ''because it wasn't required for them at that time.'' Tr. 609. Given the DI's testimony at the hearing, this allegation is not supported by substantial evidence.

*Allegation Eight—The Accountability Audits*

The Government further alleged that it had performed an audit of 50 controlled substances for the period May 31, 2003 through August 19, 2004 and that the audit ''revealed a shortage of 22,219 dosage units of controlled substances'' at Grider Drug #1 and ''105,913 dosage units of controlled substances'' at Grider Drug #2. ALJ Ex. 1, at 2–3. The evidence shows that this audit was done by a DI [21] who was a recent graduate of the Basic Diversion Investigators Course, and who told her supervisor that she ''did not have the experience'' and ''really was unsure [of] what [she] would be doing.'' Tr. 2863. According to the supervisory DI, the DI's audit was flawed because it included both invoices for Respondents' purchases and some distributions which occurred outside of the audit period. *Id.* at 607–08.

The Government did not, however, introduce this audit into evidence. Rather, it relied on a separate audit of three drugs (Xanax, alprazolam (the generic for Xanax), and methadone) which was done by the supervisory DI. GX 11. According to the DI, this audit found numerous shortages and overages, some of which would be significant if the audit was accurate. *See, e.g., id.* (finding shortages of 5,842 and 5,225 dosage units of alprazolam .5mg and 1mg respectively at Grider Drug #1 and 3,271 and 8,900 dosage units of same drugs at Grider #2, and a shortage of 3,562 and 2,786 dosage units of methadone 5 and 10mg respectively at Grider #2). However, in doing his audit, the DI used KASPER information to determine the distributions by each Respondent. Tr. 617–19. The DI did not verify the totals provided by KASPER against the individual patient information he had also obtained from KASPER. *Id.* at 619. Most significantly, in determining the quantity of the drugs that Respondents distributed, the DI did not use the pharmacies' dispensing records, even though they were required to maintain these records under the CSA and DEA regulations. *See* 21 U.S.C. 827(a)(3); 21 CFR 1304.22(c). Moreover, on cross-examination, the DI acknowledged that he had ''no idea how accurate'' the KASPER data was. Tr. 622.

Respondents put on extensive evidence challenging the DEA audits. More specifically, the evidence shows that shortly after DEA executed the August 19, 2004 search warrant, Respondents hired an entity (McDonald Group) to conduct inventories at each store on August 28, 2004. Tr. 1987–88. Respondents also hired Stivers and Associates, an accounting firm, to review the DEA audit results. Tr. 1980. David W. Hicks, CPA, who has been Stiver's Auditing Director for the past twelve years and has nearly twenty years of professional auditing experience, RX 101, at 1–2, conducted what he termed a ''consultation examination'' of Respondents. *Id.* at 3; Tr. 2009. According to Mr. Hicks, ''[a]n audit differs from our consultation examination in that our consultation examination focuses directly in one specific area and tests at 100% with available information, whereas an audit provides only reasonable assurance and sample tests available information to provide an opinion on the reliability of the information.'' RX 101, at 3; Tr. 2010.

In its report, Stivers detailed the procedures it used in conducting its examination. *Id.* at 62. For the beginning or initial inventory, Stivers used the same May 31, 2003 inventories taken by Grider #1 and #2 as DEA did in doing its audits. To determine Respondents' purchases of controlled substances, Stivers received reports directly from Respondents' suppliers and compiled a schedule for each store which tabulated the quantity purchased by drug name and strength. *Id.* at 62. In obtaining this information, Stivers also obtained credit memos for Respondents' returns of drugs to their suppliers. *Id.* Stivers then added the purchases and subtracted the returns to the initial inventory figures to determine the total amount for which Respondents were accountable (Total Accountable For). *Id.*

To determine the amount of drugs Respondents could account for (Total Accounted For), Stivers used the inventories conducted on August 28, 2004 by the McDonald Group. *Id.* at 63. With respect to outdated/expired drugs, Stivers explained that they were set aside in a separate bin apart from the pharmacies' stock until they could be disposed of, and that on September 2, 2006, Stivers inventoried the drugs that had expired prior to August 28, 2004, when the McDonald Group performed its inventory. *Id.* Mr. Hicks maintained that these drugs ''would have been removed from [the] current inventory prior to the McDonald Group's inventory'' and were thus not included in the August 28, 2004 counts. *Id.* Stivers counted a total of 2,414 dosage units of expired drugs. Tr. 2043.

As for Respondents' dispensings, Stivers tabulated the quantities for each drug ''for each location from the PC V computer software system Narcotic and Controlled Substance Drug Sales Report,'' obtaining monthly reports for the audit period for each of the fifty drugs that were initially audited by DEA. RX 101, at 63. Stivers totaled the monthly quantities for each drug to determine the total number of dosage units sold during the audit period. *Id.* Stivers then added the August 28, 2004 inventories, the outdated drugs, and Respondents' sales to determine the ''Total Accounted For'' for each drug. *Id.*

While Stivers' results demonstrate that both DEA audits were flawed (largely because the DIs used KASPER data to determine the amounts of the dispensings), they provide little comfort to Respondent because they point to massive accountability problems at each of the pharmacies. For example, at Grider #1, Stivers found that the pharmacy had the following shortages (by number of dosage units): (1) Alprazolam, 2,316; (2) Ambien, 170; (3) diazepam, 6,372; (4) Duragesic, 462; (5) Endocet, 214; (6) hydrocodone, 28,097; (7) lorazepam, 2,191; (8) Lorcet, 500; (9) Lortab, 375; (10) Valium, 40; and (11) Vicodin, 200. *Id.* at 14. Stivers also found that Grider #1 had overages in the following drugs: (1) Clonazepam, 7,568; (2) methadone, 3,025; (3) oxycodone, 1,335; (4) OxyContin, 262; (5) phentermine, 1,751; and (6) Stagesic, 514. *Id.*

At Grider #2, Stivers found that the pharmacy had the following shortages: (1) Ambien, 428; (2) Duragesic, 290; (3) hydrocodone, 8,135; (4) lorazepam, 1,253; (5) methadone, 3,207; (6) oxycodone, 1,240; (7) OxyContin,

[20] The Show Cause Order had also alleged that Grider Drug—Key Village did not take and maintain a biennial inventory. ALJ Ex. 1, at 4.

[21] To make clear, this DI did not take the closing inventories; these were done by inspectors from Kentucky Drug Control and Kentucky Board of Pharmacy. Tr. 608.

17,875; (8) phentermine, 3,203; and (9) Stagesic, 2,013. *Id.* In addition, Stivers found that Grider #2 had the following overages: (1) Clonazepam, 3,979; (2) diazepam, 2,787; (3) Endocet, 425; (4) Lorcet, 619; (5) Lortab, 342; (6) Valium, 662; and (7) Vicodin, 109. *Id.*

Moreover, even after Stivers took the figures for all three pharmacies (including Grider Key Village) to determine the combined shortages and overages, there were still substantial shortages and overages of various drugs (all figures in d.u.). The combined shortages included: (1) Alprazolam, 1,496; (2) diazepam, 7,329; (3) Duragesic, 605; (4) hydrocodone, 35,418; (5) lorazepam, 4,928; (6) OxyContin, 16,998; (7) phentermine, 2,791; and (8) Stagesic, 717. *Id.* The combined overages included: (1) Clonazepam, 31,951; (2) Endocet, 871; (3) Lorcet, 1,051; (4) Lortab, 889; (5) methadone, 15,747; (6) oxycodone, 900; and (7) Valium, 872. *Id.*

Regarding the results of his examination, Mr. Hicks testified that when all the drugs for the three stores were added up, Respondents only failed to account for an overage of 644 pills. *Id.;* Tr. 2035. He then asserted that this result is ''so minute, it's just totally immaterial.'' Tr. 2035.

This conclusion is properly characterized as ''fuzzy math,'' as contrary to Mr. Hicks' understanding, the various controlled substances which a DEA registrant handles are not fungible. Rather, pursuant to the CSA and DEA regulations, a registrant which dispenses is required to maintain ''a complete and accurate record *of each such substance* * * * received, sold, delivered, or otherwise disposed of by'' it. 21 U.S.C. 827(a)(3) (emphasis added); 21 CFR 1304.21(a). This means that each drug (including a generic (alprazolam) v. a legend drug (Xanax)), must be separately accounted for. Moreover, ''[s]eparate records shall be maintained by a registrant for each registered location.'' 21 CFR 1304.21(a). As Mr. Hicks' examination demonstrated, both Grider #1 and Grider #2 had numerous material shortages and overages of the controlled substances they handled.[22]

*Allegation Nine—Grider Drug #1 Filled Four Controlled Substance Prescriptions Which Listed Grider Drug #2 as the Issuing Physician and Grider Drug #2 Listed Itself as Issuing Physician On Several Schedule II Controlled Substance Prescriptions*

In support of this allegation, the Government offered the testimony and affidavit of the supervisory DI. *See* GX 9, at 3–11. The Government did not enter into evidence any of the prescriptions which the DI asserted listed Respondents as the prescribing physician, and the DI's affidavit makes clear that the evidentiary basis for this allegation is the data contained in KASPER reports the DI obtained on Respondents. *See id.* Because the Government produced no evidence other than the inadmissible KASPER data to prove the allegation, it is not supported by substantial evidence.

*Allegation Eleven—Respondent[s] Filled Prescriptions Issued by a Tennessee Mid-Level Practitioner in Violation of Kentucky Law*

In support of this allegation (which was raised in the Government's pre-hearing statement), the supervisory DI stated in his affidavit that the Louisville District Office ''Diversion Unit completed a * * * review of prescriptions seized on August 18, 2004 from Grider Drug #2,'' and that ''the review of these prescriptions revealed * * * [t]welve (12) instances of filling prescriptions issued by a Mid-Level Practitioner licensed in Tennessee, who is not authorized to prescribe controlled substances in Kentucky in violation of 21 U.S.C. 829(b) and 21 U.S.C. 842(a)(1) and [KRS § ] 314.011(8) and [§ ] 314.042.'' GX 9, at 16. Yet, when asked at the hearing to ''elaborate further'' on this assertion, the supervisory DI testified that ''[i]n conducting my review of the KASPER reports and of course running the DEA numbers through our system and trying to identify the prescribers, I came upon the fact that—I identified 12 prescriptions that were being filled for a nurse practitioner out of Tennessee.'' Tr. 200–01; *see also* GX 9, at 7–11 (listing KASPER data for Grider #2 including prescriptions issued by a ''TN MLP''). The DI then explained that at the time the prescriptions were filled, nurse practitioners were not authorized to prescribe drugs in Kentucky and thus the pharmacy should not have filled the prescriptions. Tr. 201.

The Government offered no further evidence establishing the identity of the prescriber and his/her licensing status. Nor, notwithstanding the DI's statement in his affidavit that he had reviewed the prescriptions, did the Government introduce into evidence the prescriptions, the pharmacy's dispensing log, or copies of the labels for the dispensed prescriptions. Indeed, given the DI's testimony at the hearing, it is unclear whether the DI based this allegation on anything other than the KASPER data. I therefore conclude that this allegation is not supported by substantial evidence.

*Allegation Twelve—Respondents Failed to Report All Thefts of Controlled Substances to DEA*

The Government put forward evidence that numerous break-ins and thefts had occurred at the Respondents and that several of them were not reported to DEA as required by federal regulations. According to the supervisory DI, he received information from Narcotics Detective with the Kentucky State Police (Scott Hammond) and the Police Chief of Russell Springs (Joe Michael Irvin), who alleged that Leon Grider was trading controlled substances for sex and ''hiding * * * the distribution[s] by reporting theft and losses for the pharmacy.'' Tr. 160. In addition to the theft and loss reports which he obtained from the Police Chief and the State Pharmacy Board, the DI also obtained from the Russell Springs Police Department a chronology of the various break-ins which had occurred at Respondents.[23] *Id.* at 162–63; *see also* GX 32.

The Government introduced into evidence an exhibit which contains sixteen police reports [24] documenting the various incidents; also included in this exhibit were a number of DEA Form 106s, a form which a registrant is required to submit to report the theft of controlled substances. *See* 21 CFR

[22] For reasons explained in my discussion of the public interest factors, I reject Respondents' exception that the Stivers' audit was not accurate and reliable as to the overages and shortages. While I conclude that the DEA audits were inaccurate, I am not required to ignore other reliable evidence in the record.

[23] It does not appear that the Government provided adequate notice of its intent to litigate this allegation in either the Show Cause Order or the Pre-Hearing Statements. However, Respondents did not object that the allegation was beyond the scope of the proceeding and that they were denied adequate notice of it. Moreover, Respondent fully litigated the issue. As judicial decisions make clear, even where the Government fails to provide notice of an allegation in the Show Cause Order or Pre-Hearing Statements, the parties, in the absence of objection, can be deemed to have litigated the allegation by consent where the parties fully litigate the issue. *See Citizens State Bank* v. *FDIC,* 751 F.2d 209, 213 (8th Cir. 1984) (citing *Kuhn* v. *Civil Aeronautics Bd.,* 183 F.2d 839, 841–42 (D.C. Cir. 1950)); *Yellow Freight System, Inc.,* v. *Martin,* 954 F.2d 353, 358 (6th Cir. 1992).

[24] While the cover of GX 33—Tab E states that it includes a report for a February 22, 2002 break-in at Grider Drug #2, the tab actually includes reports for both this break-in and a second incident, which occurred later that morning at Grider #1; however, the report for Grider #1 stated that while the store's window had been broken with a large rock, no entry was made. GX 33, Tab E, at 5.

1301.76. However, there was not an accompanying DEA Form 106 for each incident for which the police filed a report and the DI testified that on comparing the theft and loss reports which DEA had received from Respondents with the police reports, he determined that Respondents had not filed reports with DEA for some of the incidents. Tr. 169. More specifically, there were four instances in which a theft of controlled substances occurred at one of the Respondent's locations which was not also reported to DEA. *See* GX 33, at Tab E (Feb. 22, 2002 theft from Grider #2); *id.* at Tab L (Oct. 28, 2003 theft from Grider #1); *id.* at Tab M (November 2, 2003 theft from Grider #2); *id.* at Tab N (November 3, 2003 theft from Grider #2).[25]

*Allegation Thirteen—Respondents' Owner, Leon Grider, Unlawfully Distributed Controlled Substances*

In the initial Order to Show Cause, the Government alleged that in August 2005, Leon Grider had been indicted in both the Russell County and Adair County Circuit Courts on state felony charges of trafficking in controlled substances. ALJ Ex. 1, at 4. The Show Cause Order further alleged that Leon Grider had also been indicted in Russell County on charges of bribing a witness. *Id.* In its initial pre-hearing statement, the Government provided further notice that it intended to elicit testimony from Scott Hammond, a narcotics detective with the Kentucky State Police, regarding ''illicit distributions of controlled substances from'' the Respondent and various ''undercover operations.'' Gov. Pre-Hearing Statement, at 7.

As part of its case-in-chief, the Government called Detective Hammond who testified regarding the decision to initiate undercover operations and the undertaking of the operations in the investigation of Respondents. The ALJ found Detective Hammond's testimony credible.[26] ALJ 56 at nn.22 & 23. In addition, as part of its rebuttal case, the Government called LW, who had acted as a confidential informant and who obtained controlled substances from Leon Grider on various occasions without a prescription. Notwithstanding the determined efforts of Respondents' counsel to destroy the credibility of the Detective and LW, the ALJ found their testimony credible as do I. ALJ at 56 n.52.

According to the Detective, sometime in May or June 2003, SD, a female in her early to mid-twenties,[27] was arrested by the Russell Springs Police Department on a DUI charge; at the time of the arrest, PC was her passenger.[28] Tr. 1404. A day or so after their arrests, the Detective interviewed them and asked them where they got their drugs. *Id.* at 1404–5. While they were initially ''uncooperative,'' they told the Detective that they were getting drugs from Leon Grider without a prescription. *Id.* SD agreed to cooperate and told the Detective she would see Leon Grider after the pharmacy's closing, knock on the door, go in if the door was open, ask him for controlled substances, and that most of the time he gave them to her. *Id.* at 1406. When asked what she provided in return, SD denied paying for the drugs or providing stolen property to Leon Grider. *Id.* at 1407. However, when then asked if she had sex with him, SD would neither confirm nor deny doing so. *Id.* SD also admitted that she was addicted to drugs and had previously been arrested for possession of some unidentified drug. *Id.* at 1408.

SD agreed to attempt a controlled drug buy which both the Detective and

[25] Not proved by credible evidence was Respondents' far-fetched contentions that: (1) The Russell Springs Police Chief was actually behind the break-ins because he sold alarm systems on the side and Leon Grider refused to buy one from him, and/or (2) that the Russell Springs Police Chief was behind the break-ins because he was dealing the drugs that were stolen.

With respect to the latter contention, James Faller testified that he had been called by one Bobby Bunch, who ''said that he had burglarized Grider drugs'' and that when he was caught by the police, he had ''a whole lot more [pills] than what were turned into evidence,'' Tr. 5086, and that Bunch '' had agreed to testify about what had happened to him,'' but was murdered and no one has been charged with the crime because ''[i]t was another one of these whitewashing grand juries.'' *Id.* at 5103. No further evidence was offered to corroborate Faller's testimony regarding Bunch's purported statements regarding the disposition of the drugs the police seized from him, or even that Bunch had, in fact, been murdered.

Another of Faller's incoherent tales was that Leon Grider had received a call from a prisoner Brian Lawless (which Grider purportedly had on tape, but which was not produced at the hearing), who, according to Faller, had written a letter to the Commonwealth Attorney stating ''that Leon had left money for him that was paying him to break into these stores,'' and that this letter was used to get Leon Grider indicted. Tr. 5085–86. According to Faller, Lawless had stated that he wrote the letter because the Chief ''told [him] he was going to kill [his] little brother if I didn't write them.'' *Id.* While Respondents introduced a transcript of a sworn statement given by Kevin Lawless, Brian's brother, which Faller obtained in his pursuit of his public corruption claims, the only persons present were Mr. Lawless, Faller, and Grider. RX 13. Moreover, nothing in Kevin Lawless's statement corroborates Faller's contention that Brian Lawless made up his story. *Id.* Contrary to Faller's assertion that Brian Lawless's letter was used to procure Leon Grider's indictment, the record seems clear enough that the only indictments brought against Leon Grider were based on his having unlawfully trafficked in controlled substances to LW and PG and not on conduct related to the break-ins. GXs 44, 45.

[26] The Detective acknowledged that his mother had formerly worked as a cashier at Grider #2, and that she was either fired or quit on her own after the August 2004 DEA search in which the Detective assisted. Tr. 1389, 1540, 1617–18. In addition, the Detective testified that his wife's sister was married to Greg Grider, Leon Grider's oldest son. Tr. 1388.

In an attempt to impeach Detective Hammond's credibility, Mr. Faller asserted that Hammond had threatened to have LW's children murdered, that he had gotten her thrown out of her apartment, that PG (LW's former boyfriend) had told him that he had things he wanted to share but ''was afraid for his life,'' and that Hammond had ''start[ed] harassing me [Faller] and running witnesses off the road.'' Tr. 5098.

LW testified, however, that Detective Hammond had never threatened her. Tr. 5935. Moreover, while LW testified that Detective Hammond had moved her to a safe house, he had done so at her request. *Id.* at 6131.

Respondents introduced into evidence a transcription of an unsworn interview Faller conducted of PG, during which Faller made numerous suggestive statements to PG regarding the conduct of Hammond and Irvin. *See* RX 25, at 22 (p. 51,''my guess is, what happened is, they created a crime against you, too. That's my belief.''); *id.* (''I think they've threatened you ruthlessly. I think they're telling you you're going to come up with the testimony they want you to come up with. I think that they've . . . used the kids and the threat of the kids and everything else to try to force you to go along with this stuff. * * * And I think, quite frankly, you're scared to death. * * * In fact, the * * * scared to death part I'm sure of it, because I can see it. This isn't a guess * * * you know, it's nothing against you. It's clear to me you're scared to death.''). Subsequently, PG related a conversation during which Hammond and Irvin were attempting to recruit him and LW to work as informants PG said:

Leon's got enough money. If we done something like this to him, it wouldn't be no problem for him to have us took care of. And the statement was made to me not to worry about Leon, that we'd be more or less—I think their words were, they could help us or they could hurt us, make our life easier or make our life hell, and, more or less to watch what's I'm doing. And their exact words were, that they could take us out and nobody would ever find us was their exact words.

RX 25, at 32. Faller then asked, ''In other words, they'd kill you,'' to which PG said, ''uh-huh.'' *Id.* Faller then asked: That's the way you took it?'' *Id.* PG replied: ''That was their exact words, without saying, I'm going to kill you, but just, I'll take you out and nobody will ever find you. You don't have to worry about Leon.'' *Id.* Another participant in the interview then asked PG: ''They didn't use the words, I'll kill you, though?'' *Id.* PG responded: ''No. They said you don't have to worry about Leon killing you. We can take you out, nobody will ever find you. And he would, too.'' *Id.* Later, PG asserted that ''they did threaten us with Federal charges and to hurt the kids.'' *Id.*

Putting aside the ambiguity of PG's statement as to whether his life was threatened by either Hammond or Irvin, because both Detective Hammond and LW were placed under oath and were subject to cross-examination and the ALJ found them to be credible, I reject the unsworn hearsay statement of PG as inherently unreliable.

It is further noted that Respondents did not take exception to the ALJ's finding that Detective Hammond's testimony was credible. *See generally* Respondents Exceptions.

[27] The Detective described SD as having blond hair, brown eyes, and being ''probably five-four or five-five,'' and ''115 or 120 pounds.'' Tr. 1407.

[28] According to the Detective, he had first received information about SD and PC from an Investigator with the State Pharmacy Board and had discussed them with Chief Irvin of the Russell Springs Police Department. Tr. 1403.

the Police Chief (Joe Michael Irvin) observed; however, upon SD's going to Grider #1, the door was locked and she was unable to get in. *Id.* at 1409–10. After debriefing SD, who said that Grider would answer the door, the Detective went to SD's apartment complex to do surveillance (which was ''right down the road'' from Grider #1) and the Police Chief watched the back of Grider #1. *Id.* at 1410. Shortly after he arrived at SD's apartment complex, the Detective was called by the Chief and told that Grider had left the store and was carrying something. *Id.* The Detective returned to Grider #1, picked up the Chief, and the two observed Leon Grider go to his house, stay a few minutes and then leave. *Id.* at 1411–12. The Detective and Chief then watched Grider drive to a ''community called Salem,'' where he met up with a red Jeep that was behind a church. *Id.* at 1412. A woman got out of the Jeep and entered Grider's car. *Id.* at 1415. After fifteen minutes, Grider and the Jeep departed; the Detective and Chief followed the Jeep to a ''community called Eli'' and obtained its license plate number, which was traced to a female, PL. *Id.* at 1412.

Either the next day or the day after, the Detective and the Chief went to PL's residence and asked to speak with her. *Id.* at 1413. PL did not want to do so at her residence, but agreed to meet the officers at the Russell Springs Police Department, where she was interviewed. *Id.*

During her interview, PL admitted that Leon Grider had brought her both Xanax and hydrocodone, for which she did not have a prescription. *Id.* at 1414–15. When asked what she was doing in Grider's car, PL admitted to ''just messing around,'' but when asked to define what she meant, she stated ''let's just leave it at that. We were just messing around.'' *Id.* at 1415. While PL said that she also received methadone prescriptions from a physician, *id.*at 1418–19, she further stated that she had gotten controlled substances from Leon Grider both with and without a prescription, *id.* at 1416, and that when she had a prescription, she would ask for some extra. *Id.* at 1418.

PL agreed to act as a cooperating witness, and was approved by the Detective's supervisors; her background check did not reveal any felonies. *Id.* at 1416. On October 21, 2003, PL obtained a methadone prescription and met with the Detective on the outskirts of town, where she was searched, interviewed, had a transmitting/recording device placed on her, and was driven to Grider #1. *Id.* at 1419–20. PL entered the pharmacy, spoke with Leon Grider, and asked him to come out from behind the counter and into an aisle, where she gave him her methadone prescription and said that she ''need[ed] some Zs,'' street slang for Xanax. *Id.* at 1420–21.

