DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 03–21]

Medicine Shoppe—Jonesborough; Revocation of Registration

On March 14, 2003, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to the Medicine Shoppe—Jonesborough (Respondent) of Jonesborough, Tennessee. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration, BM3913781, as a retail pharmacy, and the denial of any pending application for renewal of its registration, on the ground that its continued registration would be ''inconsistent with the public interest.'' Show Cause Order at 1 (citing 21 U.S.C. 823(f)).

The Show Cause Order specifically alleged that a DEA investigation had determined that between 1990 and 1995, Royce E. Blackmon, Jr., a physician located in Butler, Tennessee, had ''issued numerous controlled substance prescriptions for no legitimate medical reason.'' *Id.* The Show Cause Order alleged that in December 1995, DEA investigators visited Respondent and determined that it had filled 947 of the controlled-substance prescriptions issued by Dr. Blackmon. *Id.* at 1–2. The Show Cause Order further alleged that on October 29, 1997, DEA investigators returned to Respondent and subsequently determined that Respondent had filled an additional 3,100 controlled-substance prescriptions issued by Dr. Blackmon. *Id.* at 2. Relatedly, the Show Cause Order alleged that on October 6, 1997, Blackmon entered into an Agreed Order with the Tennessee Board of Medical Examiners which revoked his state medical license. *Id.* at 2.

The Show Cause Order next alleged that between May 1996 and December 1997, Respondent filled 124 prescriptions issued by Edmond Watts, a veterinarian practicing in Johnson City, Tennessee, notwithstanding that Watts' DEA registration and state veterinary license had expired on May 31, 1996, and February 29, 1996, respectively. *Id.* at 2. The Show Cause Order further alleged that ''[m]any of these prescriptions were issued to persons using several aliases and false addresses,'' and that Watts was ultimately indicted and pled guilty to two state-law counts of obtaining prescription drugs by fraud. *Id.* at 2–3.

The Show Cause Order next alleged that on March 9, 1998, DEA investigators returned to Respondent to review its controlled-substance records and to conduct an accountability audit. *Id.* at 3. The Show Cause Order alleged that Mr. Jeff Street, Respondent's owner and pharmacist, told DEA investigators that ''the pharmacy's computer could not process prescription information at that time,'' and that the investigators ''would have to wait until the following morning'' to obtain the information. *Id.* The Show Cause Order further alleged ''[t]hat the following morning, Mr. Street informed investigators that the pharmacy's computer [had] 'crashed' and its data had been lost.'' *Id.* at 3. The Show Cause Order thus alleged that Respondent violated 21 U.S.C. 827(a)(3), as well as 21 CFR 1304.04 and 1304.21. *Id.*

Next, the Show Cause Order alleged that on December 14, 1999, DEA audited Respondent's handling of twenty-nine controlled substances during the period of January 11, 1999, to December 14, 1999. *Id.* The Show Cause Order alleged that the audit found that Respondent had an overage of 29,656 dosage units of diazepam, a schedule IV controlled substance, and a shortage of 3,453 dosage units of combination hydrocodone drugs, which are schedule III controlled substances. *Id.*

Relatedly, the Show Cause Order alleged that on April 10, 2001, and April 2, 2002, DEA had performed additional audits of Respondent's handling of various controlled substances and that each audit had found both overages and shortages. *Id.* at 3–4. More specifically, the Show Cause Order alleged that the April 2002 audit found that Respondent was short 4,505 tablets of some higher-strength combination hydrocodone/acetaminophen products and had overages of 2,273 lower-strength hydrocodone/acetaminophen products. *Id.* at 4. The Show Cause Order further alleged that the April 2002 audit found both ''shortages and overages of between 500 and 1,000 tablets.'' *Id.*

Finally, the Show Cause Order alleged that in analyzing Respondent's records for the period 2001 through 2002, DEA had determined that ''many patients received in excess of 2,000 dosage units of hydrocodone, often from several physicians.'' *Id.* The Show Cause Order thus alleged that ''[u]nder regulation, a pharmacy has a corresponding liability to ensure that every prescription [it] dispense[s] is for a legitimate medical purpose,'' and that ''[t]here is no indication that [Respondent] took steps to corroborate the necessity of these large amounts of controlled substances.'' Id. at 4–5.

Respondent, through its counsel, timely requested a hearing on the allegations. The matter was assigned to Administrative Law Judge (ALJ) Gail Randall, who conducted a hearing in Knoxville, Tennessee, on July 27–29, 2004, and in Greenville, Tennessee, on May 24, 2005. At the hearing, both the Government and Respondent called witnesses to testify and introduced both testimonial and documentary evidence into the record. Following the hearing, both parties filed briefs containing their proposed findings of fact and conclusions of law.

On June 9, 2006, the ALJ filed her recommended decision. In her decision, the ALJ found that while there was a factual ''dispute regarding the exact numbers involved in the three DEA audits, the record clearly shows that [the] audits and inventories of * * * Respondent revealed substantial shortages and overages of the controlled substances investigated.'' ALJ at 69. The ALJ rejected, however, the Government's contention that Respondent had failed ''on multiple occasions'' to comply with ''its corresponding responsibility to ensure that dispensed prescriptions for controlled substances were issued by the physician for a legitimate medical purpose and in the usual course of professional practice.'' Gov. Proposed Findings at 10; *see also* ALJ at 72.

While noting that ''the patient profiles did not contain any documents demonstrating that Respondent's pharmacists made any telephone calls to verify suspect prescriptions,'' the ALJ credited the testimony of Respondent's owner that he had called the doctors whose prescriptions were suspicious ''on many occasions'' to ''verify the prescriptions prior to filling them.'' ALJ at 72; *see also id.* at 75 (noting that ''Mr. Street's credible testimony concerning his personal knowledge of his customers [and] the actions he took to coordinate his dispensing with the patients' health care providers * * * dispelled many of [the] concerns'' expressed by the Government's expert witnesses). While the ALJ also found Respondent's filling of prescriptions issued by a veterinarian during 1996 and 1997 ''bothersome,'' she further reasoned that the datedness of the conduct and ''the lack of any more recent evidence of similar carelessness'' did not support the revocation of Respondent's registration. *Id.* at 78. The ALJ thus recommended that Respondent be allowed to maintain its registration subject to the condition that it undergo an annual audit by an independent auditor at its own expense for a period of three years from the date of the issuance of this Final Order. *Id.* at 78.

The Government filed exceptions to the ALJ's recommended decision. While asserting that it was not arguing ''the minutiae of the specific findings, or the issue of the credibility * * * of seriatim statements of Respondent's pharmacist owner,'' the Government's principal exception was that ''Respondent's entire defense consistently produced explanations for every fact that the Government proved,'' and that ''for every patient that the Government showed * * * was receiving excessive amounts of controlled substances, Respondent had a recitation as to the medical condition . . . which would . . . justify [the] dispensing'' and the avoidance of liability under 21 CFR 1306.04. Gov. Exceptions at 1–2. The Government further argued that Respondent's owner ''had months . . . to prepare a self-serving testimonial defense by acquiring and reviewing medical records after [the] presentation of the Government's case,'' and that Respondent did not have access to these records ''at the time the prescriptions were presented.'' *Id.* at 2. The Government thus contended that ''by accepting'' the testimony of Respondent's owner, ''the ALJ effectively negated the expert testimony of the two health care professionals who testified on behalf of the Government.'' *Id.* The Government also argued that Respondent's lack of accountability in its handling of controlled substances warranted the revocation of its registration.[1] *Id.*

Thereafter, the record was forwarded to me for final agency action. In her decision, the ALJ decision found that Respondent had ''last renewed [its] registration on January 3, 2000, and [that] the registration was due to expire on January 31, 2003.'' ALJ at 3. Under DEA precedent, ''[i]f a registrant has not submitted a timely renewal application prior to the expiration date, then the registration number expires and there is nothing to revoke.'' *Ronald J. Riegel,* 63 FR 67132, 67133 (1998). Because ''it appear[ed] that Respondent's registration had expired before the . . . proceeding was even initiated,'' the case was remanded to the ALJ to determine whether Respondent had submitted a timely renewal application in accordance with DEA's regulations and the Administrative Procedure Act (APA). *See* Order Remanding for Further Proceedings at 1–2; *see also* 5 U.S.C. 558(c) (''[w]hen [a] licensee has made timely and sufficient application for a renewal or a new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been finally determined by the agency'').

Thereafter, the ALJ conducted further proceedings in accordance with my remand order. Those proceedings determined that Respondent had submitted a renewal application prior to the January 31, 2003 expiration of its registration and had paid the appropriate fee. However, Respondent's owner was told that its registration had not been renewed pending ''administrative review.'' Affidavit of Jeffrey Street at 1. According to the Government, Respondent's registration was renewed, but ''for unknown reasons,'' the Agency's Registrant Information Consolidated System ''did not record the renewal timely submitted for the 2003–2006 period,'' Gov. Resp. to the Registration Issue on Remand at 2, and ''did not advance the expiration date from January 31, 2003 to January 31, 2006.'' Affidavit of Richard Boyd, Chief of Registration and Program Support Section, at 1. Apparently, the new registration which was issued to Respondent in January 2003, simply used the same January 31, 2003 expiration date of the previous registration. *See id.*

I therefore find that in January 2003, Respondent made a timely and sufficient application for a new registration. I further hold that because the registration which the Agency issued in January 2003 did not extend the expiration date of the registration, but rather, only re-instituted the January 31, 2003 expiration date of the existing registration, the Agency did not make a final determination on the application and Respondent therefore has maintained a valid registration throughout these proceedings.[2] *See* 5 U.S.C. 558(c). Accordingly, there is jurisdiction to determine whether Respondent's registration should be revoked and its pending application should be denied.

Having considered the record as a whole including the ALJ's recommended decision, I hereby issue this Decision and Final Order. As explained below, I adopt in part and reject in part the ALJ's findings of fact and conclusions of law. More specifically, while the ALJ rejected the entirety of the Government's allegations that Respondent dispensed controlled substances to numerous patients in violation of its corresponding responsibility under federal law, as ultimate factfinder, I conclude that the Government has proved by a preponderance of the evidence that Respondent unlawfully dispensed controlled substances to numerous persons. I also conclude that Respondent violated federal law and DEA regulations by failing to maintain complete and accurate records. Based on my findings and Respondent's (and its owner's) failure to acknowledge their misconduct, I concluded that revocation of its registration is necessary to protect the public interest. I make the following findings.

Findings of Fact

Respondent is a pharmacy which is located in Jonesborough, Tennessee. Respondent has been registered as a retail pharmacy since February 1994, and as found above, currently holds DEA Certificate of Registration, BM3913781, which remains valid pending the issuance of this Final Order. *See* Gov. Ex. 1. Respondent is owned by Mr. Jeffrey Street, who has been a licensed pharmacist since 1984. Tr. May 24, 2005 at 75.[3]

The Investigation of Respondent

Sometime in 1995, DEA investigators received information from the Tennessee Bureau of Investigation and the First Judicial District Drug Task Force that Dr. Royce Blackmon, a Butler, Tennessee based physician, was writing prescriptions for drugs containing hydrocodone, a schedule III controlled substance, *see* 21 CFR 1308.13(e), and for Dilaudid (hydromorphone), a schedule II controlled substance, *id.* 1308.12(b), without a legitimate medical purpose. Tr. 22. As part of the investigation, DEA investigators interviewed some of Dr. Blackmon's ''patients'' and determined that Blackmon would frequently write prescriptions ''without even seeing the patient.'' *Id.* at 24.[4] Dr. Blackmon's staff would then tell the ''patients'' to bring the prescriptions to Respondent for filling. *Id.* Moreover, the investigation determined that both Dr. Blackmon's

[1] I also note Respondent's response to the Government's exceptions and have considered the arguments raised therein.

[2] The Government contends that Respondent's ''registration actually expired on January 31, 2006,'' and that ''Respondent was obligated to continue to file renewal applications during the duration of the show cause process.'' Gov. Resp. to the Registration Issue (ALJ Ex. 14) at 2. While I reject the Government's contention, even if Respondent's registration had, in fact, been renewed with a new expiration date of January 31, 2006, there is no evidence that the Agency ever notified it of this fact. Respondent cannot be faulted for failing to file an application to renew a registration when the Government never informed it of the new expiration date.

[3] All citations to the transcript which do not include a date refer to the testimony taken on July 27–29, 2004.

[4] DEA investigators were, however, unable to obtain Blackmon's medical records. Tr. 56.

wife and his daughter were drug addicts, that Dr. Blackmon prescribed both Dilaudid and hydrocodone drugs for his daughter, and that Mr. Street filled some of the daughter's prescriptions. *Id.* at 53 & 86.

As part of the investigation, DEA conducted a prescription review of approximately 15 to 20 pharmacies including Respondent, which were located in the areas of Johnson City, Bristol, Kingsport and Jonesborough. *Id.* at 26. In either November or December 1995, DEA investigators visited Respondent and found that it had dispensed approximately 950 prescriptions which had been issued by Dr. Blackmon. *Id.* at 27; *see also id.* at 181. Most of the other area pharmacies had stopped filling Blackmon's prescriptions, *id.* at 26, but some continued to do so. May 24, 2005 Tr. at 9–10.

In October 1997, DEA investigators returned to Respondent to determine whether Respondent had continued to fill Blackmon's prescriptions since the previous visit. Tr. at 182. The investigators found that Respondent had filled more than 3,000 of Blackmon's prescriptions, all of which were for controlled substances. *Id.* at 183.

Mr. Richards, a private investigator retained by Respondent, testified, however, that he had interviewed Mr. James Backers, a pharmacist who had worked as a relief pharmacist for Respondent during the last three months of 1996, as well as in 1997 and 1998. May 24, 2005 Tr. at 69. According to Mr. Richards, Mr. Backers told him that ''because he had heard rumors that some . . . drugstores weren't filling Dr. Blackmon's prescriptions anymore'' he visited Blackmon at his office. *Id.* at 11. Mr. Richards testified that Mr. Backers stated that Blackmon ''was very nice to him, showed him his records, showed him that he was making referrals to specialists, [and] doing tests.'' *Id.* Moreover, Dr. Blackmon ''was writing not only pain medication, but other maintenance drugs, as well.'' *Id.* Mr. Backers told Mr. Street about his visit. *Id.* He also continued to fill Blackmon's prescriptions although he would call his office if one did not ''look right.'' Id.[5]

The Audits

In March 1998, a DI returned to Respondent with the intention of auditing its handling of controlled substances and presented an Administrative Inspection Warrant to Mr. Street. Tr. at 185–87. The DI asked Mr. Street to provide the pharmacy's purchase, dispensing and distribution records,[6] *id.* at 187–88; these are records which a pharmacy is required under regulation to maintain for two years. *Id.* at 189. Mr. Street assisted in conducting a closing inventory and provided the pharmacy's invoices for the drugs being audited. Because preparing the drug usage reports required accessing data in Respondent's computer and Mr. Street was to teach a class that night, Mr. Street printed out only two drug usage reports (one for Dilaudid and one for Lortab 5) and requested that he be allowed to print out the remaining reports in the morning. Tr. 192; May 5, 2005 Tr. at 117.[7] When the DI arrived at the pharmacy the next morning, Mr. Street reported that ''his computer had crashed and he'd lost all [of] his prescription data.'' Tr. 192. Mr. Street further told the DI that his computer's hard drive had failed. May 24, 2005 Tr. at 121.

According to Mr. Street, several days later the DI returned to the pharmacy with the backup tape. Upon loading the tape into the computer, there were no records on it. Respondent then loaded another backup tape, which he had last used in either October or November and the tape loaded up right away. *Id.* at 122. Because several months of records were missing, the DI determined that an audit could not be conducted. Tr. 193. The ALJ specifically credited the DI's testimony that while he had inspected fifty to seventy-five pharmacies, this was the only time a pharmacy had been unable to produce the required records. ALJ at 10 (citing Tr. 194).

In December 1999, the DI obtained another administrative warrant and returned to Respondent to conduct an audit.[8] GX 6, Tr. 195. Mr. Street provided the DI with a copy of Respondent's biennial inventory which had been taken on January 11, 1999. GX 5. According to Mr. Street, under the rules of the Tennessee Board of Pharmacy, a pharmacist is allowed to estimate the number of pills in an open bottle in conducting an inventory of schedule III through V controlled substances. May 24, 2005 Tr. 149.

Another DI and a state investigator conducted a closing inventory of Respondent's controlled substances. Tr. 198. Mr. Street signed the closing inventory thereby attesting to its accuracy. *Id.* at 199. According to the DI, the audit ''look[ed] . . . at all the records of purchase, all records of distribution'' including the prescription records, as well as various DEA forms for reporting theft, loss and destruction of controlled substances, and other forms that document the movement of controlled substances between the beginning and end dates of the audit. *Id.* at 201. For each audited drug, the DI added up the amount of Respondent's purchases during the audit period and added them to the opening inventory; the DI then added the total amount of each drug dispensed (and or distributed) to the ending inventory and compared the two figures. *Id.*

While the two numbers should equal each other, the DEA audit found that there were both numerous shortages and overages. GX 8. Some of the discrepancies involved substantial quantities in absolute terms. The ALJ found credible Mr. Street's testimony that the Government's audit contained eleven errors because four drug usages reports had been left out,[9] that one of

[5] It is questionable whether Mr. Backers' hearsay statements are reliable because Mr. Richards obtained them in anticipation of this litigation. I assume without deciding that the statements meet the APA's standard that evidence must be ''reliable'' and ''substantial,'' 5 U.S.C. 556(d), because I conclude that the appropriate analysis of whether Respondent dispensed controlled substances in violation of federal law should focus on the actual prescriptions it filled.

[6] Under DEA regulations, a pharmacy is required to maintain records for a minimum of two years and the records must document the purchase and receipt, dispensing, and distribution through destruction, loss, theft or a transfer between registrants of controlled substances. Tr. 190–91; *see also* 21 CFR 1304.22(c). Moreover, records pertaining to schedule II controlled substances must be ''maintained separately from all other records of the pharmacy,'' with the prescriptions ''maintained in a separate prescription file.'' 21 CFR 1304.04(h)(1). With respect to schedule III through V controlled substances, a pharmacy's records must be ''maintained separately from all other records of the pharmacy or in such form that the information required is readily retrievable from [the] ordinary business records of the pharmacy'' with prescription records ''maintained either in a separate prescription file for controlled substances in Schedules III, IV, and V only or in such form that they are readily retrievable from the other records of the pharmacy.'' *See also* 21 CFR 1304; Tr. 193.

[7] There is conflicting evidence as to when the DI obtained Respondent's backup tape. The DI testified that Mr. Street gave him the backup tape (which was stored in his files and not the pharmacy's computer) before leaving on the day that he showed up to conduct the audit. Tr. 192. Mr. Street testified that upon the DI's arrival the next morning, he assured the DI that ''everything's going to be okay because I've got a good backup tape,'' to which the DI responded ''Show it to me.'' May 24, 2005 Tr. at 121. According to Mr. Street, he then pulled the tape out of the computer's ''external drive'' and the DI took possession of it. *Id.* at 121.

I also note that Mr. Street testified that he ran a backup tape ''every night.'' May 24, 2005 Tr. at 120. Mr. Street did not testify that the backup tapes were re-used, and given the absence of such testimony, it is perplexing that Mr. Street did not have a more current backup tape available. The ALJ did not, however, reconcile her findings with this testimony.

[8] The DI was accompanied by another DI and an investigator from the Tennessee Board. Tr. 198.

[9] In his testimony, Mr. Street did not specifically identify which drug usage reports had been left out.

the five diazepam drug usage reports provided to DEA overlapped with another report resulting in an overage of 30,000 tablets of diazepam,[10] that the DI had used ''some inaccurate beginning counts . . . off of our inventory,'' and that the DI had failed to include drugs Respondent had reported stolen. May 24, 2005 Tr. 125.[11]

There is, however, no dispute that Respondent was short 800 tablets of hydrocodone/acetaminophen [12] (5/500) and more than 380 tablets of Lortab (7.5/500), a brand name drug which also contains hydrocodone and acetaminophen. *Compare* ALJ Attachments A and B. Respondent was also short 200 tablets of Dilaudid (hydromorphone) 4 mg. and 193 tablets of generic hydromorphone 4 mg. *Id.* Respondent was also short 485 tablets of acetaminophen/codeine (300/60). *Id.*

Furthermore, according to Respondent's audit, the pharmacy was short 589 tablets of hydrocodone/apap (7.5/500) and 704 tablets of Diazepam 10 mg. *Id.* at Attachment B. Moreover, Respondent's audit found substantial overages in multiple drugs include hydrocodone/apap 7.5/750 (740 tablets), hydrocodone/apap 10/650 (438 tablets), Lortab 5/500 (189 tablets), and apap/codeine 300/30 (369 tablets). *Id.* While it is not uncommon that a pharmacy will have small shortages or overages (of less than fifty dosage units), Tr. 72–73, the shortages and overages found during the 1999 audit are not trifling amounts.

