AGENDA

Florida Board of Pharmacy
Controlled Substances Standards Committee Meeting

October 5, 2015, 2 p.m.

Tampa Marriott Westshore
1001 N Westshore Blvd
Tampa, Florida 33607

Committee Members
Gavin Meshad, Committee Chair
Michele Weizer, PharmD, BCPS, Board Chair
Jeffrey Mesaros, PharmD, J.D.
Debra Glass, BPharm
Jeenu Philip, BPharm

Board Counsel
David Flynn, Assistant Attorney General
Lynette Norr, Assistant Attorney General

Special Committee Members
Michael Jackson, BPharm, Florida Pharmacy Association
Gary Cacciatore, Cardinal Health
Mark Rubenstein, M.D., Florida Medical Association
Harold Dalton, D.O., Fla. Society for Interventional Pain Physicians
Natasha Polster, Walgreens
Tom Davis, CVS
Joel B. Rose, D.O., Board of Osteopathic Medicine

Participants in this public meeting should be aware that these proceeding are being recorded.

Monday, October 5, 2015 – 2 p.m.

1. Introductions

2. Subcommittee report – Jeffrey Mesaros
    a. Proposed language – to be provided at meeting
    b. Subcommittee language
    c. Current rules
        64B16-27.831
        64B8-9.013

3. Committee member updates
    a. Gary Cacciatore – Wholesale Distributor Data

3. Validation and documentation of controlled substance prescriptions – Dan Buffington, Bob Parrado

4. Public Comment

LANGUAGE DISCUSSED AT SUBCOMMITTEE

64B16-27.831 Standards ~~of Practice~~ for the Dispensing of Controlled Substances ~~for Treatment of Pain.~~

The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment. Pharmacists should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. The Board recognizes that every patient's situation is unique and prescriptions for controlled substances should be reviewed with each patient's unique situation in mind. The Board encourages pharmacists to work with the patient and the prescriber to assist in determining the validity of the prescription.

Education:

All pharmacists shall complete a board-approved 2-hour continuing education course on the validation of controlled substance prescriptions. The course content shall include the following:

- Ensuring access to controlled substances for all pateints with a valid prescription;
- Use of the Prescription Drug Monitoring Database (PDMP);
- Assessment of prescriptions for appropriate therapeutic value;
- Detection of prescriptions not based on a legitimate medical purpose;
- The laws and rules related to controlled substance prescribing and dispensing;
- The laws and rules of controlled substance prescribers that relate to the prescribing of controlled substances;

All licensed pharmacist shall complete the required course by the end of the biennium ending on September 31, 2017. (Non license) A 2-hour course shall be taken every biennium thereafter. This course shall count towards the madatory 30 hours of CE required for licensure renewal.

Specific Authority 465.005, 465.0155 FS. Law Implemented 456.072(1)(i), 465.0155, 465.016(1)(i), (o), 465.017(2) FS. History–New 8-29-02, Amended 2-24-03, 11-18-07.

64B16-27.831 Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain.

(1) ~~An order purporting to be a prescription that is not issued for a legitimate medical purpose is not a prescription and the pharmacist knowingly filling such a purported prescription shall be subject to penalties for violations of the law.~~

* See above

(2) ~~The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:~~

~~(a) Frequent loss of controlled substance medications,~~

~~(b) Only controlled substance medications are prescribed for a patient,~~

~~(c) One person presents controlled substance prescriptions with different patient names,~~

~~(d) Same or similar controlled substance medication is prescribed by two or more prescribers at same time,~~

~~(e) Patient always pays cash and always insists on brand name product.~~

* Needs language reformatting. Pulled from NABP Consensus document

When presented with a prescription for a controlled substance, pharmacist must exercise their professional judgment and must adhere to their corresponding responsibility to determine whether a prescription for a controlled substance has been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. That evaluation determines the next steps taken by the pharmacist and includes options such as a discussion with the prescriber in order to ensure the validity of the prescription and address red flag warnings signs prior to dispensing.

These red flags may indicate that a controlled substance prescription is not being obtained for a legitimate medical purpose, but for diversion or abuse, thereby possibly necessitating additional steps by the pharmacist. Any time a red flag occurs, it should be evaluated in an attempt to appropriately interpret its nature, and patient management should be pursued based on this interpretation and the seriousness of the warning signs. Of course, the warning signs are not intended to prevent the dispensing of a legitimate controlled substance prescription.

(3) If any of the criteria in (2) is met, the pharmacist shall:

(a) Require that the person to whom the medication is dispensed provide picture identification and the pharmacist should photocopy such picture identification for the pharmacist's records. If a photocopier is not available, the pharmacist should document on the back of the prescription complete descriptive information from the picture identification. If the person to whom medication is dispensed has no picture identification, the pharmacist should confirm the person's identity and

document on the back of the prescription complete information on which the confirmation is based.

(b) Verify the prescription with the prescriber. A pharmacist who believes a prescription for a controlled substance medication to be valid, but who has not been able to verify it with the prescriber, may determine not to supply the full quantity and may dispense a partial supply, not to exceed a 72 hour supply. After verification by the prescriber, the pharmacist may dispense the balance of the prescription within a 72 hour time period following the initial partial filling, unless otherwise prohibited by law.

(4) Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 465.017(2), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substance medications being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substance medications being dispensed to a specific patient.

(5) Any pharmacist who has reason to believe that a prescriber of controlled substances is involved in the diversion of controlled substances shall report such prescriber to the Department of Health.

(6) Any pharmacist that dispenses a controlled substance subject to the requirements of this rule when dispensed by mail shall be exempt from the requirements to obtain suitable identification.

Specific Authority 465.005, 465.0155 FS. Law Implemented 456.072(1)(i), 465.0155, 465.016(1)(i), (o), 465.017(2) FS. History–New 8-29-02, Amended 2-24-03, 11-18-07.

CURRENT RULES

64B16-27.831 Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain.

(1) An order purporting to be a prescription that is not issued for a legitimate medical purpose is not a prescription and the pharmacist knowingly filling such a purported prescription shall be subject to penalties for violations of the law.

(2) The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:

(a) Frequent loss of controlled substance medications,

(b) Only controlled substance medications are prescribed for a patient,

(c) One person presents controlled substance prescriptions with different patient names,

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Specific Authority 465.005, 465.0155 FS. Law Implemented 456.072(1)(i), 465.0155, 465.016(1)(i), (o), 465.017(2) FS. History–New 8-29-02, Amended 2-24-03, 11-18-07.

64B8-9.013 Standards for the Use of Controlled Substances for the Treatment of Pain.

(1) Pain management principles.

(a) The Board of Medicine recognizes that principles of quality medical practice dictate that the people of the State of Florida have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board encourages physicians to view effective pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially important for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about effective methods of pain treatment as well as statutory requirements for prescribing controlled substances.

(b) Inadequate pain control may result from physicians' lack of knowledge about pain management or an inadequate understanding of addiction. Fears of investigation or sanction by federal, state, and local regulatory agencies may also result in inappropriate or inadequate treatment of chronic pain patients. Physicians should not fear disciplinary action from the Board or other state regulatory or enforcement agencies for prescribing, dispensing, or administering controlled substances including opioid analgesics, for a legitimate medical purpose and that is supported by appropriate documentation establishing a valid medical need and treatment plan. Accordingly, these standards have been developed to clarify the Board's position on pain control, specifically as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

(c) The Board recognizes that controlled substances, including opioid analgesics, may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The medical management of pain including intractable pain should be based on current knowledge and research and includes the use of both pharmacologic and non-pharmacologic modalities. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity and duration of the pain. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not synonymous with addiction.

(d) The Board of Medicine is obligated under the laws of the State of Florida to protect the public health and safety. The Board recognizes that inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Physicians should be diligent in preventing the diversion of drugs for illegitimate purposes.

(e) The Board will consider prescribing, ordering, administering, or dispensing controlled substances for pain to be for a legitimate medical purpose if based on accepted scientific knowledge of the treatment of pain or if based on sound clinical grounds. All such prescribing must be based on clear documentation of unrelieved pain and in compliance with applicable state or federal law.

(f) Each case of prescribing for pain will be evaluated on an individual basis. The Board will not take disciplinary action against a physician for failing to adhere strictly to the provisions of these standards, if good cause is shown for such deviation. The physician's conduct will be evaluated to a great extent by the treatment outcome, taking into account whether the drug used is medically and/or pharmacologically recognized to be appropriate for the diagnosis, the patient's individual needs including any improvement in functioning, and recognizing that some types of pain cannot be completely relieved.

(g) The Board will judge the validity of prescribing based on the physician's treatment of the patient and on available documentation, rather than on the quantity and chronicity of prescribing. The goal is to control the patient's pain for its duration while effectively addressing other aspects of the patient's functioning, including physical, psychological, social, and work-related factors. The following standards are not intended to define complete or best practice, but rather to communicate what the Board considers to be within the boundaries of professional practice.

(2) Definitions.

(a) Acute Pain. For the purpose of this rule, "acute pain" is defined as the normal, predicted physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma, and acute illness. It is generally time-limited and is responsive to opioid therapy, among other therapies.

(b) Addiction. For the purpose of this rule, "addiction" is defined as a neurobehavioral syndrome with genetic and environmental influences that results in psychological dependence on the use of substances for their psychic effects and is characterized by compulsive use despite harm. Addiction may also be referred to by terms such as "drug dependence" and "psychological dependence." Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and should not be considered addiction.

(c) Analgesic Tolerance. For the purpose of this rule, “analgesic tolerance” is defined as the need to increase the dose of opioid to achieve the same level of analgesia. Analgesic tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(d) Chronic Pain. For the purpose of this rule, “chronic pain” is defined as a pain state which is persistent.

(e) Pain. For the purpose of this rule, “pain” is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

(f) Physical Dependence. For the purpose of this rule, “physical dependence” on a controlled substance is defined as a physiologic state of neuro-adaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.

(g) Pseudoaddiction. For the purpose of this rule, “pseudoaddiction” is defined as a pattern of drug-seeking behavior of pain patients who are receiving inadequate pain management that can be mistaken for addiction.

(h) Substance Abuse. For the purpose of this rule, “substance abuse” is defined as the use of any substances for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

(i) Tolerance. For the purpose of this rule, “tolerance” is defined as a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect, or a reduced effect is observed with a constant dose.

(3) Standards. The Board has adopted the following standards for the use of controlled substances for pain control:

(a) Evaluation of the Patient. A complete medical history and physical examination must be conducted and documented in the medical record. The medical record shall document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also shall document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy, if necessary, to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient, or with the patient’s surrogate or guardian if the patient is incompetent. The patient shall receive prescriptions from one physician and one pharmacy where possible. If the patient is determined to be at high risk for medication abuse or have a history of substance abuse, the physician shall employ the use of a written agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. Urine/serum medication levels screening when requested;

2. Number and frequency of all prescription refills; and

3. Reasons for which drug therapy may be discontinued (i.e., violation of agreement).

(d) Periodic Review. Based on the individual circumstances of the patient, the physician shall review the course of treatment and any new information about the etiology of the pain. Continuation or modification of therapy shall depend on the physician’s evaluation of the patient’s progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage and related treatment plans.

(e) Consultation. The physician shall be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention must be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and may require consultation with or referral to an expert in the management of such patients.

(f) Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence, as appropriate;

2. Diagnostic, therapeutic, and laboratory results;

3. Evaluations and consultations;

4. Treatment objectives;

5. Tiscussion of risks and benefits;

6. Treatments;

7. Medications (including date, type, dosage, and quantity prescribed);

8. Instructions and agreements;

9. Drug testing results; and

10. Periodic reviews. Records must remain current, maintained in an accessible manner, readily available for review, and must be in full compliance with Rule 64B8-9.003, F.A.C, and Section 458.331(1)(m), F.S.

Records must remain current and be maintained in an accessible manner and readily available for review.

(g) Compliance with Controlled Substances Laws and Regulations. To prescribe, dispense, or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual: An Informational Outline of the Controlled Substances Act of 1970, published by the U.S. Drug Enforcement Agency, for specific rules governing controlled substances as well as applicable state regulations.

Rulemaking Authority 458.309(1), 458.331(1)(v) FS. Law Implemented 458.326, 458.331(1)(g), (t), (v) FS. History–New 12-21-99, Amended 11-10-02, 10-19-03, 10-17-10.

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Part II

Department of Justice

Drug Enforcement Administration
Masters Pharmaceuticals, Inc.; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13–39]

Masters Pharmaceuticals, Inc.; Decision and Order

On August 9, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Masters Pharmaceuticals, Inc. (hereinafter, Respondent). ALJ Ex. 1. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration Number RD0277409, pursuant to which it is authorized to distribute controlled substances in schedules II through V, at the registered location of 11930 Kemper Springs, Cincinnati, Ohio, and the denial of any pending application to renew or modify its registration, on the ground that its ''continued registration is inconsistent with the public interest.'' *Id.* (citing 21 U.S.C. 824(a)(4)).

The Show Cause Order specifically alleged that on April 21, 2009, Respondent entered into a Memorandum of Agreement (MOA) with DEA, pursuant to which it agreed ''to 'maintain a compliance program to detect and prevent [the] diversion of controlled substances as required under the [Controlled Substances Act] and applicable DEA regulations.' '' *Id.* (quoting MOA at ¶ II.1.a). The Order also alleged that in the MOA, Respondent '' 'acknowledg[ed] and agree[d] that the obligations undertaken . . . do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.' '' *Id.*

The Order then alleged that notwithstanding ''the MOA, the specific guidance provided to [Respondent] by DEA, and the public information readily available regarding the oxycodone epidemic in Florida, and in the United States, [Respondent] failed to maintain effective controls against the diversion of controlled substances . . . in violation of 21 U.S.C. 823(b)(1) and (e)(1).'' *Id.* at 1–2. The Order then alleged that from April 1, 2009 through December 31, 2009, Respondent distributed more than 37 million dosage units of oxycodone nationally and that nearly 25 million dosage units ''were distributed to its Florida customers,'' and that the latter distributions ''well exceeded'' its distributions to customers in other States.[1] *Id.* at 2. The Order further alleged that during 2010, Respondent distributed 37.86 million dosage units of oxycodone nationally, of which nearly 24.4 million dosage units ''were distributed to its Florida customers.'' [2] *Id.* Finally, the Order alleged that between January 1 and March 31, 2011, Respondent distributed 6.1 million dosage units of oxycodone nationally, of which approximately 2.76 million dosage units ''were distributed to its Florida customers.'' [3] *Id.*

Next, the Show Cause Order alleged that ''[s]ince at least 2009, the majority of [Respondent's] largest purchasers of oxycodone . . . have been retail pharmacies in the State of Florida who [it] knew or should have known were distributing controlled substances based on . . . prescriptions that were issued for other than a legitimate medical purpose and outside [of] the usual course of professional practice.'' *Id.* at 3. The Order then made allegations regarding Respondent's distributions of oxycodone 30 mg to eight pharmacies. More specifically, the Order alleged that:

1. ''From April 1, 2009 through November 30, 2010, [it] distributed approximately 591,800 dosage units . . . to Tru-Valu Drugs'';
2. ''From April 1, 2009 through January 31, 2011, [it] distributed approximately 993,100 dosage units . . . to The Drug Shoppe'';
3. ''From April 1, 2009 through March 31, 2011, [it] distributed approximately 333,000 dosage units . . . to the Medical Plaza Pharmacy'';
4. ''From April 1, 2009 through September 30, 2010, [it] distributed approximately 1.275 million dosage units . . . to Englewood Specialty Pharmacy'';
5. ''From April 1, 2009 through December 31, 2010, [it] distributed approximately 570,700 dosage units . . . to City View Pharmacy'';
6. ''From January 1, 2009 through November 30, 2010, [it] distributed approximately 1.7 million dosage units . . . to Lam's Pharmacy'';
7. ''From April 1, 2009 through August 31, 2009, [it] distributed approximately 637,400 dosage units . . . to Morrison's RX''; and
8. ''From January 1, 2009 through December 2009, [it] distributed approximately 351,600 dosage units . . . to Temple Terrace Pharmacy.''

Id.

The Show Cause Order then alleged that Respondent ''consistently ignored and/or failed to implement its own due diligence and suspicious order monitoring policies, compromising the effectiveness of those policies.'' *Id.* Continuing, the Order alleged that ''notwithstanding the large quantities of controlled substances ordered by [its] retail pharmacy customers, [Respondent] failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted'' and ''ignor[ed] and/or fail[ed] to document red flags of diversion present at many of its retail pharmacy customers.'' *Id.* Finally, the Order alleged that Respondent ''failed to detect and report suspicious orders of oxycodone products by its pharmacy customers, as required by 21 CFR 1301.74(b).'' *Id.*

Following service of the Show Cause Order, Respondent requested a hearing on the allegations. ALJ Ex. 3. The matter was placed on the docket of the Office of Administrative Law Judges, and assigned to ALJ Gail Randall (hereinafter, ALJ). ALJ's Recommended Decision (R.D.), at 1. Following pre-hearing procedures, *see generally* ALJ Exs. 5–11, the ALJ conducted an evidentiary hearing on February 24 through 28 and March 3 through 4, 2014, in Arlington, Virginia. Following the hearing, both parties filed briefs containing their proposed findings of fact and conclusions of law.

On June 19, 2014, the ALJ issued her Recommended Decision. Applying the public interest standard of 21 U.S.C. 823(b), the ALJ noted that the relevant factors were factors one—the maintenance of effective controls against diversion—and four—Respondent's experience in the distribution of controlled substances.

The ALJ rejected the Government's contention that Respondent had failed to report numerous suspicious orders, which it filled and shipped, upon subsequently determining that the customer was likely engaged in diverting controlled substances. R.D. at 154–61. Noting that the relevant regulation requires the reporting of a suspicious order ''when discovered,'' 21 CFR 1301.74(b), the ALJ opined that neither the regulation's language nor its purpose ''supports the conclusion that a registrant is required to review past orders from pharmacies the registrant later learns may be diverting controlled

[1] By contrast, the Order alleged that during this period, Respondent distributed approximately 1.47 million dosage units of oxycodone to its Nevada customers, 1.27 million to its Tennessee customers, 1.14 million to its Pennsylvania customers, and 1.09 million to its New Jersey customers. ALJ Ex. 1, at 2.

[2] By contrast, the Order alleged that during 2010, Respondent distributed approximately 2.8 million dosage units of oxycodone to its Nevada customers, 2.14 million to its Tennessee customers, 1.7 million to its New Jersey customers, and 1.37 million to its Pennsylvania customers. ALJ Ex. 1, at 2.

[3] By contrast, the Order alleged that during this period, Respondent distributed approximately 600,000 dosage units of oxycodone to its Tennessee customers, 415,000 to its New Jersey customers, 304,000 to its Pennsylvania customers, and 192,000 to its Nevada customers. ALJ Ex. 1, at 2.

substances.'' *Id.* at 157. The ALJ did, however, conclude that the regulation ''impose[s] a duty to report past orders [that] the registrant *actually* discovers were suspicious.'' *Id.* at 158. However, based on her review of the record, the ALJ concluded that Respondent had only failed to report a single suspicious order. *Id.*

Turning to the Government's contention that Respondent had failed to maintain effective controls against diversion, the ALJ concluded that the Government's evidence as to the volume of Respondent's sales to Florida and the eight pharmacies in particular did not support a finding that it was in violation of this duty. *Id.* at 164–67. As the ALJ explained, ''the sheer volume of a respondent's controlled substances sales or purchases, without some kind of contextual background to link the sales to the respondent's duty under the CSA, cannot be used to indicate that the distributor's registration would be against the public interest.'' *Id.* at 164. The ALJ further noted that the Government did not present a ''statistical expert or any other evidence to explain why the volume of Respondent's sales was necessarily indicative of diversion.'' *Id.* at 166. She also credited the testimony of Respondent's statistical expert that the ''shipments to the DEA-identified pharmacies rarely stand out from the rest of the monthly shipments''; that because Respondent does not have access to the Agency's ARCOS database, ''it cannot compare its shipments to [those] made by other distributors''; that ''Respondent's business model as a secondary supplier made comparisons across pharmacies practically useless''; and that comparing its distributions to Florida customers with those in other States was not ''very meaningful because there [are] so many factors that are relevant.'' *Id.* at 167 (citations omitted).

Next, the ALJ rejected the Government's contention that Respondent failed to follow its own policies and procedures. *Id.* at 170–79. The ALJ first found that Respondent's Policies and Procedures required that an order placed on compliance hold by its Suspicious Order Monitoring System (SOMS) be subject to additional due diligence which included: (1) Contacting the customer to discern the reason for the deviation in size, pattern, or frequency; (2) independently verifying the reason stated by the customer; and (3) conducting a complete file review. *Id.* at 73–74, 76–77. While the Government cited numerous instances in which Respondent's employees released orders without documenting having performed the above steps, the ALJ rejected its contention, reasoning that Respondent's Policies and Procedures did ''not require documentation of the reasons for the release of a held order.'' *Id.* at 171. And while noting ''that Respondent documented some reasons for abnormal orders,'' she further reasoned that ''[t]he mere absence of documentation—documentation that is not required by Respondent's Policies and Procedures, DEA regulations, or any established industry standard—does not constitute substantial evidence that the undocumented act did not occur.'' *Id.* at 172; *see also id.* at 173–74, 176.

Next, the ALJ addressed the Government's contention that Respondent failed to properly use the Utilization Reports (URs) which it obtained from its pharmacy customers. *Id.* at 179–95. While the ALJ found that Respondent was required under its policies and procedures to obtain a UR from a pharmacy customer whenever it placed an order on compliance hold and yet repeatedly failed to do so, *id.* at 181, she otherwise rejected the Government's contention that Respondent did not properly utilize the URs in its review of the held orders. *Id.* at 181–92.

In rejecting the Government's contention, the ALJ explained that because DEA was obligated under a Memorandum of Agreement (MOA) to conduct a compliance review and notify Respondent of any deficiencies in its policies and procedures and failed to do so with respect to its use of the URs, the MOA bars the Agency ''from sanctioning Respondent for not implementing additional UR analyses into its Policies and Procedures.'' R.D. at 186. While noting the parties' agreement ''that controlled substance ratios are an important aspect that should be investigated prior to shipping controlled substances,'' the ALJ then reasoned that ''[t]he Government offered no evidence that accurate information regarding controlled substance ratios can *only* be acquired through URs.'' *Id.* at 188–89. She also rejected the Government's contention that Respondent's actions in editing or deleting orders that were placed on hold by the SOMS established that it did not maintain effective controls against diversion or failed to report suspicious orders, noting that Respondent edited and deleted orders ''for business reasons.'' *Id.* at 196.

While acknowledging that the Government had proved that Respondent had failed to report a single suspicious order, the ALJ reasoned that ''Respondent fills many orders each year and has reported hundreds of suspicious orders, so one minor oversight does not render the entire system ineffective.'' *Id.* at 201. The ALJ thus concluded that Respondent had ''substantially complied with 21 CFR 1301.74(b),'' and that its failure to report the suspicious order did not justify the revocation of its registration. *Id.*

As for her finding that Respondent had violated its own policies and procedures by failing to obtain a UR every time an order was held by the SOMS, the ALJ reasoned that ''the relevant question . . . is not simply whether Respondent failed to follow its policies, but whether such failure rendered [its] system [for maintaining effective controls] ineffective . . . and/or constituted negative experience distributing controlled substances so as to justify revocation.'' *Id.* The ALJ then explained that Respondent's failure to follow its policies and procedures did not render them ineffective *per se* and that the Government was required to show that diversion was the ''direct and forseeable consequence'' of its failure to follow its policy in order to establish that its due diligence program was ineffective. *Id.* at 202. Because ''the Government made no showing that the shipments Respondent made without requiring URs were likely to be diverted,'' or ''that updated URs, had they been requested, would have indicated that the drugs were likely to be diverted,'' the ALJ concluded that Respondent's failure to obtain the URs did not ''justify revocation.'' *Id.* The ALJ thus recommended that Respondent be allowed to retain its registration and that the Administrator approve any pending renewal application. *Id.* at 203.

Both parties filed Exceptions to the ALJ's Recommended Decision. Thereafter, the record was forwarded to me for final agency action. Having reviewed the record in its entirety, and having carefully considered the ALJ's Recommended Decision as well as the parties' Exceptions,[4] I respectfully reject the ALJ's decision for reasons explained throughout this decision.

To summarize my reasons, I do agree with the ALJ that the Government's evidence as to the volume of Respondent's sales to the Florida pharmacies and the State in general does not constitute substantial evidence that the pharmacies were likely diverting controlled substances. I also agree with the ALJ's rejection of the Government's contention that Respondent, upon terminating a customer because it was likely diverting controlled substances, was obligated to review the customer's past orders and

[4] I address the various exceptions raised by the Parties throughout this decision.

determine whether any of them were suspicious and, if so, report them. However, I do so because, even assuming that the Government's interpretation is a reasonable reading of the suspicious order regulation, the Government has not provided pre-enforcement notice to the regulated community of this obligation.

Moreover, while I agree with the ALJ that ''a pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or for frequency,'' I respectfully disagree with her conclusion that these characteristics must ''make it likely that controlled substances will be diverted'' to trigger the reporting requirement. R.D. at 155. In short, the ALJ's interpretation imposes a higher standard than that of the plain language of the regulation, which requires only that the order be suspicious, a standard which is less than that of probable cause.

Although I agree with the ALJ that upon investigating an order, a distributor may determine that an order is not suspicious, I respectfully disagree with her conclusion that ''Respondent provided ample evidence that the pharmacies had legitimate reasons for the high percentage of controlled substances dispensed by the pharmacies in dispute.'' R.D. at 189. Indeed, I find the evidence offered by Respondent on this point to be seriously lacking in probative force.[5]

I also respectfully disagree with the ALJ's conclusion that the Government did not prove that Respondent repeatedly failed to contact the pharmacies and obtain an explanation for those orders which were held by the SOMS because they were of unusual size, deviated substantially from a normal pattern, or were of unusual frequency. Rather, I find that the record contains substantial evidence that Respondent represented to the Agency that it would document the reason why it filled those orders that were held by the SOMS. Thus, where there is no such documentation that Respondent contacted the pharmacy, I find that Respondent did not contact the pharmacy. Moreover, while in many instances there is no documentation that Respondent contacted the pharmacy, Respondent's records document a reason for filling the order that is extraneous to the reason one would expect to be provided by a pharmacy. Accordingly, I find that in numerous instances, the record supports a finding that Respondent failed to contact the pharmacy and obtain an explanation for those orders.

I also respectfully disagree with the ALJ's conclusion that Respondent's actions in editing or deleting orders that had been held by the SOMS (typically because they were of unusual size) does not establish that the orders were suspicious. While the ALJ reasoned that ''orders were edited and deleted for business reasons,'' I find that the weight of evidence is to the contrary and that most of the edited and deleted orders were suspicious and should have been reported.

Further, I respectfully disagree with the ALJ's rejection of the Government's contention that Respondent failed to properly use the URs because it did not use them to analyze the pharmacies' ratio of controlled to non-controlled dispensings. As for the ALJ's reasoning that the 2009 Memorandum of Agreement (MOA) bars the Government from sanctioning Respondent for failing to use the URs in this manner, nothing in the MOA provided Respondent with immunity for violations of DEA regulations occurring after March 31, 2009. Moreover, I conclude that the ALJ did not apply the correct legal standard in evaluating Respondent's contention that it reasonably relied on the Government's failure to identify the manner in which it used the URs as a deficiency in the compliance review and that therefore, the Government should be barred from sanctioning it based on this conduct. Instead, I conclude that Respondent's defense should have been evaluated under the doctrine of equitable estoppel and I reject its contention.

I also respectfully disagree with the ALJ's conclusion that use of the URs was not necessary to obtain accurate information regarding the pharmacies' dispensing ratios. Rather, I conclude that a distributor is required to use the most accurate information available to it. Because the URs show the actual dispensing level of each drug, and questionnaires and surveys provide only estimates, I conclude that a distributor must use the URs in evaluating whether a customer's dispensing ratio is suspicious.

Next, I respectfully disagree with the ALJ's conclusion that Respondent's failure to obtain a new UR every time an order was held by the SOMS did not render its policies and procedures ineffective. R.D. 202. Contrary to the ALJ's understanding, the Government was not required to show that the shipments Respondent made without requiring a new UR ''were likely to be diverted,'' *id.,* but rather, only that its failure to obtain a new UR rendered its system for detecting suspicious orders ineffective. For reasons explained in this decision, I conclude that Respondent's repeated failure to obtain new URs, both when orders were held, as well as when its own inspector recommended that it do so, rendered its suspicious order monitoring system defective.

Finally, I respectfully disagree with the ALJ's conclusion that the Government has proven only that Respondent failed to report a single suspicious order. To the contrary, I find that each of the seven pharmacies submitted numerous suspicious orders which should have been reported but were not. Accordingly, I respectfully disagree with the ALJ's ultimate conclusion that Respondent has substantially complied with the Agency's suspicious order rule and her recommendation that revocation of its registration is not warranted.

Having reviewed the entire record including the ALJ's Recommended Decision and the Parties' Exceptions, as ultimate factfinder, *see* 5 U.S.C. 557(b), I make the following factual findings.

Findings

Respondent is a secondary or ''tertiary'' wholesaler of various pharmaceutical products including controlled substances; ''[t]he vast majority of [its] customers are independent, retail pharmacies located throughout the United States,'' which are ''[o]ften . . . small, family owned and operated stores.'' RX 104, at 6–7; Tr. 994. According to its CEO and owner, it ''is not a primary or full line wholesaler'' and ''carries far fewer products than primary wholesalers.'' *Id.* Moreover, ''none of [its] customers use [it] as the sole source for all the pharmaceutical products they dispense.'' RX 104, at 7. And according to its owner, its ''business model tends to make its customers' purchasing patterns more difficult to predict and more variable than they would be if Masters were a full-line wholesaler.'' *Id.*

[5] Respondent's evidence on this point was largely comprised of the declaration of the head of its Compliance Department, Ms. Jennifer Seiple, regarding its due diligence efforts. I acknowledge that the ALJ found Ms. Seiple's testimony credible and clearly gave it substantial weight. However, for reasons explained throughout this decision, I find that much of Ms. Seiple's testimony as to the reasons why Respondent did not report the various pharmacies' orders as suspicious is unpersuasive. In other instances, her testimony is refuted by other evidence. Accordingly, I decline to give Ms. Seiple's testimony substantial weight. *See Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951) (''The substantial evidence standard is not modified in any way when the [Agency] and its [ALJ] disagree. . . . The findings of the [ALJ] are to be considered along with the consistency and inherent probability of testimony. The significance of [her] report, of course, depends largely on the importance of credibility in the particular case.'').

at 8; *see also* Tr. 997 (testimony of Respondent's former Vice-President that because it was a tertiary supplier, demand ''is very elastic'' and that ''it was very hard to pinpoint a demand from a customer who bought from you very infrequently'').

Respondent is the holder of DEA Certificate of Registration Number RD0277409, pursuant to which it is authorized to distribute controlled substances in schedules II through V, at the registered location of 11930 Kemper Springs, Cincinnati, Ohio. GX 1. While this registration was due to expire on January 31, 2014, on December 10, 2013, Respondent filed a timely renewal application. 21 CFR 1301.36(i). Accordingly, Respondent's registration has remained in effect pending this Decision and Final Order. 5 U.S.C. 558(c); 21 CFR 1301.36(i).

DEA Guidance to Distributors on Reporting Suspicious Orders and Maintaining Effective Controls Against Diversion

Prior to the events at issue here, the Deputy Assistant Administrator, Office of Diversion Control, wrote two letters which were sent to all registered distributors including Respondent. GXs 3 & 4. The letters discussed the requirements imposed by 21 CFR 1301.74 for reporting suspicious orders and the scope of a registrant's obligation ''to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels.'' GX 3, at 2. The first letter, which was dated September 27, 2006, set forth the text of 21 CFR 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Id. (quoting 21 CFR 1301.74(b)). Continuing, the letter noted that ''in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate . . . channels.'' *Id.* The letter then explained that ''a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances'' and that a ''distributor should exercise due care in confirming the legitimacy of all orders prior to filling.'' *Id.*

The letter also set forth various characteristics found by the Agency to be present in pharmacies engaged in diverting controlled substances. These included, *inter alia,* ''[o]rdering excessive quantities of a limited variety of controlled substances . . . while ordering few, if any, other drugs,'' and ordering the controlled drugs ''in quantities disproportionate to the quantity of non-controlled medications ordered.'' *Id.* at 3.

The letter also provided a list of suggested questions for distributors to ask in ''determin[ing] whether a suspicious order is indicative of diversion of controlled substances.'' *Id.* While most of these questions focused on whether a pharmacy was engaged in the unlawful distribution of controlled substances through internet schemes in which physicians prescribed drugs to patients with whom they had not established a legitimate doctor-patient relationship, some of the questions were applicable to all pharmacies. These included: (1) ''[w]hat percentage of the pharmacy's business does dispensing controlled substances constitute?'' (2) ''[a]re one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?'' and (3) ''[d]oes the pharmacy charge reasonable prices for controlled substances?'' *Id.*

The letter then explained that ''[t]hese questions [were] not all-inclusive'' and that ''the answer to any of the[ ] questions'' would not ''necessarily determine whether a suspicious order is indicative of diversion.'' *Id.* Finally, the letter concluded by advising that ''[d]istributors should consider the totality of the circumstances when evaluating an order for controlled substances.''

Id.

On December 27, 2007, the Deputy Assistant Administrator sent a second letter to all registered distributors including Respondent, the purpose of which was ''to reiterate the responsibilities of controlled substance manufacturers and distributors to inform DEA of suspicious orders in accordance with 21 CFR 1301.74(b).'' GX 4, at 1.

After reciting the regulatory text that ''suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency,'' the letter explained that ''[t]hese criteria are disjunctive and are not all inclusive.'' *Id.* (quoting 21 CFR 1301.74(b)). Continuing, the letter explained that:

> If an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a ''normal pattern'' to develop over time before determining where a particular order is suspicious. The size of an order alone, whether or not it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of a particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry.

Id.

The letter further explained that a registrant's ''responsibility does not end merely with the filing of a suspicious order report'' and that a ''[r]egistrant[] must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels.'' *Id.* Continuing, the letter warned that ''[r]eporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.'' *Id.* The letter thus advised that a registrant which ''routinely report[s] suspicious orders, yet fill[s] these orders without first determining that [the] order[s] [are] not being diverted . . . may be failing to maintain effective controls against diversion'' and engaging in acts which are ''inconsistent with the public interest.'' *Id.* at 2.

The Previous Agency Proceeding Against Respondent

On October 17, 2008, the Deputy Assistant Administrator, Office of Diversion Control, issued an Order to Show Cause to Respondent alleging that it had ''failed to maintain effective controls against diversion of particular controlled substances'' in that it ''distributed large amounts of hydrocodone,'' then a schedule III narcotic,[6] ''to customers it knew, or should have known, were diverting the [drug] into other than legitimate medical, scientific and industrial channels.'' GX 5, at 1. The Order further alleged that Respondent ''distributed extraordinarily large amounts of hydrocodone to'' two pharmacies, which were ''rogue Internet pharmacies that filled prescriptions that were not issued for a legitimate medical purpose

[6] Combination hydrocodone products have since been placed into schedule II of the CSA. *See Rescheduling of Combination Hydrocodone Products From Schedule III to Schedule II,* 79 FR 11037 (2014).

in the usual course of professional practice.'' *Id.* The Government alleged that Respondent's sales to the two pharmacies ''were consistently high compared to [its] sales of hydrocodone to other customers,'' with one of the pharmacy's purchases ''increase[ing] dramatically'' to a peak of more than 1.1 million dosage units in a single month, and the other pharmacy's purchases increasing from 30,000 to more than 156,000 dosage units in one month. *Id.* at 2. The Government also alleged that ''based upon the amounts and patterns of the hydrocodone orders and because DEA made [Respondent] aware of illegal Internet activity just prior to the unusual increases in distributions of hydrocodone to these customers,'' Respondent ''knew or should have known'' that the pharmacies ''were engaged in illegal activity'' and yet it ''failed to report [their] orders . . . as 'suspicious,' as required by'' 21 CFR 1301.74(b). *Id.*

The Government further alleged that Respondent distributed hydrocodone to two other pharmacies, with common ownership, notwithstanding that it had obtained information ''that clearly indicated that these pharmacies were operating as . . . rogue Internet pharmacies . . . and failed to report such orders as suspicious.'' *Id.* Finally, the Government alleged that ''[t]hroughout 2007 and 2008, [Respondent] . . . continued to fill orders for controlled substances from rogue Internet pharmacies and . . . failed to file suspicious order reports on such orders, in circumstances in which [it] knew or should have known that the pharmacies were operating illegally.'' *Id.*

On April 1, 2009, the Government and Respondent resolved the allegations by entering a settlement and release agreement, as well as an Administrative Memorandum of Agreement (MOA). GX 6. While Respondent was not required to admit to any of the allegations, it agreed to pay the Government the amount of $500,000 to settle ''claims or potential claims for civil penalties . . . for failing to report suspicious orders of controlled substances'' in violation of 21 U.S.C. § 842(c). *Id.* at 2, 4.

Respondent also ''agree[d] to maintain a compliance program designed to detect and prevent diversion of controlled substances as required under the CSA and applicable regulations.'' *Id.* at 2. The program was to ''include procedures to review orders for controlled substances,'' and further provided that orders ''exceed[ing] established thresholds and meet[ing] other criteria as determined by [Respondent would] be reviewed by [an] employee trained to detect suspicious orders for the purposes of determining'' either that the ''order[] should not be filled and reported to . . . DEA'' or that order was ''not likely to be diverted into other than legitimate medical, scientific or industrial channels.'' *Id.* Respondent further agreed that these obligations ''do not fulfill the totality of its obligations to maintain effective controls against the diversion of controlled substances or to detect and report to DEA suspicious orders for controlled substances.'' *Id.*[7]

Pursuant to the MOA, DEA agreed to ''conduct a review of the functionality of [Respondent's] diversion compliance program at [its] distribution center,'' including a ''review [of] the investigatory files maintained by [it] of the customers serviced by the distribution center.'' *Id.* at 4–5. DEA also agreed to ''conduct an exit interview with [Respondent's] representatives to provide DEA's preliminary conclusions regarding the Compliance Review.'' *Id.*

The MOA further provided that that review would be ''deemed satisfactory unless DEA determine[d] that the facility'' did not ''maintain effective controls against diversion,'' ''failed to detect and report . . . suspicious orders . . . after April 1, 2009,'' or ''failed to meaningfully investigate new or existing customers regarding the customer's legitimate need to order or purchase controlled substances.'' *Id.* Moreover, the MOA provided that ''[t]he Compliance Review shall be deemed 'not satisfactory' if DEA provides written notice with specificity to [Respondent] on or before 220 days from the Effective Date of [the MOA], stating that [Respondent had] failed to meet any of the requirements,'' apparently pertaining to maintaining effective controls against diversion, failing to detect and report suspicious orders, and failing to meaningfully investigate its customers.[8] *Id.* However, DEA also agreed that it would not ''find the Compliance Review 'not satisfactory' unless the failure(s) [we]re sufficient to provide . . . a factual and legal basis for issuing an Order to Show Cause under 21 U.S.C. § 824(a) against the inspected facility.'' *Id.* Moreover, the MOA provided that ''[a] finding of 'satisfactory' does not otherwise express DEA's approval of Master's compliance program.'' *Id.*

Finally, DEA agreed to release Respondent from administrative claims ''within [its] enforcement authority under 21 U.S.C. 823, 824 and 842, based on the Covered Conduct,'' as well as ''the conduct alleged in [the first] Order to Show Cause.'' *Id.* at 6. However, the MOA further provided that ''[n]otwithstanding the releases by DEA contained in this Paragraph, DEA reserved the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties (*i.e.,* Respondent) for non-covered conduct.'' *Id.*

On August 17, 2009, two DEA Diversion Investigators (DIs) went to Respondent's Kemper Springs location to conduct the compliance review and provide training to Respondent regarding its obligations under the Controlled Substances Act. Tr. 90, 92–93. Respondent's attendees included Dennis Smith, CEO; Wayne Corona, then Vice-President; Matt Harmon, then Compliance Manager; Jennifer Seiple, Vice-President of Compliance; and Eric Schulze, Compliance Clerk.

As part of the review, one of the DIs reviewed the CSA's requirements for inventories; records, including the use of schedule II order forms; and reports, including the regulation governing the reporting of suspicious orders. GX 11. The other DI, who had queried DEA's Automation of Reports and Consolidated Orders System (hereinafter, ARCOS), a database used to track the acquisition and distribution of various controlled substances including, *inter alia,* all schedule II drugs and schedule III narcotics, obtained data of Respondent's distributions between January 2007 and June 2009 and created several charts, which he presented to Respondent's representatives. GX 48A. According to the DI, he intended to show Respondent that oxycodone (a schedule II narcotic drug) and hydrocodone (then a schedule III narcotic drug when combined typically with acetaminophen but now a schedule II narcotic drug) comprised the majority of the controlled substances it distributed during this period; that the majority of the oxycodone and hydrocodone it distributed was in ''the

[7] Respondent also agreed that it would review its distributions of oxycodone, hydrocodone, alprazolam, and phentermine to its retail pharmacy and physician customers for the 18-month period prior to the signing of the MOA and identify those current customers which ''exceeded the thresholds or met other criteria established in its compliance program on the date of such review.'' GX 6, at 3. Respondent agreed that ''[t]o the extent it has not otherwise done so, [it] shall conduct an investigation for each customer where such review reveals purchasing patterns substantially deviating from the normal purchasing patterns observed . . . for that customer, and take appropriate action as required by this Agreement, DEA regulations and other procedures established under Masters' compliance program.'' *Id.*

[8] The MOA specifically referred to ''the requirements in either subsections II(2)(d)(i),(ii), or (iii) of this Agreement.'' GX 6, at 5. The provisions this sentence references are simply clauses within a single sentence and are not separate subsections.

most commonly abused dosage strengths''; and that the majority of the oxycodone it sold was distributed to its customers in Florida, which he characterized as ''the epicenter of the oxycodone epidemic.'' [9] GX 48A, at 3. The DI also testified that he presented Respondent with data and a chart showing its distributions of oxycodone to several of the pharmacies during the period of January through June 2009, including Morrison's RX (672,600 dosage units), Lam's Pharmacy (522,500), Englewood Specialty Pharmacy (262,700), and The Drug Shoppe (242,700). *Id.* at 5; GX 12, at 23. The DI testified that his intent in doing so ''was to alert [Respondent] to potentially problematic trends that [he] perceived based upon [its] ARCOS reporting.'' GX 48A, at 5–6.[10]

Consistent with the DI's testimony, a former employee of Respondent who attended the briefing testified that the DI very clearly expressed his concerns about Respondent's continued sales of oxycodone 30 mg, which he explained was the most abused form of oxycodone, to Morrison's, Englewood, The Drug Shoppe, and Lam's. Tr. 1155. The former employee further testified that as the DI reviewed Respondent's files for these pharmacies and looked at their sales volume, he would turn and look at Ms. Seiple (the Compliance Director) and ask: ''You're not selling to this guy, are you, Jennifer?'' *Id.* at 1156.[11]

Also, at the hearing, Mr. Corona admitted that oxycodone 30 mg ''was a highly abused substance'' and that it was ''being obtained surreptitiously and unlawfully down in Florida.'' *Id.* at 1071–72. Mr. Corona acknowledged that Respondent and its CEO were ''aware of the 'oxycodone epidemic' stemming from Florida'' and that ''[t]his was common knowledge at [Respondent] as well as in the pharmaceutical industry in general.'' GX 51B, at 9 ¶ 31. He further testified that Florida was ''the 'wild west' and . . . a 'free for all' when it came to sales and dispensing of oxycodone.'' *Id.*

The DI also testified that a document entitled ''Suggested Questions a Distributor should ask prior to shipping controlled substances'' was presented to Respondent at the review. Tr. 223–24; *see also* RX 13. One of the suggested questions was: ''What is the pharmacy's ratio of controlled v. non-controlled orders?'' RX 13, at 1. Next to it is the handwritten notation: ''RATIO C20—NC 80.'' *Id.* However, on cross-examination, the DI testified that nothing in the ''training materials,'' *i.e.,* the PowerPoint presentation, *see* GX 11, addressed how Respondent should evaluate the ratios of controlled to non-controlled drugs ordered by a pharmacy, Tr.114, and he did not recall what specific discussions he had with Respondent's representatives regarding the ratio of controlled to non-controlled substances. *Id.* at 182. He also acknowledged that he did not provide training ''concerning the proper use of drug utilization reports,'' *id.* at 114, and that he was not asserting that Respondent was using the utilization reports in a manner inconsistent with its written policies and procedures. *Id.* at 132. Nor did he tell Respondent that it was analyzing the information contained in the customer files incorrectly, *id.* at 115, including the URs which were in the due diligence files Respondent kept for Morrison's, Englewood, The Drug Shoppe, and Lam's. *Id.* at 141.

However, recalling the briefing provided by DEA, Mr. Corona testified that:

> DEA provided information regarding specific questions to ask Masters' customers on due diligence questionnaires and during site visits. These questions were designed to gather information to allow Masters to identify ''red flags'' that may indicate that a particular customer was involved in illegitimate dispensing of controlled substances. In particular, DEA advised us to focus on whether a customer had a high percentage of cash for controlled substance prescriptions (as compared to third-party insurance payment), refused to accept insurance for the payment of controlled substance prescriptions, and/or dispensed a high percentage of controlled substances as compared to non-controlled substances.

GX 51B, at 4 ¶ 12.

During the review, Respondent also made a presentation to the DIs regarding its controlled drug handling policies and procedures. RX 12. As part of the presentation, Respondent stated that all new controlled substance customers were required to provide ''a valid DEA registration number,'' which it verified using the National Technical Information Service database. *Id.* at 11–12. Also, new customers were required to ''[c]omplete a survey designed to screen customers for inappropriate business activity,'' which included questions as to how many prescriptions the customer filled per day and how many were for controlled substances, whether the pharmacy did mail order or internet business, and whether the pharmacy filled prescriptions for out-of-area or out-of-state doctors or patients. *Id.* at 15. Respondent further represented that it reviewed the survey responses to determine if the customer was engaged in ''inappropriate business practices'' ''[]prior to shipping even one controlled drug,'' and that if the responses were ''not indicative of inappropriate practice,'' it would approve the customer to purchase controlled substances. *Id.* at 16.

As for its existing customers, Respondent stated that beginning in October 2008, it had conducted more than 5,800 surveys and that ''[a]ll customers eligible to purchase controlled drugs . . . ha[d] undergone [its] due diligence process and been approved by [the] Compliance Department.'' *Id.* at 19. Respondent further represented that since January 1, 2008, it had conducted 346 site visits of customers located in California, Florida, Kentucky, Nevada, Ohio, Tennessee, and West Virginia. *Id.* at 20.

Respondent also briefed the DIs regarding its Suspicious Order Monitoring System (hereinafter, SOMS). More specifically, Respondent explained that every order containing at least one controlled substance was tracked by calendar month and that any time a customer placed a new order that would result in the customer receiving more controlled drugs (by drug family) in the past 30 days than its highest monthly total in any of the previous six calendar months, the order was held for review and could not be shipped until it was released by the Compliance Department.[12] *Id.* at 25–29. Respondent

[9] Other testimony described the extent of the oxycodone epidemic in Florida during this period, including that between 2005 and 2010, the State experienced a 345 percent increase in narcotic-related overdose deaths, with 11 people dying per day in 2010, as well as an increase from 250 to 1,400 in the number of newborns who were addicted to oxycodone per year. Tr. 28.

The State eventually enacted legislation requiring that a physician and clinic ''primarily engaged in the treatment of pain by prescribing or dispensing controlled substance[s]'' register as a pain management clinic with the Florida Department of Health and limited the authority of dispensing physicians in such clinics to dispensing a 72-hour supply of narcotics to those patients who paid for the drugs ''by cash, check, or credit card.'' Fla. Stat. §§ 458.3265(1)(a) (2010), 465.0276(1)(b) (2010). The following year, the State enacted legislation which barred physicians from dispensing schedule II and III controlled substances except in even more limited circumstances. Fla. Stat. § 465.0276 (2011); *see also* Tr. 31. Based on the extensive abuse of oxycodone in Florida, in July 2011 the State's Surgeon General declared a public health emergency. Tr. 30–31; GX 47.

[10] The DI further testified that he specifically identified Lam's as a customer they ''[s]hould be 'looking at.''' GX 48A, at 6.

[11] I have considered Respondent's contention that the ALJ ''incorrectly found that DEA very clearly expressed concerns about'' these four pharmacies during the Compliance Review. Resp. Exceptions, at 19. Having reviewed the record, I reject the contention.

[12] Under the SOMS, Respondent assigned a Controlled Substance Limit (CSL) for each drug family ordered by a customer. According to a

Continued

also stated that the SOMS was designed to place holds based on a change in a customer's order patterns. *Id.* at 27.

Respondent represented that every controlled substance order ''go[es] through SOMS even before our system checks to see if we have the ordered items in stock,'' and that ''[i]f the order and the account history meets [sic] or exceeds [sic] the criteria set in [the] SOMS, the order is held for review,'' which involved the Compliance Staff conducting ''additional due diligence'' and determining whether the order could be shipped. *Id.* at 30. Respondent further represented that if its Compliance Staff ''reject[ed] the order,'' it was ''considered 'suspicious' '' and would be ''reported to . . . DEA'' and the customer's controlled substance ordering privileges would be ''suspended indefinitely.'' *Id.*

Finally, Respondent represented that ''[d]ocumentation on all orders held for review and their dispositions are permanently retained.'' *Id.* (emphasis in original). *See also* GX 51B, at 6 ¶ 19 (testimony of Wayne Corona) (''The compliance department would contact the customer, advise that the order was held and request a reason why the order exceeded SOMS parameters. The reason *would be documented in the due diligence files, specifically in the 'Memos for Record' (MFRs).* It may also have been electronically documented in the 'Ship to Memos' which were also part of the due diligence file.'') (emphasis added)).

Of further note, during the briefing, Respondent provided the DIs with a six-page Appendix which explained the operations of the SOMS. RX 78, at 59–64. On the issue of the documentation of those orders that were held for review, the Appendix stated:

> All orders have a full audit trail as related to SOMS. Each order that is processed through the system will show the status of the three parts of the SOMS system along with the customer's current limits and the results of the limits as related to this order. The ultimate status, accept or reject, will be shown along with the date/time and user associated with the action. A reason code and notes will also be provided as additional detail supporting the decision.

Id. at 64.

In addition to the SOMS Appendix, Respondent provided the DIs with a copy of its compliance manual, which included its policies and procedures for evaluating its controlled substance customers and their controlled substance orders; its policy on site visits (including its site visit and due diligence survey forms); and the operation of the SOMS. GX 48A, at 8; *see also* RX 78. Because the written policy and procedures provide additional detail beyond that which was discussed in the slides used in Respondent's PowerPoint briefing, relevant provisions are discussed below.

Respondent's Policy 6.1 set forth the requirements to purchase controlled drugs. RX 78, at 30. These requirements included that any customer ''possess a valid, unexpired DEA registration'' in the appropriate drug schedules; that it provide its ''registration number and/or a copy of the registration''; and that Respondent would validate the customer's registration though the NTIS (National Technical Information Service) database. *Id.*

The Policy also required Respondent to ''perform sufficient due diligence on all customers in order to prevent the diversion of controlled drugs.'' *Id.* This included a survey; the authentication of the licenses of the facility, pharmacist-in-charge, and practitioners; a check of publicly available disciplinary records for recent disciplinary actions; and review by a compliance manager. *Id.*

The Policy further provided that ''[a]dditional due diligence shall be required of any customer when any of the following issues are indicated'' to include that: (1) There were ''[s]ignificant, recent, and/or relevant disciplinary actions relating to the handling of controlled drugs''; (2) a customer was distributing controlled substances over the internet or by mail order; (3) a customer was ''diverting controlled drugs through any other means''; (4) a ''customer place[d] a potentially suspicious order''; and (5) the compliance manager conducting the review required more information. *Id.* at 30–31. The Policy then stated that the additional due diligence could ''include any or all of the following steps, as determined by the compliance manager'': (1) Obtaining ''[d]rug [u]tilization [r]ecords''; (2) conducting a site visit; (3) inquiring of law enforcement agencies; (4) checking with ''common carriers to determine if the [customer] is using their services; and (5) ''[a]cquiring a commercial credit report . . . to verify the survey information provided by the customer.'' *Id.* at 31.

Respondent's Policy 6.2 sets forth its requirements and procedures for monitoring and reporting suspicious orders. *Id.* at 32. According to Respondent, the SOMS did four things: (1) It ''[t]racks each customer's purchase history for controlled drugs''; (2) it ''[r]eviews every order for controlled drugs . . . prior to shipment''; (3) it ''[h]olds all orders for controlled drugs that meet or exceed the criteria set forth in 21 CFR 1301.74(b)'' (the suspicious order reporting regulation); and (4) it ''[r]equires each order to be individually reviewed prior to shipment.'' *Id.* The Policy then set forth Respondent's procedures for those orders that were placed on hold by the SOMS. *Id.* These procedures required that ''[a] compliance staff member call[] the customer and request[]'' both: (1) ''[a]n explanation for the order,'' which was to be ''independently verified''; and (2) ''[a] current utilization report, listing all of the pharmaceuticals'' (including both controlled and non-controlled) dispensed by the pharmacy ''in the most recent calendar month.'' *Id.* The procedures also required that ''[t]he customer's entire file'' be reviewed, including its ''initial survey,'' its ''order

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document describing the SOMS, upon the completion of the initial due diligence, the Compliance Department would assign a default monthly limit for each control [sic] drug group based on the ''information derived from the initial due diligence.'' GX 35, at 15. This limit would set the number of doses that a customer could receive at a particular registered location ''in any given 30 day period,'' but could ''be edited for a period of six months after the first purchase of each control [sic] [drug] group.'' *Id.*

However, according to its policies and procedures, Respondent did not require that new controlled substance customers provide a utilization report showing their actual dispensings of prescription products prior to setting the initial monthly limit. Rather, under its policies and procedures, obtaining a UR was a discretionary act even when Respondent deemed it necessary to conduct additional due diligence on a new customer. RX 78, at 30–31.

According to the testimony of a former compliance department employee, based on the number of prescriptions a customer reported that it filled on a daily basis (which was typically only an estimate), Respondent would place the customer in one of three tiers and assign the initial monthly limit of dosage units for each controlled substance family (*e.g.,* oxycodone). Tr. 1380–82. While there is testimony to the effect that the tiers were set at either ''5, 10, or 15'' thousand dosage units, it is unclear whether this applied to each controlled substance family. Tr. 627 (testimony of DI). Of further note, there is no evidence as to how Respondent determined the number of dosage units for each controlled substance family and tier.

According to the materials Respondent provided (*i.e.,* the SOMS Appendix), ''[a]fter six months of full history for a control [sic] [drug] group, the customer invoice history will be used to determine the monthly limit for each control [sic] [drug] group,'' with an ''update . . . occur[ing] on the first of every month.'' RX 78, at 59–60. However, ''[t]he highest monthly total [including product that was returned] from the preceding six months will be used as the new Monthly Limit for [a] control [sic] [drug] group.'' *Id.* at 60.