Leon Grider did not say anything and went back behind the counter and filled PL's methadone prescription. *Id.* at 1420. PL left the pharmacy and had a smoke, while standing around its back entrance. *Id.* PL then re-entered the pharmacy and came back out with a white bag; PL was then picked up by the Detective, and after being searched, gave him the bag. *Id.* at 1420–21. Upon opening the bag, the Detective found a pill bottle containing methadone, as well as ''thirty orange, oval-shaped pills that were loose in the bottom of the bag.'' *Id.* at 1421. The Detective gave PL the methadone and placed the other pills in evidence bags, which he turned in to the Kentucky State Police; the orange pills were subsequently tested by the lab and determined to be Xanax. *Id.* at 1421–22. PL was debriefed and confirmed what the Detective heard through the transmitter; she was then allowed to leave. *Id.* Detective Hammond further testified that PL did not have a prescription for the Xanax. *Id.* at 1422. PL was used to obtain drugs only this one time. *Id.*

In either late November or early December 2003, the Detective received a phone call from SD, who stated that she had been at ''the Manor,'' a Government housing project in Russell Springs and had seen Leon Grider there. *Id.* at 1423. SD also stated that LW was receiving hydrocodone from Leon Grider. *Id.*

Upon receiving this information, the Detective interviewed LW, who initially denied that she received controlled substances from Leon Grider. *Id.* at 1424. However, LW then admitted ''that she was getting controlled substances from'' Grider. *Id.* During the interview, LW admitted that she had obtained hydrocodone, Xanax, and alprazolam from Leon Grider, both with and without a prescription; she also told the Detective that she believed she could get more drugs from him without a prescription. *Id.* LW, who was then in her early twenties,[29] denied trading either money or sex for the drugs. *Id.* at 1426.

While during the interview, LW agreed to perform undercover transactions for the Detective, sometime in December 2003, she then told Leon Grider about her having been contacted by the Detective, that the police knew what was going on, and that she was ''scared to death.'' *Id.* at 1427, 1435. Grider told her she ''needed to leave the county for a little while just to let them cool off of'' her.[30] *Id.* at 6019. LW then left town and would not ''answer her cell phone.'' *Id.* at 1426. However, eventually, the Detective regained contact with LW, who told him that she had gone to Leon Grider and told Grider that the state police knew what was going on. *Id.* at 1427, 1435. LW told the Detective that Grider ''gave her some money'' and ''an undetermined amount of hydrocodone and told her to leave.'' *Id.* at 1435. LW told the Detective that she had gone to Bowling Green and Somerset, Kentucky with PG, her boyfriend. *Id.*

The Detective developed additional information showing that on six occasions beginning on December 19, 2003 and ending on January 14, 2004, Leon Grider wired a total of $2800 to PG through Western Union offices in Bowling Green and Somerset, Kentucky. *See* GX 46; Tr. 1490. In a second interview he conducted with LW in January 2004, she stated that Leon Grider ''told her to leave town and stay from us.'' *Id.* at 1489.

On some date not specified in the record, LW agreed again to work as a cooperating witness and was signed up to do so.[31] Tr. 1495. LW contacted Leon Grider and said she needed to see him; Grider told her to come to Grider #1 before it opened on February 24, 2004. *Id.* Before LW went to the store, she was searched, a recorder was placed on her, and she was given instructions. *Id.* The Detective followed LW and PG to the store; upon their arrival, LW, accompanied by PG, went inside and told Leon Grider that they were going to court and were ''short on their pills'' and were concerned that they would be subjected to a pill count.[32] *Id.* at 1495–96. Grider gave them 40 hydrocodone tablets and 40 alprazolam tablets in two pill bottles, which LW brought to the Detective. *Id.* at 1496. LW did not have a prescription for the drugs. *Id.* at 1497.

On June 4, 2004, LW performed undercover transactions in both the morning and either the afternoon or evening. *Id.* at 1499; 1513–14. In the morning, the Detective drove LW, who was wearing a recorder, to Grider #1. Tr. 1515. LW went into the store and obtained Lortab and alprazolam, which

[29] The Detective described LW as being ''five-two, blond hair, blue eyes, [and] 115 pounds the last time I saw her.'' Tr. 1426.

[30] According to LW, Leon Grider never told her not to become a CI. Tr. 6020.

[31] At one point, LW testified that she was in Bowling Green for six months. Tr. 6066–67. However, other evidence suggests that she was in Bowling Green for a considerably shorter period of time. Tr. 1496; GX 46.

[32] According to the Detective, PG accompanied LW on the undercover transaction. Tr. 1498–99.

Leon Grider placed loose in a brown bag; she then got back in the Detective's car and they left the scene. *Id.; see also id.* at 6033 (testimony of LW that ''I just went in and asked him [Leon] for some pills, and he gave them to me.''); *id.* (testimony of LW that she received Lortab and Xanax at first transaction); GX 48. Notably, the pills were not placed in a prescription bottle. Tr. 6033.

As for the second set of transactions, LW and PG lived together in a trailer in Adair County, the county next to Russell County. *Id.* at 1500. LW called Leon Grider and asked him to bring some methadone to her. *Id.* During a phone call, Leon Grider explained that he needed to go to Grider #2; in a subsequent phone call, Grider told LW that he would bring some methadone to her at her residence. *Id.* Another officer followed Leon Grider to within a short distance of LW's residence, with the detective being ''just around the corner'' from LW's residence. *Id.*

Upon his arrival, Leon Grider gave LW 60 alprazolam in an envelope and 100 dosage units of methadone, which were in a sealed ''distributor's bottle.'' *Id.* at 1501. After Grider left, the Detective entered the residence and obtained the controlled substances. *Id.* LW did not have a prescription for either drug. *Id.*

On April 24, 2005, a further undercover transaction occurred. On some date not clear on the record, LW and PG contacted the Detective and indicated that they could still obtain controlled substances from Leon Grider. Tr. 1507. The Detective (along with the Police Chief) met with LW and PG, who offered to call Leon Grider and seek more drugs from him; LW and PG stated that they believed that he would give them Duragesic (fentanyl) patches. *Id.*

On the date of the transaction, LW and PG were searched and recorders were placed on them. *Id.* At 3:49 p.m., LW called Leon Grider and left a voicemail message in which she asked to meet with him; a short while later, Leon Grider returned the call. GX 27. Because Leon was going to see his mother, he agreed to meet LW (and PG) at a church graveyard on the Adair and Russell County line; the Detective and Chief observed Leon Grider arrive at the graveyard and watched the transaction from the back side of the graveyard. *Id.* at 1507–08.

The Detective used a scanner to listen to the conversation between Leon Grider, LW, and PG, during which LW asked if she could get Duragesic patches from Leon Grider. *Id.* at 1508; GX 27. Leon Grider explained what strength the patches were and that he had to go back to town to get the patches, after which he would meet LW and PG at Houchens Supermarket in Key Village. GX 27, at 3–4. However, while driving back to town, Leon Grider observed the Detective and Police Chief and called LW and PG to tell them that they were being watched; however, he still told LW and PG to go to Houchens but that he was going stay at Grider #1 for fifteen to twenty minutes. *Id.* at 4. LW passed this information on to the Detective. *Id.* Grider then told LW and PG to go to the parking lot of Houchens. *Id.*

Leon Grider returned to Grider #1. *Id.* In the meantime, the Detective also told LW to call Leon and tell him that he and the Chief were no longer around; LW did so. *Id.* The Detective and Chief switched vehicles, drove to Key Village, and parked across the parking lot from Houchens. *Id.*

Upon arriving, Leon Grider entered the store and PG went in and met him. *Id.* at 1508–09. Following a conversation, Leon Grider gave PG twenty Duragesic patches and 88 alprazolam; PG did not have a prescription for either drug *Id.* at 1509; GX 27. After PG left the store, he (and LW) met the Detective and Chief who searched them and their car; the Detective also took possession of twenty Duragesic patches and 88 Xanax pills.[33] GX 27, at 2, 4. The CIs did not have prescriptions for the drugs. *Id.* at 2.

LW testified that while she initially had legitimate prescriptions for both Lortab and Xanax, she had heard from acquaintances that Leon Grider would provide extra pills and that she noticed that she would get extra pills in her prescriptions Tr. 5911, 5915. Eventually, LW started asking Leon Grider ''if there was any way possible'' he could ''double'' her prescriptions; Grider did so. *Id.* at 5916–17. LW testified that about a year to a year and a half later, she started getting 500–1000 Lortab 10mg a week in commercial-size containers,[34] and that this continued for a period of ''about two years.'' *Id.* at 5917, 5925. LW took 50 to 60 pills a day and also sold some of them. *Id.* at 5918. According to LW, Leon Grider expressed his attraction to her and asked if he could stay at her house; however, LW denied engaging in sexual activities with him. *Id.* at 5920. LW also stated that Leon Grider had given her his cell phone number so that she could reach him without calling the store. *Id.* at 5921.

Leon Grider also told LW that some of the commercial bottles that were labeled for hydrocodone actually had pinto beans in them and were marked with either a red line or a red X. *Id.* According to LW, Leon Grider did this in the event he was robbed. *Id.* at 5921–22. LW testified that Leon Grider never gave her a hydrocodone bottle which actually contained pinto beans rather than hydrocodone. *Id.* at 5922, 6039. LW also testified that Leon Grider had told her ''not to come in the store when [his wife, Anna Mae] was around'' and that Leon Grider would leave drugs for her outside of the store in the gutter of Grider #1.[35] *Id.* at 5923, 5926–27.

LW testified that sometime probably in 2004,[36] she asked Leon Grider for some pills and Grider told her to meet him at Grider Key Village. *Id.* at 5930–31. LW parked in front of the store, knocked on the door and was let in by Leon. *Id.* at 5931. Grider gave LW a bottle with 500 pills; however, before LW could leave, Anna Mae Grider pulled up in the front and entered the store. Leon told LW to leave out the back, but the rear door was locked; LW sat in a storage room but Anna Mae came to the room, found LW, and took the pills from her. *Id.* at 5931–32. LW then left the store. *Id.* at 5932.

The next day, LW called Leon and told him that she was ''starting to detox really bad'' and asked ''if there was any way possible [she] could get that bottle back.'' *Id.* Leon told LW to meet him later, and upon meeting at Grider #1, gave her two 500-count bottles. *Id.* at 5932–33.

Anna Mae Grider also testified regarding this incident. At the hearing, Mrs. Grider asserted that the bottle contained pinto beans, Tr. 4802, and that Leon had given it to LW, who ''was in there begging for pills,'' *id.* at 4803, ''[p]robably to get her off his neck.'' *Id.* at 4804. However, in a deposition she had previously given in a civil action, Mrs. Grider testified that the bottle contained hydrocodone, that the bottle was a white bottle and not a prescription vial, and that she did not give the bottle back to LW. GX 68, at 212–15. Given the inconsistency between Mrs. Grider's testimony at the hearing and at her earlier deposition as to the contents of the bottle, I find that her deposition testimony is more credible than her testimony at the hearing. I further find that Mrs. Grider's deposition testimony corroborates LW's

[33] It is acknowledged that there is a conflict in the evidence as to the number of patches. I conclude that the conflict is not material to the resolution of this matter.

[34] LW also testified that her physician eventually stopped prescribing to her. Tr. 5928.

[35] According to LW, the gutter was at her ''head-level,'' and standing ''flat-footed,'' she could reach into it with her hand. Tr. 6042.

[36] However, LW later testified that this incident occurred before she agreed to work as a confidential informant. Tr. 6037.

testimony regarding the Key Village incident.

LW further testified that neither Detective Hammond nor Chief Irvin threatened her or threatened to take her children away from her. Tr. 5935. She also testified that neither Detective Hammond nor Chief Irvin had ever engaged in inappropriate conduct towards her. *Id.* at 5953. She further testified that neither Detective Hammond nor Chief Irvin threatened PG. *Id.* at 5936.

LW also acknowledged that she had become addicted to drugs and that she was paid $150 to $300 for each undercover transaction. *Id.* at 6046. In addition, LW ''guessed'' that her addiction had caused ''a little bit of damage'' to her brain and had caused, in the words of Respondent's counsel, ''little problems with [her] recall sometimes.'' *Id.* at 6099–6100. She further noted that it had been six or seven years since the events to which she testified. *Id.* However, LW later testified that her past drug use had no effect on her recollection of her interactions with Leon Grider. *Id.* at 6124. As noted above, the ALJ generally found LW's testimony credible as do I.[37] *See also* ALJ at 84–85.

Regarding her decision to leave Russell County upon being approached by Detective Hammond and Chief Irvin, LW testified that Leon Grider gave her $1000 and three 500-count bottles of hydrocodone and told her that she ''needed to leave town'' and ''to let them slack off of me for a while.'' *Id.* at 5939; *see also id.* at 5941–42. She also testified that when she and PG were staying in Bowling Green, Leon wired the money in PG's name because ''it would look better.'' *Id.* at 5942–43.

LW testified that in 2004, she had asked for and received a bottle of 100 methadone from Leon Grider without having a prescription. *Id.* at 5939–40. LW also testified that after she had stopped talking to Leon Grider ''as much'' and was coming off of methadone, she obtained four Suboxones from him to help her ''from detoxing.'' *Id.* at 5946. LW testified that she eventually had a seizure and woke up in an ambulance on her way to the hospital. *Id.* at 5946–47. LW further testified that she had received about twenty-five morphine [38] patches worth about $2,500 to $3,500, as well as 98 OxyContin tablets, from Leon Grider. *Id.* at 5948, 6096. Regarding her obtaining of the morphine patches, LW testified that she told Leon Grider that she needed money and was going to sell them. *Id.* at 6092.

As for the 98 OxyContin tablets, LW testified that she obtained this drug from Leon Grider before she agreed to work as a confidential informant and that she needed the drug for her addiction because she was concerned about the number of Lortab tablets she was taking and the effect of the Tylenol (acetaminophen, which is combined with hydrocodone in Lortab) on her liver. *Id.* at 6095–96. LW testified that she consumed the OxyContin in five days but did not ask Leon Grider for more because she did not think that he would provide the drug to her again. *Id.* at 6097. LW also testified that after she ''didn't have a prescription anymore,'' Leon Grider created false prescription labels so she would not ''get caught'' with the drugs if she was stopped by the police.[39] *Id.* at 6126.

In addition to the incidents involving PL and LW, the record contains substantial evidence that Leon Grider distributed controlled substances to BL without a prescription. More specifically, JD, who is BL's daughter, testified that her mother sold Suboxone (buprenorphine and naxalone) and Klonopin (clonazepam), which she obtained through prescriptions, the majority of which she filled at Grider #1. *Id.* at 3139. JD admitted that she participated in the transactions, which took place at her mother's house, by handing the drugs over to the buyer and obtaining the money. *Id.* at 3139–40. JD further testified that her mother had obtained Lortab 7.5 and Klonopin from Leon Grider without a prescription, and that while her mother initially had a prescription for the Klonopin, she had run out and yet Grider had gone to BL's house and given her more of the drug using ''the same label of the original prescription.'' *Id.* at 3142. Moreover, while JD was not present at her mother's house when Leon Grider delivered the drugs, she ''saw the medication that [her mother] didn't have a prescription for.'' *Id.* at 3173.

JD also testified that on March 15, 2006, she had spoken with Chief Irvin regarding her mother's ''slurring speech, stumbling, drunken behavior, [and] drug behavior.'' *Id.* at 3144. JD further testified that she ''had found two bottles with the same date and [that] there was another bottle of Klonopin that had been duplicated'' and that she reported this to Chief Irvin. *Id.* According to Irvin, he then met with JD who told him that Leon Grider had provided her mother with ''pills that she wasn't supposed to be getting'' when she was hospitalized. *Id.* at 3201. JD also told Irvin ''this was being done * * * with multiple pill bottles with duplicat[e] labels.'' *Id.* Irvin then told JD, who ''claimed to have'' the bottles, that if she gave them to him, he would see what he could do. *Id.* Later that day, JD called Irvin and asked to meet again; Irvin agreed and during the meeting, JD gave him the pill bottles. *Id.*

[37] Respondents took exception to the ALJ's finding that LW was credible, noting her testimony as to her drug addiction and its effect on her memory, her having admitted to selling controlled substances, as well as the incentives she had to lie about her work (such as the money she was paid for her work as a confidential informant and that she was still at risk for criminal prosecution because under Kentucky law, there is no statute of limitations for felonies). Resp. Exceptions at 11–12.

However, LW's testimony was corroborated in large part by Detective Hammond and her testimony was internally consistent. Moreover, having personally observed LW's testimony, the ALJ's finding is entitled to deference. *See Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951).

[38] LW testified that the patches were turned over to Detective Hammond and Chief Irvin. Thus, I find that this is actually the incident in which Leon Grider provided the Duragesic patches to LW. Duragesic patches actually contain fentanyl, a drug which is considerably more powerful than morphine. However, both drugs are schedule II narcotic controlled substances. *See* 21 CFR 1308.12(b) & (c).

[39] In his testimony, Faller alleged that various recordings that were made of the undercover transactions had been tampered with. Tr. 5045–64. However, Faller's testimony was (as was typical) confused and incoherent.

It is further acknowledged that Respondents submitted several affidavits of an individual who maintained that he is a Forensic Audio and Video Examiner, which were prepared for other litigation between Leon Grider and the Commonwealth and Chief Irvin. Therein, the affiant asserts that various tapes were either copies, have erasures, or were edited. RX 28. While in an affidavit (dated October 2, 2007), Respondent's Expert made reference to tapes which appear to be of the various undercover transactions engaged in by LW, even here, the affidavits fall short of establishing that any of the original tapes were altered. *See id.* at 9 (''Q–4 is a 'copy' of a video tape (not the original) of a scene behind a commercial location where an alleged transaction took place.''); (''Q–5 has been identified as a 'copy' (not the original) of a video tape with a portion of the tape as a tape over edit. I will need the original tape and proper recorder to properly determine the extent and content of the edits. (This video tape is of some sort of surveillance at a cemetery.)''). Notwithstanding that the record in this proceeding did not close for another three years, Respondents produced no credible evidence that the original recordings of these transactions had been tampered with.

Most significantly, the Government did not introduce the tapes into evidence. Nor was the Government required to as the testimony of Detective Hammond and LW, which the ALJ found to be credible, is substantial evidence that Leon Grider distributed controlled substances to LW, even though she did not have a prescription for the drugs. I thus reject Respondent's suggestion that because Detective Hammond did not actually view Leon Grider distribute the drugs to LW, the Government was required to produce the tapes. *See* Resp. Exceptions at 12–13.

I further reject the ALJ's finding that ''[t]he record casts serious doubts as to the reliability of any audio or video tapes made related to this proceeding,'' ALJ at 56 n.22, as unsupported by substantial evidence. Given that neither party introduced the tapes into evidence and the ALJ observed both Detective Hammond and LW testify and found them to be credible, this finding is both incorrect and unnecessary.

at 3202. The Government subsequently introduced into evidence photographs of two pill bottles; the bottles bear prescriptions labels for 28 Suboxone tablets under the prescription number 4439582, and list BL as the patient and a Dr. WLS as the prescriber. GX 71.

On March 18, BL called the dispatch center and the call was patched through to Chief Irvin, who was then at home. Tr. 3203. The call was recorded and played into the record; in addition, a copy of the recording was submitted into evidence. *Id.* at 3204; 3215.

During the call, BL complained that her daughter had seen Irvin ''the other day about Leon.'' *Id.* at 3215. BL further stated that her daughter had attempted to fill an outdated prescription but that Leon Grider had refused to so and that JD had told her that because Grider wouldn't fill her prescriptions, she was going to ''get him.'' *Id.* at 3216. BL accused her daughter of making up the allegations she raised with Irvin. *Id.* at 3216–17.

When BL maintained that Grider had not been giving out pills, Irvin responded: ''Well, can you explain to me why that there are bottles with your name on them, with your name on them, that are exactly duplicated, that's a violation of the law?'' *Id.* at 3217. BL replied: ''no, no, no, no, no, no, no, no,'' and in response to Irvin's follow-up question, stated: ''he has not done that.'' *Id.* After stating that he had a different view of Grider's conduct and he knew that the allegation was true, BL explained that ''[t]he only time he ever fronted me—and that was when I was in the hospital, because I missed my doctor's appointment, and he g[a]ve me a couple but he took it right back out when I came in and went to the doctor's.'' *Id.* at 3218. Asked by Irvin to explain her answer, BL then stated: ''What I mean by that is he went to the hospital. He knew I needed that medication. He knew that I was going to the doctor. And he took that back out of my prescriptions. * * * I don't see anything wrong with that.'' *Id.* BL then asserted that ''as soon as [she] got out of the hospital, [she] went to the doctor,'' and that upon filling the prescription, Grider took out ''what he had given me'' and that she did not ''see anything wrong with that.'' *Id.* When asked why she needed a pharmacist to give her medication when she was in the hospital, BL stated that she ''was getting ready to leave and * * * didn't know how quickly I could get in to my doctor.'' *Id.* at 3219. BL further asserted that Grider ''was doing this to help me out. He knew I needed the medication'' and that ''I was going to get them and that I would pay him right back.'' *Id.* at 3221.

Respondents introduced into evidence an affidavit of BL (dated April 17, 2006) which she provided in a civil action brought by Leon Grider and others against Irvin and others. RX 106. Therein, BL stated that she ''had a valid prescription for [c]lonazepam which [she] had filed [sic] at Grider Drug'' and that she had ''asked the pharmacist to provide [her with] two (2) bottles so that [she] could legally carry and possess this medication'' when she was not home as she ''did not want to carry an entire, full bottle'' on her person. *Id.* at 1. In the affidavit, BL further stated that ''Leon Grider has never provided me any prescription medications without a Doctor prescribing them.'' *Id.* at 2.

Respondents also introduced into evidence various pharmacy records including a Narcotic and Controlled Drug Sales Report (compiled from the Grider #1 pc V Pharmacy System software) listing BL's prescriptions from December 2005 through July 1, 2010, as well as copies of her prescriptions. *See* RX 121. While the sales report lists prescription number 4439582, with a date of ''01/30/06'' for Suboxone and lists Dr. WLS as the prescriber, *see id.* at 1, the exhibit does not contain a copy of the prescription. Moreover, while the sales report also lists a January 3, 2006 Suboxone prescription issued by Dr. WLS, the report indicates that no refills were authorized by it. *See id.*

Having reviewed the relevant evidence (including having listened to the recording of BL's phone conversation with Chief Irvin), I find that BL's statement in her affidavit was false. I further conclude that substantial evidence supports a finding that Leon Grider distributed Suboxone to BL on or about January 30, 2006, at which time she did not have a prescription for the drug.[40]

*Allegation Fourteen—Respondents Violated Their Corresponding Responsibility by Distributing Controlled Substance Prescription to Patients Engaged in Doctor-Shopping*

As explained above, during the course of the proceeding, the Government issued a second Show Cause Order which also immediately suspended Respondents' registrations. ALJ Ex. 21. The Order raised additional allegations that Respondents were filling controlled substance prescriptions for six patients (TA, RB, JB, JR, SR, CR), who were obtaining the prescriptions from multiple doctors, and that in doing so, Respondents were violating their corresponding responsibility because they ''knew or should have known that the * * * dispensed controlled substances were likely to be diverted or used for other than legitimate medical purposes.'' *Id.* at 2–3.

As proof of the allegation, the Government submitted exhibits showing Respondents' dispensings of controlled substances to each of these patients, which were prepared by Detective Hammond. *See* GXs 52–57. While Detective Hammond reviewed KASPER reports and developed information regarding the patients, he also subpoenaed each patient's profiles from the pharmacies, as well as his/her medical records from their doctors. Tr. 3299–301. Finally, Detective Hammond interviewed many of the prescribing physicians and/or dentists and prepared

[40] I have considered the various issues raised by Respondents to impeach both JD's and Chief Irvin's credibility. With respect to JD's credibility, I note that the ALJ repeatedly found her testimony credible notwithstanding that at the time of her testimony, she was under indictment for drug trafficking charges. ALJ at 47–48. It is further noted that BL's statement during her phone call to Chief Irvin corroborated JD's testimony with respect to Leon Grider's having distributed Suboxone to BL when she was in the hospital.

Respondents also waged an extensive assault on Chief Irvin's credibility. In her opinion, however, the ALJ cited Chief Irvin's testimony as support for her finding that BL obtained controlled substance from Leon Grider without a prescription. *See* ALJ at 48 (FoF 187 (citing Tr. 3204–05)). I also find Chief Irvin's testimony credible.

The ALJ nonetheless made several findings regarding Irvin which can only be described as gratuitous. For example, she found that ''Anna Mae Grider provided uncontested testimony concerning'' a traffic stop that Irvin made of a Grider employee (ML), which Grider alleged was done to harass ML. ALJ at 58 (FoF 227). Anna Mae Grider, however, had no firsthand knowledge of this incident and the only other evidence supporting it is an unsworn letter by ML. Thus, even if this finding would tend to show bias on the part of Chief Irvin, it is not supported by substantial evidence.

Next, the ALJ also found that ''[t]he record contains evidence of other complaints being made against Irvin'' and ''Mrs. Grider believes Det. Hammond and Chief Irvin 'have it out' for the Griders.'' *Id.* at 59 (FoFs 229 and 232).

This proceeding is neither an internal affairs review board nor an investigating grand jury such as the one which Mr. Faller got ''fired up.'' Rather, the ALJ's sole function is to make findings that are relevant and material to the allegations raised by the Government. The ALJ's findings numbers 229 and 232 are not probative of any material issue in the case.