On April 10, 2001, DEA investigators returned to Respondent to conduct another audit. For the closing counts, the DIs took an inventory of the drugs being audited which Mr. Street verified. GX 10. For most of the drugs being audited, the DIs used the inventory taken during the December 14, 1999 audit for the beginning counts.[13] Here again, the Government found several substantial shortages of hydrocodone/apap drugs and numerous overages. *See* GX 11.

Mr. Street also disputed the accuracy of this audit and testified that he found that it had eight errors. May 24, 2005 Tr 128. More specifically, Mr. Street testified that the several drug usage reports and purchase invoices were left out. *Id.* He also asserted that the diazepam was again over-accounted for. *Id.*

Mr. Street again conducted his own audit and found that Respondent had substantial shortages in numerous drugs. *See* ALJ 15, Resp. Ex. 3. With respect to generic hydrocodone/apap drugs, Respondent was short 171 tablets of 5/500 strength, 656 tablets of 7.5/500, and 657 tablets of 10/500; Respondent was also short 196 tablets of Lortab 10. Resp. Ex. 3. As for diazepam, Respondent was short 312 tablets of 5 mg. strength and 554 tablets of 10 mg. strength. *See id.* Respondent was also short 152 tablets of methadone 40 mg. (a schedule II drug, 21 CFR 1308.12(c)), and 166 tablets of acetaminophen and codeine #4. *See* Resp. Ex. 3 at 2.

On April 30, 2002, the DIs returned to Respondent and conducted an audit which covered the period between the April 10, 2001 and the date of their visit. GX 13. The DIs used the closing inventory counts from the 2001 audit for the beginning count and took an inventory of the drugs on hand for the closing count, which Mr. Street verified. *See id.*

Even though the DIs audited only twelve drugs, they again found several substantial shortages and overages, *see* GX 14, and Mr. Street disputed the accuracy of the audit. May 24, 2005 Tr. at 129 & 137. More specifically, Mr. Street testified that the DEA audit did not include three drug usage reports and that apparently, the amounts from some invoices were not properly counted. *Id.* at 129.

Once again, Mr. Street's audit found substantial shortages and overages. See Resp. Ex. 4. Specifically, Respondent was short 498 tablets of diazepam 10mg., 754 tablets of hydrocodone/apap 7.5/500, and 910 tablets of hydrocodone/apap 10/500. Resp. Ex. 4. Respondent also had overages of 442 units of hydrocodone/apap 7.5/650 and 364 units of hydrocodone/apap 10/650.

With respect to the 2001 audit, the ALJ found that Mr. Street ''credibly stated that he attributed such discrepancies to human error.'' ALJ 15. More specifically, Mr. Street testified that ''it could have been simply [that] the person was supposed to have gotten the generic and we accidentally pulled the name brand off the shelf.'' May 24, 2005 Tr. at 142–43. Mr. Street further testified that there were ''four different'' strengths of combination hydrocodone drugs ''all on the shelf together[,] and it could have been just simply the fact that we just pulled the wrong one off the shelf.'' *Id.* at 143. The ALJ also credited Mr. Street's testimony that ''there was no deliberate diversion of drugs.'' ALJ at 15 (May 24, 2005 Tr. at 143).

As for Mr. Street's contention that his pharmacy may have confused branded and generic drugs when it filled prescriptions, it would have been easy enough to prove this by showing the existence of corresponding overages and shortages in the respective drugs. Mr. Street did not, however, offer any evidence from his own audits to this effect.[14]

Mr. Street's contention that he and other pharmacy personnel may have mistakenly filled a prescription with a drug of a different strength than that prescribed by his customers' physicians is alarming. Under federal regulations, drug manufacturers and distributors are required to label the containers that they use to distribute their drugs. 21 CFR Pt. 201. Manufacturers are also required to imprint each dosage unit ''with a code imprint that, in conjunction with the product's size, shape and color, permits the unique identification of the drug product and the manufacturer * * * of the product.'' 21 CFR 206.10(a). Moreover, ''[i]dentification of the drug product requires identification of its active ingredients and its dosage strength.'' *Id.* In short, a pharmacist should know the strength of a drug he is dispensing based on both the container's labeling and the imprint on the dosage unit and make sure that he has dispensed the correct strength of a drug. Indeed, dispensing controlled substances of the wrong strength can have serious consequences for the health of patients.

As for Mr. Street's testimony that ''there was no deliberate diversion'' of the drugs his pharmacy was short of, this is pure speculation. Respondent offered no evidence that it had

Respondent also did not submit the DEA–106s into evidence.

To make clear for future cases, to successfully challenge an audit, a registrant must specifically identify the error which it claims was made. For example, if it claims that the Government left out a drug usage report, it must specifically identify the report and show how its exclusion affected the results. The generalized testimony which Mr. Street typically gave is wholly insufficient to demonstrate that the audit results were erroneous. I conclude, however, that there is no need for a remand on this issue because even Mr. Street's audits found numerous discrepancies.

[10] As discussed below, it is a registrant's responsibility to maintain accurate records. The fact that the audit may have showed an overage of diazepam because the dispensings were recorded on multiple drug usage reports is therefore further evidence of Respondent's poor recordkeeping practices.

[11] At the hearing, the DI acknowledged that he erred when he recorded the beginning inventory figure for hydrocodone/acetaminophen 10/650 from Respondent's January 11, 1999 inventory onto his spreadsheet. More specifically, the DI wrote that the pharmacy had on hand 330 tablets rather than 33. Tr. 219.

[12] Through out this decision, the term ''apap'' is used as an abbreviation for acetaminophen.

[13] For several schedule II drugs (Oxycontin and Methadone) which had not been previously audited, the DIs used for the beginning count the inventory which Respondent took on May 10, 2000. GX 11.

[14] For example, even if DEA did not audit a branded drug of the same strength as a generic drug that it audited, Mr. Street could have done so.

investigated its employees to determine whether any of them could be diverting the missing drugs. In short, Mr. Street does not know whether or not his pharmacy's employees could have been diverting drugs.

Respondent also introduced into evidence the affidavit of Mr. Timothy Mitchell Pierce, a lawyer and registered pharmacist. Resp. Ex. 6. Mr. Pierce reviewed various documents in the case, medical records, and interviewed Mr. Street. Mr. Pierce, who was presumably testifying as an expert, opined that ''the alleged overages and shortages of controlled substances as described in the Order to Show Cause are not due to deliberate diversion,'' and ''are more likely due to DEA audit errors, acceptable human error by [Respondent's] personnel and theft by person(s) not associated with'' Respondent. *Id.* at 4.

I reject the conclusions of Mr. Pierce for several reasons. First, while Mr. Pierce has been a registered pharmacist and stated that he has practiced in retail pharmacy settings, his affidavit does not establish how many years of actual pharmacy practice he has, that he has remained active in pharmacy practice,[15] and that he has any experience in conducting audits.

Second, Mr. Pierce's affidavit typically did not address the shortages which Mr. Street's own audits found. For example, in discussing the December 1999 audit, Mr. Pierce discussed only the shortage of one drug (hydrocodone/apap 7.5/500). RX 6, at 4–5. Mr. Pierce's affidavit ignores that Respondent was short 800 tablets of hydrocodone/apap 5/500, 380 tablets of Lortab (7.5/500), 200 tablets of Dilaudid 4 mg., 193 tablets of generic hydromorphone 4 mg., 485 tablets of acetaminophen/codeine (300/60), and 704 tablets of diazepam 10 mg. *See id.* Similarly, with respect to the April 2001 audits, Mr. Pierce's affidavit ignores the shortages of 312 tablets of diazepam 5 mg. and 554 tablets of diazepam 10 mg. *See id.* at 5–6. The affidavit also offers nothing but speculation regarding the shortages of hydrocodone/apap.[16]

Finally, with respect to the April 2002 audits, Mr. Pierce's affidavit does not even acknowledge the figures for the hydrocodone shortages per Mr. Street's own audit (754 tablets of hydrocodone/apap 7.5/500 and 910 tablets of hydrocodone/apap 10/500). *See id.* at 8. Mr. Pierce then opined that the shortages and overages ''were probably due'' to ''inadvertently'' dispensing the wrong strength of drug. *Id.* Mr. Pierce also opined that a name brand drug could have been ''dispensed for a generic brand drug or vice versa,'' and noted that ''[t]he name brand drugs were not audited and thus cannot be compared.'' *Id.* Again, Mr. Pierce's opinion amounts to pure speculation. His testimony is therefore rejected.

The Evidence Regarding Respondent's Dispensings

The ALJ found that during 1997, Respondent ''filled over 124 controlled substance prescriptions written by Edmond Watts,'' a veterinarian who had allowed both his DEA registration and state veterinary license to expire without renewing them, ALJ at 17 (citing Tr. 37–38, 41–42), and was therefore without authority to prescribe controlled substances. According to the credited testimony of a DEA supervisory diversion investigator, a pharmacist is required to periodically check with the appropriate state licensing authority to ensure that a practitioner holds a current license. *Id.* (citing Tr. 61).

Normally, veterinarians purchase the controlled substances they dispense directly from wholesale distributors and dispense the drugs directly to the owner of the animal. Tr. 88. Indeed, under DEA regulations, ''[a] prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.'' 21 CFR 1306.04(b).

Watts wrote the prescriptions, which were for drugs containing hydrocodone, in the names of fictitious patients,[17] Tr. 40, and had his brother present them to Respondent for filling. *Id.* at 62–63. Moreover, Watts' brother was presenting the prescriptions ''almost every day [or] every other day.'' *Id.* at 62. The drugs were then personally used by Veterinarian Watts. *Id.* at 40. Eventually, Watts was convicted of a controlled-substances related felony. *Id.* at 42.

With respect to the prescriptions issued by Watts, Respondent put on the testimony of Mr. Richards, a private investigator it had retained. Mr. Richards testified that Watts told him that he had ''deceived'' Street, and ''didn't tell him [Street]'' about his licensure status. May 24, 2005 Tr. at 14. There is, however, no evidence that Mr. Street had asked Watts whether he had a valid DEA registration and state license prior to the incident in summer of 1997 when state investigators showed up at Respondent and inquired about Watts' prescriptions. *Id.*

Moreover, Mr. Richards testified that ''all of the prescriptions that Dr. Watts wrote that Jeff filled for any kind of pain drugs contained acetaminophen. And that would alert a pharmacist to the fact that it was probably for an animal, because acetaminophen is toxic to certain animals.'' *Id.* at 16. Contrary to Mr. Richard's testimony, the fact that ''acetaminophen is toxic to certain animals'' points to the exact opposite conclusion—that the drugs were not being prescribed to treat animals for a ''legitimate medical purpose'' and that Watts was not acting in the ''usual course of his professional practice.'' 21 CFR 1306.04(a).

DEA investigators also found that Respondent was filling large amounts of prescriptions for schedule III drugs containing hydrocodone that were written by a dentist, J. Michael Haws. ALJ at 19 (citing Tr. 34–35, GX 15I). According to a DEA diversion group supervisor, Dr. Haws ''was prescribing to almost all of his patients, and even though the amounts weren't that large, the frequency was. [The patients] were going to him almost every other day and requiring additional prescriptions.'' Tr. 35. Ultimately, the state dental board placed Dr. Haws on probation for three years, and following the issuance of an Order to Show Cause, Haws voluntarily agreed to restrictions on his DEA registration. *Id.* at 37.

On cross-examination, the DEA investigator acknowledged that Haws did a lot of extractions and that it would not be unusual for a dentist to prescribe pain medication after doing this procedure. *Id.* at 59. However, on re-direct examination, the investigator testified that in his experience, dentists who performed extractions treat acute pain which ''lasts for a short period of time'' and that dentists do not ''normally'' treat chronic pain. *Id.* at 87–88. The investigator further explained that the frequency of the prescriptions issued by Haws and filled by Respondent was not consistent with the treatment of acute pain, but rather, with the treatment of chronic pain. *Id.* at 87–88.

DEA investigators also determined that Respondent was filling a large number of prescriptions issued by Dr. Frank Varney for benzodiazepines (such as Valium or diazepam), which are

[15] Indeed, it appears that Mr. Pierce has not practiced as a pharmacist in a substantial time because he graduated from a Tennessee law school in 1992, is licensed as a lawyer in Tennessee, but holds a Louisiana pharmacy license.

[16] With respect to the April 2002 audits and the diazepam shortages, Mr. Pierce's affidavit responds to the allegations of the Show Cause Order. The Show Cause Order, however, only sets the parameters of the proceeding and does not constitute evidence.

[17] Watts also wrote prescriptions ''in the name of his sister-in-law.'' Tr. 41. Watt's sister-in-law ''was interviewed and indicated [that] she never received that medication.'' *Id.*

schedule IV controlled substances. Tr. 28, 31–33, *see* 21 CFR 1308.14(c)). According to the supervisory investigator, in 1994, the state board put Dr. Varney on probation and required that he attend a course on prescribing controlled substances. Tr. 33. Before the state board action, Dr. Varney was writing prescriptions for schedule II narcotic prescriptions; after the board action, he turned to writing the benzodiazepine prescriptions. *Id.* at 33–34. Respondent filled ''over 7000'' prescriptions written by Dr. Varney, most of which were for benzodiazepines. *Id.*[18]

The Prescription Traces

The Government introduced into evidence prescriptions traces for twenty-five customers of Respondent. *See* Gov. Ex. 15 (A–Y). For each customer, the traces indicated the name and strength of the controlled substance, the quantity dispensed, the prescription number, the date of the original prescription, and the name of the prescribing practitioners. The Government also put on two expert witnesses, Dr. John Mulder, a physician with a specialty in family practice who is board certified in hospice and palliative medicine, GX 16, and Dr. James Ferrell, a pharmacist with forty-one years of experience and the former director of the Tennessee State Board of Pharmacy. Tr. 271, GX 17.

With respect to several of the traces, either one or both of the Government's experts testified that Respondent's dispensings were not improper. With respect to Customer M.B. (GX 15–A), Dr. Mulder opined that his review found ''no significant deviation from what could be expected to be a standard of care for prescribing these medications. In other words, the quantities over a period of time could be consistent with an acceptable medical reason.'' Tr. 499.

With respect to patient D.C. 2 (GX 15–C), Dr. Mulder ''found nothing that would be outside of a legitimate medical reason for the dispensing of these particular amounts and types of medications.'' *Id.* at 507. As for Government Exhibit 15–E, a trace which listed a male (D.E.) and female (J.E.) who used the same address, Dr. Mulder stated that ''[t]he amounts of medicine prescribed began to skirt the upper limit of acceptable, but [they] never actually surpassed it in terms of the number of pills dispensed within a given month.'' *Id.* at 509. Dr. Mulder further explained that ''it is conceivable that someone with a particular pain problem could be dispensed this amount of medication longitudinally, so I did not have a particular problem with this particular chart.'' *Id.* at 509–10.

Dr. Mulder also found that the prescriptions for patient B.R. (GX 15–O) ''could have been . . . for legitimate medical purposes,'' Tr. 528, that Respondent had properly dispensed to patient W.B. (GX 15–P), Tr. 530, and that Respondent ''probably met'' the standard in dispensing to patient R.S. (GX 15–S). Tr. 533. Finally, with respect to patient W.T. (GX 15–W), Dr. Ferrell noted that while ''[t]he dosages are really high . . . [w]hen your patients have cancer and they're dying, we do see . . . dosages of controlled substances [that] are really high.'' Tr. 359. Dr. Ferrell thus concluded that the prescriptions ''could be legitimate.'' *Id.* at 359–60.

The remaining traces did, however, raise substantial questions regarding the legitimacy of the prescriptions Respondent filled. Set forth below is a discussion of the evidence regarding Respondent's dispensings to those patients which the Government's experts concluded (at least initially) did not satisfy the ''corresponding responsibility'' under Federal law.

Patient D.C. 1.

This trace showed that Respondent dispensed to D.C. numerous prescriptions for Lorcet, a branded drug combining hydrocodone and acetaminophen, which were issued by J. Michael Haws, a dentist. *See* GX 15–B, at 1–2. Between June 24, 1997, and September 29, 1997, Respondent filled twenty-nine controlled substance prescriptions for narcotics; twenty-eight of the prescriptions were for hydrocodone and acetaminophen, and one of the prescriptions was for Percodan, a schedule II controlled substance which contains oxycodone and aspirin. *See* 21 CFR 1308.12(b). The prescriptions were typically issued every three to four days. *See* GX 15–B, at 1–2. Furthermore, during both July and August, the controlled substances dispensed by Respondent contained 140,400 mg. of acetaminophen or approximately 4529 mg. per day. Moreover, on July 8, 1997, one day after Respondent filled a prescription for twenty-four Vicodin ES tablets, which was issued by Dentist Haws, it filled a prescription for sixty Lorcet 10/650 tablets issued by another practitioner, Dr. Caudle. *Id.* at 2.

With respect to the prescriptions Dentist Haws issued to D.C., Dr. Ferrell observed: ''that's a lot of times, a lot of dental problems right there. At some point in time, you've got to wonder * * * why he's seeing the dentist so often and why he's having so much dental problems.'' Tr. 289. Dr. Ferrell further explained that dentists usually treat acute pain and that ''after maybe a month or two and I continued to see those things * * * I would ask the dentist to supply me some type of reason for why the prescriptions kept going on for such a long period of time.'' *Id.* at 290.

Relatedly, Dr. Mulder opined ''that the prescriptions over a longitudinal basis for this narcotic in this dose were being prescribed by a dentist who is not a physician which heightens the level of concern about this particular prescription.'' *Id.* at 504. Dr. Mulder also testified that the drugs Respondent dispensed contained acetaminophen, and that there is a ''safe limit'' as to the amount of acetaminophen an individual can take during a day without ''developing a toxic state,'' which is ''four grams a day.'' *Id.* at 500. Dr. Mulder further testified that ''[t]he number of pills dispensed to this individual were above the acceptable limit'' and could lead to serious illness if the patient was actually taking the drugs. *Id.* at 500–01.

In his testimony, Mr. Street acknowledged that the prescriptions ''slightly exceed[ed]'' the safe limit for acetaminophen ''on two separate months.'' May 25, 2005 Tr. at 79. Mr. Street testified that D.C. ''required a lot of dental work,'' and that because he was a patient ''that Dr. Haws [was] treating over a long period of time, we kept in touch with the dentist office. And it was easy to do, because the dentist office is right there in town. And kept in touch with either Dr. Haws or his receptionist * * * Ms. Williams, to verify that they were, you know, requiring ongoing treatment.'' *Id.* The ALJ credited this testimony, *see* ALJ at 35, and many of the prescriptions issued by Dentist Haws appear to have been called in to Respondent.[19] *See* GX 15–B.

[18] Mr. Richards testified that between 1997 to 1999, a competitor pharmacy ''filled 1,886 controlled substance prescriptions for Dr. Varney'' and ''Jonesborough Drug filled 25,861 hard copies during the same period.'' May 24, 2005 Tr. 32. Even if Mr. Richard's testimony regarding the prescriptions filled by Jonesborough Drug was meant to refer to controlled-substance prescriptions, the testimony is not relevant to the issue of whether Respondent filled unlawful prescriptions.

[19] The ALJ also found that ''Mr. Street had counseled [D.C. 1] not to take additional over-the-counter acetaminophen during this time.'' ALJ at 35 (citing Resp. Ex. 1, at 1). Mr. Street did not, however, testify to this under oath and the document which contains this statement was not sworn. It is also notable that Mr. Street and his counsel had approximately ten months from the time the Government rested until the hearing reconvened and thus they had ample time to prepare for his testimony. ALJ at 2. Because Mr.

Continued

None of the prescriptions, however, include a notation that the dispensing pharmacist had questioned Dentist Haws about D.C.'s continuing need for the drugs. *See Id.*

Patient E.C.

Government Exhibit 15–D shows that on several occasions, Respondent dispensed to E.C. prescriptions for combination hydrocodone and acetaminophen products issued by different doctors within a short period of other similar prescriptions. For example, on October 24, 1997, Respondent dispensed a prescription for 20 Lortab 7.5/500 issued by Dr. Hussain; the next day, it dispensed a prescription for 25 hydrocodone/apap 5/500 issued by Dr. Wiles. *See* GX 15–D at 1. Three days later (on October 28), Respondent dispensed another 30 tablets of Lortab 5/500 issued by Dr. Wiles. *Id.* Dr. Ferrell specifically noted that upon receiving such prescriptions, a pharmacist should call the prescriber and ask if he was ''aware that the patient had gotten Lortab the day before.'' Tr. 296.