As for the determination of whether an order ''is invalid'' because of its ''size,'' Respondent represented that this is made by adding ''the total number of doses invoiced in the past 30 days [on a rolling basis] plus the total doses on open orders plus the number of doses on the received order[s] and compar[ing] it to the monthly limit.'' *Id.* According to Respondent's former Vice President, even if an order placed a customer one pill over its CSL for a controlled drug group, the order would be placed on hold and trigger a review. Tr. 1001.

history with'' Respondent, and ''[t]he site visits report(s),'' if available.'' *Id.*

According to the Policy, orders held for review would be released and filled when the order was found to be ''consistent with the customer's utilization report,'' and the review of ''the customer's file, including [its] survey responses and site visits'' was found to be ''consistent with legitimate business practices.'' *Id.* The Policy further directed that a held order would not be filled upon a finding that the order was inconsistent with the utilization report, the file review ''indicate[d] that the customer may be engaged in inappropriate business practices,'' or ''[t]he customer refuses to provide . . . the information necessary to complete its evaluation.'' *Id.* at 32–33. Moreover, the Policy directed that ''[a]ll orders . . . held for review that [Respondent did] not fill for [these] reasons . . . shall be considered 'Suspicious Orders' according to 21 CFR 1301.74(b) and reported to'' DEA. *Id.* at 33. Finally, upon the determination that an order was suspicious, Respondent's policy required that ''the customer's ordering privileges for controlled drugs . . . be suspended indefinitely.'' *Id.* [13]

Respondent's Policy and Procedures included its Policy 6.5, which applied to site visits. *Id.* at 37. The Policy stated that it was Respondent's policy to conduct site visits for ''all'' customers purchasing large quantities of controlled substances, as well as when its Compliance Department determined that ''additional due diligence [was] necessary prior to'' filling a controlled substance order. *Id.* The purpose of the site visits was to verify the customer's location; its ''trade class'' (whether it was a closed door, wholesale, or community pharmacy); the representations it made during ''the due diligence process,'' such as its proximity to health care providers; and finally, to ''look[] for indications of inappropriate business activity.'' *Id.*

The Policy required that those conducting the site visits ''take comprehensive notes'' and complete a ''Pharmacy Evaluation Form.'' [14] *Id.* It also instructed that photographs should be taken of the pharmacy's exterior, as well as ''any other feature in or around the pharmacy'' that would ''be helpful in making compliance decisions about the customer.'' *Id.* Finally, the Policy directed that if the inspector ''identifie[d] anything about the pharmacy or its staff that indicated . . . that the pharmacy is currently engaged in inappropriate business activity,'' this was to be reported to the Compliance Department ''as soon as possible after the visit.'' *Id.* (emphasis in original).

As found above, the MOA required that DEA ''conduct an exit interview . . . to provide [its] preliminary conclusions regarding the Compliance Review.'' GX 6, at 5. The DI did not, however, do a formal exit interview. GX 48A, at 8. Indeed, the DI testified that because the new policies had been implemented on August 14, 2009, only four days before the Compliance Review, there was not enough time to determine if the policies were being properly implemented. Tr. 230. However, the DI testified that at the conclusion of the review, he ''explained to [Respondent] that a review of all the information and material provided indicated that Masters ha[d] progressively engaged in actions to implement policies and procedures to promote an effective system to detect and prevent diversion of controlled substances.'' GX 48A, at 8. The DI further explained that he ''based this conclusion on the written policies and procedures provided . . . by [Respondent], and [his] assessment that, if properly implemented, these policies and procedures could promote an effective system to detect and prevent diversion of controlled substances.'' *Id.* Also, although the MOA stated that if DEA found the Compliance Review to be ''not satisfactory,'' it was to ''provide[ ] written notice with specificity to [Respondent] on or before 220 days from [the MOA's] [e]ffective [d]ate,'' GX 6, at 5; DEA did not provide any such notice. Tr. 120–25.

On August 18, 2009, the same day that the review concluded, Matt Harmon, Respondent's Compliance Manager, prepared a memorandum which he provided to both Wayne Corona (Vice-President) and Dennis Smith (owner and CEO). GX 38; *see also* Tr. 1161–62. Therein, Harmon proposed various steps which Respondent should take in response to the DEA review. Harmon proposed that Respondent use the pharmacies' utilization reports to ''[i]dentify pharmacies'' whose dispensings of controlled drugs and other drugs of concern (tramadol and carisoprodol) comprised ''50% or more of their'' dispensings and if so, then determine if ''over half of their purchases in each drug family [were of] either the highest strength or otherwise frequently diverted drug products.'' *Id.* Harmon then listed five products: ''oxycodone 30 mg,'' ''methadone 10 mg,'' ''hydrocodone 10 mg,'' ''alprazolam 2 mg,'' and ''codeine syrup,'' both ''with or without promethazine.'' *Id.* at 1. Harmon then proposed that if both conditions were present with respect to a pharmacy, Respondent ''need[ed] to suspend controlled sales to'' the pharmacy until it concluded an investigation. Harmon also explained that ''[w]e should assume that every pharmacy meeting the above criteria is engaged in inappropriate business activity until proven otherwise.'' *Id.*

Harmon further proposed that Respondent's investigation of such pharmacies focus on four questions: (1) Was there ''a strong independently verifiable, legitimate reason for this pattern?''; (2) was the pharmacy ''selling a full range of non-controlled pharmaceuticals?''; (3) were ''the

[13] *See also* GX 51B, at 6 ¶ 19 (declaration of Wayne Corona) (''The compliance department would contact the customer, advise that the order was held and request a reason why the order exceeded SOMS parameters. The reason would be documented in the due diligence files. . . . The compliance department was supposed to independently verify the reason given by the customer. If the reason was valid, the order would be released. If the reason could not be validated, it was supposed to be reported as suspicious.'').

[14] A copy of the Pharmacy Evaluation Form (which was revised on May 27, 2009) and the Due Diligence Survey—For Pharmacies (which was revised on May 14, 2009) are found at RX 78, at 51–57. The Pharmacy Evaluation Form is six pages long, with questions regarding ownership information, years in business, the licenses of the pharmacy, its pharmacist-in-charge, its pharmacy staff, and the nature of its practice. As for the latter section, the pharmacy was required to list all of the pharmaceutical distributors it had purchased from in the last 24 months; answer questions regarding ''the average number of prescriptions filled per day,'' ''[w]hat percentage are ANY CONTROLLED DRUG (CII–V),'' ''[w]hat percentage are ANY SCHEDULE II DRUG (CII)''; and list the percentage of prescription revenue from private insurance, Medicare/Medicaid, cash, and other sources. *Id.* at 51–55. The pharmacy was also required to disclose if it had a Web site or was affiliated with any Web sites and, if either question was answered in the affirmative, list the URL(s). *Id.* at 55. The pharmacy was further required to disclose if it ''fill[ed] prescriptions for practitioners in the primary business of pain management,'' and if so, ''list all such practitioners and their DEA numbers.'' *Id.* Finally, the form included a section titled as ''Inspector's Notes.'' *Id.* at 55–56.

As for the Due Diligence Survey, it asked similar questions, including whether the pharmacy had a Web site; whether it did mail order; if it had a primary wholesaler and, if so, the wholesaler's name; the daily script average and daily script average of schedule II drugs; the percentage of scripts that were for controlled drugs; the percentage of scripts that were for schedule IIs; and whether the pharmacy accepted insurance and Medicare/Medicaid, and, if so, the percentage paid by insurance. *Id.* at 57. The form also asked questions regarding what the pharmacy did to prevent doctor shopping; how the pharmacy ensured that doctors were ''exercising proper standards of care for their patients''; if the pharmacy had ''ever refused to fill a prescription,'' and if so, what were ''the most common reasons''; whether it had ''ever decided to permanently stop filling'' prescriptions written by a physician, and if so, ''the reason for doing so''; whether it filled prescriptions written by out-of-area or out-of-state doctors; whether it filled prescriptions for out-of-area or out-of-state patients; and whether it filled prescriptions ''via the internet.'' *Id.*

majority of the[] controlled drug prescriptions paid for with insurance?''; and (4) did the pharmacy ''sell front-store items?'' Harmon added that those customers who met ''only some of these criteria should be subjected to additional due diligence prior to any sale.'' *Id.*

The Government's Evidence of Respondent's Sales of Oxycodone During the Period of April 1, 2009 Through March 31, 2011 to the Seven Florida Pharmacies

The main focus of the Government's case was Respondent's sales of oxycodone to seven Florida-based pharmacies during the height of the State's oxycodone crisis. Based on data submitted by Respondent through ARCOS, the Government prepared a spreadsheet of the purchases of oxycodone 15 and 30 mg by the seven pharmacies (as well as Lam's Pharmacy, which was located in Las Vegas, Nevada) identified in the Show Cause Order during the following periods: (1) April 1, 2009 through December 31, 2009; (2) calendar year 2010; and (3) January through March 2011. It also prepared spreadsheets listing the pharmacies' monthly purchases of both drugs from Respondent.[15]

In December 2010, a DI with the Detroit Field Division was directed to conduct an investigation as to whether Respondent was complying with the 2009 MOA. GX 49B, at 7, ¶ 10. After reviewing data showing Respondent's distributions of various controlled substances (which showed that oxycodone comprised more than 60 percent of its distributions during 2009 and 2010, and that 44 of its top 50 oxycodone customers were located in Florida), on Feb 8, 2011, the DI (accompanied by two other DIs) went to Respondent's Kemper Springs facility to determine whether Respondent had ''created and implemented a system designed to maintain effective controls against diversion.'' *Id.* at 8. The DIs met with Wayne Corona (Respondent's President and Chief Operating Officer), Jennifer Seiple, and Matthew Harmon, and reviewed various records. *Id.* at 8–9.

According to a DI, Corona stated that Respondent's ''employees were aware of the diversion problems with oxycodone in Florida'' but did not ''consider the geographic locations of its Florida pharmacy customers.'' *Id.* at 9.[16] Corona also stated that he was aware of the fact that DEA had suspended the registration of Harvard Drug Group, L.L.C., based on its distributions of oxycodone to Florida and that Respondent had been ''flooded with contacts from Harvard['s] customers inquiring about oxycodone products after'' the suspension of Harvard's registration. *Id.*

As part of the investigation, the DI served several administrative subpoenas on Respondent and obtained the record for 21 pharmacies including Tru-Valu Drugs, Inc.; The Drug Shoppe, Inc.; Morrison's RX, Inc.; City View Pharmacy; CIFII Corp, d/b/a Lam's Pharmacy; Englewood Specialty Pharmacy, Inc.; Medical Plaza Pharmacy of Plantation, L.L.C.; and Temple Terrace Pharmacy, d/b/a Superior Pharmacy. GX 49B, at 14; 59 n.15; 87 n.18. The DI reviewed these files, which were maintained by Respondent's compliance department and contained customer questionnaires, pharmacy evaluations, site visit forms, Memos for Record (MFRs), Ship to Memos, SOMS

[15] The Government also submitted two tables purporting to show the total number of oxycodone dosage units Respondent sold to its customers in each State during the years 2009 through 2012, as well as its average monthly sale per customer during each year. *See* GXs 10B & 10L. The ALJ found the data unreliable because the first of these tables shows that Respondent distributed nearly 25 million dosages in 2009 to its Florida customers, which was approximately 67 percent of its total oxycodone distributions, while the second of these tables, which was submitted as a rebuttal exhibit—after Respondent discredited the Government's calculation of its average monthly sale per customer in each State—shows that Respondent had sold an additional 7.6 million dosage units to its Florida customers and that this comprised approximately 66 percent of its total distributions. However, there was little change between the data in the two exhibits for calendar years 2010 and 2011. The 2010 data show that Respondent distributed 24,389,400 dosage units to its Florida customers (according to GX 10B) and 24,387,800 to its Florida customers (according to table 10L); the tables show that Respondent's total distributions were 37,866,700 (according to GX 10B) and 37,859,300 (according to GX 10L). The ALJ did not address why this portion of the data is unreliable. Moreover, Respondent did not dispute that it ''distribute[d] a lot of oxycodone to the state, lots of it.'' Tr. 1837 (closing argument of Respondent's counsel).

However, I agree with the ALJ that the data as to its total sales in Florida do not establish that Respondent failed to maintain effective controls against diversion. R.D. at 27 n.22, 164–67. I also find unpersuasive the Government's proffered comparison of Respondent's Florida sales with its sales to its customers in other States including Texas, California, and New York, which the Government argues were ''similarly situated'' in terms of demographics and the number of medical establishments. Gov. Post-Hrng. Br. 104–06. Accordingly, I reject the allegation that the volume of dosage units distributed to the pharmacies alone establishes that Respondent ''knew or should have known'' that the ''prescriptions were issued for other than a legitimate medical purpose and outside the usual course of professional practice.'' ALJ Ex. 1, at 3 (Order to Show Cause, at ¶ 5).

I also agree with the ALJ's conclusion that the Government's calculations of the average monthly purchase of oxycodone by Respondent's customers (as reflected in both exhibits) are flawed. R.D. 27 n.22. As for the calculations in GX 10B, the Government conceded that these were erroneous because each transaction was treated as if it was made by a separate pharmacy, Tr. 1736, and thus the number of pharmacies used to calculate the average was off by a factor of 14 for the 2009 calculation and 24 for the 2010 calculation. *Compare* GX 10B *with* GX 10L.

Similarly, while the calculations in GX 10L may have been based on an accurate number of pharmacies, I agree with the ALJ that the calculations are flawed because they did not take into account that Respondent's customers did not necessarily purchase oxycodone each month and thus suffer from aggregation bias. R.D. 27 n.22; *see also* Tr. 1625–26, 1755–57. Indeed, I note that while GX 10L was submitted after Respondent's expert pointed out this flaw in the Government's initial calculations, the Government still submitted calculations that did not correct for aggregation bias.

[16] Indeed, at the hearing, both Messrs. Corona and Smith testified that in early 2009, Smith, accompanied by another employee, travelled to Florida to check out the situation. Tr. 1033, 1665. At the time, Respondent was supplying pain clinics which engaged in the direct dispensing of controlled substances to patients. On his return, Smith decided to cut off the pain clinics. As Corona explained:

He [Smith] said he couldn't believe what was going on in Florida with respect to the pain clinics because he had seen park benches and bus stop benches advertising pain clinics, and he brought back a copy of City Beat with I forget how many pages of nothing but ads for pain clinics with young kids sitting around a pool in bathing suits with big smiles on their face [sic], and he said this was an issue and we're not going to participate in this anymore. So he effectively that day cut everybody off.

Tr. 1074. In his testimony, Smith confirmed Corona's recollection of the impetus for the decision to cut off the pain clinics. He testified that:

I was down there a couple of days, two or three days. We looked at the pain clinics. We looked at certain areas of town that some of the pain clinics were located in. We also got a copy of City Beat, which was a monthly or a weekly—one of those free catalogs you often see outside of restaurants—and started going through it and identified that towards the back there were a lot of advertisements for pain clinics that I thought were very unethical. It would show young people sitting around a pool and it named the pain clinic and say [sic] we dispense on site, and that really hit home hard.

Tr. 1665–66; *see also* RX 104, at 19 (Smith Decl. at ¶ 73).

Smith did not, however, cut off the pharmacies. According to Corona, this was because Smith believed that Respondent could rely on the pharmacies to vet the physicians who were writing the prescriptions. Corona then asserted that ''[w]e all knew that a licensed professional in the health care field would for the most part behave ethically and legally,'' *id.* at 1075, even though Smith testified that he had concerns about the ethics and legality of the conduct engaged in by pain-clinic physicians. *Id.* at 1665–66.

So too, while Smith admitted that he knew that oxycodone was the primary drug being sought for illicit use in Florida, *id.* at 1668, he asserted that he ''put a lot of thought into it, and I just felt that there should be segregation of duties, that the physician should write and the pharmacy should dispense, and that was an added line of due diligence on the part of the pharmacy.'' *Id.* at 1666. Apparently, the possibility that pharmacists might also act unethically or illegally never occurred to him, even though Smith was obviously aware of this possibility from his experience in addressing the allegations of the previous Show Cause Order that Respondent supplied pharmacies that were unlawfully distributing controlled substances via the internet.

Notes, Utilization Report (URs), and other forms and emails. *Id.* at 16.

According to the DI, his review showed that Respondent ''regularly ignored inconsistencies in information provided by controlled substance customers, including extremely high percentages of controlled substances being distributed by the pharmacy, significant percentages of cash sales, and other indicators of potential diversion.'' *Id.* at 16–17. The DI further asserted that the documents showed that Respondent ''deleted or edited orders that would bring customers above their threshold limit'' and that it also ''routinely utilized a 'release with reservation' or 'ship with reservation' ('RWR or SWR') designation and thus allowed orders that [it] should have viewed as potentially suspicious [to] be shipped.'' *Id.* at 17. Finally, the DI alleged that Respondent ''ignored or failed to act on information it reviewed during on-site inspections that were significant indicators of potential diversion.'' *Id.*

The Pharmacy Specific Evidence

Before proceeding to make findings specific to each of the Florida pharmacies,[17] a discussion of the parties' exceptions which bear directly on the weight to be given to the pharmacy-specific evidence is warranted. These include the Government's exception to the ALJ's finding that it failed to prove that Respondent did not comply with the provisions of its policies and procedures which required it to contact the pharmacy whenever an order was held by the SOMS and obtain an explanation for the order, which it then independently verified, as well as to obtain a new UR. Gov. Exceptions, at 43–56. As for Respondent, it asserts that ''the ALJ assumed that *all* orders identified on the SOMS notes were held by SOMS,'' and that ''[a]s a result of this misinterpretation, the ALJ vastly overstated the number of orders held by the SOMS.'' Resp. Exceptions, at 13. Respondent also argues that ''the ALJ incorrectly concluded that the . . . Order to Show Cause was not based on 'Covered Conduct' '' and that she ''failed to make factual findings required to protect [its] interests under the'' MOA. *Id.* at 16. Respondent further asserts that the ''ALJ should not have allowed evidence regarding [its] failure to review [the utilization reports] regardless of whether it was part of [its] policies and procedures.'' *Id.* at 19.

The Government's Exception

As noted above, Respondent's Policies and Procedures required that an order placed on compliance hold by the Suspicious Order Monitoring System (SOMS) be subject to additional due diligence which included: (1) contacting the customer to discern the reason for the deviation in size, pattern, or frequency; (2) independently verifying the reason stated by the customer; (3) obtaining a new utilization report; and (4) conducting a complete file review to determine if the pharmacy's order was consistent with legitimate business practices. As will be shown below, while the SOMS held numerous orders placed by the Florida pharmacies, in only rare instances do Respondent's records document that it contacted the pharmacy to obtain an explanation for the order, let alone that it independently verified that explanation.[18]

The Government points to the frequent absence of documentation showing that Respondent contacted the pharmacies, obtained an explanation for these orders, and independently verified that explanation. The Government contends that the reason there is no such documentation is because Respondent's employees did not do it.

The ALJ rejected the Government's contention, asserting that the Government acknowledged in its brief that Respondent's ''Policies and Procedures do not require documentation of the reasons for the release of a held order.'' R.D. at 171. I need not decide whether this is a fair reading of the Government's brief because, as found above, the ALJ ignored the evidence that Respondent, in its presentation to the Agency regarding ''The Process'' for monitoring controlled substance orders, represented that ''[d]ocumentation on all orders held for review and their dispositions are permanently retained.'' RX 12, at 30 (emphasis in original).

Moreover, while the ALJ acknowledged Mr. Corona's testimony that documentation was the '' 'lynchpin [sic] of the whole system in terms of explaining our behavior,' '' the ALJ then characterized his testimony as ''not[ing] that the reasons for exceeding SOMS would *often* be documented in [the] MFRs and Ship to Memos.'' R.D. at 171 (citing Tr. 1094; GX 51B at 6 ¶ 19) (emphasis added). Yet Mr. Corona actually testified that ''[t]he compliance department would contact the customer, advise that the order was held and request a reason why the order exceeded SOMS parameters. The reason *would be documented in the due diligence files, specifically in the 'Memo for Record' (MFRs).* It may also have been electronically documented in the 'Ship to Memos' which were also part of the due diligence file.'' GX 51B, at 6 ¶ 19 (emphasis added). While the ALJ also cited Mr. Corona's oral testimony as support for her characterization of his testimony that the reasons ''would often be documented,'' I reject this because it is based on a misreading of Mr. Corona's testimony.[19]

The ALJ also asserted that another witness (Mr. Schulze), who had worked in the Compliance Department, ''testified that not all research the Compliance Department conducted was documented in the MFRs or Ship to Memos, and that he did not feel that leaving some research out of the due diligence files violated Respondent's Police and Procedures.'' R.D. at 172–73. However, the thrust of Mr. Schulze's testimony was that the Compliance Department would not necessarily document in the MFRs or the SOMS notes having performed Google searches or having obtained a fax from the customer; instead, it would simply place the information in the customer's due diligence file. Tr. 1337–39. Thus, this testimony simply does not address the issue.

While Mr. Schulze also testified that he would ''not necessarily'' document ''every single time'' he made a phone call to a customer, this was in response to Respondent's counsel's suggestion that it was ''[o]ften very difficult to get in touch with pharmacists'' because they are ''very busy people'' and ''don't sit at the end of the phone and take calls from [Respondent's] compliance department all the time.'' *Id.* at 1335–36.

[17] Having reviewed the entire record, I limit my discussion of the pharmacy specific evidence to the Florida pharmacies.

[18] While Policy 6.2 required Respondent to obtain a new UR whenever an order was held by the SOMS, it is beyond dispute that Respondent rarely obtained a new UR.

[19] The actual question (by Respondent's counsel), which was based on a hypothetical, as it is not supported by any facts in evidence and is not even probative on this point, and Corona's answer follows:

Q. Now, if Jennifer Seiple made that phone call and the pharmacist said I ordered a day early because I'm going on vacation next week and she didn't document that on an MFR, you would trust her to know that that was an appropriate reason? I mean, if she didn't document it, that doesn't indicate to you that she was attempting to do anything nefarious, does it?

A. No, it does not. What I would do is ask her under the assumption that she was well within her guidelines to do that and then ask her to please document it for future reference or go back and document it because documentation was the linchpin of this whole system in terms of explaining our behavior, especially in our environment.

Tr. 1094.

Most significantly, Respondent's counsel then asked Mr. Schulze if ''[i]t was your understanding that when compliance had significant or important information or contact with a customer, that type of information should be documented in the compliance file in either the MFRs, or the SOMS notes, or the ship to notes, or somewhere, correct?'' *Id.* at 1336–37. Mr. Schulze answered: ''Yes.'' *Id.*[20]

In addition to her failure to acknowledge Respondent's representation to the Agency that ''[d]ocumentation on all orders held for review and their disposition are permanently retained,'' RX 12, at 30; the ALJ also failed to acknowledge both the representations made by Respondent in the SOMS Appendix and what the SOMS notes actually showed. As found above, the SOMS Appendix states that: ''[t]he ultimate status, accept or reject, will be shown along with the date/time and user associated with the action. *A Reason code and notes will also be provided as additional detail supporting the decision.''* RX 78, at 64 (emphasis added). Thus, I respectfully reject the ALJ's premise that Respondent's Policies and Procedures did not require it to document the inquiries it made of the pharmacies in the course of reviewing those orders that were held by the SOMS.

Moreover, as will be explained in the findings made with respect to each pharmacy, the SOMS notes did typically contain an explanation regarding the review of those orders that were held by the SOMS. However, that explanation invariably did not reflect that Respondent had contacted the pharmacy and obtained an explanation for why the order had exceeded the SOMS parameters, but rather, some other explanation, such as that the order was released because it was supported by the pharmacy's utilization report (which the evidence will show was infrequently obtained). This begs the question, which the ALJ did not answer: why, if the Compliance Department had actually contacted the pharmacy and obtained a legitimate explanation for why the order exceeded the SOMS parameters, it then documented a reason for releasing the order which had nothing to do with anything the pharmacy may have told it?

As for the ALJ's reliance on the fact that such documentation is not required by DEA regulations or any established industry standard, this is beside the point given that Respondent represented to the Agency that it would maintain such documentation. Moreover, there is ample authority to support the Government's position that the absence of such documentation proves that the pharmacies were not contacted.

As a leading authority explains: ''The *absence of an entry,* where an entry would naturally have been made if a transaction had occurred, should ordinarily be equivalent to an assertion that no such transaction occurred, and therefore should be admissible in evidence for that purpose.'' V Wigmore, Evidence § 1531, at 463 (Chadbourn rev. 1974) (citing cases); *see also United States* v. *De Georgia,* 420 F.2d 889, 891 (9th Cir. 1969) (noting that Wigmore ''expressed the view that the absence of an entry concerning a particular transaction in a regularly-maintained business record of such transactions, is equivalent to an assertion by the person maintaining the record that no such transaction occurred''); *A.Z.* v. *Shinseki,* 731 F.3d 1303, 1311 (Fed. Cir. 2013) (''The absence of certain evidence may be pertinent if it tends to disprove (or prove) a material fact.'') (other citation and quotation omitted); *cf.* Fed. R. Evid. r. 803(7).

Accordingly, as a general matter, I respectfully reject the ALJ's conclusion that the Government's reliance on the lack of documentation in Respondent's records does not prove that its compliance department failed to contact the pharmacy and obtain an explanation for the orders that were held by the SOMS (as well as that it failed to independently verify any such explanation) but were subsequently released.[21] To the contrary, where there is an absence of documentation that Respondent performed the respective act, that absence is substantial evidence that Respondent did not perform the act. And as will be shown below, with respect to most of the orders that were held by the SOMS, there is additional evidence that supports the conclusion that Respondent failed to contact the pharmacies and obtain an explanation for the orders, as most of the relevant entries provide a justification for shipping the order which has nothing to do with the type of explanation one would expect from a pharmacist.

Respondent's Exceptions

As noted above, Respondent takes exception to the ALJ's findings as to the number of orders placed by the various pharmacies that were held by the SOMS for review. Resp. Exceptions, at 13–16. While Respondent acknowledges that ''there was no direct evidence presented on this point,'' it argues that ''the ALJ incorrectly assumed that *all* orders identified on the SOMS notes were held'' for review. *Id.* at 13. Respondent contends that ''the only orders that were held by SOMS were those that also have the name of a Compliance Department employee in the 'Decision By' column and, in most cases, notes in the 'Notes' column.'' *Id.* Respondent contends that the ALJ's misinterpretation of the SOMS notes led her to ''vastly overstate[ ] the number of orders'' that were held. *Id.*

Notwithstanding that Respondent put forward no direct evidence as to the interpretation of the SOMS notes, having reviewed the entire record I agree with Respondent that the ALJ misinterpreted the notes and overstated the number of held orders. Indeed, Respondent's materials indicated that all controlled substances orders were evaluated by the SOMS, and it seems logical that if an order did not exceed one of the three parameters, a review of the order would not be conducted and no name would be listed in the ''Decision By'' column. I find this conclusion to be supported by my review of the numerous oxycodone orders set forth in the Government's ARCOS data in light of the SOMS parameters. Accordingly, I do not adopt the ALJ's findings as to the number of held orders and instead, I make findings specific to the respective orders. *See also* RX 78, at 64.

Next, Respondent argues that the ALJ erred in concluding that the Show Cause Order was not based on the covered conduct (*i.e.,* those claims based on Respondent's conduct prior to April 1, 2009) which was resolved by the MOA. *Id.* at 16. Respondent argues that, because following the August 2009 Compliance Review, the Agency ''never advised [it] of any deficiencies in its compliance program, its suspicious order reporting, or its due diligence investigations as required under the MOA,'' the Agency ''breached the terms of the MOA by . . . asserting claims for which [the Agency] has already provided a release, and by seeking to impose liability for conduct [it] took in reliance on its successful Compliance Review.'' *Id.* at 16–17. Respondent further argues that ''while the ALJ excluded some so-called 'Period of Review' evidence, she failed to make

[20] Nor did Ms. Seiple, who headed the Compliance Department, assert that its employees actually contacted the pharmacies whenever the SOMS held orders but simply failed to document doing so. *See* RX 103.

[21] Even if the Agency's regulations do not require a distributor to document the reason provided by a customer to justify a suspicious order, documenting that reason is still an essential part of maintaining effective controls against diversion because subsequent events may provide information which show that the reason was false.

factual findings . . . to ensure that [it] received the full benefit of its bargain set forth in the 2009 MOA.'' *Id.* at 17–18.

More specifically, Respondent argues that ''[t]he due diligence [it] conducted on its customers was deemed satisfactory in 2009, but DEA now deems it insufficient.'' *Id.* at 18. Respondent further contends that ''DEA expressed no concern about any order for controlled substances [it] shipped in 2009, but [DEA] now claims Masters should have reported many of those same orders as suspicious.'' *Id.* Continuing, Respondent argues that ''[t]he policies and procedures DEA deemed satisfactory in 2009 are now deemed inadequate'' and that ''DEA has built its entire case on actions Masters took in reliance on that MOA.'' *Id.* Respondent then argues that, to protect its rights under the MOA and the Due Process Clause, the ALJ should have made the following three findings:

> That as of August 18, 2009, it ''had enacted policies and procedures that constituted effective controls against diversion regarding the distribution of any controlled substance'';
>
> That as of August 18, 2009, it ''had detected and reported to DEA suspicious orders of controlled substances after April 1, 2009''; and
>
> That as of August 18, 2009, it ''had meaningfully investigated all new or existing customers, including each of the . . . pharmacies identified in the'' Show Cause Order, ''regarding the customer's legitimate need to order or purchase controlled substances.''

Id. Respondent thus contends that because the ALJ ''fail[ed] to make these findings, [it] was required to defend conduct that it took in reliance on DEA's inaction following the Compliance Review.'' *Id.* It therefore requests that I make these findings and hold ''that this proceeding was based, at least in material part, on 'Covered Conduct' as defined in the MOA.'' *Id.* at 18–19.

I reject Respondent's request. Contrary to Respondent's contention, the MOA granted Respondent immunity only for its conduct prior to April 1, 2009, and none of the orders which are at issue in this proceeding occurred before this date. Moreover, to the extent Respondent's due diligence efforts prior to April 1, 2009, are at issue (*i.e.,* to justify Respondent's failure to report an order as suspicious and/or to ship the orders which are at issue), the MOA specifically provides that ''[n]otwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes *in any other administrative proceeding against the Released Parties for non-covered conduct.*'' GX 6, at 6 (emphasis added).

As for Respondent's contention that the ALJ failed to make findings to ensure that it received ''the full benefit of its bargain,'' Resp. Exceptions, at 17–18; nothing in the MOA provides a remedy in the event the Government's representatives provided an inadequate compliance review.[22] Because the MOA provides no such remedy, Respondent's contention that it should be afforded immunity for its conduct after April 1, 2009 because it relied on the Government's failure to identify any deficiencies in its procedures following the compliance review must be evaluated by applying the principles of equitable estoppel. *See, e.g., Dantran, Inc.,* v. *U.S. Dept. of Labor,* 171 F.3d 58, 66 (1st Cir. 1999) (applying equitable estoppel and rejecting contractor's contention ''that the government should be estopped from pursuing an action based on practices . . . that drew no criticism at that time'' because it ''reasonably relied'' on ''the clean bill of health'' it received following investigation and compliance officer's failure to question its practices).

Under the traditional principles of equitable estoppel, '' 'the party claiming the estoppel must have relied on its adversary's conduct 'in such a manner as to change [its] position for the worse,' and that reliance must have been reasonable in that the party claiming the estoppel did not know nor should it have known that its adversary's conduct was misleading.'' *Heckler* v. *Community Health Services of Crawford Cty., Inc.,* 467 U.S. 51, 59 (1984) (quoting *Wilber Nat'l Bank* v. *United States,* 294 U.S. 120, 124–25 (1935)). Moreover, with respect to claims of estoppel against the Government, the Supreme Court has explained that:

> [w]hen the Government is unable to enforce the law because the conduct of its agents has given rise to an estoppel, the interest of the citizenry as a whole in obedience to the rule of law is undermined. It is for this reason that it is well settled that the Government may not be estopped on the same terms as any other litigant.

Id. at 60.

Accordingly, the D.C. Circuit has explained that:

> [a] party attempting to apply equitable estoppel against the government must show that ''(1) there was a definite representation to the party claiming estoppel, (2) the party relied on its adversary's conduct in such a manner as to change [its] position for the worse, (3) the party's reliance was reasonable[,] and (4) the government engaged in affirmative misconduct.''

Keating v. *FERC,* 569 F.3d 427, 434 (D.C. Cir. 2009) (quoting *Morris Comm. Inc.* v. *FCC,* 566 F.3d 184, 191–92 (D.C. Cir. 2009)).

Applying this test, Respondent cannot prevail.[23] Even assuming that Respondent has made the requisite showing as to the first two prongs, its contention fails because its reliance on the DIs' failure to identify specific deficiencies in its policies was not reasonable and there is no evidence that

[22] Respondent actually got more than it bargained for, at least from the ALJ, when she ''ruled that the Government will be precluded from asserting any evidence of [Respondent's] failures to report suspicious orders during the Period of Review,'' the period from April 1, 2009 through the Compliance Review. Order Granting In Part Respondent's Motion in Limine to Preclude Admission of Irrelevant, Immaterial, and/or Incompetent Evidence and to Adopt Findings, at 14. Nothing in the MOA provided Respondent with immunity for potential violations during this additional period, and the ALJ's ruling ignores that even if Respondent was unclear as to what its regulatory obligations were, it always had the option not to accept and/or fill orders from the seven pharmacies during this period.

Moreover, even though the Government did not take exception to the ALJ's ruling, in its Exceptions, Respondent specifically requests that I make the factual finding that ''[a]s of August 18, 2009, [it] had detected and reported to DEA suspicious orders of controlled substances after April 1, 2009.'' Resp. Exceptions, at 18. While I consider the suspicious order reports which are contained in RX 61, I conclude that any such finding should be based on a consideration of the entire record in this proceeding. Accordingly, I also consider the evidence as to whether the orders placed by the seven Florida pharmacies during the period from April 1 through August 18, 2009 were suspicious and, if so, whether Respondent ''detected and reported'' them to DEA.

As for the facts that the MOA provided that ''[t]he Compliance Review will be deemed satisfactory unless DEA determines that [Respondent] failed to detect and report to DEA suspicious orders of controlled substances after April 1, 2009,'' GX 6, at 5; and that the DI did not specifically identify any such orders as suspicious either at the time of the briefing or thereafter, Respondent's argument fails for the same reasons that I reject its contention regarding the DI's failure to identify specific deficiencies in its policies and procedures. As explained above, its contention that it relied on the DI's failure to identify any order as suspicious must rest on the principles of equitable estoppel. *See, e.g., Dantran,* 171 F.3d at 66.

In short, Respondent's reliance on the DI's failure to identify any specific order as suspicious was not reasonable given that the DI identified its sales to several of the pharmacies as being of concern and asked its Compliance Director if she was still selling to them. Moreover, even were I to conclude otherwise on the issue of the reasonableness of its reliance, Respondent cannot claim that the DIs engaged in affirmative misconduct when they failed to identify any specific orders as suspicious.

For the same reasons, I reject the ALJ's ''find[ing] that DEA is barred by the MOA from sanctioning Respondent for not implementing additional UR analyses into its Policies and Procedures.'' R.D. at 186.

[23] Notably, while in its Exceptions, Respondent argues that it engaged in ''conduct that it took in reliance on DEA's inaction following the Compliance Review,'' it does not acknowledge that its claim is subject to the principles of equitable estoppel.

the Government's representatives engaged in affirmative misconduct.

As the Supreme Court has explained, to establish that one's reliance was reasonable, ''the party claiming the estoppel [must show that it] did not know nor should it have known that its adversary's conduct was misleading.'' *Heckler,* 467 U.S. at 59 (citing *Wilber Nat'l Bank,* 294 U.S. at 124–25). Moreover, '' 'if, at the time when [the party] acted, [it] had knowledge of the truth, or had the means by which with reasonable diligence [it] could acquire the knowledge so that it would be negligence on [its] part to remain ignorant by not using those means, [it] cannot claim to have been misled by relying upon the representation or concealment.' '' *Id.* at 59 n.10 (quoting 3 J. Pomeroy, *Equity Jurisprudence* § 810, at 219 (S. Symons ed. 1941)).

As found above, while the DI did not identify any specific deficiencies in Respondent's policies and procedures, he advised Respondent's employees that he perceived ''potentially problematic trends'' in its sales to several of the pharmacies of various highly abused controlled substances including oxycodone 30 mg, methadone 10 mg, alprazolam 2mg, and hydrocodone. The DI also identified the expected ratio of controlled to non-controlled dispensings at pharmacies. This testimony was corroborated by the testimony of Messrs. Harmon and Corona. Indeed, as found above, Mr. Harmon testified that as one of the DIs reviewed Respondent's files, with respect to several of the pharmacies whose orders are at issue in this proceeding, he turned to Ms. Seiple and specifically asked her if Respondent was still selling to them.

As also noted above, after the Compliance Review, Mr. Harmon also wrote a memo setting forth various steps Respondent should undertake, including using the utilization reports submitted by the pharmacies whose dispensings of controlled substances comprised more than 50 percent of their dispensings and thus, in the memo's words, suggested that they were ''engaged in inappropriate business activity.'' GX 38. Thus, the fact that the DI did not specifically instruct Respondent's employees that the procedures were deficient because they did not use the URs to analyze whether the respective pharmacies' controlled substance dispensing ratios were consistent with legitimate dispensing activity provides no support to Respondent. As will be shown below, the URs provided extensive evidence that the identified pharmacies were placing suspicious orders and potentially diverting controlled substances. Respondent cannot credibly argue that it reasonably relied on the DI's failure to object to the limited manner in which it used the URs or that it had the right to ignore the evidence it obtained through the URs because the DI did not specifically instruct its employees to use the URs in this manner.

Nor does the evidence support a finding that Respondent was affirmatively misled by either the DI's statement at the completion of the review or by the Government's failure to subsequently identify any deficiencies in Respondent's policies and procedures. As the First Circuit has explained, ''[i]t is common ground that affirmative misconduct requires something more than simple negligence.'' *Dantran,* 171 F.3d at 67; *see also U.S.* v. *Hemmen,* 51 F.3d 883, 892 (9th Cir. 1995) (''When a party seeks to invoke equitable estoppel against the government, we . . . require a showing that the agency engaged in affirmative conduct going beyond mere negligence[.]'') (other citations and internal quotations omitted).

In this case, there is simply no evidence that the DI's statement at the conclusion of the compliance review (that Respondent ''ha[d] progressively engaged in actions to implement into [sic] policies and procedures to promote an effective system'' to prevent diversion, GX 48A, at 8 ¶ 15) was made with the ''intent to mislead [Respondent] about [its] responsibilities.'' *Dantran,* 171 F.3d at 67. The same is true with respect to the Government's failure to identify any deficiencies in writing following the review. In short, ''there is not the slightest whiff of affirmative misconduct'' on the part of the DI. *Id.*

There is a further reason for rejecting Respondent's exception. As the DI testified, his statement that Respondent had ''progressively engaged in actions'' to implement an effective system of diversion controls was based on Respondent's policies and procedures being ''properly implemented.'' GX 48A, at 8 ¶ 15.

As found above, during the Compliance Review, Respondent represented to the Government that when an order was held for exceeding the SOMS parameters, it would take various actions to investigate whether the order was legitimate, which included contacting the pharmacy to obtain an explanation for the order, independently verifying the explanation, and obtaining a new UR. Yet, as demonstrated below in the discussion of the pharmacy-specific evidence, the record shows that Respondent rarely complied with its policies and procedures with respect to the seven Florida pharmacies.

Thus, while Respondent contends that DEA is improperly seeking to impose liability for failing to report orders as suspicious, claiming that ''[t]he policies and procedures . . . deemed satisfactory in 2009 are now deemed inadequate,'' its contention is unavailing given the extensive evidence that it repeatedly failed to comply with these policies. Moreover, as demonstrated below, Respondent repeatedly justified its failure to report these orders (as well as its subsequent filling of the orders), notwithstanding its failure to follow these policies, on the ground that as a part of its ongoing due diligence, it had conducted an extensive investigation and determined that the orders were not suspicious and were consistent with the respective pharmacy's business model. *See generally* RX 103 (Seiple Decl.). Respondent thus placed the adequacy of its due diligence efforts at issue. I therefore reject its contention.[24]

Having addressed the relevant exceptions, I now turn to the pharmacy-specific evidence.

Tru-Valu Drugs, Inc.

According to Respondent's due diligence file, Tru-Valu Drugs, Inc., was a pharmacy located in Lake Worth, Florida which had been in business for 43 years and had the same ownership for 32 years. RX 2A, at 76–77. According to a Pharmacy Evaluation done on May 28, 2008 by a consultant retained by Respondent, Tru-Valu filled 150 prescriptions per day, of which 40 percent were for controlled substances. *Id.* at 78–81. Tru-Valu reported that 60 percent of its business was cash and that insurance and Medicare/Medicaid together comprised 40 percent. *Id.* at 78.

[24] For the same reasons, I reject Respondent's further contention that because ''the Government failed to provide any notice to [it] regarding the use of [the] URs, the ALJ should not have allowed the Government to introduce any evidence in regard to such use'' to show that it did not ''comply with the MOA, or otherwise failed to maintain effective controls again diversion.'' Resp. Exceptions, at 19.

Respondent further ignores that it put in issue the manner in which used the URs. As will be shown in the discussion of the pharmacy-specific evidence, with respect to each of the pharmacies, Ms. Seiple stated that Respondent ''was aware of the volume of oxycodone and other controlled drugs being dispensed by [the pharmacy], and the percentage of controlled drugs dispensed relative to other drugs,'' that it ''specifically investigated the reasons why [each pharmacy's] ordering and dispensing patterns were as indicated on the URs,'' and that ''[t]he URs and other information provided by [the pharmacy] were consistent with the pharmacy's business model.'' *See, e.g.,* RX 103, at 40.

It also disclosed that it had purchased from four other pharmaceutical distributors in the last 24 months, including Amerisource Bergen, H.D. Smith, ANDA, and Mason Vitamin. *Id.* at 77.

Tru-Valu was not located in a medical center. *Id.* at 79. It did not serve nursing homes, hospice programs or inpatient facilities. *Id.* at 78. However, it did fill prescriptions for pain management clinics, and its owner and pharmacist-in-charge (PIC) advised that ''[t]hey do fill a large number of narcotic prescriptions each day'' and ''that he has pushed for this business with many of the area pain doctors.'' *Id.* at 79–81. Tru-Valu's owner also advised Respondent's consultant that ''[h]e is concerned about the current restrictions put on his buying by several suppliers.'' *Id.* at 81.

Tru-Valu provided the names of five pain management doctors whose prescriptions it filled. *Id.* at 79. Tru-Valu's due diligence file contains no evidence that Respondent performed any check on the licensure and registration status of these physicians and whether the physicians had any specialized training or held board certification in pain management or addiction medicine. Nor is there any evidence that Respondent inquired of Tru-Valu's pharmacist as to the nature of the prescriptions these physicians were writing (*i.e.,* the quantity and whether drug cocktails such oxycodone 30 mg and alprazolam were being prescribed for patients). Moreover, two of these doctors (Joel Panzer and Stephanie Sadick) appear on Respondent's list of terminated customers, the former having been terminated on September 3, 2008 and the latter on April 3, 2009. RX 62A, at 3; RX 62E, at 2.

Apparently seeking an increase in the amount of oxycodone it could purchase, on May 22, 2008, Tru-Valu provided Respondent with a utilization report for April 2008 which listed and ranked the top 300 prescription drugs (both the controlled and non-controlled) it dispensed by the quantity.[25] RX 2A, at 70–76. The report showed that oxycodone 30 mg was the top drug with 132,506 dosage units dispensed, followed by methadone 10 mg at 53,842 du, alprazolam 2 mg at 55,120 du, sterile water for irrigation at 24,000 units (a non-controlled prescription product), Endocet 10/325 mg (oxycodone/acetaminophen) at 4,146 du, Hibiclens 4% liquid (a non-controlled topical anti-microbial), carisoprodol 350 mg at 3,703 du (then controlled under Florida law and since placed in schedule IV of the CSA), valproic acid 250 mg (non-controlled) at 2,400, and OxyContin 80 mg (oxycodone continuous release) at 2,220 du. *Id.* at 70. Thus, oxycodone 30 mg, methadone 10 mg, and alprazolam 2 mg constituted more than 241,000 dosage units out of the total quantity of more than 340,000 du dispensed that month.[26] *Id.* at 70, 75. In contrast, Tru-Valu dispensed only 2,479 dosage units of hydrocodone 10 mg, 120 du of hydrocodone 7.5, and 390 du of hydrocodone 5 mg, even though hydrocodone was the most widely prescribed drug nationally from 2006 through 2010. *See id.* at 70–76; RX 81, at 46–47.

Tru-Valu's file also includes additional URs for the months of December 2008, October 2009, February 2010, July 2010, and September 2010. Tru-Valu's December 2008 UR listed the top 200 prescription drugs it dispensed, which totaled more than 300,000 units. *Id.* at 64. Notably, Tru-Valu dispensed more than 192,000 dosage units of oxycodone 30 during the month. *Id.* at 61. With the exception of carisoprodol (which was then non-controlled under federal law), each of the top ten drugs Tru-Valu dispensed was a controlled substance; these included alprazolam 2 mg (27,268 du), methadone 10 mg (11,848 du), and Endocet (oxycodone) 10/325 mg (6,976 du). *Id.*

While Tru-Valu's October 2009 UR showed a decline in its dispensings of oxycodone 30 mg to a total of 83,830 du out of its total dispensings of approximately 167,000 du, *id.* at 51, 58; its February 2010 UR showed that in just these four months, its dispensings of oxycodone 30 had more than doubled to 192,110 du.[27] *Id.* at 47. The UR also showed that Tru-Valu's dispensings of oxycodone 15 totaled 38,563 du and its dispensings of alprazolam 2mg totaled 30,655 du. *Id.* These three drugs alone accounted for more than 81 percent of Tru-Valu's dispensings. Moreover, the top ten drugs by dispensing volume were comprised entirely of oxycodone products in various dosages, methadone, and alprazolam, and 17 of the top 20 drugs were federally controlled substances. *Id.*

Tru-Valu's July 2010 UR showed a further increase in its dispensing of oxycodone 30 mg to 206,132 units out of total dispensings for all prescription products of 337,314.[28] RX 2A, at 29, 36. It also showed that Tru-Valu had dispensed 32,441 du of oxycodone 15 and 31,271 du of alprazolam 2 mg during the month. *Id.* at 29–30. With the exception of carisoprodol (which was the tenth-most dispensed drug), each of the top ten drugs was a formulation of oxycodone, methadone, or alprazolam. So too, with the exception of carisoprodol and ibuprofen, each of the top 20 drugs dispensed was either a schedule II narcotic or a schedule IV benzodiazepine (alprazolam or diazepam).

The final UR in Tru-Valu's file (Sept. 2010) showed that it dispensed 146,560 dosage units of oxycodone 30 mg during the month. *Id.* Of further note, for each of the five URs in Tru-Valu's file, controlled substances were predominant among the drugs dispensed.

Tru-Valu's file also includes a form entitled ''DEA Schedule Orders—Due Diligence Report Form,'' the purpose of which was ''to evaluate customers who demonstrate a pattern of large orders of control [sic] product.'' *Id.* at 41. This form, which is dated ''1–9–09,'' noted that Tru-Valu had requested an increase in its oxycodone purchases. *Id.* The form, which apparently reflected information the pharmacy provided in a phone survey, noted that Tru-Valu's daily script average was 200, that 50 percent of the prescriptions were for controlled drugs, and that 25 percent of the prescriptions were schedule II drugs. *Id.* The form also noted that 25 percent of the prescriptions were paid for by insurance. *Id.*

The form further noted various procedures employed by the pharmacy.

[25] Twelve days before the site visit, Tru-Valu had requested an increase in the quantity of solid dose oxycodone it could purchase from Respondent. According to the form, which appears to have been completed by an account manager, Tru-Valu was using 750 bottles per month and the account manager sought an exemption from Respondent's sales limit on the basis that it qualified as a ''[l]arge full line pharmacy.'' RX 2A, at 93.

According to the file, Respondent obtained a utilization report that listed only controlled substances and then requested a report which included non-controlled drugs as well. The form bears the notations: ''Approved 25k/mo'' and ''6/4/08.'' *Id.*

[26] These were not the only controlled substances listed on the report. The report lists additional dispensings of oxycodone 30 mg under different drug codes, likely because the products were manufactured by a company other than the manufacturer whose products comprised the bulk of Tru-Valu's dispensings. *See id.* at 70 (also showing at line 28, dispensing of 540 Roxicodone 30; at line 43, 360 oxycodone 30; at line 44, 354 oxycodone 40 mg).

[27] The Feb. 2010 UR listed the top 200 drugs and total dispensing of approximately 321,400 dosage units. RX 2A, at 47.

During the cross-examination of the DI, Respondent's counsel pointed out that some of the URs only listed the top 200 or 300 drugs that were dispensed. However, Respondent's Policy 6.2 directed that it obtain ''[a] current utilization report, listing all of the pharmaceuticals'' (including both controlled and non-controlled), dispensed by the pharmacy ''in the most recent calendar month.''

[28] The July 2010 UR listed 377 line items of dispensings down to a quantity of one. RX 2A, at 36.

For example, to prevent doctor shopping, the pharmacy stated that it did not fill prescriptions if patients changed doctors and that it kept a list of where patients were getting scripts; as to how the pharmacy ensured that the prescribers were exercising proper standards of care, the pharmacy replied that ''they set limits on what they fill and they watch there [sic] patients very careful [sic] and never do early refill. They also don't fill for some docs.'' *Id.* at 42.

With respect to whether it had ever refused to fill a prescription (to which the pharmacy's answers was ''yes, every day''), the pharmacy reported that the most common reasons were ''early refill[s],'' if the patients were ''under 21,'' if patients lived ''out of area,'' or if it did not fill for a doctor. *Id.* As for whether the pharmacy had ever ''stopp[ed] filling prescriptions for a certain physician,'' the pharmacy reported that it had when it was ''not comfortable with there [sic] prescribing license.'' *Id.* The pharmacy also stated that it did not fill prescriptions written by out-of-state and out-of-area doctors and that if it got a prescription from a new doctor, it would call the DEA and check the license, and that it ''belong[ed] to a network of pharmacies that warn each other.'' *Id.* Finally, the form noted that Tru-Valu had been asked to submit its most recent pharmacy inspection report; a UR, which ''should include all controls and non-controls''; and any written policies and procedures for controlled substances. *Id.* at 43.

Tru-Valu's controlled substance limit (the SOMS trigger) for oxycodone was initially set at 25,000 dosage units and, according to the SOMS notes, remained at this level through January 2010. *Id.* at 93; *see also* GX 15, at 111 (SOMS Notes of 10/27/09: ''Ok to ship . . . oxy @ limit 25k with this order'' and Jan. 29, 2010—''ok to ship, under the CSL of 25k''). However, in November 2009, Respondent filled orders totaling 26,200 du of oxycodone products, which included 1,200 du of oxycodone 80; 9,600 du of oxycodone 30; 14,400 du of oxycodone 15; and 1,000 du of oxycodone 10/325. GX 10F, at 1–2. All but 3,600 du were ordered on the last day of the month. *Id.* at 1–2. While these orders placed Tru-Valu over the 25,000 CSL, the SOMS notes do not contain the name of a reviewer or an explanation for why the orders were shipped. GX 15, at 111.[29]

In February 2010, Tru-Valu again submitted orders in excess of the 25,000 du threshold. According to Respondent's records, Mr. Schulze, a compliance clerk, called Tru-Valu and spoke with its pharmacist-in-charge about the oxycodone order. RX 2A, at 9. The pharmacist in charge reported that an Albertson's (a supermarket) had ''closed by him'' and that he was ''getting some of [its] business.'' *Id.*

However, even though Respondent's Policy 6.2 required that the pharmacist's explanation then be independently verified, there is no documentation to support that this was done. Moreover, while the SOMS note for this order states: ''Ship with reservation UR supports Oxy order reviewed by JEN,'' GX 15, at 111; Respondent did not obtain a new UR for ''the most recent calendar month'' as required by its Policy 6.2, and had last obtained a UR in October 2009. Notwithstanding its failure to comply with its policy, during February 2010, Respondent shipped Tru-Valu 39,600 dosage units of oxycodone 30 mg and 7,200 dosage units of oxycodone 15 mg for a total of 46,800 du. GX 10F, at 1–2. Although the orders exceeded the CSL by nearly 22,000 du, Respondent did not report any of the orders as suspicious.

Even assuming that this figure became the new CSL for Tru-Valu's oxycodone orders (notwithstanding Respondent's failure to verify the legitimacy of the order), in March 2010, Tru-Valu again ordered in excess of the CSL. According to an entry dated March 15, 2010 in the Memo for Records, compliance ''requested UR for file to support this. Need site visit. RWR [release with reservation] until site visit completed.'' RX 2A, at 9. The Memo for Records includes a further note on this date stating: ''Increase in Business Due to Albertson's Closing.'' *Id.* However, while a UR was obtained for the month of February 2010, it was not obtained until April 1, 2010. *Id.; see also id.* at 47. Once again, there is no evidence that Respondent independently verified that the Albertson's had closed. *See generally* RX 2A. Respondent nonetheless shipped to Tru-Valu 43,200 du of oxycodone 30 and 12,000 du of oxycodone 15 for a total of 55,200 du. GX 10F, at 1–2.

An MFR entry dated March 31, 2010, states: ''Called to mention Oxy 15 need to be deleted. Pharmacy closed.'' RX 2A, at 9. While there is no evidence establishing the size of the oxycodone 15 order, as explained above, even assuming that the CSL had been raised to 46,800 as a result of Tru-Valu's February orders, its March orders again exceeded the CSL. Yet, here again, Respondent failed to comply with its policy by verifying the reason for the increase in the orders. Moreover, this order was not reported as suspicious.

In April 2010, Tru-Valu did not place any orders until April 27, when it ordered a total of 36,000 oxycodone 30 and 12,000 oxycodone 15. GX 15, at 112; GX 10F, at 1–2. While the orders were held for review by the SOMS (either because of frequency or pattern), because the orders were under the previous month's total of 55,200, Respondent did not deem the order to be excessive and filled the orders. GX 15, at 112 (SOMS notes). Respondent did not, however, contact the pharmacy and obtain an explanation for the order, which it independently verified.

On May 10, Tru-Valu ordered 12,000 du of oxycodone 30. GX 10F, at 1. A notation in the SOMS Notes states: ''Ok to ship first monthly purchase of Oxy leaves 13k.'' GX 15, at 112. Additional SOMS notes dated May 13 and 14 indicate that Tru-Valu placed additional orders on these dates and a notation made on the latter date states: ''RWR do nto [sic] ship over 25k without review by committee see mas and mfr.'' *Id.*

As for the MFR, it contains a handwritten note (of marginal legibility) dated May 14, which states ''increase on oxy—why orders increasing'' and that Tru-Valu's pharmacist had stated that H.D. Smith (another distributor) had ''cut back 60–70k'' and from ''40 bottles to 8 bottles'' a day, as well as a note that ''Started to cut back in March/Feb?'' RX 2A, at 7. The MFR note then states that Tru-Valu had ''purchased 120 bottles on 5–10–10'' and that there was a ''change in buy[ing] patterns due to HD Smith dropping allocation.'' *Id.* The entry continues with the following notation: ''RWR 120 bottles of oxy under CSL of 25 k. Don't ship over 25 k w/out rev @ 61k rolling 30 high due to pattern change due to allocation decreasing from wholesaler.'' *Id.*

However, here again, while the SOMS had placed the order on compliance hold, there is no evidence that Respondent's compliance department independently verified Tru-Valu's claim that H.D. Smith had reduced its allocation to the pharmacy. Nor did Respondent obtain a new UR. Moreover, three days later (May 17), Respondent filled an additional order and shipped 12,000 du of oxycodone 30 to Tru-Valu. GX 10F.