The ALJ made a further finding based on Anna Mae Grider's testimony that following a burglary at one of the Respondents, Chief Irvin retrieved a surveillance tape at the store and that ''faces were seen on the tape,'' but that Irvin took the tape and when Mrs. Grider went to the police station to view the tape, it had been erased. *Id.* (FoF 231). However, Mrs. Grider was not present when the tape was initially viewed. Tr. 4758. Moreover, while Greg Grider (another son of Anna Mae and Leon) testified that a face was visible on the tape, the ALJ did not cite this testimony as a basis for her finding and did not make any finding as to whether his testimony was credible. Thus, as ultimate factfinder, I reject this finding.

spreadsheets for each patient listing their prescriptions, the date issued, the quantity dispensed and the number of days of supply it provided, the prescriber, and the dispensing pharmacy. *Id.*

The Government also elicited the testimony of Donald Sullivan, Ph.D.,[41] a registered pharmacist who is also a Professor of Pharmacy Practice and the Department Chair of Pharmacy Practice at Ohio Northern University. Dr. Sullivan was qualified as an expert and testified as to the standards of pharmacy practice with respect to the dispensing of controlled substances; Dr. Sullivan also prepared a report based on his review of the prescriptions issued to each of the six patients and testified as to whether Respondents dispensings violated the Controlled Substances Act. GXs 65–66, Tr. 3405, 3414–26.

To refute the Government's contentions, Respondents called Eric Grider, the son of Leon Grider and pharmacist in charge of Grider #2, as well as Tonya Moses, a pharmacist and employee of Respondents who worked at each of the stores. In addition, Respondents called each of the six patients who were accused of doctor-shopping to testify, as well as several of the practitioners who prescribed to them. Additionally, Respondents introduced various documents.

*The Expert's Testimony and Report*

The ALJ found that Dr. Sullivan credibly testified as an expert witness in the areas of the standards of pharmacy practice and the standards for dispensing controlled substances. ALJ at 25; *see also* Tr. 3402. In preparing his report, Dr. Sullivan reviewed prescriptions, a report prepared by Detective Hammond, patient profiles from the Respondents, Kentucky pharmacy regulations, and KASPER reports. Tr. 3393, 3427–28, 3429–33, 3442–43, 3497–98. However, because Dr. Sullivan clearly reviewed the prescriptions and patient profiles, the Government has established that his testimony was based on sources other than the KASPER data.

Dr. Sullivan testified that the concept of ''corresponding responsibility'' means that the pharmacist and the physician ''have a shared responsibility to make sure that each prescription is for a legitimate medical purpose.'' Tr. 3403, 3418. According to Dr. Sullivan, pharmacists are taught to question prescriptions that they may find are unlawful or suspicious. Dr. Sullivan identified the following examples of ''red flags'' which should lead a pharmacist to question the legitimacy of a prescription: (1) When a patient is obtaining controlled substances from multiple doctors, (2) when patients are being prescribed duplicate controlled substances that treat the same indications, (3) when patients seek early refills, (4) when patients obtain prescriptions for large quantities and large doses, and (5) when patients travel long distances from where they live to either the prescriber or the pharmacy. *Id.* at 3404; *see also* GX 66, at 3.

Dr. Sullivan further testified as to the obligation of a pharmacist under Kentucky law to review a patient's profile and conduct a drug utilization review (DUR) prior to dispensing a prescription. Tr. 3410. As he explained in his report:

Kentucky and federal law states that, prior to dispensing every prescription, the pharmacist shall review the patient profile (prospective drug utilization review or DUR) 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,

(i) Documented food/nutritional supplements-drug interactions.

GX 66, at 2. Dr. Sullivan further explained that over-utilization could involve ''a couple of different things,'' including ''using more than one prescription drug for the same indication'' and patients seeking refills ''too early.'' Tr. 3411. As an example of incorrect/inappropriate dosing and/or duration of treatment, Dr. Sullivan explained that ''some narcotic cough syrups * * * should only be used for a limited period of time, based on the diagnosis.'' *Id.* at 3412. And as examples of abuse or misuse, Dr. Sullivan testified ''[t]hat's where you would look for patterns of patients getting things filled too early, going to multiple doctors, traveling long distances, therapeutic duplication, just a pattern of there's something not quite right going on with how this patient is using this therapy.'' *Id.*

Regarding the statement in his report that it was ''clear that the pharmacists at the Grider Drugs did not do prospective DUR,'' GX 66, at 2; Dr. Sullivan explained that this is a legal requirement, which is ''very easy'' to comply with, as it can be done ''[j]ust by pulling up the patient profile and looking at it.'' Tr. 3413. Dr. Sullivan also testified that even though a pharmacist does not have access to a patient's medical file, the pharmacist should not simply defer to the prescribing physician and fill the prescription because the corresponding responsibility requires that the prescription be issued for a legitimate medical purpose. *Id.* at 3417–18.

Dr. Sullivan testified that when confronted with these ''red flags,'' a pharmacist can take a number of steps in response, including having an extensive conversation with the patient, calling the physician, or refusing to fill the prescription. *Id.* at 3448–49. While in some instances, a pharmacist fulfills his obligation by calling the prescriber, Dr. Sullivan testified that ''there's nothing in the law that says [pharmacists] have to fill anything,'' especially if they feel that a prescription has not been issued for a legitimate medical purpose. *Id.* at 3474–75, 3477–84. Dr. Sullivan also testified that it is a pharmacist's primary responsibility to ensure patient safety. *Id.* at 3407–08; Govt. Exh. 66, at 1.

With respect to his review of patient profiles for the six patients identified in the Suspension Order, Dr. Sullivan opined that ''these patients all exhibited multiple instances of'' several of the red flags he identified. Govt. Exh. 66, at 3. Dr. Sullivan further opined that any ''reasonable and prudent pharmacist would have caught this behavior and refused to dispense controlled substances to these patients. These are all textbook examples of drug abuse and/or drug diversion. Any reasonable and prudent pharmacist would quickly recognize this based on their education, training, and experience.'' *Id.* at 8. And in his testimony, Dr. Sullivan opined that the manner in which controlled substances were dispensed by the Respondents was not in compliance with the accepted standards of practice observed by pharmacies and pharmacists in the Commonwealth of Kentucky. Tr. 3426. A discussion of the patient-specific evidence follows.[42]

[41] Dr. Sullivan obtained his Ph.D. in Pharmaceutical Administration; he also holds an M.S. in this area and a B.S. in Pharmacy; he obtained all three degrees from The Ohio State University. GX 65. Dr. Sullivan has published dozens of articles on pharmacy practice in peer-reviewed journals, as well as several books. *Id.* In addition, he has made numerous presentations on pharmacy-related topics including state and federal pharmacy laws. *Id.*

[42] Noting the ALJ's ruling on the admissibility of the KASPER data, Respondents also contend that Dr. Sullivan's opinions ''were based almost exclusively on the prescriptions information he was provided based on KASPER report data provided him.'' Resp. Exceptions at 15. Dr. Sullivan made

Continued

**TA**

TA (GX 52) is a woman in her early to mid-thirties. Between June 19, 2009 and April 29, 2010, TA obtained thirty-four prescriptions for federally-controlled substances such as Duragesic (fentanyl, a schedule II drug); Endocet (oxycodone, a schedule II drug); hydrocodone with acetaminophen (schedule III); alprazolam and clorazepate (both schedule IV drugs); as well as eight prescriptions for carisoprodol, which at the time was scheduled only under Kentucky law but which has since been placed in schedule IV of the Controlled Substances Act. GX 52, Tab C; *see* also 21 CFR 1308.12 (listing schedule II drugs), 1308.13 (schedule III), 1308.14 (schedule IV); ALJ at 5–6 (stipulated facts); 76 FR 77330 (2011) (scheduling of carisoprodol).[43] All but three of the thirty-four prescriptions were filled by either Grider #1 or Grider #2, with all but three of the prescriptions being filled by Grider #1. GX 52, Tab B, at 3 & Tab C; Tr. 3298, 3857–3859.

TA's prescriptions were written by twelve different prescribers. GX 52, at Tab C. The prescribers included two pain clinic doctors (Dr. H and Dr. P); three dentists practicing at a clinic named Associates in Dentistry (Dr. C, Dr. S, and Dr. M); another dentist (Dr. G); two oral surgeons who did not practice together (Dr. A and Dr. H); a psychiatrist (Dr. M); and his nurse practitioner (NP W). Tr. 3844–47, 4435.

While the prescriptions written by the various dentists who treated TA were typically only for a few days' supply of hydrocodone, throughout this period TA was also receiving prescriptions from pain management doctors for thirty-day supplies of both schedule II and III drugs such as Duragesic (fentanyl), Endocet (oxycodone), and hydrocodone/apap. GX 52, at Tab C. For example, on June 19, 2009, TA received prescriptions from Dr. H for 10 Duragesic patches and 90 tablets of hydrocodone 10/500, both being a thirty-day supply. *Id.* Yet on June 24, 2009, TA received an additional twelve hydrocodone/apap from Dr. C, a dentist. *Id.* Similarly, on August 15, 2009, TA received another 100 hydrocodone 10/500 (this being a twenty-five day supply) from Dr. H, and on August 24, she received another sixteen tablets of hydrocodone from Dr. G. *Id.*

On September 4, TA obtained another prescription for 100 hydrocodone 10mg, a twenty-five day supply from Dr. H (her pain doctor), followed by a prescription on September 16 for twenty hydrocodone 10mg from Dr. H (the oral surgeon), which she refilled on September 18; followed by a September 24 prescription for 120 Endocet, a thirty-day supply, from Dr. P, her new pain doctor. [44] *Id.; see also* Tr. 3882. On October 22, Dr. P issued TA a second prescription for 120 Endocet (also a thirty-day supply), and yet TA received twenty hydrocodone from Dr. S on October 31, twenty-four hydrocodone from Dr. A on November 4, and sixteen hydrocodone from Dr. C on November 16. GX 52, at Tab C.

On November 18, Dr. P issued TA another prescription for 120 (thirty-day supply) Endocet; TA then obtained ten hydrocodone from Dr. G on November 30, twelve hydrocodone from Dr. M on December 3, and twenty hydrocodone from Dr. A on December 10. *Id.* Continuing this pattern, on December 17, Dr. P issued TA another prescription for 120 (thirty-days) of Endocet; TA then obtained twelve hydrocodone from Dr. C on December 28, twelve hydrocodone on January 2, 2010 from Dr. M, twelve hydrocodone from Dr. S on January 4, and twelve more hydrocodone on January 6 also from Dr. M. *Id.* In addition to the various narcotics she received (and the carisoprodol), beginning on December 31, 2009, TA obtained prescriptions for thirty-day supplies of benzodiazepines including clorazepate and alprazolam from NP W, and Dr. M.

Over the course of time, TA had all of her teeth extracted; she also testified that she was never told that any of the extractions were unnecessary. Tr. 3912, 3926, 3969. Dr. G, one of the dentists who treated TA on various occasions in 2006 (when he extracted two of her teeth) and 2009, testified at the hearing that he had reviewed her chart and that she had ''bad teeth. They weren't in great shape and she needed extractions.'' *Id.* at 4446. Dr. G also testified that at one of TA's visits, which probably occurred in 2009, she complained that an extraction, which had recently been done by another dentist, was causing lots of pain. *Id.* at 4447. Dr. G testified that it was ''hard to tell exactly what [was] going'' and because TA claimed she had ''lots of pain,'' he referred her to an oral surgeon. *Id.* at 4448. Dr. G testified that he wrote TA a prescription for ''a few days of pain pills to give her time to get into the oral surgeon.'' *Id.* at 4449. While Dr. G testified that TA's pain complaint seemed reasonable, he further explained that when a patient comes in after having seen another doctor, he would start checking up on the patient. *Id.* at 4449–50.

Following this incident, Dr. G saw TA several more times. At the first of these visits, TA wanted another tooth extracted; however, because Dr. G ''thought that it would be a difficult extraction,'' he referred her to an oral surgeon. *Id.* at 4457. At the second visit, Dr. G told TA that she needed to have a ''full mouth extraction'' and would need to have this done by an oral surgeon. *Id.* After referring TA to an oral surgeon, Dr. G made a chart entry on TA's chart indicating that she was not to be prescribed any more pain medications. *Id.* at 4490–91.

In his report, Detective Hammond noted that TA engaged in a pattern of going to a dentist to have a procedure performed and then going to another dentist or oral surgeon to complain about the procedure that was done and to seek hydrocodone. GX 52, at Tab B, at 3. During his interview with Dr. A, one of the oral surgeons who treated TA, Dr. A noted that during her last visit (January 26, 2010), TA had complained about a procedure performed by another practice, Dental Associates, and had asked him to look at it. *Id.* However, Dr. A referred her back to Dental Associates and noted in TA's chart that ''she was seeking pain medications.'' *Id.* Detective Hammond further noted that the dental providers TA saw ''ranged from Somerset, KY to Campbellsville, KY which are about 75 miles apart.'' *Id.*

Dr. G acknowledged that it would be the ''norm'' for a patient whose teeth have deteriorated to the point of requiring a total extraction to have pain. Tr. 4459. However, when questioned as to whether he would have prescribed hydrocodone 5/500 to TA (as he did on August 24, 2009) if he had known that she had received 100 hydrocodone 10/500 from Dr. H (her first pain doctor) on August 15th, Dr. G stated that ''he wouldn't have prescribed that with knowledge of the previous prescription'' because the earlier prescription was ''twice as strong as what [he] prescribes for four days.'' *Id.* at 4467. Upon being asked by Respondents' counsel whether he ''would prescribe this limited amount as a booster on top of what she was already prescribed,'' Dr. G stated that he ''would not prescribe'' it even for a limited period.[45] *Id.* Moreover, on

clear, however, that he had also reviewed copies of the prescriptions. Tr. 3430–31.

[43] The Final Order scheduling carisoprodol discussed the extensive evidence of the abuse of carisoprodol, especially when taken in conjunction with other drugs such as narcotics and benzodiazepines. *See* 76 FR 77330.

[44] In addition to Endocet, Dr. P prescribed thirty-day supplies of carisoprodol to TA numerous times. GX 52, at Tab C.

[45] Dr. G did testify that on occasion he has had chronic pain patients, who would require extra

cross-examination, Dr. G was asked whether he would have issued his November 30 prescription for ten hydrocodone 5/500 if he had known that TA had obtained a prescription for Endocet twelve days earlier. *Id.* at 4479–80. Dr. G answered ''no'' and explained that he ''wouldn't have prescribed something that's not near as strong just because the stronger medication should normally take care of the pain.'' *Id.* at 4480. And later in his testimony, Dr. G explained that while he did not ''know what's considered a lot of medication in the world of pain clinics * * * I just know that there is no reason for me to prescribe it, and there are different doctors.'' *Id.* at 4520.

Dr. G reiterated that he did not receive a phone call from Grider #1 regarding any of the prescriptions that TA was receiving from other practitioners. *Id.* at 4511. Indeed, he testified that he was never contacted by either Grider #1 or Grider #2 regarding any of his patients. *Id.* at 4479. Moreover, upon reviewing the spreadsheet (Tab C) and examining the names of the various prescribers, Dr. G testified that ''[t]he only prescriber [he] recognize[d] are a few of the dentists and oral surgeons. All of the physicians, I assume they are physicians, I don't recognize any of their names. I don't even know what county they are in.'' *Id.* at 4468.

In her testimony, TA denied ever having sold prescriptions. Tr. 3901. However, on May 11, 2010, Detective Hammond went to Dr. P's clinic and interviewed him regarding TA; he also reviewed the medical record which Dr. P maintained on her and observed that Dr. P had performed several urine drug screens on her. GX 52, at Tab B, at 2–3. While the report for TA's March 10, 2010 urinalysis noted that she had listed that she was taking Percocet, hydrocodone, Soma, and Xanax, the results came back negative for benzodiazepines, opiates, and oxycodone. *Id.* TA, however, had received a prescription for 60 tablets (a thirty-day supply) of alprazolam on February 18, as well as a prescription for 120 tablets (also a thirty-day supply) of oxycodone on February 11.[46] GX 52, Tab B, at 3.

TA testified that she was unsure whether the dentists knew about the controlled substance prescriptions from Dr. H or Dr. P. *Id.* at 3915, 3941. However, she testified that she believed that she did not inform her dentists of those prescriptions. *Id.* at 3915–3916. TA believed the pain management doctor was the one who had to know about all of the controlled substances that were being prescribed to her. *Id.* at 3942.

Tonya Moses, a pharmacist and former employee of Respondents, also testified for Respondent. Ms. Moses acknowledged that Grider #1 had filled prescriptions for TA for a lesser strength of hydrocodone from a dentist (Lortab 5) which overlapped with prescriptions for Lortab 10 from a pain management doctor. *Id.* at 4203. The ALJ found credible Ms. Moses' testimony that the second, lesser strength prescription would not be justified, because ''[i]f the 10 mg is not controlling the pain, the five isn't. So, she had no reason to get that.'' *Id.* Ms. Moses acknowledged that this was an example of therapeutic duplication. *Id.* Ms. Moses further testified that it was ''incumbent upon a pharmacist to verify with the doctor if he sees multiple physicians prescribing, basically, the same medication.'' Tr. 4214.

Respondents also called Dr. M, a family practitioner with thirty years of medical practice, whose wife's sister is married to Eric Grider, and who is a partner with Leon Grider in the medical office building where he maintains his office and Grider #2 is located. *Id.* at 5266–67. Dr. M acknowledged the existence of doctor-shopping and the prevalence of prescription drug abuse in Eastern Kentucky. *Id.* at 5962–63. Dr. M did not treat TA. *Id.* at 5357, 5361. However, upon being shown the spreadsheet listing TA's prescriptions, Dr. M acknowledged that TA's pattern of obtaining prescriptions and ''taking about four [hydrocodone] a day on a regular basis,'' as well as other drugs, and seeing different doctors, ''would be a matter of major concern'' and ''probably [wa]s a potential'' doctor-shopping situation. *Id.* at 5364–65.

Dr. Sullivan noted the multiple instances in which Grider Drug #1 filled hydrocodone and/or oxycodone prescriptions issued by different doctors days before the date on which an earlier prescription for either of these drugs would have been totally consumed. Tr. 3416–17; Govt. Exh. 66, at 3–4. As Dr. Sullivan wrote in his report: ''[t]his pattern of filling hydrocodone and oxycodone prescriptions early when the patient still had medication left from a previous prescription occurred a total [of] 11 times during a ten-month period.'' *Id.* at 4. Dr. Sullivan also noted that ''[i]n addition to the hydrocodone and Endocet prescriptions, the patient was also receiving alprazolam and carisoprodol, which are known to be heavily abused. This provides further evidence that the patient was engaged in the abuse and/or diversion of controlled substances.'' *Id.* Finally, Dr. Sullivan opined that ''[a]ny reasonable and prudent pharmacist would have determined that the patient was either abusing and/or diverting these controlled substances.'' *Id.*

Notably, Leon Grider, who was the pharmacist at Grider #1, did not testify in the proceeding.

**RB**

RB (GX 53) is forty-year old female. Between December 2007 and April 2010, RB filled approximately 200 prescriptions which were written by two doctors (Dr. L & Dr. P) for such controlled substances as hydrocodone/apap tablets, alprazolam, and various narcotic cough syrups including Polytussin, Vicotuss, Z Hist, Tussionex, and Z Tuss.[47] GX53, at Tab C. At least 172 of these prescriptions were filled at Respondents, with all but seven filled at Grider #2. *Id.* Moreover, approximately 100 of the prescriptions were for the narcotic cough syrups. *Id.* However, according to Dr. Sullivan, narcotic cough suppressants are intended for the short-term relief of cough due to upper respiratory conditions, and in 2006, the clinical guidelines were changed to ''strongly discourage the use of any type of cough suppressant in treating any type of cough.'' Tr. 3419. Yet for the entirety of the twenty-eight months covered by the spreadsheet, RB received prescriptions from both Drs. P and L for narcotic cough suppressants which authorized the dispensing of 15,000 milliliters of these drugs. *Id.* at 3419–21; GX 66, at 4; GX 53, at Tab C.

RB also repeatedly obtained hydrocodone tablets throughout this period while she was receiving the narcotic cough suppressants. *See* GX 53, Tab C, at 1. For example, on December 7, 2007, RB filled at Grider #2 a prescription from Dr. L for 60 tablets (a thirty-day supply) of Lorcet 7.5/650mg; however, on December 12, 17, 20, as

medication for four days after a procedure, because otherwise they would run out of the medication they take for chronic pain. Tr. 4451–52. However, Dr. G explained that in this situation he would ''have to get with the pharmacist * * * or have to call [the patient's] physician.'' *Id.* at 4451. However, on both Respondents' direct examination and the Government's cross-examination, Dr. G was adamant that he would not have prescribed to TA if he had known about her prescription for 120 hydrocodone 10/500. *Id.* at 4478.

[46] While TA's urine drug screen was negative for opiates, and Detective Hammond noted that she had listed hydrocodone as a drug she was taking, TA's last hydrocodone prescriptions provided only a two-day supply and had been issued approximately two weeks earlier.

[47] This figure excludes the 52 prescriptions for Ultram (tramadol) which were listed on the spreadsheet. However, this drug is not currently controlled under federal law.

well as January 2 and 4, 2008, she also filled at Grider #2 four prescriptions for Polytussin and one for Codiclear. *Id.* Notably, while Dr. P wrote the Polytussin prescriptions, Dr. L wrote the Codiclear prescription. *Id.*

Likewise, on January 7, 2008, RB filled at Grider #2 a prescription from Dr. L for another 60 tablets (again a thirty-day supply) of Lorcet. *Id.* However, RB filled at Grider #2 two prescriptions issued by Dr. P for Polytussin on January 11 and 16, a prescription for Codiclear issued by Dr. L on January 22, and prescriptions for Z Hist issued by Dr. P on January 30 and February 4, 2008. *Id.*

As another example, on March 18, 2009, RB filled at Grider #2 a prescription issued by Dr. L for thirty tablets (a thirty-day supply) of Lorcet. *Id.* at 3. RB then filled prescriptions issued by Dr. P for Z Hist on March 20 and 30, as well as April 13, and a prescription issued by Dr. L for Tussionex on March 26. Each of these prescriptions was filled at Grider #2, and while the Z Hist prescriptions were for either four or six-day supplies, the Tussionex prescription was for a twelve-day supply. *Id.* In addition, notwithstanding that RB had obtained a thirty-day supply of Lorcet on March 18, on both March 30 and April 6, RB also filled at Grider #2 prescriptions issued by Dr. P for twenty additional tablets of Lorcet. *Id.*

In addition, even putting aside that RB was obtaining prescriptions from both doctors, the evidence shows that on multiple occasions, RB obtained early fills (or refills) of her prescriptions. For example, on July 21, 2008, RB filled at Grider #2 a prescription issued by Dr. L for a twelve-day supply of Tussionex, yet only four days later, she again obtained at Grider #2, an additional twelve-day supply of Tussionex. *Id.* at 2.

Moreover, on both April 28 and May 22, 2009, RB filled at Grider #2 prescriptions issued by Dr. L, each being for thirty tablets of Lorcet (a thirty-day supply).[48] *Id.* at 3. The latter prescription was thus filled six days early. Moreover, on June 16, RB filled a prescription (also written by Dr. L) for another thirty tablets of Lorcet at Grider #1, this also being a thirty-day supply; this dispensing was thus five days early.[49] *Id.*

Also, on July 15, 2009, RB filled at Grider #2 a prescription for 60 tablets of Lorcet (this also being a thirty-day supply). *Id.* at 4. Yet on August 5, 2009, RB filled at Grider #2 a prescription for 60 tablets of Lorcet; thus, this dispensing was nine days early. *Id.*

As for the Xanax (alprazolam), on July 23, 2009, RB filled at Grider #2 a thirty-day supply. *Id.* Yet on August 12, 2009, RB obtained another thirty-day supply; thus, this dispensing was ten days early. *Id.* Moreover, on November 6, 2009, RB filled at Grider #2 another thirty-day supply. *Id.* at 5. However, on November 27, RB obtained at Grider #2 another thirty-day supply, this dispensing being nine days early. *Id.* Finally, RB obtained at Grider # 2 a thirty-day supply on January 28, February 15, and March 8, 2010. *Id.* The February 15 dispensing was thus twelve days early, and the March 8 dispensing was nine days early.[50] *Id.*

On April 7, 2010, Detective Hammond interviewed Dr. L. GX 53, Tab B. Dr. L stated that he did not know that RB was also seeing Dr. P during the same period she was seeing him. *Id.* at 1. When Detective Hammond asked Dr. L whether he would have prescribed any controlled substances to RB if he had known that she was also obtaining the same or similar drugs from Dr. P, Dr. L answered ''absolutley [sic] not.'' *Id.*

On April 9, 2010, Detective Hammond interviewed Dr. P, who likewise stated that he was unaware that RB was also seeing Dr. L at the same time she was seeing him. *Id.* at 2. Dr. P also stated that he would not have prescribed controlled substances to RB if he had known that she was also receiving the same or similar drugs from Dr. L.[51] *Id.*

Upon reviewing the spreadsheet of RB's prescriptions, Eric Grider testified that he did not find RB's controlled substance prescriptions unusual, given the limited number of days' supply provided by each prescription. Tr. 3607–08. Regarding RB's numerous prescriptions for narcotic cough medicines, Grider asserted that these drugs could be used on both a short and long term basis, and gave as an example of the latter, COPD or chronic coronary disease with a cough. *Id.* at 3673. However, Grider admitted that he did not know if RB had either condition and that he never asked her doctors whether she had one of these conditions. *Id.* Moreover, RB testified that she never talked to a pharmacist at Grider Drugs about her medications, *id.* 4676, and that no one at Grider Drugs ever questioned her about her prescriptions. *Id.* at 4688–89.