The trace also showed that Respondent had filled multiple prescriptions for sixty tablets of alprazolam 5 mg. issued by Dr. Hussain, as well as multiple prescriptions for diazepam 5 mg. issued by Dr. Slonaker. GX 15–D. In several instances, Respondent filled the prescriptions only days apart. *See Id.* at 1 (10/26/99 Rx for 60 alprazolam and 10/27/99 Rx for 60 diazepam; 11/20/99 Rx for 60 alprazolam and 11/23/99 Rx for 60 diazepam). *Id.* at 1. Both drugs are schedule IV depressants, *see* 21 CFR 1308.14(c), and according to Dr. Ferrell ''have a synergistic effect'' when taken together. Tr. 297. Dr. Ferrell further noted that the trace showed that the patient was simultaneously receiving multiple controlled substances for pain (from Dr. Slonaker) such as hydrocodone/apap 7.5/500 and hydrocodone/apap 10/500, *Id.* at 298, and that the pharmacy should have questioned this. *Id.* at 300; GX 15–D at 2. Relatedly, Dr. Mulder testified that ''[it] is generally considered not appropriate to be mixing different short-acting analgesic medications at the same time'' such as E.C. was receiving, and that the pharmacist should have contacted the physician. Tr. 508. None of the prescriptions indicated that Respondent had contacted the prescriber. *See* GX 15–D.

Mr. Street testified that ''I'd talk to Dr. Slonaker about this before, because he does this for many of his patients'' and that ''he likes to prescribe a stronger pain med for severe pain, and a weaker pain med * * * for mild to moderate pain.'' May 24, 2005 Tr. 81–82. Mr. Street also testified that E.C. had been a patient since Respondent opened, that he had ''chronic back problems'' and ''has seizures'' related to a fall he had in November 1997. *Id.* at 81. Mr. Street, however, offered no testimony regarding Respondent's frequent (and sometimes nearly simultaneous) dispensings of the alprazolam and diazepam prescriptions which were written by different doctors.

Respondent also introduced into evidence the affidavit of Joseph Montgomery, a physician with thirty years of experience. *See* RX 5. Dr. Montgomery reviewed the medical records of most of the patients identified in the traces. Dr. Montgomery opined that it was ''probably * * * medically justified'' for E.C. ''to receive the degree of pain medications prescribed.'' RX 5, Ex. A. at 2. Dr. Montgomery offered no opinion, however, as to whether the prescriptions Respondent repeatedly filled for alprazolam and diazepam were issued for a legitimate medical purpose. *See Id.*

Patient S.F.

The prescription trace for S.F. shows that beginning in January 1996 and ending in April 1997, Respondent filled approximately 126 prescriptions issued by Dr. Blackmon which were primarily for Dilaudid (schedule II) and Lorcet 10/650 (schedule III). GX 15–F. Dr. Ferrell noted that in 1996, Respondent filled approximately 47 hydrocodone/apap prescriptions for a total of 3,915 dosage units and 35 Dilaudid prescriptions for 3,090 dosage units. Tr. 306. Dr. Ferrell further explained that this amounted to ten tablets a day of hydrocodone and eight tablets a day of Dilaudid, ''which is real heavy usage of * * * the two opioids.'' *Id.* Moreover, in the first three-and-a-half months of 1997, Respondent filled 23 prescriptions totaling 2,070 dosage units of hydrocodone and 16 prescriptions totaling 1,454 dosage units of Dilaudid. *Id.* This amounted to approximately 17 tablets a day of hydrocodone and 12 tablets a day of Dilaudid. *Id.* Dr. Ferrell also noted that Respondent had filled a prescription for Buprenex, a narcotic agonist-antagonist which can cause acute withdrawal symptoms in patients taking Dilaudid, an opioid agonist. *Id.* at 307.

Dr. Ferrell further noted that the Buprenex prescriptions contained no notation that Respondent had contacted the prescriber. *Id.* at 308. Dr. Ferrell added that based upon the dosages being prescribed, S.F. was ''at least physically dependent'' on the opioids and that he would have ''probably refuse[d] to fill his prescriptions.'' *Id.*

Dr. Mulder added that the quantities of dosage units of hydrocodone/acetaminophen drugs ''were twice the acceptable limits'' and ''would be potentially toxic.'' *Id.* at 511. He further testified that a pharmacist has an obligation ''not to dispense medication knowingly harmful to the patient'' and ''to contact the physician to let him know that the prescriptions were exceeding acceptable norms.'' *Id.* Dr. Mulder also noted that Respondent was dispensing ''two different narcotics simultaneously in relatively large quantities.'' *Id.*

The ALJ found credible Mr. Street's testimony that S.F. had ''three major back surgeries'' and had difficulty walking. ALJ 40. The ALJ also found credible Mr. Street's testimony that he ''had to make frequent phone calls about him, because he was always wanting his medications early, or he would * * * bring a prescription in that was * * * too frequent, too close to the other one he brought in.'' May 24, 2005 Tr. 85. Mr. Street maintained, however, that Dr. Blackmon ''was monitoring him closely,'' and that while Dr. Blackmon acknowledged that ''he was giving [S.F.] a high amount of narcotics, he felt [S.F.] needed these just so * * * he could function in every day life.'' *Id.*

The ALJ also found credible Mr. Street's testimony that while he provided early refills of S.F.'s prescription, he never did so without verifying it with Dr. Blackmon and then ''document[ed] the transaction in the computer.'' ALJ at 40 (citing May 24, 2005 Tr. at 85–86). Respondent did not, however, produce any printouts of this documentation (or for any other instance in which he claimed to have contacted a prescriber) and testified on cross-examination that he did not know if the ''specific notes for each specific patient'' could even be printed out. May 24, 2005 Tr. at 154.

As for the filling of the Buprenex, the ALJ credited Mr. Street's testimony that the drug's package insert ''gives no interactions or contraindications to ingestion with hydrocodone.'' ALJ at 40. The ALJ also credited Mr. Street's testimony that ''[t]he only precaution regarding Buprenex and hydrocodone is that the combination may 'increase * * * drowsiness.'' *Id.* at 40–41 (citing May 24, 2005 Tr. 87).

Respondent, however, offered no testimony in response to Dr. Mulder's testimony that Respondent was filling prescriptions for combination hydrocodone/acetaminophen at quantities that exceeded acceptable safe

Street could have testified to this but chose not to, I give no weight to this statement.

limits.[20] Furthermore, I take official notice of the package insert for Buprenex.[21] Under the section captioned ''Use in Narcotic-Dependent Patients,'' the insert states: ''Because of the narcotic antagonist activity of Buprenex, use in the physically dependent individual may result in withdrawal effects.'' *Buprenex Injectable Package Insert,* at 1. I therefore reject the ALJ's finding crediting Mr. Street's testimony on the issue. I further find that at the time Respondent filled the Buprenex prescription, it had filled more than sixty prescriptions issued to S.F. for both Dilaudid (hydromorphone) and combination hydrocodone drugs, both of which are narcotics. *See* GX 15–F, at 1 & 3; *see also* 21 CFR 1300.01(b)(30); *Id.* 1308.12(b)(1); *Id.* 1308.13(e).

Patient B.J.

This trace showed that twenty-one different physicians had prescribed controlled substances to B.J. The prescriptions were for multiple schedule IV benzodiazepines including alprazolam, lorazepam, clonazepam, temazepam, and triazolam; multiple schedule III narcotics including combination hydrocodone/apap, Fiorinal with Codeine,[22] and propoxyphene/apap, some schedule II endocet (oxycodone with acetaminophen), and four prescriptions for Stadol (butorphanol), a schedule IV drug (21 CFR 1308.14(f)), which is a mixed agonist/antagonist but which has opioid antagonist properties. Tr. 548.

The trace showed that Respondent repeatedly filled alprazolam and lorazepam prescriptions which were issued by different physicians for B.J. and that in multiple instances the prescriptions were filled within several days of each other. *See* GX 15–G at 1 (Compare Dr. Greenwood Rx for 60 alprazolam on 5/24/99 with Dr. Varney Rx for 90 lorazepam on 5/25/99; Greenwood Rx for 45 alprazolam on 6/23/99 with Varney Rx for 90 lorazepam on 6/21/99; Greenwood Rx for 60 alprazolam on 10/26/99 with Varney Rx for 90 lorazepam on 11/1/99; Greenwood Rx for 60 alprazolam on 11/30/99 with Varney Rx for 90 lorazepam on 11/29/99).[23] The trace also showed multiple instances in which Respondent filled prescriptions for schedule III narcotics such as generic Fiorinal with Codeine and propoxyphene—which again were issued by different doctors—within a short time of each dispensing. Moreover, the trace showed numerous instances in which Respondent filled prescriptions for hydrocodone/apap issued by six practitioners. *Id.* at 8.

Finally, the trace showed that Respondent filled prescriptions for Stadol on April 19 and 24, 1999, September 30, 1999, and November 6, 1999. *Id.* at 1–2. Respondent, however, was also filling prescriptions for narcotics contemporaneously with its Stadol dispensings. *See Id.*

In his testimony, Dr. Ferrell explained that ''[a] pharmacist is basically the gatekeeper of the medical delivery system.'' Tr. 310. After noting the numerous instances in which Respondent filled prescriptions for different benzodiazepines which were issued by different doctors and the large quantities of these drugs it dispensed, *Id.* at 312, Dr. Ferrell explained that a pharmacist must contact the prescriber, ask him if he is ''familiar with the fact [that] the patient'' is on another drug of the same class, and ask if he really wants the patient to receive the drug. *Id.* at 313. Dr. Ferrell also found problematic Respondent's filling of the prescriptions for hydrocodone/apap which were written by six different practitioners. *Id.* at 315.

Dr. Mulder found problematic Respondent's filling of ''simultaneous prescription[s] of narcotic analgesics'' and noted that ''there were six different narcotics being * * * dispensed simultaneously by a number of different physicians.'' *Id.* at 512–13. Dr. Mulder further found that ''[t]he number of pills dispensed * * * exceeded the acceptable safe limits and would have been toxic to the patient.'' *Id.* at 513.

Dr. Mulder also explained that prescribing an agonist/antagonist such as Stadol ''at the same time that you're giving an agonist * * * precipitate[s] a withdrawal reaction [in] the patients.'' *Id.* Dr. Mulder further explained that Stadol and narcotic agonist drugs ''cannot be given simultaneously and they were given simultaneously in this particular patient.'' *Id.* at 513–514. According to Dr. Mulder, Respondent ''should not have filled'' the Stadol prescriptions. *Id.* at 514. Respondent also should have notified the physician that ''he cannot fill'' the prescription because of the ''potential medical problems'' that can occur ''by dispensing these two medications together'' and also that the ''numbers of pills are too much.'' *Id.*

Finally, with respect to Respondent's dispensing of multiple benzodiazepines, Dr. Mulder opined that ''the patient was receiving as many as three different benzodiazepines as the same time [and] [t]here [is] no medical indication for it whatsoever.'' Tr. 515. Dr. Mulder further explained that ''to dispense'' these prescriptions was ''problematic,'' because ''the combined effect'' of the drugs ''could be devastating for the patient.'' *Id.*

Mr. Street testified that B.J. had ''a lot of medical problems'' including chronic pain, chronic headaches, chronic kidney problems and numerous hospital stays. May 24, 2005 Tr. 87. Mr. Street also testified that B.J. had seen four different primary care physicians because the first two she saw had closed their practices or Tenncare had required her to change doctors. *Id.* at 88. Mr. Street further stated that B.J. ''didn't see [the physicians] at the same time.'' *Id.*

Mr. Street also testified that B.J. ''is a mental health patient,'' and that she went to a mental health group practice which had ''five or six doctors.'' *Id.* Mr. Street maintained that B.J. would not necessarily see the same doctor at each appointment. *Id.*

As for the three different benzodiazepines, Mr. Street testified that Dr. Varney was her primary care physician and was prescribing her one benzodiazepine for tension because she had headaches and another for sleep. *Id.* at 89. Moreover, a physician at the mental health group was prescribing alprazolam to her for anxiety. *Id.* The ALJ further credited Mr. Street's testimony that he had called both Dr. Varney and the mental health group and that ''[t]hey were both aware they were both prescribing at the same time.'' *Id. See also* ALJ at 43. The ALJ also credited Mr. Street's testimony that he documented this in his computer. *Id.* Mr. Street did not, however, testify as to

[20] Neither Mr. Street nor his expert witness, Dr. Montgomery, offered any evidence to refute this testimony. *See* RX 5, at 3–4. Moreover, while Dr. Montgomery stated that ''the records showed that Jeff Street called Dr. Blackmon's office regarding the quantity of pain medicine and Soma that [S.F.] received,'' RX 5, at 5, Dr. Montgomery offered no opinion as to why it was appropriate to dispense either quantities of drugs that are potentially toxic or multiple opiates. *See id.* at 4–5.

[21] In accordance with the Administrative Procedure Act (APA), an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is ''entitled on timely request to an opportunity to show to the contrary.'' 5 U.S.C. § 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within fifteen days of service of this order which shall commence with the mailing of the order.

[22] A branded drug containing butalbital, aspirin, caffeine and codeine phosphate.

[23] There were also similar instances on February 9 and 15, 1999; March 6 and 11, 1999; April 27, 29, 30 and May 1, 1999, in which Respondent filled prescriptions for these drugs which were issued by these two doctors for B.J. *See* GX 15–G, at 2. There were also many instances in which the prescriptions were presented within a week to two weeks of each other but were for large quantities.

when he first called the respective physicians.

Moreover, Mr. Street did not address why Respondent, between March and October 1999, repeatedly filled prescriptions for propoxyphene/apap and butalbital with codeine, which were continually issued by Drs. Gastineau and Varney respectively.[24] *See* GX 15–G, at 1–2. Nor did he offer any testimony as to why Respondent filled the four Stadol prescriptions when it was also dispensing narcotics to B.J.[25] Moreover, while Dr. Montgomery's affidavit concluded that B.J. ''is an unfortunate patient who has multiple medical/dental producing pain syndromes which were appropriately treated,'' the affidavit does not address the prescribings of narcotics by Drs. Varney and Gastineau. RX 5, at 11. Nor did it address the medical appropriateness of the simultaneous prescribing of alprazolam and lorazepam by Drs. Greenwood and Varney. *See Id.*

Patient W.L.

The prescriptions for W.L. indicate that between December 21, 1995, and February 15, 1997, Respondent filled 239 controlled substances prescriptions (including refills) issued by Dr. Blackmon for such drugs as Buprenex, Diazepam, Lortab 7.5/500, generic hydrocodone/apap 10/650, and Tussionex Pennkinetic Suspension (hydrocodone with chlorpheniramine) oral solution. *See* GX 15–H. In 1996, Respondent made 163 dispensings of Buprenex totaling 5,380 dosage units for ''approximately 14 units a day,'' thirty-one dispensings of hydrocodone/apap totaling 2550 dosage units, and twenty-two dispensings of diazepam totaling 1530 dosage units. Tr. 317; *see also* GX 15–H, at 1–4.[26]

Dr. Ferrell re-iterated that ''Buprenex is a narcotic antagonist'' and ''has many drug interactions'' including ''respiratory and cardiovascular bouts * * * in patients receiving therapeutic doses of diazepam.'' *Id.* Dr. Ferrell stated that he ''probably would not have filled the prescription.'' *Id.* at 318.

Relatedly, Dr. Mulder testified that Respondent did not comply with its corresponding responsibility under federal law for three reasons. Tr. 515–16. Specifically, Dr. Mulder noted: (1) That ''the number [of] pills dispensed * * * would have been toxic if taken as prescribed''; (2) ''the simultaneous prescription of two or more analgesic medications''; and (3) ''the combination of * * * agonist and the antagonist, agonist medications which are contraindicated to be given together.'' *Id.* at 516. Dr. Mulder concluded that Respondent should have notified the physician that the medications prescribed were contraindicated and that it should not have filled the prescriptions. *Id.*

The ALJ credited Mr. Street's testimony that W.L. was disabled and had chronic back pain. ALJ at 43. (citing May 24, 2005 Tr. at 90). On the issue of the interaction of Buprenex and diazepam, Mr. Street testified that ''the only thing the package insert says about combining the two drugs is that there have been reports of respiratory problems when Diazepam is given with Buprenex.'' May 24, 2005 Tr. at 90. Mr. Street further added that the insert then ''tells the physician to proceed with caution if you're going to administer the two drugs.'' *Id.* The ALJ also credited Mr. Street's testimony that while W.L. was receiving ''a pretty heavy dose of narcotics, * * * we stayed [in] contact with Dr. Blackmon's office; and Dr. Blackmon * * * said he was monitoring him close,'' and needed the high doses ''for his medical condition.'' *Id.* at 90–91; ALJ at 44.

According to the Buprenex package insert (which I have taken official notice of), ''[t]here have been reports of respiratory and cardiovascular collapse in patients who receive therapeutic dose of diazepam and Buprenex,'' and ''[p]articular care should be taken when Buprenex is used in combination with central nervous system depressant drugs.'' Buprenex Package Insert at 1. The package insert further states, however, that ''[p]atients receiving Buprenex in the presence of other narcotic analgesics [and] benzodiazepines * * * may exhibit increased CNS depression. When such combined therapy is contemplated, it is particularly important that the dose of one or both agents be reduced.'' *Id.* (emphasis added).

The prescription traces indicate, however, that Dr. Blackmon's prescriptions did not reduce the dosing of the Buprenex, the diazepam, or the hydrocodone/apap and Tussionex. For example, while in January 1996, Blackmon twice prescribed only thirty Lortab, on February 7, he issued a prescription for sixty Lortab (7.5/500) with one refill, and on February 21, he issued a prescription for ninety hydrocodone/apap (10/650) with two refills. Blackmon proceeded to prescribe ninety Lortab in various strengths with refills until February 1997. *See* GX 15–H, at 1. Moreover, while Blackmon initially prescribed only thirty tablets of diazepam, approximately two weeks later, he issued a prescription for sixty tablets with one refill. *See Id.* Two weeks later, Blackmon issued another prescription for sixty diazepam with one refill. *See Id.* Three weeks later, Blackmon increased the diazepam prescriptions to ninety tablets with one refill, and similar prescriptions were issued on approximately a monthly basis until Blackmon's prescription writing ended. *See Id.*

Moreover, the trace indicates that Blackmon increased the quantity and number of refills of Buprenex notwithstanding that he was also prescribing the other drugs. *See id.* Thus, the evidence indicates that Blackmon did not reduce the dosing of either the Buprenex or the other drugs as called for in the Buprenex warnings but actually increased them.[27] Respondent nonetheless filled the prescriptions.

Patient A.L.

This trace indicated that between August 23, 1997, and January 12, 1998, Respondent filled twenty-four prescriptions for Angela L. (who was married to Rex L., GX 15–J) which were issued by Dentist Haws. Most of the prescriptions were for either Lorcet 10/650 or Lortab 10/500. *See* GX 15–I. Respondent also filled three prescriptions Dentist Haws issued for Tussionex Pennkinetic Suspension, a combination of hydrocodone and chlorpheniramine which is prescribed for cough and upper respiratory symptoms. The original prescription was dated 9/11/97, and the trace indicates that Respondent also dispensed two re-fills. GX 15–I. The trace also showed that Respondent filled other prescriptions for Lortab which were issued by a Dr. Caudle/Caudill.

Based on the stickers that had been attached to the original prescriptions, Dr. Ferrell noted that some of the prescriptions were issued to Rex L. but were apparently dispensed to Angela L. *See id.* at 4; Tr. 320–21. Dr. Ferrell

[24] Dr. Gastineau was also a family and internal medicine practitioner and practiced in Elizabethon, Tennessee; Dr. Varney was not a member of Dr. Gastineau's group and practiced in Jonesborough. *See* GX 15–G, at 38 & 71.

[25] As explained at footnote 19, Respondent submitted an exhibit entitled ''Comparison/Analysis of Patients in Exhibit 15.'' RX 1. With respect to B.J., the documents states that ''MD OK'd Stadol, but not with other meds. Drug literature says can be given with a narcotic, and to use caution when doing so.'' RX 1, at 3. The ALJ did not rely on this statement and the exhibit was not sworn. As stated above, because Mr. Street could have testified to this (and been subject to cross-examination) but did not, I conclude that the statements in this document are entitled to no weight.