On May 18, Tru-Valu apparently placed a further order. GX 15, at 112. According to the Memo for Records, the order was ''deleted due to past 30 days @73k.'' RX 2A, at 7. Continuing, the entry states: ''Can place order after 5–27–10 Committee Rev.'' *Id.* However,

[29] The actual oxycodone orders placed by Tru-Valu (as opposed to the amount shipped) are not in the record. However, various entries in the Memo for Records and SOMS notes include notations as to the size of various orders.

while the order again placed Tru-Valu well over its CSL, the order was not reported to DEA as suspicious.[30]

On May 27, Tru-Valu placed additional orders for both oxycodone 30 and 15. GX 10F, at 1–2. According to the Memo for Records, Tru-Valu requested 12,000 du of oxycodone 15 in addition to 24,000 du of oxycodone 30. RX 2A, at 7. The Memo for Record further includes an illegible word (or two) followed by the words ''allotment 55,200—Current size in Soms is @24 k/can get 31,200 for current period.'' *Id.* Further notations on the same day indicate that Respondent talked to the pharmacist and that he requested that 72 bottles (of 100 du each) ''be sent from the Oxy 15's of 120.0 requested,'' *id.,* and other evidence shows that Respondent shipped 24,000 du of oxycodone 30 and 7,200 du of oxycodone 15 to Tru-Valu on this date. GX 10F, at 1–2.

Thus, during May, Respondent had shipped 65,200 du of oxycodone to Tru-Valu; it had also deleted the May 18 order, the size of which is unknown, and edited 4,800 du off the May 27 order. Yet even though the orders clearly exceeded the CSL and Respondent had never verified Tru-Valu's explanation, it did not report the orders as suspicious.

A note in the Memo for Records dated June 2, 2010, states that ''this account to be reviewed @25 Do not ship over 25 w/out committee review. . . . order on 5–27 was released w/out review by committee/management this was a mistake the account can not [sic] receive any more.'' *Id.* The Memo for Records includes a notation that the committee conducted its review the next day and determined that ''25k is place for review.'' *Id.* The notes also indicate that Tru-Valu was contacted and told that ''the account has received over allotment mistake both months'' followed by illegible writing. *Id.*

Notwithstanding the above entry, Respondent shipped 12,000 du of oxycodone 30 and 9600 du of oxycodone 15 to Tru-Valu on June 9, followed by an additional 12,000 du of oxycodone 30 on June 15, for a total of 33,600 du. GX 10F, at 1–2. The SOMS notes for both orders include notations to the effect: ''release with reservation per committee.'' GX 15, at 112. Here again, while the orders exceeded the CSL as determined by the committee, there is no evidence that Tru-Valu was contacted after it placed the June 15 order for 12,000 oxycodone 30. Nor did Respondent obtain a new UR. And Respondent did not report the orders as suspicious.

According to an email train, on June 21, Tru-Valu placed an additional order for 120 bottles of oxycodone 30. RX 95, at 2. Here again, this order placed Tru-Valu's orders over its oxycodone CSL. While the order was cancelled, apparently at the request of the PIC because insurance paid less than Respondent's price, *id.* at 1–2, it was not reported as suspicious even though it placed Tru-Valu's orders over its CSL.

Still later that month, the Memo for Records includes a note for June 30, with the entry: ''order deleted placed too early[.] See SOMs review of last 30 days.'' RX 2A, at 2. Here again, even assuming that Respondent contacted Tru-Valu regarding this order before deleting it, there is no documentation as to what the pharmacist may have told Respondent as to why he placed the order, and a new UR was not obtained.

Tru-Valu apparently resubmitted the order the following day (July 1), as Respondent shipped to it 13,200 du of oxycodone 30. GX 10F, at 1. After noting ''RWR'' (release with reservation), the SOMS note states: ''order for 132.0 bottles from 288 per may-30 on the pattern high of 46,800 rest of order can be resubmitted for review after 7/15/10.'' GX 15, at 112. However, on shipping the 132 bottles, Respondent had shipped 46,800 du of oxycodone on a rolling 30-day basis and Tru-Valu's orders totaled 62,400 du. Even assuming that the CSL was raised to 33,600 du from the 25,000 du level (discussed in the notes for the June 3rd committee review) based on Tru-Valu's June orders, there is no documentation that Respondent contacted Tru-Valu to obtain an explanation for the increase in its orders or that it verified Tru-Valu's previous assertion that H.D. Smith had reduced its allocation. Nor did it obtain a new UR. And it did not report the orders as suspicious.

On July 15, 2010, Tru-Valu apparently resubmitted the rest of its order as Respondent shipped 20,400 du of oxycodone 30 to it. GX 10F, at 1. The corresponding note states: ''ok to ship a total of 204 Oxy,[31] order was edited from 336 to 204 to meet csl of 33600.'' GX 15, at 112. Moreover, a note in the Memo for Records for this date states: ''Oxy CSL is @ 33,600 do not go over this amount w/o review.'' RX 2A, at 2.

Even assuming that Tru-Valu's oxycodone CSL had been raised to 33,600 du (and excluding the deleted June 30 order and the amount deleted from the July 1 order), Tru-Valu's July 2010 orders still totaled 46,800 du and thus exceeded the CSL. Yet Respondent again failed to obtain an explanation from Tru-Valu for why it was ordering the quantities that it was, and obviously, having failed to obtain an explanation, there was nothing to independently verify. Nor did Respondent obtain a new UR. And it failed to report the order as suspicious.

On August 2, Tru-Valu ordered and Respondent shipped to it 25,200 du of oxycodone 30 and 1,200 du of oxycodone 15. GX 10F. The same day, Respondent obtained a UR for the month of July, and on August 6, its inspector conducted a site visit. RX 2A, at 2.

According to the site visit report, Tru-Valu was a retail community pharmacy filling 200 prescriptions per day, of which 60 to 80 percent were controlled substances and ''60% of total'' were schedule II drugs. RX 2A, at 12, 18. Tru-Valu reported that H.D. Smith was its primary wholesaler and that Amerisource and Respondent were its secondary wholesalers. *Id.* at 18. While Respondent's inspector noted that Tru-Valu appeared to have ''a full selection of pharmaceuticals'' and an ''extensive selection of front store merchandise,'' he also wrote that the pharmacy was ''very busy'' with a ''long line of mostly younger people'' who were ''thin, tattooed, casually dressed,'' and that there were ''10 people'' and ''more coming in.'' *Id.* at 19. The inspector noted the time of his report as 2:44 p.m. *Id.*

The inspector further documented that the pharmacy had posted signs stating ''No insurance for: Oxycontin, oxy solution, [and] oxycodone by Mallinckrodt, Actavis.'' *Id.* at 20. The pharmacist on duty had only worked at Tru-Valu for two months and did not know why the signs were posted. *Id.* According to an MFR note, several weeks later, a member of Respondent's compliance department spoke with Tru-Valu's PIC, who stated that insurance did not reimburse at ''high enough'' rate ''to make up for the expense.'' *Id.; see also* RX 2A, at 2. The inspector also observed signs stating that there was a ''pill limit'' of 180 du on oxycodone 30 and 90 du on oxycodone 15, as well as a sign stating: ''must have recent MRI report.'' *Id.* However, in contrast to the questions about whether Tru-Valu accepted insurance on oxycodone

[30] According to the SOMS Appendix, ''[t]o determine if an order . . . is invalid for size, the system calculates the total number of doses invoiced in the past 30 days plus the total doses on open orders plus the number of doses on the received order and compares it to the monthly limit.'' RX 78, at 60. While this suggests that quantities that were edited downwards or deleted from an order were not counted in evaluating a new order, it also suggests that the entire quantity of a new order was to be considered in determining whether a new order exceeded the CSL.

[31] This is a reference to 100 du bottles.

prescriptions, there is no evidence that Respondent asked about the pill-limit signs or the MRI requirement.

A note in the margin next to the August 2 MFR entry, which is dated August 16, states that an order, the size of which is unclear, was deleted ''per review until [the] review completed.'' RX 2A, at 2. However, the order was not reported as suspicious.

While no additional oxycodone orders were filled during August, on September 1, Respondent shipped to Tru-Valu 24,000 du of oxycodone 30 and 2,400 du of oxycodone 15. GX 10F. An MFR note of the same date states: ''under compliance for [illegible] of site visit.'' RX 2A, at 2. A second entry of the same date memorializes a discussion with Tru-Valu's PIC regarding why he did not accept insurance on oxycodone with the further notation of ''RWR Orders pending.'' *Id.* However, there is no evidence that Respondent questioned Tru-Valu's PIC about the other observations recorded by its inspector, including the signs imposing pill limits on oxycodone and requiring that the patients have a recent MRI, or the long line of mostly younger people who were apparently filling their prescriptions and doing so in the middle of the afternoon.

On September 21, Respondent shipped 7,200 du of oxycodone 30 mg. GX 10F, at 1. The SOMS note for this dates states: ''oxy edited for csl on product.'' GX 15, at 113. Likewise, the MFR notes include the notation ''RWR'' and the statements: ''order edited from 264—72 per SOMS'' and ''Do not release any more product [illegible] reservations addressed.'' RX 2A, at 2. Here again, Tru-Valu's orders had totaled 52,800 du and exceeded the CSL, yet Respondent did not contact the pharmacy to obtain an explanation for the order and a new UR. Nor did it report the order as suspicious.

The next day, Respondent shipped an additional 13,200 du of oxycodone 30 to Tru-Valu. GX 10F. According to the MFR notes, on this day, Respondent contacted Tru-Valu's PIC to discuss the edit of his order and asked him if he got a lot of out-of-state customers. RX 2A, at 2. According to the notes, the PIC said: ''not any more since we stopped filling out of state scripts about a year ago.'' *Id.* Tru-Valu's PIC stated that he ''runs out of product'' and ''only fills for regulars,'' followed by the words ''in state customers w/Florida ID'' which is in clearly different handwriting.[32] *Id.* Respondent did not, however, obtain an explanation as to why Tru-Valu was running out of oxycodone product.

Additional notes for this date indicate that an account review was conducted, during which the compliance committee and Wayne Corona reviewed the site visit, the UR, and information about Tru-Valu's Web site.[33] *Id.* at 3. The MFR notes indicate that Corona directed that Tru-Valu be approved to increase its oxycodone purchases up ''to the pattern high of 46800 over the last 12 months.'' *Id.* at 2. Additional notes cryptically state: ''to pattern high of 46,800 less than 70% of UR[34] on fill with current allotment from Masters taken into consideration 46,800 42% of UR.'' *Id.* at 3. Respondent then approved the shipment of an additional 13,200 du of oxycodone 30 to Tru-Valu. *See id.* at 2–3; GX 10F, at 1.

Apparently, because Respondent had edited 19,200 du off the order Tru-Valu had placed the day before, the new order did not place Tru-Valu's orders over the new CSL of 46,800 du. Tru-Valu's file offers no explanation for why Corona disregarded the information as to the highly suspicious circumstances documented in the recent site visit report and the most recent UR. As for the latter, it showed that 18 of the top 20 drugs being dispensed were controlled substances, including 11 oxycodone products, three alprazolam products, two diazepam products, methadone, and dilaudid. Moreover, Tru-Valu's dispensings of oxycodone 30 mg products alone totaled 206,132 du and its dispensings of oxycodone 15 totaled 32,441 du. RX 2A, at 29–34. Thus, out of its total dispensings of 337,314 du, Tru-Valu's dispensings of oxycodone 30 alone comprised 61 percent of its dispensings of all prescription products, and its dispensings of both the 30 and 15 milligram dosages (which totaled 238,603 du) comprised nearly 71 percent of its total dispensings.

On October 1, 5, and 13, Respondent filled orders for oxycodone 30 in the amounts of 24,000 du, 14,400 du, and 6,000 du respectively; on October 1, it also filled an order for 2,400 du of oxycodone 15. GX 10F, at 2. Upon filling the October 5 order, Respondent had shipped 58,800 du on a rolling 30-day basis, thus exceeding the CSL of 46,800 du. Yet the only notation in the SOMS notes is ''RWR.'' GX 15, at 113. The order was not reported as suspicious.

A SOMS note of October 13, 2010 for an order placed the previous day states: ''order reviewed edited to 60 bottles to keep mfr csl of 46800.'' *Id.* Yet on filling the October 13 order, Respondent had actually shipped 64,800 du on a rolling 30-day basis. Here again, while Tru-Valu's filled orders exceeded the CSL by 18,000 du, there is no evidence that Respondent contacted Tru-Valu's PIC and asked why he was ordering in excess of this amount.[35]

On November 1, 2010, Tru-Valu placed orders, which Respondent filled, for 24,000 du of oxycodone 30 and 2,400 du oxycodone 15. GX 10F, at 2. Thereafter, on November 8, Tru-Valu placed additional orders, which Respondent filled, for 14,400 du of oxycodone 30. *Id.* A note dated November 9 states: ''CH Review Business Model Re-Review'' followed by the initials of JS. RX 2A, at 1. Notes dated November 10 state that the account was ''placed in non-control status permanently'' and that the ''account has been monitored closely on and off [compliance hold] monitoring business model'' and that ''the account was reviewed by'' the compliance committee, apparently after Respondent received a letter from Mallinckrodt (a manufacturer) raising ''concerns on the account.'' *Id.* An entry for the following day states that Tru-Valu was getting ''rebates'' from a ''buying group'' and that Ms. Seiple told the PIC that it was on non-controlled status. *Id; see also* GX 15, at 109.

There is no evidence that Respondent filled any more controlled substances thereafter. However, none of Tru-Valu's orders were ever reported as suspicious.

In her declaration, Ms. Seiple asserted that Tru-Valu's PIC explained that its ''business model included active marketing to various nearby pain clinics,'' and that he ''provided the names and DEA . . . numbers of the doctors writing prescriptions for patients of those clinics.'' RX 103, at 39. She then offered the conclusory assertion that ''[t]hese marketing efforts accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.'' *Id.*

[32] It is noted that the words ''a couple'' are written in the date column immediately preceding the words ''a year ago'' in the notes area of the MFR form, suggesting that these words were inserted after the initials of Mr. Corona and the words ''No Servicing Out of State.'' RX2A, at 2.

[33] There is no evidence that Tru-Valu was using its Web site to distribute controlled substances.

[34] A note on the previous page states: ''within parameters 70%.'' RX 2A, at 2.

[35] The records show that several weeks later, Respondent contacted Tru-Valu's PIC in response to his having placed orders for morphine and methadone for the ''first time . . . since 2009.'' RX 2A, at 1. The PIC stated that he ordered the drugs from Respondent because it had cheaper prices and Respondent obtained a new UR for the month of September 2010. *Id.* No explanation was offered as to why similar inquiries were not documented following the October 12 oxycodone order that took Tru-Valu over its limit.

Ms. Seiple further asserted that ''[a]fter Tru-Valu's account was approved, [Respondent's] SOMS system identified and held any order for controlled substances placed by Tru-Valu that deviated from its typical volume, pattern or frequency. All such orders were released only after review by [Respondent's] Compliance Department'' and that ''[o]n some occasions, the Compliance Department would request Tru-Valu to provide a UR as part of its review of orders that had been held.'' *Id.* Ms. Seiple's statement is misleading because the SOMS was not even in operation until August 2009.

Ms. Seiple further asserted that ''[a]s a result of our ongoing due diligence, [Respondent] was aware of the volume of oxycodone and other controlled drugs being dispensed by Tru-Valu, and the percentage of controlled drugs dispensed relative to other drugs. [Respondent] specifically investigated the reason why Tru-Valu's ordering and dispensings patterns were as indicated on the UR's.'' *Id.* at 40. She then asserted that ''[t]he UR's and other information provided by Tru-Valu were consistent with the pharmacy's business model as explained by [its PIC] and confirmed in the May 2008 site inspection. Tru-Valu appeared to be a full line pharmacy that was dispensing a large of variety of both controlled and non-controlled drugs, and that serviced the patients of several nearby pain management physicians.'' *Id.*

However, Tru-Valu had provided the names of only five pain management physicians. Moreover, while it dispensed a variety of non-controlled drugs, Ms. Seiple did not refute the DI's contention that ''oxycodone 30 [was] being dispensed in significantly larger volume than any other drug; [that] the majority of the top 20 drugs dispensed are controlled substances; [and that there was] an absence of more commonly dispensed drugs by a retail pharmacy.'' GX 49B, at 20–21.

Ms. Seiple further asserted that ''[b]ased on [Respondent's] extensive investigation, it determined that the orders it shipped to Tru-Valu were not suspicious.'' RX 103, at 41. Yet, as found above, Respondent repeatedly failed to comply with its policies and procedures when reviewing those orders that were held.

Finally, Ms. Seiple declared that she was concerned that during the August 6, 2010 site visit, Respondent's inspector had observed a sign stating that Tru-Valu did not accept insurance for oxycodone products manufactured by Mallinckrodt or Actavis. *Id.* Ms. Seiple stated that the PIC explained that because he ''had received insurance cards'' from some patients who actually did not ''have current valid insurance coverage'' and ''was concerned that if [he] submitted invalid claims, it would jeopardize [his] relationship with insurers.'' *Id.* According to Ms. Seiple, the PIC stated that ''he placed the sign to try and limit the number of new patients who attempted to use insurance'' for oxycodone but that he did accept insurance for oxycodone from those patients he knew had valid insurance. *Id.*

Yet this story was inconsistent with the PIC's previous explanation that the reason for the sign was that insurance did not pay enough. And even if the PIC's subsequent explanation was true, Ms. Seiple did not address why she did not find it concerning that the inspector had reported that the pharmacy had also posted signs stating that there was a pill limit of 180 du of oxycodone 30 (and 90 du of oxycodone 15) and that the patients ''must have a recent MRI report.'' Nor did Ms. Seiple address why she did not find it concerning that the inspector found the pharmacy was ''very busy'' with ''a long line of mostly younger people'' who were ''thin, tattooed, [and] casually dressed.'' Notably, even after the concerns raised during this site visit, Respondent continued filling Tru-Valu's orders for another three months and did not report a single order to DEA as suspicious.

The Drug Shoppe

According to Respondent's due diligence file, The Drug Shoppe is a retail or community pharmacy located in Tampa, Florida. RX 2B, at 27, 126. While it is unclear when The Drug Shoppe first began purchasing controlled substances from Respondent, the due diligence file includes a Dunn and Bradstreet Report dated March 28, 2008, along with printouts of the same date showing that Respondent verified that it had a valid Florida pharmacy license and DEA registration, and that its PIC had a valid pharmacist's license. *Id.* at 121–39.

The file also includes a Schedule Drug Limit Increase Request Form dated March 28, 2008 and a Due Diligence Report Form dated Mar 31, 2008. *Id.* at 120, 126–27. The Drug Limit Increase form shows that The Drug Shoppe was seeking an increase in solid dose oxycodone and noted that its monthly usage in February and March was ''323–192.'' *Id.* at 120. The form also includes the notation: ''CSOS Report Over Limit.'' *Id.* While the form includes a section in which the account manager could check various exemptions that a customer could qualify for, such as its having been a long-term customer (*i.e.,* more than one year), none of the exemptions was checked. *Id.*

The Due Diligence Report noted that The Drug Shoppe had a daily script average of 150, that 40 percent of the prescriptions were for controlled substances, that 20 percent of the prescriptions were for schedule II drugs, and that 70 percent of the prescriptions were paid by insurance. *Id.* at 126. The Report also stated that The Drug Shoppe prevented doctor shopping by verifying prescriptions and that its PIC knew ''most of his patients,'' that its PIC knew the doctors and that ''most are anesthesiologists,'' and that it was located ''next to [sic] hospital.'' *Id.* According to the form, the PIC had refused to fill a prescription for several reasons, including that a prescription was for ''too high Qtys.'' *Id.* at 127.[36]

On April 15, 2008, the Account Manager completed a second Drug Limit Increase Request, again indicating that The Drug Shoppe was seeking an increase in solid dose oxycodone, solid dose hydrocodone, and alprazolam. *Id.* at 119. A note on this form indicates that Respondent had ''already received'' a UR for ''all items . . . they fill.'' *Id.*

The UR, which covered the month of February 2008, showed that The Drug Shoppe dispensed 181 prescriptions totaling 38,689 du of oxycodone 30, for an average quantity of 214 du per prescription.[37] *Id.* at 214–15. It also showed that the pharmacy had dispensed 43 prescriptions totaling 8,239 du of oxycodone 15, for an average quantity of 192 du per prescription. The Drug Shoppe dispensed more than 56,600 du of oxycodone products (including Endocet) out of its dispensings of all prescription products, which totaled 165,068 du. *Id.* at 209, 214–15, 218.

The next day, Matt Harmon sent an email to The Drug Shoppe informing it that Respondent had reviewed its account and was increasing its ''purchase limit of Oxycodone solid dose products to 25,000 doses (pills) per calendar month.'' *Id.* at 219. While Respondent held off on The Drug Shoppe's requests to increase its hydrocodone and alprazolam purchases, it approved the oxycodone increase before it had even inspected the pharmacy.

[36] The Drug Shoppe's PIC also stated that he did not fill if a refill was ''too early,'' if he did not know the doctor and could not get hold of the doctor, and if a patient ''ha[d] been to too many docs.'' RX 2B, at 127. He also represented that he checked the doctor's license, and if a doctor was ''more than 20 miles away [he] will visit, call or not fill.'' *Id.*

[37] This total includes a 240 du prescription for Roxicodone 30 mg, a branded drug. RX 2B, at 215.

On April 28, 2008, Respondent's consultant conducted a site visit and determined that the pharmacy was a compounding pharmacy. *Id.* at 27. While the pharmacy reported that it did not engage in internet business, it acknowledged filling prescriptions for five pain management doctors, whose names were listed on the evaluation form; however, there is no evidence that Respondent verified that these physicians were properly licensed and registered, let alone whether they held any specialty training or board certification in pain management. *Id.* at 27–30.

According to the report, the pharmacy did not service nursing homes, hospice programs, or inpatient facilities. *Id.* at 29. The pharmacy reported that it filled 100 prescriptions per day, of which 50 percent were for controlled substances, and that cash and insurance each comprised 50 percent of the payments it received. *Id.*

Respondent's consultant reported that The Drug Shoppe ''appears to be a very professionally run pharmacy,'' which took ''exceptional care in secure storage of [its] controlled substances inventory.'' *Id.* at 30. The consultant further noted the PIC's complaint that he was ''finding it hard to fill some of the prescriptions presented because of the limitation placed on the quantities he can purchase.'' *Id.* at 30–31. The consultant also obtained a copy of the pharmacy's most recent state inspection report, which showed no violations. *Id.* at 32.

On or about August 14, 2008, Respondent approved an increase in The Drug Shoppe's oxycodone purchasing limit from 25,000 to 50,000 du.[38] *Id.* at 115. Notes on a form entitled ''Limit Increase Request Conclusion'' state: ''Previously raised to 25k. Clean license. Satisfactory visit by L. Fisher,'' who was Respondent's consultant. *Id.*

In April 2009, Respondent shipped to The Drug Shoppe 43,000 du of oxycodone 30; 10,800 oxycodone 15; 600 du of Endocet 10/650; 600 du of oxycodone/apap 10/325; and 200 du of oxycodone/apap 5/325, for a total of 55,200 du. GX 10F, at 29–33. Notwithstanding that The Drug Shoppe's purchasing limit was still set at 50,000 du for all oxycodone products, Respondent's records contain no documentation as to why it was allowed to exceed its purchasing limit.

While in both May and June 2009, Respondent's shipments of oxycodone to The Drug Shoppe did not exceed the 50,000 du purchasing limit, in July it shipped 60,000 du of oxycodone 30; 1,000 du of Endocet 10; and 1,000 du of Endocet 5 for a total of 62,000 du. *See id.* The Drug Shoppe's due diligence file contains no explanation for why it was allowed to exceed the purported purchasing limit.

On or about July 14, 2009, Respondent obtained a new UR from The Drug Shoppe, which covered the period of May 14 through July 14, 2009. *Id.* at 148–204. Oxycodone 30 mg was the number one drug dispensed. *Id.* at 148. Indeed, the UR showed that The Drug Shoppe had dispensed 595 prescriptions of oxycodone 30 totaling 105,570 du, for an average of 52,785 du per month and an average prescription size of 177 du. *Id.* at 148 & 161. While The Drug Shoppe dispensed only 54 oxycodone 15 prescriptions totaling 9,360 du (an average of 4,680 per month), the average prescription size was 173 du. *Id.* at 149–50. Including all formulations of oxycodone, Respondent dispensed more than 136,400 du or 68,200 du per month.[39]

A Ship to Memo note dated July 28, 2009 states: ''increase accepted from 50k to 62k on oxy.'' GX 16, at 221. There is, however, no further documentation explaining the justification for the increase. During the month of July 2009, Respondent shipped 60,000 du of oxycodone 30 as well as 2,000 du of combination oxycodone products to The Drug Shoppe. GX 10F, at 29, 31–33.

During August 2009, Respondent shipped to The Drug Shoppe a total of 60,500 du of oxycodone 30, as well as 1,000 du of Endocet 10/325 and 500 du of oxycodone/apap 5 mg. *See id.* However, while the total monthly shipments did not exceed the recently approved 62,000 du limit, the SOMS had gone into effect on August 1 and on several occasions during the month, The Drug Shoppe's orders exceeded the CSL on a rolling 30-day basis.

For example, on August 13, Respondent filled an order for 1,000 du of Endocet 10/325, thus placing The Drug Shoppe's total of filled orders at 62,500 du on a rolling 30-day basis.[40] Although the SOMS was supposed to place an order on hold even if it exceeded the CSL by a single dosage unit and thus trigger the requirements that the Compliance Department obtain an explanation for the order, which was independently verified, as well as that it obtain a new UR, the only notation in Respondent's file states: ''ok to ship within current limit.'' GX 16, at 234.

An entry dated August 20, 2009 in the Memo for Records notes: ''order deleted over current limit compliance review[.] Hold for review.'' RX 2B, at 4. A subsequent entry for the same day states: ''Requested Review of Disc Docs and File.'' *Id.*

The next day, Respondent shipped 19,500 du of oxycodone 30 to the Drug Shoppe. GX 10F, at 29. Of note, on a rolling 30-day basis, The Drug Shoppe's orders totaled 74,000 du of oxycodone, with 72,500 du being for 30 mg tablets.[41]

An MFR entry of the same date states: ''Request Update Survey,'' ''U/R Looks Strong + Voluminous,'' ''OK TO 62,000—oxy family,'' ''HIV,'' ''Large # RX's For HIV Disease State,'' ''Methadone Ok'd @10k.'' RX 2B, at 4. Unexplained is how it was ''ok to 62,000'' when, with this order, The Drug Shoppe was over its CSL by more than 12,000 du. Also, notwithstanding Respondents' representation (to the DI only days before) that its policy required it to independently verify the information it obtained from its customers, there is no evidence that Respondent did so with respect to The Drug Shoppe's claim that a large number of the prescriptions were for HIV patients.[42]

In September 2009, Respondent shipped an additional 62,000 dosage units of oxycodone 30 mg. However, on each occasion on which the orders were shipped, The Drug Shoppe's orders exceeded the 62,000 CSL by a wide

[38] The document also indicates that Respondent set The Drug Shoppe's purchasing limit for hydrocodone and alprazolam at 25,000 du for each drug. RX 2B, at 115.

[39] As for other formulations, the UR showed that The Drug Shoppe dispensed 2,843 du of OxyContin 80; 600 du of OxyContin 60; 3,394 du of OxyContin 40; and 480 du of OxyContin 20. RX 2B, at 148–205. It also dispensed 8,886 du of oxycodone/acetaminophen (apap) 10/325; 2,320 du of oxycodone/apap 10/650; 2,031 du of oxycodone/apap 5/325; and 950 du of oxycodone 5 mg. *Id.*

[40] The total includes orders for oxycodone 30 in the following amounts and on the following dates: 8,000 du on July 16; 12,000 du on July 28; 20,000 du on Aug. 3; 20,000 du on Aug. 7; 1,000 du on Aug. 10; it also includes orders for 500 du of Endocet 5 on Aug. 6; and 1,000 du of Endocet 10 on Aug. 13. GX 10F, at 29, 32–33.

[41] The total includes orders for oxycodone 30 in the following amounts: 12,000 du on July 28; 20,000 du on Aug. 3; 20,000 du on Aug. 7; 1,000 du on Aug. 10; 19,500 on Aug. 21; it also includes orders for 500 du of Endocet 5 on August 6 and 1,000 du of Endocet 10 on Aug. 13. GX 10F, at 29, 32–33.

[42] The file includes a due diligence survey of the same date. According to the survey, The Drug Shoppe reported that it filled 160 prescriptions per day, of which 60 percent were controlled and 40 percent were schedule II drugs. RX 2B, at 6. The Drug Shoppe asserted that it declined 20 prescriptions a day, and that in ensuring that the doctors were exercising proper standards of care, it looked at the age of its patients, talked to the doctor, and asked about the kind of pain and reason. *Id.* The Drug Shoppe also asserted that it had stopped filling prescriptions for a certain physician because the doctor was ''writing too much pain med or staff gives run around.'' *Id.* However, the size of the oxycodone 30 prescriptions that The Drug Shoppe was fillings begs the question of what quantity was ''too much.''

margin. Specifically, on September 1, Respondent filled an order for 17,500 du of oxycodone 30, bringing the total of the filled orders to 79,500 du.[43] GX 10F, at 29; 32–33. The only note pertaining to the order is a SOMS note indicating that Ms. Seiple released the order, the reason being: ''shipping under current limit of 175 bottles.'' GX 16, at 234. Despite the representations Respondent made to DEA regarding its policy for reviewing those orders held by the SOMS, there is no evidence that it contacted The Drug Shoppe and obtained an explanation for the order and a new UR. Nor did it report the order as suspicious.

Two days later, Respondent shipped 15,000 du of oxycodone 30; with this shipment, The Drug Shoppe's filled orders totaled 74,500 du on a rolling 30-day basis.[44] GX 10F, at 29, 32–33. There are SOMS notes corresponding to two orders on this date: The first, entered by Ms. Seiple, states: ''shipping with reservation review with wayne''; the second, entered by Mr. Schulze, states: ''ok to ship under current size limit.'' GX 16, at 234. However, here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order and a new UR. Nor did it report the order as suspicious.

On September 8, Respondent shipped another 15,000 du of oxycodone 30; with this shipment, The Drug Shoppe's filled orders totaled 69,000 du on a rolling 30-day basis.[45] GX 10F, at 29, 32. A SOMS note corresponding to this date indicates that Ms. Seiple approved an order and states: ''ok to ship see UR on miox.'' [46] GX 16, at 234. Here again, there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order and a new UR. Nor did it report the order as suspicious.

On September 16, Respondent shipped another 14,500 du of oxycodone 30; with this shipment, The Drug Shoppe's filled orders totaled 81,500 du on a rolling 30-day basis.[47] A SOMS note of this date states: ''ok to ship at current limit this order is 62k.'' GX 16, at 235. Unexplained is how The Drug Shoppe's order placed it at its current limit when its orders exceeded the CSL by 19,500 du. And here again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order and a new UR. Nor did it report the order as suspicious.

In October, Respondent shipped to The Drug Shoppe 55,200 du of oxycodone 30 mg; 3,600 du of oxycodone 15 mg; 600 oxycodone 20 mg; and 2,600 du of combination oxycodone products for a total of 62,000 du. GX 10F, at 29, 31–33. None of the orders placed The Drug Shoppe over its CSL.

On November 9, Respondent shipped to The Drug Shoppe 14,400 du of oxycodone 30 and 1,000 du of oxycodone 10/325. Thus, on a rolling 30-day basis, Respondent had filled orders totaling 74,700 du.[48]

An MFR entry dated November 9 states: ''update UR last on file w 5/09'' and ''called to get updated UR.'' Further notes state: ''Per Jen ship w/reservation'' and ''still need UR for future orders.'' RX 2B, at 4; *see also* GX 16, at 236 (SOMS note: ''Ship update reservation getting an updated ur'').

The next day, Respondent obtained a UR for the month of October 2009. *Id.; see also id.* at 72–80, 140–146. However, the UR listed the drugs in alphabetical order (rather than the drugs by the quantity dispensed) and did not provide a figure for the pharmacy's total dispensings. *See id.* Moreover, there is no evidence that Respondent obtained an explanation for the order from The Drug Shoppe.

As for the UR, it showed that The Drug Shoppe had dispensed 357 prescriptions totaling 66,271 du of oxycodone 30 (for an average of 186 du per prescription) and 33 prescriptions totaling 4,997 du of oxycodone 15 (for an average of 151 du per prescriptions). *Id.* at 141–42. The UR also showed that The Drug Shoppe had dispensed 4,208 du of various formulations of OxyContin and extended release oxycodone,[49] as well as 480 du of oxycodone 5mg and 4,650 du of combination oxycodone drugs (including Endocet), for a total of 80,606 du of oxycodone products. *Id.* at 77, 142.

On November 16, Respondent filled an order for 2,400 du of oxycodone 30; upon filling the order, Respondent had shipped 63,900 du of oxycodone on a rolling 30-day basis, thus placing The Drug Shoppe's orders over the CSL.[50] GX 10F, at 29. The corresponding SOMS note states: ''ok to ship w/reservation oxy within size for period. Current site visit needed.'' GX 16, at 237. There is, however, no evidence that Respondent contacted the pharmacy and obtained an explanation for the order.

The next day, Respondent filled orders for 2,400 du of oxycodone 30; 2,400 du of oxycodone 15; 1,200 du of oxycodone 10/325; and 500 du of oxycodone 5/325. GX 10F, at 29, 32–33. Upon filling the orders, Respondent had shipped 70,400 du of oxycodone to The Drug Shoppe on a rolling 30-day basis, again placing its orders over the CSL.[51]

A SOMS note for this date states: ''ok to ship oxy within size for period see mfr.'' GX 16, at 237; *see also* RX 2B, at 4. (MFR note: ''ok to ship under current limit''). Here again, it is unexplained how this order could be deemed to be ''within size for period'' or ''under [the] current limit'' given Respondent's representation that the orders were reviewed on a rolling 30-day basis. Moreover, here again, there is no evidence that Respondent obtained an explanation for these orders from The Drug Shoppe. Nor did it report the orders as suspicious.

Yet, the next day (Nov. 18), Respondent shipped an additional 3,000 du of oxycodone 30 to The Drug Shoppe, thus bringing its rolling 30-day total to 73,400 du. GX 10F, at 30. The

[43] This total includes orders for oxycodone 30 in the following amounts: 20,000 du on Aug. 3; 20,000 du on Aug. 7; 1,000 du on Aug. 10; 19,500 du on Aug. 21; it also includes 500 du of Endocet 5 on Aug. 6 and 1,000 du of Endocet 10 on Aug. 13. GX 10F, at 29, 32–33.

[44] This total includes orders for oxycodone 30 in the following amounts: 20,000 du on Aug. 7; 1,000 du on Aug. 10; 19,500 du on Aug. 21; and 17,500 du on Sept. 1; it also includes 500 du of Endocet 5 on Aug. 6 and 1,000 du of Endocet 10 on Aug. 13. GX 10F, at 29, 32–33.

[45] This total includes orders for oxycodone 30 in the following amounts: 1,000 du on Aug. 10; 19,500 du on Aug. 21; 17,500 du on Sept. 1; and 15,000 du on Sept. 3; it also includes 1,000 du of Endocet 10 on Aug. 13. GX 10F, at 29, 32–33.

[46] The last four letters of this entry could also be ''mlox.'' GX 16, at 234. Regardless, Respondent's records contain no explanation for what either miox or mlox means.

[47] This total includes orders for oxycodone 30 in the following amounts: 19,500 du on Aug. 21; 17,500 du on Sept. 1; 15,000 du on Sept. 3; and 15,000 du on Sept. 8.

[48] This total includes orders for oxycodone 30 in the following amounts: 18,000 du on Oct. 12; 14,400 du on Oct. 20; 7,200 du on Oct. 23; and 14,400 du on Nov. 2; it also includes an order for 600 du of oxycodone 20 on Oct. 22; an order for 3,600 du of oxycodone 15 on Oct. 20; and orders for 300 and 800 du of Endocet 10 on Oct. 20 and 26. GX 10F, at 29, 33–33.

[49] This included 21 prescriptions totaling 2,078 du of OxyContin 80 mg (for an average quantity of 99 du per Rx), as well as 26 prescriptions totaling 1,590 du of OxyContin (and oxycodone er) 40 mg.

[50] This total includes orders for oxycodone 30 in the following amounts: 14,400 du on Oct. 20; 7,200 du on Oct. 23; 14,400 du on Nov. 2; 14,400 du on Nov. 9; 2,400 du on Nov. 12; and 2,400 du on Nov. 13. It also includes an order for 600 du of oxycodone 20 on Oct. 22; an order for 3,600 du of oxycodone 15 on Oct. 20; orders for 300 and 800 du of Endocet 10 on Oct. 20 and 26; and an order for 1,000 du of oxycodone/apap 10/325 on Nov. 9. GX 10F, at 29, 32–33.

[51] This total includes orders for oxycodone 30 in the following amounts: 14,400 du on Oct. 20; 7,200 du on Oct. 23; 14,400 du on Nov. 2; 14,400 du on Nov. 9; 2,400 du on Nov. 12; 2,400 du on Nov.13; and 2,400 du on Nov. 16. It also includes an order for 600 du of oxycodone 20 on Oct. 22; an order for 3,600 du of oxycodone 15 on Oct. 20; orders for 300 and 800 du of Endocet 10 on Oct. 20 and 26; and an order for 1,000 du of oxycodone/apap 10/325. GX 10F, at 29, 33–33.

corresponding SOMS note states: ''ok to ship, at 43,500 for this month, this order of 3,000 OXY puts them at their limit for the month.'' GX 16, at 237.

MFR notes state that on November 17, 2009, the committee reduced The Drug Shoppe's oxycodone CSL by 25 percent to 46,500 du. *Id.* at 3; GX 16, at 221 (Ship to Memo). However, here again, there is no explanation as to why Respondent ignored that The Drug Shoppe's orders exceeded the CSL on rolling 30-day basis by nearly 27,000 du and failed to obtain an explanation for the orders.

While during November 2009, Respondent limited its shipments of oxycodone to 46,500 du,[52] in December it shipped 58,600 du of oxycodone 30 mg, as well as 1,200 du of Endocet 10/325 and 200 du of oxycodone/apap 7.5/325, for a total of 60,000 du. GX 10F, at 30, 32–33. Indeed, as early as December 16, The Drug Shoppe's orders exceeded the new CSL on a rolling 30-day basis when Respondent filled an order for 12,000 du of oxycodone 30, thus bringing the total filled orders to 51,700 du.[53] GX 10F, at 29–33. The SOMS note for this order states: ''ok to ship-file current-oxy @42200 w/this order.'' GX 16, at 238. Here again, there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order. Nor did it obtain a UR for the month of November. And it did not report the order as suspicious.

An MFR note for Dec. 23 states: ''Order for 15,500 Oxy 30, already at their . . . CSL 46,500[.] Called to let customer know order will be deleted, customer said that Rep said their allotment was at 62,000[.] Said that they will call their sales rep. Spoke to Laurie.'' RX 2B, at 3.[54] This order placed The Drug Shoppe's oxycodone orders at 62,000 on a rolling 30-day basis (as well as on a calendar-month basis) and thus exceeded the CSL.[55] Yet Respondent did not obtain a new UR.

Moreover, the next day, Respondent shipped 13,500 du of oxycodone 30 to The Drug Shoppe. GX 10F, at 30. On filling this order, Respondent had shipped 60,000 du of oxycodone since December 3, with the 30 mg dosage accounting for 58,600 du, and The Drug Shoppe had again exceeded the CSL. GX 10F, at 30, 32–33. The only SOMS note for December 24 does not even appear to pertain to the order as it states: ''ok to ship-hydro @7,700. for period with this order.'' GX 16, at 238. Consistent with the SOMS note, the Government's evidence shows that Respondent filled orders for 2,000 du of combination hydrocodone drugs on this date.[56] GX 10F, at 35.

Even assuming that Respondent relied on the explanation it had obtained the day before, the record is devoid of an explanation as to why the CSL was ignored and the order was shipped. And here again, Respondent did not obtain a new UR.

On nine occasions during January 2010, Respondent filled orders for oxycodone products, which repeatedly placed The Drug Shoppe's orders above the CSL of 46,500. Indeed, several of these orders even placed The Drug Shoppe above the previous CSL of 62,000 du. And as explained below, while on or about January 25, The Drug Shoppe's oxycodone CSL was raised to 60,000 du, GX 16, at 221; four days later, Respondent filled an order for 15,000 du of oxycodone, notwithstanding that the order placed its total shipments on a rolling 30-day basis at 75,000 du.

More specifically, on January 4, Respondent filled an order for 6,000 du of oxycodone 30, thus placing The Drug Shoppe's filled orders on a rolling 30-day basis at 61,200 DU. GX 10F, at 30. Yet the corresponding SOMS note merely states ''ok to ship—oxycodone @ 6k with this order.'' GX 16, at 238.

The next day, Respondent filled an order for 9,600 du of oxycodone 30, thus placing The Drug Shoppe's filled orders at 70,800 du on a rolling 30-day basis. GX 10F, at 30. While there are SOMS notes on this date for two orders, one stating ''ok to ship, under the CSL,'' the other ''ok to ship, frequency not excessive,'' what is clear[57] is that there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR.

On January 7, Respondent filled another order for 9,600 du of oxycodone 30 (and 100 du of Endodan 4.8/325), thus placing The Drug Shoppe's filled orders at 69,500 du on a rolling 30-day basis. GX 10F, at 30, 34. Here again, there are SOMS notes for two orders on this date, both of which refer to oxycodone. The first states: ''ok to ship file current this order for Oxy puts them @25,200 for Jan.'' GX 16, at 239. The second note states: ''ok to ship-file current-oxycodone @15,700. w/this order for Jan-frequency @29/31.'' *Id.*

Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR.

On January 12, Respondent filled orders for 500 du of oxycodone 5 and 100 du of oxycodone 7.5/500, thus placing The Drug Shoppe's filled orders at 55,700 du on a rolling 30-day basis and above the 46,500 du CSL. GX 10F, at 33. A SOMS note dated Jan. 13, which appears to discuss the order, states: ''ok to ship under csl for oxy 25,900 as of 1/13/10.'' [58] Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR.

On January 13, 2010, Jeffrey Chase, an employee of Respondent, conducted a site visit at The Drug Shoppe. In multiple places on his reports, Mr. Chase noted that the pharmacy's dispensing ratio of controlled to non-controlled drugs was 40 percent for controlled drugs and that this was ''a little high.'' RX 2B, at 21, 24. While Mr. Chase noted that The Drug Shoppe ''appears to be a well run pharmacy,'' he recommended that ''we need a utilization report to compare to site visit.'' *Id.* at 21.

On January 20, Mr. Corona reviewed Mr. Chase's recommendation. *Id.* However, as the evidence shows, Respondent did not obtain a new UR for another five months. Nor did it compare the utilization report it had last obtained with The Drug Shoppe's representation as to its dispensing ratio, as recommended by Mr. Chase.

The day after the site visit, Respondent filled orders for 9,600 du of oxycodone and 1,000 du of oxycodone

[52] The shipments included 41,400 du of oxycodone 30; 2,400 du of oxycodone 15; 2,200 of oxycodone/apap 10/325; and 500 du of oxycodone/apap 5/325. GX 10F, at 29–33.

[53] The total includes orders for oxycodone 30 of 2,400 du on Nov. 17; 3,000 du on Nov. 18; 4,800 du on Dec. 3; 9,600 du on Dec. 8; 7,200 du on Dec. 10; 7,200 du on Dec. 11; and 12,000 du on Dec. 16. It also includes orders filled on Nov. 17 for 2,400 du of oxycodone 15; 500 du of oxycodone 5; and 1,200 du of oxycodone 10/325; and orders filled on Dec. 7 for 1,200 du of oxycodone 10/325 and 200 du of oxycodone 7.5/325. GX 10F, at 29–33.

[54] A later MFR entry of the same date states: ''Shipped w/reservation W OK. See email from Diane per Wayne.'' RX 2B, at 3. The due diligence file does not, however, contain the email and it is unclear whether this entry applies to this order or the order for 13,500 du of oxycodone 30 that shipped the following day.

[55] The total includes orders for oxycodone 30 of 4,800 du on Dec. 3; 9,600 du on Dec. 8; 7,200 du on Dec. 10; 7,200 du on Dec. 11; 12,000 du on Dec. 16; and 4,300 du on Dec. 17; it also includes orders filled on Dec. 7 for 1,200 du of oxycodone 10/325 and 200 du of oxycodone 7.5/325. GX 10F, at 29–33.

[56] There is a SOMS note for December 23, 2009 by Ms. Seiple, which states: ''shipping with reservation see mfr.'' GX 16, at 238.

[57] Neither of the notes identifies the drug that was ordered. *See* GX 16, at 238.

[58] While the dates of the order and the SOMS note do not match, this was not unusual. Moreover, The Drug Shoppe did not order any oxycodone on January 13, *see* GX 16, at 252 (showing that only non-controlled drugs ordered on this date); and the total referred to in the SOMS note of 25,900 equals the total of The Drug Shoppe's January oxycodone orders through that date.

10/325, thus bringing The Drug Shoppe's total of filled orders to 66,300 du on a rolling 30-day basis. GX 10F, at 30, 32. The SOMS note for the transaction states: ''ok to ship under csl for Oxy 36500 with this order frequency not excessive.'' GX 16, at 239. Of course, the order was not under the CSL, and here again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order or a new UR.

On January 18, Respondent filled an order for 9,600 du of oxycodone 30, and on January 19, it filled orders for 9,600 du of oxycodone 30, 900 du of oxycodone 10/325, and 500 du of oxycodone 5. GX 10F, at 30, 32–33. Upon Respondent's filling of the January 18 order, The Drug Shoppe's filled orders totaled 59,600 du, and upon its filling of the January 19 orders, The Drug Shoppe's filled orders totaled 70,600 du. Yet the SOMS note for the January 18 order states: ''ok to ship, under the CSL of 46,500 on Oxy, this order puts them at 46,100 for the month.'' GX 16, at 239. As for the January 19 orders, only one of the three SOMS entries contains a note and the name of a reviewing employee. The note states: ''ok to ship order reviewed by Jen.'' *Id.*

Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for either the January 18 or 19 orders. Nor did it obtain a new UR.

On January 23, The Drug Shoppe placed an order for 2,900 du of oxycodone 30 and on January 25, Respondent filled the order, thus placing The Drug Shoppe's total filled oxycodone orders at 60,000 du on a rolling 30-day basis.[59] GX 16, at 239; GX 10F, at 30. The SOMS note for the order states: ''ok to ship-oxycodone @60k for current period.'' GX 16, at 239.[60] A January 25 MFR entry notes that the ''oxycodone @57,100—requesting 2,900—more would place @60 k for period'' and that ''Per Jen Oxy @60k.'' RX 2B, at 3; *see also* GX 16, at 221 (Ship to Memo dated 1/25/10 with subject of ''oxycodone limit''; memo states ''currently set @60k for a period'').

Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR. Of further note, none of these documents contain any explanation for why Ms. Seiple approved the increase in the oxycodone CSL.

Notwithstanding the purportedly new oxycodone limit of 60,000 du, on January 29, Respondent shipped an additional 15,000 du of oxycodone 30 mg. Upon Respondent's filling of the order, The Drug Shoppe's filled orders totaled 75,000 du on a rolling 30-day (and monthly) basis. GX 10F, at 30–33.

An MFR note (date Jan. 29) acknowledged that The Drug Shoppe was ''already at 60 k this month need to review w/Jen.'' RX 2B, at 3. A note in the Ship to Memos (which is actually dated two days before the above note) states: ''OK to ship controls requested up to current UR if supported.'' GX 16, at 221. SOMS notes for two orders (which are dated January 29) and made by Ms. Seiple state: ''rele3ase [sic] order supported by ur plus 10% committee ok'' and ''release order supported by ur.'' GX 16, at 240. And an MFR note dated five days later (February 3), which bears Ms. Seiple's initials, states: ''Ship to UR per committee review per company policy.'' RX 2B, at 3. Here again, even though the order clearly placed The Drug Shoppe's orders over the new increased CSL, there is no evidence that Respondent contacted the pharmacy to obtain an explanation for why it needed still more oxycodone and to obtain a new UR.

On February 1, Respondent shipped 9,600 du of oxycodone to The Drug Shoppe. GX 10F, at 30. On filling the order, Respondent had shipped 84,600 du of oxycodone to The Drug Shoppe on a rolling 30-day basis and had thus exceeded the CSL, whether it was set at 60,000 du as per the January 25 note or based on the highest monthly total within the last six months, this being the January total of 75,000 du.

Yet the SOMS note for the order merely states: ''ok to ship jen reviewed 30 day rolling for oxy.'' GX 16, at 240. Here again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order and a new UR. Nor did Respondent report the order as suspicious.

The next day, Respondent shipped 2,400 du of oxycodone 15 to The Drug Shoppe, thus bringing the rolling 30-day total of the filled orders to 87,000 du. GX 10F, at 31. There are two SOMS notes which are potentially applicable to the order: One, by Ms. Seiple, stating ''release order within the csl,'' and the second, by Mr. Schultze, stating ''ok to ship frequency not excessive.'' GX 16, at 240. In any event, here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order and a new UR.

On February 13 (a Saturday), The Drug Shoppe placed an order for 12,000 du of oxycodone 30 and 600 du of oxycodone 10/325. GX 16, at 240; GX 10F, at 30, 32. On filling these orders (on February 15), Respondent had shipped 63,100 du of oxycodone to The Drug Shoppe on a rolling 30-day basis.

While it is unclear whether The Drug Shoppe's CSL was 60,000 du or 75,000 du, the orders were nonetheless held for review by the SOMS for some reason. GX 16, at 240. Two SOMS notes dated February 13, state: ''ok to ship oxy and methadone [sic] under csl'' and ''ok to ship with reservations.'' *Id.* As explained previously, Respondent's Policy 6.2 imposed the same obligations of obtaining an explanation for the order, which was then independently verified, and obtaining a new UR, regardless of the reason the order was held. *See* RX 78, at 32. Yet none of these steps were taken during the review of this order.

On February 18, Respondent shipped 9,600 du of oxycodone 30; 2,400 du of oxycodone 15; and 1,000 du of oxycodone 10/325. GX 10F, at 30–32. According to the SOMS notes, the order was held but subsequently released, the reason documented being: ''ok to ship oxy under csl and frequency not excessive.'' GX 16, at 240. Again, there is no evidence that Respondent contacted The Drug Shoppe and obtained a reason for the order. Nor did it obtain a new UR.

So too, on February 25, Respondent filled an order for 3,600 du of oxycodone 15. GX 10F, at 31. While the order was held by the SOMS, it was released with the following reasons provided: ''ok to ship frequency not excessive-oxycodone within csl for period.'' GX 16, at 241. Again, there is no evidence that Respondent contacted The Drug Shoppe and obtained a reason for the order. Nor did it obtain a new UR.

Likewise, through the ensuing months, The Drug Shoppe placed multiple orders for oxycodone products that were held by the SOMS. *See* GX 16, at 241. Even if these orders did not place The Drug Shoppe's orders over the CSL but were held because they were of either unusual frequency or unusual pattern, the evidence still shows that Respondent released numerous orders without having contacted The Drug Shoppe to obtain an explanation for the orders, which it then verified, and that it rarely obtained a new UR. *See* GX 16, at 241–42, 222–32.

In March, Respondent shipped 55,200 du of oxycodone 30 mg; 2,400 du of

[59] The order was apparently placed on a Saturday and not shipped until the following Monday.

[60] Through the first 25 days of January 2010, Respondent shipped orders totaling 56,900 du of oxycodone 30; 1,900 du of oxycodone/apap 10/325; 100 du of both Endocet 7.5/500 and Endodan; and 1,000 du of Endocet 5 mg, thus bringing its total shipments of oxycodone to The Drug Shoppe to 60,000 du. *See* GX 10F, at 30, 32–33.

oxycodone 15 mg; and 4,500 du of various oxycodone combination products, for a total of 62,100 du. GX 10F, at 30–34. Of note, a SOMS note dated March 22 (which corresponds to an order for 600 du of oxycodone 10/325) states: ''ok to ship, size not excessive on OXY, CSL is 46,500, this order is for 600. Putting them at 44700 for the month.'' GX 16, at 242.

And on March 30, Respondent filled an order for 16,800 du of oxycodone 30. GX 10F, at 30. On filling this order, Respondent had shipped 62,700 du of oxycodone on a rolling 30-day basis and thus The Drug Shoppe's orders exceeded both the CSL referred to in the March 22nd SOMS note and the CSL referred to in the January 25 Ship to Memos and MFR notes.[61] A SOMS note for the order states that it was released because ''ur on file supports oxy order.'' GX 16, at 222. However, the most recent UR was from October 2009. Moreover, once again, Respondent failed to contact The Drug Shoppe and inquire as to why it was ordering in excess of its CSL and obtain a new UR.

On four occasions in April, The Drug Shoppe's filled oxycodone orders exceeded 60,000 du on a rolling 30-day basis including April 2 (rolling total of 60,600 du); April 5 (rolling total 70,200 du); April 7 (rolling total 70,400 du); and April 9 (rolling total 67,500 du). SOMS notes indicate that several of these orders were held for review. GX 16, at 222. However, each order was released, with the reasons provided being that the order was ''within csl for period'' and/or ''frequency was not excessive.'' *Id.* Notably, notwithstanding that the orders were held, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order and a new UR.

Likewise, in May, The Drug Shoppe's filled oxycodone orders totaled 63,300 du (on May 7); 64,900 du (on May 18); 73,000 du (May 19); and 60,600 du (May 26) on a rolling 30-day basis. The MFRs contain a note dated May 7, 2010, after The Drug Shoppe had placed 4 orders, each for 9,600 du of oxycodone 30, within the first seven days of the month, apparently because this was an unusual pattern. *See* GX 10F, at 30. While Respondent contacted The Drug Shoppe and documented that it had not ordered for a week and a half because an employee named Laurie had been out for two weeks and was ''stocking back up,'' RX 2B, at 2; once again, Respondent did not obtain a UR. Yet the SOMS note for the order states: ''ok to ship UR supports Oxy order puts thm [sic] @39,500—5/7.''[62] GX 16, at 223. In total, during May 2010, Respondent shipped to The Drug Shoppe 57,600 du of oxycodone 30 mg; 1,200 du of oxycodone 15 mg; and 1,800 du of oxycodone combination products, for a total of 60,600 du. GX 10 F, at 30–33.