Eric Grider further testified that, notwithstanding that RB was being prescribed narcotic cough syrups by two different doctors, he did not see any potential for abuse or misuse of the medications. *Id.* at 3678. However, in retrospect, Grider conceded that he should have contacted RB's doctors to ensure they were aware that the other was prescribing to her. *Id.*

As for RB's having filled the prescriptions at several different pharmacies, Eric Grider acknowledged that this was ''sometimes'' indicative of doctor-shopping. *Id.* at 3680. However, Grider testified that because his store was not signed up to obtain KASPER reports and RB did not have insurance and was ''a cash-paying patient,'' there was ''no way to know'' that she was getting prescriptions filled at other (non-Grider) pharmacies. *Id.* at 3602.

Dr. Sullivan concluded that RB's behavior ''clearly indicates this patient was abusing and or diverting this medication.'' GX 66, at 4. Dr. Sullivan opined that this abuse and or diversion ''should definitely have been caught by the pharmacist.'' *Id.* Also, at the same time RB was taking this narcotic cough suppressant containing hydrocodone, RB was also taking hydrocodone-containing pain killers. Such drug overlap indicates a duplicate therapy was being used. Tr. 3421. Dr. Sullivan also noted a pattern of early refills of Xanax prescriptions. He concluded that ''[n]o reasonable and prudent pharmacist would fill Xanax prescriptions this early on so many occasions.'' GX 66, at 5.

**JB**

JB is a female in her mid-fifties. GX 54, Tab A. Between September 2, 2009 and May 4, 2010, JB filled fifty-seven controlled substance prescriptions; fifty of the prescriptions were filled at Grider #2, with the remaining seven being filled at the Russell Springs Pharmacy. *Id.* at Tab C. The prescriptions, which were issued by three different doctors,

[48] Also, on both May 13 and June 18, Grider # 2 filled a prescription for twenty tablets of Lorcet issued by Dr. P. GX 53, Tab C, at 3–4.

[49] While the spreadsheet does not list what pharmacy this prescription was filled at, a listing of RB's Medical Expenses establishes that she filled the prescription at Grider # 1. GX 53, at Tab D.

[50] There is also evidence showing that RB also filled prescriptions for hydrocodone and alprazolam at other pharmacies, during the same period in which she was obtaining these drugs at Respondents. *See* GX 53, Tab C.

[51] Respondent introduced a statement from Dr. P. stating that RB ''has a legitimate reason to take pain medicine'' because of various displaced discs. RX 127. However, Dr. P further stated that he ''did not know until April 2010 she was seeing other physicians,'' thus corroborating in part the statement in Detective Hammond's written report. *Id.*

However, even if RB has a legitimate reason to take pain medicine for her back, Dr. P's statement does not explain why she was obtaining narcotics from Dr. L as well. Nor does Dr. P's statement establish that RB had a medical condition which warranted the prescribing of narcotic cough syrups, or the alprazolam. Thus, this letter does not refute the Government contention that RB was engaged in doctor-shopping and that Respondents violated their corresponding responsibility under federal law in filling her prescriptions.

were for Lyrica (pregabalin), Propoxyphene N/Apap, Tussionex (a schedule III drug containing hydrocodone indicated for cough and allergy), hydrocodone/apap, alprazolam and Valium (diazepam). *Id.*

The evidence shows that Grider #2 repeatedly filled prescriptions presented by JB for alprazolam and Valium which were issued by two different doctors. Specifically, on September 17, 2009, Grider #2 filled a prescription issued by Dr. B for 90 alprazolam .5mg (a thirty-day supply), and yet on September 24, Grider #2 filled a prescription issued by Dr. E for 60 Valium 10mg (a twenty-day supply). *Id.* On October 13, Grider #2 filled a prescription issued by Dr. E for another 60 diazepam (also a twenty-day supply), and three days later, it filled a prescription issued by Dr. B for 90 alprazolam (thirty-day supply). *Id.* Respondent filled additional prescriptions issued by Dr. E for 60 diazepam (twenty-day supply) on October 31, December 7, 2009, and January 28, February 17, March 9, April 9, and April 30, 2010; it also filled additional prescriptions issued by Dr. B for 90 alprazolam (thirty-day supply) on November 19, December 18, 2009, and January 21, February 17, March 18, and April 21, 2010. *Id.* In total, Grider #2 dispensed eight alprazolam prescriptions, each providing a thirty-day supply, for a total of 240-days' supply of this drug, and nine diazepam prescriptions, each providing a twenty-day supply, for a total of 180-days' supply of this drug; these prescriptions thus provided 420-days' supply of medication for a period which was only eight-months in duration.

With respect to these prescriptions, Dr. Sullivan explained that alprazolam and diazepam are controlled substances in the same therapeutic class of benzodiazepines. Continuing, Dr. Sullivan explained that:

> [t]he two drugs, diazepam 10mg and alprazolam 0.5mg are used for the same indication. I cannot think of any clinical reason why a patient would be using these two drugs at the same time for a period of seven months. Any reasonable and prudent pharmacist would not have filled prescriptions for these two medications to be taken at the same time. This is an obvious sign of either prescription drug abuse and/or diversion.

GX 66, at 5. Dr. Sullivan also observed that on February 17, 2010, Grider #2 had filled prescriptions for both diazepam and alprazolam presented by JB. *Id.*

With respect to JB, the evidence also shows that throughout most of the period in question, she was simultaneously receiving prescriptions for hydrocodone from both Dr. E and Dr. J. GX 54, at Tab C. However, while JB filled Dr. E's prescriptions at Grider #2, she filled Dr. J's prescriptions at the Russell Springs Pharmacy. *Id.*

Respondents called JB to testify. Tr. 5072. However, after some preliminary questions, JB informed the tribunal that she was under indictment for prescription fraud and that she was invoking her Fifth Amendment privilege. *Id.* at 5073. JB was excused, and although she was subject to recall, *id.* at 5077, Respondents did not recall her.

Eric Grider, pharmacist at Grider Drug #2, also testified regarding JB's prescriptions. Grider, who offered the remarkable testimony that he did know of any doctor-shopping having occurred in Russell County, *id.* at 3639, testified that JB's prescriptions did not raise a red flag with him even though she was simultaneously obtaining them from three doctors.[52] *Id.* at 3613. Regarding the hydrocodone prescriptions which JB was simultaneously filling at both Grider #2 and the Russell Springs Pharmacy, Eric Grider testified that Russell Springs Pharmacy was not connected with Grider Drugs. *Id.* at 3611. Mr. Grider then suggested that the only way he would have known about the prescriptions filled at Russell Springs Pharmacy was if it had billed Medicaid because JB had Medicaid, but if Russell Springs Pharmacy did not ''bill her Medicaid, [he] wouldn't [have] know[n]'' about those prescriptions. *Id.* However, in his testimony, Mr. Grider admitted that Respondents did not subscribe to KASPER and thus did not check to see whether their patients were obtaining drugs from multiple doctors or pharmacies. *Id.* at 3539–40, 3551.

As for the prescriptions that Grider #2 filled, Mr. Grider maintained that he had talked with the patient and that ''the rest of them [we]re legitimate prescriptions for her symptoms.'' *Id.* at 3613. He also asserted that the prescriptions were not a large number given the number of days' supply they provided. *Id.* at 3615; RX 120F; GX 54, Tab C. However, Grider offered no further explanation as to why it was appropriate to fill JB's prescriptions for alprazolam and diazepam, and as found above, the prescriptions for these two drugs provided 420 days' supply for period of eight months' duration.

**JR**

JR is a male in his late fifties. GX 55, Tab A. Between November 2, 2009 and April 29, 2010, JR filled thirty-four prescriptions for narcotics including hydrocodone, OxyContin, and Tussionex, which were issued by five different doctors; all but one of the prescriptions were filled at Grider #1. *Id.* at Tab C. However, JR testified that he was diagnosed with colon cancer in September or October 2009, and that he was terminally ill at the time of his testimony in December 2010.[53] Tr. 4235. JR further testified that Dr. W was his family doctor and that Dr. M worked with Dr. W, that Dr. N was his oncologist, that Dr. K was a surgeon who had performed various procedures on him, and Dr. B was a pain management specialist. *Id.* at 4238–39. In addition, a Dr. JB performed a surgical procedure on JR. RX 120B, at 9, 34.

JR testified that he had several bulging or ruptured disks in his back and that he had been on disability for a long time and been receiving painkillers for fifteen years. *Id.* at 4243. According to JR, Dr. W issued the November 2 prescription for 90 hydrocodone 7.5/500 (a thirty-day supply) for his back pain; Dr. K issued the November 23 prescription for 20 hydrocodone 10/500 (for a three-day supply) for post-surgery pain, likely following a biopsy. *Id.* at 4244. On December 1, JR received an additional 60 hydrocodone 7.5/500 (this also being a thirty-day) supply, and two days later, Dr. JB wrote him an additional prescription for twenty hydrocodone 10/500 (also a three-day supply), for pain following the installation of a chemotherapy port.[54] GX 55, at Tab C; RX 120B, at 34; Tr. 4246. Dr. W wrote additional prescriptions for 60 hydrocodone 10/500 (these being fifteen-day supplies) on December 31, as well as on January 14 and 28, and February 10, 2010. GX 55, at Tab C. However, on January 21, JR also filled a prescription for another 30 hydrocodone issued by Dr. N, his oncologist. *Id.*

On February 19, 2010, Grider #1 dispensed to JR 60 tablets of OxyContin 20mg (a thirty-day supply) based on a prescription issued by Dr. K. *Id.* Yet one week later (Feb. 26), Grider #1 filled for JR a prescription for 60 hydrocodone 7.5/500 (also a thirty-day supply) issued by Dr. W, and five days later (March 3), Respondent dispensed to JR 120

[52] According to Eric Grider, Dr. J is a family physician, Dr. E is an ear, nose and throat specialist, and Dr. B is a psychiatrist. Tr. 3612–13.

[53] The ALJ did not, however, make a finding as to whether she found this testimony credible. *See* ALJ at 37–39.

[54] While the actual prescription was written by Dr. JB, the label for the prescription that was dispensed listed Dr. K as the prescriber. RX 120B, at 34. On December 18 and 23, as well as January 8, 2010, Dr. K wrote additional short term prescriptions for hydrocodone10/500. The record does not, however, establish why.

hydrocodone 10/500 (a thirty-day supply), based on a prescription issued by Dr. B. *Id.*

Moreover, on March 8 (just five days later), Grider #1 dispensed to JR another 60 tablets of OxyContin 20mg (a thirty-day supply) which was prescribed by Dr. B, and on March 19, it dispensed to JR 60 tablets of OxyContin 30mg (a thirty-day supply), as well as 30 tablets of hydrocodone 10/500, both of which were prescribed by Dr. K. *Id.* Only one week later (on March 26), Grider #1 dispensed to JR another 60 OxyContin 20mg (thirty-day supply) and another 30 hydrocodone 10/500; both prescriptions being issued by Dr. K. *Id.* On April 2, JR filled at Grider #1 a prescription for 120 hydrocodone 10/500 (thirty-day supply) issued by Dr. B; he also filled, albeit at a different pharmacy, a prescription for 60 OxyContin 20mg, which was also issued by Dr. B.[55]

Ms. Moses filled several of JR's prescriptions at Grider #1; she also reviewed Grider #1's records and prepared notes regarding several of the dispensings. On November 23, 2009, she had filled a prescription for twenty tablets of hydrocodone 10mg which was issued by Dr. K. Ms. Moses documented on the prescription that JR had filled a prescription for Lortab 7.5mg on November 2, to be taken one tablet, twice a day. Dr. K's prescription was for one tablet every six hours. Ms. Moses justified filling the hydrocodone 10mg prescription because JR had seen a surgeon, the strength of the drug was higher, and the dosing interval had increased. Tr. 4164–65.

Ms. Moses became aware of the Lortab 7.5mg prescription from the pharmacy technician who had run the Lortab 10mg prescription through the computer. Ms. Moses did not call either physician. *Id.* at 4165–66. She asked JR if he had had surgery done, and JR told her that Dr. K had put in a port for his chemotherapy. *Id.* at 4166; *but see id.* at 4244 (JR's testimony that he may have had a biopsy done on this date). Ms. Moses testified that she collected this information on November 23, before she filled the prescription. *Id.*

According to Ms. Moses, a similar scenario arose with the prescription of December 3, 2009, because she knew JR was a cancer patient and had undergone a colon re-section. *Id.* at 4167–68. Moreover, the December 3rd prescription (issued by Dr. JB) was limited to a three-day supply of hydrocodone 10mg to help JR control his pain. *Id.* While Ms. Moses was aware that JR had also obtained hydrocodone 7.5mg from his primary care physician, she testified that she used her professional judgment in deciding to fill the hydrocodone 10mg prescription because she knew that hydrocodone 7.5mg twice a day would not control his post-surgical pain. Tr. 4167–68; RX 120B. Ms. Moses knew that after the 3-day supply was exhausted, JR would return to the hydrocodone 7.5mg medication for pain control. Tr. 4168.

Ms. Moses also testified regarding a January 21, 2010 prescription issued to JR by his oncologist Dr. N. *Id.* According to Ms. Moses, JR presented a prescription for the same strength (hydrocodone 10/500) and dosing interval (four tablets per day) as provided in a prescription Grider #1 had filled one week earlier which was issued by JR's primary care doctor. *Id.* at 4168. Ms. Moses testified that she called JR's oncologist to get his approval to fill the prescription and was told by a nurse that it was ''okay to fill,'' which she annotated on the hard copy of the prescription. *Id.* The evidence corroborates this. *See* RX 120B, at 46–47.

Ms. Moses offered a similar explanation as to why Grider #1 filled a March 8, 2010 prescription for OxyContin 20mg. Tr. 4169. Ms. Moses testified that she recognized that JR had received an earlier prescription for OxyContin 20mg on February 19, and that she told JR that she could not fill the prescription until March 17. *Id.* JR then told Ms. Moses that ''he was completely out of his medicine, because * * * the dosing * * * wasn't controlling his pain.'' *Id.* Ms. Moses testified that she agreed to call the ''the surgeon's office'' and that the nurse said ''that they were aware that [JR] was out of his medicine, and gave me the okay to fill that.'' *Id; see also* RX 120B, at 65. Ms. Moses further stated that it was within professional standards to fill this prescription. *Id.*

Respondents' counsel also asked Ms. Moses about the March 26, 2010 OxyContin prescription for a thirty-day supply which was filled by Leon Grider. *Id.* This prescription was at issue because the previous OxyContin prescription, which was also for a thirty-day supply, had been filled only one week earlier. As Ms. Moses testified, the March 26 prescription bore the notation: ''ok early per MD—last RX stolen pt had police report.'' RX 120B, at 71. As noted above, both the March 19 and 26 prescriptions were issued by Dr. K. GX 54, at Tab C. Ms. Moses testified that filling this prescription was within professional standards. Tr. 4170.

Next, Respondents' counsel asked Ms. Moses about the May 5, 2010 refill request it received from Dr. W, JR's primary physician. This form, which was faxed into Grider #1, stated ''needs all meds called in (including cough syrup)'' and listed numerous medications; however, various controlled drugs including Lortab and OxyContin were crossed out and the document also bore the notation ''No controlled drugs except Ativan.'' RX 120B, at 80.

According to Ms. Moses, a staff member at Dr. W's office ''wrote down all of [JR's] medications, including OxyContin 20mg, which Dr. W does not prescribe for him. Therefore, Dr. W was aware of JR's taking this for pain control from another physician.'' *Id.; see also* Tr. 4170–71. However, even if this evidence establishes that Dr. W was aware that JR was receiving OxyContin from another doctor (and it does not establish whether Dr. W was aware that JR was still obtaining prescriptions from another doctor on the various dates when he prescribed a thirty-day supply of hydrocodone to JR), it does not address whether Drs. K and B, who were prescribing OxyContin and hydrocodone to JR during the same time period, were aware that they were also simultaneously prescribing these drugs.

JR testified that he told Dr. K and Dr. N about the prescriptions he was receiving from Dr. W for his chronic back pain. Tr. 4246, 4256. However, during an interview Detective Hammond conducted with Dr. K on May 4, 2010, Dr. K stated that ''he had given him [JR] multiple prescriptions while treating him but had he known he was getting controlled substances from other doctors he would not have prescribed him anything other than right after surgery and he wouldn't have prescribed him as much.'' GX 55, Tab B, at 1. Dr. K further told the Detective that JR ''did not tell him what he was getting from other doctors'' and that while ''[h]e assumed Dr. W, his family physician, had given him something for pain * * * he did not know it was an ongoing situation. Also, he did not know [JR] was going to a pain clinic.'' *Id.*

On the same date, Detective Hammond interviewed Dr. W, JR's primary care physician who had referred him to Dr. K. *Id.* at 2. Dr. W stated that he knew JR ''would get something from Dr. K after his surgery but did not know [JR] would be continually getting medications * * * from Dr. K.'' *Id.* Dr. W further stated that he would not have prescribed the hydrocodone and Tussionex if he had

[55] In addition, on ten occasions throughout this period, Dr. W prescribed a ten-day supply of Tussionex, a hydrocodone based cough syrup, to JR. GX 55, at Tab C.

known [that JR] was getting the same and/or similar medication from Dr. K because [JR] was getting 'too much' with both of them prescribing.'' *Id.* Dr. W also stated that JR ''did not tell him that Dr. K was also giving him pain medications on a regular basis.'' *Id.*[56]

Detective Hammond also interviewed Dr. B, who runs a pain management clinic at a hospital in Danville, Kentucky. *Id.* at 3. Dr. B. stated that ''he did not know [JR] was getting OxyContin from Dr. K or controlled substances from Dr. W.'' *Id.* Dr. B also stated that ''patients at his clinic * * * are locked into a pain management contract in which they are the only ones that will be treating their pain,'' and that if he had known that JR was getting controlled substances from other doctors, he would not have treated him.[57] Id.

With respect to JR's OxyContin and hydrocodone prescriptions, Dr. Sullivan noted that that while ''on rare occasions, cancer patients will use a second narcotic like hydrocodone for break-through pain on an 'as needed basis' for a short-term period[,] [t]he same doctor would write prescriptions for both.'' GX 66, at 6. However, Dr. Sullivan then noted that JR ''was receiving prescriptions from both Dr. [K] and Dr. [B] for both drugs at the same time. He also received Tussionex (hydrocodone) prescriptions from Dr. [W] as well during this period.'' *Id.* Dr. Sullivan then explained that ''[t]his is a major red flag that the patient was receiving hydrocodone prescriptions from three different doctors and OxyContin from two different doctors at the same time. Any reasonable and prudent pharmacist would have caught this and not filled these prescriptions.'' *Id.*

Dr. Sullivan further noted ''[o]f the thirty three controlled substance prescriptions filled'' by Grider #1, ''at least eleven times the pharmacy filled the medication too early.'' *Id.* Dr. Sullivan opined that ''[t]his is clearly a sign of the pharmacy not conducting prospective DUR for abuse/misuse[,]'' and that ''[n]o reasonable or prudent pharmacist would have filled this many narcotic prescriptions this early.'' *Id.* Finally, Dr. Sullivan noted that the ''duplicate therapy with both hydrocodone and oxycodone (OxyContin) from more than one prescriber is a clear indication of drug abuse and/or diversion and any reasonable and prudent pharmacist would have detected this.'' *Id.*

**CR**

CR is a male in his late fifties. CR testified that in July of 1996, he was involved in an incident in which another person beat his back with a two-by-four and broke two of his ribs; CR was treated in the emergency room and prescribed Lorcet. Tr. 4030–31. Thereafter, Dr. P, CR's family doctor, treated his back injury, and prescribed controlled substances to him. *Id.* at 4033. CR also testified that sometime in 2007, he again injured his back while he was visiting a hospital; however, CR told two different versions of this incident, as he initially testified that as he was leaving a bathroom, boxes fell off a cart and knocked him back against the wall, but then testified that he was run over by a cart that weighed 1200 pounds. *Compare id.* at 3985 *with id.* at 4044. However, CR testified that he was not on pain medication at the time of this incident. *Id.* at 4044.

CR testified that Dr. P referred him to Dr. C for potential surgery and pain management. *Id.* at 4033–34, 4042–43. CR decided not to have the surgery until he changed his mind in January 2010. *Id.* at 4035. CR filled his controlled substance prescriptions at the Respondents. *Id.* at 4040.

The Government submitted a spreadsheet showing CR's controlled substance prescriptions between November 16, 2007 and April 2, 2010. GX 56, Tab C. The spreadsheet shows that during this period, CR filled approximately 170 controlled substance prescriptions,[58] and of these, all but seven were filled at either Grider #1 or Grider #2. *See id.* The prescriptions were for such drugs as alprazolam (schedule IV), hydrocodone combined with acetaminophen (schedule III), Demerol (schedule II), and various narcotic cough medicines including Pneumotussin, Z Hist, and Z Tuss Acc.[59] *See id.*

Moreover, CR was simultaneously obtaining prescriptions for narcotics from both Drs. P and C. Typically, CR would receive a prescription for 120 tablets of Vicodin 5 (hydrocodone 5/500mg) for a thirty-day supply from Dr. C, each of which he filled at Grider #1.[60] *See id.* While by themselves these prescriptions would not appear to be suspicious given the quantity and dates of issuance, throughout the period, CR also obtained and filled 49 additional prescriptions for twenty tablets of hydrocodone 7.5/650mg which were issued by Dr. P. *See id.* While the prescriptions issued by Dr. P were generally for only a three or five-day supply, notably, CR filled all but two of these prescriptions at Grider #2.[61] Also, CR obtained seven prescriptions

[56] In their Exceptions, Respondents contend that ''[t]he fact that a patient's surgeon over this period was prescribing small quantities of the same controlled substance, although in varying degrees of strength, that the patient's primary care physician was prescribing would not trigger the need to question either of these doctors' prescriptions.'' Resp. Exceptions at 19. Respondents do not cite any evidence to support this contention, and the statements of Drs. K and W indicate that had they known that JR was obtaining prescriptions they would have taken steps to reduce the quantities that were being prescribed.

[57] With respect to Dr. K's authorization of a new prescription (which was filled on March 26, 2010) based on the theft of JR's OxyContin, Detective Hammond noted that the theft had occurred at the Russell County Hospital and that the incident was captured by a video camera. *Id.* at 2. Detective Hammond interviewed the police officer who responded to this incident and noted that upon reviewing the video tape, JR's ''car was not locked and the person who broke into the vehicle appeared to know exactly where the pills were located'' as she ''was in the vehicle only a short amount of time and did not appear to be searching in the vehicle.'' *Id.* The responding officer also stated that JR ''was very persistent * * * about the pills being stolen and that she [the officer] may have to talk to the doctor so he could get his pain pills. [JR] was also very knowledgeable about the fact that the break in should be caught on video as he was within range of a security camera, [and] in fact he informed [the officer] of this.'' *Id.*

In his report, Detective Hammond also noted various notations in the patient filed maintained by Dr. W. These included a report that on October 29, 2009, JR called and requested a refill of Lortab, which Dr. W apparently rejected as he noted in the chart: ''Hell no! not due.'' *Id.* Moreover, on November 19, 2009, a person called Dr. W's office to report that JR was ''selling his pain pills and Xanax'' to her daughter. *Id.* Also, a chart note dated November 20, 2009 stated: ''Patient needs to bring in pill bottles next week for pill counts and UDS-any day next week.'' According to the chart, on November 23, JR ''brought in his Xanax bottle with 2½ pills left'' and did not have a bottle for the Lortab. *Id.* at 3. The chart further noted: ''Patient stated no Lortab left, no bottle, his yorkies get the lids off.'' *Id.* Notably, Detective Hammond's statements regarding both the November 19 phone call and JR's November 23 visit are corroborated by other evidence in the record. *See* GXs 75 and 76.

In his report, Detective Hammond then noted that while he was at Dr. B's clinic, he was approached by a nurse (JB), who told him that ''she had received a call from a Russell Co. phone number, in which the caller said [JR] was diverting his pain pills to her grandson in exchange for him mowing his yard'' and that ''her grandson is addicted to pain pills.'' *Id.* Also, in his testimony, JR admitted that he had ''loaned'' controlled substances to friends on occasion. Tr. 4317–18, 4320–21.

Accordingly, I find that while JR had a serious medical condition which warranted the prescribing of controlled substances, there is also substantial evidence that he engaged in the diversion of controlled substances.

[58] This figure excludes some twenty-six tramadol prescriptions.

[59] CR filled approximately twenty prescriptions for narcotic cough syrups throughout the nearly thirty-month period covered by the spreadsheet. *See* GX 56, Tab C.