[26] Some of the refills may have dispensed in the first week of January of the next year.

[27] Dr. Montgomery's affidavit does not discuss W.L. *See* RX 5.

stated that this should not have occurred. *Id.* at 321. Dr. Mulder testified that the number of pills dispensed would have been ''toxic if taken the way they were prescribed and dispensed.'' *Id.* at 517. He further explained that the pharmacist should have ''[a]dvised the patient as to the * * * problem * * * and notified the physician that an excess amount of pills were prescribed.'' *Id.* at 518.

Mr. Street testified that Angela L. was a typical patient of Dentist Haws because she had a ''low income,'' ''no insurance'' and ''needed a lot of work.'' May 24, 2005, Tr. 91. He also testified that ''as with all his patients that he was treating over a long period of time, we stayed in contact'' with Dr. Haws and ''verified that they were still getting treatment.'' *Id.* The ALJ credited this testimony. ALJ at 45. Mr. Street further testified that while Angela L.'s prescriptions may have exceeded the acetaminophen limits ''slightly,'' this happened in only one month and she was getting ''lots of dental work done.'' May 24, 2005 Tr. 91.

In discussing Respondent's dispensings to Rex L., Mr. Street testified that he had discovered that a ''relief pharmacist'' had filled a prescription for Tussionex, which Mr. Street caught ''when [he] came back to work.'' May 24, 2005, Tr. 93. Mr. Street then testified:

> And I alerted Dr. Haws to the fact that * * * it's not within your usual course of practice to prescribe Tussionex. And so * * * I explained to him why. I said, ''That's—basically, that's not a pain syrup, that's a cough syrup, and that's not within your usual course of practice.'' And after that, he ceased doing that. I've never seen him do it again.

Id. According to the trace for Rex L., Respondent filled or refilled Tussionex prescriptions issued by Dr. Haws on August 1, 4, and 29, 1997. *See* GX 15–J, at 2, 5 & 13.

The trace for Angela L. shows, however, that Respondent filled a Tussionex prescription which Dr. Haws issued on September 11, 1997, after Mr. Street claimed to have called Haws. *See* GX 15–I, at 1. Moreover, Respondent refilled this prescription twice. *See id.* Mr. Street offered no explanation as to why these prescriptions and the refills were also not outside the usual course of Dr. Haws' professional practice. *See* May 24, 2005 Tr. at 91. Nor did he explain why Respondent filled the prescriptions. *See id.*

Patient R.L.

This trace showed that Respondent dispensed numerous prescriptions for diazepam and combination hydrocodone products (primarily Lorcet 10/650) between February 27, 1996, and April 15, 1997. *See* GX 15–J. According to Dr. Ferrell, in 1996, Respondent filled 53 prescriptions (with refills) written by Dr. Blackmon totaling 3,180 dosage units of combination hydrocodone/apap, and twenty-one prescriptions totaling 1,200 dosage units of diazepam. Tr. 323.

Rex L. also received numerous prescriptions from Dentist Haws for combination hydrocodone drugs and the two prescriptions for 720 ml. of Tussionex. Regarding the Tussionex, Dr. Ferrell testified that not only is it ''unusual to see a dentist write for cough syrup,'' but these prescriptions were for a very large quantity and he could not ''think of any reason why a prescription for [720 ml.] of Tussionex'' would be necessary. *Id.* at 324–25. According to Dr. Ferrell, ''the usual dosage'' of Tussionex ''is 5 milliliters every 12 hours,'' so that 720 ml. provides 144 dosage units. *Id.* at 325.[28]

The stickers attached to the actual hard copy prescriptions show that on August 1, 1997, Respondent dispensed to Rex. L. 720 ml. of Tussionex, and that three days later, it dispensed to him an additional 360 ml. GX 15–J, at 13. Furthermore, on August 29, 1997, Respondent dispensed to Rex L. an additional prescription for 720 ml. of Tussionex based on Dr. Haws' authorization. *Id.* at 5. Dr. Ferrell further noted that Dr. Haws' Tussionex prescriptions did not appear to include specific directions as to how the drug should be taken. Tr. 326; *see also* GX 15–J, at 5 & 13.

Regarding Rex L., Dr. Mulder testified that the quantities of pills Respondent dispensed ''could have been toxic if taken as prescribed.'' Tr. 519. Dr. Mulder further noted that there was evidence that Rex L. was ''Doctor Shopping,'' a practice in which drug abusers and prescription drug-dealers ''will go from physician to physician to present the same story to'' each doctor so as to ''amass their quantities of medications.'' *Id.* at 520–21.

According to the trace, on November 10, 14, and 18, 1997, Respondent filled prescriptions which Rex L. obtained from Dentist Haws for 24 Lorcet (10/650). GX 15–J, at 2. Thereafter, on November 22, Respondent filled a prescription Rex L. obtained from Dr. Egidio for another 60 Lorcet. Next, on November 29, Respondent filled a prescription Rex L. obtained from Dr. Caudill for 90 Lortab 10/500; Respondent then refilled this prescription twice. *See id.*

This was followed by a December 5 dispensing of a prescription for 240 ml. of Tussionex issued by Dr. Caudell,[29] dispensings on December 9 and 12 of prescriptions for 20 and 24 Lorcet issued by Dentist Haws, a December 17 dispensing of a prescription for 100 tablets of MS Contin 100 mg. (a schedule II drug containing morphine) issued by Dr. Caudle, and a December 23 dispensing of a prescription for 65 Dilaudid 4 mg. issued by Dr. Egidio. *See id.* These were followed by dispensings of 24 Lorcet tablets on December 31, 1997, and January 5, 1998, pursuant to prescriptions issued by Dentist Haws, followed by a January 9 dispensing of a prescription for 240 ml. of Tussionex issued by Dr. Caudill, and additional prescriptions for Lorcet issued by Dentist Haws. *See id.*

The ALJ found credible Mr. Street's testimony that Rex L. suffered from ''extreme chronic pain'' and that Respondent contacted Dr. Blackmon who informed him that ''he needed this dose for his chronic pain.'' May 24, 2005, Tr. 92; *see also* ALJ at 46. The ALJ also found that Mr. Street was aware that patients may develop a tolerance and require larger doses of pain medication. ALJ at 46.

Regarding the Tussionex, the ALJ found credible Mr. Street's testimony ''that the prescription * * * was filled by a relief pharmacist.'' ALJ at 46 (citing May 24, 2005 Tr. at 93. The ALJ also found credible Mr. Street's testimony that he called Dr. Haws and discussed that the prescriptions ''would not normally be within the usual course of a dentist's practice,'' and ''that, after the phone call, he did not see anymore Tussionex prescriptions issued by Dr. Haws.'' *Id.* (Citing May 24, 2005 at 93). For the reasons stated in the discussion regarding Angela L., I reject the ALJ's credibility finding regarding Mr. Street's phone call.

In his testimony, Mr. Street did not specify which of the three Tussionex prescriptions issued by Dr. Haws for Rex L. were filled by the relief pharmacist. Nor did he testify as to which of these prescriptions prompted his phone call to Haws. *See* May 24, 2005 Tr. 93.

Moreover, Mr. Street offered no testimony responding to Dr. Mulder's opinion that Rex L. was engaged in doctor shopping. More specifically, Mr. Street did not testify at all as to why his pharmacy filled the prescriptions that

[28] Dr. Ferrell testified that if a patient took the usual dosage of five ml. twice a day, 144 dosage units would last 36 days. *Id.* at 326. This appears to be a math error as 144 dosage units, if taken twice a day, should last 72 days.

[29] It is not clear whether this is a misspelling of Dr. Caudill's name.

Rex L. presented from multiple practitioners between November 1997 and January 1998.[30] *See id.* at 92–93.

Patient K.P.

This trace showed that Respondent filled prescriptions K.P. had received from ''some 22 different prescribers.'' [31] Tr. 328. Most of the prescriptions were for combination hydrocodone/acetaminophen in various strengths. *See* GX 15–K. There were, however, also prescriptions for alprazolam, propoxyphene/apap, Tussionex, Fiorinal with Codeine, and phentermine. *See id.*

Dr. Ferrell noted that between April 20, 2001, and April 19, 2002, Respondent dispensed to K.P. 58 prescriptions for combination hydrocodone/apap products totaling 2,355 dosage units. Tr. 328. According to Dr. Ferrell, Respondent ''absolutely should have called'' the prescribers ''on each case.'' *Id.* at 329. Dr. Ferrell opined that K.P. was a ''doctor shopper.'' *Id.* at 330.

Dr. Mulder likewise identified ''the number[] of physicians for whom prescriptions were being filled over a relatively short period of time,'' and that the ''quantity of pills * * * exceeded * * * acceptable limits.'' Tr. 522. Dr. Mulder further testified that Respondent ''[h]ad a responsibility not to fill prescriptions for more pills than what would be considered safe and acceptable'' and to ''notify * * * the physicians that the patient was receiving the same prescription from multiple physicians over the same period of time.'' *Id.* at 522–23.

Regarding K.P., Mr. Street testified that she had complications from neck surgery. May 24, 2005 Tr. at 94. He further testified that ''over the course of time [K.P.] had to see five different primary care physicians'' either because the physician closed his/her practice or Tenncare moved her to a different physician. *Id.* Mr. Street added that K.P. had ''seen neurosurgeons'' and they had ''referred her to a pain management doctor who * * * was writing her pain meds.'' *Id.* Mr. Street further added that ''[t]hey were both aware that they were prescribing them at the same time.'' *Id.* Finally, Mr. Street added that during the April 2001 to April 2002 period, K.P. ''had to see seven emergency room doctors,'' and added that this was ''not surprising, considering * * * she had the two major surgeries [and] all the complications.'' *Id.*

While the ALJ credited this testimony, Mr. Street did not identify the names of the doctors by their practice areas. Nor, other than in his vague testimony that the neurosurgeons (Drs. Wiles and Vaught) and the pain management doctor (Dr. Smyth) were each aware of the other's prescribing, did Mr. Street testify as to his pharmacy having contacted any of the other prescribers, such as the orthopedic surgeons (Drs. Beaver and J. Williams) and the emergency room physicians she was also seeing in the same time frame. Moreover, while Dr. Mongtomery opined that there was medical justification for K.P. to have received ''tremendous amounts of narcotics,'' his affidavit does not address the issue of doctor shopping. RX 5, at 12.

Patient P.P.

The prescription trace indicated that Respondent filled prescriptions for P.P. that were issued by eleven different prescribers. *See* GX 15–L. Dr. Ferrell specifically noted that during February 2002, P.P. obtained prescriptions for hydrocodone/apap from Doctors Goulding, Smyth, Haws and Pelletier for a total of 79 dosage units.[32] Tr. 331. Dr. Ferrell further concluded that ''if [Respondent] was telling the different physicians about [the] history of this patient, [it] probably could have cancelled their prescriptions.'' *Id.* at 332.

There is also evidence that during the fall of 1999, Respondent filled prescriptions for narcotics that were issued in close proximity to other prescriptions for either the same or similar narcotics and that P.P. was engaged in doctor shopping. For example, on October 4, 1999, Respondent dispensed an original prescription for 60 hydrocodone/apap (5/500) that was issued by Dr. Lynch; Respondent dispensed refills of the prescription on both October 15 and 25, 1999. GX 15–L, at 1. On October 18, 1999, Respondent dispensed two prescriptions issued by Dr. Wyche: one for 30 hydrocodone/apap (5/500), and one for 48 propoxyphene/apap. *Id.* Moreover, on November 17, 1999, Respondent dispensed a prescription for 36 propoxyphene/apap issued by Dr. Wyche, and on November 18, Respondent dispensed a prescription for 48 hydrocodone/apap, which was also issued by Dr. Wyche.[33] *Id.*

Dr. Mulder testified that Respondent had not met its corresponding responsibility in its dispensings to P.P. for several reasons. In support of his conclusion, Dr. Mulder cited ''the numbers of prescriptions that were [being] dispensed within each given month, the combination of two or more narcotics at the same time, and [that] multiple physicians [were] writing prescriptions for this patient.'' Tr. 523–24. Dr. Mulder also observed that K.P. (GX 15–K) ''had the same address as'' P.P., and ''there was a very significant amount of narcotics going into this household every day.'' *Id.* at 524. Dr. Mulder further explained that in his experience, it is ''highly unusual that you would have two family members with medical problems that would require the same level of prescribing within each individual month.'' *Id.*

Dr. Mulder also testified that he would have contacted law enforcement officials regarding what ''may be going on in that particular household.'' *Id.* at 525. Finally, Dr. Mulder testified that a pharmacist should not ''fill what is inappropriate from a dosage perspective,'' and that a pharmacist should ''notify the physicians that the patients are receiving multiple prescriptions from multiple physicians for the same thing.'' *Id.* at 524.

Mr. Street testified that P.P. was K.P.'s husband and that he was another ''chronic pain patient.'' May 24, 2005 Tr. at 95–96. Mr. Street further testified that P.P. mainly saw Dr. Tochev, a primary care physician, and Dr. Tanner, who was also in the same group. *Id.* at 96.

Mr. Street added that Dr. Tochev referred P.P. to a pain management group, which started writing prescriptions for pain meds for him. *Id.* Mr. Street then testified that ''we contacted pain management about that, and Dr. Tochev, and neither one * * * [was] aware the other one was prescribing. Well, after we contacted them, pain management cease to write [P P.] any more pain meds.'' *Id.*

Concluding his testimony regarding P.P., Mr. Street stated that ''he had seen ER doctors a couple of times; he had seen a dentist a couple of times.'' *Id.* Mr. Street then explained that ''if you knew the doctors in the area like I do, it shouldn't present a problem.'' *Id.*

Notably, Mr. Street offered no testimony regarding the multiple

[30] Again I note that in Respondent Exhibit 1, there is a notation that ''MDs (Caudill and Egidio) were contacted to make sure both were aware patient was seeing each. Both had agreed to see patient since Caudill was semi-retired.'' RX 1, at 4. As explained previously, I decline to give any weight to this document. I further note that even if Mr. Street contacted both doctors, his statement says nothing about whether he notified each of them as to what drug the other doctor (as well as Dr. Haws) was prescribing.

[31] There actually appear to have been 26 different prescribers. *See* GX 15–K.

[32] The prescriptions were dated between February 14, 2002, and February 25, 2002. GX 15–L, at 2.

[33] On November 5 and 10, 1999, Respondent also dispensed a prescription and refill which Dr. Wyche wrote for 180 ml. of acetaminophen with codeine elixir. GX 15–L, at 1.

prescriptions his pharmacy filled that were issued by Drs. Wyche and Lynch. P.P. saw these doctors two years before he saw Dr. Tochev, the physician who referred P.P. to the pain management specialist.[34] *See* GX 15–L, at 16–17. Moreover, of the doctors who prescribed to P.P. during the period when Dr. Tochev was also treating P.P., only Dr. Smyth's prescriptions indicate a specialty of pain management, and the trace suggests that P.P. saw Dr. Smyth on at least two occasions. *Id.* at 4.

On February 20, 2002, Dr. Smyth wrote P.P. a prescription for 30 hydrocodone/apap (5/500) with one refill. *Id.* at 8. Respondent filled the initial prescription the same day and the refill on March 19, 2002. *Id.* at 2. Moreover, the next day, Respondent also filled a prescription issued by Dr. Haws for 24 hydrocodone/apap 7.5/500. *Id.* This was followed by a February 25, 2002 dispensing of 14 tablets of hydrocodone/apap 5/500 pursuant to a prescription of Dr. Pelletier, and the dispensing of a March 5, 2002 prescription by Dr. Haws for another 40 tablets of hydrocodone/apap 7.5/500. *Id.*

Two days later on March 7, 2002, Respondent filled a prescription for 60 tablets of hydrocodone/apap 7.5/500 which P.P. obtained from Dr. Tochev; on March 25, Respondent refilled the prescription. *Id.* at 2. Thereafter, on March 27, 2002, Dr. Tochev issued another prescription for 60 hydrocodone/apap 7.5/500; Respondent filled the prescription the same day. *Id.*

Finally, on April 2, 2002, Respondent dispensed another prescription for 62 hydrocodone/apap 7.5/500 which was issued by Dr. Smyth, the pain management doctor who according to Mr. Street, had stopped writing prescriptions after being informed that Dr. Tochev was also writing prescriptions for the same drug. *Id.*; May 24, 2005 Tr. 96. Furthermore, Government Exhibit 15–L also contains a copy of a prescription for methadone (a schedule II drug, 21 CFR 1308.12(c)) which Dr. Smyth issued on April 25, 2002; attached to the prescription is the sticker that is created upon the dispensing of a drug which includes the Rx number, name of the drug, the quantity and patient instructions, and price. *See* GX 15–L, at 3–4. I thus find that on April 25, 2002, Respondent also dispensed 62 tablets of methadone to P.P.

In his testimony, Mr. Street did not specify the date that he contacted the pain management doctor and Dr. Tochev regarding the fact that both doctors were writing prescriptions for narcotic pain medications. Perhaps at some point he did. The fact remains, however, that Respondent filled multiple prescriptions for hydrocodone that were being issued by multiple doctors within the same time period.

For example, Respondent refilled a Dr. Smyth issued prescription on March 19, notwithstanding that on March 7, it had filled Dr. Tochev's prescription. On March 25, it refilled Dr. Tochev's prescription even though it had refilled Dr. Smyth's prescriptions six days earlier. Then, two days later, it filled another prescription by Dr. Tochev; less than a week later, it filled another prescription from Dr. Smyth. Finally, Respondent also filled prescriptions issued by Dentist Haws during the same period it was filling the prescriptions from Dr. Smith, Tochev, and two other physicians (Goulding and Pelletier).[35]

Patient S.P.

This trace shows numerous instances in which Respondent filled prescriptions that were issued contemporaneously by multiple providers for either the same or similar drugs. These included narcotic pain medicines such as combination hydrocodone/apap, codeine/apap, and propxyphene/apap, as well as benzodiazepines such as clonazepam and temazepam. GX 15–M, at 1–2.

Dr. Ferrell noted that S.P. has seen multiple physicians (fourteen by his count), and noted various instances in which ''two pain relievers of * * * essentially the same type characteristics'' were prescribed by different doctors a day apart. Tr. at 333 & 335. Dr. Ferrell specifically noted that on February 8, 1999, Respondent filled a prescription for 40 tablets of acetaminophen with codeine # 3 which was issued by Dr. Varney; the next day, Respondent filled a prescription for 30 propoxyphene with acetaminophen which was issued by Dr. Huddleston. Tr. 333. Similarly, on August 13, 1997, Respondent filled a prescription for 30 acetaminophen with codeine # 3 which was issued by Dr. Sykes; the next day, Respondent filled a prescription for 60 propoxyphene with acetaminophen which was issued by Dr. Varney. *Id.* Dr. Mulder likewise noted that Respondent had violated its corresponding responsibility based on its having dispensed excessive quantities of pills, ''two or more narcotics at the same time, and [the] numbers of physicians * * * for whom prescriptions were being filled.'' *Id.* at 526.

The trace also shows that on January 14, 1999, Respondent dispensed 25 tablets of acetaminophen with codeine # 3 issued by Dr. Huddleston; on January 19, it dispensed another 20 tablets of the same drug issued by Dr. Varney. GX 15–M, at 2. On January 21, Respondent then dispensed 60 tablets of hydrocodone/apap 5/500 issued by Dr. Anderson, and on January 25, it dispensed another 25 tablets of acetaminophen with codeine # 3 issued by Dr. Huddleston. *Id.* This was followed by a January 27 dispensing of 30 propoxyphene with acetaminophen, and a January 29 dispensing of acetaminophen with codeine # 3, both of which were authorized by Dr. Varney. *Id.* The trace also shows that in April and May 1999, Respondent filled numerous prescriptions for narcotic pain medicines that were issued by Drs. Varney, Huddleston, and Hudson. *Id.*

Finally, the trace also shows numerous instances in which Respondent dispensed temazepam prescriptions issued by Dr. Varney and, sometimes within a day, dispensed clonazepam prescriptions issued by Dr. Shah. *See id.* at 2. Both of these drugs are benzodiazepines. As Dr. Mulder earlier testified, taking multiple benzodiazepines has synergistic effects and could be devastating to the patient. Tr. 515.