In June 2010, The Drug Shoppe placed orders for 9,600 du of oxycodone 30 mg on June 1, 3, 8, 14, and 15. GX 10, at 30; RX 2B, at 2. According to the MFR and SOMS notes, on June 15, 2010, an order for 96 bottles of oxycodone 30 mg was edited to 54 bottles and the ''difference of 42 bottles can be place[d] for review after June 20th.'' GX 16, at 225; *see also* RX 2B, at 2. As a result, The Drug Shoppe's oxycodone orders on a rolling 30-day basis totaled 67,600 du.[63] However, Respondent contacted The Drug Shoppe and obtained a UR for the month of May 2010. RX 2B, at 2.

The UR shows that during May 2010, The Drug Shoppe dispensed 316 prescriptions totaling 64,250 du of oxycodone 30 mg, an average of 203 du per prescription. RX 2B, at 66. As for oxycodone 15 mg, the UR showed that The Drug Shoppe dispensed 29 prescriptions totaling 3,524 du, an average of 121.5 du per prescription. *Id.* It also showed that The Drug Shoppe dispensed 18 prescriptions of oxycodone/apap 10/325 mg totaling 2,851 du, an average of 158 du per prescription. *Id.* at 60 & 66.

On June 25, Respondent shipped an additional 6,000 du of oxycodone 30 mg to The Drug Shoppe. GX 10F, at 30. Yet a SOMS note of the same date attributed to Ms. Seiple states: ''oxy edited to zero per csl and policy.'' GX 16, at 225. Respondent offered no evidence to explain this inconsistency.

Moreover, SOMS notes and an MFR note dated June 28 show that The Drug Shoppe placed an order for 3,600 du of oxycodone but that the order was deleted. *Id.; see also* RX 2B, at 2. A further entry in the MFR notes of the same date states: ''can place another order after 6/30/10.'' RX 2B, at 2. However, the order was not reported as suspicious. During the month of June 2010, Respondent shipped a total of 49,800 du of oxycodone 30 mg, 1,200 du of oxycodone 15 mg, and 1,500 du of combination oxycodone products, for a total 52,500 du. GX 10 F, at 30, 32–33.

In July 2010, Respondent shipped to The Drug Shoppe 9,600 du of oxycodone 30 mg on the 1st, 6th, 12th and 19th of the month, as well as 2,400 and 1,600 du of the same dosage on July 15th and July 26th. *Id.* at 30. According to a SOMS note dated July 19, The Drug Shoppe's oxycodone CSL was 42,420 du. GX 16, at 226. Yet as of July 19, Respondent had filled orders totaling 46,800 du of oxycodone 30 on a rolling 30-day basis, placing it over the CSL.[64] A further SOMS note dated July 26 states: ''rwr oxy edited to meet CSL for July.'' *Id.* Here again, there is no evidence that Respondent contacted The Drug Shoppe regarding either the July 19 or 26 orders or obtained a new UR. Nor did it report either order to DEA as suspicious.

In August 2010, Respondent shipped 40,000 du of oxycodone 30 mg, 2,400 oxycodone 15 mg, and 700 du of combination oxycodone products, totaling 43,100 du. Here again, on multiple occasions, The Drug Shoppe's oxycodone exceeded the CSL as referred to in the July 19 SOMS note. Specifically, on August 4, Respondent filed an order for 1,200 du of oxycodone 30, placing The Drug Shoppe's orders at 43,600 du on a rolling 30-day basis.[65] GX 10F, at 31. Yet a SOMS note of the same date establishes that the order was approved, the reason noted as ''oxy under csl.'' GX 16, at 227. Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR.

So too, on August 9, Respondent filled an order for 9,600 du, bringing The Drug Shoppe's total orders to

[61] There were several other instances in which The Drug Shoppe's orders on a rolling 30-day basis may have placed it over the CSL, including on March 11, 15, and 19, when the orders totaled 60,600 du, 60,900 du and 61,100 du. However, it remains unclear whether The Drug Shoppe's oxycodone CSL was set at 60,000 du, 75,000 du, or 46,500 du.

[62] As for the May 18 order (9,600 du of oxycodone 30 and 1,200 du of oxycodone 15, *see* GX 10F, at 30–31), there are three entries in the SOMS notes for this date, two of which contain the name of a reviewer and a notation. These notations simply state: ''Ok to ship under CSL'' and ''RELEASE ORDER SUPPORTED BY UR.'' GX 16, at 223. However, it is unclear which of the three entries pertain to this order.

There are two SOMS notes dated May 19, which correspond to shipments of 9,000 du of oxycodone 30 and 300 du of oxycodone 10/325. *See* GX 10F, at 30, 33. However, only one includes the name of the reviewer (J. Seiple); it states ''rwr.'' GX 16, at 224. So too, there are two entries dated May 26, but only one contains the name of a reviewer; it states ''ok to ship under CSL UR on File is from OCT.'' *Id.*

[63] This total includes orders for 9,600 du of oxycodone 30 on May 18 and 19, June 1, 3, 8, and 14, as well as orders for 9,000 du on May 19 and 600 du on May 26. GX 10F, at 30, 32–33. The total also includes orders for 1,200 du of oxycodone 15 on May 18 and June 1; orders for 400 and 600 Endocet 10/625 on May 17 and June 10; orders for 300 and 600 oxycodone/apap 10/325 on May 19 and June 1, and an order for 300 oxycodone 5/325 on June 10. *Id.*

[64] This includes the June 25 order for 6,000 du.

[65] On August 2, Respondent had filled an order for 9,600 du of oxycodone 30, which when added to the orders filled on July 6, 12, 15, 19, and 26, totaled 42,400 du. GX 10F, at 30–31. Thus, the Aug. 4 order placed The Drug Shoppe at 43,600 du on a rolling 30-day basis.

44,800 on a rolling 30-day basis.[66] GX 10F, at 31. The SOMS note for the order states: ''rwr Oxy within buying pattern leaves 20820.'' GX 16, at 227. Here again, there is no evidence that Respondent contacted The Drug Shoppe and obtained an explanation for the order. Nor did it obtain a new UR.

On August 23, Respondent filled orders for 8,400 du of oxycodone 30; 1,200 du of oxycodone 15; and 200 du of Endocet 7.5/500; the next day, it filled orders for 300 du of oxycodone 10/325 and 200 du of Endocet 7.5/500. GX 10F, at 31–33. On their respective dates, the orders placed The Drug Shoppe's orders at 44,200 and 44,700 du on a rolling 30-day basis.[67] A SOMS note for August 23 states: ''oxy at 42,400 as of 8/20/10—at csl, need reviewed [sic] if order [sic] again'' and ''ok to ship, size not excessive on 2 ENDO 7.5/500 under CSL of 42420 this order puts them at 33000 for the month.'' GX 16, at 227.

A note in the MFR of the same date states: ''The UR Supports—Qty 60 Endo 7.5–500, Endo 10/325 = 2371, Oxy 15mg 3404, Oxy 30 61285 mal + Oxy 30mg Act—2965 totaling 70,085.'' RX 2B, at 1. A further note in the same entry states: ''CSL is already @42,600.'' However, as found above, The Drug Shoppe's August 23 orders placed it at 44,200 du, 1,800 du over its CSL, and its orders for the month were already nearly 10,000 du more than the 33,000 du figure used to justify shipping the orders.

As for the August 24 orders, the SOMS notes show that Ms. Seiple released the order. As for Ms. Seiple's reason, the SOMS note merely states: ''rwr.'' GX 16, at 227.[68] Yet for both days' orders, Respondent made no inquiry as to why The Drug Shoppe was ordering in excess of the CSL and a new UR (the UR in the file being three months old) was not obtained.

In September 2010, Respondent filled orders for 43,200 du of oxycodone 30 mg and 1,800 du of three oxycodone combination products, for a total of 45,000 du. GX 10F, at 31–33. Moreover, on each date during the month that Respondent filled The Drug Shoppe's oxycodone orders, The Drug Shoppe exceeded the CSL of 42,400 du that was documented in the SOMS and MFRs.

On September 1, Respondent filled orders for 9,600 du of oxycodone 30 and 300 du of oxycodone 10/325, placing The Drug Shoppe's orders on a rolling 30-day basis at 43,400 du. The next day, Respondent filled an order for 300 du of oxycodone 5, placing The Drug Shoppe's orders on a rolling 30-day basis at 43,700 du.[69] Both orders were released with reservation because the orders were ''within [the] monthly buying pattern.'' GX 16, at 228. However, in neither case did Respondent contact The Drug Shoppe and obtain an explanation for the order and a new UR.

On September 7, Respondent filled orders for 9,600 du of oxycodone 30; 600 du of oxycodone 10/325; and 200 du of oxycodone 7.5/325; bringing The Drug Shoppe's rolling 30-day total to 51,700 du. GX 10F, at 31, 33. Two SOMS notes of the same date made by Ms. Seiple state: ''rwr over 30 days under csl supported by u r dd complete'' and ''rwr.'' GX 16, at 228. However, with the order, The Drug Shoppe was more than 9,000 du over the CSL as documented in Respondent's records.[70] Moreover, Respondent had not obtained a new UR in three months, and there is no evidence that it contacted The Drug Shoppe and obtained an explanation for its order.

On September 13, Respondent filled another order for 9,600 du of oxycodone 30; this order brought The Drug Shoppe's rolling 30-day total to 52,100 du.[71] GX 10F, at 31. While the SOMS notes show that three orders were placed that day, only one of the orders lists the name of a reviewer, Ms. Seiple, who simply wrote ''rwr.'' GX 16, at 228. Again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order and a new UR. Nor did it report the order as suspicious.

So too, on September 20, Respondent filled an order for 9,600 du of oxycodone 30, bringing The Drug Shoppe's rolling 30-day total to 50,500 du, and on September 23, it filled an order for 4,800 du of oxycodone 30, bring The Drug Shoppe's rolling 30-day total to 55,300 du. GX 10F, at 31. While the SOMS notes include two entries for Sept. 20, only one of them lists the name of a reviewer, again Ms. Seiple, who wrote: ''rwr under csl.'' GX 16, at 228. Likewise, the SOMS entry for the September 23 order again lists Ms. Seiple as the reviewer and provides the reason as: ''rwr.'' [72] *Id.* Again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for either order and a new UR.[73] Nor did it report the orders as suspicious.

In October 2010, Respondent filled orders from The Drug Shoppe totaling 39,600 du of oxycodone 30 and 1,700 du of three oxycodone combination products, for a total of 41,300 du. GX 10F, at 31, 33–34. Here again, on four occasions, Respondent filled orders that placed The Drug Shoppe over the 42,420 du CSL.

Specifically, on October 4, Respondent filled an order for 9,600 du of oxycodone 30, bringing The Drug Shoppe's rolling 30-day total to 44,400 du. GX 10F, at 31, 33. While a SOMS note lists the name of the reviewer, it then merely states: ''oxy at 9600 10/4/10,'' ignoring that the order placed The Drug Shoppe over its CSL. GX 16, at 229.

On October 7, Respondent filled an order for 600 du of oxycodone 5, bringing The Drug Shoppe's rolling 30-day total to 45,000 du. GX 10 F, at 33. Here again, while the SOMS note shows that the order was reviewed, it then states: ''rwr Oxy within monthly buying pattern,'' ignoring that the order placed The Drug Shoppe over its CSL. GX 16, at 229.

On October 11 Respondent filled an order for 9,600 du of oxycodone 30, bringing The Drug Shoppe's rolling 30-day total to 43,800 du. GX 10F, at 31. While the SOMS notes show that the order was reviewed, it was released with the reviewer noting only that: ''oxy at 19800 as of 10/11/10,'' again ignoring that the order placed The Drug Shoppe over its CSL. GX 16, at 229.

On October 18, Respondent filled orders for 9,600 du of oxycodone 30 and 200 du of Endocet 10/650, bringing The Drug Shoppe's rolling 30-day total to 44,300 du and over the CSL. GX 10F, a 31–33. While both orders were reviewed, the reviewer simply noted ''oxy at 29700 10/18/10'' (upon review of the oxycodone 30 order) and ''oxy at 29900 2nd order today 10/18/10'' (upon

[66] This total includes the orders from July 12 forward, including an order for 1,200 du of oxycodone 30 placed on August 5.

[67] These totals include orders on August 16 for 9,600 du of oxycodone 30, and orders on August 18 for 400 du of oxycodone 30 and 1,200 du of oxycodone 15. GX 10F, at 31–32.

[68] According to Mr. Corona, if an order placed a customer even one pill over its CSL, the SOMS placed the order on hold and subjected it to review. Tr. 1000–01.

[69] These totals include orders for 1,200 du on Aug. 4 and 5; 9,600 du on Aug. 9 and 16; 400 du on Aug. 18; and 8,400 du on Aug. 23; it also includes orders for 1,200 du of oxycodone 15 on Aug. 18 and 23; 300 du of oxycodone 10/325 on Aug. 24; and 200 du of oxycodone 7.5/500 on Aug. 23 and 24. GX 10F, at 31–34. The total of the orders as of Sept. 2 includes the 9,600 du of oxycodone 30 and 300 du of oxycodone 10/325. *Id.*

[70] In addition to the previous references that the CSL had been set at 42,420 du, a SOMS entry for October 26 also states that the CSL was set at 42,420. GX 16, at 230.

[71] This total includes a Sept. 8 order for 400 du of oxycodone 10/325. GX 10F, at 33.

[72] While there is a second SOMS entry dated Sept. 23, the accompanying note shows that it was for ''[h]ydro'' and not oxycodone. GX 16, at 228.

[73] Of further note, there are no entries in either the Ship to Memos or the MFRs for any of September orders. *See* GX 16, at 221; RX 2B, at 1–2.

review of the Endocet order). GX 16, at 229.

Of note, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for any of these orders, let alone that it independently verified any such explanation. Nor, in reviewing these orders, did Respondent obtain a new UR.

During November, Respondent filled orders from The Drug Shoppe totaling 10,800 du of oxycodone 30 and 1,300 du of combination oxycodone products.[74] GX 10F, at 31, 33. To be sure, this marked a substantial decrease in the amount of oxycodone Respondent shipped to The Drug Shoppe.

However, on November 1, Respondent filled an order for 9,600 du of oxycodone 30, bringing The Drug Shoppe's total of filled orders to 50,900 du on a rolling 30-day basis.[75] GX 10F, at 31. While the SOMS note indicates that the order was reviewed, the reviewer released the order noting: ''ok to ship 96 OXY 30mg, order os within roling [sic] 30 day.'' GX 16, at 230. Here again, while the order exceeded the CSL, there is no evidence that Respondent obtained an explanation for the order and a new UR.

Likewise, on November 9, Respondent filled an order for 1,200 du of oxycodone 30, bringing The Drug Shoppe's total filled orders to 42,500 du on a rolling 30-day basis.[76] The order was released with the reviewer providing the following reason in the SOMS note: ''rwr Oxy order under last monthly purchse[sic] pattern leaves 29,900—11/9/10.'' GX 16, at 230. Here again, there is no evidence that Respondent contacted The Drug Shoppe to obtain an explanation for the order and a new UR.

On November 18, 2010, Respondent conducted another site visit. RX 2B, at 12. During the visit, Respondent's inspector was told by a pharmacy technician that The Drug Shoppe's PIC would be changing the following week. RX 2B, at 12. The inspector was also told that controlled drugs comprised 40 percent of the prescriptions the pharmacy filled and that 10 percent of its prescriptions were for any schedule II drug. *Id.* at 13. The inspector was further told that 85 percent of the controlled substance prescriptions were paid for with cash. *Id.*[77] Respondent did not, however, obtain a new UR (and had not obtained a new UR since June (for the month of May)) and would not obtain a new UR until December 15. RX 2B, at 1, 52. According to a note in the Ship to Memos, Respondent requested that The Drug Shoppe provide a UR for the month of October because of ''allocation issues in November for Oxy.'' GX 16, at 221.

The UR shows that during October, The Drug Shoppe dispensed 262 prescriptions totaling 49,637 du of oxycodone 30 mg, for an average of 189 du per prescription. RX 2B, at 46. Yet The Drug Shoppe's total dispensings of all drugs (including non-controlled) were 184,679 du. *Id.* at 51. Thus, oxycodone 30 mg alone comprised 27 percent of The Drug Shoppe's dispensings.

With respect to oxycodone 15 mg, the UR showed that The Drug Shoppe dispensed 21 prescriptions totaling 3,140 du of oxycodone (and Roxicodone) 15 mg, for an average of 149.5 du per prescription. *Id.* at 46, 48. In addition, the UR showed that The Drug Shoppe also dispensed 1,653 du of continuous release oxycodone products (*e.g.,* OxyContin), 3,171 du of combination oxycodone drugs, and 560 du of oxycodone 5 mg, for a total of 58,161 du, or more than 31 percent of its total dispensings.[78] RX 2B, at 39, 46.

Notwithstanding this information, during December 2010, Respondent shipped 24,400 du of oxycodone 30 and 2,000 du of oxycodone 15 mg, for a total of 26,400 du. GX 10F, at 31. Notably most of the orders were shipped on or after December 15, the date it received the UR. *Id.;* RX 2B, at 52.

In January 2011, Respondent shipped 17,000 du of oxycodone 30 mg, 2,700 du of oxycodone 15 mg, and 2,100 du of five combination oxycodone products. GX 10F, at 31–34. While an MFR note dated January 10, 2011, which is of marginal legibility, suggests that The Drug Shoppe was on CR (compliance review) ''for re-review,'' another note in the ''sign off'' column states ''RWR [release with reservation] until file reviewed [unintelligible].'' RX 2B, at 1.[79] Moreover, after January 11, Respondent filled orders for 12,000 du of oxycodone 30 and 1,200 du of oxycodone 15.

On February 8, 2011, Respondent filled orders from The Drug Shoppe for 3,000 du of oxycodone 30 mg; 900 du of oxycodone 15 mg; 200 du of oxycodone 5mg; and 800 du and 1,100 du of various oxycodone combination products. GX 10F, at 31–34. The same day, several DEA Diversion Investigators went to Respondent's Kemper Springs facility and requested The Drug Shoppe's file. RX 2B, at 1. While it is unclear whether the Investigators discussed with Respondent's staff that The Drug Shoppe had been issued an Order to Show Cause based on allegations that its owner and PIC (Bhupendra Agravat) had engaged in the unlawful distribution of controlled substances,[80] or that Mr. Agravat had recently agreed to settle the matter on the pharmacy's behalf by, in part, having no management, operational, or ownership interest in it, an MFR note states that ''file was reviewed/requested by DEA on 2/8/11'' and that ''the account was placed on NC [non-controlled] for review.'' RX 2B, at 1. A further MFR note states that during a phone call on February 10, Mr. Agravat admitted that during 2004–05, he was involved in distributing hydrocodone and Xanax over the internet but ''did not know [he] was being prosecuted by DEA.'' *Id.* Thereafter, Respondent finally terminated The Drug Shoppe as a controlled substance customer. *Id.*

On February 23, 2011, The Drug Shoppe placed an order for 500 du of alprazolam 2mg. GX 40, at 14. Respondent reported the order to DEA as suspicious. *Id.*

In her declaration, Ms. Seiple asserted that because The Drug Shoppe's PIC provided a written description of its policies and procedures to prevent diversion, Respondent's ''Compliance

[74] Evidence in the record suggests that the reduction in the orders Respondent filled during this month was ''due to allocation issues.'' GX 16, at 221. There is some evidence that late in a year, there could be a supply shortage of oxycodone.

[75] The total includes orders for 9,600 du of oxycodone 30 on Oct. 4, 11, 18, and 25, and an order for 1,200 du on Oct. 26; it also includes orders for 600 oxycodone 5 on Oct. 7; 200 du of Endocet 10/650 on Oct. 18; 600 du of oxycodone 10/325 on Oct. 25; and 300 du of oxycodone 5/325 on Oct. 13. GX 10F, at 31,33.

[76] The total included orders for 9,600 du of oxycodone 30 on Oct. 11, 18, 25, and Nov. 1, and 1,200 du of oxycodone 30 on Oct. 26. It also includes orders for 200 du and 300 du of Endocet 10/650 on Oct. 8 and Nov. 3 respectively; 600 du and 300 of oxycodone 10/325 on Oct. 25 and Nov. 3; and 300 du of oxycodone 5/325 on Oct. 13.

[77] Immediately following the inspector's report in the due diligence file is a page with the following handwritten notations: ''Assumption-,'' ''Comparisons of Business Norms,'' ''Patterns of Distribution,'' and ''compare like Nationally.'' RX 2B, at 15. However, the record does not establish who wrote the notations and his/her purpose in doing so.

[78] The October 2010 UR also showed that The Drug Shoppe had dispensed 9,697 tablets of methadone 10 mg, another schedule II drug. RX 2B, at 44.

[79] There is no corresponding entry in the SOMS notes for the same date. GX 16, at 232.

[80] The Show Cause Order issued to The Drug Shoppe alleged that: 1) Mr. Agravat had engaged in an unlawful internet distribution scheme by filling controlled substances prescriptions which violated 21 CFR 1306.04(a) because the physicians, who were located in different States than their patients, did not establish a valid doctor-patient relationship; 2) on May 22, 2009, Agravat had pled guilty in Arizona Superior Court to facilitation to commit the sale of narcotic drugs; and 3) Agravat had distributed 480 du of OxyContin to a single individual, by filling four prescriptions written in four different names, in exchange for $5,350. GX 17, at 10.

Department believed that Drug Shoppe understood its obligations to prevent diversion . . . and was taking affirmative steps to meet those obligations.'' RX 103, at 42–43. She further asserted that because its PIC told Respondent's consultant that its ''business model included filling prescriptions for a number of patients suffering from . . . HIV/AIDS[,] [t]his accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.'' *Id.* at 43. Yet Respondent simply accepted this assertion without any further inquiry into how many HIV/AIDS patients The Drug Shoppe was dispensing to, let alone how many of these patients were being prescribed oxycodone 30. Nor did she identify the other drugs which the HIV/AIDS patients, who filled their oxycodone prescriptions at The Drug Shoppe, were presumably taking, and compare the number of prescriptions for these drugs with the number of the oxycodone prescriptions.

Next, Ms. Seiple asserted that both a sales manager and sales representative ''were personally acquainted with Mr. Agravat (they referred to him as 'Boo') and vouched for his character and that of the pharmacy.'' *Id.* However, the fact that these two employees referred to Agravat by his nickname hardly establishes that they had sufficient personal knowledge to vouch for his character.

Ms. Seiple also asserted that ''[a]fter Drug Shoppe's account was approved, [Respondent's] SOMS . . . identified and held any order for controlled substances placed by Drug Shoppe that deviated from its typical volume, pattern or frequency'' and that ''[a]ll such orders were released only after review by [the] Compliance Department.'' *Id.* at 43–44. However, as found above, this statement is misleading as the SOMS did not become operational until August 2009, and during the period from April 1, 2009 through the date on which the SOMS became operational, Respondent shipped to The Drug Shoppe quantities that placed the pharmacy over its oxycodone purchasing limit and failed to document why it did so; it also did not report the orders as suspicious. Moreover, as found above, even after the SOMS became operational, on numerous occasions Respondent shipped oxycodone in quantities that placed The Drug Shoppe over the CSL and yet failed to obtain an explanation for the order from the pharmacy, which it then independently verified, and only rarely obtained URs, even though its Policy 6.2 required doing so on the review of each held order.

In her declaration, Ms. Seiple failed to specifically address the numerous instances in which the Compliance Department released orders which placed The Drug Shoppe over its CSL without obtaining an explanation (which was independently verified), as well as its repeated failure to obtain new URs. Instead, she offered only conclusory assertions to the effect that Respondent ''was aware of the volume of oxycodone and other controlled drugs being dispensed by Drug Shoppe, and the percentage of controlled drugs dispensed relative to other drugs,'' that it ''specifically investigated the reasons why Drug Shoppe's ordering and dispensing patterns were as indicated on the URs,'' and that ''[t]he URs and other information provided by Drug Shoppe were consistent with the pharmacy's business model as explained by Mr. Agravat and confirmed in the April 2008 site inspection.'' *Id.* at 44.

Addressing the January 2010 site visit, after which Mr. Chase noted that The Drug Shoppe's dispensing ratio of controlled to non-controlled drugs seemed ''a little high'' and recommended that a new UR be obtained, Ms. Seiple offered the unresponsive assertion that Respondent's policies and procedures ''do not specify any particular percentage of controlled . . . to non-controlled drugs that the Company considers 'high' or 'a little high.' '' *Id.* at 45. She then maintained that ''Mr. Chase did not recommend that [Respondent] stop selling controlled drugs to Drug Shoppe following his inspection,'' *Id.*, while entirely failing to address why Respondent ignored his recommendation to obtain a new UR and did not obtain a new UR until five months later. *Id.* at 46.

As for the circumstances surrounding the eventual termination of The Drug Shoppe, Ms. Seiple asserted that Respondent was unaware that Mr. Agravat had ''any drug-related criminal issues'' and believed that he left the country because he had a visa problem. *Id.* at 46–47. She stated that while Mr. Agravat had admitted (in 2008) that in 2006, he had been disciplined by the Florida Board of Pharmacy, he did not inform Respondent ''of any other criminal, regulatory, or disciplinary actions [including any action by DEA] taken against him or [The] Drug Shoppe,'' and that it was only in February 2011 that Agravat told Respondent ''that he was under investigation for issues relating to pharmaceutical sales on the internet that occurred in 2004 or 2005.'' *Id.* at 47. She further asserted that DEA does not publish information to the pharmaceutical industry regarding the issuance of Show Cause Orders. *Id.*

Even accepting that Respondent was unaware of the criminal case against Mr. Agravat until February 2011 and that the record does not establish the date on which he was charged by the State of Arizona, it is notable that, with the exception of the May 2008 site visit report, the various forms used by Respondent's employees and consultants in performing due diligence did not even contain a question as to whether the pharmacists had ever been criminally charged with offenses related to controlled substances. *See generally* RX 2B. Moreover, while the form used for the May 2008 site visit included a question which asked if ''any of the staff pharmacists'' had ever ''been criminally prosecuted[] or subjected to civil fines relative to the sale or dispensing of controlled substances,'' Respondent's consultant did not document an answer. *Id.* at 28. Yet there is no evidence that Respondent ever followed up on this omission.

Englewood Specialty Pharmacy

Englewood Specialty Pharmacy, which did business as Gulf Coast Pharmacy and was located in Port Charlotte, Florida, first became a customer of Respondent on January 29, 2008. RX 2C, at 71, 74. According to the due diligence file, the pharmacy, which had opened three years earlier, had begun ''as almost all compounding'' but had since become ''more of a retail pharmacy.'' *Id.* at 81. Printouts (dated March 14 & 17, 2008) in the due diligence file establish that Respondent verified the license and registration status of the pharmacy, as well as the license status of a pharmacist named Kevin Parkosewich. *Id.* at 86, 91–92. Of note, however, Respondent's ''DEA Schedule Orders—Due Diligence Report Form,'' which indicates that a review was done on March 17, 2008, lists one Dan Farris as the pharmacist and owner but there is no license verification for him in the due diligence file.[81] *Id.* at 81.

According to the Due Diligence Report Form, Englewood had requested an increase in its purchasing limits for hydrocodone and oxycodone. *Id.; see also id.* at 89. On the form, Englewood disclosed that its daily prescription average was 190, that 30 percent of the

[81] There is a license verification dated Sept. 8, 2008 for a Michael A. Farris, who was listed as the pharmacy ''prescription department manager'' on a Florida Department of Health Inspection Report dated August 30, 2007. RX 2C, at 74. The Report was signed, however, by ''D. Farris.'' *Id.*

prescriptions were for controlled drugs, and that 15 percent of the prescriptions were for schedule II drugs. *Id.* It also reported that 60 percent of its prescriptions were paid for by insurance and that they had a ''good relationship'' with a pain clinic doctor who was located ''across the street.'' *Id.* Englewood represented that to prevent doctor shopping it made ''sure the RX is valid''; that if a doctor was from outside the area, it called the doctor; and that it validated the doctors' DEA numbers. *Id.* at 82.

Respondent also obtained a UR showing Englewood's dispensings during the month of January 2008. RX 2C, at 129–162. The UR shows that Englewood had dispensed a total of 342,760 dosage units for all prescription drugs; this included 161,729 du of schedule II drugs; 19,953 du of schedule III drugs; 45,817 of schedule IV drugs; 2,518 du of schedule V drugs; and 112,743 du of non-controlled legend drugs. *See id.* at 131, 134, 137–38, 162. By dosage units, Englewood's controlled substance dispensings constituted 67 percent of its dispensings, and schedule II drugs comprised 47 percent of its total dispensings.[82]

The UR also showed the total number of prescriptions for each scheduled and legend drug. Specifically, it showed that the pharmacy had filled 1,286 schedule II Rxs, 208 schedule III Rxs, 513 schedule IV Rxs (after subtracting out carisoprodol), 11 schedule V Rxs, and 1,952 legend drug Rxs (including carisoprodol). Thus, the schedule II prescriptions actually comprised more than 32 percent, and all controlled substances comprised 51 percent of the total prescriptions dispensed, both figures being substantially larger than the figure reported by the PIC. Respondent nonetheless approved Englewood to purchase oxycodone, with documents suggesting that the amount was initially set at 250 bottles or 25,000 du per month. *Id.* at 87, 89.

A ''Schedule Drug Limit Increase Request'' form states that on September 3, 2008, Englewood requested that its oxycodone limit ''be bumped up to the next level.'' *Id.* According to the form, Englewood now reported that its monthly usage of oxycodone was 95,000 du. *Id.* According to a Due Diligence Report Form (dated September 8) which noted that Englewood had requested an increase for oxycodone, the pharmacy reported that it filled 220 prescriptions per day, of which 30 percent were controlled drugs and 20 percent were schedule II drugs. *Id.* at 71. Respondent again asked Englewood for information regarding its policies and procedures; in the words of Respondent's account manager, its owner/pharmacist ''basically sa[id] the same answers as before.'' *Id.* at 73. While Respondent re-verified Englewood's pharmacy license and DEA registration, as well as the pharmacists' licenses of Michael Farris and Kevin Parkosewich, it again failed to verify the license of Dan Farris, its owner and pharmacist-in-charge. *See generally* RX 2C.

On September 22, Respondent obtained a new UR from Englewood which listed the pharmacy's dispensings of all prescription products from March 1 through that morning. RX 2C, at 114–28. The report showed that during that period, Englewood dispensed 345,175 du of oxycodone 30, an average of 51,355 du per month, and 154,008 du of oxycodone 15, an average of 22,947 du per month.[83] The report also showed that Englewood dispensed 185,426 du of various dosage strengths of oxycodone continuous release drugs (including OxyContin), an average of 27,268 du per month. Finally, the report showed that Englewood dispensed 118,420 du of combination oxycodone products, an average of 17,645 du per month, as well as 27,768 du of oxycodone 10 mg and 5 mg, an average of 4,137 du per month. In total, Englewood dispensed 830,797 du of oxycodone during the period of the report, an average of 123,789 du per month. By contrast, even including Englewood's dispensings of carisoprodol (99,222 du) (which was then controlled in the State of Florida but not under the CSA) in calculating its dispensing of non-controlled prescription drugs, Englewood's dispensings of these drugs totaled only 556,938 du.

In total, Englewood's UR showed that it dispensed more than 1,280,332 du of schedule II drugs;[84] 400,581 du of schedule III through V drugs (excluding carisoprodol); and 2,238,571 du of all prescription drugs. Thus, schedule II drugs comprised a total of 57 percent of Englewood's total dispensings, and all controlled substances comprised 75 percent of its dispensings.

The UR also showed the number of prescriptions Englewood filled for each drug and provided a separate total for all schedule IIs (9,928 Rxs), all schedule III through V (6,724 Rxs), and Legend drugs (5,663 Rxs), for a total of 22,315 prescriptions. *Id.* at 122, 127, 128. Thus, schedule II prescriptions comprised 44.5 percent of all prescriptions, nearly three times what the PIC had reported during the initial due diligence survey. Moreover, even after subtracting out the 1,129 prescriptions for carisoprodol from the total for schedules III through V, *id.* at 114, 117; controlled substance prescriptions totaled 15,523 prescriptions and nearly 70 percent of all prescriptions, more than double the figure reported by the PIC.

On November 3, 2008, Respondent's consultant performed a site visit at Englewood. RX 2C, at 75. On his report, the consultant listed Dan Farris as the Pharmacist-in-Charge. *Id.* He also noted that the pharmacy filled 220 prescriptions per day, but did not service nursing homes, hospice programs or inpatient facilities. *Id.* at 77. He also noted that 25 percent of the prescriptions were for controlled substances, and that the pharmacy filled prescriptions for pain management clinics and listed the names of six pain management physicians. *Id.* at 77–78. While the consultant then wrote that Englewood was ''[a]djacent to 2 large hospitals and several buildings with doctors offices in them,'' and ''appears to be a busy prescription store,'' he further noted that ''*[h]e [the PIC] appears to be doing a larger narcotic business than he admits to.*'' *Id.* at 78 (emphasis added).

The due diligence file contains no evidence that Respondent did anything to address the consultant's observation, even though it had the UR. Nor does it contain any evidence that Respondent compared the prescription percentage reported by the consultant with the most recent UR. Instead, a notation on the Schedule Drug Limit Increase Request form from two months earlier indicates that on November 25, 2008, Respondent approved Englewood to purchase 50,000 du per month of oxycodone. *Id.* at 87. The due diligence

[82] On a Schedule Drug Limit Increase Request Form dated March 13, 2008, an account manager for Respondent noted that Englewood used 70,000 du of solid dose oxycodone per month. RX 2C, at 89. However, the data in the January 2008 UR show that the pharmacy was actually dispensing more than 102,000 du of all formulations of oxycodone, which included 39,469 du of oxycodone (and Roxicodone) 30; 17,303 du of oxycodone 15; 13,040 du of OxyContin 80 and 450 du of oxycodone 80 CR; 10,254 du of OxyContin 40; 2,725 du of oxycodone 5; 1,678 of oxycodone 20 CR; 880 du of OxyContin (and oxycodone CR) 10; 1,170 du of Endocet 10/650; 11,675 du of Endocet 10/325; 350 du of Endocet 7.5/500; 860 du of Endocet 7.5/325; and 2,447 du of Endocet 5/325, for a total of 102,301 du. RX 2C, at 129–31.

[83] The monthly averages were calculated by dividing 30.5 by the total number of days from March 1 through and including September 21 (205), and then multiplying this figure (.149) by the total dispensings.

[84] The UR for Englewood's schedule II dispensings lists the number of units dispensed as 128,033. RX 2C, at 122. As the first entry on the UR indicates that Englewood dispensed 183,154 du of methadone, *see id.* at 119, it is apparent that the total figure is in error and that the last digit was cut off.

file contains no documentation that Englewood's oxycodone purchasing limit was raised between this date and April 1, 2009.

However, in April 2009, Respondent filled multiple orders placed by Englewood for 71,900 du of oxycodone 30 and 8,400 du of oxycodone 15, for a total of 80,300 du of oxycodone. GX 10F, at 16–17. Notwithstanding that these orders (and in particular the April 29 order for 30,300 du) exceeded the purported oxycodone purchasing limit by more than 30,000 du, the due diligence file contains no explanation for why this order was approved. Moreover, the order was not reported as suspicious.

In May 2009, Respondent filled orders totaling for 50,000 du of oxycodone 30. GX 10F, at 16–17. However, on June 1, it filled an order for 50,000 du of oxycodone 30, and on June 11, it filled orders for 52,000 du of oxycodone 30, for a monthly total of 102,000 du. *Id.* at 17. Here again, notwithstanding that Englewood's June 11 orders placed it more than 50,000 du over (and at more than double) its oxycodone purchasing limit, the due diligence file contains no explanation as to why the June 11 orders were approved. And here again, the orders were not reported as suspicious.

On July 1, 2009, Respondent filled orders for 100,000 du of oxycodone 30, and 2,000 du of oxycodone 15, for a total of 102,000 du. *Id.* at 17. Again, Englewood's due diligence file contains no documentation explaining why these orders, which were more than double the oxycodone purchasing limit, were approved. And here again, the orders were not reported as suspicious.

On August 3, Respondent filled orders for 90,000 du of oxycodone 30 and 12,000 du of oxycodone 15, for a total of 102,000 du. *Id.* And on September 28, Respondent filled orders totaling 90,000 du of oxycodone 30 mg, as well as for 10,000 du of oxycodone 15, for a total of 100,000 du. *Id.* The SOMS notes indicate that neither set of orders were held for review. *See* GX 18, at 163.

An MFR note dated October 1, states: ''need updated UR report. [P]urchased 1000 pills in two days on CH. [Talked To] Michele K.[85] Will be purchasing Oct. 26th.'' RX 2C, at 4. And an MFR note dated October 5 states that Respondent contacted Englewood to request a UR, spoke with Dan (the PIC), and received a UR for the month of September later that day. *Id.*

The UR showed that during that month, Englewood dispensed a total of 302,459 du of schedule II drugs; 20,608 du of schedule III drugs; 52,283 du of schedule IV drugs (excluding carisoprodol); 1,480 du of schedule V drugs; and 112,947 du of non-controlled prescription drugs (including carisoprodol). RX 2C, at 43, 45, 48–49, 69. Of Englewood's total dispensings of 489,777 du, schedule II drugs comprised 62 percent and all controlled substances were 77 percent.

The UR further showed that during that month, Englewood dispensed a total of 123,476 du of oxycodone 30 mg; 26,097 du of oxycodone 15 mg; 41,619 du of various strengths of oxycodone extended release and OxyContin; and 21,485 du of other oxycodone drugs including oxycodone 5 mg (2,930 du) and combination drugs. *Id.* at 40, 42–43. Englewood's dispensings of oxycodone alone totaled 212,677 du, more than 43 percent of all dispensings.

As for the number of prescriptions, the UR showed that Englewood had dispensed 2,392 sch. II Rxs, 218 sch. III Rxs, 870 sch. IV Rxs (excluding carisoprodol), 9 sch.V Rxs, and 1,804 legend drug Rxs (including carisoprodol). Thus, the schedule II prescriptions alone accounted for 45 percent and all controlled substances were 66 percent of all prescriptions dispensed.

On October 8, Ms. Seiple spoke with Englewood's PIC who now claimed that his pharmacy was filling 250 to 300 prescriptions per day. GX 18, at 166. The PIC also claimed that his pharmacy was located ''in close proximity'' to two hospitals and that it got ''most of [its] business from pain clinics in the area,'' including a clinic which was ''lacated [sic] across the street.'' [86] *Id.* The PIC further stated that his methadone prescriptions ''range from 60–1000 pills per script'' and they averaged ''480–600 pills per script.'' *Id.*

Ms. Seiple also noted that ''[t]he account is showing usage of 150k oxy in month of September'' and that Englewood was also purchasing controlled substances from Amerisource Bergen. *Id.* Continuing, Ms. Seiple noted that her ''recommendation is to review [the] account and reduce limits . . . on these two products until committee review to 12k on methadone and 50k on oxy to contain purchasing.'' *Id.* Ms. Seiple also noted that Englewood's PIC had ''indicate[d] [that] he will be doin[sic] the bulk of his purchasing now at the end of the month to take advantage of the full 45 days.'' *Id.*

A handwritten MFR note by Ms. Seiple of the same date states: ''we need to override limits @ 12k methadone 500 on Oxy'' and ''very concerned w/ quantity dispensed per ur.'' RX 2C, at 4. Indeed, while Englewood's pharmacist had previously stated that the methadone prescriptions averaged 480–600 pills per script, the September UR showed that Englewood had dispensed 194 prescriptions totaling 50,004 du, an average of 258 du per prescription.

Yet there is no evidence that Respondent compared the PIC's statement with what the UR actually showed. This was just one of multiple times when Englewood's PIC had made false statements to Respondent's employees regarding his controlled substance dispensings, which could have been easily verified but were not.

According to the SOMS notes, on October 27, 2009, Englewood ordered 100,000 du of oxycodone 30 and 20,000 du of oxycodone 15; however, the order was held for review by the SOMS. GX 18, at 163. Notes in the MFR and Ship to Memos showed that the committee reviewed Englewood's account and approved the limits of 50,000 du of oxycodone and 12,000 du of methadone, which Ms. Seiple had previously imposed pending the review. *Id.; see also* RX 2C, at 4. A note in the MFR further shows that Respondent contacted Englewood's PIC and was made ''aware'' that his ''order was edited'' and ''[r]educed from 100k to 50k.'' RX 2C, at 4; *see also* GX 18, at 163 (SOMS note: ''order revised shipped 50k on oxy for the month edited order from 100k on oxy 30 and 15 mg edit from 20 to 0''). Respondent did not, however, report the order as suspicious.

On October 29, Respondent filled an order for 50,000 du of oxycodone 30. GX 10F, at 17. Respondent did not, however, report the order as suspicious.

In November, the compliance committee further reduced Englewood's oxycodone CSL from 50,000 to 37,500 du.[87] GX 18, at 166. Consistent with the new limit, on November 30, Respondent filled Englewood's order for 37,500 du of oxycodone 30. GX 10F, at 17; RX 2C, at 3.

[85] Various documents in the due diligence file list a Michelle Kostoff as Respondent's account manager for Englewood. RX 2C, at 84–85, 89.

[86] While at the Nov. 2008 site visit, Respondent's consultant had noted that Englewood was located ''adjacent'' to ''several buildings with doctors offices in them,'' he did not specify that there was a pain clinic across the street. RX 2C, at 78. Moreover, while Englewood's PIC attempted to justify the pharmacy's orders for narcotics by claiming that a pain clinic—which he named—was located across the street, there is no evidence that Respondent did anything to verify this statement.

[87] Entries in the MFR dated December 17 suggests that this reduction was not motivated by concern that Englewood was diverting the drugs but by Respondent's decision to ''allocate'' its supply of oxycodone because it had a reduced inventory. *See* RX 2C, at 3.

However, just three days later, Englewood placed an order for 50,000 du of oxycodone 30 and 24,000 du of methadone. RX 2C, at 3. An MFR note states that the oxycodone order was deleted because Englewood had ''just purchased'' on November 30 with the further notation of ''rolling 30.'' *Id.* The MFR notes further show that Ms. Seiple called the PIC and told him that the ''order was deleted'' and that orders for the account would not be filled until there was a review by the committee. *Id.*

Of further note, the MFR contains no reference as to the PIC's explanation for the order and a new UR was not obtained. Here again, the order was not reported as suspicious, even though the order placed Englewood's oxycodone orders on a rolling 30-day basis at 87,500 du, more than double its CSL.

On December 17, Englewood placed another order for 50,000 du of oxycodone and 24,000 du of methadone. RX 2C, at 3. While Wayne Corona directed that the orders not be filled because they exceeded Englewood's CSLs on a ''rolling 30'' day basis, the note further indicated that the committee would review the account after 12–21–09 and that Respondent ''only will allocate 37,500 oxy [and] 12k meth[adone] per committee review.'' *Id.* Continuing, the note states: ''get w/ Wayne to see if he wants to ship 37,500 or decrease,'' as well as ''see email to wayne'' and ''correspondence on account.'' *Id.* However, neither the email nor any ''correspondence on account'' is in the due diligence file submitted by Respondent.

A second entry for December 17 indicates that Ms. Seiple called Englewood's PIC and ''advised [that] order is not shipping'' and ''referred to'' their conversation of two weeks earlier. RX 2C, at 3. The PIC asked Ms. Seiple if an order placed on December 21 would be shipped and if he was ''guaranteed product this month.'' *Id.* Seiple noted that she referred to Respondent's ''script and reasoning on allocation in industry per training,'' and that after assuring the PIC that the decision ''was not personal,'' she told him that she would ''advise Michele [the account manager] to place [the] order on 12–21–09 for review.'' *Id.* A further note in the margin adjacent to this entry states: ''will be resubmitting if approved to ship only can have 375 of oxy 120 of meth.'' *Id.*

While the order clearly placed Englewood above its CSL, here again there is no evidence that Ms. Seiple asked its PIC why his pharmacy needed so much oxycodone 30. Nor did she obtain a new UR. Moreover, Respondent did not report the order as suspicious.

On December 28, 2009, the compliance committee conducted a new review and approved Englewood for an order of 50,000 oxycodone 30 and 24,000 methadone, which was shipped. RX 2C, at 2; *see also* GX 10F, at 17. The MFR note further states that Englewood was on the site visit list. RX 2C, at 2.

On January 12, 2010, Jeff Chase conducted a site visit at Englewood. *Id.* at 34–38. Mr. Chase noted that Dan Farris was the owner/PIC. *Id.* at 35. The form included the question: ''Has the Pharmacy, the PIC, or the owner ever had their DEA license, or any other license in any State, suspended, revoked, or disciplined?'' *Id.* Mr. Chase checked ''No.'' *Id.* However, once again, there is no evidence that Chase or anyone else at Respondent verified this information even though this could have been easily done by accessing the Florida Department of Health's Web page and had never been done with respect to the PIC.

Mr. Chase noted that Englewood filled an average of 265 prescriptions per day. *Id.* at 36. He then noted that ''40%'' were for any controlled substances—adding the comment ''A little high!''—and that ''25% were for schedule II drugs.'' *Id.*

In contrast to the PIC's representation in October that a pain management practice was located across the street, Mr. Chase noted that a ''G.P. Doctor [was] next door and a couple [of] pain clinics [were] in the area.'' *Id.* at 37. He also noted that there were ''two hospitals down the street.'' *Id.* However, no further information was documented as to how many controlled substance prescriptions issued by physicians at the hospitals were being filled at Englewood, nor the types of drugs involved in those prescriptions. While Mr. Chase further noted that pharmacy appeared to have a full selection of pharmaceuticals available, he also noted that it had a ''small selection of OTCs.'' *Id.*

As part of his visit, Mr. Chase also prepared a ''Site Visit Recommendation'' form. *Id.* at 34. While Mr. Chase indicated that the site visit was acceptable, he recommended that a new UR be requested. *Id.* Mr. Chase checked three reasons for his recommendation, noting that the pharmacy had ''Minimal OTCs,'' that controlled drugs were ''40%'' which was ''*a little high,*'' a point he reiterated under ''Other'' reasons. *Id.* (underlining in original). As to the latter, Mr. Chase wrote: ''This pharmacy appears to be a well ran [sic] pharmacy but is a *little high on CII–Vs!!* We need to get a Utilization Report & compare it to what was reported to site visit.'' *Id.* (underlining in original). The form bears the circled initial of ''W'' and the date ''1/20/10,'' *id.,* and an MFR note, which discusses the site visit, states that it was ''signed by Wayne.'' RX 2C, at 2.

However, here again, Mr. Chase's recommendation was disregarded. Instead, a new UR was not obtained until August 12, 2010. *See id.* at 2, 13.

On January 26, Respondent filled Englewood's order for 47,600 du of oxycodone 30 and 2,400 du of oxycodone 15. GX 10F, at 17. This order placed Englewood's total oxycodone orders at 100,000 du on a rolling 30-day basis and again exceeded the CSL (which, according to a Jan. 27 note by Ms. Seiple, was still set at 37,500 du). GX 18, at 163. Moreover, it was more than double the amount approved by the compliance committee in December. As for why the order was approved, an MFR note of the same date states: ''Ship per UR per Committee signed by Wayne.'' RX 2C, at 2.

The next day, Respondent filled Englewood's orders for an additional 20,000 du of oxycodone 30. GX 10F, at 17. Thus, with the order, Englewood's oxycodone orders on a rolling 30-day basis totaled 70,000 and again exceeded the CSL.

While the order was held, a SOMS note made by Ms. Seiple states: ''releasing order supported by ur csl 37500 on oxy committee ok 50k in dec and to ur in jan.'' GX 18, at 163. And a note in the Ship to Memos by Ms. Seiple states: ''per committee 50k in dec and ship to ur on 1/26/10. Order for 20k releasing on 1/27/10 month to date on oxy 70k.'' *Id.* at 167. *See also* RX 2C, at 2 (MFR note: ''Order for 20,000 Oxy 30 mg,'' ''Release order @50k w/order,'' and ''70k on the month for oxy'').

Here again, there is no evidence that Respondent contacted Englewood to obtain an explanation for the January 26 and 27 orders. And notwithstanding that: (1) It had not obtained a new UR in four months; (2) its inspector had recommended that it obtain a new UR; and (3) its policy required that it obtain a new UR whenever it reviewed an order held by the SOMS; Respondent still failed to obtain a new UR.

On February 25, Respondent filled Englewood's order for 50,000 du of oxycodone 30; the order placed Englewood's oxycodone orders at 70,000 du on a rolling 30-day basis. GX 10F, at 17. There are two SOMS notes of the same date, but neither specifically refers to oxycodone. The first establishes that an order was reviewed by Ms. Seiple, who released the order, because it was ''supported by ur.'' GX 18, at 164. The second shows that an order was reviewed by another

employee, who wrote: ''ok to ship all controls within csl for period.'' *Id.* However, as found above, the February 25 oxycodone order placed Englewood over its CSL.

The next day, Respondent filled Englewood's orders for another 14,000 du of oxycodone 30 and 6,000 du of oxycodone 15, again totaling 70,000 du on a rolling 30-day basis (as well as for the month). *Id.* A SOMS note dated Feb. 26, 2010 shows that Ms. Seiple released the order because it was ''supported by UR.'' GX 18, at 164.

Here again, there is no evidence that Respondent obtained an explanation from Englewood for either the Feb. 26 or 27 orders. Moreover, the last UR Respondent obtained was five months old.

In March, Respondent filled even larger orders for Englewood. Specifically, on March 17, it filled an order for 50,000 du of oxycodone 30, and on March 26, it filled an order for another 30,000 du of oxycodone 30. GX 10F, at 17. The March 17 order placed Englewood's oxycodone orders at 120,000 du on a rolling 30-day basis, and the March 26 order placed Englewood's oxycodone orders at 150,000 du on a rolling 30-day basis. *Id.*

A SOMS note shows that the March 17 order was released by Mr. Schulze, who noted: ''oxy supported by ur.'' GX 18, at 164. Likewise, Ms. Seiple released the March 26 order noting that it was ''supported by ur.'' *Id.* Notwithstanding that Englewood's orders exceeded the previously set CSL by a factor of three to four (and 82,500 and 112,500 du), Respondent did not contact the pharmacy and obtain an explanation for the orders. Nor did it obtain a new UR. And it did not report either order as suspicious.

On March 29, Respondent filled an order for 9,600 du of oxycodone 15, thus totaling 89,600 du for the month and again exceeding the CSL by more than 50,000 du.[88] GX 10F, at 17. *Id.* According to a SOMS note, the March 29 order was ''ok to ship-oxycodone ur supported increase for period.'' GX 18, at 164. Here again, Respondent failed to obtain an explanation for the order and a new UR. It also failed to report the order as suspicious.

On April 15, Respondent filled an order for 50,000 du of oxycodone 30, which according to the SOMS was approved because it was ''under [the] CSL.'' GX 18, at 164. Yet on placing the order, Englewood's oxycodone orders totaled 139,600 du on a rolling 30-day basis and thus clearly exceeded the CSL. Here again, there is no evidence that Respondent obtained an explanation for the order from the pharmacy and it did not report the order as suspicious.

Thereafter, on April 26, Englewood ordered an additional 30,000 du of oxycodone 30 and 10,000 du of oxycodone 15, placing its total orders at 99,600 du on a rolling 30-day basis. GX 10F, at 17; RX 2C, at 2. According to an MFR note, the order was released with ''reservation per committee'' as it was ''supported by [the] UR.'' RX 2C, at 2; *see also* GX 18, at 164 (SOMS note: ''order supported by ur per committee order is released see mfr''). Here again, there is no evidence that Respondent obtained an explanation for the order from the pharmacy and it did not report the order as suspicious.

On May 17, Englewood ordered 70,000 du (700 bottles) of oxycodone 30 mg. RX 2C, at 2; GX 18, at 164. The order (before it was edited) placed Englewood's oxycodone orders at 110,000 du on a rolling 30-day basis and well over its CSL. GX 10F, at 17. According to notes in the SOMS and MFRs, the order was edited from 700 bottles to 500 bottles ''due to [its] pattern and size.'' RX 2C, at 2; GX 18, at 164. While the MFR states ''[s]till only using Masters & ABC,'' it further states ''pattern & size was always 500 in middle of month.'' RX 2C, at 2. However, here again, even inferring that Respondent contacted Englewood to determine what distributors it was using, it did not obtain a new UR and failed to report the order as suspicious.

In addition to filling the above order at 50,000 du, on May 26, Respondent filled an order for an additional 30,000 du of oxycodone 30, and on May 28, it filled an order for an additional 10,000 du of oxycodone 30. GX 10F. These orders placed Englewood's oxycodone orders at 80,000 and 90,000 du on a rolling 30-day basis. Moreover, during the month, Respondent again shipped a total of 90,000 du of oxycodone to Englewood.

While there is a SOMS note dated May 26 by Ms. Seiple, which states ''release order under csl,'' it is unclear what Englewood's oxycodone CSL was at this point, and notes pertaining to the following month suggest that the CSL was considerably lower than 90,000 du. GX 18, at 164.

On June 25, Respondent shipped an order for 50,000 du of oxycodone 30, and on June 28, it shipped an additional 13,000 du of oxycodone 30 to Englewood. GX 10F, at 17. A SOMS note dated June 28, states: ''order edited from 400 bottles of oxy to 130 per csl.'' GX 18, at 164. Given that as of the June 28 order, the only other order that had been filled on a rolling 30-day basis was the June 25 order for 50,000 du, the SOMS note establishes that Englewood's oxycodone CSL was then set at 63,000 du. Yet this order was not reported as suspicious. Moreover, here again there is no evidence that Respondent obtained an explanation for the order and a new UR.

Moreover, a note made by Ms. Seiple in the Ship to Memos dated June 30 suggests that Englewood made an additional order for oxycodone two days later as it states: ''left a message for pharmacy recieved [sic] vm again orders for 96 each on oxy deleted at csl per policy[.] have been unable to get a hold of dan,'' the Owner/PIC. GX 18, at 167. Notwithstanding that Englewood had again ordered in excess of its CSL, Respondent again failed to report the order as suspicious.

On July 13, Respondent shipped an order for 50,000 du of oxycodone 30. GX 10F, at 17. This order brought the rolling 30-day total of Englewood's oxycodone orders to 113,000 du, nearly double its CSL.[89] A SOMS note of the same date shows that Ms. Seiple released the order, explaining that ''dan [the PIC] is not ordering allotment anymore at the end of the month was only doing so for 60 day billing.'' GX 18, at 164. It is unclear what to make of this given that the PIC had ordered large quantities of oxycodone (typically 50,000 du) on multiple occasions in the middle of the months of March, April, and May. *See* GX 10F, at 17. Moreover, the PIC subsequently continued to order substantial quantities (13,000 du) of oxycodone 30 towards the end of subsequent months, including on July 27. *See id.* And in any event, Ms. Seiple did not obtain a new UR and had not done so in nine months.

As for the latter order, a SOMS note dated July 26, which is the only order noted in the SOMS between July 16 and August 10, shows that Ms. Seiple reviewed the order. The note then states: ''rwr edit order 300 to 130.'' GX 18, at 164. As found above, Respondent had filled oxycodone 30 orders on June 28 for 13,000 du and on July 13 for 50,000 du. Thus, on placing the order, Englewood's orders totaled 93,000 du on a rolling 30-day basis.