[60] In total, CR received thirty such prescriptions from Dr. C; however, the last two prescriptions, which were also for a thirty-day supply, were for only 90 tablets. GX 56, Tab C, at 7.

[61] On December 26, 2007, CR also obtained a prescription for twenty-eight hydrocodone/apap from NP CR, which he filled at Grider #2.

from Dr. P for Demerol, which he also filled at Grider #2. *See id.*

Notably, while CR testified that Dr. P knew he was also seeing Dr. C, CR testified that he did not tell Dr. P that he was also getting controlled substances from Dr. C and Dr. P did not ask him if he was. Tr. 4028–29. Moreover, on April 9, 2010, the Detective, who had reviewed the medical record maintained by Dr. P on CR, interviewed Dr. P and asked him whether he would have prescribed controlled substances to CR if he had known that CR was getting the same or similar drugs from Dr. P. GX 56, Tab B, at 2. Dr. P answered ''no.'' *Id.*

The Detective also interviewed Dr. C, who said that he had asked CR if he was obtaining controlled substances from any other doctors and that CR said ''he was not.'' GX 56, Tab B, at 1.[62] The Detective then asked Dr. C if he would have prescribed controlled substances to CR if he had known that CR was obtaining the same or similar drugs from other doctors. *Id.* Dr. C answered ''absolutely not.'' *Id.*

Respondents did not call either Dr. P or Dr. C to testify. Instead, they called a Nurse Practitioner C–R,[63] who worked in an emergency room and treated CR after an accident in which he represented that he had hurt his elbow. Tr. 4051–52. NP C–R prescribed twenty-eight tablets of hydrocodone/apap 7.5/650mg, which CR filled at Grider #2. However, six days earlier, CR had filled at Grider #1 a prescription issued by Dr. C for 120 tablets of hydrocodone/apap 5/500mg. *Id.* at 4006–07, 4052; GX 56, Tab C, at 1.

NP C–R did not remember CR or any facts surrounding her treatment and prescribing to him. Tr. 4360–63, 4367. However, upon being shown the evidence that CR had filled the prescription for 120 tablets only six days earlier, NP C–R testified that given the close proximity of the two prescriptions, she would have expected the pharmacist to call her to verify the authenticity of the second prescription. *Id.* at 4429.

Ms. Tanya Moses, Respondent's witness, also testified regarding these two prescriptions. Similar to the testimony of NP C–R, Ms. Moses testified that if NP C–R's prescription had been presented to her, she would have called the physician to let him/her know of the overlapping prescription. *Id.* at 4220–21.

Dr. Sullivan further noted that on multiple occasions, Respondents had filled prescriptions for both hydrocodone tablets and narcotic cough suppressants, which contain hydrocodone. GX 66, at 7. Most significantly, in his report, Dr. Sullivan opined that ''[a] reasonable and prudent pharmacist would have not allowed a patient to take these medications at the same time and noticed this as a potential indication of prescription drug abuse and/or drug diversion.'' *Id.*

In addition to the narcotic prescriptions, the evidence shows that CR received 64 alprazolam prescriptions and refills that were authorized by Dr. P, each of which was for a thirty-day supply, for a total of 1,920 days' supply of the drug during a period of thirty months. *See* 56, Tab C. Of these prescriptions, all but seven of them were filled at Respondents, and of the seven which were not filled by Respondents, CR did not start filling these at another pharmacy until late April 2009. *See id.* Thus, for approximately seventeen months, CR filled all of the alprazolam prescriptions at either Grider #1 or Grider #2. Indeed, the frequency at which CR presented the alprazolam prescriptions and sought refills of them provides compelling evidence that CR was engaged in self-abuse and/or diversion.

For example, on November 23, 2007, Grider #2 filled a thirty-day supply; it also refilled the prescription on December 18 and on January 31, 2008. *See id.* at 1. Yet on December 29, 2007, Grider #1 also filled a thirty-day supply based on a different prescription; it refilled the prescription on January 26, February 23, and March 21, 2008. *See id.* Moreover, notwithstanding that it had dispensed a refill the previous day, on February 1, 2008, Grider #2 filled a new prescription for thirty-day supply, which it refilled on February 29 and March 27, 2008. *See id.* Moreover, on March 31, 2008, Grider #1 dispensed a new prescription, even though it had refilled the previous prescription only ten days earlier and that Grider #2 had refilled a prescription only four days earlier. *Id.*

The evidence shows numerous other instances in which Respondents filled or refilled the alprazolam prescriptions within days of having filled or refilled an earlier prescription. For example, on April 24, 2008, Grider #2 dispensed a refill, and yet, just six days later on April 30, it dispensed a new prescription. *Id.* at 2. Moreover, on April 28, Grider #1 dispensed a refill. *Id.*

Likewise, on May 24, 2008, Grider #1 dispensed a further refill, and yet, on May 27, Grider #2 also dispensed a refill. *Id.* Moreover, on June 20, Grider #1 dispensed another refill, and on June 23, Grider #2 dispensed another refill. *Id.* Grider #2 also dispensed a new prescription on July 3, refilled a previous prescription on July 21 (which was first filled on April 30), and then on July 31, it refilled the July 3rd prescription. *Id.*

As other examples, Grider #1 filled or refilled thirty-day alprazolam prescriptions on December 29, 2008, as well as on January 16 and 27, February 14 and 23, and March 12, 2009. *Id.* at 3–4. Grider #2 also filled or refilled thirty-day prescriptions on January 5, February 27, and and March 27, 2009.[64] *Id.*

Regarding the alprazolam prescriptions, CR offered two explanations, neither of which is credible. First, when questioned about the alprazolam prescriptions he filled on January 31, as well as on February 1, 2008, CR claimed that he got the extra alprazolam because he ''was going out of town for a couple or three weeks.'' Tr. 4013. Yet earlier in his testimony, CR stated that the earliest he ever got a refill was three to four days early; he also testified that he did not regularly go out of town. *Id.* at 3995–96. Moreover, CR had just obtained a refill on January 26. Thus, even if CR actually was going out of town, he had no need for either the January 31 or February 1, 2008 refills and I find that this testimony is patently disingenuous.

Next, when asked about the alprazolam prescriptions he filled on March 21, 27, and 31, 2008, CR testified that Dr. P had written him another prescription because ''I was going through some bad things,'' and that while he was ''not sure,'' Dr. P did so instead of writing a prescription for two

[62] CR testified that he did not recall that the patient history forms he completed for Dr. C had asked about what drugs he was taking. Tr. 4047. However, CR admitted that he never told Dr. C that he was also receiving controlled substances from Dr. P, stating that:

I never had any reason to. I didn't know if he knew or—I mean I just figured everybody knowed [sic]. I thought they could pull these KASPERS I think they call it and find out anything so I didn't think there was anything wrong. I thought you could go from little drug to just a tiny bit stronger. Because Lortab 75's ain't enough to—nothing to even touch what pain I have most days.

*Id.* at 4039.

[63] NP C–R testified concerning her current practices in prescribing controlled substances and reviewing KASPER reports. Tr. 4340–4434.

[64] As noted above, CR apparently decided to become somewhat less brazen as beginning in late April 2009, he started filling some of the alprazolam prescriptions at a Rite Aid. However, even then there were numerous instances in which he filled or refilled alprazolam prescriptions at Respondents within days of each other. For example, on August 21, 2009, Grider #1 filled a new prescription, and yet, on August 25, Grider #2 refilled a prescription. *See* GX 56, Tab C, at 5. Also, on October 15, 2009, Grider #1 refilled a prescription, and yet on October 22, Grider #2, filled a new prescription. *Id.*

tablets a day or 60 tablets. *Id.* CR then stated that it was his belief that this ''is the way it is done.'' *Id.*

Yet the alprazolam prescriptions (including those in which Dr. P purportedly doubled his dosing) all gave the same dosing instruction of ''one tab at bedtime.'' RX 120, Tab C. Moreover, one would expect that if a doctor was actually doubling a patient's frequency of dosing, the prescription would reflect this as is required by federal regulations. *See* 21 CFR 1306.05(a) (requiring that a prescription list, *inter alia,* a drug's ''strength * * * [the] quantity prescribed, [and the doctor's] directions for use''). Thus, if it had been the case that Dr. P had determined that CR had a legitimate medical need to double his dose of alprazolam, Dr. P should have simply increased the dosing instructions on the prescription. And even if CR's condition required that his dose be doubled, that still would not explain why he filled or refilled the prescription three times within a ten-day period (March 21–31, 2008), or did so an additional three times within a six-day period the following month (April 24–30, 2008). Here again, CR's testimony was patently ludicrous and disingenuous.[65]

Eric Grider, the pharmacist in charge at Grider #2, recalled that CR was seeing Dr. P for some back problems, but did not recall the nature of those back problems. Tr. 3744–45. Moreover, Eric Grider admitted that he did not talk to Dr. P about CR, *id.* at 3786, even though Dr. P's office is in the same building as Grider #2. *Id.* at 3989–90.

Eric Grider further asserted that Grider #2 would not have known about the controlled-substance prescriptions CR filled at other pharmacies (including at Grider #1) because CR was ''a cash-paying patient.'' *Id.* at 3619. In addition, Grider stated that he would be unaware of the prescriptions CR filled at Grider #1 ''unless [he] looked in [the patient's] files,'' and then offered the unconvincing explanation that he ''had no reason to'' do so. *Id.* Grider then testified that he did not recall inquiring with Grider Drug #1 about CR's filling of prescriptions at that location, or that Grider #1 had asked Grider #2 about the latter's filling of CR's prescriptions. *Id.* at 3689, 3694. Also, as found above, Grider testified that he was not signed up to obtain KASPER reports on the pharmacy's patients. *Id.* at 3621.

In addition, on direct examination, Eric Grider asserted that the prescriptions which CR filled at Grider #2 would not, by themselves, raise a red flag or lead him to conclude that CR was a problem patient. *Id.* at 3621–22. He also denied being aware of any unauthorized refills which occurred at Grider #2. *Id.* at 3623. Yet when asked on cross-examination about Grider #2's filling of alprazolam prescriptions (on February 1, 2008, notwithstanding having dispensed a refill of an earlier prescription the day before) and refilling (on April 24 and then April 30, 2008), Grider maintained that ''the only way'' he would have done so was if he checked with the doctor (Dr. P) to ensure it was okay to do so. *Id.* at 3690–3. However, the ALJ found that Grider could not specifically recall if he did so in regards to these prescriptions and I find that he did not. ALJ at 43–44 (citing Tr. 3692–93).

Eric Grider then conceded that CR appeared to be a doctor-shopper who engaged in conduct that fit Grider's definition of a problem patient. *Id.* at 3694, 3696. Moreover, contrary to Grider's claim that he had no reason to check the patient profile maintained on CR by Grider #1, I find that given the numerous early alprazolam prescriptions CR presented, Eric Grider had reason to know that CR was engaged in either drug abuse or diversion and thus, Grider had ample reason to check with Grider #1 to determine whether CR was also filling prescriptions there.[66]

Dr. Sullivan noted that there were ''multiple instances where'' CR filled the alprazolam prescriptions ''early at both pharmacies.'' GX 66, at 7. Indeed, after listing four instances of dispensings made by Respondent which ranged from fifteen to ''twenty-nine days too early,'' Dr. Sullivan observed that ''[t]his pattern of filling alprazolam too early for this patient occurred on at least ten other occasions.'' *Id.* Dr. Sullivan then explained that a ''reasonable and prudent pharmacist would never have filled these alprazolam prescriptions as early as the Grider pharmacies did. This shows a pattern of either abuse and/or drug diversion.'' *Id.* I agree with Dr. Sullivan's conclusion.[67]

**SR**

SR is a woman in her mid-fifties. GX 57, at Tab A. SR testified that she has Type 2 diabetes, that she had neuropathy in her feet, bad arthritis in her shoulders, hands, back, and knees, and anxiety; she also testified that she had to have a tooth extracted and developed a dry socket following this procedure. Tr. 4694–95.

According to the spreadsheet of her prescriptions, between October 3, 2009 and April 23, 2010, SR filled twenty-four controlled substance prescriptions at Grider #2. GX 57, at Tab C. The prescriptions included sixteen for hydrocodone/apap, one for Endocet (oxycodone), and seven for clonazepam.[68] *Id.* While all of the

[65] As another example of CR's frequently disingenuous testimony, on cross-examination, CR initially denied seeing any physician (other then when he went to an emergency-room) in Florida, where, at the time of the hearing, he was renting a house in Palmetto, Florida with others. Tr. 4103–04, 4109, 4025. However, upon being confronted with a prescription he had obtained (on November 29, 2010) for oxycodone 30mg from a doctor at the Pain Center of Broward, a pain clinic located in Fort Lauderdale, *see* GX 73, CR then changed his testimony claiming that he had ''got to hurting so bad'' because he had ''been cut off'' by his Kentucky doctors in April 2010 (seven months before he got the oxycodone in Florida), apparently after they were interviewed by Detective Hammond. Tr. 4107. Subsequently, CR claimed that the day before he obtain the oxycodone he had hurt his back moving furniture and that his pain level following this incident was an ''[e]leven'' on a scale of ''one to ten.'' *Id.* at 4125.

When asked how he had found out about the Pain Center of Broward, CR claimed that he had woken up at about four in the morning because he ''couldn't breathe'' and had his roommates take him to the emergency room, where he asked the doctor where he could get ''a family doctor'' because he ''was having trouble with [his] back.'' *Id.* at 4131–32. CR then made the absurd assertion that Broward is ''kind of a suburb[] of Tampa.'' *Id.* Pursuant to 5 U.S.C. 556(e) and 21 CFR 1316.59, I take official notice of the map of the State of Florida contained in the 1994 Rand McNally Business Traveler's Road Atlas, at 22–23. As this shows, Palmetto and Fort Lauderdale are located on opposite coasts of the State of Florida and are more than 200 miles apart. This begs the further question of why, if CR's pain level was so high, he would travel more than 200 miles to get drugs instead of seeking treatment closer to where he lived.

At another point in his testimony, CR was asked by the Government if he ''ever g[a]ve his pills away to anybody else?'' *Id.* at 4098. CR replied: ''I'd rather not say. Is that okay? I mean can I get by with that or do I have to answer that?'' *Id.* CR then added: ''I've never sold a pill, I'll put it like that.'' *Id.* at 4099.

In short, much of CR's testimony was transparently disingenuous.

[66] There was also evidence that CR saw a Dr. C, who surgically treated him for a hernia, Tr. 4008–09, as well as other doctors because he believed that Dr. P was planning on retiring. These included a Dr. L (who he saw twice), a Dr. W (who he saw three or four times), and a Dr. B (who he saw two to three times). *Id.* at 4010–11, 4056–57, 4065, 4068–69. There was also testimony that CR obtained hydrocodone and Valium from Dr. W and both a cough syrup containing a controlled substance and several hydrocodone prescriptions from Dr. B. *Id.* at 4056–57, 4061, 4068–69, 4071. While the ALJ found that these prescriptions were filled at Respondent and that Dr. B's prescriptions overlapped with those of Dr. P (ALJ at 41, FoF #s 162–63), with the exception of the prescriptions issued by Dr. C, no further evidence was put forward establishing the dates on which these other prescriptions were filled. I thus do not adopt the ALJ's findings on the prescriptions.

[67] As noted above, Leon Grider, the pharmacist in charge at Grider #1, did not testify in the proceeding.

[68] The spreadsheet also lists a prescription for Fioricet, but it is unclear whether this formulation is controlled.

clonazepam prescriptions were issued by Dr. Z, SR received five of the hydrocodone prescriptions and the Endocet prescription from Dr. H; of the hydrocodone prescriptions, eight were issued by Dr. S, and one prescription each was issued by Dr. M, Dr. W, and Nurse Practitioner H. *Id.*

SR denied that she was a doctor shopper, stating that Dr. Z was her psychiatrist and treating her for anxiety. Tr. 4697, 4711. She also stated that Dr. H was an orthopedic surgeon who had performed surgery on her shoulder in March 2010, *id.* at 4697, 4720; that Dr. S and NP H were in the same practice and that Dr. W had replaced Dr. S and was her family practitioner who was treating her for arthritis; [69] that Dr. JS was her foot doctor; and that Dr. M was a dentist who was in an office which had several dentists. *Id.* at 47087, 4711.

The evidence shows that on October 5, 2009, SR received 42 hydrocodone 5/500, a fourteen-day supply, from Dr. S (her then family practitioner); that on October 13, 2009, SR received twelve hydrocodone 7.5/650 (this being a three-day supply), from Dr. M, a dentist;[70] and that on October 21, 2009, SR received 42 hydrocodone 5/500 from NP H. All three prescriptions were filled at Grider #2. Tr. 3592–94, 3710, 3714–15, 4710–11; GX 57, Tab C & Tab D, at 2.

However, SR's dental records include a list of medications she was taking as of October 8, 2009, the date on which she had a tooth extracted; this list is also repeated on the first page of the chart which is an undated form which includes the type of information which a patient would typically complete on the initial visit (such as Identifying Information, Dental Insurance, Medical History, Acknowledgement of Receipt of Notice of Privacy Practices, and Consent). *See* GX 77. Notably, hydrocodone is not on either list even though SR had been prescribed this drug just three days earlier. *See id.* at 1, 3; GX 57, at Tab C & Tab D, at 2.

RS initially testified that she had just forgotten to list hydrocodone because she has ''trouble with [her] memory.'' Tr. 4716. However, she later denied having written the list of drugs which appears on the first page of the form, *id.* at 4727, and did not recall when she had written out the list on page 3 of the form which is dated ''10/8/09.'' *Id.* at 4726.

In addition, the evidence shows that on March 8, 2010, Dr. S (her family doctor) prescribed 90 tablets of hydrocodone 5/500 (a thirty-day supply) and that after this, Dr. H (her orthopedic surgeon) prescribed her thirty tablets of hydrocodone 7.5/500 on March 10, 18, 24, and April 1; most of the prescriptions had dosing instructions of one tablet every six hours, thus providing a week's supply. GX 57, Tab C. In addition, on April 8, Dr. W (who replaced Dr. S as her family doctor but was in the same office) prescribed her 90 more hydrocodone 5/500 (also a thirty-day supply) and on April 23, Dr. H issued her a prescription for another 30 tablets of hydrocodone 7.5/500. *Id.* In total, between October 5, 2009 and April 23, 2010, SR received sixteen prescriptions for hydrocodone representing a 247-day supply. RX 120A.[71]

On May 7, 2010, Detective Hammond interviewed Dr. H, who acknowledged that he was treating SR for a shoulder injury. GX 57, Tab B, at 1. Dr. H stated that he may have given SR the Endocet prescription ''after surgery or told her to double up on the hydrocodone if he had known she was still receiving them from Dr. S.'' *Id.* at Tab C, at 1. However, Dr. H stated that ''he would not have prescribed * * * hydrocodone [to SR] if he was aware [that] she was receiving it from Dr. S.'' *Id.* Thereafter, Detective Hammond reviewed Dr. H's chart on SR and noted that he ''was aware that she was taking hydrocodone.'' *Id.* Detective Hammond conducted a further interview in which he asked Dr. H about this; Dr. H stated that ''the medication list shown in her records is generated automatically by computer from SR's past visits and that she had been a patient since 2003.'' *Id.* Dr. H further stated ''that at the time in question he did not know [SR] was receiving hydrocodone from Dr. S or he would not have given it to'' her. *Id.* Dr. H also stated that ''he would have contacted Dr. S and they would have decided who would be treating [SR] for pain to avoid an overlap in [her] prescriptions.'' *Id.*

Detective Hammond also interviewed Dr. M, who had performed the extraction. *Id.* at 2. Dr. M stated that if SR had ''disclosed [that] she was receiving hydrocodone from another doctor he would not have prescribed it to her.'' *Id.*

Detective Hammond interviewed Dr. S, her former family physician. Dr. S stated that SR had entered into a contract under which she was not permitted to receive controlled substances from another physician without his prior authorization. *Id.* Dr. S also stated that ''[h]e did not know that that [SR] was receiving pain medication from other doctors,'' and that if he had known, ''he would not have prescribed her anything.'' *Id.* While Dr. S was aware that SR ''was going to have surgery and would potentially receive a controlled substance right after surgery[,] * * * he was not aware that she was receiving controlled substances from the surgeon beyond the initial surgery.'' *Id.*

Finally, on May 19, 2010, Detective Hammond met with Dr. W. *Id.* Dr. W, who had seen SR on April 8, 2010 and had prescribed 90 tablets of hydrocodone to her, stated that she was unaware that SR was receiving controlled substances from Dr. H; she also stated that SR was subject to a controlled-substances contract pursuant to which she could not obtain controlled substances from ''other doctors without notifying'' her practice. *Id.* Dr. W further stated that she would not have prescribed hydrocodone if she had known that SR was getting the drug from ''somewhere else.'' *Id.*

As noted above, all of SR's prescriptions were filled at Grider #2, where Eric Grider was the pharmacist charge. In her decision, the ALJ made the following finding: ''Mr. Eric Grider believes, for it is his practice, that he would have told SR not to take the hydrocodone prescribed to her by Dr. S while she takes the stronger hydrocodone prescribed to her by Dr. M. However, he could not specifically recall doing so in this instance, and he does not make notes regarding such counseling because he usually does not have time.'' ALJ at 44 (citing Tr. 3717–18, 3734–38). However, SR testified that no one at Grider Drugs counseled her about her prescriptions. Tr. 4701–02, 4719. SR also testified that she was never questioned by a pharmacist at Grider Drug #2 about the prescriptions she received from Drs. S, M, or any other practitioners. *Id.* at 4719. She was also unaware of anyone from that pharmacy contacting her prescribers. *Id.* at 4724.

Eric Grider acknowledged that he had an obligation to counsel the patient, given the therapeutic duplication noted in these prescriptions. *Id.* at 3724. He also stated that he possibly would call the prescribing practitioners, but he could not recall whether he called Dr. H, and that he did not call Dr. M.[72] *Id.*

[69] SR also referred to Dr. W by her married name of Dr. D. Tr. 4708.

[70] SR's dental record contains a chart note which indicates that her tooth was extracted on October 8, 2009 and that she was prescribed the twelve hydrocodone on that date. GX 77, at 2.

[71] RX 120A is a computation chart showing these sixteen prescriptions and the Respondent's computation of the number of days each prescription should last if the medication is taken as prescribed.

[72] Eric Grider testified that he was aware that SR was seeing Dr. H for a shoulder injury, and he believed SR had told him that information. Tr. 3708. However, he did not contact Dr. H regarding this surgery. Tr. 3789.

at 3725–26. Likewise, he did not recall whether Dr. W had been contacted regarding the therapeutic duplication involved in SR's prescriptions. *Id.* at 3729. Grider denied that he had an obligation to contact the prescribing practitioner, explaining that he views such contact as a courtesy. *Id.* at 3727–28. Grider also testified that he did not believe he had an obligation to call these physicians if he had counseled the patient concerning the appropriate manner in which to consume these duplicative drugs. Tr. 3730.

Grider also testified that he did not find the quantity of hydrocodone he dispensed to SR to be unusual, given the limited number of days' dosage represented by each prescription. *Id.* at 3597–98, 3716. However, as found above, SR received 247 days of hydrocodone during a period of a little more than six and one-half months' duration.

Dr. Sullivan observed that sixteen of SR's prescriptions were for hydrocodone, and ten of these were filled too early because the patient should still have had medication left from a previous prescription. GX 66, at 7.

**Summary of Dr. Sullivan's Testimony**

With respect to the six patients discussed above, Dr. Sullivan concluded that ''the evidence presented * * * is overwhelming and shows a pattern of dispensing controlled substances significantly early to patients who [were] either abusing controlled substances themselves or [were] diverting prescription drugs for illegal purposes. There are dozens of instances of this occurring in these six patients.'' GX 66, at 8. The pharmacist should have caught this during the process of conducting prospective [drug utilization reviews] before filling these prescriptions.'' *Id.* at 2. Dr. Sullivan explained that it was ''extremely obvious'' that these patients were ''either abusing controlled substances, obtaining them for the purpose of diversion, or a combination of the two.'' *Id.* at 3. In addition, Dr. Sullivan noted that while a pharmacist may ''on an extremely rare occasion fill a prescription for a controlled substances early,'' he then observed that ''[t]here are dozens of instances'' of Respondents providing early refills to these patients. *Id.* at 8.

Dr. Sullivan thus concluded that any ''reasonable and prudent pharmacist would have * * * refused to dispense controlled substances to all six of these individuals.'' *Id.* Noting that these persons were ''textbook examples'' of persons engaged in ''drug abuse and/or drug diversion,'' Dr. Sullivan explained that ''[a]ny reasonable and prudent pharmacist would quickly recognize this based on their education, training, and experience.'' *Id.* Dr. Sullivan concluded that the Respondents' dispensings to these patients violated the accepted standards of practice observed by pharmacies and pharmacists in the Commonwealth of Kentucky.[73] Tr. 3426. I agree with Dr. Sullivan's conclusions.