The ALJ found credible Mr. Street's testimony that S.P. had knee surgeries, hip surgeries, rotator cuff surgeries, and a partial amputation of her leg. ALJ at 49 (citing May 24, 2005 Tr. at 96). Mr. Street also testified that while it seemed like she had seen 15 different doctors, five of the doctors practice in the same orthopedic group and three of the doctors practice in the mental health group. May 24, 2005 Tr. at 97. Mr. Street also testified that Dr. Varney was ''her primary care physician'' and that he ''likes to write two different pain meds * * * one for severe pain and one for milder pain.'' *Id.* Mr. Street also stated that Dr. Varney had referred S.P. to the orthopedic group, which ''was prescribing her some more pain meds for acute pain,'' and he had ''stayed in contact with'' the doctors who ''thought it was okay.'' *Id.* at 98.

The Government did not rebut Mr. Street's testimony on these points, and upon reviewing the prescriptions, it appears that some of the doctors were in the same group. Mr. Street, however,

[34] Neither Dr. Wyche nor Dr. Lynch presents him/herself as a pain management specialist. *See* GX15–L, at 16–17. Dr. Wyche's scripts indicate that he has a ''FAMILY PRACTICE,'' and Dr. Lynch's scripts contain no indication of a specialty. *Id.*

[35] Regarding P.P., Dr. Montgomery stated that ''[t]his patient has a tremendous pain syndrome due to documented medical and trauma etiologies. It is my opinion that this patient was appropriately treated and the large numbers of pain medicines were reasonable care.'' RX 5, at 12. Again, Dr. Montgomery's statement does not address whether it was appropriate for Respondent to fill multiple prescriptions from multiple doctors within the same time frame.

offered no testimony regarding Respondent's numerous dispensings of benzodiazepine prescriptions by Dr. Varney (S.P.'s family practitioner), and Dr. Shaw. Moreover, while Dr. Montgomery opined that S.P. was ''a difficult patient who received a lot of multiple narcotics and it was reasonable to treat her in this fashion,'' RX 5, at 12, he offered no opinion as to whether it was reasonable for her to receive multiple benzodiazepines simultaneously.

Patient J.P.

This trace showed that Respondent dispensed multiple narcotic pain medicines including Darvocet (propoxyophene/apap), Lortab (hydrocodone/apap 5/500), Tylenol with codeine # 4, and Stadol spray; benzodiazepines including diazepam and temazepam; Pondimin (fenfluramine, a schedule IV drug, 21 CFR 1308.14(d)); and phentermine, a schedule IV stimulant (21 CFR 1308.14(e)). *See* GX 15–N. Most of the drugs were prescribed by Dr. Varney, although the Lortab was prescribed by Dr. Johnson, who issued fourteen prescriptions of the drug to J.P. throughout 1999. *See id.* Moreover, the trace shows that Dr. Varney would issue as many as four to five prescriptions for different controlled substances at a time. *See id.*

Dr. Ferrell testified that he did not ''understand why a doctor would prescribe two drugs like [Tylenol with Codeine and propoxyphene/apap] at the same time.'' Tr. 336. Dr. Ferrell noted that Darvocet and Tylenol # 3 provide ''about the same in relief of pain.'' *Id.* at 338. Dr. Ferrell also found problematic the prescribing of Stadol at the same time that Darvocet and Tylenol with codeine were being dispensed and noted that this happened repeatedly. *Id.* at 337.

Dr. Mulder testified while ''[t]he actual quantities of pills looked at in an isolated manner were not * * * of that much concern,'' J.P. ''was prescribed seven different addicting medications simultaneously.'' *Id.* at 527. Dr. Mulder further explained that J.P. ''had stimulants and depressants, she had analgesics and anxiolytics and this is a whole host of different sorts of addicting medications.'' *Id.* Continuing, Dr. Mulder added that ''[a]t the very least, it would have warranted a discussion with the physician [to] help me understand what's going on here so I feel comfortable about these ying-yang sorts of things I'm doing with this patient's pharmacologic regime.'' *Id.*

Mr. Street testified that he ''remember[ed] talking to Dr. Varney'' about the five or six different controlled substances he was prescribing. According to Mr. Street's testimony, Varney was prescribing two drugs for pain pills. May 24, 2005 Tr. 98–99. The ALJ found credible Mr. Street's testimony that J.P. weighed 350 to 400 pounds and that Dr. Varney wrote her prescriptions for scheduled diet drugs to treat obesity. ALJ at 50 (citing *id.*). Moreover, Varney also ''prescribed her something for sleep [and a] muscle relaxer.'' May 24, 2005 Tr. 99.

As for the Stadol, Mr. Street acknowledged that it was an agonist-antagonist which might cause ''withdrawal problems.'' *Id.* Mr. Street testified, however, that the warning in the Stadol insert applies only to a person who ''is severely dependent on narcotics.'' *Id.* at 100. Mr. Street further testified that he talked with a physician, who he did not identify, about the use of Stadol and was told its use would not pose a problem unless the patient was ''a street addict.'' *Id.* Mr. Street also testified that he asked this physician about whether it was appropriate to prescribe the drug if a patient was ''getting two or three pain pills a day.'' *Id.* According to Mr. Street, the physician told him that it would not be a problem as long as the drug was used ''on an acute'' or an ''as needed basis,'' and that he instructed the patient not to take their ''pain pill * * * in the same time period.'' *Id.*

The ALJ found this testimony credible and the Government did not rebut it. Mr. Street, however, offered no testimony as to why Respondent also filled the prescriptions for Lortab that were issued by Dr. Johnson during the same period it was also filling the prescriptions issued by Dr. Varney for the three opiates (Stadol, Darvocet and Tylenol 3).[36]

Patient A.S.

This trace showed that between April 25, 2001, and March 12, 2002, Respondent filled prescriptions which A.S. obtained for various strengths of combination hydrocodone/apap products from eight different practitioners. GX 15–Q. Dr. Ferrell specifically noted that there were seventeen different prescriptions totaling 369 dosage units. Tr. 343–44.

Dr. Mulder testified, however, that ''the number of pills were acceptable,'' and that ''[t]he only disturbing thing about this was the use of the number of different physicians for filling these prescriptions.'' *Id.* at 531. Dr. Mulder further testified that, under these circumstances, ''[i]t would have been appropriate for the pharmacist to have notified the multiplicity of physicians that a number of different prescriptions were being received for this narcotic so that they could concentrate that in one place.'' *Id.* Dr. Mulder did not, testify, however, that doing so was required for Mr. Street to comply with his corresponding responsibility given the limited number of pills being dispensed. *See id.*

Moreover, the ALJ found credible Mr. Street's testimony that A.S. had to switch her primary care physician multiple times because a physician closed her practice. ALJ 53. Furthermore, several of the prescriptions were for small amounts and were issued by her dentist and emergency room physicians. *Id.* Mr. Street thus testified that this did not ''throw up any red flags.'' May 24, 2005 Tr. at 104; *see also* ALJ at 53. The Government did not offer any evidence rebutting Mr. Streets' testimony or demonstrate through other evidence that it was implausible.

Patient R.S.

This trace showed that R.S. had received prescriptions from nine different prescribers. *See* GX 15–R, at 1–4. According to the trace, in 1999, Respondent filled thirty one prescriptions for alprazolam, nineteen prescriptions for clonazepam, two prescriptions for diazepam, and one prescription for lorazepam. *See id.* at 1–3.

The alprazolam prescriptions were issued by Drs. Lynch, Wiley, and Niner; the clonazepam prescriptions were written by Dr. Wiley. *See id.* Most significantly, the trace showed that both Drs. Lynch and Wiley were writing alprazolam prescriptions during the same time period. More specifically, Dr. Lynch wrote prescriptions for 100 alprazolam which Respondent filled on January 5, February 11 and 24, March 11 and 15, April 15 and 26, May 13, June 4 and 28, August 11, September 7 and 13, October 4, November 24, and December 6, 1999. *Id.* Dr. Wiley wrote prescriptions for 60 alprazolam which Respondent filled on January 27, February 4 and 22, March 13 and 31, April 6 and 22, May 10 and 29, June 15, July 5 and 22, August 9, and September 3, 1999. *Id.* Dr. Niner also wrote an alprazolam prescription on September 25, 1999. *Id.* at 2.

Dr. Lynch was R.S.'s primary care physician. May 24, 2005 Tr. 105; *see also id.* at 8. Dr. Wiley was a psychiatrist. *Id.* at 26. These physicians

[36] While Dr. Montgomery opined that treating J.P. with narcotics was medically justified, his affidavit does not address whether it was appropriate for multiple physicians to be simultaneously prescribing opiates to her. RX 5, at 12–13.

had offices in different cities and did not practice together.

Respondent also filled numerous prescriptions for combination hydrocodone/apap and oxycodone/apap drugs which were written by Dentist Haws and Dr. Lynch; most of the prescriptions were filled only days apart. *Id.* at 1–2. Specifically, on May 5, 1999, Respondent dispensed a prescription for 60 Lortab 10/500 issued by Dr. Lynch. *Id.* at 1. Moreover, pursuant to prescriptions issued by Dr. Haws, on May 12 and 18, 1999, Respondent dispensed two prescriptions for the schedule II drug Endocet (oxycodone/apap 5/325), and on May 21 and June 8, 1999, it dispensed two prescriptions for Percocet (also oxycodone/apap). *Id.* at 2. Furthermore, on June 1, 1999, Respondent dispensed a prescription issued by Dr. Lynch for 60 Lortab 10/500; on June 12, it refilled the prescription. *Id.*

During February through April 2002, there were again repeated instances in which Respondent dispensed prescriptions for combination hydrocodone/apap products which were issued by Drs. Lynch and Haws only days apart. *Id.* at 4. More specifically, Respondent dispensed prescriptions issued by Dr. Lynch for 60 hydrocodone/apap 10/650 on February 2, 14, and 26, March 7, 16, 21, and 29, and April 5, 9, and 22. *Id.* As for Dr. Haws' prescriptions, Respondent dispensed 24 hydrocodone/apap (typically 10/650) on February 21, March 13 and 14, and April 24 and 26, and prescriptions for 12 hydrocodone/apap on March 18 and April 8. *Id.*

Both Dr. Ferrell and Mulder found Respondent's dispensings of both the benzodiazepine and narcotics to be in violation of Respondent's corresponding responsibility. Tr. 347 & 532. Dr. Ferrell testified that there ''[s]hould have been some coordination between the two prescribers.'' *Id.* at 347. Dr. Mulder noted that the number of pills being dispensed ''exceeded safe, acceptable'' limits and that Respondent should have notified the physicians ''that multiple prescriptions were being written.'' *Id.* at 532.

Mr. Street testified that R.S. had been wounded in a robbery attempt and had ''extreme chronic pain'' in his shoulder and upper back. May 24, 2005 Tr. 104–05. Mr. Street further testified he was seeing both a primary care doctor and was ''a mental health patient.'' *Id.* at 105. Continuing, Mr. Street testified:

> There was a question about similar drugs being prescribed together. That was his mental health doctor that started that. He was prescribing benzodiazepines; namely alprazolam for anxiety and clonazepam for depression. So we called the doctor and he told me the reason he was prescribing those. Now, later on his primary care doctor, Dr. Lynch, started prescribing him alprazolam exclusively for anxiety, but he continued to get the clonazepam from his mental health doctor for the depression.

Id.

As for the multiple narcotic prescriptions, Mr. Street testified that ''Dr. Lynch was prescribing Lortab for his chronic pain * * * due to the gunshot wound he had years ago. And at the same time he started seeing Dr. Haws. And Dr. Haws * * * more or less just pulled all of his teeth and made him a * * * complete partial—complete full plate.'' *Id.* at 105–06. Continuing, Mr. Street testified that ''[w]e made contact with both doctor and dentist to make them aware that both were prescribing.'' *Id.* at 106. According to Mr. Street, Dr. Lynch stated that she was prescribing for chronic pain and ''realize[d] the need for acute pain * * * when he sees Dr. Haws,'' and thus Dr. Lynch approved the prescription as did Dr. Haws. *Id.* The ALJ found Mr. Street's testimony credible.

There is evidence corroborating Mr. Street's testimony that he called Dr. Lynch ''regarding narcotic prescriptions.'' RX 5, at 14 (affidavit of Dr. Montgomery). In his testimony, however, Mr. Street did not explain why for eight months, his pharmacy repeatedly dispensed alprazolam prescriptions that were being issued by both Drs. Lynch and Wiley, many of which were filled only days apart. Relatedly, Dr. Montgomery's affidavit does not address why it would be medically appropriate for two physicians to be simultaneously prescribing alprazolam to a patient.

Patient J.S.

Both Drs. Ferrell and Mulder identified Respondent's simultaneous dispensings of pentazocine/naloxone and acetaminophen with codeine # 3 as problematic because pentazocine/naloxone ''is a narcotic antagonist,'' Tr. 351, and acetaminophen with codeine # 3 is a narcotic agonist. *Id.*; *see also id.* at 534; GX 15–T. Mr. Street testified, however, that the antagonist part of pentazocine/naloxone (naloxone) ''is not active when you take it by mouth or orally.'' May 24, 2005 Tr. 107. The ALJ found this testimony to be credible and the Government offered no evidence to rebut it.

Patient H.T.

This trace showed multiple instances in which Respondent dispensed three different narcotic pain medications either on the same day or within only a couple of days of dispensing the other narcotic drugs. For example, on April 19, 1999, Respondent dispensed 100 acetaminophen with codeine # 3, 100 propoxyphene/apap, and 100 hydrocodone/apap 7.5/500. GX 15–U at 2. This pattern of dispensing was repeated on May 10–12, July 2, August 10, October 6, October 28–29, and November 23. *Id.* at 1–2. Most of the prescriptions were written by a single physician, Dr. Hartsell, although a Dr. Sibley wrote several of the hydrocodone prescriptions. *Id.* In addition, on January 20, 1999, Respondent filled a prescription issued by Dr. Huddleston for 30 hydrocodone/apap 7.5/500; on January 23, it filled a prescription issued by Dr. Hartsell for 100 hydrocodone/apap 5/500; and on January 27, it filled a prescription issued by Dr. Sibley for 50 hydrocodone/apap 7.5/500. *Id.* at 2.

Moreover, between April 10, 2001, and April 5, 2002, Respondent dispensed 23 prescriptions for combination hydrocodone/apap totaling 2,440 tablets. *Id.* at 4. The prescriptions were issued by five different doctors including Drs. Hartsell and Sibley. *Id.*

Dr. Ferrell testified that Respondent did not comply with its corresponding responsibility because it should have closely monitored the patient and communicated with the various prescribers to make them aware of the multiple prescriptions and the large number of dosage units being prescribed. Tr. 353–55. Dr. Mulder testified that Respondent did not comply with its corresponding responsibility because of the ''[l]arge numbers of pills being dispensed on a monthly basis of multiple narcotics,'' and that ''[i]n some cases, three different narcotics [were] being dispensed within a couple of days of one another and this was a repetitive pattern, month after month.'' *Id.* at 535–36. Dr. Mulder also noted that there were ''multiple physicians prescribing these medications.'' *Id.* at 536. Dr. Mulder added that the pharmacy should have ''notif[ied] the physicians that multiple prescriptions were coming in from this patient, not fill unsafe amounts of these medications, [and] notify the patient that it's inappropriate to take [the] medications together.'' *Id.*

Mr. Street testified that H.T. ''had a host of medical conditions'' including ''severe chronic lung problems,'' as well as ''severe chronic pain in the knees, and lower back.'' May 24, 2005 Tr. 108. Mr. Street further testified that H.T. was seeing both Dr. Hartsell, who was her primary care physician, and Dr. Sibley, who was her internal medicine doctor,

and that Dr. May ''practice[d] in the same group'' as Dr. Sibley. *Id.*

Mr. Street added that Dr. Hartsell's prescribing of propoxyphene and Tylenol #3 and Dr. Sibley's simultaneous prescribing of Lortab ''thr[ew] up a red flag.'' *Id.* at 109. Mr. Street then testified to having called both doctors who ''confirmed they were both treating her.'' *Id.* Mr. Street added that both doctors ''were aware they were both giving her meds[,] one for milder pain, one was for more severe pain.'' *Id.* Mr. Street further testified that H.T. also had to see some specialists who wrote her prescriptions for acute pain. *Id.* Finally, Mr. Street testified that he documented his contacts with Drs. Sibley and Hartsell in the computer and that both had ''okayed'' the prescribings. *Id.* The ALJ found Mr. Street's testimony credible and the Government produced no evidence to rebut it.

Patient W.T.

This trace shows that Respondent dispensed prescriptions for W.T. that were written by fifteen different physicians for such drugs as alprazolam, Endocet 325 (a combination of oxycodone and acetaminophen), generic oxycodone with acetaminophen (5/500), various strengths of hydrocodone/apap, and propoxyphene-hcl 65 mg. *See* GX 15–V, at 1–3. The trace also shows that Respondent repeatedly dispensed prescriptions for both propoxyphene and oxycodone throughout the same time period, and that in some instances, did so on the same day. *See id.* at 1. Regarding these prescriptions, Dr. Ferrell testified that ''it's unusual to see a patient who's taking Oxycodone and also taking Propoxyphene.'' Tr. 356–57.

Most significantly, the trace shows that Respondent dispensed two separate prescriptions on a single day, each being for 300 tablets of schedule II drugs containing oxycodone which were issued under the name of Dr. Donovan. *See* GX 15–V, at 1. More specifically, on July 31, 1997, Respondent dispensed to W.T. 300 tablets of oxycodone/apap 5/500 pursuant to prescription number 2003283, and 300 tablets of Endocet 325 pursuant to prescription number 2003284. *See id.* at 1 & 21.

Regarding one of these dispensings, Dr. Ferrell testified that 300 tablets of oxycodone/apap ''is an unusual quantity'' and ''would be more than a month's supply.'' Tr. 357. On this day, however, Respondent dispensed to W.T a total of 600 tablets of drugs containing oxycodone.[37] While Dr. Donovan had previously prescribed both Endocet and generic oxycodone/apap to W.T., the prescriptions had never exceeded 100 tablets and he had never prescribed both drugs at the same time.

Moreover, on August 14, only fourteen days after dispensing 600 tablets of oxycodone, Respondent dispensed another 40 tablets of Endocet 325, and six days later, on August 20, it dispensed another 100 tablets of oxycodone/apap 5/500. *See* GX 15–V, at 21–22. Finally, the trace also shows that Respondent dispensed to W.T. several prescriptions for Endocet 325 that were written by Dr. Haynes during the same period in which it was filling Dr. Donovan's prescriptions for the same drug. *See id.* at 1. Drs. Donovan and Haynes did not practice in the same group. *See id.* at 22.

Dr. Mulder concluded that Respondent violated its corresponding responsibility because of the ''very large quantities of pills being dispensed on a monthly basis.'' Tr. 537. He also noted that there were ''multiple analgesic agents,'' and that there were ''multiple numbers of physician[s] on a monthly basis.'' *Id.*

Regarding W.T., Mr. Street testified that she had ''started off seeing a Dr. Donovan and a Dr. Barbarito, who was in the same group,'' and then ''had to switch to a Dr. Steffner.'' May 24, 2005 Tr. 110. Mr. Street further testified that W.T. had seen ''numerous specialists because of surger[ies] she's had'' on various body parts including her hand, shoulder, and gall bladder. *Id.* Mr. Street added that W.T.'s ''primary care doctor was the one that was prescribing the bulk of her pain meds,'' and that she also had ''chronic abdominal pain.'' *Id.* Mr. Street testified that W.T.'s primary care physician had ''prescribed her a stronger pain med for severe pain, and a weaker pain med for less severe or milder pain.'' *Id.*

Notably, at no time in his testimony did Mr. Street state that either he or any other of Respondent's pharmacists had contacted any of the doctors who prescribed to W.T. to verify the legitimacy of the prescriptions. Mr. Street likewise offered no testimony regarding his pharmacy's dispensing of 600 dosage units of schedule II drugs containing oxycodone on a single day. Nor did he testify as to why Respondent filled prescriptions for drugs containing oxycodone that were issued by Drs. Donovan and Haynes, who did not practice together, within the same timeframe.

Patient B.W.