Here again, even though the order clearly placed Englewood over its oxycodone CSL, Respondent did not obtain an explanation for the order or a

[88] Moreover, even on a calendar-month basis, Englewood's March orders were nearly 20,000 du greater than its February orders.

[89] As previously explained, this total does not include the 370 bottles (37,000 du) that were deleted from the June 28 order or the June 30 order for 96 bottles which was entirely deleted.

new UR. And it did not report the order as suspicious.

On August 10, Respondent shipped an order for 50,000 du of oxycodone 30. On a rolling 30-day basis, Englewood's orders (not counting what was deleted) totaled 113,000 du. A SOMS note by Ms. Seiple states: ''rwr pending updated ur.'' GX 18, at 164. Unexplained is why the order was released given that it: (1) Was now seven months since Mr. Chase had conducted his site visit, after which he warned that Englewood seemed ''a little high'' on its controlled substance dispensings, and recommended that a new UR be obtained, and (2) it was also ten months since Respondent had obtained the last UR. Moreover, the order was not reported as suspicious.

An MFR note made the next day states: ''compliance hold until ur updated provided.'' RX 2C, at 2. On August 11, Englewood provided Respondent with a UR for the month of July 2010. *Id.* at 13.

The UR showed that Englewood had dispensed 204,291 du of oxycodone 30 (including 80 du of Roxicodone 30) and 15,210 du of oxycodone 15 (including 60 du of Roxicodone 15) during the month. *Id.* at 13, 28–29. It also showed significant dispensings of other oxycodone products, as well as other schedule II drugs and schedule IV benzodiazepines.[90] Notably, Englewood's total dispensings of all prescriptions drugs totaled 519,071 du. *Id.* at 32. Moreover, with the exception of carisoprodol, each of the top ten drugs dispensed by quantity was an oxycodone product, methadone, or alprazolam, and of the top 20 drugs dispensed, the only other non-controlled drug was albuterol. *Id.* at 13.

Notwithstanding the information provided by the UR, on August 23, Respondent filled an additional order for 13,000 du of oxycodone 30. GX 10F, at 17. MFR notes of the same date state: ''250 oxy 30 mg currently at 50k[.] CSL is 63k,'' and ''Edited oxy from 250 to 130.'' RX 2C, at 1; *see also* GX 18, at 165 (SOMS notes entry dated Aug 23: ''order edited per mfr''). On a rolling 30-day basis, Englewood's orders totaled 88,000 du (25,000 du more than its CSL), and even after Ms. Seiple edited the order, Englewood's orders still exceeded its CSL by 13,000 du.

On September 10, Respondent filled an order for 50,000 du of oxycodone 30. GX 10F, at 17. While this order did not place Englewood over its CSL, a SOMS note establishes that on September 27, 2010, Englewood ordered an additional 18,000 du of oxycodone 30. GX 18, at 165. Ms. Seiple edited the order ''from 180 to 130 for csl on oxy,'' *id.,* and Respondent shipped 13,000 du to Englewood. GX 10F, at 17.

However, once again, Englewood had placed an order that exceeded its CSL, and once again, Respondent failed to obtain an explanation for the order and to report the order as suspicious.

The next day, Respondent filled orders for 1,200 du of oxycodone 20 mg and 600 du of oxycodone 10 mg, bringing its rolling 30-day total to 64,800 du and over its CSL. GX 10F, at 17. While the orders were held for review, the orders were released with the SOMS note stating: ''ok to ship with reservations [sic] first time purchase on Oxy since 2009.'' GX 18, at 165. Yet, as found above, Englewood had repeatedly purchased oxycodone from Respondent throughout 2010. Once again, Respondent did not obtain an explanation for the order and failed to report it as suspicious.

On October 6, 2010, Respondent performed another site visit at Englewood. RX 2C, at 5–7. According to the inspector's report, the PIC stated that he did not fill for out-of-state or out-of-area patients. *Id.* at 6. He also stated that 40 percent of the prescriptions it filled were for controlled substances, and 20 percent were for schedule II drugs. *Id.* at 6. After noting that the pharmacy had a ''small selection of OTCs,'' the inspector wrote the following:

> When I arrived I observed a man appearing to be in his mid 20's waiting in a KY licensed car in front of the store. While waiting I observed other men appearing to be in their late 20's to early 30's taking large trash bags out from the pharmacy to a dumpster. The men spoke to and went into the KY licensed vehicle. When leaving, I observed other men in their mid 30's in the pharmacy waiting area. A TN temporary licensed car was in the parking lot. There were no other businesses open near the pharmacy and open at that time. Front of store was designed more as a waiting room rather than a store front. Owner reported filling for patients from local Pain Clinic.

Id. at 7.

An MFR note of October 7 states that the ''site visit [was] questionable,'' that the account needed to be reviewed, and that it was placed on compliance hold based on ''suspicious activity outside of pharmacy.'' RX 2C, at 1. The noted further stated that the account was terminated, and that when the decision was communicated, Respondent PIC ''was upset'' and ''felt that [Respondent was] being a little harsh.'' *Id.*

Regarding Respondent's sales to Englewood, Ms. Seiple offered testimony similar to that which she offered with respect to the pharmacies previously discussed. For example, she asserted that because the PIC had provided copies of its policies and procedures for preventing diversion and described them to Respondent, the ''Compliance Department believed that Englewood understood its obligations to prevent . . . diversion . . . and was taking affirmative steps to meet those obligations.'' RX 103, at 48–49. She further asserted that ''before shipping any pharmaceutical products to Englewood, [Respondent] verified that its Florida pharmacy license and DEA registration were valid, current, and in good standing.'' *Id.* at 49. Yet Ms. Seiple made no claim that Respondent had verified the status of the PIC's license and there is no evidence that it ever did so.

Next, Ms. Seiple asserted that because during the 2008 site visit, the PIC ''explained that Englewood's business model included servicing patients from two large hospitals and a number of [nearby] physician offices,'' as well as ''patients from several nearby pain clinics[,] . . . this accounted for the volume of pain medications and other controlled substances, including oxycodone, being dispensed relative to other drugs.'' *Id.* at 49. However, hospitals usually have their own pharmacies and, in any event, a pharmacy's mere proximity to a hospital does not explain why the quantity of oxycodone 30 prescriptions being dispensed at Englewood dwarfed the quantity of the most commonly prescribed non-controlled prescription drugs, such as those used to treat high cholesterol, hypertension, or hypothyroidism. *See* RX 81 (showing top five prescription drugs from 2006 through 2010, which did not include oxycodone).[91] So too, a pharmacy's mere proximity to buildings with doctors' offices falls well short of what is necessary to explain why a pharmacy's dispensings of oxycodone

[90] As for other oxycodone products, Englewood dispensed 13,436 du of OxyContin 80; 7,266 du of OxyContin 40; 2,025 du of OxyContin 60; 800 du of OxyContin 30; 644 du of OxyContin 20; 70 du of OxyContin 10. *See* RX 2C, at 13–15, 28. It also dispensed 12,183 du of Endocet 10/325; 2,250 du of oxycodone 20; 710 du of Endocet 10/650; 594 du of oxycodone 5/325; 402 du of oxycodone 5; 140 du of oxycodone 7.5/500; 90 du of oxycodone 7.5/325; and 120 du of Endodan (oxycodone and aspirin). *See id.* at 13, 15–16, 18–19, 22, 24–25. Its total dispensings of oxycodone came to nearly 258,000 du.

It also dispensed 53,583 du of methadone 10 mg; 20,407 du of alprazolam 2 mg; and 9,899 of alprazolam1 mg. *See id.* at 13.

[91] As Respondent's Exhibit 81 shows, while combination hydrocodone drugs were the most frequently prescribed drugs during 2008 through 2010, the next most frequently prescribed drugs were non-controlled drugs including Lipitor (a statin), Simvastatin, Lisinopril, Levothyroxine, and Azithromycin.

30 prescriptions dwarf its dispensings of non-controlled prescription drugs.

While it is true that Respondent's consultant also obtained the names of six pain clinic doctors, two of these doctors were located in Sarasota, which is more than 47 miles from Port Charlotte.[92] *See http://maps.randmcnally.com/mileage-calcualtor.do.* Moreover, there is no evidence that Respondent verified the licensure and registration status of any of these doctors, let alone whether they had any specialty training or board certification in pain management.

Ms. Seiple further asserted that ''[a]fter Englewood's account was approved, [the] SOMS . . . identified and held any order for controlled substances placed by Englewood that deviated from its typical volume, pattern or frequency'' and that ''[a]ll such orders were released only after review by [the] Compliance Department.'' RX 103, at 49. As explained previously, this statement is misleading because the SOMS was not even operational until August 2009. Moreover, notably absent from this paragraph of Ms. Seiple's declaration is any claim that the Compliance Department's employees followed the policies and procedures which required contacting the pharmacy and obtaining a reason for why a held order exceeded the SOMS parameters, followed by independently verifying that reason. As found above, Respondent's Compliance Department repeatedly failed to comply with its policies and procedures.

While it is true that ''[o]n some occasions, the Compliance Department would request . . . a UR as part of its review of orders that had been held by the SOMS,'' the evidence shows that it obtained a new UR infrequently. As the evidence shows, after April 1, 2009, it did not obtain a new UR until October 5, 2009, at which point it had not obtained a new UR in more than a year, and it did not obtain the next UR until August 11, 2010, ten months later. Yet Respondent's policy required that it obtain a new UR whenever an order was held for review.

As for Ms. Seiple's assertions that Respondent ''specifically investigated the reasons why Englewood's ordering and dispensings patterns were as indicated on the URs'' and that ''[b]ased on [its] extensive investigation, it determined that the orders it shipped to Englewood were not suspicious,'' *id.* at 50–51, it did no such thing. As an example, during the initial site visit, Respondent's consultant wrote that ''[h]e [the PIC] appears to be doing a larger narcotic business than he admits to.'' RX 2C, at 78. In her declaration, Ms. Seiple offered no explanation as to what was done in response to this observation, and her assertion that ''the URs and other information provided by Englewood were consistent with the pharmacy's business model as explained by Mr. Farris and confirmed in the November 2008 site inspection'' is just one example as to how Respondent's Compliance Department simply accepted the inadequate explanations provided by its consultant and employees to support its continued selling of controlled substances to Englewood, while ignoring numerous red flags as to the legitimacy of the pharmacy's dispensings of controlled substances.

Ms. Seiple provided still another example of this in her discussion of the Compliance Department's response to the January 2010 site visit by Mr. Chase. As found above, following the visit, Mr. Chase recommended that Respondent obtain a new UR and compare it with Englewood's claim that 40 percent of the prescriptions it dispensed were for control substances, which in Mr. Chase's view, was ''a little high.'' Respondent did not, however, obtain a new UR in response to his recommendation and failed to obtain a new UR until August 11, some seven months later.

As with the pharmacies previously discussed, Ms. Seiple's explanation of this was that Respondent's policies and procedures did ''not specify any particular percentage of controlled drugs to non-controlled drugs that the Company considers 'high' or 'a little high,' '' and that ''Mr. Chase did not recommend that [Respondent] stop selling controlled drugs to Englewood following his inspection in January 2010.'' RX 103, at 51. Ms. Seiple's testimony fails to explain why the Compliance Department ignored Mr. Chase's recommendation to obtain a new UR and did not do so until seven months later.

While Ms. Seiple acknowledged that Respondent was aware of the volume of oxycodone and other controlled substances being dispensed and the percentage of controlled drugs being dispensed relative to other drugs, *id.* at 50, there is no evidence in the Englewood file that Respondent ever actually calculated the ratio of its dispensings of oxycodone and controlled substances to other drugs. *See generally* RX 2C. Indeed, throughout the course of its dealings with Englewood, its PIC repeatedly understated the level of its controlled substance (including its schedule II) dispensings and did so by a wide margin and Respondent was put on notice of this as early as the November 2008 site visit. RX 2C, at 78. The PIC's false statements as to the percentage levels of his controlled substances dispensings were another red flag that he was engaged in the diversion of controlled substances and the falsity of his representations could have been easily determined because the URs calculated the total number of prescriptions for each schedule of controlled substances and the non-controlled prescription drugs the pharmacy dispensed. Instead, Respondent's Compliance Department ignored available information (and failed to request information) which would have shown that the PIC was providing false information.

It is true that after the October 6, 2010 inspection, during which Respondent's inspector observed that Englewood's clientele included persons who were driving vehicles with Kentucky and Tennessee license plates and who were engaged in suspicious activity (and yet was told by the PIC that he did not fill for out-of-state patients), Respondent finally made the decision to terminate Englewood. However, Englewood had been purchasing controlled substances (including oxycodone) from Respondent for at least two years at this point and yet, only in the face of the above, did it finally stop selling controlled substances to Englewood. The evidence thus suggests that Respondent's Compliance Department was primarily concerned with justifying the continued sale of controlled substances and not with identifying those entities that were engaged in diversion. Moreover, Respondent did not file a single suspicious order report during the course of its dealings with Englewood.

City View Pharmacy

City View Pharmacy, a retail community pharmacy located in Orlando, Florida, opened in January 2005. RX 2D, at 74. While it is unclear when City View first became a controlled substance customer of Respondent, a Schedule Drug Limit Increase Request Form dated March 17, 2008, indicates that City View was seeking an increase in its purchasing limit for both alprazolam and solid dose oxycodone. *Id.* at 73. According to the form, City View was using 200 100-count bottles or 20,000 du of oxycodone per month. *Id.*

[92] Pursuant to 5 U.S.C. 556(e), I take official notice of the distance between Port Charlotte and Sarasota as determined by using the online Rand McNally mileage calculator. Pursuant to 21 CFR 1316.59(e), Respondent may dispute this finding by filing a properly supported motion no later than 10 days from the date of this Order.

After verifying that City View held a DEA registration and state license, on March 25, Respondent contacted City View and prepared a DEA Schedule Order-Due Diligence Report Form; it also obtained from City View a State Inspection Report and a UR. According to the Due Diligence Report Form, City View reported that it filled 80 prescriptions per day, that 60 percent of the prescriptions were for controlled drugs, and 40 percent were for schedule II drugs. *Id.* at 74. City View also reported that it accepted insurance and well as Medicare and Medicaid and that 80 percent of the prescriptions were paid for by insurance. *Id.* As for its policies and procedures, City View's pharmacist represented that to prevent doctor shopping, it worked ''mainly'' ''with three doctors,'' and that it ''call[ed] any new doctors.'' *Id.* As for how it ensured that doctors exercised proper standards of care, City View's pharmacist stated that he called a pain management clinic. *Id.* As for whether he had ever refused to fill a prescription, City View's pharmacist represented that he did so ''all the time'' as he required the patients to present a driver's license and would refuse to fill the prescriptions ''if they don't supply it.'' *Id.* at 75. Finally, City View's pharmacist represented that he refused prescriptions written by physicians who had problems with their DEA registrations or other disciplinary actions. *Id.*

The UR provided by City View covered the month of February 2008, and showed that the pharmacy had dispensed a total of 101,908 du of all prescription products. *Id.* at 100. The UR further showed that during the month, City View dispensed 150 prescriptions totaling 24,928 du of oxycodone 30, an average of 166 du per prescription. *Id.* at 97. It also showed that City View dispensed 20 prescriptions for 2,300 du of oxycodone 15, as well as 32 prescriptions totaling 3,525 du of Endocet 10/325.[93] *Id.* at 92, 97. In total, City View dispensed more than 36,000 du of oxycodone products (35.5 percent of all its dispensings), and its dispensings of oxycodone 30 alone accounted for more than 24 percent of its dispensings. Indeed, the UR showed that the next largest drugs dispensed were two other highly abused drugs: Alprazolam 2 mg (6,940 du), a schedule IV controlled substance, and carisoprodol 350 mg (5,609 du dispensed), a drug which was then controlled under Florida law and which has since been controlled under the CSA. *See id.* at 89, 91.

As found above, City View also provided Respondent with a copy of a Florida Department of Health inspection report dated November 29, 2006. *Id.* at 76. The Report identified multiple deficiencies, including that City View did not maintain ''[c]omplete pharmacy prescription records'' and the ''[p]rescription records did not identify the responsible dispensing pharmacist''; the pharmacist was not initialing the controlled substance prescriptions (as well as the refills) that were filled; DEA Schedule II order forms were not being properly completed; and several controlled substance prescriptions were missing required information such as the prescriber's name, address and DEA number as well as the patient's name and address. *Id.* at 76.

On June 25, Respondent's consultant conducted an onsite inspection of City View. *Id.* at 104. According to the consultant's report, City View represented that it had purchased drugs from five different distributors including Respondent during the past 24 months. *Id.* at 105. It also represented that it filled an average of 100 to 120 prescriptions per day, that 35–40 percent of the prescriptions were for controlled substances, and that only 20 percent of the prescriptions were paid for with cash. *Id.* at 106. It also acknowledged that it filled for pain management clinics and identified six physicians and their DEA numbers.[94] The consultant also reported that City View was located next door to the Police Department and that this ''does tend to keep some of the drug abusers away according to the pharmacist.'' *Id.* at 108.

Finally, the consultant noted that the pharmacy was willing to provide a copy of its most recent state inspection report, and a report dated May 1, 2008 is in the due diligence file. *Id.* at 105, 109. Notably, while the report showed that several of the deficiencies identified at the previous inspection had been corrected, City View's pharmacist was still not properly completing the Schedule II order forms. *Id.* at 109. Several weeks later, on July 1, 2008, Respondent approved City View to purchase 25,000 du of oxycodone per month. *Id.* at 73.[95]

In April 2009, Respondent filled orders placed by City View for 18,500 du of oxycodone 30 and 1,200 du of oxycodone 15, and in May, it filled orders for 24,000 du of oxycodone 30 and 1,000 du of oxycodone 15. GX 10F, at 3–4. In June, Respondent filled orders for 28,000 du of oxycodone 30 and 2,000 du of oxycodone 15 (as well as 200 oxycodone 80), followed by orders in July for 26,000 du of oxycodone 30; 3,000 du of oxycodone 15; 1,000 du of Endocet 10/325; and 300 du of oxycodone 80 mg. *Id.* at 3–5.

On August 3, 2009, Respondent filled orders placed by City View for 20,000 du of oxycodone 30, as well as 2,400 du of oxycodone 15. *Id.* at 3. A note in the Ship to Memos added by Ms. Seiple on August 5 states: ''8/3/09 please keep on hold until UR is received per file.'' GX 19, at 111. Of note, Respondent had not obtained a new UR since February 2008 and would not do so until October 5. RX 2D, at 5–6. Yet, on August 25—a week after it had presented its Policies and Procedures to the DIs—Respondent filled City View's order for an additional 7,600 oxycodone 30, GX 10F, at 3, bringing its total filled orders on a rolling 30-day basis to 33,000 du, even though it had not received a new UR.[96] According to a SOMS note for this order, the order was ''ok to ship'' because it was at City View's ''oxy limit for the month.'' GX 19, at 118.

Yet on September 1, 8, and 14, Respondent filled three separate orders by City View for 10,000 du of oxycodone 30, notwithstanding that Respondent had yet to receive a UR and the account was supposedly on hold. GX 10F, at 3. As for the September 1 order, it placed City View's oxycodone orders at 40,000 du on a rolling 30-day basis and thus over the previously noted limit. Yet the order was released by Ms. Seiple, who noted in the SOMS that it was ''under current limit.'' GX 19, at 118. And while it is clear that the order was held for review, there is no evidence that Respondent contacted City View and obtained an explanation for the order.

The September 8 order did not place City View over the CSL. However, with the September 14 order, City View's oxycodone orders totaled 37,600 du on

[93] As for other oxycodone products, the UR showed that City View dispensed 1,310 du of OxyContin (and generic OxyContin) 40 mg, 990 du of OxyContin (and generic OxyContin) 80 mg, 906 du of oxycodone 5 mg, 1,035 du of Endocet 5/325, 300 du of Endocet 10/650 mg, 240 du of OxyContin 20 mg, 210 du of Endocet 7.5/325 mg, 200 du of Endocet and generic oxycodone 7.5/500 mg, and 38 du of oxycodone/apap 5/500. RX 2D, at 92, 97.

[94] With respect to whether the pharmacy serviced nursing homes, hospices, and inpatient facilities, the consultant wrote the word ''pending'' next to each of these categories and did not identify a single such facility which City View actually serviced. RX 2D, at 106.

[95] A note on the Schedule Drug Limit Increase Request Form indicates that Respondent did not approve City View's request to purchase alprazolam because it was ''too new'' a customer. RX 2C, at 73. Unexplained is why City View was not too new a customer to purchase oxycodone.

[96] City View had placed an order for 3,000 du of oxycodone 30 on July 28, thus bringing the rolling 30-day total to 33,000 du. GX 10F, at 3.

a rolling 30-day basis. A SOMS note establishes that Ms. Seiple released the order and provided the following reason: ''ok to ship puts them at their current limit.'' GX 19, at 119. Here again, notwithstanding Respondent's purported policies and procedures, there is no indication that City View was contacted to provide an explanation for the order, which was then independently verified, and Respondent still had not obtained a new UR.

Moreover, according to an MFR noted dated September 23, City View placed an additional order for 10,000 du of oxycodone 30 mg which Respondent deleted. RX 2D, at 6. The note further states that City View's ''calendar limit [was] 30,000'' and that it had ''already received 37,600 within 30 days.'' *Id.*

A second MFR note of the same date shows that Ms. Seiple called City View's pharmacist a second time that day and that the pharmacist stated that he ''did not want the 100 bottles only [the] hydromorphone 8mg.'' *Id.* Ms. Seiple further documented that she ''tried to get info'' but the pharmacist said he had to go, and that after she ''asked him to call [her] back,'' the pharmacist said he would ''and hung up.'' *Id.* Ms. Seiple then documented that she had talked to Mr. Corona about the situation and was told to place City View ''on compliance hold.'' *Id.* The same day, Ms. Seiple also made a note in the Ship to Memos for the account, which states: ''Need to have an updated survey and UR before ordering any CONTROLS.'' GX 19, at 111. Yet the order was not reported as suspicious.

An MFR note dated September 28 made by Ms. Seiple again acknowledged that Respondent did not have a current UR on file. RX 2D, at 6. The note further states: ''put 1k pills for oxy back in today'' and refers to Ms. Seiple's having called another employee of Respondent, and that the employee was ''getting'' with City's View pharmacist. *Id.* According to a note made the next day, this order was placed on hold. *Id.* However, notwithstanding that City View was on compliance hold, on October 1—and before City View provided a new UR—Respondent filled an order for 2,000 tablets of hydrocodone/apap 10/500 mg. GX 10F, at 5. Moreover, there is no evidence that Respondent did a new due diligence survey.

The evidence also suggests that on or about October 1, City View placed an order for 10,000 du of oxycodone 30. Specifically, a Ship to Memo dated October 2, 2009 by Ms. Seiple states: ''TIL ur IS RECEIVED THE ORDER WAS DELETED FOR OXY 30 100 BOTTLES.'' GX 19, at 111; *see also* RX 2D, at 5 (MFR note dated October 1 noting that message was left for pharmacist ''to call me back need UR or order will not ship & will be deleted'').

On October 5, Respondent finally obtained a new UR from City View. RX 2D, at 5–6. The UR showed that during the month of September, City View dispensed 324 prescriptions totaling 47,472 du of oxycodone 30, an average of 146.5 du per prescription, as well as 30 prescriptions totaling 3,505 du of oxycodone 15, an average of 124 du per prescription. RX 2D, at 62–71. City View's dispensings of all prescription products totaled 116,180 du. Thus, oxycodone 30 alone comprised nearly 41 percent of City View's total dispensings. Moreover, the top ten drugs dispensed were comprised entirely of three oxycodone products (oxycodone 30, oxycodone 15, and 2,340 du of Endocet 10/325), four alprazolam products (9,722 du of four different manufacturers' version of 2 mg dosage and 1,230 du of one manufacturer's 1 mg tablet), carisoprodol 350 mg (5,124 tablets), and hydrocodone/apap 10/500 (2,423 tablets). *See id.*

A second MFR note dated October 5 states that Respondent was ''shipping 100 bottles'' and that the order had been put in the same day. RX 2D, at 5. The note further states: ''however, his limit is 30,000 current limit No.'' *Id.* A Ship to Memo note of the same date states: ''Released oxy order for 100 bottles based on UR and clean file.'' GX 19, at 111. Thereafter, Respondent filled additional orders by City View for 10,000 du of oxycodone 30 on both October 12 and 20. GX 10F, at 3.

On October 29, City View placed still another order for oxycodone 30 mg. GX 19, at 111; RX 2D, at 5. According to both the Ship to Memos and MFRs, City View's oxycodone order was edited off the order. *See id.* Ms. Seiple further noted that City View's oxycodone limit needed ''to be reviewed'' because the pharmacy ''only buys 30 mg Mall,'' [97] that the ''UR is 46k as of September,'' and added, ''decrease limit to 20k see Wayne.'' *See id.* However, the same entry then contains an additional note (in different color ink) that: ''No limit is 30k—please call,'' and further noted that an employee had spoken with City View's pharmacist and that oxycodone had been ''cut from order.'' RX 2D, at 5.

While it is unclear what the size of the order was, it is clear that the order would have placed City View's oxycodone orders over its 30,000 du CSL on a rolling 30-day basis. Yet Respondent did not report the order as suspicious.

On November 2 and 6, Respondent filled orders totaling 10,000 du of oxycodone 30 on each date. GX 10F at 3. Even ignoring the deleted order of Oct. 29, each of the orders placed City View's orders at 40,000 du on a rolling 30-day basis.

As for the November 2 order, a SOMS note made by Ms. Seiple states: ''ok to ship is provided non control business per committee limit 22500.'' GX 19, at 119. Entries in the MFRs and Ship to Memos show that on either November 3 or 4, the compliance committed had conducted a review and reduced City View's oxycodone limit by 25 percent to 22,500 du. RX 2D, at 5; GX 19, at 112. As for the November 6 order, the corresponding SOMS notes states: ''ok to ship oxycodone @20k with this order—within size for current period.'' GX 19, at 120. However, whether City View's oxycodone CSL was 22,500 du or 30,000 du, the orders clearly exceeded the CSL and yet there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the November 2 and 6 orders and a new UR. Nor did it report the orders as suspicious.

On November 16, City View placed an order for 10,000 du of oxycodone 30. *See* RX 2D, at 4 (MFR note: ''release 25 Qty. requested 100.0—limit of oxy @ 22,500''). While Respondent edited the order and only shipped 2,500 du, *id.,* the order still placed City View's orders at 40,000 du on a rolling 30-day basis. GX 10F, 3; *see also* GX 19, at 120. (SOMS note: ''ok to ship—oxy revised to 25.0 to met [sic] current size allotment'').

Here again, City View had placed orders which, on a rolling 30-day basis, exceeded the CSL. Yet there is no evidence that Respondent obtained an explanation for the order from the pharmacy and a new UR. Nor was the order reported to DEA as suspicious.

Moreover, on December 1, 2009, Respondent filled two orders totaling 20,000 du of oxycodone 30. GX 10F, at 3. With these orders, Respondent had filled orders totaling 42,500 du on a rolling 30-day basis. A SOMS note of the same date states: ''ok to ship-oxy within size for period @10K with this order.'' GX 19, at 120. The same reviewer made a second SOMS note, which, while bearing the date of ''11/24/09,'' is interspersed between the above note and another note of ''12/1/09'' which states: ''ok to ship oxy @20K with this order for period 12–1–09.'' *Id.* Notwithstanding that City View had

[97] This is likely an abbreviation for Mallinckrodt, a manufacturer of controlled substances. Other evidence establishes that Respondent distributed oxycodone manufactured by Mallinckrodt.

again clearly exceeded its CSL, there is no evidence that Respondent contacted City View to obtain a reason for the orders and a new UR. Nor did it report the orders as suspicious.

On December 14, Respondent filled an additional order for 2,500 du of oxycodone 30. GX 10F, at 3. Thereafter, on January 4 and 11, 2010, it filled orders for 10,000 du of oxycodone 30 on each date, followed on January 19 by an additional order for 2,500 du of oxycodone 30, for a monthly total of 22,500 du. *Id.*

On February 1, 8, and 18, Respondent filled three separate orders for 10,000 du of oxycodone 30. *Id.* Upon filling both the Feb. 1 and 8 orders, Respondent had shipped 32,500 du on a rolling 30-day basis and thus exceeded the CSL whether it was set at 22,500 or 30,000 du.[98] However, the SOMS note for the Feb. 1 and 8 orders respectively state: ''ok to ship, under the CSL'' and ''ok to ship oxy under csl.'' GX 19, at 113.

Of note, on February 17, 2010, Mr. Chase conducted a site visit at City View. According to his report, City View filled an average of 100 prescriptions per day, with controlled substances comprising 30 percent of the prescriptions. RX 2D, at 43. Mr. Chase reported that schedule II controlled substances comprised 15 percent of all prescriptions. *Id.* While Mr. Chase reported that City View appeared to be a full service pharmacy with a ''good selection'' of front store items, he did not document that City View serviced any pain clinics. *Id.* at 40, 45.

While on the Site Visit Recommendation Form, Mr. Chase checked that the site visit was acceptable, he also recommended that a new utilization report be obtained, noting that controlled substances were 30 percent of City View's dispensings. *Id.* at 40. And on the Recommendation Form, Mr. Chase further wrote: ''We Need A Utilization Report & Compare it to Site Visit.'' *Id.*

As for the Feb. 18 order, an MFR entry dated February 18 states: ''Order for 10,000 Oxy 30 mg CSL Is 22,500, already at 20,000 this month—last order on Oxy 30 was 2/8/10 + 2/1/10.'' RX 2D, at 4. An additional entry below the above states: ''limit approved on 10/09 for 30k'' and ''order would be 2500 over thus releasing w/reservation.'' *Id.* And a separate MFR note of the same date states: ''shipped 10k w/reservation CSL @32500'' and ''Must be reviewed w/ committee along w/[illegible].'' RX 2D, at 5. Additional notes in the same entry state: ''30k on oxy'' and ''CSL for month @[ ] 15k.'' *Id.*

As for the February 1 and 8 orders, while they clearly exceeded the CSL—indeed, during this period, Respondent's records repeatedly indicate that the CSL was 22,500 du and do so even in notes made after the Feb. 18 MFR entry—there is no evidence that Respondent complied with its policies and procedures by contacting the pharmacy and obtaining an explanation for the increase in its orders, which was then independently verified. Nor did Respondent obtain a new UR. Moreover, Respondent provided no explanation at the hearing as to why the SOMS notes state that the CSL was 22,500 but then was suddenly increased to 32,500 du on February 18. As these notes indicate, Respondent simply ignored the CSL and manipulated it to justify the distributions.

There is also no evidence that Mr. Chase's site visit and recommendation were reviewed before the February 18 order was shipped. Indeed, a SOMS note of February 23 clearly suggests that the site visit report and recommendation were not reviewed until that date. GX 19, at 112. Significantly, this note also states: ''CR [compliance review]—CH [compliance hold] UR on file needs to be reviewed with site visit.'' *Id.*

Here again, there is no indication that the previous UR was reviewed and compared with the information Mr. Chase had reported as to the percentage of City View's dispensings comprised by controlled substances and the percentage comprised by schedule II drugs. As for the recommendation that a new UR be obtained, Respondent did not obtain a new UR until late April, more than two months later.

On March 3, Respondent filled an order for 10,000 du of oxycodone 30, which according to the SOMS was released, with the reason being that it was ''under csl.'' GX 10F, at 3; GX 19, at 114.

On March 12, Respondent filled an additional order for 10,000 du of oxycodone 30. GX 10F, at 3. The SOMS note of this date states: ''ok to ship, under the CSL of 22,500, this is their 2nd order for 10k OXY 30mg this month.'' GX 19, at 114. *See also* RX 2D, at 3 (MFR note: ''Order for 10,000 Oxy 30 mg—this order is under CSL of 22,500 they purchased 30k last month.''). However, the March 12 order placed City View's orders at 30,000 du on a rolling 30-day basis, and thus the order actually placed City View above the CSL level referred to in the SOMS note. A March 15 MFR note by Ms. Seiple justified the shipment stating: ''order above supported by UR and last month of 30k supported by UR per committee.'' RX 2D, at 3. Notably, Ms. Seiple did not state that Respondent had contacted the pharmacy and obtained an explanation for the order as well as a new UR.

On March 18, Respondent shipped a new order for 10,000 du of oxycodone 30. GX 10F, at 3. A SOMS note of this date states: ''ok to ship, order supported by UR on the OXY, this order for 10k puts them at 30K for the month.'' GX 19, at 114. However, when added to the previous orders Respondent shipped to City View on February 18, as well as March 3 and 12, each of which was for 10,000 du, Respondent had shipped 40,000 du on a rolling 30-day basis, and thus again exceeded the CSL, whether it was set at 22,500 or 30,000 du. Once again, there is no evidence Respondent contacted City View and obtained an explanation for the order and a new UR.

On March 22, Respondent filled an order for 1,200 du of oxycodone 30, thus bringing City View's rolling 30-day total to 31,200 du. GX 10F, at 3. Various notes explain that the order was released because it was supported by the UR, even though Respondent still had not followed the recommendation of its inspector to obtain a new UR and the previous UR was nearly six months old. RX 2D, at 3; GX 19, at 114.

Two days later, Respondent filled an order for an additional 10,000 du of oxycodone 30. GX 10F, at 3. The corresponding notes states: ''ok to ship, CSL is 22,500, they have already purchased 31,200 this month, this order is for 10K, putting them at 41200 for the month, UR supports order see file.'' GX 19, at 114. Here again, there is no evidence that Respondent obtained an explanation from City View's pharmacist regarding the increase in its orders (which it independently verified) and obtained a new UR. Nor did it report the order as suspicious even though the order placed City View's orders at nearly double its CSL.

Moreover, on March 27 (a Saturday), City View placed two orders, each being for 10,000 du of oxycodone 30. GX 19, at 114; RX 2D, at 3. City View's orders thus totaled 61,200 du on a rolling 30-day (as well as on a calendar month) basis, and were nearly three times the CSL and more than double the previous highest month's shipments. While on March 29 Respondent shipped only 10,000 du, it again justified the

[98] Both SOMS notes and an MFR note indicate that City View also placed an order for 2,000 du of oxycodone on February 16. *See* GX 19, at 113 (''ok to ship, under the CSL of 22,500 on OXY, this order puts them at 22,000 for the month''); RX 2D, at 4 (''Order for 2000 oxy CSL 22,500 already ordered 20,000 this month. This order puts them at 22,000 for the month.''). The ARCOS report does not, however, list an order on either this date or of this size as having been filled by Respondent. GX 10F, at 3–5.

shipment on the ground that the ''UR supports release—places CSL @51,200 for current period.'' RX 2D, at 3; GX 10F, at 3.

An MFR note corresponding to the second March 29 order states that Respondent called City View's pharmacist, who ''said that he placed this order to be released on April 1, 2010, please hold order until 4/1/10.'' RX 2D, at 3. While that may be, Respondent did not document that it questioned the pharmacist about the order it did fill that day, notwithstanding that the orders it filled during March represented a more than 70 percent increase from the previous month's orders, and it also failed to obtain a new UR. Nor did Respondent report the orders as suspicious. Yet here again, City View's CSL was increased even though Respondent repeatedly failed to follow its own policies and procedures for verifying the legitimacy of the pharmacy's orders.

In April, Respondent continued its practice of failing to follow its policies and procedures when City View's oxycodone orders clearly exceeded the CSL. On April 1, Respondent filled the order for 10,000 du of oxy 30 which City View had previously submitted. GX 10F, at 4. Even assuming that Respondent had a valid basis for resetting City View's oxycodone CSL to 51,200 du based on the March shipments, upon filling this order, Respondent had shipped 61,200 du of oxycodone 30 on a rolling 30-day basis. GX 10F, at 3–4. Yet the MFR note corresponding to the order states only that ''order was released from 3/29'' and the SOMS note states: ''ok to ship-oxycodone within csl for period.'' RX 2D, at 3; GX 19, at 114.

On April 5, Respondent filled another order by City View for 10,000 du of oxycodone 30. GX 10F, at 4. Here again, upon filling the order, Respondent had shipped 61,200 du to City View on a rolling 30-day basis and City View's orders exceeded the CSL. *Id.* Yet Respondent's records contain no documentation to explain why it shipped the order. *See generally* RX 2D, at 1–6 (MFRs); GX 19, at 111–12 (Ship to Memos); *id.* at 114 (SOMS notes during relevant time period). Indeed, there is no SOMS entry for April 5 and the next SOMS entry (April 8) does not contain the name of a reviewer and a reason, thus indicating that the order (whether it was for oxycodone or some other drug) was not reviewed.

So too, on April 12, Respondent filled a further order by City View for 10,000 du of oxycodone 30. GX 10F, at 4. Here again, upon filling the order, Respondent had shipped 61,200 du of oxycodone 30 to City View on a rolling 30-day basis. *Id.* The SOMS note for the transaction states: ''ok to ship, OXY 30mg, already purchased 20K this month this order is for 10K putting them at 30K for the month UR supports order (4/12/10) (last month they were at 51200).'' GX 19, at 114. Here again, while the order exceeded the CSL, there is no evidence that Respondent contacted the pharmacy to obtain an explanation for the order and a new UR.

On April 19, Respondent filled a further order by City View for 10,000 du of oxycodone 30. GX 10F, at 4. Here again, upon filling the order, Respondent had shipped 61,200 du of oxycodone 30 to City View on a rolling 30-day basis. *Id.* The MFR note pertaining to the order states: ''released order for 10k Oxy 30mg, with this order they are at 40k for the month,'' RX 2D, at 3; and the SOMS note states: ''puts them at 40k for the month, UR soppurts [sic] order (4/19/10).'' GX 19, at 114. Again, there is no evidence that Respondent obtained an explanation for the order and a new UR from City View.

On April 21, Respondent filled an order by City View for 2,000 du of oxycodone 15 mg, and on April 22, it filled an order for 2,000 du of oxycodone 30. GX 10F, at 4. Upon filling the April 21 order, Respondent had shipped 62,000 du within the rolling 30-day period, and on filling the April 22 order, it had shipped 64,000 du within the rolling 30-day period. GX 10F, at 3–4. A SOMS note dated April 21 simply says ''ok to ship,'' [99] and two SOMS notes dated April 22 state: ''ok to ship-oxycodone increase released off ur support'' and ''ok to ship-oxycodone increase-current ur supports.'' GX 19, at 114.

However, at this point, the most recent UR was more than six months old, and neither note acknowledges that City View's orders were more than 10,000 du over the purported CSL. And once again, there is no evidence that Respondent obtained an explanation for the order and a new UR from City View.

On April 26, Respondent filled an order by City View for 10,000 du of oxycodone 30, thus again resulting in the rolling 30-day total of orders (and shipments) of 64,000 du. GX 10F, at 3–4. An MFR note discussing the order explains: ''Order for 100—Oxy 30mg already at 44,000 this month[.] [T]his order will put them at 54,000[,] most they have gotten was 51,200 (last month)[.] [C]alled to get an updated UR[.] TT [pharmacist] he will fax it over today.'' RX 2D, at 1. An additional MFR note of the same dates states: ''UR received—supports Oxy increase CSL @ 54k for current Period.'' *Id.*

The UR covered March 1–30, 2010. RX 2D, at 26–34. However, the UR was clearly incomplete as it did not list the total number of prescriptions and dosage units which were dispensed during the period. *Compare id.* at 34, *with id.* at 71 (last page of March 09 UR providing this information) and *id.* at 100 (last page of Feb. 08 UR providing this information). However, a Diversion Investigator calculated the total dispensings listed on the UR at 178,458 du. GX 49B, at 53.

The UR showed that City View had dispensed 586 prescriptions totaling 93,943 du of oxycodone 30 during the period as well as 98 prescriptions totaling 10,746 du of oxycodone 15.[100] *Id.* at 32–33. Of consequence, City View's dispensings of oxycodone 30 had nearly doubled from the amount on the previous UR (47,472 du) and comprised more than 52.5 percent of its total dispensings. The UR also showed that City View's dispensings of oxycodone 15 had more than tripled from the amount on the previous UR (3,715 du). And the UR further showed that City View's dispensings of alprazolam 2 mg, another controlled substance highly sought after by narcotic abusers for use as part of a drug cocktail, now totaled 19,738 du, more than double the amount on the previous UR (9,722). *Id.* at 26.

However, here again, notwithstanding that its policies and procedures required Respondent to obtain a reason for why City View's order exceeded the CSL, and also required a review of its file to determine whether the order was ''consistent with legitimate business practices,'' RX 78, at 32–33; Respondent ignored this information and shipped the order. It also failed to report the order as suspicious.

On May 5, Respondent filled an order for 10,000 du of oxycodone 30; on May 10, it filled two orders totaling 20,000 du of oxycodone 30 as well as an order for 1,000 du of Endocet 10/325; and on May 18, it filled a further order for 10,000 du of oxycodone. GX 10F. at 4–5. Here again, even if the CSL had been raised to 54,000 du based on the April orders, upon filling the May 10 orders, City View's oxycodone orders totaled 65,000 du on a rolling 30-day basis and thus exceeded the CSL. Incredibly, a SOMS note of the same dates states: ''Ok

[99] While this note does not refer to a specific drug, it is the only SOMS note dated April 21, 2010. GX 19, at 114.

[100] In contrast to the previous UR which ranked City View's dispensing by the quantity dispensed for each drug by NDC, this UR listed the drugs in alphabetical order. *Compare* RX 2D, at 26–34, *with id.* at 62–71.

to ship-oxy within csl for period.'' GX 19, at 115.

So too, upon filling the May 18 order, Respondent had shipped 65,000 du of oxycodone to City View on a rolling 30-day basis and thus exceeded the CSL. Yet the corresponding SOMS note states: ''ok to ship undr [sic] CSL leave 10,200 for May on 5/18.'' *Id.* at 115. And a note in the Ship to Memos states: ''PER COMMITTEE CSL IS 51200 WHICH IS THE MARCH CSL. PLEASE DO NOT SHIP OVER 51200 WITHOUT REVIEWS.'' *Id.* at 111. *See also* RX 2D, at 1.[101] While Respondent conducted a due diligence survey by telephone, even assuming that it considered the various statements discussed in the footnote to be the explanation for the order (such as that it was servicing two small nursing homes), there is no evidence that it independently verified any of these statements. Nor did it obtain a new UR. And it did not report the order as suspicious.

On June 1, 7, and 14, Respondent filled three separate orders for 10,000 du of oxycodone 30 mg, for a total of 30,000 du for the month. GX 10F, at 4. A SOMS note of June 1 states that this order was ''flagged for frequency'' but was released because the order was ''not excessive.'' GX 19, at 115. A subsequent MFR note states that Respondent decreased City View's allocation of oxycodone per policy. RX 2D, at 1. The note, however, does not state what City View's new oxycodone CSL was.

On June 28, Respondent performed a new site inspection of City View. *See id.* at 35–37. During the inspection, City View asserted that it filled ''only in town RX,'' that it filled an average of 100 prescriptions per day, that 30 percent of the prescriptions were for controlled substances, and that 20 percent were for schedule II drugs. *Id.* at 36. The inspector reported that City View was located two blocks from a hospital and that there were pain clinics in the area. *Id.* at 37. He also reported that City View appeared to have a full selection of pharmaceuticals available and that it had a limited supply of front store items. *Id.* Finally, he reported that business was ''slow while [he] was there'' and that he observed ''nothing untoward.'' *Id.*

On July 1, Respondent filled an order for 10,000 du of oxycodone 30, and on July 6, it filled orders for 5,000 more du of oxycodone 30 and 2,000 du of oxycodone 15. GX 10F, at 4. An MFR note dated July 7 states that the site visit was reviewed and that the account was placed on compliance hold pending the receipt of an updated UR and that the CSL was set at 28,700. RX 2D, at 1; *see also* GX 19, at 111 (noting compliance hold and that ''full ur for june is needed'').

Notwithstanding this entry, Respondent did not obtain a new UR from City View until on or about December 2, nearly five months later. RX 2D, at 7. According to the Ship to Memos, on July 13, Respondent conducted an account review using the previous UR and the recent site visit, after which it took City View off of the compliance hold and apparently maintained its CSL at 28,700 du. GX 19, at 111.

Yet on July 13, Respondent also filled an order for 10,000 du for oxycodone 30, bringing City View's total filled orders to 37,000 du on a rolling 30-day basis. GX 10F, at 4. Respondent's records contain no explanation for why the order was shipped given that it placed City View's orders at more than 8,000 du above the new CSL and that City View had not provided a new UR.[102] Nor was the order reported as suspicious.

Next, on July 28, Respondent filled an order for 1,700 more du of oxycodone 30. GX 10F, at 4. While City View's filled orders totaled 28,700 du, a SOMS note of the same date states: ''rwr Oxy edited to meet CSL for July.'' GX 19, at 116. Here again, City View's oxycodone orders exceeded the CSL, and yet there is no evidence that Respondent obtained an explanation for the order as well as a new UR. Nor did it report the order as suspicious.

In August, Respondent filled orders totaling 20,300 du, including 15,000 du of oxycodone 30, and 3,000 du of oxycodone 15. GX 10F, at 4–5. In September, Respondent filled orders totaling 28,700 du, including orders for 20,000 du of oxycodone 30; 7,600 du of oxycodone 15; and 1,100 du of Endocet products. However, a SOMS note dated September 28 (which corresponds to orders for 5,000 du of oxycodone 30 and 1,600 du of oxycodone 15) states that City View's order was ''edited to meet CSL,'' GX 19, at 117; and on a rolling 30-day basis, City View's oxycodone orders actually totaled 34,700 du.[103] GX 10F, at 4–5. Here again, while the September 28 orders clearly placed City View over its CSL, there is no evidence that Respondent obtained an explanation for the orders and a new UR. And it also failed to report the orders as suspicious.

In October, Respondent filled orders placed on five different days totaling 29,300 du, including 20,000 du of oxycodone 30; 8,000 du of oxycodone 15; and 1,300 du of Endocet. GX 10F, at 4–5. Moreover, on each date, upon filling the orders, City View exceeded the CSL of 28,700 du on a rolling 30-day basis.

Specifically, on October 5, Respondent filled orders for 7000 du (5,000 oxycodone 30 and 2,000 oxycodone 15), bringing City View's rolling 30-day total to 35,300 du.[104] *Id.* A SOMS note of this date simply states: ''ok to ship order for 20 OXY 15mg & 50 OXY 30mg is under CSL.'' GX 19, at 117.

On October 12, Respondent again filled orders for 7000 du (5,000 oxycodone 30 + 2,000 oxycodone 15), bringing City View's rolling 30-day total to 35,200 du.[105] GX 10F, at 4–5. The corresponding SOMS notes states: ''rwr Oxy under CSL leaves 14,400 as of 10/12.'' GX 19, at 117.

On October 20, Respondent again filled orders for 7,000 du (5,000 oxycodone 30 + 2,000 oxycodone 15), bringing City View's rolling 30-day total to 35,200.[106] GX 10F, at 4–5. Here again, a SOMS note simply states ''oxy under csl.'' GX 19, at 117.

On October 26, Respondent again filled orders for 7,000 du (5,000

[101] On May 18, 2010, Respondent conducted an updated due diligence survey, apparently by telephone. RX 2D, at 38. According to the survey, City View reported that its daily prescription average was 100–120, that the ratio of controls to non-controls was 30–70 percent, that it was near a medical center, and that it was now servicing two small nursing homes. *Id.* Here again, there is no evidence that Respondent attempted to verify City View's claims regarding the ratio of controlled to non-controlled drugs dispensed which was clearly inconsistent with the March 2010 UR. Nor did it inquire as to the names of the nursing homes City View was servicing, how many residents the homes had, and the types and quantities of prescriptions it filled for their residents.

[102] A Ship to Memo of the same date made by Ms. Seiple merely states: ''accoutn [sic] review using ur on file for 3/10 new site visit complete 6/28/10 maintaining soms csl.'' GX 19, at 111. A July 12, 2010 SOMS note (there being no SOMS note for July 13) made by Ms. Seiple states: ''rwr order sitevisit [sic] and ur on fiel [sic].'' *Id.* at 116.

[103] In addition to the September orders, this total includes orders filled on August 30 for 5,000 du of oxycodone 30 and 1,000 du of oxycodone 15. GX 10F, at 4; GX 19, at 116.

[104] The total includes Sept. 9 orders for 7,400 du (5,000 oxycodone 30; 2,000 oxycodone 15; and 400 Endocet 10/650); Sept. 16, orders for 7,000 du (5,000 oxycodone 30 and 2,000 oxycodone 15); Sept. 23 orders for 7,300 du (5000 oxycodone 30; 2,000 oxycodone 15; and 300 Endocet 5); and Sept. 28 order for 6,600 du (5,000 oxycodone 30 and 1,600 oxycodone 15). GX 10F, at 4–5.

[105] The total includes Sept. 16 orders for 7,000 du (5,000 oxycodone 30 and 2,000 oxycodone 15); Sept. 23 orders for 7,300 du (5000 oxycodone 30; 2,000 oxycodone 15; and 300 Endocet 5); and Sept. 28 order for 6,600 du (5,000 oxycodone 30 and 1,600 oxycodone 15), and the October 5 orders for 7,000 du. GX 10F, at 4–5.

[106] The total includes the Sept. 23 orders for 7,300 du (5000 oxycodone 30; 2,000 oxycodone 15; and 300 Endocet 5); the Sept. 28 orders for 6,600 du (5,000 oxycodone 30 and 1,600 oxycodone 15), and the October 5 and 12 orders for 7,000 and 7,300 du. GX 10F, at 4–5.

oxycodone 30 + 2,000 oxycodone 15), bringing City View's rolling 30-day total to 34,900 du.[107] GX 10F, at 4–5. A SOMS note of this date states: ''ok to ship, size not excessive on a total of 70 OXY this order puts them at 28300 for the month, CSL is 28700.'' GX 19, at 117.

Finally, on October 27, Respondent filled an order for 1,000 du of Endocet 10, bringing City View's rolling 30-day total to 35,900 du. GX 10F, at 4–5. A SOMS note merely states: ''rwr under 30 on csl of oxy.'' GX 19, at 117.

With respect to each of these dates, Respondent filled orders which clearly placed City View's orders over the oxycodone CSL on a rolling 30-day basis. Yet, there is no evidence that Respondent ever obtained an explanation for the order, which it then independently verified, and a new UR. And it did not report any of the orders as suspicious.

Similarly, Respondent filled orders totaling 28,700 du for the month of November. This included orders for 5,000 du of oxycodone 30 and 2,000 du of oxycodone 15 on November 2; orders for 6,500 du of oxycodone 30 on and 500 Endocet on November 9; 8,000 du of oxycodone 30 on November 18, and 6,700 du of oxycodone 30 on November 29. GX 10F, at 4–5. Here again, on each occasion, City View's orders placed its oxycodone orders over 28,700 du CSL on a rolling 30-day basis.

Specifically, City View's filled orders from October 5 through November 2 totaled 36,300 du; its filled orders from October 12 through November 9 also totaled 36,300; and its filled orders from October 20 through November 18 totaled 37,000 du. GX 10F, at 4–5. SOMS notes for both November 2 and 18 show that Ms. Seiple released the orders; as for the reason, Ms. Seiple wrote ''rwr'' for both orders. GX 19, at 117–18.

As for the November 9 order, the SOMS note states: ''rwr Oxy within buying pattern under CSL leaves 14,700 as of 11/09/10 @947am.'' GX 19, at 118. As for the November 29 order, the SOMS note states: ''order edit to 67 bottles from 70,'' *id.,* thus once again establishing that City View's actual orders totaled 29,000 du and again exceeded the CSL.

Here again, notwithstanding that each of City View's November orders placed it over the oxycodone CSL, Respondent failed to obtain an explanation for the orders, which it then verified, as well as new URs. And again, it did not report any of the orders as suspicious. On December 2, Respondent filled an order for 700 du of two Endocet products. GX 10F, at 5. According to MFR notes, the same day, an employee of Respondent requested that City View provide a new UR; City View provided a UR for the month of November. However, the UR was incomplete, a fact which Ms. Seiple herself noted in an MFR dated December 17. RX 2D, at 1. Indeed, this UR clearly did not list City View's total dispensings of all prescription products.[108] *Id.* at 14.

Notwithstanding that City View had provided an incomplete UR, and that this was the first UR it had obtained since the March 2010 UR, on December 6, Respondent filled orders for 8,000 du of oxycodone 30 and 1,000 du of oxycodone 15.[109] GX 10F, at 4–5. While there are three entries in the SOMS notes for this date, only one lists the name of a reviewer (Ms. Seiple) with the following explanation: ''rwr under csl and last 30 days not excessive due to allocation of market producet [sic].'' GX 19, at 118.

A note in the Ship to Memos (made on Jan. 8, 2011) states that City View's account was placed on compliance hold on December 9 ''due to updated information [being] needed'' and that the account was terminated on December 16 ''due to business model of insurance ratio.'' GX 19, at 111; *see also* RX 2D, at 1.

Additional notes which are dated December 2, but which may have been added after the fact,[110] state that City View's November 2010 UR ''will be low due to allocation in market.'' RX 2D, at 2. Other notes for the entry list figures of 35,530 and 5,400; these figures correspond to line entries on the UR for City View's dispensings of oxycodone 30 (with the NDC for product manufactured by Mallinckrodt) and alprazolam 2 mg. *Compare id. with id.* at 7 (UR line entries #s 1 & 5). Additional notes state: ''11/10 25200 Malinkrodt [sic] purchased'' and ''1000 KVK.'' *Id.* at 2. As found above, these numbers correspond to Respondent's total shipments of 26,200 du of oxycodone 30 during the month of November 2010. Still more notes appear to compare the number of oxycodone 15 and alprazolam 2 mg dispensed by City View with the quantities Respondent distributed to it, with the notes indicating that City View's Xanax CSL was being reduced to 3,800 du or 70 percent of the November UR. *Id.*

Thereafter, the notes state ''hold order until review complete'' and ''*concerns regarding # of doses dispensed as opposed to noncontrols*'' and then refer to a phone call made to City View's pharmacist on December 15. *Id.* (emphasis added). According to the note, during the call Respondent told its pharmacist that its ''order will hold.'' *Id.* Further notes state ''only purchases from Cardinal & Masters'' and ''insurance how does he make profit??'' *Id.*

A note dated December 16 recounts that City View's file was ''reviewed in length.'' *Id.* Therein, Ms. Seiple further wrote that she ''spoke to customer on phone multiple times regarding ratio of controls & noncontrols,'' as well as ''in regards to ratio cash vs. insurance,'' and that per Respondent's policy, City View was ''placed in noncontrolled status due to customer indicating cash in OXY.'' *Id.*[111]

On December 17, City View requested a review of its status. GX 19, at 111. Respondent requested that City View provide a UR for the month of October, which it did. RX 2D, at 1. The UR showed that during October 2010, City View had dispensed a total of 310 prescriptions totaling 51,725 du of oxycodone 30 and 148 prescriptions totaling 11,259 du of oxycodone 15. RX 2D, at 16–17. According to the UR, City View's total dispensings for the month were 122,626 du.[112] *Id.* at 25. Thus, City View's dispensings of oxycodone 30 alone amounted to 42 percent of its total dispensings, and its dispensings of both oxycodone 30 and 15 amounted to 51 percent of its total dispensings.