[73] It is acknowledged that Dr. Sullivan is licensed in Ohio but not Kentucky. Because of this, the ALJ explained that she did not recognize Dr. Sullivan as an expert in the obligations of a pharmacy specifically under Kentucky law, Tr. 3401–02, and that she gave less weight to his testimony only as it relates to the unique standards imposed by the Commonwealth of Kentucky. ALJ at 47 n.15. The ALJ did not provide any further explanation as to what testimony of Dr. Sullivan she gave less weight to.

In any event, even after *Gonzalez* v. *Oregon,* 546 U.S. 243 (2006), several courts of appeals ''have applied a general-practice standard when determining whether the practitioner acted in the 'usual course of professional practice.' '' *See United States* v. *Smith,* 573 F.3d 639, 647–48 (8th Cir. 2009); *see also id.* at 648 (discussing *Moore;* ''Thus informed by the Supreme Court and other controlling and persuasive precedent, we believe that it was not improper to measure the 'usual course of professional practice' under § 841(a)(1) and [21 CFR] 1306.04 with reference to generally recognized and accepted medical practices * * *.''); *see also United States* v. *Merrill,* 513 F.3d 1293, 1306 (11th Cir. 2008) (quoting *Moore,* 423 U.S. at 139) (''The appropriate focus is not on the subjective intent of the doctor, but rather it rests upon whether the physician prescribes medicine 'in accordance with a standard of medical practice generally recognized and accepted in the United States.' ''); *United States* v. *Feingold,* 454 F.3d 1001, 1009 (9th Cir. 2006) (''[B]oth the Supreme Court and this Circuit have previously approved jury instructions that refer to a national standard of care.'').

Nor is *Volkman* v. *DEA,* 567 F.3d 215 (6th Cir. 2009), to the contrary. As the Sixth Circuit observed, in *Gonzales,* the Supreme Court invalidated the Attorney General's interpretive rule that ''[a]ssisting suicide is not a 'legitimate medical purpose' within the meaning of 21 CFR 1306.04'' and a violation of the CSA which would subject a practitioner's registration to revocation under 21 U.S.C. 824(a)(4), without regard to whether state law authorized a physician to engage in such conduct. *Id.* at 222 (other citation omitted). The Sixth Circuit further explained that the Supreme Court held in *Gonzales* that ''the Controlled Substances Act does not give the Attorney General the authority to 'define general standards of medical practice.' '' *Id.* at 223. Thus, the Supreme Court invalidated the interpretive rule ''because it was not based on the 'public interest' factors described in 21 U.S.C. § 823(f) but was instead the Attorney General's own judgment on a controversial practice without regard to state law.'' *Id.* However, as the Sixth Circuit further recognized, the Supreme Court affirmed that the CSA '''regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug-dealing and trafficking.' '' *Id.* Thus, in *Volkman,* the Sixth Circuit rejected a physician's challenge to the denial of his application based on *Gonzales,* noting that the Agency's ''assessment of Volkman's prescribing and record-keeping practices was tethered securely to state law,'' and that the Agency's action was consistent with the CSA's '''recognition of state regulation of the medical profession.' '' *Id.* (quoting 546 U.S. at 272).

*Allegation Fifteen—Respondents Violated Kentucky Law by Failing To Provide Complete and Accurate Information to KASPER*

The Government also alleged that Respondents violated Kentucky law by failing to file KASPER reports. Gov. Post-Hrng Br. at 12, 88. In support of this allegation, the Government introduced into evidence a letter (dated May 13, 2005) from Dave Sallengs, a Registered Pharmacist and Pharmacist Investigator who is the manager of the Drug Enforcement Professional Practices Branch of the Kentucky Cabinet for Health and Family Services Office of the Inspector General, to Grider #2. GX 28; Tr. 2302–03. Therein, Mr. Sallengs noted that the KASPER records show that Grider #2 had not reported any prescriptions for the periods of February 18 through 27, 2003; July 4 through August 4, 2003; and February 1, 2005 to the date of the letter. GX 28. In addition, the Government noted that the KASPER data reported by Respondents contained numerous inaccuracies (such as the double reporting of prescriptions) or the misreporting (or non-reporting) of various prescriber's DEA registration numbers.

Mr. Sallengs, who was called as a witness by Respondents, equivocated as to whether this letter established a serious breach of state law by Grider #2. Tr. 2394–95. More specifically, Mr. Sallengs testified that while ''it's serious from the standpoint that state law says you have to report, and it has to be within certain days, but in our dealings with it, we understand that a lot of times * * * the pharmacy might not even be aware of this until they get this letter.'' *Id.* at 2394. Mr. Sallengs then explained that if his office did not get a response from a pharmacy to such a letter (which they send out to approximately fifteen to twenty pharmacies a week), it would send out a follow-up letter and copy the letter to

It is further noted that although Dr. Sullivan's testimony and report were largely based on generally accepted standards of pharmacy practice, he did review the Kentucky Board of Pharmacy's rule on Drug Utilization Review. Tr. 3410–14; GX 66, at 2. With the possible exception of the issue of whether under Kentucky law, a pharmacy technician (rather than a licensed pharmacist or pharmacy intern) can lawfully contact a prescribing physician to question the legitimacy of a prescription, regarding which Dr. Sullivan testified that ''[t]echnicians should not be making those phone calls, judgment or discussions with physicians, even if it's not that way in Kentucky law,'' Tr. 3463–64, no other evidence was put forward showing that the duties of a pharmacist to which he testified would prohibit conduct permitted under state law. Thus, I find that his testimony regarding a pharmacist's obligations to be generally reliable and probative of whether Respondents (and their pharmacists) violated their corresponding responsibility under federal law.

the state pharmacy board, which would determine whether to cite the pharmacy for a violation. *Id.* at 2395. Mr. Sallengs further explained that the letter would not cause him to believe that a pharmacy was being improperly operated because usually a pharmacy's failure to report is due to either changing a computer system or a maintenance problem with a computer system. *Id.* at 2396–97. With respect to the letter sent to Grider #2, Mr. Sallengs did not know if his office had sent out a second letter to it. *Id.* at 2398.

Moreover, Mr. Sallengs expressed the view that where multiple entries under the same prescription number were reported within a few days of each other, it was likely a result ''of a glitch or a technical error, [an] insurance billing issue, or something like that.'' *Id.* at 2391. Indeed, Mr. Sallengs testified that some pharmacy software systems would report under a single prescription number, both when a patient presented a prescription to a pharmacy but could not pay for it that day, as well as the subsequent dispensing of the prescription. *Id.* at 2338. Mr. Sallengs further noted that there were several innocent explanations for the misreporting of various prescribers' DEA registration numbers, including errors in using the database provided by pharmacy software (which typically use a dropdown menu listing all prescribers in the country and which may include both a practitioner's current and expired registration numbers). *Id.* at 2323–25. Mr. Sallengs also explained that from the inception of KASPER until two months before his testimony, once a pharmacy reported information to the database, it was not able to correct any errors in the data. *Id.* at 2446.

On cross-examination, Mr. Sallengs acknowledged that the May 13 letter set forth violations of state law which are a Class A misdemeanor under Kentucky law. *Id.* at 2418. However, Mr. Sallengs further testified that Kentucky law proscribed only the knowing or intentional failure to transmit the information. *Id.* at 2485. Moreover, Mr. Sallengs testified that while he would ''love for everything to be exactly right'' in the KASPER reports, his office does not consider every error to constitute a violation of the statute.

*Allegation Sixteen—Respondents Committed Medicaid Fraud*

While not alleged in the Order to Show Cause, the Government provided notice in its initial and supplemental pre-hearing statements that it intended to elicit the testimony of an Agent of the Medicaid Fraud Division of the Kentucky Attorney General's Office. More specifically, the Government provided notice that the Agent ''will speak of the recent indictment of Eric Grider, the son of Leon Grider, on six counts related to devising schemes to defraud the Kentucky Medical Assistance Program (KMAP).'' Gov. Supplemental Pre-Hearing Statement at 5–6.

At the hearing, there ensued nearly three days of testimony by the Agent regarding her investigation of Respondents' billing practices, the execution of a search warrant and the seizure of Respondents' records by state officials, and the subsequent indictment of Eric Grider on six state counts of having submitted fraudulent claims to the KMAP ''for prescriptions not dispensed as billed,'' GX 43. *See* Tr. 842–1372. Regarding the alleged fraud, the Agent testified that ''the patient got what was prescribed'' but that ''Medicaid was billed for something different'' Tr. 1092, if the drug was not in the Medicaid formulary. *Id.* at 1108; *see also id.* at 860 (Agent's testimony that ''if a patient came in with a prescription, that patient would receive what the doctor ordered.''). Throughout the Agent's testimony, there was but a single vague comment relating the allegations of misconduct to Respondents' handling of controlled substances, which occurred when the Agent was asked by Respondent's counsel whether the types of drugs being billed for and the types of drugs being dispensed were controlled or non-controlled drugs, and answered: ''They were across-the-board.'' *Id.* at 1116. Ultimately, the indictment against Eric Grider was dismissed by the state court, after it declared a mistrial. RX 128. No further evidence has been offered establishing that the indictment was reinstated and that Eric Grider (or Respondent) has been convicted of an offense which subjects Respondents to mandatory exclusion from participation in federal health care programs under 42 U.S.C. 1320a–7(a).[74]

**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).[75] In the case of a practitioner, which includes a pharmacy,[76] the CSA requires that the Agency consider the following factors in making the public interest determination:

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

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

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

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

(5) Such other conduct which may threaten the public health and safety. *Id.* § 823(f).

''[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, although I ''must consider each of these factors,'' I am not required to make ''explicit findings as to each'' factor. *MacKay* v. *DEA,* 664 F.3d 808, 816 (10th Cir. 2011); *see also Volkman* v. *DEA,* 567 F.3d 215, 222 (6th Cir. 2009) (quoting *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 a 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.*

[74] Of course, once the Government was allowed to pursue this allegation, understandably, Respondents did not simply rely on their counsel's cross-examination of the Agent but also put on the testimony of their own witnesses regarding the allegations.

[75] DEA is also authorized to suspend or revoke a registration upon a finding that a registrant ''has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42.'' 21 U.S.C. 824(a)(5). However, the Government did not cite this provision as a basis for the proceeding.

[76] *See* 21 U.S.C. 802(21).

*Miller,* 53 FR 21931, 21932 (1988))), *pet. for rev. denied, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appdx. 409 (6th Cir. 2008). *See also MacKay,* 664 F.3d at 817.

''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 its actions and demonstrate that it 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, 64283 (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 each Respondent ''has committed such acts as would render [its] registration * * * inconsistent with the public interest.'' [77] 21 U.S.C. 824(a)(4). I further conclude that Respondents have not rebutted the Government's *prima facie* case.

*Factors Two and Four—Respondents' Experience in Dispensing Controlled Substances and Record of Compliance With Applicable Laws Related to Controlled Substances*

While many of the allegations are not proved by substantial evidence because the Government relied on inadmissible KASPER reports and data (or failed to put forward anything other than conclusory evidence), the record nonetheless establishes numerous violations on the part of each Respondent. More specifically, substantial evidence supports a finding that Leon Grider violated the CSA by distributing controlled substances to several persons who did not have prescriptions for the drugs and that both Respondents (and their pharmacists) violated their corresponding responsibility under 21 CFR 1306.04(a) by dispensing controlled substances to several individuals who were clearly engaged in drug-seeking behavior. In addition, the record shows that Respondents could not account for massive quantities of various controlled substances they handled and thus violated their obligations under 21 U.S.C. 827(a) to maintain complete and accurate records of the controlled substances they purchased, distributed, or dispensed. Finally, there is also substantial evidence establishing that Respondents dispensed controlled substances but could not produce either the original prescription or documentation that a prescription was called in, that it filled (or refilled) prescriptions which were not authorized by the prescriber, and that it failed to report several theft incidents to DEA.

*Leon Grider's Distributions to PL, LW, and BL*

Under the CSA, ''[p]ersons registered by the Attorney General * * * to manufacture, distribute or dispense controlled substances * * * are authorized to possess, manufacture, distribute, or dispense such substances * * * *to the extent authorized by their registration and in conformity with the other provisions of this subchapter.''* 21 U.S.C. 822(b) (emphasis added). Under 21 U.S.C. 823(f), a pharmacy registration authorizes its holder to dispense controlled substances, *i.e.,* ''to deliver a controlled substance to an ultimate user * * * by, or pursuant to the lawful order of, a practitioner.'' *Id.* § 802(10).

The CSA further provides that ''[e]xcept when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with * * * 21 U.S.C. 353(b).'' 21 U.S.C. 829(b); *see also* 21 CFR 1306.21 (''A pharmacist may dispense directly a controlled substance listed in schedule III, IV, or V which is a prescription drug * * * only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or [her] agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist.'').[78] The CSA thus makes it ''unlawful for any person * * * who is subject to the requirements of part C [the registration provisions] to distribute or dispense a controlled substance in violation of section 829.'' 21 U.S.C. 842(a)(1). *See also* 21 U.S.C. 841(a)(1).

As found above, on October 21, 2003, PL, who was cooperating with law enforcement, went to Grider #1 and presented a methadone prescription to Leon Grider; PL also told Grider that she needed some Zs, a street term for Xanax. Tr. 1420–21. However, PL did not have a prescription for Xanax. *Id.* at 1422. After leaving the pharmacy to have a smoke, PL re-entered the pharmacy and then emerged with a white bag, which she turned over to Detective Hammond. *Id.* at 1421. Upon inspecting the bag, Hammond found a pill bottle holding methadone, as well as thirty orange oval-shape pills, which were loose in the bottom of the bag. *Id.* Hammond took custody of the orange pills and submitted them for testing; the pills tested as Xanax. *Id.* at 1421–22. Substantial evidence thus supports the conclusion that Leon Grider violated the CSA in distributing Xanax to PL. 21 U.S.C. 829, 841(a)(1) & 842(a)(1).

The evidence further shows that Leon Grider unlawfully distributed controlled substances to LW on multiple occasions. On February 24, 2004, Leon Grider gave LW forty tablets of both hydrocodone and alprazolam when LW, accompanied by her boyfriend, went to Grider #1 and told Leon Grider that they were going to court but were short on their pills and were concerned that they would be subjected to a pill count. Tr. 1495–96. LW did not have a prescription for the drugs. *Id.* at 1497. Substantial evidence thus supports the conclusion that Leon Grider violated the CSA in distributing

[77] As to factor one, the Kentucky 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 pharmacy license or the pharmacist's license of either Leon or Eric Grider, 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 in the record that either Leon or Eric Grider (or either of the Respondents) 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 and thus, ''the absence of such a conviction is of considerably less consequence in the public interest inquiry.'' *MacKay,* 664 F.3d at 818. DEA has therefore 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 both Respondents may still hold Kentucky pharmacy licenses and Leon and Eric Grider may still hold their pharmacist licenses is not dispositive. So too, that neither the Respondents, nor either Leon or Eric Grider, have been convicted of an offense related to controlled substances, is not dispositive.

[78] *See also* 21 CFR 1306.11(d) (except in emergency, ''[a] pharmacist may dispense directly a controlled substance listed in schedule II, which is a prescription drug * * * only pursuant to a written prescription signed by the practitioner'').

both hydrocodone and alprazolam to LW. 21 U.S.C. 829, 841(a)(1) & 842(a)(1).

On June 4, 2004, LW obtained drugs from Leon Grider without a prescription on two occasions. First, in the morning, LW went to Grider #1 and obtained both Lortab (hydrocodone) and Xanax. As LW testified, she just went in and asked Leon Grider for some pills which he gave her loose in a brown bag. Tr. 6033. Given that placing loose pills in a bag is not how a prescription is dispensed in the usual course of professional pharmacy practice, *see* 21 CFR 1306.24, and that Leon Grider did not testify in the proceeding, I conclude that he distributed Lortab and Xanax to LW without a prescription.

Later that day, LW called Leon Grider asked him to bring her some methadone. Tr. 1500. Grider agreed to do so and delivered both methadone, which was in a sealed distributor's bottle and another 60 alprazolam (Xanax), which were in an envelope, to LW at her residence. *Id.* at 1500–01. LW did not have a prescription for either drug. *Id.* Substantial evidence thus supports the conclusion that on June 4, 2004, Leon Grider unlawfully distributed Lortab, methadone, and alprazolam to LW. *See* 21 U.S.C. §§ 829, 841(a)(1), 842(a)(1).

On April 24, 2005, LW participated in a further undercover operation. On this occasion, LW (accompanied by PG) met with Leon Grider at a graveyard and asked him for some Duragesic patches. Tr. 1507–08; GX 27. Leon Grider agreed, and later that day, he met PG at a local supermarket, where he gave PG nineteen or twenty Duragesic patches and 88 Xanax pills. *Id.* at 1508–09; GX 27. Neither LW nor PG had a prescription for the drugs. GX 27, at 2. Moreover, LW testified that she told Leon Grider that she was going to sell the patches because she needed money. Tr. 6092. Once again, substantial evidence supports the conclusion that on April 24, 2005, Leon Grider violated the CSA by unlawfully distributing Duragesic (fentanyl, a schedule II drug) and alprazolam, to LW and PG. *See* 21 U.S.C. §§ 829, 841(a)(1) & 842(a)(1).

In addition to the three undercover operations in which she participated, LW credibly testified regarding other instances in which she obtained controlled substances from Leon Grider. More specifically, LW testified that when she was initially confronted by Detective Hammond, Leon Grider gave her $1,000 and three 500-count bottles of hydrocodone and told her that she ''needed to leave town'' to let the authorities ''slack off of [her] for a while.'' Tr. 5396, 5941–42. It does not matter whether this conduct constituted bribing a witness under Kentucky law. Rather, what matters is that this is another example of Leon Grider's distributing controlled substances to LW when she did not have a prescription authorizing the dispensing. Thus, substantial evidence supports the conclusion that Leon Grider unlawfully distributed 1,500 hydrocodone tablets to LW. *See* 21 U.S.C. §§ 829, 841(a)(1) & 842(a)(1).

LW also testified regarding an incident in which Leon Grider had given her a 500-count bottle at the Key Village store only to have his wife (Anna Mae) walk in on the deal. Tr. 5930–32. While Anna Mae testified in the hearing that she took the bottle from LW and that the pills were actually pinto beans, *id.* at 4803, as found above, in a deposition she had previously given, Mrs. Grider testified that the bottle (which was a white bottle and not a prescription vial) contained hydrocodone. GX 68, at 212–15. Moreover, LW testified that the next day, she called Leon Grider, who agreed to meet her at Grider #1, and that upon meeting, Grider gave her two 500-count bottles. Tr. 5932–33. Once again, substantial evidence supports the conclusion that on this occasion, Leon Grider unlawfully distributed 1,000 hydrocodone tablets to LW. *See* 21 U.S.C. §§ 829, 841(a)(1) & 842(a)(1).

LW further testified that she had also received 98 OxyContin tablets as well some Suboxone, also without a prescription, and that Leon Grider would create false prescription labels to provide cover for LW if she was caught by the police. Tr. 5946, 6095–96, 6125. Thus, substantial evidence supports the conclusion that Leon Grider distributed both OxyContin and Suboxone to LW in violation of the CSA. *See* 21 U.S.C. §§ 829, 841(a)(1) & 842(a)(1).

In addition, substantial evidence supports the conclusion that Leon Grider unlawfully distributed Suboxone to BL when she did not have a prescription for the drug. With respect to this allegation, the evidence included a contemporaneous recording of a phone conversation between BL and Chief Irvin in which BL acknowledged that Leon Grider had given her the Suboxone when she was in the hospital and did not have a prescription for the drug, photos of the vials (and their labels) which Leon Grider used to distribute the drug that was delivered, and the testimony of BL's daughter. In addition, while Respondent produced a copy of a sales report listing BL's prescriptions, and this report shows drugs that had previously been prescribed to her, no refills were authorized under the previous prescription and Respondents did not produce a copy of any prescription corresponding to the prescription listed on the vials. I therefore hold that substantial evidence supports the conclusion that Leon Grider distributed Suboxone to BL in violation of the CSA. *See* 21 U.S.C. §§ 829, 841(a)(1) & 842(a)(1).

I further hold that Leon Grider's conduct in unlawfully distributing controlled substances to PL, LW, and BL, is egregious, and is sufficient, by itself, to support the conclusion that Respondents have committed acts which render their registrations ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). Thus, this conduct provides reason alone to revoke each Respondent's registration and to deny their applications to renew their registrations.

*Respondents' Violations of 21 CFR 1306.04(a)*

Under a longstanding DEA regulation, a prescription for a controlled substance is unlawful unless it has been ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). 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.'' [79] *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.' '' *East Main St. Pharmacy,* 75 FR 66149, 66163 (2010) (quoting *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

[79] As the Supreme Court has 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)).

(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).

As the Government's Expert explained, pharmacists are required under Kentucky law to perform a prospective drug utilization review (DUR) prior to dispensing every prescription. *See* 201 Ky. Admin. Regs. 2:210; § 4. The Kentucky regulation requires that the DUR ''shall include an assessment of a patient's drug therapy and the prescription order.'' *Id.* In addition, the DUR ''shall include a review by the pharmacist of the'' following:

(a) Known allergies;

(b) Rationale for use;

(c) Proper dose, route of administration, and directions;

(d) Synergism with currently employed modalities;

(e) Interaction or adverse reaction with applicable:

1. Drugs;

2. Foods; or

3. Known disease states

(f) Proper utilization for optimum therapeutic outcomes; and

(g) Clinical misuse or abuse.

*Id.*

The Government's Expert further identified various ''red flags'' that pharmacists are trained to be aware of to identify suspicious and unlawful prescriptions. These include: (1) When a patient is obtaining controlled substances from multiple doctors, (2) when patients are being prescribed duplicate controlled substance medications that treat the same indications, (3) when patients seek early refills, (4) when patients are obtaining prescriptions for large quantities and large doses, and (5) when patients travel long distances from where they live to either the prescriber or the pharmacy. *Id.* at 3404.

While Dr. Sullivan explained that when confronted with a red flag, there are several steps a pharmacist can take including talking to the patient, calling the physician, or refusing to fill the prescription, he further opined that each of the six patients whose prescription profiles were entered into the record were ''textbook examples'' of persons engaged in ''drug abuse and/or drug diversion.'' GX 66, at 8. According to Dr. Sullivan, each patient ''exhibited multiple instances of'' such red flags as obtaining controlled substances from multiple doctors, obtaining duplicate controlled substances to treat the same indication, and seeking early refills, *i.e.,* filling a prescription or seeking a refill when the patient should still have medication left from a prior dispensing. *Id.* at 3. Dr. Sullivan thus concluded that ''any reasonable and prudent pharmacist would have caught this behavior and refused to dispense controlled substances to'' the six patients. *Id.*

For example, TA, who filled all but three of her prescriptions at either Grider #1 or Grider #2, obtained prescriptions from twelve different prescribers including dentists, oral surgeons, pain clinic doctors, a psychiatrist, and a nurse practitioner. The record is replete with instances in which even though TA had recently received controlled substances (and more specifically schedule II (fentanyl and Endocet) and III narcotics (hydrocodone), which provided lengthy supplies (25 to 30 day supplies), TA obtained more prescriptions for the same or a similar drug which Respondents filled notwithstanding that she should have had ample medication left from her previous prescription. This pattern occurred over and over. *See* GX 66, at 4 (Expert noting that it occurred eleven times in a ten-month period). Moreover, even if TA had legitimate dental problems which caused pain, Dr. G, a dentist who treated TA (who was called by Respondent), testified that he would not have prescribed hydrocodone even on a short-term basis if he had known that TA had recently obtained narcotics from pain doctors. Tr. 4467, 4478–80, 4520. Dr. G also testified that he was never called by Grider #1 regarding any of the prescriptions TA was receiving from other practitioners.[80] *Id.* at 4520.

Tonya Moses, a pharmacist and former employee of Respondents who also testified on their behalf, acknowledged that Grider #1 had filled hydrocodone prescriptions from a dentist which overlapped with even stronger hydrocodone prescriptions TA received from a pain management doctor. Ms. Moses further admitted that these prescriptions were not justified and involved therapeutic duplication and that it was ''incumbent upon a pharmacist to verify with the doctor if he sees multiple physicians prescribing, basically, the same medication.'' *Id.* at 4214. And upon being shown TA's prescription profile, Dr. M, another of Respondents' witnesses, acknowledged that TA's pattern of drug use and seeing different doctors ''would be a matter of major concern'' and ''probably'' was ''a doctor-shopping situation.'' *Id.* at 5364–65. Yet Grider #1's pharmacists did not even call the prescribers.

Dr. Sullivan further noted that in addition to such narcotics as hydrocodone and Endocet, TA was also obtaining alprazolam and carisoprodol, ''which are known to be heavily abused.'' GX 66, at 4. Accordingly, I agree with Dr. Sullivan's conclusion that ''any reasonable and prudent pharmacist would have determined that [TA] was either abusing and/or diverting these controlled substances.'' *Id.* I further conclude that substantial evidence supports a finding that Respondents violated their corresponding responsibility in dispensing controlled substances to TA.[81] 21 CFR 1306.04(a).