Respondent dispensed numerous prescriptions issued by Dr. Blackmon for Lortab 7.5/500 and Valium (diazepam) between May 1996 and March 1997, when Dr. Blackmon's prescriptions ended. GX 15–X at 1–3. Also, between February 16 and November 11, 1999, Respondent filled each month prescriptions issued by Dr. Egidio for several controlled substances including Oxycontin 20 mg., Lortab 7.5/500, and alprazolam 0.5 mg. *Id.* at 2. All but the first two Oxycontin prescriptions were for 60 tablets; most of the Lortab prescriptions were for 90 tablets. *Id.* The trace further showed that between April 19, 2001, and April 9, 2002, Respondent dispensed thirteen prescriptions issued by Dr. Egidio for Oxycontin 40 mg. *Id.* at 3. The first five of the prescriptions were for 60 tablets; the remaining eight prescriptions were for 90 tablets. *Id.*

Dr. Ferrell noted that Dr. Blackmon had prescribed 1,621 dosage units of hydrocodone and 1,300 dosage units of diazepam and that both quantities were ''high.'' Tr. 361. He also noted that several of Dr. Egidio's prescriptions for Oxycontin gave ''PRN'' as the direction for taking the drug, *id*; this term means to take as needed. *Id.* Oxycontin is, however, typically taken on a scheduled basis. *Id.* While Dr. Ferrell concluded that Respondent violated its corresponding responsibility in dispensing the prescriptions issued by Dr. Blackmon, he concluded that Respondent's dispensings of Dr. Egidio's prescriptions were not improper even though they contained the erroneous directions for taking the Oxycontin. *Id.* at 362.

Relatedly, Dr. Mulder concluded that Respondent had not met its corresponding responsibility because ''the number of pills being dispensed within a given month * * * exceeded safe limits.'' *Id.* at 540. Dr. Mulder further testified that the pharmacist should have told the patient that ''he cannot fill those'' prescriptions and notified the doctor. *Id.*

Mr. Street testified that B.W. had degenerative disk disease and chronic pain in the lower back. May 24, 2005 Tr. 111–12. Mr. Street testified that Dr. Blackmon's prescribing of hydrocodone

[37] According to Dr. Montgomery's review of W.T.'s medical records, a progress note prepared on the same day stated that ''she has become dependent upon Xanax and Darvocet.'' RX 5, at 17. Dr. Montgomery did not specify the name of the doctor who prepared this note. However, at the beginning of this paragraph, Dr. Montgomery noted that ''[f]urther records indicate that this patient was followed by HG Barbarito, MD, at the medical group in Johnson City,'' and Mr. Street testified that Drs. Donovan and Barbarito were in the same group. May 24, 2005 Tr. 110. Notably, the affidavit does not address whether it was appropriate for Respondent to dispense this quantity of drugs (600 dosage units) or to dispense prescriptions for these drugs that were being issued in the same timeframe by multiple prescribers.

and diazepam was standard treatment. *Id.* at 112. He further testified that Dr. Blackmon had been called and ''verified what he was treating [B.W.] for when we called him.'' *Id.* Mr. Street was thus ''certain that her meds were for a legitimate medical purpose.'' *Id.* Finally, Mr. Street testified that ''we called Dr. Egidio * * * when [B.W.] started seeing him, and confirmed the diagnosis and treatment[,] so all her meds were given for a legitimate medical purpose.'' *Id.* The ALJ found Mr. Street's testimony credible and the Government offered no evidence to rebut it.

Patient J.Y.

Most of the prescriptions listed on this trace were written by Drs. Blackmon and Haws. *See* GX–15Y. Between August 16, 1996 and March 3, 1997, Dr. Blackmon issued and Respondent dispensed eleven prescriptions for combination hydrocodone/apap drugs and five for diazepam. *Id.* at 2.

Moreover, between April 7 and December 1, 1997, Dr. Haws issued, and Respondent dispensed, seventeen prescriptions for various strengths of hydrocodone/apap products and one prescription for Percodan, a schedule II drug which contains oxycodone and aspirin. *See id.* at 2; *see also* 21 CFR 1308.12(b)(1). There is then a gap in the trace until March 30, 1999, when Respondent recommenced dispensing prescriptions issued by Dr. Haws for combination hydrocodone/apap. GX15–Y, at 2. Between March 30 and November 22, 1999, Respondent dispensed a total of 20 such prescriptions. *Id.* Moreover, between June 29, 2001, and February 18, 2002, Respondent dispensed another five prescriptions issued by Dr. Haws to J.Y. for combination hydrocodone/apap drugs. *Id.* at 1.

Regarding Dr. Haws' prescriptions, Dr. Ferrell testified that ''[y]ou've got to wonder what point in time was he actually having dental problems,'' and that ''[i]n that long of a treatment, I would have had to have some kind of documentation on what's wrong with the patient.'' Tr. 363. Dr. Ferrell further testified that Respondent ''should have verified that [the] patient had a legitimate need for a controlled substance for that long a period of time.'' *Id.* at 364.

While Dr. Mulder found that the prescriptions issued by Dr. Blackmon ''could have been dispensed for legitimate purposes,'' he further explained that ''in [his] experience, to have prolonged dental pain that requires narcotics over that length or period of time is somewhat problematic.'' *Id.* at 541. Dr. Mulder added that ''this is unusual for dentists to be prescribing [analgesic medications] for an ongoing period of time,'' and that ''[f]or dentists to prescribe, it's usually short-term, episodic, due to acute pain * * * or for operative issues and not for long-term chronic pain problems.'' *Id.* at 542. Dr. Mulder further testified that it ''would be quite unusual'' for a dentist to be ''qualified to treat chronic pain,'' *id.* at 543, and that the dentist should have been called and asked what type of treatment the patient was undergoing. *Id.* at 542.

On re-direct examination, Dr. Mulder testified that ''[t]here's obviously a finite limit to how many teeth you can pull out.'' Tr. 563–64. Dr. Mulder then testified, however, that ''the repetitive prescription, month after month after month, it just seemed * * * with that particular file, I—it probably—I couldn't state that it violated standards. It just seemed a little unusual to have that many sequential prescriptions from a dentist for the same patient.'' *Id.* at 564.

Mr. Street testified that J.Y. ''was another typical Dr. Haws patient'' who had ''low income, no insurance,'' and needed much work. May 24, 2005 Tr. 112. Mr. Street further testified that ''we stayed in contact with * * * Dr. Haws'' office * * * frequently to confirm that they were still getting treatment * * * on a regular basis[,]'' and asked ''[i]s this patient still getting work done?'' *Id.* Mr. Street then testified that ''they would confirm that, and that would be documented in the computer.'' *Id.* at 112–13. Here, again, the ALJ found this testimony credible, *see* ALJ at 62, and the Government offered no evidence to rebut it.[38]

Respondent's Other Evidence

As previously stated, Respondent elicited extensive testimony on a variety of factual issues from Mr. Richards, a private investigator it hired following the initiation of this proceeding. Beyond the testimony that has been discussed above, Mr. Richards also testified about interviews he conducted with some of the physicians, some employees of both the physicians and Mr. Street, and some of the patients whose prescriptions were discussed above.

All of this testimony was, of course, hearsay, and while hearsay is admissible in these proceedings, it must still be ''reliable, probative, and substantial.'' 5 U.S.C. 556(d). As for the reliability of this evidence, when asked by the ALJ whether he found the people he interviewed to be credible, Mr. Richards attempted to bolster their credibility by asserting that ''they didn't have a dog in the fight,'' [39] but then added ''whether they were 100% credible, who the heck knows.'' May 24, 2005 Tr. 72. Moreover, it is undisputed that these statements were gathered during the course of, and for the very purpose of being used in, this litigation. The statements which Mr. Richards testified to were generally not sworn and were made by their various declarants long after the underlying events. Furthermore, the record does not reflect what preliminary discussions occurred between Mr. Richards and the declarants and the extent to which the declarants needed to have their memories refreshed or may have been prompted by suggestive interviewing techniques. Finally, the statements were generally vague as to dates of the underlying events and lack probative force.

With regard to the prescribers that he interviewed, Mr. Richards testified that Dr. Blackmon stated that Mr. Street ''called many times checking on patients and prescriptions that he wrote.'' *Id.* at 19. Dr. Blackmon's statement does not discuss any specific conversations or prescriptions and thus, even if I held that it was reliable, lacks probative value. To similar effect is Mr. Richard's testimony regarding the statements of Dr. Lynch and Dr. Slonaker. *Id.* at 21–22; *id.* at 24.

Mr. Richards also testified that Dr. Hartsell stated to him that:

> [m]y file on Ms. [H.T.] reflects that Jeff or someone in his pharmacy called and verified one of her Lorazepam prescriptions. Her file shows that on July 19, 2001, * * * the Medicine Shoppe called and said that she was trying to have an Ativan prescription filled a little early. I had cut her dosage down on Ativan, but since she was out of the drug she must have been doubling up.

Id. at 20–21. The prescription trace for H.T. indicates, however, that the actual prescription was telephoned in to Respondent. *See* GX 15–U, at 15. Thus, Dr. Hartsell's statement does not accurately reflect the circumstances surrounding the filling of the prescriptions. And given all of the prescriptions that Dr. Hartsell wrote for

[38] While Dr. Montgomery could not review J.Y.'s medical record because they were ''not available,'' he then stated that ''Dr. Haws is a dentist and I probably can surmise the patient was having significant dental problems given the number of prescriptions that are recorded.'' RX 5, at 18. Dr. Montgomery's statement is nothing more than speculation.

[39] The evidence suggests, however, that Drs. Blackmon, Egidio, and Slonaker had previously been investigated by various law enforcement and licensing authorities including DEA. Tr. 60; May 24, 2005 Tr. 56–58. Furthermore, those patients who were having their illegitimate prescriptions filled by Respondent clearly had ''a dog in the fight.''

H.T., that he frequently wrote prescriptions for as many as three different opiates at a time,[40] and that Mr. Street testified that both Drs. Hartsell and Sibley were aware that each was prescribing opiates to H.T. at the same time and that each doctor ''okayed it,'' May 24, 2005 Tr. 109, it is perplexing that Dr. Hartsell did not relate that H.T.'s file contained a note that he had received a phone call from Mr. Street or his employees regarding the prescriptions being issued by Dr. Sibley and thus corroborating Mr. Street's testimony.[41]

Mr. Richard's testimony regarding the interviews he conducted with the employees of various doctors was also typically lacking in probative force. For example, Mr. Richards testified that an employee of a clinic ''said that she talks frequently to people in Jeff's pharmacy.'' May 24, 2005 Tr. at 22. Likewise, Mr. Richards also testified that an employee of a neurology group had told him that she had worked for the group ''for three years, and during that period Jeff has called my office questioning prescriptions written by physicians in our group.'' *Id.* at 23.[42] Again, neither this testimony—nor the other hearsay statements of various doctors' employees—addresses any of the specific prescriptions at issue in this proceeding.

Mr. Richards also testified as to interviews he conducted of several employees of Mr. Street. According to Mr. Richards, these employees generally stated that they had seen Mr. Street call physicians to verify prescriptions. However, none of these statements relate to any specific patient or prescription. *See id.* at 25–26; 27–30. Mr. Richards further testified that these employees had told him Mr. Street ''called doctors anytime he had a prescription that he was not certain about, and that he documented it in his computer.'' [43] *Id.* at 28.

According to Mr. Richards, a pharmacy technician who worked for Mr. Street ''was aware of several instances where Mr. Street reported customers to the police for forged prescriptions.'' *Id.* at 30. Mr. Richards subsequently testified that he had talked with a retired detective regarding various police reports involving Respondent. According to Mr. Richards, Mr. Street reported incidents of suspected prescription fraud to the police on January 16 and September 13, 2001, and February 11 and April 5, 2002. *Id.* at 71–72. The actual incident reports were not, however, introduced into evidence and Mr. Richards testified only to the date, time and drug involved and not the underlying circumstances of each incident. *See id.*

Mr. Richards also testified that he had interviewed many of the patients whose prescriptions were discussed above. While the patients typically related to Mr. Richards that Mr. Street had never refilled their medications early and had counseled them regarding the addictive nature of their drugs, only two of the patients related that Mr. Street had called a particular physician. *See* May 24, 2005 Tr. at 45–46 (statement of W.L. that Mr. Street had called Dr. Blackmon many times); *id.* at 50 (B.W.'s statement that she was aware that Mr. Street called Dr. Egidio but not specifying the date). Because Mr. Street specifically testified that he called Dr. Blackmon regarding W.L.'s prescriptions, *id.* at 90–91, and Dr. Egidio regarding B.W.'s prescriptions, *id.* at 112, and the ALJ credited Mr. Street's testimony in each instance, it is unnecessary to decide whether to give either of these statements any weight.

Discussion

Section 304(a) of the Controlled Substance 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 his registration under section 823 of this title inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a). In determining the public interest, the Act directs that the Attorney General consider the following factors:

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

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

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

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

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

Id. section 823(f).

''[T]hese factors are * * * considered in the disjunctive.'' *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003). I ''may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether a registration should be revoked.'' *Id.* Moreover, case law establishes that I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Finally, where the Government has made out its *prima facie* case, the burden shifts to the Respondent to show why its continued registration would be consistent with the public interest. *See, e.g., Theodore Neujahr,* 65 FR 5680, 5682 (2000); *Service Pharmacy, Inc.,* 61 FR 10791, 10795 (1996).

In this case, having considered all of the factors, I conclude that the Government's evidence with respect to factors two and four establishes a *prima facie* case that Respondent's continued registration is ''inconsistent with the public interest,'' 21 U.S.C. 823(f), and that Respondent failed to refute this showing. Accordingly, Respondent's registration will be revoked and its pending application for renewal of its registration will be denied.

Factor Two—Respondent's Experience in Dispensing Controlled Substances

Under DEA's regulation, a prescription for a controlled substance is unlawful unless it has been ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a). The regulation further provides that while ''[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, * * * a *corresponding responsibility rests with the pharmacist who fills the prescription.'' Id.* (emphasis added). Continuing, the

[40] The drugs were hydrocodone/apap, apap/codeine # 4, and propoxyphene/apap. *See* GX 15U at 1–2.

[41] Mr. Richards also testified that Dr. Egidio had stated that Mr. Street had called him regarding four specific patients, R.S., B.R., D.C., and B.W. *Id.* at 19. With respect to three of the patients (D.C., B.R. and R.S.), the Government's experts did not find Mr. Street's dispensing to be improper. Finally, because I conclude that the Government did not prove that Respondent's dispensings to B.W. were unlawful, I need not decide whether Mr. Richard's testimony should be given any weight.

[42] Mr. Richards further testified that during his interview of Ms. Timbs, ''she was shown a copy of a prescription'' that was written by one of the physicians who practiced with her employer, Doctor's Care. May 24, 2005 Tr. 22. Mr. Richards went on to testify that ''Mr. Street felt the prescription was suspicious and called Doctors Care,'' which told him that the physician had not prescribed Xanax, but only Triamcinolone Cream. *Id.* Notably, Mr. Richards did not testify that Ms. Timbs told him that she recalled Mr. Street's phone call or the circumstances surrounding the prescription. *See id.*

[43] Given this, it is perplexing that Mr. Street did not produce any printouts from his computer to support his claims of having called the physicians who issued the many suspicious prescriptions which he filled, and that he testified that he did not even know if he could print this information. *See* May 24, 2005 Tr. 154.

regulation states that ''the person knowingly filling such a purported prescription, as well as the person issuing it, [is] subject to the penalties provided for violations of the provisions of law relating to controlled substances.'' *Id.*

DEA has consistently interpreted this provision as prohibiting a pharmacist from filling a prescription for a controlled substance when he either ''knows or has reason to know that the prescription was not written for a legitimate medical purpose.'' *Medic-Aid Pharmacy,* 55 FR 30043, 30044 (1990); *see also Frank's Corner Pharmacy,* 60 FR 17574, 17576 (1995); *Ralph J. Bertolino,* 55 FR 4729, 4730 (1990); *United States* v. *Seelig,* 622 F.2d 207, 213 (6th Cir. 1980). This Agency has further held that ''[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescription.'' *Bertolino,* 55 FR at 4730 (citations omitted).[44]

Accordingly, when a customer presents a suspicious prescription, at a minimum, a pharmacist has a duty to verify the prescription with the prescriber. Moreover, even if a prescriber tells a pharmacist that a prescription has been issued for a legitimate medical purpose, a pharmacist cannot ignore evidence which provides reason to believe that the prescription has not been issued for a legitimate medical purpose or that the prescriber is acting outside of the usual course of his or her professional practice.

The ALJ found that Respondent's dispensed ''over 124 controlled substance prescriptions'' which were written by Dr. Watts, a veterinarian, and which were presented by Dr. Watts' brother even though they were written in the names of fictitious patients. ALJ at 17. The drugs were then diverted to Dr. Watts, who personally abused the drugs. During the period in which Respondent filled these prescriptions, Dr. Watts did not hold a DEA registration or a state license as he had allowed both to expire. *See United Prescription Services, Inc.,* 72 FR 50397, 50407(2007) (''A controlled-substance prescription issued by a physician who lacks the license necessary to practice medicine within a State is * * * unlawful under the CSA.''); *United States* v. *Moore,* 423 U.S. 122, 140–41 (1975) (''In the case of a physician, [the CSA] contemplates that he is authorized by the State to practice medicine and to dispense drugs in connections with his professional practice.'').[45]

Moreover, the prescriptions were being presented ''almost every day [or] every other day,'' Tr. 62, and were for drugs which contain hydrocodone. As Respondent's own witness testified, ''all of the prescriptions that Dr. Watts wrote that [Mr. Street] filled for any kind of pain drugs contained acetaminophen,'' a drug which ''is toxic to certain animals.'' May 24, 2005 Tr. 16.

While the ALJ did not consider this evidence in her analysis of whether Respondent dispensed controlled substances in violation of the prescription requirement,[46] she nonetheless noted that ''the pattern of Dr. Watts' brother bringing these prescriptions to the Respondent for filling, and the fact that the prescriptions were written in other people's names, should have caused Mr. Street to investigate the prescriptions prior to dispensing the medications.'' ALJ at 76. The ALJ also noted that ''[s]uch conduct by the Respondent's main pharmacist could threaten the public health and safety, for such conduct [by Dr. Watts] easily could have indicated diversion of controlled substances. Yet Mr. Street filled these prescriptions without further investigation.'' *Id.* at 76–77.

I agree. There was ample evidence available to Mr. Street (and Respondent) to question the legitimacy of the prescriptions even if Mr. Street was unaware that Dr. Watts no longer held a DEA registration and a state license. Beyond the testimony that veterinarians usually purchase the controlled substances they dispense directly from wholesale distributors and dispense the drugs directly to an animal's owner, the repeated appearance of Dr. Watts' brother at Respondent to present prescriptions which were issued in other persons' names and pick up the drugs was highly suspicious and should have prompted Mr. Street to question the legitimacy of the prescriptions. Finally, Dr. Watts was writing prescriptions that according to Mr. Richards, were for pain drugs which ''contained acetaminophen'' and ''acetaminophen is toxic to certain animals.'' This should have alerted Mr. Street to the fact that Dr. Watts' prescriptions were not being issued for a ''legitimate medical purpose'' and that Watts was not acting in the ''usual course of his professional practice.'' 21 CFR 1306.04(a). I thus conclude that Mr. Street (and his pharmacy) had reason to know that these prescriptions were unlawful under federal law and that he repeatedly violated his corresponding responsibility when he filled them.[47]

The Prescription Traces

As explained above, the Government also introduced into evidence twenty-five prescription traces which it contends show that Mr. Street and Respondent repeatedly dispensed controlled substances in violation of federal law. While noting that the traces and the Government's expert testimony suggest that the Government had ''met its burden of proof,'' the ALJ then concluded that ''Respondent presented evidence that demonstrated that Dr. Mulder and Dr. Ferrell did not have the complete picture of the Respondent's dispensing practices from the selected prescription traces.'' ALJ at 75. In support of her conclusion, the ALJ specifically noted ''Mr. Street's credible testimony concerning his personal knowledge of his customers, the actions he took to coordinate his dispensings with the patients' health care providers,'' and the testimony of Mr. Richards. *Id.* The ALJ thus rejected the entirety of the Government's prescription trace evidence.

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

[45] A pharmacy has a duty to periodically check to see that a practitioner retains the authority to practice medicine and dispense a controlled substance. As the ALJ recognized, failure to do so could threaten public health and safety because there is usually a good reason for why a practitioner has lost his or her state license and DEA registration. In light of the other evidence regarding Respondent's filling of Dr. Watts' prescriptions, I need not decide whether it also violated this duty.

[46] The ALJ considered the evidence regarding Respondent's filling of Dr. Watts' prescriptions only under factor five. ALJ at 76. This evidence is, however, also highly relevant in the consideration of Respondent's experience in dispensing controlled substances.

[47] The Show Cause Order also alleged that Dr. Blackmon ''issued numerous controlled substance prescriptions for no legitimate medical reason'' and that Respondent filled large numbers of these prescriptions. Show Cause Order at 1–2. While the Government appears to rely on the fact that some of Blackmon's patients traveled great distances to have their prescriptions filled at Respondent, some other area pharmacies continued to fill Blackmon's prescription.