Thereafter, Respondent did not re-instate City View as a controlled substance customer. However, there was

[107] The total includes the Sept. 28 orders for 6,600 du (5,000 oxycodone 30 and 1,600 oxycodone 15), and the prior October orders. GX 10F, at 4–5.

[108] The UR also listed substantially fewer drugs than other URs. *Compare* RX2D, at 14 (listing 272 drugs), *with id.* at 34 (Mar. 2010 UR listing 396 drugs although also missing total dispensings); *id. at* 71 (Sept. 2009 UR listing 401 drugs); *id.* at 100 (Feb. 2008 UR listing 495 drugs).

[109] A SOMS note dated Dec. 4, 2010 states: ''oxy edited off order mallinkrodt [sic].'' GX 19, at 118.

[110] This note is written on a blank sheet following the lined MFR page which contains notes dated Dec. 16 and 17, but not Dec. 2. *See* RX 2D, at 1–2.

[111] This entry includes an additional statement which suggests that Respondent was ''not clear on [City View's] business model.'' RX 2D, at 2. However, because of legibility issues, the meaning of the rest of the sentence cannot be determined.

[112] This included three prescriptions for Gavilyte-N Solution, which according to the UR totaled 12,000 units. RX 2D, at 17. Gavilyte-N Solution is a product which is mixed with water to create a solution with a volume of four liters; it is used to clean a patient's bowels before undergoing procedures such as a colonoscopy. *See http://www.drugs.com/pro/gavilyte-n.html.* Thus, while Gavilyte-N is a prescription product, assigning a quantity of 12,000 du to three prescriptions arguably distorts City View's total dispensings of all drugs, as well as its dispensing ratio of controlled to non-controlled drugs. However, the total quantity of dispensings as listed on the UR was used in calculating the dispensing percentages for oxycodone 30 and oxycodone 15 and 30.

really nothing new in the information Respondent had developed on City View.

In her declaration, Ms. Seiple asserted that because City View's PIC had ''provided an explanation of the policies and procedures [it] used to prevent diversion,'' the ''Compliance Department believed that City View understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.'' RX 103, at 53. The answers provided by City View's PIC reflected only that when confronted with a suspicious prescription, he would call the prescriber; more, however, is required under federal law. *See United States* v. *Hayes,* 595 F.2d 258, 261 (5th Cir. 1979) (''Verification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact finder's concluding that the pharmacist had the requisite knowledge despite a purported but false verification.''). Significantly, when asked whether he ever refused to fill prescriptions, the PIC responded that he did so only if a patient would not present his driver's license or if the physician had a problem with his/her DEA registration or other disciplinary action.

However, a pharmacist has a duty to fill only those prescriptions which are issued for a legitimate medical purpose by a practitioner acting within the usual course of professional practice, *see* 21 CFR 1306.04(a), which requires that a pharmacist must ''pay[] attention to the 'number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment,' the number of doctors writing prescriptions and whether the drugs prescribed have a high rate of abuse.'' *Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409, 412 (6th Cir. 2008). Moreover, during the June 25, 2008 site visit, Respondent's consultant simply drew a dash in the place for answering the question whether the pharmacy could supply a copy of any written policies and procedures it ''might have in place to prevent drug diversion and doctor shopping,'' thus suggesting that there were no written policies, a fact confirmed during the June 2010 site visit. RX 2D, at 36, 105. Thus, I find that the explanation City View provided as to its policies and procedures to prevent diversion was clearly inadequate to support the conclusion that the pharmacy ''understood its obligations to prevent the diversion of controlled substances, and was taking affirmative steps to meet those obligations.'' RX 103, at 53.

In her declaration, Ms. Seiple also asserted that City View's PIC had explained that the pharmacy's ''business model included marketing to 'closed door' facilities such as nursing homes, hospice programs, and in-patient medical facilities.'' *Id.* Yet, there is no indication that this explanation was provided during the initial due diligence survey, RX 2d, at 73–75; and during the June 2008 site visit, the consultant had noted only that City View's servicing of each of these types of facilities was ''pending.'' *Id.* at 106. Significantly, nearly two years later, City View reported only that it serviced two small nursing homes, with 20–30 beds. *Id.* at 38.

Ms. Seiple also asserted that the pharmacy was located within two blocks of two hospitals. RX 103, at 53. Yet this was not noted by either the consultant following the June 2008 site visit or by Mr. Chase after the February 2010 inspection. While it was noted in the report for a third site visit (June 28, 2010), the names of the hospitals were not identified, and in any event, the mere proximity of a pharmacy to a hospital does not justify dispensing levels of oxycodone 30 which are grossly disproportionate to the dispensings of the most commonly prescribed drugs. Indeed, in City View's case, its URs consistently showed that highly abused controlled substances (including other strengths of oxycodone and alprazolam) were predominant among the pharmacy's dispensings.

Ms. Seiple stated that City View had informed Respondent ''that it filled prescriptions for patients from several pain clinics, and identified the physicians who wrote the prescriptions for those patients.'' RX 103, at 53–54. While it is undoubtedly true that this ''accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs,'' *id.* at 54, this does not establish that the oxycodone was being dispensed by City View pursuant to prescriptions that were issued by the identified physicians for a legitimate medical purpose. *See* 21 CFR 306.04(a). Nor is there any evidence that Respondent verified the licensure status of the identified physicians and whether they had any specialized training or board certification in pain management.

Next, Ms. Seiple asserted that after City View's account was approved, the SOMS ''identified and held any order for controlled substances . . . that deviated from its typical volume, pattern or frequency'' and that ''[a]ll such orders were released only after review by [the] Compliance Department.'' RX 103, at 54. As found previously, the SOMS did not become operational until August 2009. Moreover, as found above, numerous orders were released even though Respondent's personnel failed to comply with its purported policy which required that it contact the pharmacy and obtain an explanation for the order, which it then independently verified, as well as that it obtain a new UR. Indeed, Respondent rarely obtained new URs, as Ms. Seiple's declaration makes clear. *Id.*

Ms. Seiple further acknowledged that Respondent ''was aware of the volume of oxycodone and other controlled drugs being dispensed by City View, and the percentage of controlled drugs dispensed relative to other drugs.'' *Id.* Unexplained by Ms. Seiple is why she did not find it suspicious that City View's actual dispensings of controlled substances (including its schedule II dispensings) constituted a much greater percentage of its total dispensing than the dispensing ratio identified in the August 2009 Compliance Review. *Compare* RX 2D, at 62–63, 71 (Sept. 2009 UR showing that oxycodone 30 dispensings alone comprised 41 percent of total dispensings) *with* RX 13, at 1 (suggested questions document with notation that typical pharmacy's dispensing ratio of controlled to non-controlled drug as 20 to 80 percent); GX 51B, at 4 ¶ 12 (testimony of Wayne Corona that DEA ''advised us to focus on whether a customer . . . dispensed a high percentage of controlled substances as compare[d] to non-controlled substances'').

Indeed, discussing the February 2010 site visit, Ms. Seiple simply noted that ''Mr. Chase did not note any suspicious activity during his inspection, and determined that the site inspection was acceptable.'' RX 103, at 55. Yet Mr. Chase recommended that a new UR be obtained and compared to the site visit. RX 2D, at 40. Ms. Seiple entirely failed to address why Mr. Chase's recommendation was not followed until more than two months later. *See* RX 103, at 55. Moreover, as found above, while City View's pharmacist had told Mr. Chase that schedule II drugs were 15 percent of all dispensings, the March 2010 UR showed that City View's dispensings of oxycodone 30 had nearly doubled from the level of the previous UR (totaling nearly 94,000 du on the new UR), and its dispensings of this drug alone comprised 52.5 percent of its total dispensings. So too, the UR showed a doubling in City View's dispensings of alprazolam 2 mg, another

controlled substance highly sought after by drug abusers.

As for why Respondent continued to fill City View's orders and failed to report them as suspicious even when they were held by the SOMS, Ms. Seiple offered several inadequate explanations. These included that Respondent ''specifically investigated the reasons why City View's ordering and dispensing patterns were as indicated on the URs,'' that ''it appeared to be a full-line pharmacy that was dispensing a large variety of both controlled and non-controlled drugs, and appeared to be servicing patients of nearby hospitals, closed-door facilities, and pain management physicians,'' RX 103, at 54, and that ''based on [Respondent's] extensive investigation, it determined that the orders it shipped to City View were not suspicious.'' *Id.* at 55.

I find, however, that the reality is far different, as Respondent simply accepted at face value whatever superficial explanation it believed would support its continued selling of controlled substances while ignoring numerous red flags as to the legitimacy of the pharmacy's dispensing of controlled substances. And with respect to those orders which were held by the SOMS, Respondent typically did not investigate the orders as it routinely failed to contact City View to obtain a reason for the order, which it independently verified.

Remarkably, Ms. Seiple explained that City View's account was terminated because Respondent ''developed concerns following its review of URs [it] obtained from City View,'' and that ''[d]uring a discussion of City View's dispensing patterns and volume [she] had with [its PIC] on or about December 6, 2010, [she] became concerned because of discrepancies in the information he provided to [her] and the dispensing history set forth on the UR.'' *Id.* at 55–56. As found above, notes in Respondent's records show that there were concerns as to the number ''of doses dispensed as opposed to noncontrols,'' and the ''ratio of controls & noncontrols.'' RX 2D, at 2. Yet these issues had been present for the entire period in which Respondent distributed controlled substances to City View, and Ms. Seiple offered no credible explanation for why it took Respondent so long to terminate the account.[113]

Medical Plaza Pharmacy

Medical Plaza Pharmacy was a community pharmacy located in Plantation, Florida. RX 2F, at 137. According to Respondent's due diligence file, Medical Plaza became a customer of Respondent in November 2008. *Id.* at 131. However, documents in the due diligence file indicate that the pharmacy was sold the next month and a printout verifying the pharmacy's license states that the new owner's license was issued on December 30, 2008. *Id.* at 131, 137.[114] Respondent also verified the license of its PIC; the verification showed that he had not been subject to discipline. *Id.* at 138.

On March 24, 2009, Respondent conducted an initial due diligence survey for purchasing controlled substances, speaking to the pharmacy's PIC. *Id.* at 131. According to the survey, the PIC reported that Medical Plaza's daily prescription average was 120 and that it filled schedule II prescriptions. *Id.* He further reported that 35 to 40 percent of the prescriptions were for schedule II drugs. *Id.* However, with respect to the percentage of its dispensings comprised by all controlled substances, the PIC stated that he was ''unsure'' and ''didn't want to give [the] wrong answer.'' *Id.*

The PIC also reported that Amerisource was Medical Plaza's primary wholesaler, that he did not fill prescriptions that had been issued ''via the Internet,'' that the pharmacy accepted insurance, and that 70 to 80 percent of the prescriptions were paid for by insurance. *Id.* With respect to its policies and procedures, the PIC stated that he had refused to fill prescriptions if he did not have the ''item in stock'' or if he felt that the prescription was ''not valid.'' *Id.* at 132. He also reported that he did not fill controlled substance prescriptions written by out-of-area or out-of-state doctors. *Id.* As for whether he filled controlled substance prescriptions for out-of-area or out-of-state patients, the PIC reported that he ''normally'' did not for ''CS,'' but did if the patient was ''visiting'' and ''g[o]t hurt or something.'' *Id.* At the bottom of the form, Respondent's employee noted that the PIC had ''answered questions ok.'' *Id.*

On the same day, Respondent also conducted the same survey of the Hillmoor Plaza, d/b/a IV Plus pharmacy. *See id.* at 133–34. On the checklist for the due diligence review on Hillmoor Plaza, Ms. Seiple wrote: ''N/C too new 6 month review.'' *Id.* at 130. Notably, no such note appears on the checklist for Medical Plaza Pharmacy, and while the words ''site visit'' are written on the top of this document, *id.* at 129, the evidence shows that Respondent did not perform a site visit until June 18, 2009. *Id.* at 56. Moreover, Respondent did not obtain a UR from the pharmacy until August 11, 2009, nearly five months after it had approved Medical Plaza to purchase controlled substances.

In April 2009, Respondent filled three orders placed by Medical Plaza totaling 5,000 du of oxycodone 30; on May 1, it filled an order for 4,800 du of oxycodone 30; and on June 2, it filled an order for 5,000 du of oxycodone 30. GX 10F, at 42. Respondent thus shipped to Medical Plaza 14,800 du of the drug before it even conducted a site visit, which took place on June 18. RX 2F, at 56.

During the site visit, Respondent's inspector noted that Medical Plaza was located in a medical center next to a hospital and appeared to be very busy. *Id.* at 61. He also noted that the pharmacy was not a specialty pharmacy, did not engage in mail order business, that it sold front store items and appeared to be a full service pharmacy, that it was not affiliated with any Web sites, and did not fill prescriptions for physicians who were primarily engaged in pain management. *Id.* at 58–60. He also documented that the pharmacy had used at least two other distributors.[115] *Id.* at 59.

Respondent's inspector then noted that the pharmacy filled 100–120 prescriptions per day, that controlled substances comprised 60 percent of the prescriptions, and that schedule II drugs comprised 20 percent of the prescriptions. *Id.* According to the inspector, 25 percent of the prescriptions were paid for with cash. *Id.* at 60. The inspector further noted that Medical Plaza ''want[ed] an increase in Oxy's—Maybe to Next Tier?'' and that this was ''ok by me!'' [116] *Id.* at 58. In his concluding comments, the inspector further wrote: ''Masters needs to meet this pharmacy's needs.'' *Id.* at 61.[117]

[113] While Respondent's records note that there were concerns over the ratio of cash to insurance and the ''business model of insurance ratio,'' in her testimony, Ms. Seiple did not cite these as reasons for the termination of the account.

[114] The due diligence file also includes documents establishing that the owners of Medical Plaza also owned Hillmoor Plaza Pharmacy, Inc., which did business under the name of IV Plus, and was located in Wellington, Florida. RX 2F, at 139–40. However, the Government's evidence focused entirely on Respondent's distributions to the pharmacy located in Plantation. *See* GX 10F, at 41–42.

[115] The form actually lists a fourth distributor; however, the name of the distributor is in a different color and different handwriting than the majority of the notations on the form. RX 2F, at 59.

[116] Next to this is the following notation: ''will be reviewed by committee JS. 8–21–09.'' RX 2F, at 58.

[117] In addition, Respondent's inspector obtained a copy of a December 23, 2008 Florida DOH

Continued

On July 15, 2009, Respondent filled an order by Medical Plaza for 5,000 du of oxycodone 30, and on August 6, it filled an order for 10,000 du of oxycodone 30. GX 10F, at 42.

The due diligence file includes a ''Schedule Drug Limit Increase Request Form.'' RX 2F, at 110. The form, which is dated August 11, appears to have been submitted by Respondent's account manager for the pharmacy. *Id.* A handwritten notation states: ''order on hold'' and ''please see if we can release it—Thanks!'' *Id.* Further notations, which were apparently also made by the account manager, state: ''Please Review customer, In a medical building of 60 doctors, and next to a hospital. Dispenses *many* controls. *Thanks,''* followed by the initials of the account manager. *Id.* The form also includes two additional notes which were handwritten diagonally across the page and initialed by Ms. Seiple. The first states: ''We Donot [sic] Do limit increases''; the second states: Please have UR sent in for review by committee.'' *Id.*

The same day, Respondent finally obtained a UR from Medical Plaza. The UR covered the month of July and showed that the pharmacy had dispensed a total of 201,444.74 du for all prescription products. RX 2F, at 127.

The UR further showed that Medical Plaza had dispensed 369 prescriptions totaling 61,130 du of oxycodone 30 mg and 229 prescriptions totaling 27,122 du of oxycodone 15 mg.[118] *Id.* at 111–12. Thus, Medical Plaza's dispensings of oxycodone 30 mg alone amounted to more than 30 percent of its total dispensings, and its dispensings of both dosage strengths (which totaled 88,252 du) amounted to nearly 44 percent of its total dispensings. Moreover, Medical Plaza's dispensings of all oxycodone products including OxyContin and combination drugs such as Endocet 10/325 and 10/650 totaled 112,401 du, 56 percent of its total dispensings.[119] Yet, during the June inspection, the pharmacy's PIC had represented that schedule II drugs comprised only 20 percent of its prescriptions.

Moreover, while the UR ranked the drugs by the number of prescriptions (per NDC) as opposed to the quantity of dosage units dispensed, with the exception of carisoprodol, controlled substances were predominant by either measure. *Id.* The UR also contained financial information for each drug including the adjudicated amount, the acquisition cost, the profit in dollars, and profit percentage. *See* RX 2F, at 111–17. However, the data for the most dispensed controlled substances were blacked out.[120] *See id.*

The next day (Aug. 12, 2009), Respondent filled Medical Plaza's orders for 5,000 du of oxycodone 15 and 3,600 du of Endocet 10/325. GX 10F, at 42. A SOMS note of the same date states: ''order does not exceed current size limit, ok to ship.'' GX 22, at 143. Moreover, the MFR notes establish that the compliance committee did not conduct its review of the site visit and UR until August 21. RX 2F, at 1. Yet the two orders were shipped nine days earlier.[121]

Respondent did not ship any oxycodone to Medical Plaza during September 2009, and in October, it filled a single order for 10,000 du of oxycodone 30 and two orders totaling 1,000 du of OxyContin 80. GX 10F, at 41–42. An MFR note dated November 11 states that ''UR was received on 8/11 for month of July'' and ''Need survey updated—completed 11/18.'' RX 2F, at 1.

On November 17, Respondent filled Medical Plaza's orders for 1,200 OxyContin 80, 1,200 of Endocet 10/325 and 200 du of Endocet 5/325. GX 10F, at 41–42. An MFR note dated November 17 states: ''order flagged for oxy 15 + 30 order is for 100, CSOS limit is 5000 already order 1400 on 11–17–09'' and ''[c]alled to let customer know order was not shipping today[.] The ph[arma]cy] was closed.'' RX 2F, at 1.

Medical Plaza's orders for 7,000 du of oxycodone 30 and 3,000 du of oxycodone 15 placed its total oxycodone orders at 23,600 du on a rolling 30-day basis; however, its highest monthly total during the previous six months was 18,600 du during August. GX 10F, at 41–42. Thus, the November 17 orders for oxycodone placed Medical Plaza's oxycodone orders at 5,000 du more than its CSL.

On November 18, a member of the compliance department contacted Medical Plaza and conducted a second due diligence survey. *Id.* at 68. According to the form, Respondent's representative asked its owner: ''what is the pharmacy's primary customer base?'' *Id.* Respondent's representative checked the box for ''community,'' leaving blank such boxes as ''Geriatric,'' ''Worker Comp,'' and ''Pain Management.'' *Id.* Respondent's representative also documented that the pharmacy did not do any ''Institutional' or ''Closed Door Business.'' *Id.* According to the form, Medical Plaza reported that McKesson was its primary wholesaler and that it also purchased from Anda. *Id.* It also reported that its daily prescription average was 120, that it filled ''C2s,'' and that its ''daily ratio of controls to non controls'' was ''40/60.'' *Id.* It further reported that it accepted insurance as well as Medicare and Medicaid and that ''70–80%'' of the prescriptions were paid for ''by insurance.'' *Id.*

As for its policies and procedures, Medical Plaza again reported that it filled prescriptions for out-of-state or out-of-area patients visiting the area but that it did not fill prescriptions written by out-of-state or out-of-area physicians. *Id.* at 69. It also denied soliciting practitioners and retirement communities for business. *Id.*

To prevent doctor shopping, Medical Plaza stated that it ''check[ed] profile'' and ''verif[ied] w/doctor.'' *Id.* And to ensure that doctors were exercising proper standards of care, Medical Plaza reported that it ''call[ed] to verify doctor information.'' *Id.* Medical Plaza also advised that it had a refused to fill a prescription because the prescription was not valid. *Id.* However, when asked whether it had ''ever decided to permanently stop filling scripts for a certain physician,'' it answered ''No.'' *Id.*

Notwithstanding that it conducted the due diligence survey, there is no evidence that Respondent's employee obtained an explanation for the November 17 orders or a new UR as required by its Policy 6.2 Yet the same

Inspection Report. RX 2F, at 62. The report noted that it was for ''an OPENING INSPECTION'' and that ''many responses [were] NOT APPLICABLE.'' *Id.*

[118] For each NDC, the report also calculated the average quantity dispensed per prescription. Specifically, the first line entry for oxycodone 30 (34,784 du) showed an average of 157 du per prescription; the second entry for oxycodone 30 (25,356 du) showed an average of 178.5 du per prescription; and the third entry (810 du) showed an average of 162 du per prescription. RX 2F, at 111, 114.

[119] The UR also showed that Medical Plaza had dispensed 75 prescriptions totaling 9,654 du of Endocet 10/325; 59 prescriptions totaling 5,047 du of OxyContin (and oxycodone er) 80 mg; 35 prescriptions totaling 2,487 du of OxyContin (and oxycodone er) 40 mg; 23 prescriptions totaling 2,120 du of oxycodone (and Roxicet) 5/325; 21 prescriptions totaling 1,700 du of oxycodone/apap 5/325; 14 prescriptions totaling 1,656 du of Endocet 10/650; 10 prescriptions totaling 1,140 du of oxycodone 5 mg; 7 prescriptions totaling 840 du of OxyContin (and oxycodone er) 10 mg; 10 prescriptions totaling 720 du of OxyContin (oxycodone er) 20 mg; 4 prescriptions totaling 295 du of Endocet 7.5/325; and 3 prescriptions totaling 190 du of Endocet 7.5/500. RX 2F, at 111–22.

[120] Given that the financial data for particular drugs on URs from other pharmacies were not blacked out, the fair inference is that Medical Plaza blacked out the data.

[121] Another SOMS note dated August 7 made by Ms. Seiple states: ''Or [sic] to ship please see UR and site visit.'' GX 22, at 143. Even if this entry does not correspond to one of the oxycodone orders that were filled the previous day, it should be noted that Respondent had yet to obtain a UR from Medical Plaza.

day (Nov. 18), Respondent filled the aforesaid orders which were for 7,000 du of oxycodone 30 and 3,000 du of oxycodone 15. GX 10F, at 41–42. According to notes in both the SOMS and MFRs, the orders were ''shipped [with] reservation'' and an ''updated UR was requested.'' RX 2F, at 1; GX 22, at 143.

On December 14, Medical Plaza placed an order for 15,000 du of oxycodone 30. RX 2F, at 2. On a rolling 30-day basis, Medical Plaza's oxycodone orders totaled 27,600 du, 9,000 du over the CSL of 18,600 (with August being the highest monthly total). Respondent contacted Medical Plaza to obtain a new UR, and the next day, Medical Plaza provided a UR for the month of November 2009. *Id.; see also id.* at 72–90. While Respondent did not fill the order, apparently because Medical Plaza was not ordering enough non-controlled products, there is no evidence that Respondent obtained an explanation for the order. RX 2F, at 2. (MFR note stating: ''Per Diane Customer need [sic] to order 3800 in non control [sic] products as of 12.15'').[122] Nonetheless, Respondent failed to report the order as suspicious even though it had been placed on hold because of its unusual size.

As for the November 2009 UR, it showed that Medical Plaza had dispensed 479 prescriptions totaling 92,404 du of oxycodone 30 mg [123] (an average of 193 du per Rx) and 348 prescriptions totaling for 44,051 du of oxycodone 15 (an average of 127 du per Rx); [124] it also showed that Medical Plaza's total dispensings of prescription products were 246,255 du. RX 2F, at 72, 74, 83, 90. Thus, since the previous UR, Medical Plaza's dispensings of oxycodone 30 had increased by 31,274 du, an increase of 51 percent, and its dispensings of oxycodone 15 had increased by 16,929 du, an increase of 62.4 percent.[125]

Moreover, Medical Plaza's dispensings of oxycodone 30 comprised 37.5 percent of its total dispensings, and its dispensings of oxycodone 15 comprised 17.9 percent. Thus, these two dosages alone accounted for 55.4 percent of its total dispensings, and its dispensings of all oxycodone products comprised nearly 64 percent of its dispensings. Yet during the previous due diligence survey, Medical Plaza had represented that *all* controlled substances constituted 40 percent of its dispensings. And once again, the financial data pertaining to the most dispensed controlled substances were blacked out. *Id.*

Respondent did not ship any more oxycodone to Medical Plaza until February 24, 2010, when it filled orders for 3,600 du of oxycodone 30 and 6,000 du of oxycodone 15. GX 10F, at 41–42.

In March 2010, Respondent filled orders for Medical Plaza for 49,000 du of oxycodone 30 and 31,500 du of oxycodone 15, for a total of 80,500 du. GX 10F, at 41–42. Notably, during the preceding six months, Medical Plaza's highest monthly total purchase of oxycodone was 12,600 du during the month of November. *Id.* As found above, according to Respondent, the SOMS reset the CSL ''for each control [sic] group . . . on the first of every month'' based on ''[t]he highest monthly total from the preceding six months.'' RX 78, at 60. Thus, the CSL should have been set at 12,600 du.

On March 11, Respondent filled Medical Plaza's orders for 4,000 du of oxycodone 30 and 4,000 du of oxycodone 15. GX 10F, at 41–42. With these orders, Medical Plaza's rolling 30-day total of oxycodone was 17,600 du, 5,000 du more than its CSL. According to a SOMS note, the order was ''ok to ship'' because its ''size was not excessive.'' GX 22, at 144. Here again, there is no evidence that Respondent obtained an explanation for the order and a new UR.

On March 16, Respondent filled Medical Plaza's orders for 10,000 more du of oxycodone 30, raising its total orders on a rolling 30-day basis to 27,600 du, a level more than double the CSL. GX 10F, at 41. The corresponding SOMS notes states: ''oxy 30 supported bu [sic] UR increase due to getting things squared away with AR.'' GX 22, at 144. An MFR note which is dated either March 11 or 16 states: ''Oxy orders have varied due to understanding ratio & problems with AR.'' RX 2F, at 2. While Respondent provided no further explanation as to the meaning of ''problems with AR,'' this order also placed Medical Plaza over its CSL, and even assuming that this explanation was provided by the pharmacy, Respondent did not obtain a new UR.

On March 18, Respondent filled an order for 7,500 du of oxycodone 30. GX 10F, at 41. With this order, Respondent had filled orders for 25,500 du just in March, as well as 9,600 du on February 24, for a total of 35,100 du on a rolling 30-day basis, placing Medical Plaza's filled orders at nearly three times the CSL.

The corresponding SOMS note states: ''ok to ship over 1,763 over UR for Oxy 30.'' GX 22, at 144. Once again, there is no evidence that Respondent contacted the pharmacy to obtain an explanation for the order as well as a UR. Of further note, while on numerous occasions Respondent filled orders notwithstanding that the orders exceeded the CSL, it typically justified doing so (even if improperly) because the order was under the dispensing levels showed by the UR. In short, the justification documented in the SOMS makes no sense.

On March 19, Respondent filled Medical Plaza's orders for 7,500 du of oxycodone 30 and 7,500 du of oxycodone 15, thus placing its total orders on a rolling 30-day basis at 50,100, a level more than four times the CSL. GX 10F, at 41–42. A note in the MFR states: ''RWR [Release with

[122] The evidence shows that this policy was not motivated by the concern that a customer that ordered only controlled substances was likely diverting drugs, but rather, out of the sales department's interest in using the availability of controlled substances to increase sales of other products. *See* GX 25, at 19 (email (Feb. 25, 2010) from Diane Garvey, Senior Vice President to Sales Department: ''DO NOT EVER ENTER A C2 ORDER UNLESS THE SYSTEM IS SHOWING 10% . . . . also the second you receive an csos [controlled substances ordering system] email and you see your customer has not reached the 10% that order will be put on hold for one day ONLY to try to secure the 10% then it will be deleted.''); *id.* (email (Feb. 25, 2010) from Jennifer Seiple to Compliance Department: ''Compliance does not hold orders for ratio. Ratio is controlled by sales. It is not factored in when the order is reviewed.''). *See also id.* at 5 (email Dec. 1, 2010 from Diane Garvey to Sales Department: ''When you get a csos order and your customers are NOT at 10% the order will hold no need to email us simply call the customer and get them to 10%. You should be calling them anyway and thanking them for the order and selling the daily specials, syringes, etc.''); Tr. 1276 (testimony of former compliance department employee regarding Ms. Garvey's Dec. 1, 2010 email that it was ''correct'' that Respondent ''did not want its customers to . . . purchase nothing but controlleds. It wanted to maximize its revenue by selling other products, specifically noncontrolleds, to the same customers, correct?'').

[123] Of further note, the first page of the UR contains the following handwritten notations: ''91,804 oxy 30's'' and ''43,991 Oxy 15's.'' RX 2F, at 72. These figures are the sum of the quantities listed in the entries on the first page of the UR for oxycodone 30 and oxycodone 15. However, the UR also includes an entry for 600 tablets of Roxicodone 30 mg (the same drug as oxycodone 30), *see id.* at 74, and an entry for 60 tablets of oxycodone 15 under a different NDC. *See id.* at 83.

[124] The UR also showed that Medical Plaza had dispensed a total of 20,095 du of other oxycodone products including OxyContin (and oxycodone extended release) and oxycodone combination drugs. *See* RX 2F. These included 6,740 du of Endocet and generic oxycodone 10/325; 4,469 du of OxyContin 80; 2,700 du of Percocet and generic oxycodone 5/325; 1,812 du of OxyContin 40; 1,158 du of Endocet 10/650; 984 du of OxyContin 10; 780 du of OxyContin 20; 420 du of Endocet and generic oxycodone 7.5/325; 364 oxycodone 5; 360 OxyContin 60; 150 du of OxyContin 30; and 150 du of Endocet 7.5/500. *See id.*

[125] The UR also showed the quantity per prescription for each drug by NDC code—thus Respondent's employees who reviewed the UR did not even have to calculate this figure; the UR showed that for oxycodone 30 with NDC 00406–8530–01, the average quantity was 195.59, and for NDC code 52152–0215–02, the average quantity was 186.91. RX 2F, at 72.

Reservation]—order supported by UR fluctuation in buying pattern due to credit & sales,'' RX 2F, at 2; and a SOMS note states: ''ok to ship UR supports Oxy order.'' GX 22, at 144.

Regarding the MFR's reference to the fluctuation in Medical Plaza's buying pattern because of credit and sales, the record does contain a February 8, 2010 email from Dennis Smith, Respondent's CEO, to various employees including Ms. Seiple and Mr. Corona which states: ''Sales on these Oxycodone and and [sic] SOMS activity should grow significantly due to reduced prices on these products to the retail trade. Look for KVK Oxycodone sales to increase dramatically.'' RX 20. However, while it would be reasonable for a pharmacy to increase its purchases of a product to take advantage of a discount being offered by a manufacturer or distributor, there is no evidence that any of Respondent's employees who reviewed Medical Plaza's orders contacted the pharmacy and were provided this explanation by it for any order until late April.

On March 24, Respondent filled Medical Plaza's orders for 10,000 du of oxycodone 30 and 10,000 du of oxycodone 15, thus placing its total orders during the rolling 30-day period at 70,100 du, a level nearly six times the CSL. GX 10F, at 41–42. A SOMS note states that the order was ''ok to ship-oxycodone increase ur supported-frequency not excessive.'' GX 22, at 144. Again, there is no evidence that Respondent contacted Medical Plaza to obtain an explanation for the increase in its orders, or that it obtained a new UR even though the UR on file was then four months old.

On March 25, Respondent filled two more orders from Medical Plaza for 10,000 du each of oxycodone 30 and 15, thus placing its total orders during the rolling 30-day period at 90,100 du, a level more than seven times its CSL. GX 10F, at 41–42. A SOMS note by Ms. Seiple states: ''rwr [release with reservation] per committee supported by ur on file please do not exceed quantity on ur for roxy 30 and 15.'' GX 22, at 144. An MFR note by Ms. Seiple further states: ''Ship to UR per committee order released for 20k (10k Oxy 30 10k OX 15) only ship to UR on file Do not ship over UR.'' RX 2F, at 2. Here again, there is no evidence that Respondent contacted Medical Plaza and obtained an explanation for the order and a new UR.

Medical Plaza's March orders marked a more than four-fold increase in its oxycodone purchases over its previous highest month's purchases (18,600 du in August), and a nearly six-fold increase over its highest month's purchases during the previous six months. Yet Respondent failed to report any of the March orders as suspicious.

On April 1, Respondent filled Medical Plaza's order for 10,000 du of oxycodone 30, bringing its total orders on a rolling 30-day basis to 90,500. GX 10F, at 41. Yet a SOMS note on the order states: ''ok to ship-morphine and oxycodone within csl for period.'' GX 22, at 144. However, even assuming that Medical Plaza's oxycodone CSL was automatically increased to 80,500 du based on the March 2010 orders, the April 1 order still placed it 10,000 du over the CSL. Here again, there is no evidence that Respondent contacted Medical Plaza and obtained an explanation for the order and a new UR. Nor did it report the order as suspicious.

Thereafter, on April 8, Respondent filled Medical Plaza's orders for 3,700 du of oxycodone 30 and 10,000 du of oxycodone 15, bringing its total orders on a rolling 30-day basis to 104,200 du and nearly 24,000 du over its CSL . GX 10F, at 41–42. Incredibly, a SOMS note for the transactions states: ''ok to ship, size & [f]requency not excessive on OXY CSL is 15k, this order is for (100) OXY 15mg & (37) OXY 30mg already purchased 10k this month.'' GX 22, at 144. Here again, there is no evidence that Respondent contacted Medical Plaza and obtained an explanation for the orders and a new UR. Nor did it report the orders as suspicious.

On April 15, Respondent filled Medical Plaza's orders for 42,000 du of oxycodone 30 and 10,000 du of oxycodone 15, thus bring its total orders on a rolling 30-day basis to 138,200 du, nearly 58,000 du over its CSL. GX 10F, at 41–42. Two SOMS notes of the same date state: ''ok to ship oxy ur supports order'' and ''ok to ship Oxy 15 & 30 ur supprts [sic].'' GX 22, at 144. A note in the Ship to Memos states: ''Oxy 30mg-91,804'' and Oxy 15mg–43,991.'' *Id.* at 141. These numbers correspond to the numbers in the handwritten notation on the first page of the November 2009 UR. *See* RX 2F, at 72; *see also supra* n. 125. And a second note in the Ship to Memos, which was added later that day, states: ''released 10k of Oxy 15mg leaves 23,991 . . . 30k of the Oxy 30mg leaves 14,804 for the month of April.'' GX 22, at 141. Once again, there is no evidence that Respondent contacted Medical Plaza and obtained an explanation for the order and a new UR. Nor did it report the orders as suspicious.

The evidence also shows that on or about April 23, Medical Plaza placed additional orders for 30,000 du of oxycodone 30 and 15,000 du of oxycodone 15. RX 2F, at 2. On a rolling 30-day basis, these orders placed the Medical Plaza's oxycodone orders at 140,700 du, a level more than 60,000 du above the March shipments.[126]

Regarding the April 23 orders, an MFR note states: ''order pending 15k oxy 15 oxy 30, 30 K.'' *Id.* The note then states that the account was ''currently @ 55k on OX 30 mg for month & 20k on Oxy 15 mg'' and that the order was ''not supported [by] the UR.'' *Id.* The note then states: ''get updated UR from March for Review'' and ''let them know order will not ship & will be reviewed in [illegible] days.'' *Id.* A further note in the Ship to Memos states: ''In April shipped 75700 Oxy. The account was reviewed to not ship over this amount[.] An order was deleted for 450 bottles above the 75700 already shipped.'' GX 22, at 141.

Other MFR notes show that Respondent contacted the pharmacy and was told that the order was because of ''price'' and that the pharmacy was ''stocking up.'' RX 2F, at 3. The pharmacist also said he would accept a lower quantity and that ''business [wa]s still about the same.'' *Id.* According to the note, Respondent's employee told the pharmacist that the last UR was from November,[127] to which the pharmacist replied that ''nothing changed.'' *Id.* Respondent's employee told the pharmacist that the order would be reviewed, and in a later phone call, told the pharmacist that the order would not be shipped that day. *Id.* According to the MFR, the pharmacist said ''ok it was for over stock anyway.'' *Id.*

An MFR note of April 26 indicates that Ms. Seiple called Medical Plaza and talked with its pharmacist. *Id.* The additional note states: ''McKesson is wholesaler—Advertise promoting sending out flyers.'' *Id.* A further note states that the account was reviewed with Wayne Corona and that the pharmacy's oxycodone limit was currently at 75k. *Id.* The notes also indicate that Respondent had already shipped 75,700 du in April and that the decision was made to keep the limit at 75k and to not ship ''over 75K.'' *Id.* Further notes establish that Medical Plaza's pending order for 450 bottles of oxycodone (45,000 du) was then deleted and that Respondent contacted the pharmacist and ''explained not able to ship more than the 75,700 Oxy already shipped.'' *Id.*

[126] This total includes the Mar. 25 orders for 10,000 du of oxycodone 30 and 10,000 du of oxycodone 15; the April 1 order for 10,000 du of oxycodone 30; the April 8 orders for 3,700 du of oxycodone 30 and 10,000 du of oxycodone 15; and the April 15 orders for 42,000 du of oxycodone 30 and 10,000 du of oxycodone 15. GX 10F, at 41–42.

[127] According to another note, Respondent's employee had called the pharmacy earlier, spoken to a floater, and asked for a new UR. RX 2F, at 3.

Notably, the April 23 orders were not reported as suspicious, even though Medical Plaza's employees gave inconsistent explanations for the order, with one saying the order was placed because of price, that it ''was for overstock anyway,'' and that the ''business [wa]s still about the same,'' and the other indicating that the order was needed because Medical Plaza was promoting its business. This was so even though the orders placed Medical Plaza's oxycodone orders at more than 60,000 du over its CSL.

Moreover, while the orders had initially prompted Respondent to request a new UR, Medical Plaza did not provide one. Indeed, Respondent did not obtain another UR until August 19, 2010, even though it continued to ship oxycodone to Medical Plaza. *Id.* at 12; GX 10F, at 42.

On May 3, 2010, Medical Plaza placed orders for 30,000 oxycodone 30 mg and 20,000 oxycodone 15 mg. GX 22, at 145. On a rolling 30-day basis, Medical Plaza's orders thus totaled 115,700 du, 40,000 du above the CSL of 75,700 (calculated based on the orders filled in April). GX 10F, at 41–42. A note in the MFR states: ''Called @1.46 p.m. spoke w/Dana Call back @ 2:30 TT—Jeff.'' RX 2F, at 3. Not only is it unclear whether Respondent's employee called back the pharmacy and spoke with Jeff, but even if he/she did, there is no evidence as to what explanation was provided for the order. However, what is clear is that a new UR was not obtained. Moreover, while the evidence shows that Respondent edited the orders to 10,000 du for each dosage strength, it did not report the orders as suspicious. GX 10F, at 42; GX 22, at 145 (SOMS note: ''ok to ship qty was reduced from 200 OXY 15mg to 100 & 300 OXY 30mg to 100'').

Respondent did not fill another oxycodone order for Medical Plaza until June 28, 2010, when it shipped 14,000 du of oxycodone 30 mg to it.[128] GX 10F, at 42. An MFR note for the transaction states that ''Order for 200 bottles of Oxy has been reduced to 140 bottles @CSL for June 14K. Called + spoke w/Jeffery + told him he can reorder after the 30th.'' RX 2F, at 4; *see also* GX 22, at 145 (SOMS note: ''releasing Oxy with reservation reduced to be @CSL for June.''). While the CSL is far closer to the CSL which should have been in place at the time of the March 2010 orders, there is no evidence as to how this new CSL level was set.

On July 1, 2010, Medical Plaza placed an order for 20,000 du of oxycodone 30 mg. GX 22, at 145. However, Respondent shipped only 14,000 du. GX 22, at 145. A SOMS note for the order states: ''ok to ship 140 Oxy 30 mg, order has been edited from 200 to meet CSL of 14000.'' *Id.* Yet, on filling the order, Respondent had actually shipped 28,000 du in the last three days, thus exceeding the CSL on a rolling 30-day basis. However, Respondent did not contact the pharmacy to obtain an explanation for the order and it again failed to obtain a new UR.

According to a July 14 note in the Ship to Memos made by Ms. Seiple, on that date, Respondent placed Medical Plaza's account ''on termination per sales surrounding issues of customer and ratio.'' GX 22, at 141. However, on July 22, Ms. Seiple created a second Ship to Memo which states that Medical Plaza was actually only ''on noncontrol status per sales until further notice'' and that she would ''get [an] update from sales'' four days later. *Id.* at 142. Ms. Seiple noted that she had ''request [an] updated ur'' and placed Medical Plaza on the ''tentative site visit list.'' *Id.*

An initial entry in the MFRs for July 30 states that an order for 10,300 oxycodone 30 was deleted because Medical Plaza was on non-control status. RX 2F, at 4. However, a further entry establishes that the same day, the sales department approved the pharmacy to resume purchasing controlled substances. *Id.* While Ms. Seiple had requested that Medical Plaza provide a new UR eight days earlier, Respondent filled its order for 10,300 du of oxycodone 30 mg without obtaining the UR. GX 10F, at 42. Moreover, the order placed Medical Plaza's orders on a rolling 30-day basis at 24,300 du, more than 10,000 du over its CSL.[129]

However, there is no evidence that Respondent obtained an explanation for the order.

Only four days later on August 3, Respondent filled Medical Plaza's order for 12,200 du of oxycodone 30. GX 10F, at 42. Moreover, while the order clearly placed the pharmacy over the 14,000 du CSL on a rolling 30-day basis,[130] the SOMS notes contain no indication that the order was flagged for additional review.[131]

On August 17, Medical Plaza placed an order for 20,000 du of oxycodone 30. GX 22, at 145. While both the MFRs and SOMS notes state that the order was reduced to 1,800 du to keep Medical Plaza at its CSL of 14,000 du, other notes state that Respondent deleted the order and told its pharmacist that he needed to provide an ''updated UR'' and needed to re-order after the UR was reviewed. RX 2F, at 4; GX 22, at 145.

On August 19, Medical Plaza faxed to Respondent a UR for the month of July 2010. RX 2F, at 12–30. The UR showed that during that month, Medical Plaza had dispensed 118,848 du of oxycodone 30 and 41,160 du of oxycodone 15; its total dispensings of just these two drugs were 160,008 du, out of its total dispensings of 285,977.85 du. RX 2F, at 12–13, 20, 30. Thus, Medical Plaza's dispensings of oxycodone 30 alone comprised 41.6 percent of its total dispensings, and its dispensings of oxycodone 15 comprised 14.4 percent. Moreover, the UR showed that Medical Plaza had also dispensed 21,455 du of other oxycodone products including OxyContin and combination oxycodone drugs.[132] Thus, Medical Plaza's dispensings of oxycodone amounted to 63.5 percent of all drugs it dispensed. These figures were again flatly inconsistent with what the pharmacy had reported during the last due diligence survey. RX 2F, at 68

[128] There are, however, entries in both the SOMS notes and MFRs dated May 10, 2010. The MFR note states ''UR on file Oxy 30 68k 15 mg 23k'' and ''Only purchases 30's & 15's.'' RX 2F, at 4. To be clear, the last UR on file had been obtained on December 15, 2009 and covered the month of November 2009. Further entries in the MFR notes state ''April 75K, March 80K,'' an apparent reference to the pharmacy's oxycodone purchases from Respondent in the two previous months, and then lists the names of its distributors: ''McKesson, Anda[,] Masters.'' *Id.* The final entry in this note states: ''120 scripts a day, currently.'' *Id.*

As for the SOMS note, it states ''rlease [sic] order do nto [sic] ship over 50k without review.'' GX 22, at 145. As stated above, there is no other evidence that Medical Plaza placed any order for oxycodone on or about May 10 and it is unclear to which drug this note pertains.

[129] A Ship to Memo dated July 14 states that the ''last control [sic] purchase'' was ''being returned'' because the ''wrong product'' was ordered. GX 22, at 141. However, according to materials Respondent provided on the SOMS, the monthly totals used in determining whether an order exceeded the CSL ''include product returned when it is calculated'' and ''[t]he rolling 30 day invoice history will include invoices and credit memos from the past 30 days.'' RX 78, at 60. Thus, the fact that Medical Plaza returned the July 1 order should have had no effect on whether subsequent orders exceeded the CSL on a rolling 30-day basis.

[130] Notwithstanding that the SOMS materials state that returned product would be counted in calculating the CSL, an August 17 SOMS note states that the CSL remained at 14,000 du. GX 22, at 145.

[131] As discussed above, in its Exceptions, Respondent contended that ''the only orders that were held by SOMS were those that also have the name of a Compliance Department employee in the ''Decision By'' column and in most cases, notes in the ''Notes'' column. Resp. Exceptions, at 13. While there are two entries for orders in in the SOMS notes on August 3, 2010, neither entry includes the name of an employee or notes explaining the decision that was made on the shipment.

[132] The dispensings included 4,493 du of OxyContin 80; 1,915 du of OxyContin 40; 60 du of OxyContin 30; 1,800 du of OxyContin 20; 690 du of OxyContin 10; and 810 du of oxycodone 5; it also included 1,723 du of Endocet 10/650; 7,352 du of Endocet 10/325; 162 du of Endocet 7.5/325; 2,075 du of oxycodone 5/325; and 375 du of Roxicet 5/325. RX 2F, at 12–13, 15, 17, 20, 23.

(representing that all controlled substances comprised 40 percent of all dispensings).

As with the previous URs, with the exception of carisoprodol, the top ten drugs dispensed were controlled substances, whether this was determined on the basis of the number of prescriptions or the number of dosage units. *Id.* at 12. So too, the financial data for drugs such as oxycodone 15 and 30, as well as alprazolam 2, were blacked out. *Id.* And once again this information was ignored by Respondent.

Also on August 19, Medical Plaza placed an order for 20,000 du of oxycodone 30 mg. GX 22, at 145. Upon placing this order, Medical Plaza's oxycodone orders totaled 42,500 du on a rolling 30-day basis, more than three times the CSL of 14,000 du. GX 10F, at 42.

Regarding the order, the SOMS note states: ''ok to ship 64 bottles of Oxy 30mg, order was edited from 200 to 64. Another order can be resubmitted after 9/1/10.'' GX 22, at 145. Moreover, a note in the Ship to Memos of the same date states: ''maintain 18600.'' GX 22, at 142. While Respondent shipped only 6,400 du (bring the total filled orders to 28,900 du), GX 10F, at 42; Respondent's various records contain no explanation as to why the order was approved even though the order placed the Medical Plaza over the CSL (both before and after editing), whether the CSL was 14,000 du, 18,600 du, or even if the CSL had been revised upwards (to 24,300) based on the July orders. Moreover, the order was not reported as suspicious.

On September 1, Respondent filled Medical Plaza's order for 10,000 du of oxycodone 30 mg. GX 10F, at 42. On a rolling 30-day basis, Medical Plaza orders totaled 28,600 and thus again exceeded the CSL. *Id.* The SOMS note for the order states: ''rwr Oxy w/in monthly buying pattern leaves 8600 as of 9/1.'' GX 22, at 145. Here again, the fact that the CSL had been exceeded was ignored and Respondent failed to contact Medical Plaza and obtain an explanation for the order and a new UR.

On September 7, Medical Plaza placed an additional order for oxycodone and the evidence shows that Respondent shipped 8,600 du of oxycodone 30. GX 10F, at 42. The corresponding SOMS note states: ''rwr Oxy edited to meet CSL.'' GX 22, at 145. While the evidence does not establish order's size before it was edited, upon filling the order, Respondent had shipped 25,000 du of oxycodone 30 on a rolling 30-day basis. GX 10F, at 42. Thus, even if the CSL had been reset at 24,300 du based on Medical Plaza's July orders, Respondent again filled an order which placed the pharmacy over its CSL. Yet there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order or a new UR.

On October 1, Respondent filled an order for 16,800 du of oxycodone 30. GX 10F, at 42. Upon filling this order, Respondent had shipped 25,400 du of oxycodone 30 within the rolling-30-day period and thus exceeded the CSL. *Id.* While there are multiple SOMS entries for orders that were placed on this date, two of which indicate that Ms. Seiple reviewed them, the only notation for either of these orders is ''rwr'' or release with reservation. GX 22, at 146. No further explanation exists anywhere in Medical Plaza's file explaining why Respondent filled the oxycodone 30 order, and there is no evidence that Respondent contacted the pharmacy to obtain an explanation for the order and a new UR.

On November 5, Respondent filled an order for 8,400 du of oxycodone 30 mg, and on December 1, it filled two orders totaling 16,800 du of oxycodone 30 mg. GX 10F, at 42. While the November 5 order did not exceed the CSL, upon filling the December 1 order, Respondent had shipped to Medical Plaza 25,200 du on a rolling 30-day basis and thus exceeded the CSL. GX 10F, at 42. As for the two December 1 SOMS entries, only one provides the name of a reviewer (Ms. Seiple) and the accompanying note merely states: ''rwr.'' GX 22, at 146. Again, no further explanation exists in Medical Plaza's file for why Respondent filled the order, and there is no evidence that Respondent contacted the pharmacy to obtain an explanation for the order and a new UR.

On January 4, 2011, Medical Plaza placed an order for 20,000 du of oxycodone 30 mg. GX 22, at 143. According to the SOMS, the order was edited to 16,800 du, *id.,* and according to the Government's evidence, this amount was shipped. GX 10F, at 42. An MFR note of the same date states: ''Keep Oxy @16,800'' and ''Don't Ship over'' with an arrow pointing to ''16,800,'' as well as ''CSL is 14k.'' RX 2F, at 4.

Additional notes in the same MFR entry, which appear to have been made by Ms. Seiple, state: ''inquire on vendors McKesson/?'' and ''said they use quite a bit of insurance on oxy? How then can their [sic] be a profit?'' *Id.* A further entry includes the names of two distributors (McKesson and Keysource) and indicates that Medical Plaza was being reimbursed by insurance at a lower rate ($32.00) than the cost of the oxycodone ($39.00) and was ''losing money.'' [133] *Id.*

The same day, Respondent obtained a new UR from Medical Plaza. *Id.* at 31. The UR, which covered the month of December 2010, showed that Medical Plaza had dispensed 58,173 du of oxycodone 30 mg and 7,006 du of oxycodone 15 mg and that its total dispensings of all drugs were 190,760 du.[134] *Id.* at 31–32, 42, 53. Moreover, in contrast to the previous URs, the financial data for oxycodone and other highly abused drugs were not blacked out and showed that Medical Plaza was making profits approximately three times its acquisition cost for oxycodone 30.[135] Thus, contrary to what Ms. Seiple expressed in the MFR, Medical Plaza was clearly not losing money on oxycodone.

On February 1, 2011, Respondent filled an order from Medical Plaza for 10,000 du of oxycodone 30, and on February 2, it filled an order for 6,800 du of the drug. GX 10F, at 42. Notes written on the UR and in the MFRs show that Ms. Seiple reviewed the UR and determined that oxycodone in the dosage strength of 30 mg and 15 mg amounted to ''63K'' out of ''190K'' or ''33%'' of its dispensings.[136] RX 2F, at 5. An MFR note of February 2 indicates that Ms. Seiple raised with Wayne Corona the ''reimbursement issue w/ insurance'' and that Corona stated that the issue was ''not a problem.'' *Id.* at 4. Still another MFR note made by Ms. Seiple on the same day states: ''68 bottles of oxy released per committee RWR'' and ''purchasing multiple NDC on product—Monitor.'' *Id.* at 5.

According to an MFR note, on March 2, 2011, Medical Plaza placed an order for 16,800 du of oxycodone 30mg, which was released with reservation. *Id.* However, an MFR note of March 3 made

[133] The entry also states that ''released 100 of 168 bottles ordered.'' RX 2F, at 4. However, while I find that the order was edited, the Government's evidence establishes that Respondent shipped 16,800 du of oxycodone 30 to Medical Plaza. GX 10F, at 42.

[134] While this represented a decrease in Medical Plaza's dispensings, by this date, law enforcement and regulatory authorities had begun cracking down on rogue pain clinics in Florida.

[135] With respect to oxycodone (NDC 00406–8530–01), Medical Plaza dispensed 23,960 du; its acquisition cost was $11,631.61 and its profit was $35,482.44. RX 2F, at 31. With respect to oxycodone (NDC 57664–0224–88), Medical Plaza dispensed 14,078 du; its acquisition cost was 11,262.40 and its profit was $32,483.17. *Id.* With respect to oxycodone 30 (NDC 52152–0215), Medical Plaza dispensed 10,721 du; its acquisition cost was $4,458.87 and its profit was $25,190.92. *Id.* With respect to oxycodone 30 (NDC 10702–0000–01), it dispensed 8,014 du; its acquisition cost was $6,972.18 and its profit was $19,108.37. *Id.*

[136] The actual figures are 65,179 du and 34 percent.

by Ms. Seiple states: ''suspended sales until physicians list is provided and reviewed by compliance committee in addition to site visit.'' *Id.* Continuing, the note states: ''Account will remain on CH [compliance hold] until detailed physicians list and review is completed.'' *Id.*

Yet a SOMS note dated March 4, 2011 states: ''rwr-oxy @qty 168.0 3–4–11,'' thus indicating that the March 2 order was filled after Medical Plaza had purportedly been placed on compliance hold. GX 22, at 143; *see also* GX 10F, at 42. Notably, Medical Plaza's file does not contain a physicians list and an MFR entry for April 1, 2011 states: ''CH—no information sent to date for review.'' RX 2F, at 5. While the SOMS notes contain entries suggesting that additional controlled substance orders were placed on March 7 and April 13, 2011, *see* GX 22, at 143; the Government's printout of filled orders does not include any additional orders after March 4, 2011.[137] However, Respondent never reported any of Medical Plaza's orders as suspicious.

As for Respondent's distributions to Medical Plaza, Ms. Seiple's declaration was comprised primarily of the same testimony she provided with respect to the previous pharmacies. For example, Ms. Seiple noted that before shipping controlled substances to Medical Plaza, Respondent verified that its Florida pharmacy license and DEA registration were valid and that it obtained a copy of the most recent DOH inspection. She also asserted that based on the description provided by Medical Plaza as to its policies and procedures, Respondent believed that the pharmacy understood its obligations to prevent diversion ''and was taking affirmative steps'' to prevent diversion. RX 103, at 66. Yet in contrast to previous surveys, Respondent did not ask how the pharmacy ensured that the prescriptions were issued by doctors acting in accordance with the standard of care, let alone how the pharmacy ensured that the prescriptions it filled were being issued for a legitimate medical purpose.

Ms. Seiple further asserted that based on a due diligence survey and the onsite inspection that was conducted on June 18, 2009, Respondent obtained information that ''Medical Plaza was located in a medical center with 60 physicians, and the pharmacy serviced patients from that medical center and an adjacent hospital.'' *Id.* at 66–67. Ms. Seiple then asserted that ''[t]his accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.'' *Id.* Yet during the site visit, Respondent's inspector had noted that the pharmacy *did not fill prescriptions for practitioners who were primarily engaged in pain management. See* RX 2F, at 60.