With respect to RB, the evidence shows that in a twenty-eight month period, she filled 172 controlled substance prescriptions at Respondents, with all but seven being filled at Grider #1. RB's prescriptions were written by two doctors, and were for hydrocodone tablets, alprazolam, and various narcotic cough syrups.

Regarding the latter medications, the Government's Expert gave unrefuted testimony that these drugs are intended for short-term relief of cough and that clinical guidelines were changed in 2006 (before any of the prescriptions at issue were dispensed) to ''strongly discourage the use of any type of cough

[80] TA herself admitted she did not tell the various dentists she saw about the controlled substance prescriptions she was obtaining from her pain management doctor. Tr. 3915–16.

[81] Respondents took exception to the ALJ's conclusion that any evidence as to TA's medical conditions is ''irrelevant'' because there is no evidence that any pharmacist at Grider #1 was aware of her conditions at the time the prescriptions were filled. Resp. Exceptions, at 10 and 22 (citing ALJ at 31 n.12). However, even if Leon Grider was aware of TA's medical condition, there is unrefuted evidence that even where a patient may have a medical condition warranting the prescription of controlled substances, a pharmacist has a duty to determine whether filling a prescription will result in therapeutic duplication and to take appropriate action. Notably, Respondent's witness Ms. Moses testified that she had reviewed the prescriptions of the various patients whose prescriptions were the subject of the Immediate Suspension Order, and while Ms. Moses offered testimony as to why various prescriptions were filled for some of the patients, she offered no testimony regarding any notations on TA's prescriptions establishing that Leon Grider (or other any other pharmacist) notified the prescribing physician that TA was receiving controlled substances from other prescribers. In addition, while Respondents entered into evidence TA's prescriptions, none of them contain a notation that the pharmacist (whether Leon Grider or someone else) had called TA's prescriber. *See* RX 120D. Moreover, Ms. Moses admitted that Grider #1 had filled prescriptions for TA that were unjustified. Tr. 4202–03. I therefore reject this exception.

suppressant in treating any type of cough.'' Tr. 3419. Yet RB filled approximately 100 such prescriptions (for a total of 15,000 ml of the drugs) at Respondents during the period and was obtaining the prescriptions from two doctors. Tr. 3419–21; GX 66, at 4; GX 53, at Tab C. Moreover, in addition to receiving the narcotic cough syrups, RB also filled at Respondents prescriptions for hydrocodone tablets, which she also was obtaining from the two doctors.

In other instances, Respondent filled prescriptions for hydrocodone tablets issued by one doctor, even though RB should still have had a large amount of hydrocodone tablets from a thirty-day prescription she had recently filled which was issued by another doctor. Finally, the evidence also shows that RB obtained early fills or refills of prescriptions for hydrocodone tablets, narcotic cough syrups, and alprazolam, even when the prescriptions had been written (or authorized pursuant to an earlier prescription issued) by a single doctor. Indeed, many of the dispensings were more than five days early, and some were as much as nine to twelve days early.

RB testified that no one at Grider Drugs had ever talked to her about her medications or questioned her about her prescriptions. Tr. 4676, 4688–89. Moreover, while Eric Grider, the pharmacist in charge at Grider #2, where RB filled most of her prescriptions, testified that narcotic cough syrups could be prescribed on a long-term basis for COPD or chronic coronary disease with a cough, he subsequently admitted that he did not know whether RB had either condition and had never asked her doctors if she had either condition. *Id.* at 3673. As for Eric Grider's self-serving testimony that even though RB was obtaining medications from two doctors, he did not see any potential for abuse or misuse of them by her;2 Grider eventually conceded that he should have contacted her doctors to ensure that each was aware that the other was also prescribing to her.[82]

Dr. Sullivan concluded that RB's behavior clearly indicated that she was either abusing and/or diverting controlled substances and that this ''should definitely have been caught by the pharmacist.'' GX 66, at 4. He further noted that RB was obtaining duplicate therapy [83] (in that she was obtaining both narcotic cough suppressants and hydrocodone tablets), and with respect to the Xanax, he concluded that ''[n]o reasonable and prudent pharmacist would fill Xanax prescriptions this early on so many occasions.'' *Id.* at 5. I agree with Dr. Sullivan's conclusions and I further conclude that substantial evidence supports a finding that Respondents violated their corresponding responsibility in dispensing controlled substances to RB. 21 CFR 1306.04(a).

As to JB, the evidence shows that during an eight-month period, Grider #2 repeatedly filled prescriptions for alprazolam and diazepam, which are both benzodiazepines, which she obtained from two doctors. The evidence further shows that Grider #2 frequently did this within days of having filled a previous prescription, and that it even filled (or refilled) prescriptions JB presented for both drugs on the same day. Moreover, during the eight-month period covered by JB's prescription profile, Grider #2 dispensed eight alprazolam prescriptions, each for a thirty-day supply, as well as nine diazepam prescriptions, each being for a twenty-day supply, and thus provided 420-days' supply of these drugs during the period.

Regarding JB, Eric Grider offered the self-serving testimony that JB's prescriptions did not raise a red flag and that they were not a large number given the number of days' supply they provided. Tr. 3613, 3615. However, Grider offered no further explanation as to why it was appropriate to dispense 420-days' worth of alprazolam and diazepam during the eight-month period when these drugs are prescribed for the same indication.

Moreover, Dr. Sullivan observed he could not ''think of any clinical reason why a patient would be using these two drugs at the same time for a period of seven months'' and that ''[a]ny reasonable and prudent pharmacy would not have filled prescriptions for these two medications to be taken at the same time.'' GX 66, at 5. Dr. Sullivan further explained that ''[t]his is an obvious sign of either prescription drug abuse and/or diversion.'' *Id.* I agree with Dr. Sullivan's conclusions and hold that substantial evidence supports a finding that Respondents violated their corresponding responsibility in dispensing controlled substances to JB. 21 CFR 1306.04(a).

As for JR, it is undisputed that JR had been taking painkillers for a back injury for a lengthy period of time and that he had been recently diagnosed with colon cancer and had undergone various procedures, including a colon re-section, and was undergoing chemotherapy. However, while these were undoubtedly serious medical conditions which could cause pain and warrant the prescribing of controlled substances, Respondent Grider #1 filled prescriptions JR was simultaneously obtaining from multiple doctors for narcotics including OxyContin and hydrocodone.

It is acknowledged that Ms. Moses offered credible evidence explaining why several of the short-term prescriptions were filled, as well as why two of the OxyContin prescriptions had been filled early. Moreover, even assuming (as Ms. Moses testified) that the refill request form which Dr. W's office faxed into Grider #1 establishes that Dr. W was aware that JR was taking OxyContin for pain control, it does not explain why Respondents also filled prescriptions for both OxyContin and hydrocodone which JR was obtaining from Drs. K (his surgeon) and B (a pain management specialist) at the same time he was also obtaining hydrocodone from Dr. W.

With respect to JR's OxyContin and hydrocodone prescriptions, Dr. Sullivan noted that while ''on rare occasions, cancer patients will use a second narcotic like hydrocodone for break-through pain on an 'as needed basis' for a short-term period[,] [t]he same doctor would write prescriptions for both.'' GX 66, at 6. As Dr. Sullivan then explained, ''[t]his is a major red flag that the patient was receiving hydrocodone prescriptions from three different doctors and OxyContin from two different doctors at the same time. Any reasonable and prudent pharmacist would have caught this and not filled these prescriptions.'' *Id.* In addition, Dr. Sullivan noted that ''[o]f the thirty-three controlled substance prescriptions filled'' by Grider #1, ''at least eleven times the pharmacy filled the medication too early.'' *Id.*

[82] Grider also asserted that he had no way of knowing whether RB was a doctor shopper because Respondents did not have an account with KASPER. I note that Dr. Sullivan offered no testimony as to whether the standards of pharmacy practice in either Kentucky (or nationally) require that a pharmacist use an available prescription monitoring database where one is available. Thus, I place no weight on Leon or Eric Grider's failure to run KASPER reports on any of the six patients.

While Grider also asserted that because RB did not have insurance, he had no way of knowing whether she was filling prescriptions at other non-Grider stores, Tr. 3602, I note that Grider did not even check to see what prescriptions RB filled at the other Grider stores.

[83] As explained in footnote 52, while Dr. P provided an unsworn statement that RB had ''a legitimate reason to take pain medicine,'' he offered no explanation as to why she needed to obtain narcotics from another doctor. Nor did he explain what condition RB had that warranted the long-term prescribing of narcotic cough syrups or alprazolam. Indeed, Dr. P corroborated Detective Hammond's statement that he did not know RB was seeing another physician until April 2010.

Dr. Sullivan thus concluded that the ''duplicate therapy with both hydrocodone and oxycodone (OxyContin) from more than one prescriber is a clear indication of drug abuse and/or diversion and any reasonable and prudent pharmacist would have detected this.'' [84] *Id.* Accordingly, while JR had a serious medical condition for which the prescribing of controlled substances was warranted, I conclude that substantial evidence supports a finding that Grider #1 violated its corresponding responsibility in dispensing multiple prescriptions for these drugs to him. 21 CFR 1306.04(a).

The evidence with respect to CR shows that between November 2007 and early April 2010, he filled at Respondents approximately 163 prescriptions for such drugs as Demerol, hydrocodone/apap tablets, various narcotic cough syrups, and alprazolam. While CR asserted that he had a back injury, the evidence shows, throughout the period, that while he received prescriptions from Dr. C for 120 tablets of Vicodin 5/500mg (a thirty-day supply), which he filled at Grider #1, he also filled an additional 49 prescriptions for twenty tablets of hydrocodone 7.5/650, which he obtained from Dr. P. Notably, CR filled all but two of Dr. P's hydrocodone prescriptions at Grider #2. In addition, on multiple occasions, CR filled prescriptions for both hydrocodone tablets and narcotic cough suppressants.

In addition, CR obtained 64 alprazolam prescriptions and refills, each being authorized by Dr. P and providing a thirty-day supply. All but seven of these were filled at Respondents, and while CR eventually started filling some of the alprazolam prescriptions at another pharmacy, he did not do so until late April 2009. The evidence further shows that on numerous occasions, Respondents filled or refilled an alprazolam prescription within days of having filled or refilled a prescription for the drug. As found above, CR obtained a total of 1,920 days' supply of alprazolam in a period lasting approximately 900 days.

CR admitted that he did not tell Dr. P that he was also getting controlled substances from Dr. C, and claimed that Dr. P did not ask him. Tr. 4029. Moreover, CR admitted that he never told Dr. C that he was also receiving controlled substances from Dr. P. *Id.* at 4039.

Eric Grider admitted that he did not talk to Dr. P about CR. Moreover, he then offered the self-serving testimony that because CR was a cash-paying patient, he was unaware that CR was filling prescriptions at other pharmacies; indeed, Grider raised the ostrich defense, claiming that he ''had no reason to'' even check to see if CR was filling prescriptions at Grider #1. *Id.* at 3619.

Most remarkably, Grider offered the patently disingenuous testimony that he was unaware of unauthorized refills which occurred at Grider #2, notwithstanding that on February 1, 2008, it filled a new alprazolam prescription even though it had refilled a prescription for the drug the day before. GX 56, Tab C, at 2. Moreover, on April 30, 2008, Grider #2 dispensed a new alprazolam prescription even though it had dispensed a refill of a previous alprazolam prescription six days earlier, and on April 28, Grider #1 also filled an alprazolam prescription for CR. *Id.* Thus, early on in the period covered by the spreadsheet, Eric Grider had reason to know that CR was engaged in either drug abuse or diversion. Yet Eric Grider failed to question CR's doctors to determine if they knew that other doctors were also prescribing to him and could not even be bothered to check to see whether CR was filling prescriptions at Grider #1.

As Dr. Sullivan noted, ''in multiple instances,'' CR filled alprazolam prescriptions ''early at both pharmacies,'' and did so approximately fourteen times, with some of the refills occurring as much as ''twenty-nine days too early.'' GX 66, at 7. As Dr. Sullivan further explained, ''a reasonable and prudent pharmacist would never have filled these alprazolam prescriptions as early as the Grider pharmacies did. This shows a pattern of either abuse and/or drug diversion.'' *Id.* I agree with Dr. Sullivan's conclusions and hold that substantial evidence supports a finding that Respondents violated their corresponding responsibility in dispensing controlled substances to CR.[85] 21 CFR 1306.04(a).

With respect to SR, the evidence shows that during a period of less than seven months, she filled twenty-four controlled substance prescriptions at Grider #2 for hydrocodone, oxycodone, and clonazepam. Five of the hydrocodone prescriptions and one oxycodone prescription were issued by Dr. H, an orthopedic surgeon; eight were issued by Dr. S, a family practitioner; one by NP H, who was in the same practice as Dr. S, and one by Dr. M, who was a dentist. More specifically, on October 5, SR filled a prescription issued by Dr. S for 42 hydrocodone 5/500, this being a fourteen-day supply; on October 13, she filled a prescription from Dr. M for twelve hydrocodone 7.5/650, this being a three-day supply; and on October 21, she filled a prescription issued by NP H for another 42 hydrocodone, also a fourteen-day supply.

Other evidence shows that on October 8, 2009, SR had a tooth extracted and that she was prescribed the hydrocodone for post-operative pain. However, SR's dental records contained no indication that she had reported her use of hydrocodone to Dr. M.

SR's prescriptions in March and April 2010 provide more convincing evidence that she was engaged in doctor-shopping. Specifically, on March 8, 2010, Dr. S (her family doctor) prescribed 90 tablets of hydrocodone 5/500, a thirty-day supply, and on April 8, Dr. W (who replaced Dr. S as her family doctor but was in the same office) prescribed her another 90 tablets. Moreover, on March 10, 18, and 27, as well as April 1 and 23, SR filled prescriptions issued by Dr. H, each being for thirty tablets of hydrocodone 7.5/500.

Detective Hammond interviewed Drs. H, M, S, and W, each of whom told Hammond that they would not have prescribed controlled substances to SR if he/she had been aware that SR was obtaining controlled substances from another physician. Drs. S and W further told Hammond that SR was subject to a pain management contract pursuant to which SR could not obtain controlled substances from another physician without prior authorization. In addition, Dr. H stated that if he had known that SR was receiving controlled substances from Dr. S, he would have contacted Dr. S to ensure that they were not issuing overlapping prescriptions.

By contrast, SR, who testified that she had undergone surgeries on both her elbow and shoulder, testified that she told the admitting nurse prior to a surgery performed by Dr. H that she was taking hydrocodone fives, thus suggesting that Dr. H knew that she was obtaining controlled substances from

[84] As Detective Hammond found in reviewing JR's patient file, there is other reliable evidence establishing that JR engaged in drug abuse and/or diversion. *See supra* n.60. Moreover, as found above, JR admitted to sharing his medications with others. While a pharmacist would not have this information, Respondent did have evidence that JR was obtaining prescriptions for the same drugs from multiple doctors and yet chose to fill the prescriptions anyway.

[85] Upon being shown the evidence that CR had filled a prescription for twenty-eight tablets of hydrocodone only six days after filling a prescription for 120 hydrocodone tablets, Ms. Moses, who testified on behalf of Respondent, stated that she would have called the physician to let her know of the overlapping prescription. Tr. 4429.

her family doctor.[86] Tr. 4721. However, in her decision, the ALJ did not address whether she found SR's testimony, which was vague as to the date of the incident, credible.

In any event, I conclude that it is not necessary to resolve this dispute because Eric Grider acknowledged that SR's prescriptions involved therapeutic duplication and he did not recall having called either Dr. H or Dr. W. Indeed, Grider denied having any obligation to call SR's prescribers, asserting that such contact was ''a courtesy'' and that he fulfilled his obligation if he counseled a patient as to the appropriate manner in which to take the drugs. However, SR testified that she was neither questioned by anyone at Grider #2 about her prescriptions nor counseled as to how to take the medications.

As Dr. Sullivan testified, when confronted with evidence of red flags, there are several things a pharmacist can do, including having an extensive conversation with the patient, calling the physician, or refusing to fill the prescription. *Id.* at 3448–49. However, with respect to SR, Eric Grider did none of the above. Indeed, as Dr. Sullivan testified, it is clear that Respondents did not do prospective DUR with respect to any of the six patients even though this is required by the Kentucky Board of Pharmacy's rules. *Id.* at 3453–54. I therefore conclude that substantial evidence supports a finding that Grider #2 dispensed controlled substances to SR in violation of 21 CFR 1306.04(a).

I further hold that Respondents' dispensing violations are egregious and provide further support for the conclusion that each has committed acts which render its registration ''inconsistent with the public interest'' and thus support the revocation of its registration.[87] 21 U.S.C. 824(a)(4).

*The Audits*

As found above, DEA Investigators performed two audits of Respondents' handling of controlled substances. However, the Government conceded that the first audit was flawed because it included both purchases and distributions which occurred outside of the audit period. While the supervisory DI performed a second audit on a limited number of controlled substances, this audit was also flawed because it relied on KASPER data (notwithstanding that Kentucky does not guarantee the accuracy of the data, Tr. 2335, and KASPER reports contain this caveat, *id.* at 2337), rather than the dispensing records which Respondents are legally required to maintain under the CSA and DEA regulations to determine the quantities of drugs which they dispensed.

Recordkeeping is one of the CSA's principal tools for preventing the diversion of controlled substances. *Paul H. Volkman,* 73 FR 30630, 30644 (2008). Under the Act, ''every registrant * * * dispensing a controlled substance or substances shall maintain, on a current basis, *a complete and accurate record* of each such substance * * * received, sold, delivered, or otherwise disposed of by him.'' 21 U.S.C. 827(a) (emphasis added). I have further explained that ''a registrant's accurate and diligent adherence to [its recordkeeping] obligations is absolutely essential to protect against the diversion of controlled substances.'' *Volkman,* 73 FR at 30644.

One of the purposes of performing an audit is to assess a registrant's level of compliance with the CSA's recordkeeping requirements. Thus, using data from a non-CSA required record rather than CSA required records, cannot, by definition, provide an accurate picture as to the adequacy of a registrant's compliance with section 827.[88] That error is compounded where, as here, the source of the data expressly disclaims any guarantee that its data is accurate and it is unclear to what degree the reports are accurate. Indeed, the DI acknowledged that he had ''no idea how accurate'' the KASPER data was. Tr. 622. Thus, this audit was also flawed.

Nonetheless, I agree with the ALJ's conclusion that the results of the ''consultation examination'' performed by Stivers and Associates provide substantial evidence that Respondents cannot account for significant quantities of various controlled substances and thus have violated section 827. ALJ at 85–87. Indeed, the shortages and overages that Stivers found at each of the Grider stores are stunning and establish that Respondents have committed egregious recordkeeping violations and likely diverted thousands of dosage units (d.u.) of controlled substances.

As found above, Grider #1 had shortages of the following benzodiazepines: 2,316 d.u. of alprazolam, 6,372 diazepam, and 2,191 lorazepam. With respect to the narcotics it handled, Grider #1 had shortages of 28,097 d.u. of hydrocodone, 462 Duragesic (fentanyl) patches, 500 Lorcet, 375 Lortab, 214 Endocet, and 200 Vicodin. Grider #1 also had overages of 7,568 clonazepam, 3,025 methadone, 1,751 phentermine, 1,335 oxycodone, 514 Stagesic, and 262 OxyContin.

Grider #2 had shortages of 17,875 d.u. of OxyContin, 8,135 hydrocodone, 3,207 methadone, 3,203 phentermine, 2,013 Stagesic, 1,253 lorazepam, 428 Ambien, and 290 Duragesic. It also had overages of 8,615 clonazepam, 2,787 diazepam, 662 Valium, 619 Lorcet, 425 Endocet, 342 Lortab, and 109 Vicodin.

Moreover, even after combining the shortages and overages for all three stores, Respondents had shortages of 1,496 alprazolam, 7,329 diazepam, 4,928 lorazepam, 605 Duragesic (fentanyl) patches, 35,418 hydrocodone, 16,998 OxyContin, and 2,791 phentermine. Respondents also had overages of 31,951 clonazepam, 15,747 methadone, 1,051 Lorcet, 900 oxycodone, 889 Lortab, 871 Endocet, and 872 Valium.[89] As explained in my findings of fact, under the CSA, Respondents are required to maintain accurate and complete records for each registered location and for each finished form of a drug.

In their Exceptions, Respondents contend that its audit ''was not presented as a final and accurate audit

[86] SR also testified that she did not tell her family practitioner about the prescription she had obtained from her dentist ''because it was in between visits when I got the ones from'' the dentist. Tr. 4722. The Government also asked SR whether she told Dr. W that she was receiving controlled substances from Dr. S; SR, who was apparently confused by the question, testified that she told Dr. W that she had gotten pain medicine after her surgery. *Id.* at 4723. However, as noted above, Drs. S and W were both family practitioners who worked at the same office.

[87] Respondents further contend that the Government was ''only able to identify these six instances of what [it] alleges to be 'doctor shopping.''' Respondent Exceptions, at 21. Suffice it to say that the Government's evidence is more than enough to sustain the allegations, given that several of the patients demonstrated a sustained pattern of obtaining prescriptions for similar drugs issued by different prescribers or presenting numerous early refills.

Respondents also contend that because Dr. Sullivan based his conclusions ''by looking only at the prescription patterns'' of the patients and testified that he was generally unaware of their medical conditions, this does not constitute substantial evidence of doctor-shopping. *Id.* at 21–22 & n.3. However, with respect to several of the patients, several of Respondent's witnesses acknowledged that the prescription patterns were indicative of doctor-shopping. Indeed, even Eric Grider conceded (albeit, grudgingly) that CR was a doctor shopper; he also acknowledged that he should have called RB's and SR's prescribers.

[88] This is not to say that using other data sources would be inappropriate in all cases. For example, if sizeable portions of a registrant's dispensing records are missing, use of data or records from a non-CSA source would be justified to determine whether diversion is occurring. Of course, in such a case, it would already be clear that the registrant had failed to comply with its recordkeeping obligations. However, in this case, there is no evidence that either of the Respondents was missing any dispensing records.

[89] To make clear, under section 827, each registrant is required to maintain complete and accurate records. While I discuss the combined figures for all three stores, as found above, each of the Grider stores could not account for massive quantities of controlled substances.

of the period in question'' but ''was presented to demonstrate that the DEA audit was not reliable.'' Exceptions at 5. Mr. Hicks, however, testified at length as to the procedures his firm employed in performing its examination and it is clear that those procedures provided an accurate result. For example, while Respondents argue that Mr. Hicks ''did not review some prescriptions when he performed the audit,'' his report stated that he tabulated the quantities of the dispensings from the Respondents' pc V computer software system Narcotic and Controlled Substances Drug Sales Report, a record which constitutes a dispensing record for purposes of the CSA. *See* RX 101, at 63.

Because Registrants are required to maintain the dispensing records under federal law and Agency regulations, and those records are required to be ''complete and accurate,'' 21 U.S.C. § 827, an audit is not rendered invalid because the hard copy prescriptions were not reviewed. Indeed, in performing audits, DEA personnel typically review only the dispensing log to determine the respective quantities of the various controlled substances which have been distributed.

Equally unpersuasive is Respondents' claim that the Stivers' results were skewed by ''an inaccurate beginning inventory.'' Exceptions, at 5. As Mr. Hicks explained in his report, his firm ''used the same beginning inventory [May 31, 2003] as the DEA did.'' RX 101, at 62. However, the evidence shows that the beginning inventories which DEA used were actually inventories which Respondents had themselves performed. Thus, if the beginning inventories used by Mr. Hicks's firm were inaccurate, it is because Respondents themselves did not take accurate inventories. Moreover, Mr. Hicks was adamant that the ending inventories were reliable, Tr. 2095, and that he had relied on ''source documentation,'' *i.e.,* records provided by the companies that sold controlled substances to Respondents to determine their purchases. *Id.* at 2102.

Thus, it is patently disingenuous for Respondents to now assert that their own audit is not reliable. And as explained above, each DEA registrant is required to maintain complete and accurate records for each controlled substance it handles. Thus, the testimony of Mr. Hicks that when all the controlled substances are added up across all three stores, the audit shows an overage of 644 pills, which in his view is immaterial, is utter nonsense. Rather, the audit reflects an abject failure on Respondents' part to comply with the CSA's record keeping requirements and gives substantial credence to the Government's contention that Respondents were engaged in massive diversion. This provides further reason to conclude that Respondents have committed acts which render their registrations ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4).

*Other Violations*

As explained above, a principal component of the Government's evidence in support of many of the remaining allegations was data or reports obtained from KASPER. However, because the Government did not obtain a court order, it cannot rely on that evidence in this proceeding. Nonetheless, a few of the allegations were proved by substantial evidence.