The record does not establish, however, how many of Dr. Blackmon's patients were traveling great distances to fill their prescriptions at Respondent. Moreover, with respect to J.Y., one of Blackmon's patients whose prescriptions were entered into evidence, the Government's own experts testified that Respondent's dispensings were not improper. I thus conclude that the appropriate resolution of whether Respondent was unlawfully dispensing prescriptions should focus on the evidence of its actual dispensings as indicated in the traces and not on the Government's generalized assertions.

While I agree that the Government failed to prove that Respondent unlawfully dispensed control substances to a number of the patients, in other instances the ALJ ignored relevant evidence. More specifically, with respect to multiple patients, the ALJ ignored clear evidence of doctor shopping for which Mr. Street had no explanation. She also ignored several instances in which Mr. Street's testimony failed to address the Government experts' testimony, as well as instances in which his testimony was inconsistent with other evidence.

As found above, either one or both of the Government's experts concluded that Respondent did not violate its corresponding responsibility in the dispensings it made to the following patients: M.B. (GX 15–A); D.C. 2 (GX 15–C), D.E. & J.E. (GX 15–E), B.R. (GX 15–O); W.B. (GX 15–P), R.S. (GX 15–S), and W.T. (GX 15–W). Based on my findings with respect to J.S. (GX 15–T), I also conclude that the Government did not prove by a preponderance of the evidence that Respondent unlawfully dispensed controlled substances to him.

With respect to patient A.S., to whom Respondent dispensed a total of 369 dosage units of combination hydrocodone/apap drugs over a ten-and-a-half month period pursuant to prescriptions issued by eight different prescribers, Dr. Mulder testified only that ''[i]t would have been appropriate for [Respondent] to have notified'' the various physicians that it was receiving a number of different prescriptions ''for this narcotic so that they could concentrate that in one place.'' Tr. 531. Dr. Mulder did not testify that Respondent's failure to notify the physicians was a breach of its corresponding responsibility. Moreover, the ALJ credited Mr. Street's testimony that A.S. had to switch her primary care physicians because they closed their practices and had also gone to the emergency room. The Government did not rebut this testimony. I therefore conclude that Respondent's dispensings to A.S. did not violate federal law.

With respect to patient B.W., Drs. Ferrell and Mulder respectively concluded that Dr. Blackmon's hydrocodone/apap (7.5/500) prescriptions were high and ''exceeded safe limits.'' Tr. 540. These dispensings averaged, however, only 170 tablets per month and less than six tablets per day and were thus substantially under the four gram level at which acetaminophen causes toxicity. Finally, the ALJ found credible Mr. Street's testimony that he had verified the prescriptions with Dr. Blackmon and the Government offered no evidence to rebut his contention. I therefore conclude that Respondent's dispensings to B.W. did not violate federal law.

Next, both patients D.C. (GX 15–B) and J.Y. (GX 15–Y) received large numbers of prescriptions from Dr. Haws, a dentist. As found above, on re-direct examination regarding J.Y., Dr. Mulder testified that ''[t]here's obviously a finite limit to how many teeth you can pull out.'' Tr. 563–64. Continuing, Dr. Mulder testified that ''the repetitive prescription, month after month after month, it just seemed * * * with that particular file, I—it probably—I couldn't state that it violated standards. It just seemed a little unusual to have that many sequential prescriptions from a dentist for the same patient.'' *Id.* at 564.

Based on Dr. Mulder's testimony, I conclude that the Government has not proved that Respondent violated federal law in its dispensings to J.Y. Furthermore, because Respondent's dispensings to D.C., fit the same pattern, I also conclude that the Government has not proved that Respondent violated federal law in its dispensings to D.C.

The evidence pertaining to the remaining patients does, however, establish that Respondent repeatedly dispensed controlled substances in violation of federal law. In particular, the record shows that Respondent repeatedly filled prescriptions presented by persons who were clearly engaged in doctor shopping. Moreover, the evidence shows that Respondent also filled prescriptions which could have been toxic if taken in the prescribed amounts or were for drugs which were contraindicated for the patient.

It is true that in some instances, Mr. Street testified that he had contacted a patient's prescribers and that they were ''okay'' with the fact that the other doctor was also prescribing. While the ALJ credited this dubious testimony, I need not reject her credibility findings *in toto* to conclude that the Government proved its case with respect to the remaining patients because there were numerous dispensings for which Mr. Street offered no explanation at all. Indeed, there is even evidence that Respondent filled prescriptions which Mr. Street himself acknowledged were outside of the course of the practitioner's professional practice and did so after Mr. Street claimed to have notified the prescriber that the prescriptions for that drug were unlawful.

For example, Respondent repeatedly dispensed to Patient E.C. alprazolam prescriptions issued by Dr. Hussain and diazepam prescriptions issued by Dr. Slonaker. GX 15–D. In several instances, the prescriptions were dispensed only days apart and the Government's experts testified that these drugs ''have a synergistic effect'' when taken together, Tr. 297, and that taking these drugs in combination could have devastating effects. *Id.* 515. Moreover, Respondent also dispensed to E.C. three prescriptions for hydrocodone/apap that were issued by Dr. Hussain (who wrote two of the Rxs) and Dr. Wiles within a four-day period; the first two of these prescriptions were filled on consecutive days.

Mr. Street testified only as to why Respondent had also filled the prescriptions which Dr. Slonaker simultaneously issued for two combination hydrocodone/apap drugs. He offered no testimony to explain why Respondent dispensed the hydrocodone prescriptions issued by Drs. Hussain and Wiles and the benzodiazepine prescriptions issued by Drs. Hussain and Slonaker. I thus conclude that Respondent repeatedly violated federal law in dispensing these prescriptions to E.C.

With respect to patient S.F., the Government's evidence showed that Respondent simultaneously dispensed extraordinary quantities of Lorcet, a combination hydrocodone/apap 10/650 drug, and Dilaudid, a schedule II controlled substance, based on prescriptions which were written by Dr. Blackmon. More specifically, Dr. Ferrell testified that S.F. was receiving approximately 17 tablets a day of Lorcet and 12 tablets a day of Dilaudid. Tr. 306. Dr. Ferrell further noted that S.F. was ''physically dependent'' on the drugs. *Id.* at 308. Moreover, Respondent was dispensing Lorcet in amounts which, as Dr. Mulder testified, clearly exceeded ''acceptable limits'' and ''would be potentially toxic.'' [48] *Id.* at 511. The trace also showed that Respondent dispensed a prescription for Buprenex, a drug which can cause acute withdrawal symptoms in patients taking Dilaudid and other opiates. Tr. 307.

Mr. Street testified that he contacted Dr. Blackmon frequently because S.F. ''was always wanting his medications

[48] Although Dr. Mulder testified that the dosages of hydrocodone/apap products was twice the acceptable limits, when Respondent was dispensing an average of 17 tablets a day, the amount was nearly three times the acceptable limit.

While there was testimony that patients can develop a tolerance to opiates, *see* RX 5, at 5, Respondent offered no evidence as to why it would be appropriate to continue to prescribe combination hydrocodone drugs at this level when other stronger opiates, which do not contain acetaminophen, are available. In any event, I do not rely solely on the quantity of the hydrocodone/apap prescriptions, but rather on all the evidence related to S.F. in concluding that Respondent should not have filled the prescriptions.

early,'' and was presenting prescriptions ''too close to'' the other prescriptions ''he brought in.'' May 24, 2005 Tr. 85. He also asserted that Dr. Blackmon was ''monitoring him closely,'' and that Blackmon told him that S.F. needed large amounts of narcotics to ''function.'' *Id.* Mr. Street offered no evidence to refute the testimony of Dr. Mulder—who is a pain management specialist—that the level of drugs being prescribed by Blackmon was potentially toxic. Consistent with the testimony of Dr. Mulder that a pharmacist has an obligation ''not to dispense medication knowingly harmful to the patient,'' I conclude that contacting Dr. Blackmon was not enough and that Mr. Street had an affirmative obligation to refuse to dispense these drugs to S.F.

The quantities of drugs which Dr. Blackmon was prescribing were extraordinary, greatly exceeded acceptable levels of acetaminophen, and were potentially toxic. Moreover, that S.F. was ''always wanting his medications early'' and presenting prescriptions ''too close to'' other prescriptions he had brought in were telltale signs that he was either a drug abuser or selling the drugs to others.

Dr. Blackmon's issuance of the Buprenex prescription provided a further reason why Mr. Street should have questioned the legitimacy of the prescriptions and stopped filling them. Mr. Street justified dispensing this drug on the ground that ''[t]he *only* precaution regarding Buprenex and hydrocodone is that the combination may increase drowsiness,'' May 24, 2005 Tr. at 87 (emphasis added). Mr. Street's testimony is false. As found above, under the caption ''Use in Narcotic-Dependent Patients,'' the package insert clearly states that: ''[b]ecause of the narcotic antagonist activity of Buprenex, use in the physically dependent individual may result in withdrawal effects.'' Given the prescriptions Dr. Blackmon was writing and S.F.'s conduct which indicated—as Dr. Ferrell observed—that he was physically dependent, I conclude that Mr. Street had reason to know that Dr. Blackmon was not writing prescriptions for legitimate medical purposes. Respondent therefore violated federal law by filling these prescriptions.[49]

Patient B.J. obtained controlled-substance prescriptions (which Respondent filled) from twenty-one different prescribers for five different benzodiazepines, three different schedule III narcotics (hydrocodone/apap, propoxyphene/apap, and Fiorinal with codeine), Endocet, a schedule II drug, and Stadol. GX 15–G. More specifically, the evidence showed that Respondent repeatedly dispensed multiple prescriptions issued by Dr. Greenwood for alprazolam and Dr. Varney for lorazepam for a period of six months. The trace also showed that in multiple instances, Respondent dispensed schedule III narcotics such as Fiorinal with codeine and propoxyphene which were issued by different doctors within the same timeframe. *Id.*

Mr. Street testified that he called both Dr. Varney and Dr. Greenwood's practice group and that ''[t]hey were both aware they were both prescribing at the same time.'' May 24, 2005 Tr. 89. Mr. Street did not, however, testify as to why, between March and October 1999, his pharmacy repeatedly filled prescriptions for propoxyphene/apap, which were written by Dr. Gastineau, and Fiorinal (butalbital) with codeine, which were written by Dr. Varney. Here again, the evidence establishes that Mr. Street and Respondent failed to comply with their corresponding responsibility under federal law.

The evidence regarding W.L. showed that Dr. Blackmon prescribed, and Respondent dispensed, 239 controlled substance prescriptions in a fourteen-month period. In 1996, Respondent made 163 dispensings (totaling 5,380 dosage units) of Buprenex, thirty-one dispensings of hydrocodone/apap (totaling 2550 dosage units), and twenty-two dispensings of diazepam (totaling 1530 dosage units). Furthermore, the Buprenex package insert warns that ''[p]articular care should be taken when Buprenex is used in combination with central nervous system depressant drugs,'' that ''[p]atients receiving Buprenex in the presence of other narcotic analgesics [and] benzodiazepines * * * may exhibit increased CNS depression,'' and that ''[w]hen such combined therapy is contemplated, *it is particularly important that the dose of one or both agents be reduced*.'' (emphasis added).

Blackmon did not, however, reduce the dosing of the Buprenex, the hydrocodone, or the diazepam. Rather, he prescribed to W.L. increasingly large amounts of the three drugs and Respondent filled these prescriptions.

The ALJ credited Mr. Street's testimony that ''the only thing the package insert says about combining the two drugs of respiratory problems when Diazepam is given with Buprenex'' and that the physician should ''proceed with caution if you're going to administer the two drugs.'' ALJ at 43. Mr. Street's testimony did not accurately reflect the entire scope of the Buprenex warnings,[50] which clearly showed that Blackmon's prescriptions were improper.

As the testimony established, a pharmacist is responsible for knowing how a drug will interact with other drugs his patient is taking. Tr. 280–81; *see also* Tennessee Bd. of Pharmacy R. 1140–3.01(3)(a). I thus adopt Dr. Mulder's conclusion that the prescriptions should not have been filled. Tr. 516. I further conclude that Mr. Street and Respondent failed to comply with their corresponding responsibility under federal law in the dispensings to W.L.

The evidence regarding Angela L. showed that she had received numerous prescriptions from a dentist, Michael Haws. While most of the prescriptions were for combination hydrocodone/apap drugs, on September 11, 1997, Respondent also dispensed a prescription (which was also issued by Haws) for Tussionex Pennkinetic Suspension, a combination of hydrocodone and chlorpheniramine. Respondent also dispensed two refills of the Tussionex to Angela L.

As found above, Respondent had previously made three dispensings of large quantities of Tussionex (which again was prescribed by Dr. Haws) to Rex L., who was Angela's spouse. Regarding Respondent's dispensings of Tussionex to Rex L., Dr. Ferrell testified that it is ''unusual to see a dentist write for cough syrup.'' Tr. 325. Responding to this testimony, Mr. Street explained that ''this was filled by a relief pharmacist,'' and that when he ''came back to work'' and caught it, he then ''alerted Dr. Haws to the fact that * * * it's not within your usual course of practice to prescribe Tussionex.'' May 24, 2005 Tr. at 93. Mr. Street then testified that ''he [Haws] ceased doing that[,]'' and ''I've never seen him do it again.'' *Id.*

While Mr. Street's testimony did not specify which of the dispensings to Rex L. had prompted him to contact Dr. Haws, the evidence clearly shows that Respondent dispensed Tussionex to Angela L. pursuant to prescriptions issued by Dr. Haws on three occasions after the dispensings it made to her husband. Based on Mr. Street's testimony that prescribing Tussionex was outside of the course of Dr. Haws's professional practice, I also conclude that the Tussionex prescriptions which Haws wrote, and Respondent filled for Angela L., were also outside of the

[49] Under the CSA, it does not matter whether S.F. was physically dependent on the drugs or was selling them on the street.

[50] I therefore also reject the ALJ's credibility finding.

course of his professional practice. Mr. Street offered no explanation as to why his pharmacy filled these prescriptions. I thus conclude that Mr. Street and Respondent violated federal law in dispensing them.[51]

Relatedly, the Tussionex prescriptions issued to Rex L. were for very large quantities. As the evidence showed, on August 1, 1997, Respondent dispensed to Rex L. 720 ml. of this drug; three days later, it dispensed to him another 360 ml. Moreover, on August 29, 1997, Respondent dispensed to Rex L. another 720 ml. of the drug. Dr. Ferrell testified that ''the usual dosage'' of this drug ''is 5 milliliters every 12 hours,'' (approximately 300 ml. for a thirty day period) and that he could not ''think of any reason why a prescription for'' 720 ml. would be necessary. Tr. 324–25.

Dr. Mulder also noted the evidence that Rex L. was engaged in doctor shopping. As found above, between November 10, 1997 and January 9, 1998, Respondent filled numerous prescriptions for opiates which included Lorcet, Lortab, Tussionex, MS Contin, and Dilaudid. The prescriptions were written by three different doctors (Drs. Haws, Caudill, and Egidio), and most of them were dispensed only days apart.

While the ALJ found credible Mr. Street's testimony that a relief pharmacist filled the Tussionex prescription that was issued by Dr. Haws, ALJ at 46, the evidence shows that Respondent made a total of three dispensings of this drug pursuant to prescriptions by Dr. Haws. Moreover, even if a relief pharmacist made all three dispensings, Respondent is still properly charged with violating its corresponding responsibility. Moreover, Mr. Street did not testify as to why his pharmacy filled the prescriptions that Rex L. presented for opiates from Drs. Haws, Caudill, and Egidio. I thus conclude that Mr. Street and Respondent violated their corresponding responsibility in making these dispensings.

The evidence showed that K.P. (GX 15–K) received prescriptions from more than two dozen prescribers which were dispensed by Respondent. Most of the prescriptions were for combination hydrocodone/apap drugs, although she also obtained prescriptions for several other controlled substances. Between April 20, 2001, and April 19, 2002, Respondent dispensed to K.P. 58 prescriptions for a total of 2,355 dosage units of combination hydrocodone/apap drugs. Both Drs. Ferrell and Mulder concluded that K.P. was a doctor shopper.[52]

The ALJ credited Mr. Street's testimony that K.P. had seen five different primary care physicians either because the physicians closed their practices or the State's Tenncare program had moved her to a different physician. The ALJ also credited Mr. Street's testimony that K.P. had seen neurosurgeons who referred her to a pain management specialist (Dr. Smyth), who also proceeded to prescribe narcotics for her, and that both were ''aware that they were prescribing them at the same time.'' [53] ALJ at 47 (citing May 24, 2005 Tr. 94). Finally, the ALJ credited Mr. Street's testimony that K.P. had seen seven emergency room doctors because of complications she had from major surgeries.

Notably, two of the physicians K.P. obtained prescriptions from were orthopedic surgeons (Drs. Beaver and J. Williams) and Mr. Street offered no testimony that he had contacted them to verify their prescriptions and make them aware that K.P. was also obtaining prescriptions from Dr. Wiles (the neurosurgeon). Nor did he testify that he contacted Dr. Wiles to inform him that K.P. was obtaining prescriptions from Drs. Beaver and Williams. Accordingly, I conclude that Mr. Street and Respondent violated their corresponding responsibility under federal law in dispensing to K.P.

Patient P.P. (GX 15–L), who was K.P.'s husband, obtained prescriptions from eleven prescribers which were dispensed by Respondent. The evidence showed that during the same period in which it was dispensing hydrocodone/apap prescriptions written by Dr. Lynch, it was also dispensing prescriptions for hydrocodone/apap, propoxyphene/apap, and codeine/apap which were written by Dr. Wyche. The trace also showed that between June 2001 and April 2002, Respondent dispensed to P.P. prescriptions for hydrocodone/apap which she obtained from seven different doctors.

In his testimony, Dr. Mulder concluded that Respondent had failed to comply with its corresponding responsibility because of the number of prescriptions that were being dispensed each month, the dispensing of multiple narcotics at the same time, and that multiple physicians were prescribing to P.P. Dr. Ferrell also noted the prescribing by multiple physicians. Finally, Dr. Mulder noted that K.P. and P.P. lived at the same address and that it is ''highly unusual'' for two family members to have ''medical problems that * * * required the same level of prescribing within each * * * month.'' Tr. 524.

Mr. Street testified that P.P. was mainly seen by Drs. Tochev and Tanner, who were his primary care physicians, and that Dr. Tochev referred P.P. to a pain management group, which started prescribing pain medications for him. Mr. Street further testified that ''we contacted'' the pain management group and Dr. Tochev, and that ''neither one * * * were [sic] aware [that] the other one was prescribing.'' May 24, 2005 Tr. at 96. Mr. Street added that ''after we contacted them, pain management cease[d] to write any more pain meds'' for P.P. *Id.* As for the other evidence of doctor shopping, Mr. Street explained that P.P. had seen dentists and emergency room doctors a couple of times and that ''if you knew the doctors in the area like I do, it shouldn't present a problem.'' *Id.* Mr. Street did not testify that his pharmacy called any of these other prescribers and the fair inference to be drawn from this testimony is that Mr. Street did not call either the dentists or the emergency rooms before filling the prescriptions.[54]

[51] I also reject the ALJ's finding that Mr. Street credibly testified that following his phone call to Dr. Haws, Respondent did not receive any more Tussionex prescriptions that were issued by Dr. Haws.

[52] This Agency is well familiar with ''doctor shopping.'' Expert testimony is not essential to prove that a person engaged in it. Rather, ''doctor shopping'' can be proved based solely on documentary evidence.

[53] The implication of Mr. Street's testimony was that the doctors agreed that K.P. could receive narcotics from multiple physicians in different practices. K.P.'s pain management specialist was also Dr. Smyth, the same doctor who Mr. Street, in testifying about P.P. (K.P.'s husband), claimed had stopped writing prescriptions for narcotics upon being notified by Mr. Street that he was also receiving ''pain meds'' from his primary care physician. May 24, 2005 Tr. at 96.

[54] In rejecting the Government's evidence, the ALJ also relied on Mr. Street's ''knowledge of [his customer's] medical history and treatments.'' ALJ at 74. While acknowledging that ''Mr. Street reviewed medical records in preparation for this hearing,'' the ALJ credited his testimony because it ''demonstrated a more generic knowledge of each patient's situation, [and] not a prompted, detailed knowledge that would come from reviewing and attempting to memorize patients' medical conditions.'' ALJ at 74 n.12. The ALJ thus concluded that Mr. Street's testimony was ''a credible rendition'' of what he knew about his customers ''at the time he dispensed the controlled substances.'' *Id.*

Even assuming that Mr. Street would recall the medical conditions of these twenty-five patients out of the 17,000 patients he testified Respondent had, and crediting Mr. Street's testimony, *see* May 24, 2005 Tr. 95, a pharmacist's knowledge of a customer's medical conditions does not excuse him from his duty to verify the legitimacy of prescriptions when there is reason to suspect that the customer is engaged in doctor shopping. Nor does it excuse a pharmacist from his responsibility not to dispense drugs that are either being prescribed in quantities which would be toxic to the patient if taken as directed, or contraindicated because of other drugs a patient is taking or the patient's medical conditions.