So too, the mere presence of 60 doctors located in the same medical office building, without any investigation into the doctors' specialties and the drugs they would prescribe in the course of their respective professional practices does not justify the volume of pain medications being dispensed by Medical Plaza or the percentage of oxycodone the pharmacy was dispensing relative to other drugs. Also, Respondent did not even obtain a UR until August 11, 2009, at which point it had been selling oxycodone to Medical Plaza for more than four months, and that UR showed that oxycodone comprised more than 51 percent of the pharmacy's total dispensings. Moreover, the percentage of Medical Plaza's total dispensings comprised by oxycodone alone was more than 2.5 times the 20 percent figure provided by DEA during the Compliance Review for all controlled substances as a percentage of a pharmacy's total dispensings.

As with the previous pharmacies, Ms. Seiple asserted that ''[a]fter Medical Plaza's account was approved, [the] SOMS . . . identified and held any order for controlled substances placed by Medical Plaza that deviated from its typical volume, pattern or frequency'' and that ''[a]ll such orders were released only after review by [the] Compliance Department.'' RX 103, at 67. Here again, the SOMS was not even operational until August 2009, more than four months after Medical Plaza had begun purchasing controlled substances from Respondent.

Moreover, even after the SOMS became operational, there were numerous instances in which Medical Plaza's orders placed it over the CSL on a rolling 30-day basis and yet Respondent failed to obtain an explanation for the order, or a new UR, even though these steps were required by Respondent's policy and procedure for reviewing held orders. And in numerous instances when orders were either deleted or edited, Respondent failed to file a suspicious order report.

While Ms. Seiple further asserted that ''[o]n some occasions, the Compliance Department would request [Medical Plaza] to provide a UR,'' *id.,* it obtained only four URs over the course of the nearly two-year period in which it distributed oxycodone to the pharmacy. And when it obtained URs for the months of November 2009 and July 2010, it ignored information showing that the pharmacy was dispensing increasing quantities of oxycodone, as well as that Medical Plaza's dispensing of oxycodone products comprised 62 percent of its total dispensings.

So too, while Medical Plaza represented at various points that 70 to 80 percent of the prescriptions were paid for by third party payors (such as insurance and Medicare/Medicaid), the financial data showing the profits on its sales of oxycodone 30 and 15 were blacked out on all but the final UR it provided. Yet there is no evidence that Respondent ever questioned Medical Plaza as to why it blacked out the data. Moreover, when Respondent did obtain the final UR, the data (which were not blacked out) showed that Medical Plaza was making profits three times or more its acquisition cost on generic oxycodone 30 and 15 products.

Ms. Seiple documented her concerns as to how Medical Plaza could be making any money given that its cost for the oxycodone was more than the amount that insurance would reimburse for it, as well as that she had raised the issue with Wayne Corona, who overruled her concerns. While Ms. Seiple asserted that the URs and other information were ''consistent with the pharmacy's business model as explained by [its PIC] and confirmed in the June 2009 site inspection,'' she failed to address why Respondent did not question Medical Plaza as to why the financial data for its controlled substance dispensings were blacked out on the URs. Ms. Seiple also failed to address why Respondent continued selling controlled substances even after the fourth UR showed that Medical Plaza was not ''losing money'' on its dispensings of oxycodone but making substantial profits.

Ms. Seiple acknowledged that Respondent did not report any of Medical Plaza's orders as suspicious, asserting that ''[b]ased on [its] extensive investigation, it determined that the orders it shipped to Medical Plaza were not suspicious.'' RX 103, at 68. Here again, however, Respondent simply accepted whatever reason it could find that it believed would justify ignoring the evidence provided by the URs regarding the level of Medical Plaza's dispensings of oxycodone and continued to distribute the drugs to Medical Plaza. Thus, while—as Ms. Seiple admitted—Respondent was obviously ''aware of the volume of oxycodone and other controlled drugs being dispensed by Medical Plaza and

[137] The Government's printout of ARCOS data would not have included schedule IV drugs such as alprazolam. 21 CFR 1304.33(d). Nor would it have included drugs such as tramadol and carisoprodol, which were subject to the SOMS.

the percentage of controlled drugs dispensed relative to other drugs,'' it had no valid basis for failing to report the orders as suspicious.

Temple Terrace Pharmacy D/B/A Superior Pharmacy

Superior Pharmacy, a community pharmacy located in Temple Terrace, Florida, became a customer of Respondent in January 2008. RX 2H, at 81; RX 103, at 72. Prior to Superior's first purchase of controlled substances, Respondent obtained copies of its DEA registration and State license. RX 2H, at 18–19.

On May 2, 2008, an account manager completed a Schedule Drug Limit Increase Request Form, requesting an increase in the amount of solid dose oxycodone products Superior could purchase and noting on the form that Superior was using 25,000 du per month. *Id.* at 83. Thereafter, on May 9, 2008, Respondent verified that Superior's PIC, as well as another officer of the entity, held active Florida pharmacist licenses. *Id., see also id.* at 79–80.[138]

As part of reviewing Superior's request, on June 6, 2008, Respondent contacted Superior to complete a Due Diligence Report Form. *Id.* at 81. On the form, Respondent documented that Superior filled an average of 130 prescriptions per day and that 15 percent of the prescriptions were for schedule II drugs; Superior also reported that controlled substance prescriptions comprised 20 percent of the prescriptions. *Id.* Superior represented that it did not do mail order, that it serviced one nursing home but had no contracts with such facilities, that it accepted insurance as well as Medicare and Medicaid, and that 90–95 percent of the prescriptions were paid for by insurance. *Id.*

Elsewhere on the form, Respondent lined out the section which asked whether the pharmacy had ''[r]elationships with specific doctors/clinics,'' thus indicating that Superior had no such relationship. *Id.* As for its policies and procedures, Superior reported that it prevented doctor shopping by verifying prescriptions, by not providing early refills, and by keeping a patient profile. *Id.* at 82. As for how it ensured that doctors exercised proper standards of care, Superior replied that it did a ''license check.'' *Id.* Superior also reported that it had refused prescriptions because the quantities were large, the prescription looked strange, or it could not verify the prescriptions with the doctor. *Id.* As for whether it had ever refused to fill prescriptions written by ''a certain physician,'' Respondent's employee noted that Superior had ''not cut off doctor, but refuses scripts often.'' *Id.* While the form also included the question of whether ''the pharmacy practices due diligence on specific prescribers,'' the box next to this question was left blank with a small line drawn in the space for providing a description.[139] *Id.*

Finally, Respondent's employee noted that she had requested that Superior provide its ''[m]ost recent state inspection report'' and a ''[c]omplete usages controls/non-controls of one full calendar month.'' *Id.* Of further note, Respondent's employee noted that Superior's pharmacist had said ''they are way to busy to deal with this,'' and that after she requested the additional documents, the pharmacist ''said she doubts she will *ever* fax that to me.'' *Id.*

However, on June 11, Superior faxed to Respondent a UR and a copy of its most recent DOH inspection report. As the fax cover sheet from Superior notes, the documents were faxed ''so that our quota on C2 may be increased.'' *Id.* at 74. But as the cover sheet explained, the UR, which covered the period of January 1 to through June 10, 2008, only included Superior's ''top 100 drugs dispensed.'' *Id.; see also id.* at 71–72.

As for the UR, it showed that oxycodone 30 mg was the drug most dispensed by Superior during the period, with total dispensings of 337,201 du or 63,503 du per month. *Id.* at 71. It also showed that Superior had dispensed 21,779 du of oxycodone 15 and 48,341 du of Endocet 10/325 during the period. *Id.*

On June 24, 2008, a consultant for Respondent conducted a site visit at Superior. *Id.* at 65. According to the consultant's report, Superior did not engage in internet business and sold ''minimal'' front store items. *Id.* at 65. The consultant also reported that Superior filled 100 prescriptions per day, of which 25 percent were for controlled substances. *Id.* at 66. While Superior reported that it did not service nursing homes and hospice programs, it reported that it serviced a juvenile inpatient facility. *Id.* The pharmacy further reported that 10 percent of its business was cash and 90 percent was paid for by either insurance or Medicare/Medicaid. *Id.* Next, Superior reported that it had three distributors in addition to Respondent. *Id.* at 67. Superior also acknowledged that it filled prescriptions for pain management clinics and provided the names of four pain management physicians, their DEA numbers, and indicated that they practiced in Tampa.[140] *Id.* at 70.

In the additional comments section of his report, Respondent's consultant wrote that the pharmacy shared its ''waiting area'' with ''a pain/weight control clinic.'' *Id.* The consultant further documented that ''[t]he pharmacy is located within a space that it shares with Superior Medical Center. This center specializes in weight loss and pain management. Many of their prescriptions originate within the clinic.'' *Id.* at 69–70. Included with the report were two photographs which showed the front of the pharmacy and its signage. The top portion of Superior's sign read: ''SUPERIOR PHARMACY • WALK IN CLINIC'' and the bottom portion read: ''Pain Management & Weight Loss.'' *Id.* at 68.

On July 1, 2008, Respondent printed out the Web page for Superior Medical Center. *Id.* at 49. The left side of the page promoted Superior Medical Center with the words ''Pharmacy • Pain • Weight Loss'' underneath. *Id.* On the right side, the page promoted Superior Pain Clinic with a banner that read: ''Are You Experiencing Pain?'' then listing various cause of pain, followed by ''Stop suffering in silence. >> Let us help you!'' *Id.*

The center of the page contained the heading ''Superior Medical Centers are here to help you!'' along with additional blurbs promoting its pain management clinic (''Don't live in pain. Trust the medical professionals at Superior Pain Clinic to help you enjoy life again!''), its weight loss and walk-in clinics,[141] and the pharmacy (''Superior Pharmacy is your neighborhood drug store offering personalized customer service and free home delivery.''). *Id.* Still other blurbs offered a ''free office visit or $20 dollar credit on RX'' for referring ''a friend or family'' and promoted that ''No Appointment Needed.'' *Id.*

On the same day, Respondent approved an increase in Superior's oxycodone purchasing limit to 25,000

[138] It also re-verified that the Superior held a valid state license and a DEA registration. RX 2H, at 77–78.

[139] Off to the right of this question (in and near the margin) is the notation: ''Tampa—100 mile radius.'' RX 2H, at 82. While the form contains other notations in the right margin, including one which is dated ''6/23/09,'' *id.,* it is unclear when this notation was made.

[140] In the form's section which lists the names of the four pain physicians, the name ''Merced'' is also listed without a DEA number and the name of the city in which he practiced. RX 2H, at 70. A note in the margin dated ''9–25–09'' suggests that this name was added on that date.

[141] Other photographs in the due diligence file show that the Pain Clinic and Walk-In Clinic were one and the same. RX 2H, at 28.

du per month. *Id.* at 83. While the record contains no evidence regarding the level of Superior's oxycodone purchases before April 1, 2009, the evidence shows that during April 2009, Respondent filled numerous orders totaling 16,800 du of oxycodone 30; 4,800 du of oxycodone 15; 1,200 du of Endocet 10/650; and 6,000 du of Endocet 10/325; for a total of 28,800 oxycodone products. GX 10F, at 43–44. There are, however, no notes discussing any of these orders.

On May 1, 2009, Superior placed orders, which Respondent filled, totaling 25,000 du of oxycodone 30. GX 10F, at 44. Here again, there are no notes discussing the orders.

On June 2, Superior placed orders, which Respondent filled, totaling 25,000 du of oxycodone 30. *Id.* Moreover, on June 24, Superior placed orders, which Respondent filled, for 30,000 du of oxycodone 30; 5,000 du of oxycodone 15; and 5,000 du of Endocet 10/325. *Id.* Respondent thus shipped a total of 65,000 du of oxycodone products to Superior during the month. Here again, there are no notes discussing any of these orders and the orders were not reported as suspicious even though they were more than double the April and May orders.

On June 18, Respondent obtained a second UR from Superior, which covered the month of May. *Id.* at 57–64; 96–104. Notably, with the exception of carisoprodol, which was then controlled under Florida law but not the CSA, each of the top 25 drugs was a controlled substance under federal law. *Id.* at 96. Moreover, the top four drugs were oxycodone products, three of which were different manufacturers' oxycodone 30 products, the other being Endocet 10/325. *Id.* Also among the most dispensed drugs were the stronger formulations of the benzodiazepines alprazolam (1 mg and 2 mg) and diazepam (5 mg and 10 mg), as well as other narcotics including oxycodone 15 mg and the strongest formulation of combination drugs containing either 7.5 or 10 mg of hydrocodone. *Id.*

As for Superior's dispensings of oxycodone, the UR showed that during May, it had dispensed a total of 60,274 du of oxycodone 30; 6,272 du of oxycodone 15; and 11,641 du of Endocet 10/325. RX 2H, at 96, 99, and 103. During the month, Superior's total dispensings of all prescriptions products were 209,481 du. *Id.* at 64. Thus, Superior's dispensings of oxycodone 30 alone comprised 28.8 percent of its total dispensings, and its dispensings of its top three oxycodone products (78,187 du) comprised 37.3 percent of its total dispensings.

On June 23, Respondent conducted a due diligence assessment (apparently by telephone) and re-verified that Superior held a DEA registration and a Florida Pharmacy license. RX H2, at 53, 56. According to the due diligence assessment, Superior did not claim that its primary customer base was workers compensation, pain management, or bariatric patients.[142] *Id.* at 51. Yet as found above, during the site visit, Respondent's consultant had reported that Superior shared space with a pain management and weight loss clinic [143] and that Superior's staff had told him that ''[m]any of their prescriptions originate within the clinic.'' *Id.* at 70.

Moreover, Superior now reported that it filled ''280'' prescriptions per day and that its ''daily ratio of controls to noncontrols [was] ''50/05'' [sic]. *Id.* Yet during the site visit, Superior had reported that it filled 100 prescriptions per day and that 25 percent of the prescriptions were for controlled substances. *Id.* at 66.

As for its policies and procedures, Superior reported that it did not fill prescriptions for patients and prescriptions written by doctors, unless the patients and doctors were within ''a 100 mile radius around Tampa.'' *Id.* at 52. As for its procedures to prevent doctor shopping, Superior advised that it called and verified all controlled prescriptions and watched the patients, and as for its procedures to ensure the prescribers were exercising proper standards of care, it asserted that it would ''[c]all and verify.'' *Id.* While Superior reported that it had ''refused to fill a prescription'' if it was ''too soon,'' it also advised that it had never ''decided to permanently stop filling scripts for a certain physician.'' *Id.*

Next, Superior provided the names of two physicians whose controlled substance prescriptions it filled (Dr. Mercedes and Dr. Hubang). *Id.* The same day, Respondent printed out a license verification and practitioner profile for the aforementioned Dr. Merced (but not a Dr. Mercedes) from the Florida DOH Web site. *Id.* at 54–55. Of note, the printouts showed that Dr. Merced's address of record was in Jamestown, North Carolina and not Tampa. *Id.*

Moreover, Respondent did not obtain printouts for either a Dr. Mercedes or a Dr. Hubang, and it did not conduct any further investigation into these physicians who were practicing pain management at Superior. *See generally* RX 2H. As for the latter, MFR notes dated September 25 spell the latter's name as Mubang. RX 2H, at 1. Yet there is no evidence that Respondent's compliance department conducted a license verification on a Dr. Mubang either, even though the notes indicated that Respondent was aware that he was writing prescriptions at the Superior Pain Clinic. *See generally* RX 2H. Nor did it check the license status of any of the physicians who Superior had previously identified as pain management physicians whose prescriptions it filled. And while various forms in the Due Diligence file indicate that Respondent conducted a Google Search of Superior Pharmacy, *id,* at 50–52, it did not conduct a Google Search of the doctors who were working at the Superior Medical Center. Had it done so, it would likely have come across a press release issued on July 16, 2008 by the Florida Department of Law Enforcement announcing the arrest of John Nkolo Mubang ''for allegedly trafficking in prescription drugs while he worked as an internal medicine doctor at a Tampa medical facility he owns and operates.'' [144]

Finally, the form provided a place to note either ''unusual answers'' or other relevant information. *Id.* at 52. In this place, Respondent noted: ''60% open door and 45% clinic'' [sic]. *Id.*

The next day (June 24), Respondent filled Superior's orders for 30,000 du of oxycodone 30; 5,000 du of oxycodone 15; and 5,000 du of Endocet 10/325. GX 10F, at 44. It did not report the orders as suspicious, notwithstanding that Superior's June orders were 40,000 du and 2.6 times greater than its May orders and despite the various inconsistencies in the information it possessed regarding Superior's business.

On July 1, Respondent filled Superior's orders for 45,000 du of oxycodone 30 and 200 du of Endodan, a drug combining oxycodone and aspirin. GX 10F, at 43–44. Moreover, on July 23, Respondent filled Superior's orders for 20,000 du of oxycodone 30, thus resulting in total shipments of 65,200 du for the month. *Id.* at 44. There is, however, no documentation explaining why the orders, which exceeded Superior's purchasing limit, were filled. Nor were the orders reported as suspicious.

[142] Indeed, it is unclear what Superior reported as its primary customer base, as the box for a ''community'' pharmacy was not checked (nor the box for ''other'') and there is no description next to the box that was checked. RX 2H, at 51.

[143] Superior did report that it was located within a medical clinic. RX 2H, at 51.

[144] Pursuant to 5 U.S.C. 557(e), I take official notice of the aforesaid press release, which can be accessed at *http://www.fdle.state.fl.us/Content/News/2008/July-2008/Hillsborough-County-Doctor-Charged-with-Prescripti.aspx.* Respondent shall have ten (10) business days from the date of issuance of this order to refute the above facts by filing a motion with this Office.

On August 11, Respondent filled Superior's order for 40,000 du of oxycodone 30. GX 10F, at 43. However, while there are SOMS notes for orders placed on August 6 and 7—thus indicating that the system was then functioning—there are no entries for orders placed on August 11. GX 24, at 106.

Moreover, on August 28, Respondent filled Superior's order for 35,000 du of oxycodone 30, thus bringing its total shipments of oxycodone 30 to 75,000 du or the month. GX 10F, at 43. While there are multiple orders listed in the SOMS notes with the date of August 27, several of which list the name of an employee who approved the order and notations such as ''to ship within current size limit for 30 day period,'' the notes do not specify which drugs these orders were for. GX 24, at 106. Moreover, because the record contains no evidence as to Superior's orders before April 1, 2009, there is insufficient evidence as to its six-month ordering history and thus, its oxycodone CSL cannot be determined as of this month.

On September 14, Respondent filled Superior's orders for 30,000 du of oxycodone 30 mg. GX 10F, at 43. Moreover, on September 24, Respondent filled an order for 5,000 du of Endocet 10/325. GX 10F, at 43. According to a note in the MFRs, on September 24, Superior placed three orders ''for 30k [thousand] pills'' and the order was ''held.'' RX 2H, at 1. While this entry does not specifically identify that the order was for oxycodone, an MFR entry for the next day supports the inference that it was.

The note, which bears Ms. Seiple's initials, states that she ''researched [Superior's] file and looked [at] the site visit as well as Web sites from 2008,'' noting that ''[t]he pharmacy is located inside clinic.'' *Id.* Ms. Seiple then wrote that she called the ''pain clinic and inquired about service'' and ''if I would come in for service d[id] they have a pharmacy inside [the] clinic. They said yes.'' *Id.* Continuing, Ms. Seiple wrote that ''per Web site & pics [photos,] orders are being deleted customer on CH.'' *Id.* Ms. Seiple further noted that Superior ''owes 60 K most due 10/10 9/21'' and ''will tell account @ limit for month.'' *Id.* Ms. Seiple then wrote that she would encourage another employee ''to get payment'' and she would ''not tell customer'' that it was ''on non controls til [sic] paid in full.'' *Id.* Ms. Seiple then noted that Superior was ''on compliance review.'' *Id.*

To the right of this statement are more notes stating ''Additional updated Due Diligence Survey updated,'' below which were the following bullet points: ''File updated,'' ''location inside clinic,'' ''limits reduced,'' ''280 scripts a day,'' and ''practitioner that write scripts Dr. Mercedes'' and ''Dr. Mubang.'' *Id.* Still other notes for this entry included the names ''Dr—Merced'' and ''John Mubang,'' along with the number ''280'' surrounded by a circle, and ''65k to 25k.'' *Id.* Of note, however, all of this information was at least three months old and much of it had been acquired 14 months earlier. Also, while the order was placed on compliance hold, Respondent did not obtain an explanation for the order from Superior, which it then verified.

Respondent did, however, obtain a new UR, which covered the month of August 2009. *Id.* at 31–46. The UR showed that Superior had dispensed 80,302 du of oxycodone 30; 4,070 du of oxycodone 15, and 7,655 du of Endocet 10/325; it also showed that its total dispensings were 242,818 du. RX 2H, at 32, 34, 41, 46. Thus, Superior's dispensings of oxycodone 30 alone amounted to 33 percent of its dispensings, and its dispensings of the three oxycodone products amounted to 37.9 percent of its total dispensings. Moreover, here again, most of the drugs (19) among the top 25 drugs dispensed by Superior were controlled substances and included other narcotics such as methadone and hydrocodone, as well as three formulations of alprazolam and two formulations of diazepam. RX 2H, at 32. Of further note, carisoprodol was the third most dispensed drug. *Id.*

Notwithstanding this information and the notations indicating that Superior had been placed on compliance hold and non-controlled status, or alternately, that its CSL had been reduced to 25,000 du of oxycodone, on September 30, Respondent filled three orders totaling 30,000 du of oxycodone 30 mg. GX 10F, at 43. Entries in the SOMS notes made the same day suggest that the orders did not even trigger a review as they do not contain the name of a person who reviewed the order nor contain any notes regarding the order. GX 24, at 106.

On October 26, Respondent shipped to Superior orders for 20,000 du of oxycodone 30. GX 10F, at 43. Yet on November 2, Respondent shipped to Superior three orders totaling 25,000 du of oxycodone 30. *Id.* The SOMS notes for this date include three entries, none of which include the name of a reviewer or a note, thus indicating that the orders were not held for review. GX 24, at 106. Yet entries in the Ship to Memos and MFRs state that on November 3, the account was reviewed by the committee and ''reduce[d] from 65k to 25k'' and that Superior had to ''give non control [sic] orders.'' *Id.* at 105; *see also* RX 2H, at 1. Neither the notes nor Ms. Seiple's testimony explain why Superior's limit had not actually been reduced on September 25, as Ms. Seiple had documented in the MFR note of that date.

According to an MFR note, on or about November 17, Superior placed an order for 25,000 du of oxycodone. RX 2H, at 2. The MFR note states that ''as of 11/3 per committee [pharmacy] need [sic] to give a non control [sic] order before releasing Oxy order sent email to rep.'' *Id.* Continuing, the note states: ''Acct is at their [sic] limit for the month[.] [O]rder will be deleted.'' *Id.* The note further states that an employee of Respondent contacted Superior's PIC, who stated that ''he didn't know his limits were drop [sic] to 25k.'' *Id.* Respondent did not, however, report Superior's oxycodone order as suspicious. Moreover, the next day, Respondent approved orders totaling 2,500 du of hydrocodone, which were shipped the following day. GX 10F, at 43.

An MFR note of November 19 states that Superior's pharmacist was being called ''due to wrong [sic] fill 8109 product'' and that its ''limits cut.'' RX 2H, at 2. Continuing, the note states: ''per Wayne collect moneys and terminate,'' ''put on CH until paid,'' ''gradually reduced allotment to collect moneys'' and ''owes 46k.'' *Id.* Still another note for this date (which is written in the space for dating an entry) states: ''partnership in clinic'' and ''[b]oth connected owns both.'' *Id.*

According to an MFR entry of November 30, on this date Superior placed two orders for 200 bottles (20,000 du) of oxycodone 30. RX 2H, at 2. Other notes in this entry include: ''Ike own [sic] clinic & pharmacy,'' ''1% on non-controls'' and ''owes 31k.'' *Id.* A SOMS note of the same date by Ms. Seiple states: ''ok to ship do not ship over 10k on oxy this month without committee review.'' GX 24, at 107. And while a December 1 MFR entry then states: ''order holding'' and ''TT [talk to] Teri,'' an MFR entry for December 2 reads ''CSL reduced in SOMS to 10k,'' followed by (in blue ink) ''RWR terminate—once bill is pd.'' *Id.*

The same day (December 2), Respondent shipped to Superior 10,000 du of oxycodone 30. GX 10F, at 43. Respondent did not report the order as suspicious even though it knew that Superior's pharmacist owned both the pharmacy and the pain clinic.

Moreover, on December 7, Respondent filled an order for 200 du of hydrocodone/ibuprofen tablets, a schedule III controlled substance. *Id.*

According to an MFR note, on December 10, the compliance committee reviewed Superior's status. RX 2H, at 2. While the MFR note states that the account was terminated (and also that Superior still owed money), *id.,* a note in the Ship to Memo states: ''do not ship controls without review by jen or wayne.'' GX 24, at 105.

While there is no evidence that Respondent filled any controlled substance order for Superior after December 7, 2009, on January 11, 2010, Respondent conducted a site visit at the pharmacy. RX 2H, at 21–29. On the form, Respondent's inspector documented that Superior reported that controlled substances (in schedule II–V) constituted 50 percent of its dispensings; the inspector circled the figure and wrote ''too high,'' which he underlined for emphasis. *Id.* at 23. He further noted that there was ''[a] pain management doctor in the same place of business,'' which he also circled. *Id.* at 24. And in the space for providing a general description of the pharmacy, he wrote: ''A busy 4-lane roadway in a strip mall w/a pain clinic inside the pharmacy.'' *Id.*

The inspector further recommended that a compliance review be conducted based on the fact that controlled substances comprised 50 percent of Superior's dispensings. *Id.* at 21. The inspector also checked that he had observed suspicious activity outside of Superior, noting that there were ''several persons hanging outside pharmacy & sitting in vehicles—20–30 year olds—not using canes or walking with limps—talking about getting their meds!'' *Id.*

On a second site visit recommendation which is dated two days later, the inspector noted that he had observed ''6 people out front of pharmacy *talking about getting their oxys* as I walked in!'' *Id.* at 29. He also noted that there were ''[n]umerous persons 20–35 yrs. old, hanging inside & outside pharmacy to by [sic] oxys with no apparent *disabilities*! No one limping or using canes.'' *Id.*

While Respondent subsequently terminated Superior, Respondent's compliance staff had known since the original site visit that both a purported pain management clinic and the pharmacy were operating out of the same retail space. Yet for nearly a year and a half, Respondent failed to raise any questions as to the ownership of the clinic and the relationship between the physicians who practiced there and the pharmacy owner.

Regarding Respondent's distributions to Superior Pharmacy, Ms. Seiple noted that before shipping controlled substances to the pharmacy, Respondent verified that its Florida pharmacy license and DEA registration were valid and obtained a copy of the most recent DOH inspection. She also asserted that based on the description provided by Superior as to its policies and procedures, Respondent believed that the pharmacy understood its obligations to prevent diversion ''and was taking affirmative steps'' to prevent diversion. RX 103, at 73. Ms. Seiple did not, however, address what significance she attached to the note on the Due Diligence Report Form (next to the question whether the pharmacy practiced due diligence on specific prescribers) which states, ''Tampa—100 mile radius,'' and thus suggests that Superior would fill prescriptions for prescribers as long as they were located within 100 miles of Tampa.

Next, Ms. Seiple asserted that because during the June 2008 site inspection, Superior's PIC had ''explained that [its] business model included filling prescriptions for a juvenile in-patient facility, and a weight-loss and pain management facility located in an adjacent office . . . [t]hese factors accounted for the volume of controlled substances being dispensed, and the percentage of oxycodone dispensed relative to other drugs.'' *Id.* However, while the consultant reported that Superior claimed it was servicing a juvenile in-patient facility, Respondent obtained no information regarding the facility, including its name, the number of patients it treated, the type of conditions it treated and the drugs prescribed in the course of treatment, and the names of its doctors. Thus, the mere fact that Superior provided prescriptions for this facility falls well short of justifying the volume of its oxycodone dispensings and the percentage of its dispensings comprised by oxycodone.

As for Ms. Seiple's assertion that the pain management and weight loss clinic were ''located in an adjacent office,'' Respondent's consultant actually reported that ''[t]he pharmacy is located within a space that it shares with Superior Medical Center.'' RX 2H, at 70. Of further note, interspersed with the pages of the consultant's report were photographs showing the store front and its signage; these photos clearly showed that the pharmacy and clinic were located in the same space. *Id.* at 68.

Moreover, one week after the consultant conducted his inspection, Respondent obtained a printout of Superior's Web page. The Web page clearly showed that Superior was marketing itself as both a pain clinic and pharmacy, thus providing a form of one-stop shopping. And a second printout of Superior's Web page—which was not obtained until September 2009—provided the same street address for both the pharmacy and the pain clinic. Thus, while the presence of Superior's pain clinic may well have been a factor which ''accounted for the volume of controlled substances being dispensed, and the percentage of oxycodone dispensed relative to other drugs,'' this does not establish that those dispensings were for a legitimate medical purpose.

In her declaration, Ms. Seiple did not address why, in light of the information she had obtained that the clinic and pharmacy shared the same space and were marketed together, Respondent failed to investigate the relationship between the pharmacy and pain clinic until 15 months later.[145] *See generally* RX 103, at 72–75. Nor did Ms. Seiple explain why it took 17 months for her to even ask Superior's PIC about the ownership of the clinic. *See id.* Moreover, while at the hearing Respondent asserted that in early 2009, it had cut off selling to physicians who were directly dispensing oxycodone to their patients, Ms. Seiple offered no explanation for why this policy did not warrant cutting off Superior given that it promoted itself as both a pain clinic and pharmacy. *See id.* Nor did she explain why Respondent continued to distribute oxycodone to Superior even after she called the pain clinic and was told that there was ''a pharmacy inside [the] clinic.'' *See id.; see also* RX 2H, at 1.

The rest of Ms. Seiple's assertions regarding Superior's ordering and dispensing patterns are similarly unavailing. For example, she asserted that ''[a]fter Superior's account was approved, [the] SOMS . . . identified and held any order . . . that deviated from its typical volume, pattern or frequency'' ' and that these orders were released only after review by the Compliance Department. RX 103, at 73–74. She also asserted that ''[b]ased on [Respondent's] extensive investigation,

[145] As found above, two weeks before the site visit, Respondent conducted a phone survey to evaluate Superior for an increase in its oxycodone purchasing limit. RX 2H, at 81. One of the questions on that form specifically asked if the pharmacy had ''[r]elationships with specific doctors/clinics?'' *Id.* Respondent's reviewer left the answer block blank and added scribble on the line provided for explaining the answer. *Id.*

While this non-answer was clearly inconsistent with the information obtained during the site visit, there is no evidence that Respondent investigated whether the form was completed in this manner because Superior's PIC had denied the existence of any such relationship, or because Respondent's employee falsified the form or failed to ask the question.

it determined that the orders it shipped to Superior were not suspicious.'' *Id.* at 75. And she asserted that ''[t]he URs and other information provided by Superior were consistent with the pharmacy's business model as explained by the customer. *Id.* at 74.

Here again, Respondent filled numerous orders for oxycodone products during the period between April 1 and early August 2009 during which the SOMS was not even operational. Moreover, while the evidence shows that Superior's oxycodone limit was set at 25,000 du per month effective July 1, 2008, and that Respondent shipped it a total of 28,800 du (for all oxycodone products) in April 2009 and 25,000 of oxycodone 30 during May 2009, Respondent shipped it a total of 65,000 due of oxycodone products during June 2009. Even though the June orders were more than double the April and May orders and the purported 25,000 du limit, Ms. Seiple did not deem them suspicious. So too, she did not report the July orders, which totaled more than 65,000 du, as suspicious.

Notwithstanding that various orders for 30,000 du of oxycodone 30 were held on September 24, 2009, prompting Ms. Seiple to place a call to the pain clinic during which she was told that the pharmacy was located inside the clinic, followed by her deleting the orders, the orders were not reported as suspicious. Moreover, the compliance hold was short-lived as only six days later, Respondent filled three orders from Superior for 30,000 du of oxycodone 30. And while notes made in various documents indicate that Superior's CSL had been reduced to 25,000 du, these orders were shipped without any review and were not reported as suspicious.

Here again, Ms. Seiple failed to address why these orders were not reported as suspicious and were shipped. She also failed to address why various orders in October and early November 2009 did not even trigger review even though the orders placed Superior well over the 25,000 du CSL which was supposedly instituted on September 25, 2009.

So too, in her declaration, Ms. Seiple failed to explain why in December 2009, Respondent shipped 10,000 more du of oxycodone 30 even though Ms. Seiple had by then determined that Superior's PIC owned both the pharmacy and the pain clinic. And here again, Respondent failed to report the order as suspicious. In short, Ms. Seiple's assertion that Respondent ''determined that the orders it shipped to Superior were not suspicious'' (RX 103, at 75) is disingenuous.

As for her further assertion that the URs and other information provide by Superior were consistent with the pharmacy's business model as explained by its PIC, the evidence does show that the PIC explained at various points that much of the pharmacy's business involved filling the prescriptions written by the doctors at his pain clinic. Indeed, this has been reported by Respondent's consultant following the site visit, RX 2H, at 69–70; as well as documented in the report of the June 23, 2009 due diligence assessment which noted that 45 percent of the prescriptions were from the clinic. *See id.* at 52. Yet while during the June 2008 site visit, the PIC had reported that 25 percent of the prescriptions it filled were for controlled substances, during the June 2009 due diligence assessment he now reported that 50 percent of the prescriptions were for controlled substances. Moreover, the May 2009 UR showed that with the exception of carisoprodol, each of the top 25 drugs dispensed by NDC code was a controlled substance, with three of the top four drugs being oxycodone 30 products (the other being Endocet 10). Also among the top 25 drugs were multiple narcotics including still more oxycodone products, including three oxycodone 15 products, OxyContin in both 40 and 80 mg dosage, three hydrocodone products, methadone, two hydromorphone products, and five benzodiazepines. *Id.* at 96. Contrary to Ms. Seiple's assertion, the information Respondent obtained from Superior was not consistent with that of a pharmacy that was dispensing only legitimate prescriptions but rather that of a pharmacy that was engaged in suspicious activity.

Morrison's Rx

Morrison's Rx (hereinafter, Morrison's) is a community pharmacy located in Sunrise, Florida. RX 2G, at 127. According to Ms. Seiple, Morrison's established its account with Respondent in September 2007. RX 103, at 69. Also according to Ms. Seiple, prior to Respondent's first distribution of controlled substances to Morrison's, Respondent conducted a due diligence survey, obtained a credit application and a Dun & Bradstreet report. *Id.* While the record also establishes that Respondent obtained a copy of Morrison's DEA registration in September 2007, Ms. Seiple made no claim that Respondent verified that Morrison's and its PIC held state licenses prior to shipping, and there is no evidence that the licenses were verified until an April 2008 site visit.

As for Respondent's initial due diligence survey, Morrison's reported that its daily prescription average was 265 and that controlled substances comprised 60 percent of the prescriptions; it also reported that 35 percent of the prescriptions were for schedule II drugs. RX 2G1, at 1. As for Morrison's due diligence procedures, the PIC reported that she would call the doctor when a physician was a new prescriber, for ''unusual prescriptions,'' and if a patient was ''too early.'' *Id.* The PIC further represented that patients were required to provide their driver's license number and that she would refuse to fill prescriptions if she suspected a patient was ''doctor shopping,'' was ''too early,'' was presenting ''forged scripts,'' or was ''visibl[y] intoxicat[ed].'' *Id.* Finally, the PIC stated that if a patient presented ''too many scripts,'' she would tell the patient that he/she ''can only fill one'' and that she would ''[v]oid scripts when the doctor authorizes.'' *Id.*

Prior to the completion of the due diligence survey, Morrison's provided utilization reports but only for the oxycodone products it sold. *Id.* at 130–46. It also provided a list of some 22 pain management doctors whose prescriptions it filled, along with the names and addresses of their clinics. *Id.* at 148–49. There is no evidence, however, that Respondent's staff conducted any further inquiries into the licensure status of these physicians.

As for the URs, they showed Morrison's dispensings of each oxycodone product (by dosage and by NDC code) for the months of September and October 2007, as well as for a portion of November. The URs did not, however, show Morrison's total dispensings of all products.

With respect to oxycodone 30, the URs showed that during September, Morrison's dispensed 1,256 prescriptions totaling 227,801 du, an average of 181 du per prescription. RX 2G, at 135–36. As for October, the URs showed that Morrison's dispensed 1,466 prescriptions totaling 262,773 du, an average of 179 du per prescription. *Id.*

With respect to oxycodone 15, the URs showed that during September, Morrison's dispensed 211 prescriptions totaling 23,814 du, an average of 113 du per prescription. *Id.* at 132–33. As for October, the URs showed that Morrison's dispensed 227 prescriptions totaling 24,449 du, an average of 108 du per prescription. *Id.*

According to a memo in Morrison's due diligence file, on April 1, 2008, an employee of Respondent requested a re-

evaluation of Morrison's purchasing limits ''due to a glitch in the CSOS system which enabled the pharmacy to order over their [sic] limit.'' *Id.* at 128. Respondent's employee documented that she had verified the licenses of both the pharmacy and its PIC; she also documented that Morrison's had reported that 40 percent of the prescriptions were schedule II drugs and that it was filling 250 rather than 265 prescriptions per day. *Id.*

As part of the update, Respondent's employee obtained Morrison's most recent state inspection reports (which found a single violation in that its compounding records were not properly maintained). *Id.* at 109. She also obtained a UR for the period January 1 to April 1, 2008, which showed the dispensings of the top 500 drugs (by NDC code). *Id.* at 115. With respect to oxycodone 30, the UR showed that during the period, Morrison's had dispensed 1,088 prescriptions totaling 189,947 du, an average of 63,316 du per month and 174.6 du per prescription. *Id.* The UR further showed that during the period, Morrison's dispensed 153 prescriptions totaling 15,547 du of oxycodone 15, an average of 5,149 du per month and 101 du per prescription.[146] *Id.* at 115, 123. Oxycodone 30 alone accounted for more than 38 percent of the dispensings listed on the report. Moreover, while the UR's ranking did not actually list the drugs in decreasing order by the number of units dispensed, even a cursory review shows that controlled substances (and carisoprodol) comprised nearly all of the top 15 drugs Morrison's dispensed.

Notwithstanding the information provided by the UR, a note on the bottom of the re-evaluation of limits memo states that Respondent approved Morrison's ''for 50k.'' *Id.* at 128. The note, however, is undated.[147] *Id.*

On April 24, Respondent's consultant made a site visit. *Id.* at 110–14. While the consultant verified that Morrison's held a valid state license and DEA registration and that its PIC held a state license, he also noted that the pharmacy sold a ''very limited'' selection of front store items and did not sell medical supplies other than by special order. *Id.* at 110–11. He further noted that the pharmacy had purchased drugs from three other distributors, that it filled 200 prescriptions on an average day, that 30 percent of the prescriptions were for controlled substances, and that 20 percent of the pharmacy's business was paid for with cash. *Id.* at 112. He also noted that Morrison's serviced ''1 nursing home'' and one ''inpatient facility'' which was identified as St. Joseph; however, the report included no further information as to the type of treatment provided at the inpatient facility, its size, and the types and quantity of prescriptions that were being filled for its patients. *Id.* So too, the report contained no information as to the size of the nursing home, and the types and quantity of prescriptions that Morrison's was filling for its patients.

Next, the consultant noted that the pharmacy filled prescriptions for pain management clinics and listed the names of five doctors, their locations, and their DEA numbers. *Id.* at 113. There is, however, no evidence that Respondent conducted any further inquiries regarding these doctors such as license verifications and whether they had any specialty training or board certification in pain management.

Finally, the consultant provided ''additional comments.'' *Id.* Therein, the consultant wrote:

> The pharmacy is set up [with] only a waiting area in the front—no front store merchandise. The pharmacy area has a small stock of Rx drugs. It seems to be professionally operated. The pharmacist indicated that she isn't filling as many CII prescriptions as she used to as many of the physicians in her area now dispense themselves. The pharmacy services primarily elderly patients.

Id. at 113–14.

A second ''Schedule [sic] Drug Limit Increase Request Form'' establishes that on or about July 28, 2008, Morrison's requested an increase in its oxycodone ordering limit to 100,000 du per month. *Id.* at 104. There is, however, no documentation as to whether the request was granted.

On January 30, 2009, Respondent obtained from Morrison's various documents including its ''policy and procedure'' for dispensing controlled substances to treat pain. *Id.* at 48–50. It also obtained a UR for the period of November 1, 2008 through January 30, 2009, which showed the dispensings of 34 schedule II drugs listed by their NDC. *Id.* at 46. With respect to oxycodone 30, the UR showed that Morrison's dispensed 1,839 prescriptions totaling 335,114 du, an average of 111,705 du per month and 182 du per prescription. *Id.* As for oxycodone 15, the UR showed that Morrison's dispensed 851 prescriptions totaling 77,417 du, an average of 25,806 per month and 91 du per prescription. *Id.*

Thereafter, on February 2, Respondent's account manager sought an increase in Morrison's solid dose oxycodone ordering limit, noting that its monthly usage was 200,000 du and that it qualified for the increase both because it was a ''long-term'' customer and a ''large full-line pharmacy.'' *Id.* at 51. Written on the form is the notation: ''Table need usage report.'' *Id.* However, there is a further notation on the request form stating that on a date, the month of which is obscured, Morrison's was approved to purchase 200,000 du of oxycodone per month.[148] *Id.* Respondent did not obtain a new UR until May 6, 2009. *Id.* at 100.

Subsequently, on February 17, an employee of Respondent completed a due diligence report form on Morrison's. *Id.* at 3–4. Therein, Morrison's reported that it was now filling 180 prescriptions per day. *Id.* at 3. Morrison's further reported that controlled substances comprised 30 to 60 percent and schedule II drugs comprised 15 to 30 percent of the prescriptions it filled. *Id.*

The form also included several questions regarding Morrison's policies and procedures. *Id.* at 4. As for how it ensured that prescribers were exercising proper standard of care, Morrison's asserted that ''[i]f they get a large Qty of CIIs they get a copy of [the] MRI and if anything is ever questionable they call the doctor.'' *Id.* Morrison's further asserted that it had refused to fill prescriptions because the refill was too soon, the ''script are [sic] questionable'' and for an ''extremely lrg. Qty.''

Morrison's PIC further reported that she had stopped prescriptions for ''1 physician that was under investigation.'' *Id.* Apparently, short of an investigation, Morrison's did not permanently stop filling prescriptions for any physician

[146] While these figures clearly represented a substantial decrease in the volume of Morrison's oxycodone dispensings, the reason for this became apparent three weeks later during a site visit, when Morrison's PIC told Respondent's consultant ''that she isn't filling as many CII prescriptions as she used to as many of the physicians in her area now dispense themselves.'' RX 2G, at 113–14.

[147] The due diligence file also includes a Schedule Drug Limit Increase Request Form, which is dated ''3/31'' and which requested an increase in Morrison's solid dose oxycodone ordering limit to 50K based on an ''exemption'' Respondent provided for a ''large full line pharmacy.'' RX 2G, at 105. The record is otherwise unclear as to what criteria were used to determine if a pharmacy was qualified as such. A further note on the bottom of this page which is dated April 29, 2008, states: ''Leaving at 50k Re-Eval 6 mos. Call & informed Jen Seiple sales rep.'' *Id.*

[148] There are additional documents in this time period including the result of a Google search conducted on Morrison's, printouts from Morrison's Web site, a printout on Morrison's from a Web site known as LegitScript.com, and a Dunn and Bradstreet report. RX 2G, at 54–74. While the printout from the LegitScript Web site stated that the pharmacy met LegitScript's ''Internet pharmacy verification standards,'' *id.* at 62–63, it did not otherwise address whether Morrison's was filling legitimate prescriptions. *See id.* at 62 (''LegitScript simply represents that, at the time that LegitScript reviewed the Web site, available information indicated that the Web site met or did not meet our standards as represented on this Web site.'').

even though it claimed that it had refused to fill prescriptions because the refill was too soon, the ''scripts [we]re questionable,'' or were for an extremely large quantity.

As for whether it filled prescriptions written by out-of-state or out-of-area doctors, Respondent's employee noted ''no. She's in South Florida; if someone comes from N. Florida she wouldn't or if they came from the west coast they wouldn't.'' *Id.* Unclear is whether this answer was referring to the location of the prescriber or the persons presenting the prescriptions. Moreover, as for whether the PIC would fill prescriptions for out-of state patients, Respondent's employee noted that the PIC would fill ''only if they are visiting or on vacation.'' *Id.*

The final question on the form asked if ''the pharmacy practice[d] due diligence on specific prescribers.'' *Id.* Respondent's employee wrote: ''They practice due dilligence [sic] on all prescribers.'' *Id.* No further explanation was provided as to what Morrison's due diligence involved.

Thereafter, during the month of April 2009, Respondent filled numerous orders placed by Morrison's for oxycodone products which totaled 171,700 du of oxycodone 30; 37,200 du of oxycodone 15; 6,400 du of Endocet 10/325; 400 du of Endocet 10/650; 500 du of oxycodone 5/325; 300 du of oxycodone 80 mg; and 1,300 du of oxycodone 40 mg. GX 10F, at 22–24. During this month alone, Respondent shipped to Morrison's orders totaling 217,800 du of oxycodone.

On May 6, 2009, Respondent obtained a UR which showed Morrison's dispensings during the period of January 1, 2009 to May 6, 2009 but covered only the top 100 drugs dispensed. RX 2G, at 101–03. Oxycodone 30 was the top drug dispensed, with 1,868 prescriptions totaling 335,895 du, an average of 81,726 du per month [149] and 180 du per prescription. *See id.* at 101–2 (line entries #s 1 & 80). Moreover, oxycodone 15 was the second largest drug dispensed by quantity, with 882 prescriptions totaling 79,991 du, an average of 19,463 du per month and 90.7 du per prescription. *Id.* at 101. Thus, Respondent's April distributions of oxycodone 30 were more than double Morrison's average monthly dispensings of the drug, and its April distributions of oxycodone was nearly two times (1.9) Morrison's average monthly dispensings. Yet there is no evidence that Respondent contacted Morrison's and questioned the orders, and Respondent did not report any of the orders as suspicious.[150]

Throughout May 2009, Respondent filled numerous orders totaling 141,200 du of oxycodone 30; 10,800 du of oxycodone 15; 9,300 of Endocet 10/325; 1,000 du of Endocet 10/650; 500 du of oxycodone 5/325; 700 du of oxycodone 40; and 300 du of oxycodone 80. GX 10F, at 22–25. In total, Respondent shipped 163,800 du of oxycodone products to Morrison's during the month. Here again, Respondent's shipments of oxycodone 30 exceeded Morrison's monthly average dispensings (according to the previous UR) by a substantial margin, *i.e.,* more than 59,000 du or more than 76 percent. Once again, there is no evidence that Respondent contacted Morrison's regarding its oxycodone 30 orders—all of which were placed over the course of three days (May 26–28), GX 10F, at 22; and questioned the orders. Nor did it report the oxycodone 30 orders as suspicious.

In June 2009, Respondent filled orders totaling 81,600 du of oxycodone 30; 39,900 du of oxycodone 15; 14,300 du of Endocet 10/325; 1,000 du of Endocet 10/650; 400 du of oxycodone 80; and 300 du of oxycodone 40. GX 10F, at 22–25. While these orders, which totaled 137,500 du, marked a reduction from the total amount Respondent had filled for Morrison's in the previous months, the pharmacy's oxycodone 15 orders were still more than double the amount of its average monthly dispensings of the drug according to the previous UR.

In July 2009, Respondent filled numerous orders totaling 141,300 du of oxycodone 30; 48,000 du of oxycodone 15; 9,100 du of Endocet 10/325; 1,200 du of Endocet 10/650; 700 du of oxycodone 80; and 200 du of oxycodone 40. GX 10F, at 22–25. Morrison's oxycodone orders thus totaled 200,500 du. As was the case two months earlier, Morrison's orders for oxycodone 30 were 61,000 du (76 percent) greater than its average monthly dispensings of the drug per the existing UR, and its orders for oxycodone 15 were nearly 2.5 times larger than its average monthly dispensings of the drug. Here again, there is no evidence that Respondent inquired as to why Morrison's was ordering these quantities. Moreover, Respondent failed to file a suspicious order report for any of the oxycodone 30 and 15 orders.

Through the first 17 days of August 2009, Respondent filled orders totaling 101,600 du of oxycodone 30; 39,600 oxycodone 15; 4,300 du of Endocet 10/325; 900 du of Endocet 10/650; 500 du of Endocet 5/325; 400 du of oxycodone 80; and 300 du of oxycodone 40. GX 10F, at 22–26. These orders totaled 147,600 du.

In contrast to the orders that were placed between April 1 and July 31, 2009, there are SOMS notes for these orders, including several entries indicating that the orders were reviewed prior to shipping. GX 23, at 151. Specifically, there is a SOMS note for an order placed on August 5, 2009 (on this date 13,200 du of oxycodone 30 and 4,800 du of oxycodone 15 were shipped) which lists Ms. Seiple as the decision-maker and states: ''ok to ship UR supports order.'' GX 23, at 151.

Of note, there is no documentation that Ms. Seiple contacted Morrison's to obtain an explanation for the order which she then independently verified. Moreover, Respondent did not obtain a new UR until August 17. RX 2G, at 10–28.

Likewise, while the SOMS notes indicate that the oxycodone orders that Morrison's placed on August 11 and 12 were subject to review, the notes indicate that orders were released because they were under the current size limit.[151] GX 23, at 151. Here again, there is no evidence that Respondent contacted Morrison's and obtained an explanation for the orders. So too, while the SOMS notes indicate that the oxycodone orders Morrison's placed on August 13 and 14 were also subject to review, the accompanying explanations for why the orders were released merely state: ''Ok to ship reviewed by jss'' and ''ok to ship per jss.'' *Id.* Here again, there is no evidence that Respondent

[149] The average was calculated by adding the total days of the report through May 5 (125) and dividing it by the average number of days in a month in a non-leap year (30.41); the total dispensings were then divided by this figure (4.11) to determine the average monthly dispensings.

[150] As noted repeatedly, Respondent frequently used the URs to justify the release of orders, reasoning that if an order was less than the amount shown to have been dispensed, it was supported by the UR and was ''ok to ship.'' This, however, was not the case with Morrison's.

[151] Of note, Respondent's Policy 6.2, which set forth the procedures for the review and disposition of those orders which were held by the SOMS, did not distinguish between the various reasons why an order was held. Thus, whether an order was held because it was of an unusual size, it deviated substantially from a normal pattern, or the orders were of unusual frequency, the same procedure of calling the customer and obtaining an explanation for the order, which was independently verified, followed by requesting a UR, was required by its Policy.

Policy 6.2 was revised on August 14, 2009 though the manner in which it was revised is unclear on the record. Even so, it is obvious that Morrison's orders were greatly in excess of the amounts its most recent UR (which was then three months old) showed were being dispensed on a monthly basis. Yet this did not prompt Respondent's compliance department to even obtain an explanation for the orders, let alone a new UR, before shipping the orders.

contacted Morrison's and obtained an explanation for the order or a new UR. Yet Respondent's SOMS materials state that ''a [r]eason code and notes will also be provided as additional detail supporting the decision'' whether to accept or reject an order. RX 78, at 64.

As found above, on August 17, a DEA Diversion Investigator specifically identified Morrison's as one of Respondent's customers whose oxycodone orders were of concern. Tr. 217–18 (testimony of DI); *id.* at 1154–55 (testimony of former employee); GX 48A, at 5; GX 12, at 23. The same day, Respondent obtained a new UR, which showed Morrison's dispensings of some 836 prescription products during July 2009. RX 2G, at 10–28. The UR showed that Morrison's had dispensed 1,006 prescriptions totaling 196,069 du of oxycodone 30, an average of 195 du per prescription, and 576 prescriptions totaling 63,658 du of oxycodone 15, an average of 110.5 du per prescription. *Id.* at 11. Here too, the UR showed that such highly abused drugs as alprazolam 2 mg (more than 39,700 du), Endocet 10/325, methadone, and carisoprodol were the largest drugs dispensed by quantity. *Id.*

The next day, Morrison's placed orders for 8,400 du of oxycodone 30; 1,200 oxycodone 15; 300 Endocet 10/325; and 200 methadone. RX 2G, at 9. The same day, Respondent placed Morrison's on compliance hold. GX 23, at 150. According to an entry in the MFRs, on August 20, 2009, Respondent deleted Morrison's August 18 orders and terminated it as a controlled substances customer. RX 2G, at 8. However, Respondent did not report these four orders as suspicious.

In her declaration, Ms. Seiple offered the same explanations as to why Respondent failed to report Morrison's orders as suspicious as she did with the previous pharmacies. For example, she asserted that because Morrison's provided a copy of its written policies and procedures to prevent diversion, Respondent believed that the pharmacy understood its obligation to prevent diversion. RX 103, at 69–70. Next, she asserted that because Morrison's PIC explained that the pharmacy's ''business model included servicing a nearby nursing home and an in-patient facility, . . . filling prescriptions for a large number of elderly patients who lived in a nearby residential area,'' as well as ''prescriptions for patients of pain management clinics,'' this ''accounted for the volume of pain medications being dispensed, and the percentage of oxycodone dispensed relative to other drugs.'' *Id.* at 70.

As before, Respondent did not inquire further into the number of residents at the nursing home who were receiving prescriptions for oxycodone 30. Nor did it even inquire into the type of treatment being provided at the aforesaid ''inpatient facility,'' the number of patients, and the number of patients who were receiving oxycodone prescriptions. So too, Respondent made no inquiry into the number of elderly patients who were receiving oxycodone 30. Thus, these factors do not account for the volume of pain medications being dispensed and the percentage of oxycodone dispensed relative to other drugs.

As for the lengthy list of pain management doctors which Morrison's PIC provided to Respondent, this may well account for the large volume of pain medications being dispensed and the percentage of oxycodone dispensed relative to other drugs. However, here again, notwithstanding that Morrison's was dispensing more than 250,000 du of oxycodone 30 per month, Respondent conducted no further inquiries into the physicians' licensure status and whether they had any specialized training or board certification in pain management. Moreover, several physicians on this list were also customers of Respondent who were terminated at various points prior to April 1, 2009. *Compare* RX 2G, at 148–49, *with* RX 62, at A2–A3 (Drs. Moulton Keane, Martin E. Hale, Joseph M. Ossorio, Gerald J. Klein, and Lucien Armand). Thus, the fact that Morrison's provided this list does not establish that its dispensings of oxycodone were consistent with legitimate medical purposes.

Next, Ms. Seiple asserted that ''after Morrison's account was approved, [the] SOMS systems identified and held any orders for controlled substances placed by Morrison's that deviated from its typical volume, pattern or frequency'' and that ''[a]ll such orders were released only after review by [the] Compliance Department.'' RX 103, at 70. As found above, Respondent filled numerous oxycodone orders from April 1 through July 31, 2009, and on multiple occasions, Morrison's monthly orders were far in excess of what the most recent UR showed it was dispensing on a monthly basis. These orders clearly were not held by the SOMS, because the SOMS was not yet operational. Nor is there any evidence that these orders were reviewed. And the orders were not reported to DEA even though they deviated substantially in terms of their size and were clearly suspicious.