For example, in several instances, the Government produced copies of labels for various prescriptions which were dispensed and yet they could not find either the original signed prescriptions or a called-in prescription which authorized the dispensing. These included prescriptions for hydrocodone (*see* GX 15, at 4; Tr. 422) and Xanax (GX 16, at 6; Tr. 442). As explained previously, under 21 U.S.C § 829 and 21 CFR 1306.21(a), a pharmacist may dispense controlled substances (in schedules III through V) ''only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist.'' 21 CFR 1306.21(a). Moreover, a pharmacy is required to maintain the prescription for a period of two years.[90] 21 U.S.C. 827(b); 21 CFR 1304.04 (a) & (h).

In addition, the record contains substantial evidence (apart from KASPER data) that Leon Grider provided an unauthorized refill of a Lortab (hydrocodone) prescription to BW. *See* GX 30; GX 70; Tr. 3040, 3050–52, 3054–55. Dr. CS, BW's physician, testified that BW wanted to get off of Lortab and that she was tapering BW off of the drug and had authorized no refills. Nonetheless, Leon Grider provided refills to BW, thus interfering with the clinical judgment of Dr. CS. It is manifest that Grider's action is outrageous and threatened the safety of BW.

The Government further established that a number of the prescription labels Respondent prepared contained the name of a physician other than the one who had actually prescribed the drug. *See* GX 26, at 1–2; 7–8; 9–10. This is a violation of 21 CFR 1306.24(a) (''The pharmacist filling a prescription for a controlled substance listed in schedule III, IV, or V shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, [and] *the name of the practitioner issuing the prescription * * *.''*) (emphasis added). In addition, other evidence shows that Respondent put false prescription labels on bottles. *See* Tr. 5946, 6095–96, 6126 (testimony by LW) and Tr. 3201, GX 71 (Chief Irvin's testimony and evidence of duplicate pill bottles for BL).

Finally, the Government also established that on several occasions,

[90] Respondents also take exception to the ALJ's finding that they dispensed controlled substances without retaining a hard copy of the prescriptions ''because the only basis for the alleged violations are[sic] the failure of Agent Otero to find the hard copies of the prescriptions in the records he seized'' on August 19, 2004. Resp. Exceptions at 24. Respondents further noted that on November 21, 2005, the State Pharmacy Board seized its prescriptions pursuant to three administrative subpoenas, and that they have been unable to obtain copies of the documents seized by the Pharmacy Board. *Id.*

Respondents thus argue that ''the substantial evidence that the Respondents did not have hard copies of some prescriptions for schedule II drugs was Otero's inability to find those hard copies in the record the DEA seized. There was no evidence presented by the Government that Otero had searched the records seized by the Kentucky Pharmacy Board to determine whether the missing hard copies of the prescriptions in question were there.'' *Id.* at 25.

DI Otero testified, however, that during the search, the Investigators could not find some of the prescriptions, even though under Federal law, Respondents were required to maintain them at the respective registered location. Tr. 213; 671–72. This testimony is more than enough to provide substantial evidence that Respondent could not provide hard copies of various prescriptions. Contrary to Respondents' understanding, the Investigators were not required to conduct a subsequent search to establish this violation, let alone a review of the records seized by another agency more than a year later.

Respondents also contend that because of the ongoing state criminal proceedings against both Leon and Eric Grider, the ALJ ''should not [have] allow[ed] the inability of the Respondents to rebut these alleged violations by providing the requisite hard copies of the prescriptions and call-in scripts carry the day * * * when it is a matter of record that the Respondents have been deprived of their records throughout these proceedings.'' Resp. Exceptions, at 26.

To make clear, DEA did not deprive Respondents of any of their records, but rather allowed them to make copies of the records seized by the Agency. Tr. 214–16. Beyond this, the argument is to no avail because under Federal law and DEA regulations, Respondents were required to have the prescriptions at issue on hand and available on the date of the DEA search. *See* 21 U.S.C. 827(b) (''Every inventory or other record required under this section * * * shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.''); *see also* 21 CFR 1304.04(a).

Respondents failed to report thefts of controlled substances to DEA. This is a violation of 21 CFR 1301.76(b), which requires that a registrant ''notify the Field Division Office of the Administration in his area, in writing, of the theft and significant loss of any controlled substances within one business day of the discovery of such loss or theft'' and to complete and submit a written report of the incident on DEA Form 106. However, these violations are relatively minor when compared to the other misconduct proved in this matter.

The Government also contends that Respondents violated Kentucky law by failing to provide complete and accurate information to KASPER. *See* Gov. Post-Hearing Br., at 100–101. However, under Kentucky law, only the knowing or intentional failure to transmit such information is a violation and there is no evidence that the State has undertaken enforcement action against Respondents, let alone held them to be in violation. Indeed, much to the Government's dismay, Mr. Sallengs, the director of KASPER, did not seem particularly troubled by Respondents' various reporting errors and omissions. In light of this, I dismiss this allegation.

*Factor Five*

In its post-hearing brief, the Government also contends that the findings of an investigation of the Kentucky Medicaid Fraud Division establish that Grider #2 engaged in the billing fraud when it billed Medicaid for drugs that were not actually dispensed including controlled substances. Gov. Post-Hrng. Br., at 92. However, in support of its contention, the Government offered nothing more that the conclusory assertion that ''[f]actor five is also relevant to findings of the investigation of the Kentucky Medicaid Fraud Division that * * * Grider Drug #2 unlawfully billed Medicaid (including transactions involving prescriptions for controlled substances) where prior authorization was not provided.'' *Id.* The Government did not cite any authority for its position.

The ALJ agreed with the Government, reasoning that this conduct constitutes ''[s]uch other conduct which may threaten public health and safety'' because ''[w]hen a registrant clearly engages in conduct involving controlled substances that is untruthful, that registrant creates yet another risk of diversion.'' ALJ at 93–94 (citing *Alexander Drug Company, Inc.,* 66 FR 18299, 18304 (2001); *Nicholas A. Sychak, d/b/a Medicap Pharmacy,* 65 FR 75959,75968 (2000); *Arthur Sklar, d/b/a King Pharmacy,* 54 FR 34623, 34627 (1989)). Based on her finding that Eric Grider and another pharmacist ''reported to Medicaid one medication when they actually dispensed another'' and that ''[t]hese medications included controlled substances,'' the ALJ further explained that ''the prescription check and balance such Medicaid reporting creates was circumvented by this false method of reporting'' and that ''[w]ithout such trust and truthfulness, the system of monitoring the transit of controlled substances falls apart.'' *Id.* at 94.

However, while two of the three cases cited by the ALJ arguably support the proposition that billing fraud constitutes conduct which is actionable under factor five, in both cases the creation of a fraudulent record was clearly part of a scheme to divert controlled substances. For example, in *Alexander Drug,* a pharmacist had dispensed lorazepam to himself ''without a prescription issued by a practitioner in the usual course of professional practice'' and then created a false prescription in his wife's name because her insurance did not require a co-payment. 66 FR at 18301. Likewise, in *Sychak,* there were findings which support the conclusion that the billing fraud was engaged in as part of a scheme to divert drugs. *Id.* at 75965 (noting interview of pharmacy employee that when she reviewed her prescription profile, she ''discovered numerous prescriptions listed as billed to her insurance carrier that were allegedly issued to her by various physicians she had never seen for drugs she had never received'' and that when the employee confronted the pharmacist, he replied: ''How do you think I pay for your health insurance?'').[91]

Most significantly, more than seven weeks before the ALJ issued her decision in this matter, I issued my Decision in *Terese, Inc., D/B/A Peach Orchard Drugs,* 76 FR 46843 (2011). Yet the ALJ failed to even acknowledge *Terese,* let alone explain why it is not controlling.

In *Terese,* the Agency sought, pursuant to its public interest authority, to revoke a pharmacy registration issued to the spouse of a pharmacist, who had opened up a new pharmacy, after her spouse and his pharmacy had been convicted of health care billing fraud. *Id.* Therein, the Government alleged four reasons for doing so: (1) The pharmacy owner's spouse had been convicted of health care fraud and mandatorily excluded from participation in federal health care programs pursuant to 42 U.S.C. 1320a–7(a); (2) that the pharmacy had materially falsified its state Medicaid application; (3) that the pharmacy had failed to provided information that was requested by the state Medicaid program; and (4) that the convicted pharmacist had unlawfully dispensed Medicaid controlled substance prescriptions. *Id.* There was, however, no evidence substantiating the allegation that the convicted pharmacist (and his pharmacy) had committed violations of the CSA. *Id.* at 46846.

In rejecting the Government's contentions, I noted that the CSA, as originally enacted, authorized the revocation of a registration only on the following three grounds: (1) Where a registrant has materially falsified an application for registration; (2) where a registrant has been convicted of a felony related to controlled substances; and (3) where a registrant is no longer authorized by state law to handle controlled substances. *See* 21 U.S.C. 824(a)(1)–(3). I further noted that it was not until 1984 that Congress, having concluded that the existing grounds had proved '''overly limited''' and had '''a severe adverse impact on Federal anti-diversion efforts,''' amended the CSA to add the public interest authority. 76 FR at 46847–48 (quoting H.R. Rep. No. 98–1030, at 266 (1984)).[92] However, in *Terese,* I also noted that Congress did not amend section 824 to grant the Agency authority to revoke the registration of an individual or entity subject to mandatory exclusion by the Secretary of HHS from Medicare or Medicaid until three years after it enacted public interest provisions. *Id.* at 46848 (discussing history of 21 U.S.C. 824(a)(5)).

Moreover, as I explained in *Terese,* under 42 U.S.C. 1320a–7(a), the Secretary's mandatory exclusion is triggered *only* when an individual or entity *has been convicted* of one of four categories of offenses such as for ''program-related crimes,'' which includes, in part, ''a criminal offense related to the delivery of an item or service under * * * 42 U.S.C. §§ 1395 *et seq.* * * * or under any State health care program,'' or ''a conviction 'under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health program * * * operated by or financed by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement

[91] As for *Sklar,* that case contains no discussion of billing fraud and whether it is actionable conduct under factor five.

[92] The House Report was reprinted in 1984 U.S.C.C.A.N. 3182, 3448.

* * * or other financial misconduct.''' 42 U.S.C. 1320a–7(a) (emphasis added). Accordingly, a person or entity's DEA registration is not subject to revocation under section 824(a)(5) unless he/it has been convicted of an offense falling within one of the four enumerated categories. Notably, section 824(a)(5) does not give the Agency authority to revoke the registration of a person or entity which is subject only to the Secretary's permissive exclusion authority, even though the Medicare/Medicaid exclusion statute contains some sixteen separate grounds for permissive exclusion, many of which involve acts of misconduct which reflect adversely on the truthfulness of the person subject to the exclusion. *See* 42 U.S.C. 1320A–7(b).

In *Terese,* I further explained that under the Government's interpretation of the scope of its authority under the CSA's public interest provisions, there was no need for Congress to enact section 824(a)(5) and that its interpretation would render this provision, and the limitation it imposes, meaningless. 76 FR at 46848. However, as I noted, statutes ''are not to be construed in a manner that renders their texts superfluous.'' *Id.* (citing *Bloate* v. *United States,* 130 S.Ct. 1345 1355 (2010) (quoting *Duncan* v. *Walker,* 533 U.S. 167, 174 (2001) (''[A] statute ought, upon, the whole, to be so construed that, if it can be prevented, no clause, sentence or word shall be superfluous, void, or insignificant.''))). In short, were an allegation that a Registrant has committed Medicaid fraud actionable under factor five of the public interest standard as ''such other conduct which may threaten public health and safety,'' then Congress did not need to amend section 824 by adding subsection (a)(5). Yet not only did Congress amend the statute, it then limited the Agency's revocation authority to those instances in which a registrant has been convicted of a felony enumerated in 42 U.S.C. 1320A–7(a).

In *Terese,* I also explained that where an allegation both implicates a public interest factor (or another of the Agency' revocation authorities), as well as falls within the Secretary's permissive exclusion authority, DEA retains authority to revoke under the applicable authority of section 824. However, as *Terese* makes clear, the Agency cannot disregard clear statutory text and the CSA's history. Thus, even though it is indisputable that committing billing fraud is egregious misconduct, simply overcharging the Government without more does not necessarily threaten ''threaten public health and safety.'' 21 U.S.C. 824(a)(5).

As explained above, the ALJ concluded that Respondent's alleged Medicaid billing falls within factor five because ''the prescription check and balance such Medicaid reporting creates was circumvented by this false method of reporting'' and that ''[w]ithout such trust and truthfulness, the system of monitoring of controlled substances falls apart.'' ALJ at 94.

However, there is no evidence in this proceeding that Medicaid billing records are used to monitor the disposition of controlled substances and whether they are being diverted, and as explained above, the CSA creates its own scheme of recordkeeping to monitor the disposition of controlled substances. Second, to the extent the Government's evidence even constitutes substantial evidence of billing fraud—an issue which need not be decided—there is no evidence that Grider #2's pharmacists engaged in the fraud as part of a scheme to divert controlled substances.

As the KBI agent testified, the fraud involved billing for a drug in the Medicaid formulary when a patient brought in a prescription for a drug which was not covered by the formulary and would require pre-authorization. However, the KBI Agent testified that the patient received the drug that the doctor prescribed. Indeed, while in response to the question of whether the drugs involved controlled or non-controlled substances, the KBI Agent testified that ''[t]hey were across-the-board,'' Tr. 1116, neither the Agent in her testimony, nor any of the Interview Summaries of Respondents' employees, provide any basis for concluding that Respondents engaged in the scheme to facilitate the diversion of controlled substances.

In short, the Government's evidence simply establishes run-of-the-mill billing fraud, without any further proof as to how the fraud threatened public health or safety as required under factor five. Moreover, no evidence was offered that either Eric Grider or Grider #2 has been convicted of health care fraud and is subject to mandatory exclusion from participation in federal health care programs pursuant to 42 U.S.C. 1320a7(a).

This is not to deny the ALJ's well-placed concern that the commission of health care fraud raises a serious question as to the trustworthiness of a registrant. However, with respect to allegations that a registrant has engaged in health care fraud, because the CSA limits the Agency's revocation authority to those instances in which a registrant has been convicted of an offense which subjects it to mandatory exclusion, absent evidence that the fraud was engaged in as part of scheme to divert controlled substances, the CSA clearly contemplates that these allegations are to be litigated in the first instance in federal and state criminal courts, and not in DEA registration proceedings.[93] The allegation is thus not properly considered in this proceeding.

*Summary of the Government's Case*

As found above, under factors two and four, the Government has proved with substantial evidence numerous violations of the CSA. These include: (1) Leon Grider's distribution of controlled substances either without a prescription or by providing refills which were not authorized by the prescribing physician; (2) Respondents' repeated dispensing of controlled substances to persons who were obviously either engaged in drug abuse or diversion; (3) Respondents' clear inability to account for substantial amounts of the controlled substances they handle; (4) their inability to provide prescriptions for various dispensings; and (5) the creation of false prescription labels. In sum, Respondents (and their principals, Leon and Eric Grider) have committed egregious misconduct which supports the further finding that they have ''committed such acts as would render [their] registration[s] * * * inconsistent with the public interest'' and which supports the revocation of their registrations. 21 U.S.C. 824(a)(4). I further conclude that the allegations underlying the Immediate Suspension Order have been proved by substantial evidence.

**Sanction**

Where, as here, the Government has made out a *prima facie* case, the burden shifts to the Respondents 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.*

[93] Even where there is evidence that billing fraud was engaged in as a part of a scheme to divert controlled substances, the fraud is, at most, secondary to the diversion and adds little to the Government's case. In this matter, the Government's decision to litigate the issue resulted in at least five days of additional testimony (if not more) and prompted an interlocutory appeal, thus further delaying the resolution of the serious charges raised in this matter. Notwithstanding the importance of the issue to its case (at least as presented at the hearing), the Government's discussion of the allegation produced but a single sentence in its brief.

*for rev. denied, Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appdx. 409 (6th Cir. 2008). *See also MacKay,* 664 F.3d at 817.

''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 its actions and demonstrate that it 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, 64283 (1998); *Prince George Daniels,* 60 FR 62884, 62887 (1995).

Respondents have utterly failed to rebut the Government's *prima facie* case. With respect to Grider #1, as the ALJ noted, Leon Grider, the pharmacist in charge at Grider #1, and the principal owner of both pharmacies, did not testify in the proceeding.[94] Moreover, Grider #1 produced no evidence as to corrective measures it has undertaken to prevent a re-occurrence of the misconduct it has committed. Thus, Respondent has produced no evidence that it (as well as its owner and pharmacist in charge) accept responsibility for their misconduct and that they will not engage in future misconduct.[95] *Cf. Baxter* v. *Palmigiano,* 425 U.S 308, 319 (1976) (''[T]he Fifth Amendment does not forbid adverse inferences against parties to civil actions when they refuse to testify in response to probative evidence offered against them.'').

While Eric Grider testified regarding the violations committed by Grider #2, he acknowledged that only one of the patients (CR) to whom Grider #2 had unlawfully dispensed controlled substances was engaged in doctor-shopping, and even then, did so grudgingly. Moreover, when taken as a whole, Eric Grider's testimony manifests that he neither accepts responsibility for his misconduct nor has implemented corrective measures to prevent diversion in the future. For example, when confronted with evidence of a patient obtaining prescriptions from multiple doctors, Grider testified that he nonetheless considers calling the prescriber to be a courtesy. As a further example, Grider testified that he would not even check to see if a patient was obtaining controlled substances from his father's store. Finally, Grider offered no evidence as to any remedial measures which have been undertaken at Grider #2. Thus, I conclude that Eric Grider remains utterly indifferent as to the scope of his and Grider #2's obligations under both Kentucky and Federal law to prevent the abuse and diversion of controlled substances. Accordingly, I conclude that Respondents have failed to rebut the Government's case.

Respondents nonetheless argue that I should reject the ALJ's conclusions that because Leon Grider did not testify, there is no evidence that he is remorseful or has implemented any corrective measures. Resp. Exceptions at 6. Noting that they made ''repeated efforts to stay this proceeding,'' Respondents argue that because Leon Grider was under two state court indictments at the time of this hearing, the ALJ should have stayed this proceeding until the conclusion of the two state criminal cases so as not to '' 'undermine the party's Fifth Amendment privilege against self-incrimination.' '' *Id.* at 8–9 (quoting *SEC* v. *Dresser Industries, Inc.,* 628 F.2d1368, 1375–76 (D.C Cir. 1980)).[96]

Respondents acknowledge that '' 'as a general matter, due process is not infringed merely because an accused person is subjected, without his consent, to an administrative hearing concerning matters involved in a pending criminal proceedings.' '' *Id.* at 9 (quoting 628 F.2d at 1376 n.21). However, Respondents point to *Dresser Industries'* further dictum that ''an administrative proceeding can in some circumstances prejudice the rights of a citizen or the government,'' and that '' '[i]n such cases the agencies and courts may have a duty to take appropriate correction action.' '' *Id.* Thus, they argue that Leon Grider's decision ''not to testify in this proceeding should not be used against the Respondents in any way in these proceedings,'' and that ''having declined to continue these proceedings despite Leon Grider facing two pending state criminal indictments, this tribunal cannot in turn penalize Leon Grider for declining to testify in this hearing.'' *Id.*

Respondents' argument gives no reason to reject the ALJ's conclusions.[97] The Fifth Amendment protects a witness only from being compelled to testify against himself. Notably, the Government did not call Leon Grider as a witness, and in any event, the Fifth Amendment privilege is not ''a sword whereby a claimant asserting the privilege [is] freed from adducing proof in support of a burden which would otherwise have been his.'' *United States* v. *Rylander,* 460 U.S 752, 758 (1983). *See also MacKay,* 664 F.3d at 820 (quoting *Keating* v. *Office of Thrift Supervision,* 45 F.3d 322, 326 (9th Cir. 1995)).

As explained above, it is settled that where the Government has established a *prima facie* case, ''the burden shifts to the [registrant] to show why [its] continued registration would be consistent with the public interest.'' *MacKay,* 664 F.3d 817 (citing cases). Because Respondents have failed to rebut the Government's *prima facie* case, I will revoke the existing

[94] The Government did not call Leon Grider to testify; nor did he testify on Respondents' behalf.

[95] Other evidence, while not essential to reach this conclusion, supports this finding. Specifically, the evidence shows that even though Leon Grider was aware that he was under investigation, he continued to unlawfully distribute controlled substances to persons such as LW and BL.

[96] On June 4, 2008, Respondent filed a motion ''to stay the proceedings until after October 10, 2008, the date Leon Grider's Kentucky State Court Trial is presently scheduled to conclude.'' Therein, Respondents ''stipulated and agreed that any continuance of the Russell Circuit Court trial beyond October 10, 2008 will not be a basis to extend the stay of proceedings, should the Administrative Judge grant this motion and order the requested stay of proceedings.'' Motion for Stay, at 3. Having made this representation, Respondents cannot now complain that the ALJ eventually lifted the stay.

[97] As *Dresser Industries* notes, ''[t]he civil and regulatory laws of the United States frequently overlap with the criminal laws creating the possibility of parallel [administrative] and criminal proceedings, either successive or simultaneous'' and that ''[i]n the absence of substantial prejudice to the rights of the parties involved, such parallel proceedings are unobjectionable.'' 628 F.2d at 1374. As the D.C. Circuit observed: ''[t]he Constitution * * * does not ordinarily require a stay of civil proceedings pending the outcome of criminal proceedings.'' *Id.* at 1375.

While the D.C. Circuit further explained that ''the strongest case for deferring civil proceedings is where a party under indictment for a serious offense is required to defend a civil or administrative action involving the same matter,'' the potential harm to a party's Fifth Amendment privilege is just one of four reasons which may justify staying the noncriminal proceeding. *Id.* at 1375–76. Continuing, the court explained that ''[i]f delay of the noncriminal proceedings *would not seriously injure the public interest,* a court may be justified in deferring it.'' *Id.* (emphasis added).

It is, of course, commonplace that matters involving DEA registrants will lead to both a revocation proceeding and a criminal investigation and subsequent charges at either the federal or state level. Moreover, the very purpose of a proceeding brought under 21 U.S.C. 823(f) and 824(a)(4) is to protect the public interest.

Here, it is noted that the ALJ did stay the proceeding for approximately nine months (between June 2008 and March 2009). Moreover, even after the stay was lifted, the actual hearing did not commence until August 11, 2009, five months later, and Respondents did not start putting on their case until December 2009. At that point, the two criminal cases against Leon Grider had been pending since August 2005, and thus for more than four years.

It is further noted that during the period of the stay, Respondents continued diverting controlled substances. Thus, the delay of this proceeding did cause serious injury to the public interest. As this case demonstrates, under *Dresser,* a stay of a DEA revocation proceeding brought under section 824(a)(4) is unlikely to ever be justified.

registration of Grider Drug #1 and deny the pending application of both Grider Drug #1 and Grider Drug #2.[98]

[98] Respondents further contend that an email from the supervisory DI to the DI he initially assigned to conduct the investigation, evidences ''bad faith or malicious government tactics'' and that the tribunal therefore has ''a duty to take appropriate corrective actions'' to ensure that Leon Grider's decision not to testify, because of the two state criminal cases, is not used against Respondents ''*in any way.*'' Resp. Exceptions at 10 (citing RX 103) (emphasis added).

In support of their contention, Respondents quote the following paragraph from an email the supervisory DI wrote to his subordinate, who had expressed concern as to whether she could handle the matter:

All we need to do with [Leon Grider] is document how many scripts are bad for possible criminal sanctions, how many civil violations he has for nonconformance and a fine, and what we intend to do when we have the full picture (revocation/suspension/etc.). It will just take a while, that's all. He got off the hook before. We will not give him the opportunity this time. We cannot cut corners with him. We will drown him in violations. The more concrete the violation, the better.

*Id.* (quoting RX 103).

This email does not even remotely establish bad faith or malicious intent on the part of the supervisory DI. Indeed, in a subsequent portion of the email, the supervisory DI told his subordinate to ''look[] for bogus scripts, unauthorized refills, and failure to comply with prescriptions requirements, such as refilling schedule II's,'' each of which constitutes a violation of the CSA. RX 103. He then instructed her ''to be methodical. Pick a doctor with lots of scripts and question them. Record the bad ones and write a report. Look at whether any of these were filled early per KASPER, per early refill book, that would confirm fraudulent reporting.'' *Id.*

Notably, nowhere did the supervisory DI instruct his subordinate to find violations even in the absence of probable cause or to violate Leon Grider's constitutional rights. And ultimately, Respondents were allowed to test the Government's evidence with respect to every violation of the CSA which it alleged. Likewise, each of the two state criminal proceedings was initiated by indictment, which requires a finding of probable cause.

I therefore reject Respondent's contention that it was improper for the ALJ to rely on Leon Grider's silence in concluding that Respondents had not rebutted the Government's *prima facie* case.

## Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration AG3498347, issued to Grider Drug #1, be, and it hereby is revoked. I further order that any pending applications of Grider Drug #1 and Grider Drug #2, be, and they hereby are, denied. This Order is effective immediately.[99]

Dated: July 13, 2012.

**Michele M. Leonhart,**

*Administrator.*

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[99] Based on the extensive and egregious acts of diversion proved on this record, I concluded that the public interest necessitates that this Order be effective immediately. *See* 21 CFR 1316.67.