Mr. Street offered no testimony as to why his pharmacy filled (sometimes only days apart) the multiple narcotic prescriptions that were issued by Drs. Lynch and Wyche during October and November 1999. Moreover, his testimony that he contacted P.P.'s pain management doctor (Dr. Smyth) to inform him that Dr. Tochev was still prescribing and that Dr. Smyth stopped writing is not consistent with the evidence. While Mr. Street did not specify the date that he contacted Dr. Smyth, the evidence shows that his pharmacy filled multiple prescriptions for hydrocodone/apap drugs that were issued by both Drs. Smyth and Tochev between February and April 2002. Indeed, the evidence shows that Dr. Smyth issued, and Respondent filled, a prescription for hydrocodone/apap nearly six weeks after P.P. presented the first prescription he obtained from Dr. Smyth, and only a week after it had filled two additional prescriptions for the same drug that were issued by Dr. Tochev. Moreover, three weeks later, Respondent filled a prescription for methadone which was also issued by Dr. Smyth.

In short, the evidence does not support Mr. Street's testimony. Moreover, his statement to the effect that his dispensings of prescriptions issued by dentists and emergency room physicians should not present a problem if you know the doctors ''like I do,'' is a non-explanation. Even if a pharmacist knows the practice specialty of a prescriber, he must still verify the legitimacy of a prescription when a person is repeatedly presenting prescriptions for the same drug from other prescribers and doing so at frequent intervals. Consistent with the testimony of Drs. Ferrell and Mulder, I thus conclude that Mr. Street and Respondent violated their corresponding responsibility under federal law in dispensing to P.P.

S.P. (GX 15–M) was another patient who presented prescriptions from numerous providers. While most of the testimony focused on narcotic prescriptions, the evidence also showed that in numerous instances, Respondent dispensed to S.P. temazepam prescriptions issued by Dr. Varney and clonazepam prescriptions issued by Dr. Shah. In some instances, the dispensings occurred only a day (or a couple of days) apart. Both of these drugs are benzodiazepines, and as Dr. Mulder testified, taking multiple benzodiazepines has a synergistic effect and can be devastating to the patient.

Mr. Street offered no testimony regarding Respondent's dispensings of these drugs. I therefore conclude that Mr. Street did not contact either prescriber to verify the legitimacy of the prescriptions and to inform them that S.P. was presenting prescriptions from the other physician for another benzodiazepine. Accordingly, I also conclude that Mr. Street and Respondent did not comply with their corresponding responsibility under federal law in dispensing these prescriptions to S.P.

The evidence regarding patient J.P. (GX 15–N) showed that Respondent was dispensing to her multiple opiates (Stadol, Darvocet (propoxyphene/apap) and Tylenol 3 (codeine/apap)), as well as benzodiazepines and schedule IV drugs such as fenfluramine and phentermine based on prescriptions issued by Dr. Varney. Moreover, for nearly a year, Respondent repeatedly dispensed to J.P. hydrocodone/apap (for a total of 14 Rxs) that were issued by Dr. Johnson at the same time that it was dispensing the prescriptions issued by Dr. Varney.

Dr. Mulder noted that J.P. was receiving ''seven different addicting medications simultaneously,'' which included ''stimulants and depressants,'' and ''analgesics and anxiolytics.'' Tr. 527. Dr. Ferrell also noted that Darvocet and Tylenol # 3 provide ''about the same'' level of pain relief and did not understand why a physician would simultaneously prescribe them. *Id.* at 336–38.

While Mr. Street testified that he called Dr. Varney regarding his prescribing to J.P. and that there were legitimate medical purposes for this regime, May 24, 2005 Tr. 99, Mr. Street offered no evidence that refuted Dr. Ferrell's testimony on the simultaneous prescribing of Darvocet and Tylenol # 3. Moreover, Mr. Street offered no testimony as to why Respondent repeatedly dispensed the Darvocet and Tylenol # 3 prescriptions issued by Dr. Varney during the same period in which it also dispensed the fourteen Lortab prescriptions that were issued by Dr. Johnson.

I therefore conclude that Mr. Street and Respondent did not verify the legitimacy of the Lortab prescriptions with Dr. Johnson and inform him that J.P. was receiving multiple opiates. I further conclude that Mr. Street and Respondent violated federal law in dispensing the Lortab prescriptions to J.P. when it was also dispensing the Darvocet and Tylenol # 3 prescriptions issued by Dr. Varney.

The evidence regarding R.S. (GX 15–R) showed that during 1999, Respondent dispensed to him 30 prescriptions for alprazolam, 19 prescriptions for clonazepam, two prescriptions for diazepam, and one prescription for lorazepam. Most significantly, for approximately eight months, Respondent dispensed prescriptions for 100 tablets of alprazolam which were written by Dr. Lynch (R.S.'s primary care physician), while it was also dispensing prescriptions for 60 tablets of alprazolam which were written by Dr. Wiley (R.S.'s psychiatrist). Dr. Wiley also prescribed clonazepam, another benzodiazepine, throughout 1999. Both Drs. Ferrell and Mulder found that Respondent's dispensing of the drugs was a violation of its corresponding responsibility.

Mr. Street's justification for the dispensings was that Dr. Wiley had started prescribing the benzodiazepines, ''namely alprazolam for anxiety and clonazepam for depression,'' and that ''we called the doctor and he told me the reason he was prescribing those.'' May 24, 2005 Tr. at 105. Mr. Street then explained that ''later on [R.S.'s] primary care doctor, Dr. Lynch, started prescribing him alprazolam exclusively for anxiety, but he continued to get the clonazepam from his mental health doctor for the depression.'' *Id.*

Mr. Street's testimony suggests that after Dr. Lynch began prescribing alprazolam, R.S. received only clonazepam from Dr. Wiley. But as explained above, for approximately eight months, Respondent repeatedly dispensed alprazolam to R.S. pursuant to prescriptions written by both doctors and many of the dispensings occurred only days apart. Mr. Street offered no explanation for why his pharmacy did so. I thus conclude that Mr. Street and Respondent violated federal law in dispensing the alprazolam prescriptions to R.S.

The evidence shows that Respondent dispensed prescriptions for W.T. (GX 15–V) that were written by fourteen different prescribers for such drugs as alprazolam, Endocet 325, generic oxycodone with acetaminophen, various strengths of hydrocodone/apap, and propoxyphene-hcl. Most significantly, on a single day, Respondent dispensed to W.T. two separate 300-count prescriptions purportedly written by Dr. Donovan for schedule II drugs containing oxycodone and acetaminophen, Endocet 325 and generic oxycodone/apap 5/500. This, as Dr. Ferrell explained, was ''an unusual quantity.'' Tr. 357. Indeed, while Dr. Donovan had previously prescribed these drugs to W.T., the prescriptions had never exceeded 100 tablets and he had never prescribed both drugs at the same time.

Moreover, during the same period, Respondent was also simultaneously dispensing propoxyphene prescriptions written by Dr. Donovan. Finally, Respondent also dispensed three prescriptions for Endocet 325 written by Dr. Haynes during the same period in which it was dispensing Dr. Donovan's prescriptions for drugs containing oxycodone. Dr. Haynes and Donovan did not practice together.

While Mr. Street testified as to the various doctors that W.T. had seen and her medical conditions, at no time did he state that either he or his employees had contacted any of W.T's doctors to verify the legitimacy of the prescriptions. *See* May 25, 2005 Tr. at 110. Mr. Street likewise offered no testimony as to why Respondent dispensed 600 dosage units of oxycodone on a single day or as to why Respondent filled prescriptions for oxycodone that W.T. had presented from Drs. Donovan and Haynes in the same time frame. I thus conclude that Mr. Street and Respondent failed to comply with their corresponding responsibility under federal law when they dispensed to W.T. 600 units of oxycodone on a single day and the oxycodone prescriptions that were written by Drs. Haynes and Donovan during the same period.[55]

Accordingly, having reviewed all of the evidence, I conclude that in numerous instances, Respondent violated federal law in dispensing controlled substances. In so holding, I acknowledge that pharmacists do not practice medicine. But requiring a pharmacist to identify doctor shopping does not require him to practice medicine.

In his affidavit, Dr. Montgomery opined that the prescribing physician ''is the primary responsible party for drug selection and quantity based upon the physician's assessment of the patient.'' RX 5, at 6. While acknowledging—in his words—that ''[t]here are a few occasions when it would appear that [Respondent] fell short of what I would consider optimal pharmacy recognition of a potential drug abuser profile,'' Dr. Montgomery then asserted that ''the physicians who prescribed the patients controlled substances were more responsible for any abuse than the pharmacy filling said prescriptions.'' *Id.*

Respondent's attempt to deflect responsibility for its unlawful dispensings is unavailing. Under the Tennessee Board of Pharmacy's Standards of Practice, a pharmacist is required to review ''a patient's record prior to dispensing each * * * prescription order.'' GX 21, at 2 (Rule 1140–3.01(3)(a)). As part of this review, the pharmacist is further required to evaluate the prescription for, *inter alia*, ''over-utilization,'' ''therapeutic duplication,'' ''drug-drug interactions,'' ''incorrect drug dosage or duration of drug treatment,'' and ''clinical abuse/misuse.'' *Id.* Holding Mr. Street and his pharmacy accountable for dispensing prescriptions when there was reason to believe those prescriptions were not issued for legitimate medical purposes (because those prescriptions were contraindicated to other drugs a patient was taking or the drugs were being prescribed in amounts that would be potentially toxic if taken as directed) thus does no more than require him to comply with the duties imposed on him as a pharmacist under the State of Tennessee's regulations.

Contrary to Dr. Montgomery's opinion, this case is not simply about a few dispensings which ''fell short of * * * optimal pharmacy recognition of a potential drug abuser.'' RX 5, at 6. Rather, it is about the numerous instances in which Respondent and Mr. Street unlawfully dispensed a controlled substance under federal law by ignoring evidence which provided reason to believe that the prescription was illegitimate. *Bertolino*, 55 FR at 4730 (citations omitted). Accordingly, Mr. Street and Respondent are responsible for the numerous unlawful dispensings found above including those which were made to Dr. Watts.

Furthermore, many of the dispensings cannot be attributed to mere oversight, but rather, are flagrant violations of federal law because they involved repeated dispensings to persons who were clearly engaged in doctor shopping and went on for months on end. Moreover, the quantities and combinations of drugs dispensed (including the interactions which would occur if the drugs were actually taken) also support the conclusion that the violations were flagrant. Accordingly, notwithstanding the evidence that Respondent had 17,000 patients, May 24, 2005 Tr. 95, I conclude that Respondent's experience in dispensing controlled substances warrants a finding that its continued registration is inconsistent with the public interest.[56] This finding provides reason alone to revoke Respondent's registration.

Factor Four—Respondent's Compliance With Applicable Laws

As found above, Respondent repeatedly violated DEA regulations and federal law in its dispensings of controlled substances. That analysis is incorporated herein and will not be repeated.

Respondent also failed to comply with federal law and DEA regulations by failing to maintain ''a complete and accurate record of each [controlled] substance [it] received, sold, delivered, or otherwise disposed of.'' 21 U.S.C. 827(a); *see also* 21 CFR 1304.21(a). While the ALJ credited Mr. Street's testimony regarding the 1998 computer ''crash,'' the fact remains that significant discrepancies were found during each of the three audits that were subsequently conducted. Moreover, while Mr. Street challenged the accuracy of each of these audits and presented his own figures, even his audits found that his pharmacy had substantial shortages in multiple drugs.

For example, according to Mr. Street's December 1999 audit, his pharmacy was short 800 tablets of generic hydrocodone/apap 5/500, 589 tablets of generic hydrocodone/apap 7.5/500, 380 tablets of Lortab 7.5/500, 485 tablets of acetaminophen with codeine 300/60, 704 tablets of diazepam 10mg., 200 tablets of Dilaudid (hydromorphone) 4 mg., and 193 tablets of generic hydromorphone 4 mg. There were also numerous overages. These discrepancies are especially noteworthy as the audit period used Respondent's January 11, 1999 inventory as the beginning date and covered only an eleventh-month period.

As for Mr. Street's assertion that the DEA audit was in error because Respondent's diazepam dispensings were recorded on multiple drug usage

[55] In light of the abundant evidence of Respondent's unlawful dispensings, it is unnecessary to make any legal conclusions regarding Respondent's dispensing to Patient H.T, (GX 15–U), who received numerous prescriptions for three different narcotic pain medicines from two prescribers. The ALJ credited Mr. Street's testimony that he had contacted each prescriber, that each was aware that the other was prescribing as well, and that they both ''okayed'' H.T.'s receipt of the prescriptions.

Putting aside that Dr. Hartsell's statement to Mr. Richards made no mention of Mr. Street ever having called him to discuss the fact that H.T. was also presenting prescriptions for hydrocodone/apap from another physician, May 24, 2005 Tr. at 20–21, the notion that a competent physician would willingly continue to prescribe highly abused drugs knowing that her patient was also receiving similar drugs from another prescriber stretches the limits of plausibility. While the Government's experts testified that the prescribing of controlled substances should be coordinated between a patient's physicians so that only one physician is prescribing, neither definitively stated that it is a violation of standards of medical practice for two physicians to be doing so. *See, e.g.*, Tr. 570.

[56] The fundamental question under the CSA is whether Respondent ''has committed acts as would render [its] registration inconsistent with the public interest.'' 21 U.S.C. § 824(a)(4). No amount of legitimate dispensings can render Respondent's flagrant violations ''consistent with the public interest.''

reports, under federal law it is Respondent's responsibility to maintain accurate dispensing records. Respondent's failure to do so further supports the conclusion that its recordkeeping is not in compliance with federal law.

Mr. Street's April 2001 audit found shortages of 657 tablets of generic hydrocodone/apap 10/500, 656 tablets of generic hydrocodone/apap 7.5/500, 171 tablets of generic hydrocodone/apap 5/500, and 196 tablets of Lortab 10. Respondent was also short 312 tablets of diazepam 5 mg. and 554 tablets of diazepam 10 mg., 166 tablets of acetaminophen with codeine # 4, and 152 tablets of methadone 40 mg.

Finally, while the April 2002 audit involved only twelve drugs and covered a period of a little more than a year, once again even Mr. Street's figures showed substantial discrepancies. More specifically, Respondent was short 498 tablets of diazepam 10 mg., 754 tablets of generic hydrocodone/apap (7.5/500), and 910 tablets of generic hydrocodone/apap (10/500).

While the ALJ reasoned that these discrepancies ''only represented 2% of the Respondent's business,'' ALJ at 70, they are nonetheless substantial and occurred at each of the three audits. Moreover, having conducted his own audit following the April 2001 DEA visit, Mr. Street was clearly aware that Respondent had serious recordkeeping problems. Yet substantial discrepancies were still found during the subsequent audit even though only twelve drugs were audited. Moreover, at the hearing, Mr. Street offered no evidence to show that he and Respondent had taken corrective action to prevent similar discrepancies from occurring in the future.[57] I therefore also find that Respondent's failure to maintain complete and accurate records of its handling of controlled substances supports an adverse finding under this factor. This factor thus further supports the conclusion that Respondent's registration is ''inconsistent with the public interest.'' 21 U.S.C. 823(f).[58]

Sanction

As found above, Respondent's numerous violations pertaining to its dispensing practices and its failure to maintain complete and accurate records establish a *prima facie* case that its continued registration is ''inconsistent with the public interest'' and that its registration should therefore be revoked. *Id.* Where the Government has made out its *prima facie* case, the burden shifts to the Respondent to show why its continued registration would nonetheless be consistent with the public interest. See, *e.g., Theodore Neujahr*, 65 FR 5680, 5682 (2000); *Service Pharmacy, Inc.*, 61 FR10791, 10795 (1996).

In discussing the appropriate sanction, the ALJ relied largely on her conclusion that the Government had failed to prove that Respondent had improperly dispensed controlled substances. While the ALJ noted Mr. Street's ''bothersome'' conduct in filling the prescriptions which Dr. Watts (the veterinarian) wrote for his personal use, she further reasoned that this conduct had occurred in 1996–97, and that ''the lack of any more recent evidence of similar carelessness,'' does not now support revoking Respondent's registration. ALJ at 78.

Respondent's dispensing violations were not, however, limited to what the ALJ found. Rather, the violations include numerous instances in which it flagrantly violated federal law and regulations by: (1) Dispensing controlled substances to persons clearly engaged in doctor shopping, (2) dispensing controlled substances which were contraindicated to other controlled substances it was also dispensing to the same patient, (3) dispensing controlled substances that were outside of the scope of the prescriber's professional practice, and (4) dispensing various controlled substances in quantities that clearly were excessive and would, with respect to some of the drugs, be toxic if they were taken as prescribed. Moreover, the record contains evidence—specifically, the unlawful dispensings Respondent made to K.P. and P.P.—which occurred shortly before this proceeding was commenced.

In Respondent's favor, there is some evidence that Mr. Street reported four forged prescriptions to the police.[59] Respondent did not, however, submit the actual reports that were filed and the circumstances surrounding these incidents were not established. Moreover, I conclude that the harm to public health and safety caused by Respondent's unlawful dispensings was far greater than the benefits that may have resulted from his reporting of the fraudulent prescriptions.

Most significantly, under Agency precedent, where the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must '''present[] sufficient mitigating evidence to assure the Administrator that [it] can be entrusted with the responsibility carried by such a registration.''' *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988)). Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs., Inc.*, v. *DEA*, 54 F.3d 450, 452 (7th Cir. 1995), this Agency 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. *See Jackson*, 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Prince George Daniels*, 60 FR 62884, 62887 (1995). *See also Hoxie* v. *DEA*, 419 F.3d at 483 (''admitting fault'' is ''properly consider[ed]'' by DEA to be an ''important factor[]'' in the public interest determination).

Here, Respondent has not even acknowledged that it has serious recordkeeping problems, let alone that it committed numerous violations of federal law in dispensing controlled substances. Relatedly, Respondent has presented no evidence that it has reformed its shoddy recordkeeping practices and its abysmal dispensing practices.[60] Accordingly, it has not rebutted the Government's *prima facie* showing that its continued registration ''is inconsistent with the public interest.'' 21 U.S.C. 823(f). I therefore conclude that revocation of its registration is essential to protect the public interest.

[57] I place no weight on the statements of Mr. Pierce and Mr. Street that there was no deliberate diversion of drugs. As found above, Mr. Pierce's affidavit frequently did not even address the shortages that Mr. Street's audits found. Moreover, Mr. Street did not testify that he had investigated any of his employees to determine whether they may have been diverting. Instead, he attributed the discrepancies to human error. As for Mr. Street's assertion that ''if we could have audited both name brand and generic'' versions of a drug, ''they might have balanced out there,'' May 24, 2005 Tr. 144, Mr. Street was not prevented from doing exactly that in his own audits. Mr. Street's testimony that the discrepancies are the result of human error is as much speculation as his assertion that there was no deliberate diversion. In fact, no one knows.

[58] I acknowledge that the state board has not taken any action against Mr. Street or Respondent and that neither Mr. Street nor his pharmacy has been convicted of a crime. My findings regarding Respondent's dispensing and recordkeeping violations, however, greatly outweigh these factors.

[59] The ALJ also reasoned that ''Mr. Street's assistance to the DEA during its audit and his provision to the DEA of all the information and documentation it requested'' was ''a factor to be weighed.'' ALJ at 70. Mr. Street had, however, been served with a warrant prior to each audit. See GXs 4, 6, 9, and 12. Mr. Street's assistance during the audits is thus entitled to only slight weight.

[60] As Respondent's own expert acknowledged, its recognition of drug abusers ''fell short of * * * optimal.'' RX 5–6. Yet Respondent does not even admit that it has a problem.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I hereby order that DEA Certificate of Registration, BM3913781, issued to the Medicine Shoppe—Jonesborough, be, and it hereby is, revoked. I further order that any pending application of Respondent for renewal or modification of its registration be, and it hereby is, denied. This order is effective February 1, 2008.

Dated: December 13, 2007.

Michele M. Leonhart,

Deputy Administrator.

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