As for the orders that Morrison's placed during August 2009, there are SOMS notes for several of them indicating that the orders were held for review. However, the notes show that some of the orders were released without the compliance department obtaining an explanation for the orders from the pharmacy, and others were released without documenting the reason for releasing the order. Of note, in her declaration, Ms. Seiple only asserted that the orders were reviewed and made no claim that the Compliance Department contacted Morrison's and obtained an explanation for the orders, which it then verified. *Id.*

Ms. Seiple acknowledged that Respondent continued to sell oxycodone to Morrison's until the DIs ''inadvertently revealed during the August 2009'' meeting that the Agency was investigating the pharmacy and ''the account was then placed on non-controlled status.'' *Id.* at 72. She then asserted that Respondent ''did not report a suspicious order placed by Morrison's because no order was pending at that time.'' *Id.*

However, as found above, the day after Morrison's was identified by the DIs (whether as a customer whose orders should be of concern or as a target of an investigation), Morrison's placed four orders for nearly 10,000 du of oxycodone (most of which was for the 30 mg tablets), as well as methadone. Yet none of these orders were reported, and while Ms. Seiple deleted the orders, this does not refute the fact that Morrison's placed the orders and Respondent failed to report them.[152]

[152] I acknowledge that the ALJ found Ms. Seiple's testimony credible and clearly gave it substantial weight. However, much of Ms. Seiple's testimony is either amply refuted by the extensive documentary evidence of record or is unresponsive to other evidence. Accordingly, I decline to give it substantial weight for reasons which should be evident by now. *See Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 496 (1951) (''The findings of the [ALJ] are to be considered along with the consistency and inherently probability of testimony. The significance of [her] report, of course, depends largely on the importance of credibility in the particular case.'').

For example, in discussing Superior Pharmacy, Ms. Seiple asserted that during the June 2008 inspection, its pharmacist explained that its business model including filling prescriptions for . . . a weight loss and pain management facility *located in an adjacent office.''* RX 103, at 73 (emphasis added). Yet the 2008 inspector's report clearly stated that ''[t]he pharmacy is located within a space that it shares with Superior Medical Center,'' RX 2F, at 70; and the January 11, 2010 inspection report noted that: ''A Pain Mgmt doctor in the same place of business,'' as well as that the pharmacy was located ''in a strip mall w/a Pain Clinic inside the pharmacy.'' *Id.* at 24. So too, photographs in Superior's due diligence file show that the pharmacy and clinic used the same waiting area and that the counters for the pharmacy and clinic were only feet apart.

Ms. Seiple further mischaracterized the evidence when she asserted that Respondent ''has never

Continued

Respondent's Other Evidence

Respondent elicited the testimony of Joanna Shepherd-Bailey, Ph.D., who testified as an expert in statistics. Tr. 1576–77. Ms. Shepherd-Bailey testified that she reviewed Respondent's monthly oxycodone shipments to each of its Florida pharmacy customers for the period of April 2009 through July 2011 and prepared charts which compare the monthly shipments to the seven pharmacies at issue (which are represented by red dots) with the monthly shipments to all of Florida pharmacy customers (which are represented by blue dots). RX 102, at 7; *see also* RX 69–75. According to Ms. Shepherd-Bailey, the charts show that the ''shipments to the DEA-identified pharmacies rarely stand out from the rest of the monthly shipments'' and that ''for many of the months, shipments to the DEA-identified pharmacies are squarely in the mid-range of monthly shipments.'' RX 102, at 7. Ms. Shepherd-Bailey also testified that she prepared a Z-score analysis to determine the extent to which the monthly shipments to the seven pharmacies were atypical when compared to the rest of the shipments. *Id.* According to Ms. Shepherd-Bailey, her analysis ''confirms that most of the monthly shipments to the [seven] pharmacies do not stand out as atypical'' and that ''fewer than half of the monthly shipments to the [seven] pharmacies are statistically significant at the 0.05 significance level.'' *Id.* Ms. Shepherd-Bailey thus concluded that Respondent's ''shipments to the [seven] pharmacies did not stand out as unusually large'' and that ''the shipment volume to [them] would not have appeared extraordinary to'' Respondent. *Id.*

However, to the extent this evidence was offered to refute the allegation that Respondent failed to report suspicious orders, I find it unpersuasive for several reasons. First, the analysis ignores the significant information obtained by Respondent with respect to each of the seven Florida pharmacies. Second, there is no evidence that Respondent's compliance department ever conducted a similar analysis during the course of its dealings with the pharmacies. Third, in determining whether a pharmacy's order was of unusual size, Respondent's SOMS did not compare the order with those of other pharmacies but compared the order only to the customer's previous orders. Fourth, because the analysis was based only on the shipments made to Respondent's Florida customers during the acknowledged oxycodone epidemic in the State to the exclusion of its shipments to customers in other States, I conclude that the analysis suffers from selection bias. Finally, even ignoring the selection bias, in some instances, the charts show that the shipments to several of the pharmacies were among the highest monthly shipments. *See* RX 71 (shipments to Englewood); RX 74 (shipments to Morrison's).

Respondent also submitted for the record copies of numerous suspicious order reports it filed with DEA.[153] *See* RX 61A–C. However, these reports were in the numerical format used to submit them to the Agency and Respondent offered no evidence explaining the circumstances giving rise to the decision to file the reports. Moreover, as to the pharmacies at issue in this proceeding, it is undisputed that Respondent filed only a single suspicious order report, that being upon its termination of The Drug Shoppe for ordering alprazolam. *See* GX 40, at 14; RX 103A, at 47.

Respondent also entered into evidence copies of lists it had previously submitted to DEA of those customers it terminated. However, a former member of Respondent's compliance department testified that in his opinion, ''the customers who were easily suspended or terminated from purchasing controlled substances from [it] were not the big money accounts.'' GX 52, at 7. (Decl. of Eric Schulze).

As to whether Respondent acknowledges any misconduct and has undertaken any remedial measures, Respondent stipulated that it:

> does not accept responsibility for any alleged wrongdoing in this matter. Furthermore, any evidence presented by [it] of changes, modifications or enhancements [it] made to its internal Policies and Procedures in the ordinary course of business, on its own accord, or based on alleged guidance or communications from the [DEA] does not constitute evidence of remedial measures. This stipulation is binding during the administrative hearing before DEA as well as any appellate litigation that may occur after a Final Order is issued by the Administrator.

ALJ Ex. 8.

Discussion

The Public Interest Analysis

Section 304(a) of the Controlled Substances Act (CSA) provides that ''[a] registration . . . to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render [its] registration under section 823 . . . inconsistent with the public interest as determined under such section.'' 21 U.S.C. 824(a)(4). With respect to an entity registered to distribute controlled substances in schedules I or II, Congress directed that the following factors be considered in making the public interest determination:

> (1) maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, or industrial channels;
>
> (2) compliance with applicable State and local law;
>
> (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
>
> (4) past experience in the distribution of controlled substances; and
>
> (5) such other factors as may be relevant to and consistent with the public health and safety.

21 U.S.C. 823(b). These factors are considered in the disjunctive. I may rely

cancelled, deleted, or edited orders to bring customers within their controlled substance limit . . . to make suspicious orders appear non-suspicious, or to otherwise thwart review by the Compliance Department.'' RX 103, at 13. However, as found above, Respondent repeatedly engaged in these practices and Ms. Seiple offered no alternative explanation for why Respondent deleted and edited those orders that were held by the SOMS, especially those which placed a pharmacy over its CSL.

Also, with respect to each of the pharmacies, Ms. Seiple asserted that ''after [the respective pharmacy's] account was approved, the SOMS identified and held any order for controlled substances . . . that deviated from its typical volume, pattern or frequency.'' *See, e.g., id.* at 54. However, the SOMS was not even operational during the months of April through July 2009, and yet Respondent filled numerous oxycodone orders during this period placed by each of the pharmacies while failing to report them as suspicious.

The ALJ also gave weight to Ms. Seiple's testimony ''that orders held by SOMS for each of the . . . pharmacies in question were not shipped until reviewed and approved by the Compliance Committee.'' R.D. 172 (other citations omitted). The issue, however, is not simply whether the orders were reviewed and approved, but whether the compliance department investigated those orders that were held by the SOMS, by obtaining an explanation for the order which it then verified. Ms. Seiple's testimony is simply unresponsive to the evidence which shows that, with respect to nearly every order discussed above, Respondent failed to contact the pharmacy and obtain an explanation for the order which it then independently verified. Also, as found above, the evidence shows that, in several instances, oxycodone orders were still shipped, notwithstanding that the pharmacy's account had been placed on compliance hold and was to be reviewed by the compliance committee.

Finally, as for Ms. Seiple's testimony that based on its due diligence, Respondent determined that the orders placed by each of the pharmacies were not suspicious notwithstanding the information it had obtained as to the volume of oxycodone and the percentage of controlled to non-controlled drugs being dispensed, as explained above, I give little weight to her testimony.

[153] As discussed previously, in its Exceptions, Respondent sought a finding that ''[a]s of August 18, 2009, [it] had detected and reported to DEA suspicious orders of controlled substances after April 1, 2009.'' Resp. Exceptions, at 18. However, the earliest suspicious order reports contained in the Exhibit it submitted are dated August 6, 2009. RX 61A, at 1.

on any one or a combination of factors and give each factor the weight I deem appropriate in determining whether to revoke a registration or to deny a pending application for renewal of a registration. *See Green Acre Farms, Inc.,* 72 FR 24,607, 24,608 (2007); *ALRA Laboratories, Inc.,* 59 FR 50,620, 50,621 (1994). Moreover, I am ''not required to make findings as to all of the factors.'' *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005); *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005).

The Government bears the burden of proving that Respondent's continued registration would be inconsistent with the public interest. 21 CFR 1301.44(e). Where, however, the Government establishes a *prima facie* case, the burden shifts to Respondent to show why its continued registration would not be inconsistent with the public interest. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62,315, 62,323 (2012); *Southwood Pharmaceuticals, Inc.,* 72 FR 36,487, 36,502 (2007).

In this case, the Government contends that the evidence with respect to factors one, four and five establishes that Respondent's continued registration would ''be inconsistent with the public interest.'' 21 U.S.C. 823(b). The ALJ, however, rejected nearly the entirety of the Government's case, including its allegations that Respondent repeatedly failed to obtain an explanation for orders that were held by the SOMS, and found that the Government has proved only that Respondent had failed to report a single suspicious order, that being an order placed by Englewood Specialty Pharmacy the day before it was terminated as a customer. As noted in the discussion of the procedural history, both parties also filed extensive exceptions to the ALJ's legal conclusions. To the extent their contentions have not been previously addressed, they are discussed below where applicable.

Factors One and Four—Maintenance of Effective Controls Against Diversion Into Other Than Legitimate Channels and Past Experience in the Distribution of Controlled Substances

Pursuant to 21 CFR 1301.71(a), ''[a]ll applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.'' This regulation further directs that ''[i]n order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72–1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.'' 21 CFR 1301.71(a).

At issue here is Respondent's compliance with the requirements pertaining to the detection and reporting of suspicious orders which are found at 21 CFR 1301.74(b). This regulation provides:

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Id. at 1301.74(b).

The parties dispute the scope of this regulation. More specifically, Respondent contends that ''suspicious orders are only those [orders] that are of an unusual size, that deviate substantially from a normal pattern, or which are of an unusual frequency.'' Resp. Exceptions, at 3 n.1. It argues that the regulation's use of the word ''include'' was intended to limit the scope of the regulation to the three enumerated categories. *Id.* at 24–27. As support for its contention, Respondent points to the draft of the regulation as published in the 1971 Notice of Proposed Rulemaking, which provided that ''suspicious orders may include, but are not limited to'' the three categories, and argues that the rule was subsequently amended to its present text to provide the industry with ''greater predictability and clarity with respect to the security requirements (including the definition of 'suspicious order' ''). *Id.* at 28–29. And finally, it asserts that the ALJ's reading of the regulation—as simply setting forth three non-inclusive examples of what constitutes a suspicious order—violates due process by failing to provide fair warning ''of what constitutes a suspicious order, or when a report is required of a registrant.'' *Id.* at 30–31.

I reject Respondent's contentions. As the ALJ recognized, the Supreme Court has explained that ''the term 'including' is not one of all-embracing definition, but connotes simply an illustrative application of the general principle.'' *Federal Land Bank of St. Paul* v. *Bismarck Lumber Co.,* 314 U.S. 95, 100 (1941) (citing *Phelps Dodge Corp.* v. *NLRB,* 313 U.S. 177, 189 (1941)).[154] *See also Dong* v. *Smithsonian Institution,* 125 F.3d 877, 880 (D.C. Cir. 1997) (citing *Federal Land Bank*) (''the word 'includes' normally does not introduce an exhaustive list but merely sets out examples of some 'general principle' ''). Indeed, ''this interpretation fits with common dictionary definitions and examples.'' *DIRECTV Inc.* v. *Budden,* 420 F.3d 521, 527–28 (5th Cir. 2005) (discussing definitions given by The American Heritage Dictionary of the English Language (1976) and Webster's Third New World Dictionary (1961)). *See also* Black's Law Dictionary 831 (9th ed. 2009) (defining ''include'' as meaning ''[t]o contain as a part of something • The participle *including* typically indicates a partial list'').

Nor do I attribute any significance to the alteration of the regulation's text between the Notice of Proposed Rulemaking and the Final Rule. As Black's explains, ''some drafters use phrases such as *including without limitation* and *including but not limited to*— which mean the same thing'' as ''including.'' *Id.* While it is true that the **Federal Register** notice which promulgated the final rule states that ''[m]any manufacturers and distributors objected to security controls set forth in §§ 301.92 to 301.97'' and that ''[m]ost of these paragraphs have been revised to meet the objections filed,'' 36 FR 7776, 3776 (1971), these provisions imposed numerous other security requirements. Thus, this statement is too general to conclude that the drafters of the suspicious order reporting rule intended to depart from the common accepted meaning of the term ''include'' and instead set forth a limit on the scope of the rule.

Moreover, limiting the scope of suspicious orders to only those orders which are of unusual size, deviate substantially from a normal pattern, or are of unusual frequency would have ill-served the CSA's purpose of preventing the ''illegal . . . distribution, . . . possession and improper use of controlled substances.'' 21 U.S.C. 801(2). Under Respondent's view, even if it had acquired actual knowledge (let alone developed a suspicion) that a customer was ordering controlled substances from it for the purpose of diverting them, it would have no obligation to report the order as long as the order was of a usual size, did not deviate substantially from the customer's normal ordering pattern, or was consistent with the usual frequency of the customer's orders. But even orders that do not fall within the three categories set forth in 21 CFR 1301.74(b) can be diverted. Thus, I agree with the ALJ's reasoning ''that a pharmacy's

[154] Respondent distinguishes *Federal Land Bank of St. Paul* v. *Bismarck* on the ground that ''in *Bismarck* there was a 'general principle' to apply, and the Court interpreted the word 'including' consistent with that principle.'' Resp. Exceptions, at 25. This argument goes nowhere because there is also a ''general principle'' to apply here, that being the duty to report suspicious orders.

business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency.'' R.D. at 154.

Nor do I find persuasive Respondent's contention that construing the regulation as encompassing orders that are suspicious by virtue of circumstances other than those of size, pattern, or frequency denies it fair warning.[155] The regulation requires a distributor to report suspicious orders, and those who participate in a highly regulated industry such as the distribution of prescription controlled substances should know that one of the CSA's core purposes is to prevent prescription drug abuse and the diversion of drugs to persons who seek to abuse them.

As the Supreme Court explained in *United States* v. *Moore,* 423 U.S. 122 (1975), ''Congress was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.'' *Id* at 135 (citations omitted). *See also* 21 CFR 1306.04(a) (''A prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.''); *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (explaining that ''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, the provision also bars doctors from peddling to patients who crave the drugs for those prohibited uses.'').

Thus, viewed in light of the CSA's purpose of preventing drug abuse and diversion, ''a person of ordinary intelligence [has] fair notice of what'' the regulation requires. *FCC* v. *Fox Television Stations, Inc.,* 132 S.Ct. 2307, 2309 (2012) (quoting *United States* v. *Williams,* 553 U.S. 285, 304 (2008)); *see also General Elec. Co.* v. *EPA,* 53 F.3d 1324, 1329 (D.C. Cir. 1995) (''If, by reviewing the regulations and other public statements issued by the agency, a regulated party acting in good faith would be able to identify, with 'ascertainable certainty,' the standards with which the agency expect parties to conform, then the agency has fairly notified a petitioner of the agency's interpretation.'') (citing *Diamond Roofing Co.* v. *OSHRC,* 528 F.2d 645, 649 (5th Cir. 1976).

Construing the regulation as requiring the reporting of an order, when circumstances other than the order's size, pattern, or frequency render the order suspicious, is fully encompassed by the regulation's text. *Cf. Pennsylvania Dept. of Corrections* v. *Yeskey,* 524 U.S. 206, 212 (1998) (''[T]he fact that a statute can be applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth.'') (internal quotations and citations omitted). It is also supported by the Agency's public statements, including its administrative precedents. *See Southwood Pharmaceuticals, Inc.,* 72 FR 36,487 (2007).

Based in part on the ALJ's conclusion that she was bound by the interpretation of 21 CFR 1301.74 given by the Deputy Assistant Administrator in his December 2007 letter, R.D. at 154, Respondent argues that the various statements contained in ''these letters . . . impose substantive and binding requirements on DEA registrants'' and therefore cannot be enforced absent their promulgation through notice and comment rulemaking.[156] Resp. Exceptions, at 32; *see also id.* (''Ironically, the ALJ's recognition of the Rannazzisi Letters as binding on Masters and on herself—in this and in future cases—cements their status as *illegally promulgated* substantive rules.'').

It is true that the ALJ deemed herself to be bound by the position taken in the 2007 letter issued by the Deputy Assistant Administrator of the Office of Diversion Control. R.D. at 154 (''I am without authority to reject a position the Agency has taken on a matter of law. This is true even where the Agency's position is announced by means other than the formal adjudication process.''). In support of her conclusion, the ALJ cited *CropLife America* v. *EPA,* 329 F.3d 876 (D.C. Cir. 2003), a case involving EPA's decision to cease considering third-party human studies in evaluating the safety of pesticides, which was announced in a letter and press release. In a parenthetical, the ALJ set forth her understanding of *CropLife* as standing for the proposition ''that an ALJ does not have authority to ignore an Agency position announced in a press release.'' R.D. at 154.

While in *CropLife,* the D.C. Circuit rejected the EPA's argument that its ALJs could nonetheless ''rule on particular third-party human studies,'' it noted that the directive ''says no such thing'' and that the EPA Administrator's ''statement prohibiting the agency from considering such studies'' was ''unequivocal.'' 329 F.3d at 882. Indeed, contrary to the ALJ's understanding (in this matter), in rejecting the EPA's contention that the position was merely a policy statement and not a binding regulation, the D.C. Circuit did not rest on the fact that the position was taken in a press release but on the agency's intent to ''create[ ] a '' 'binding norm' '' that is '' 'finally determinative of the issues or rights to which it [was] addressed.' '' '' 329 F.3d at 881 (quoting *Chamber of Commerce* v. *U.S. DOL,* 174 F.3d 206, 212 (D.C. Cir. 1999) (quoting *Pacific Gas & Elec. Co.* v. *FPC,* 506 F.2d 33, 38 (D.C. Cir. 1974))). As the D.C. Circuit noted, the press release had stated that ''the [EPA] *will not consider* or rely on any [such] human studies in its regulatory decision making.'' *Id.* (emphasis added). Thus, the court concluded that ''EPA has enacted a firm rule with legal consequences that are binding on both petitioners and the agency, and petitioners will be afforded no additional opportunity to make the arguments to the agency that they now present in this petition.'' *Id.* at 882.[157]

[155] Of note, Respondent's Policy 6.2 states that ''[a]ll orders that have been held for review that Masters does not fill for the reasons set out in Section III(b)(ii), above, shall be considered 'Suspicious Orders' according to 21 CFR 1301.74(b) and reported to the'' DEA. RX 78, at 33. Among the reasons listed are that ''[t]he customer's file, including survey responses and site visits, indicates that the customer may be engaged in inappropriate business practices, [or] [t]he customer refuses to provide Masters with the information necessary to complete its evaluation.'' *Id.* Unexplained by Respondent is why evidence that a customer may be engaged in inappropriate business practices becomes relevant to the determination of whether an order is suspicious only if that order triggers a SOMS hold.

[156] It should be noted that the ALJ actually only relied on the 2007 letter, and not the earlier letter of September 27, 2006. R.D. at 154. The latter set forth multiple examples of characteristics present in the ordering patterns of ''pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose.'' GX 3, at 3. It also suggested a number of questions that a distributor should ask a pharmacy customer in ''determin[ing] whether a suspicious order is indicative of diversion.'' *Id.* The letter then advised that the questions were ''not all-inclusive'' and that ''the answer to any of these questions'' would not necessarily be determinative of ''whether a suspicious order is indicative of diversion.'' *Id.*

[157] So too, in rejecting EPA's contention that the press release was only a policy statement and thus not subject to judicial review, the court examined both ''the effects of the [EPA's] action'' and the EPA's ''expressed intentions.'' 329 F.3d at 883 (citing, *inter alia, Cmty. Nutrition Inst.* v. *Young,* 818 F.2d 943, 946 (D.C. Cir. 1987) and *Molycorp., Inc.* v. *EPA,* 197 F.3d 543, 545 (D.C. Cir. 1999)). The

The ALJ did not analyze whether the Rannazzisi letters were intended to, or even could, have binding effect in this proceeding. However, a review of the letters shows that they were not intended to have binding effect but were simply warning letters.

The 2007 letter, which primarily discussed the obligation to report suspicious orders, also noted that ''registrants that routinely report suspicious orders, yet fill these orders without first determining that [the] order is not being diverted into other than legitimate medical, scientific, and industrial channels, *may* be failing to maintain effective controls against diversion.'' GX 4, at 2 (emphasis added). Continuing, the letter stated: ''[f]ailure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 U.S.C. 823 and 824, *and may result in the revocation of the registrant's DEA Certificate of Registration.'' Id.* (emphasis added). Contrary to the ALJ's understanding, this simply is not language that manifests an intent to bind the Agency.

Nor is the 2006 letter fairly read as manifesting an intent to bind the Agency. While the letter notes that ''in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate . . . channels,'' the letter then explains that the ''[f]ailure to exercise such due diligence *could, as circumstances warrant,* provide a statutory basis for revocation or suspension of a distributor's registration.'' GX 3, at 2 (emphasis added).

Moreover, that an official vested with prosecutorial authority issues a letter advising entities that he views certain conduct as violative of a regulation or as conduct which is ''inconsistent with the public interest,'' does not establish that those entities are foreclosed from challenging that interpretation in any subsequent proceeding. Indeed, under the Department of Justice's regulations, the ultimate authority to determine the meaning of DEA's regulations, as well as whether certain conduct is ''inconsistent with the public interest,'' is vested in the Office of the Administrator and Deputy Administrator. *See* 28 CFR 0.100(b) & 0.104 (Appendix to Subpart R of Part O—Redelegation of Functions);[158] *see also Jeffery J. Becker,* 77 FR 72,387, 72,388–91 (2012) (rejecting Government's interpretation of Agency disposal rule); *Edmund Chein,* 72 FR 6580, 6593 (2007) (rejecting Government's interpretation of rule requiring that electronic records be readily retrievable). However, while the ALJ erred in deeming herself to be bound by the letters, I conclude that her error was non-prejudicial.

Respondent further argues that the letters do not ''merely restate or interpret obligations already present in the regulations,'' but rather ''supplement DEA regulations with additional and burdensome obligations on registrants'' and ''represent[s] a fundamental change to the regulations.'' Resp. Exceptions, at 33 (citing *Syncor Int'l. Corp.* v. *Shalala,* 127 F.3d 90, 96 (D.C. Cir. 1997) and *Paralyzed Veterans of Amer.* v. *DC Arena,* 117 F.3d 579, 586 (D.C. Cir. 1997)). Thus, it argues that the Agency was required to announce the positions taken in the letter by engaging in notice and comment rulemaking. Respondent's argument is not well taken.

At issue in *Syncor* was the FDA's decision to supersede earlier guidelines which ''unequivocally stated that nuclear pharmacists who operated an accelerator to produce radioactive drugs to be dispensed under a prescription . . . were not required to register under [Section] 510 of the Food, Drug, and Cosmetic Act.'' 127 F.3d at 93. The earlier guidelines also stated ''that if a nuclear pharmacist was not required to register,'' other requirements of the FDCA, ''including the new drug provision and compliance with current good manufacturing practices, would not apply.'' *Id.* However, more than ten years later, the FDA issued a ''Notice,'' which the Agency alternatively referred to in its text as ''guidance'' and as a ''policy statement.'' *Id.* at 92. Therein, the FDA stated that manufacturers of these drugs were required to comply with several of the FDCA's provisions, including those pertaining to adulteration, misbranding, new drugs, and registration listing of all drugs it manufactured. *Id.*

The *Syncor* court rejected the FDA's contention that the Notice was merely an interpretive rule, explaining that the Notice ''does not purport to construe any language in a relevant statute or regulations; it does not interpret anything. Instead, FDA's rule uses wording consistent only with the invocation of its general rulemaking authority to extend its regulatory reach.'' *Id.* at 95. The court specifically noted the FDA's statement that '' 'having considered the available information, including that presented to the agency at the hearing and in written materials, FDA has *concluded* that radiopharmaceuticals *should be regulated* under the provisions of the Federal Food, Drug, and Cosmetic Act.' '' *Id.* And the court also noted that in issuing the earlier guidelines, FDA had ''made a careful, considered decision not to exercise the full extent of its regulatory authority . . . over nuclear pharmacies in 1984,'' and that the agency had previously said that '' 'where the nuclear pharmacy is operating within applicable local laws regulating the practice of pharmacy and only prepares and dispenses a radioactive drug upon receipt of a ''valid prescription,'' the pharmacy exemption [of section 510(g)(1)] clearly applies.' '' *Id.* (quoting FDA, Nuclear Pharmacy Guideline; Criteria for Determining when to Register as Drug Establishment (1984)).

In *Syncor,* the court further explained that a policy statement ''merely represents an agency position with respect to how it will treat—typically enforce—the governing legal norm. By issuing a policy statement, an agency simply lets the public know its current enforcement or adjudicatory approach. The agency retains the discretion and authority to change its position—even abruptly—in any specific case because a change in its policy does not affect the legal norm.'' *Id.* at 94.

Thus, *Syncor* provides no support for Respondent. As for its contention regarding the scope of what constitutes a suspicious order,[159] no decision of

court concluded that ''there is little doubt that the directive in the . . . Press Release 'binds private parties [and] the agency itself with the ''force of law,''' and thus constitutes a regulation,'' because it ''clearly establishes a substantive rule declaring that third-party human studies are now deemed immaterial in EPA regulatory decisionmaking.'' *Id.* (quoting *General Elec. Co.* v. *EPA,* 290 F.3d 377, 382 (D.C. Cir. 2002)).

[158] While Section 7 of the Appendix authorizes the Deputy Assistant Administrator ''to exercise all necessary functions with respect to the promulgation and implementation of'' regulations related to the Diversion Control Program, it further provides ''that final orders in connection with suspension, denial or revocation of registration shall be made by the Deputy Administrator of DEA.''

[159] The breadth of Respondent's contention is not entirely clear. More specifically, it takes issue with the ALJ for ''reiterat[ing] the conclusion that the regulatory criteria that define a suspicious order . . . 'are disjunctive and are not all inclusive,' '' thus suggesting that it believes that all three criteria must be met for any one order to be suspicious. Resp. Exceptions, at 33 (quoting R.D. at 154). Yet the plain language of the regulation makes clear that these are disjunctive as the word ''orders'' precedes each of the three criteria.

While I reject Respondent's contention that it has not received fair notice that suspicious orders are not limited to the three criteria set forth in the regulation, as explained later, I agree with its contention insofar as the Government contends that

Continued

this Agency has previously interpreted the rule as being limited to only those orders that meet all three criteria. Nor has DEA ever held that suspicious orders are limited only to those orders that meet one of the criteria set forth. Thus, in contrast to *Syncor,* this is not a matter in which DEA has changed its position to impose a new requirement beyond that already required by its regulation.

As for Respondent's reliance on *Paralyzed Veterans,* that case has now been expressly overruled by the Supreme Court on the very proposition for which it is cited by Respondent. *See Perez* v. *Mortgage Bankers Ass'n,* 135 S. Ct. 1199, 1206–07 (2015) (''Because an agency is not required to use notice-and-comment procedures to issue an initial interpretative rule, it also is not required to use those procedures when it amends or repeals that interpretive rule.''). As the Supreme Court further recognized in *Perez,* ''[o]ne would not normally say that a court 'amends' a statute when it interprets its text. So too can an agency 'interpret' a regulation without 'effectively amend[ing]' the underlying source of law.'' *Id.* As explained above, the suspicious order regulation requires the reporting of all suspicious orders; notice and comment rulemaking is not necessary to impose liability on Respondent where the evidence shows that it failed to report an order which was suspicious because of the circumstances surrounding a customer's business or dispensing practices.

Respondent also takes issue with the ALJ's discussion of the position taken in the letters that '' ''in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders'' and that the duty to report suspicious orders ''is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.'' '' Resp. Exceptions, at 33–34 (quoting R.D. at 163 n.94 (quoting GXs 3 and 4)).

Respondent, however, misstates the ALJ's reasoning. The ALJ discussed the letters only after noting that, under the DEA regulations and the Agency's decision in *Southwood Pharmaceuticals, Inc.,* ''the duty to maintain effective controls against diversion is separate from the duty to detect and report suspicious orders,'' and that in *Southwood,* the two duties were analyzed ''separately under factor one.'' R.D. at 163 (citing 72 FR at 36,487–98). *See also* 21 CFR 1301.71(a) (''All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.''). The ALJ further explained that under *Southwood,* ''because registrants have a general duty to maintain effective controls against diversion, they may not ignore indicators of diversion simply because they come in forms other than suspicious orders. *Southwood* specifically mentions that this general duty to prevent diversion includes the duty to perform due diligence.'' R.D. at 163 (citing 72 FR at 36,500). The ALJ thus explained that ''Respondent has an ongoing duty to ensure that the controlled substances it distributes are not being diverted by at least performing meaningful due diligence on its customers.'' *Id.* Indeed, it was only in a footnote after her discussion of *Southwood* that the ALJ noted the letters' discussion of the due diligence responsibilities that are part of a distributor's obligation to maintain effective controls against diversion. *See id.* n.94 (''This interpretation of the interplay between the duty to maintain effective controls and the duty to report suspicious orders comports with the guidance the Agency gave to Respondent in 2006 and 2007.'') (citing GXs 3 and 4).

Eventually acknowledging that the Agency's due diligence rule was announced in an adjudication, thus rendering its arguments regarding the effect of the letters irrelevant, Respondent contends that ''reliance on'' Southwood ''not only as a 'basis for this action,' but also through the ALJ Recommendation, is in error.'' Resp. Exceptions, at 37. This is so, Respondent argues, because ''[t]he decision provided little legal precedence'' as ''it relies on [a] 2001 DEA Guidance on internet pharmacies, and its opinion turns on the specific facts presented to the ALJ.'' *Id.* Respondent thus contends that ''[i]f the DEA, including the ALJ[,] wants to apply *Southwood*'s approach in this or future cases, then DEA must amend its binding regulations through the processes set forth in the APA.'' *Id.*[160]

The Supreme Court, however, long ago rejected the contention that an agency must announce all rules it adopts only through notice and comment rulemaking. *See NLRB* v. *Bell Aerospace Co.,* 416 U.S. 267, 290–95 (1974); *SEC* v. *Chenery Corp.,* 332 U.S. 194, 199–204 (1947). Moreover, because the due diligence rule was announced in an adjudication, Respondent was of course, free to argue why the rule should not be applied in this matter as it has here. However, the reasons offered by Respondent for why *Southwood* should not be applied to its conduct are unpersuasive.

As for Respondent's contention that *Southwood* should not be followed because, in that case, the Agency relied in part on the 2001 Guidance Document, Respondent's argument is not entirely clear. Apparently, Respondent's argument is that the 2001 Guidance Document (which was published in the **Federal Register** and provided by DEA personnel to Southwood during a briefing) had set forth the Agency's view as to the potential illegality of dispensing controlled substances via the internet because such prescriptions did not arise out of a valid doctor-patient relationship.[161] Thus, the company had fair notice that the pharmacies to which it was distributing controlled substances were filling unlawful prescriptions. *See* 72 FR at 36,500–01 n. 23.

Yet *Southwood* also noted that during a conference call conducted by a DEA representative with the firm, the DEA representative had discussed several Supreme Court decisions including *United States* v. *Moore* and *Direct Sales Co.,* v. *United States,* 319 U.S. 703 (1943). 72 FR at 36,492. Of note, *Moore* discussed the provisions of both the CSA (and its predecessor, the Harrison Narcotic Act, 38 Stat. 785 (1914)) that prohibit a physician from dispensing controlled substances other than in the course of professional practice. *See* 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a). As for *Direct Sales,* it upheld the conviction of a registered manufacturer and wholesaler for conspiracy to violate the

''pursuant to the regulation, it was the responsibility of the registrant to review controlled substance orders previously shipped to a terminated . . . customer to determine whether those previously shipped orders were in fact suspicious.'' Gov. Br. 126.

[160] Respondent then contends that '' 'an administrative agency may not slip by the notice and comment rule-making requirements needed to amend a rule by merely adopting a *de facto* amendment to its regulation through adjudication.' '' Exceptions, at 37 (quoting *Marseilles Land & Water Co.* v. *FERC,* 345 F.3d 916, 920 (D.C. Cir. 2003). However, *Marseilles Land* involved an ambiguous regulation. Moreover, DEA has not previously interpreted the regulation as limited to only those orders which are of unusual size, deviate substantially from a normal pattern, or are of unusual frequency, and the interpretation is supported by the regulation's plain meaning as well as agency precedent. As the D.C. Circuit has recognized, ''[a]lthough the agency must always provide 'fair notice' of its regulatory interpretations to the regulated public, in many cases the agency's pre-enforcement efforts to bring about compliance will provide adequate notice.'' *General Elec. Co.* v. *EPA,* 53 F.3d 1324, 1329 (D.C. Cir. 1995).

[161] The existence of a valid doctor-patient relationship is a long-standing requirement for establishing that a prescription has been issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. *See George Mathew,* 75 FR 66,138, 66,145–46 (2010) (citing cases).

Harrison Narcotic Act by supplying a physician with morphine ''in such quantities, so frequently and over so long a period it must have known he could not dispense the amounts received in lawful practice and was therefore distributing the drugs illegally.'' 319 U.S. at 705.

The *Southwood* decision also noted that the DEA representative had discussed with the firm's management the suspicious order reporting rule, the requirement under the CSA that prescriptions be issued for a legitimate medical purpose in accordance with 21 CFR 1306.04(a), and its obligations to maintain effective controls against diversion. 72 FR at 36,492. The DEA representative also discussed with the firm's management various facts that should be considered in evaluating its customers, including the percentages of controlled to non-controlled drugs dispensed by the typical retail pharmacy (5 to 20 percent controlled versus 80 to 90 percent non-controlled), the typical monthly quantity being purchased by brick and mortar pharmacies of the drug at issue (hydrocodone), the size and frequency of orders, and the range of products ordered by the pharmacy. *See id.* The decision also noted that the DEA representative had specifically identified several of the firm's pharmacy customers as engaged in suspicious activity. *Id.*

Thus, I am unpersuaded by Respondent's suggestion that *Southwood* should not be followed because it involved an entity engaged in distribution to pharmacies that were filling internet prescriptions. Resp. Exceptions, at 3. As *Southwood* makes clear, a distributor's duty to perform due diligence on its customers stems from the requirement that a registrant ''shall provide effective controls and procedures to guard against theft and diversion of controlled substances,'' 21 CFR 1301.71(a), as well as the registration requirements of section 823, which, in the case of a distributor, direct the Agency, in making the public interest determination, to consider the ''maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical . . . channels.'' 21 U.S.C. 823(b); *see also id.* § 823(e).

As for the scope of the duty to perform due diligence, *Southwood* makes clear that doing ''nothing more than verifying a pharmacy's DEA registration and state license'' is not enough. 72 FR 36,498. Rather, a distributor must conduct a reasonable investigation ''to determine the nature of a potential customer's business before it'' sells to the customer, and the distributor cannot ignore ''information which raise[s] serious doubt as to the legality of [a potential or existing customer's] business practices.'' *Id.* Thus, where, for example, a customer provides information regarding its dispensing practices that is inconsistent with other information the distributor has obtained about or from the customer, or is inconsistent with information about pharmacies' dispensing practices generally, the distributor must conduct ''additional investigation to determine whether [its customer is] filling legitimate prescriptions.'' *Id.* at 36,500. So too, depending upon the circumstances, a distributor may need to perform site visits before it engages in any distribution of controlled substances. Moreover, the obligation to perform due diligence is ongoing throughout the course of a distributor's relationship with its customer. *See generally id.* at 36,498–36,500.

Accordingly, I reject Respondent's exceptions as set forth in pages 23–37 of its Exceptions Brief.

Failure To Report Suspicious Orders

As explained above, I agree with the ALJ that ''a pharmacy's business model, dispensing patterns, or other characteristics might make an order suspicious, despite the particular order not being of unusual size, pattern or frequency. In other words, orders placed by a pharmacy which engages in suspicious activity, but places orders of regular size, pattern, and frequency, could still be deemed suspicious.'' R.D. at 154.

Notwithstanding her conclusion, the ALJ analyzed only four orders placed by the pharmacies on or after April 1, 2009 to determine whether they were suspicious, either because the pharmacy's business model, dispensing patterns, or other characteristics made the orders suspicious, or because the orders were of unusual size, pattern or frequency. *See generally* R.D. at 154–60, 168–70. Rather, her discussion focused primarily on the Government's theory that upon terminating a customer for compliance reasons, Respondent had an obligation to review the customer's prior orders, including those which were shipped, to determine if any of them were suspicious, and if so, report them.[162]

Noting that the regulation requires the reporting of a suspicious order ''when discovered by the registrant,'' the ALJ explained that ''the term 'when discovered' implies a duty to report orders Respondent has actually discovered to be suspicious.'' R.D. at 155 (quoting 21 CFR 1301.74(b)). The ALJ further reasoned that:

> When Respondent releases an order held by SOMS, decides to conduct additional due diligence, and then terminates the customer based on the findings of the investigation, Respondent has in fact ''discovered'' a suspicious order. Put another way, if the additional due diligence Respondent conducts pursuant to a potentially suspicious order held by SOMS fails to justify the shipment of that order, then the order is suspicious and must be reported. Similarly, if an order causes Respondent to conduct additional due diligence and leads Respondent to believe that a pharmacy's business model or other characteristics make it likely that controlled substances will be diverted, then the order should be reported to DEA. This is so because an order is not only suspicious by virtue of its internal properties—*i.e.,* being of unusual size, pattern, or frequency—but by virtue of the suspicious nature of the pharmacy which placed [the order].

Id. at 155–56.

While I agree with most of the ALJ's analysis, I disagree with two aspects of it. First, as to the ALJ's suggestion that only those orders which are ''actually discovered'' are subject to reporting, the ALJ asserted that ''this does not incentivize registrants to turn a blind eye to suspicious activity'' because ''[w]hile a distributor-registrant maintains an active account for a customer, the registrant has an ongoing duty to conduct meaningful due diligence and to detect suspicious orders from that customer.'' *Id.* at n.88. The ALJ then reasoned that ''[t]urning a blind eye will not negate that duty, and the Government can prove a violation . . . by showing that a suspicious order should have been detected through meaningful due diligence or an effective suspicious orders monitoring program.'' *Id.*

Yet turning a blind eye is an apt description of the manner in which Respondent reviewed the orders placed by the seven Florida pharmacies and the information it obtained from them. Moreover, the ALJ's discussion of the orders placed by City View shows that were her interpretation of the regulation adopted, it would do exactly that, *i.e.,* incentivize registrants to turn a blind eye.

More specifically, the ALJ reasoned that:

> The March 2010 UR showed a significant increase in oxycodone dispensing by City View-almost double the amount it dispensed in September 2009. Although these concerns were present since at least March 2010,

[162] This, however, was not the Government's only theory as to why the orders were suspicious. Gov. Br. 118, 121–24.

which was the time period covered by the most recent UR, they were not *actually* discovered by Respondent until its review in December 2010. Thus, failing to report the December 6 order was not a violation simply by virtue of the order's close proximity to the termination date.

R.D. at 159.

The ALJ's reasoning is inconsistent with her previous statement that ''[l]imiting the duty to report suspicious orders to orders *actually* discovered does not incentivize registrants to turn a blind eye to suspicious activity.'' *Id.* at n.88. Rather, consistent with the ALJ's earlier statement that a violation can be proved ''by showing that a suspicious order should have been detected through meaningful due diligence or an effective suspicious orders monitoring program,'' *id.,* I hold that an order has been discovered to be suspicious and the regulation has been violated where the registrant has obtained information that an order is suspicious but then chooses to ignore that information and fails to report the order. Moreover, a registrant cannot ignore information it obtains that raises a suspicion not only with respect to a specific order, but also as to the legitimacy of a customer's business practices. Nor, in assessing whether a pharmacy's orders are suspicious, can it ignore information it has obtained as to the scope of drug abuse in a particular area in which it distributes controlled substances. Certainly, a registrant cannot claim that it has conducted meaningful due diligence or has an effective suspicious orders monitoring program when it ignores information it has acquired which raises a substantial question as to the legitimacy of a customer's dispensing practices.

The ALJ's reasoning is erroneous for a second reason. In the ALJ's view, the standard for reporting an order as suspicious is that due diligence must ''lead[ ] Respondent to believe that a pharmacy's business model or other characteristics *make it likely* that controlled substances will be diverted.'' R.D. at 155. (emphasis added). I reject the ALJ's reasoning because it conflates the standard for whether an order can be shipped consistent with the obligation to maintain effective controls against diversion with that for whether the order must be reported as suspicious.[163]

Suspicion as to the existence of a circumstance (*i.e.,* that a customer is engaged in diversion) is simply a far lower standard of proof than whether it is ''likely'' that the circumstance exists. For example, Black's Law Dictionary defines suspicion as ''[t]he apprehension or imagination of the existence of something wrong based only on inconclusive or slight evidence, or possibly no evidence.'' Black's Law Dictionary 1,585 (9th ed. 2009); *see also* Webster's Third New International Dictionary of the English Language 2304 (1976) (defining ''suspicious'' as ''arousing or tending to arouse suspicion'' and defining ''suspicion'' as ''the act or an instance of suspecting: Imagination or apprehension of something wrong . . . without proof or on slight evidence''). Moreover, even the concept of ''reasonable suspicion,'' *see Terry* v. *Ohio,* 392 U.S. 1 (1968), does not require proof that it is likely a crime will be committed, but only ''[a] particularized and objective basis, supported by specific facts, for suspecting a person of criminal activity.'' Black's, at 1,585. Accordingly, the regulation's adoption of suspicion as the threshold for triggering the requirement that a distributor inform the Agency about the order does not even rise to the level of probable cause.

Thus, while I agree that a distributor's investigation of the order (coupled with its previous due diligence efforts) may properly lead it to conclude that the order is not suspicious, the investigation must dispel all red flags indicative that a customer is engaged in diversion to render the order non-suspicious and exempt it from the requirement that the distributor ''inform'' the Agency about the order. Put another way, if, even after investigating the order, there is any remaining basis to suspect that a customer is engaged in diversion, the order must be deemed suspicious and the Agency must be informed.

Noting that Respondent eventually concluded that each of the pharmacies were likely diverting controlled substances and terminated them as customers, the Government points to the regulation's provision which requires that a suspicious order be reported ''when discovered'' and argues that ''[t]he regulation makes no distinction between orders that are pending or have already been shipped.'' Gov. Proposed Findings of Fact and Conclusions of Law, at 126. It further notes the testimony of a Diversion Investigator and argues that ''[p]ursuant to the regulation, it was the responsibility of the registrant to review controlled substance orders previously shipped to a terminated . . . customer to determine whether those previously shipped orders were in fact suspicious.'' *Id.* at 126.

The ALJ rejected the Government's contention, explaining that while the regulation's '' 'when discovered' provision implies a duty to report orders that are *actually* discovered, it implies no duty to review all prior orders placed by a pharmacy terminated for compliance reasons.'' R.D. at 156. Continuing, the ALJ reasoned that:

> [a] registrant's duty in regards to a certain customer has ended when the registrant has made the decision to permanently discontinue sales of controlled substances to that customer and has reported to DEA all *known* suspicious orders from that customer. So long as past orders were, at the time they were placed and shipped, reasonably justified by meaningful due diligence, the registrant has no duty to review all such past orders when new information places the legitimacy of the customer under question.

Id.

The ALJ then noted that the ''only guidance'' provided by the Agency as to the meaning of the ''when discovered'' provision is that found in the 2007 letter. As the ALJ noted, that letter explained that:

> [t]he regulation also requires that the registrant inform the local DEA Division Office of suspicious orders *when discovered* by the registrant. Filing a monthly report of completed transactions (*e.g.,* [an] ''excessive purchase report'' or ''high unit purchases'') does not meet the regulatory requirement to report suspicious orders.
>
> When reporting an order as suspicious, registrants must be clear in their communications with DEA that the registrant is actually characterizing an order as suspicious. Daily, weekly, or monthly reports submitted by a registrant indicating ''excessive purchases'' do not comply with the requirement to report suspicious orders, even if the registrant calls such reports ''suspicious order reports.''

Id. at 156–57 (quoting GX 4, at 1–2).

The ALJ thus explained that ''the main purpose of the 'when discovered' provision is to prevent distributors from simply filing 'daily, weekly, or monthly' suspicious order reports.'' *Id.* at 157. The ALJ also noted that ''periodic reports delay the reporting of suspicious orders that are placed at the beginning of the period, meaning that DEA cannot act quickly when necessary,'' and that because periodic reports could include multiple orders, these reports ''can make it difficult for the Agency to determine why each order was deemed suspicious.'' *Id.*

I agree with the ALJ that the purpose of the ''when discovered'' language is to impose a time period for ''informing'' the Agency about a specific suspicious order. The plain language of the regulation simply creates no express obligation on a distributor who has terminated a customer for engaging in

[163] It should be noted that while Respondent agreed in the MOA to report suspicious orders in a particular manner, the regulation requires only that the registrant ''*inform* the Field Division Office . . . in his area.'' 21 CFR 1301.74(b) (emphasis added).

suspicious activity to go back through previously shipped orders and re-evaluate whether those orders should now be deemed suspicious, and if so, inform the Agency.

Moreover, while an Agency's reasonable interpretation of its own regulation is entitled to deference, *Martin* v. *OSHRC,* 499 U.S. 149, 150 (1991) (other citations omitted), the Deputy Assistant Administrator's letter suggests that the ''when discovered'' language has an entirely different purpose than what the Government now urges for it. But most significantly, neither of the letters notified the regulated community that upon terminating a customer for engaging in suspicious activity, a distributor must then review the customer's previous orders (going back to some unspecified date) to determine if they were also suspicious. In short, if the Government wishes to impose such a requirement on distributors, it must provide pre-enforcement notice of its intent to do so. *See General Elec. Co.* v. *EPA,* 53 F.3d at 1329–30 (collecting cases); *see also Gates & Fox Co.,* v. *OSHRC,* 790 F.2d 154, 156 (D.C. Cir. 1986) (while ''[c]ourts must give deference to an agency's interpretation of its own regulations . . . [w]here the imposition of penal sanctions is at issue . . . the due process clause prevents that deference from validating the application of a regulation that fails to give fair warning of the conduct it prohibits or requires''); *see also Diamond Roofing Co.,* v. *OSHRC,* 528 F.2d 645, 649 (5th Cir. 1976).

Thus, liability can be imposed on Respondent only with respect to those orders which, based on the then-existing circumstances, it should have determined were suspicious and reported to the Agency. However, this matter presents the additional issue of whether Respondent violated the suspicious order rule when it failed to notify the Agency of numerous orders that were held by the SOMS and which were not properly investigated.

As found above, the SOMS held those orders that were of unusual size, unusual pattern, or unusual frequency; thus, where an order was held, that order met the specific criteria of a suspicious order as set forth in 21 CFR 1301.74(b). Indeed, in the materials it provided to the Agency, Respondent specifically represented that ''[t]he purpose of the [SOMS] is to ensure that potentially suspicious orders are flagged and reviewed by the compliance department.'' RX 78, at 59. As Respondent also represented, the SOMS' function was to ''[h]old[ ] all orders for controlled drugs that *meet or exceed the criteria set out in 21 CFR 1301.74(b),''* those being ''orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.'' *Id.* at 32 (emphasis added).

As found above, Respondent further represented that under its Policy 6.2, where an order was held by the SOMS, it would call the customer and obtain ''[a]n explanation for the order,'' and that it would then ''independently verify any information provided with this explanation.'' *Id.* Respondent also represented that it would request ''[a] current utilization report, listing all of the pharmaceuticals (DEA Schedule and non-schedule) that the pharmacy has dispensed in the most recent calendar month.'' *Id.* The Policy then required that the ''customer's entire file [be] examined.'' *Id.*

Thus, even were I to find that, pursuant to its due diligence obligations, Respondent had conducted a meaningful investigation of each of the pharmacies, upon receiving an order which met one of the aforesaid criteria, Respondent was still required to investigate the order and determine that it was not suspicious. Accordingly, where Respondent entirely failed to investigate an order by contacting the pharmacy and obtaining an explanation for why the order exceeded the aforesaid criteria, which it then independently verified, it cannot now claim that the order was not suspicious. If it chose not to investigate, then it was obligated to report the order.[164]

Applying these principles, I find that the Government has proved by a preponderance of the evidence that Respondent repeatedly failed to report suspicious orders with respect to each of the seven Florida pharmacies. Pertinent to each of the Florida pharmacies, the evidence shows that Respondent's senior officials were, at the time of the orders at issue here, well aware of the serious problem of diversion and drug abuse, and in particular, the diversion and abuse of oxycodone, then existing in the State of Florida.

As found above, both Mr. Corona, Respondent's former Vice-President, and Mr. Smith, Respondent's owner/CEO, acknowledged in their testimony that they were well aware of the oxycodone epidemic then occurring in the State of Florida and that oxycodone 30 was a highly abused substance which was ''being obtained surreptitiously and unlawfully in Florida.'' Tr. 1072. As Mr. Corona testified, Florida's oxycodone epidemic was common knowledge at both Respondent and in the drug industry in general, with Corona further testifying that Florida was ''the 'wild west and . . . a free for all' when it came to the sale and dispensing of oxycodone.'' GX 51B, at 9 ¶ 31. Indeed, it was this knowledge that prompted Mr. Smith to travel to the State in early 2009 (before it entered the MOA) and check out the pain clinics, only to discover that the pain clinics were advertising in a manner that he thought was ''very unethical'' because the ads would show ''young kids sitting around a pool in bathing suits with big smiles on their faces.'' Tr. 1074.

This is not to say that Respondent's knowledge of the extensive oxycodone problem in the State of Florida was, by itself, enough to render suspicious all orders Respondent received from all of its Florida customers. It was, however, information that Respondent was obligated to consider in evaluating the orders it received from its Florida customers. Yet the evidence shows that Respondent's employees did not ''consider the geographic locations of its Florida pharmacy customers'' in reviewing their orders. I now turn to each of the pharmacies.

Tru-Valu

The evidence shows that prior to April 1, 2009, Respondent had acquired substantial information raising a strong suspicion as to the legitimacy of Tru-Valu's business practices. Specifically, at various points, Respondent obtained information that controlled substances comprised an abnormal percentage of its dispensings. On May 28, 2008, Respondent's consultant noted that 40 percent of the prescriptions Tru-Valu filled were for controlled substances and that the PIC acknowledged that the pharmacy ''fill[ed] a large number of

[164] While the above discussion is based on the specific policies at issue here, it should be clear that while conducting a meaningful investigation of a customer is a necessary part of a distributor's due diligence obligations, even where the investigation provides no reason to question the legitimacy of the customer's dispensing practices, upon receipt of an order meeting one of the criteria set forth in 21 CFR 1301.74(b), the order must either be reported as suspicious or investigated. However, where an order is investigated, the investigation must dispel the suspicion in order to excuse a distributor from its obligation to report the order. Of further note, reporting an order as suspicious does not excuse a distributor that seeks to fill that order from its obligation to ''to exercise due diligence to avoid filling suspicious orders that might be diverted.'' GX 3, at 2. *See also* GX 4, at 1 (''Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.'').

narcotic prescriptions each day'' and had ''pushed for this business with many of the area pain doctors.''

Moreover, just six days earlier, Respondent had obtained a utilization report for the month of April 2008, which showed Tru-Valu's dispensings of its top 300 drugs. While this apparently was not a complete UR, it nonetheless revealed significant information calling into question the legitimacy of Tru-Valu's controlled substance dispensings.

More specifically, the UR showed that Tru-Valu's dispensings of three highly abused drugs were predominant, with its dispensings of oxycodone 30 totaling 132,506 du; its dispensings of methadone 10 totaling 53,842 du; and its dispensings of alprazolam 2mg totaling 55,120 du; these three drugs alone constituted 241,000 du out of a total of 340,000 du for that month. By contrast, even though hydrocodone was the most widely prescribed drug nationally during this period, *see* RX 81, at 47; Tru-Valu's dispensings of this drug did not even total 3,000 du, a fraction of the oxycodone.

Further, in January 2009, Tru-Valu requested an increase in its oxycodone purchasing limit, and reported that 50 percent of the prescriptions it filled were for controlled drugs and 25 percent were for schedule II drugs. Respondent obtained a UR for December 2008, and while it showed only the top 200 drugs dispensed, it showed that Tru-Valu had dispensed more than 192,000 du of oxycodone 30 during the month (out of the total dispensings listed on the report of 300,000 du), an increase of nearly 60,000 du and more than 50 percent from the previous UR. The UR also showed that the pharmacy had dispensed 27,628 du of alprazolam 2 mg and 11,848 du of methadone 10, each of which is a highly abused controlled substance.[165] And the UR showed that with the exception of carisoprodol, which was then non-controlled under the CSA (but controlled under Florida law and highly sought after by drug abusers for use with narcotics and benzodiazepines), each of the top ten drugs dispensed was a controlled substance.

As explained above, in the *Southwood* decision, which was published in the **Federal Register,** the Agency had noted that the ratio of controlled to non-controlled substances dispensed by a typical retail pharmacy ranged up to 20 percent for controlled versus 80 to 90 percent for non-controlled drugs.[166] *See* 72 FR at 36,492. Thus, based on the UR alone, as of April 1, 2009, Respondent had substantial information which raised a strong suspicion as to the legitimacy of Tru-Valu's dispensing practices.

It is of no consequence that the Government did not produce a statistical study to show how many standard deviations Tru-Valu's dispensing ratio as reflected by the URs was outside that of a typical retail pharmacy. As explained above, to conclude that an order is suspicious, the information presented to the distributor is not required to establish, to a statistical certainty, that a pharmacy was likely diverting controlled substances. Rather, the evidence must only create a suspicion, a standard which is less than that of probable cause. And aside from the volume of Respondent's oxycodone and controlled substance dispensings, Respondent also knew that Tru-Valu was actively seeking out business from the area's pain doctors, even though in early 2009, Respondent's owner/CEO had determined to stop selling to pain doctors who were engaged in direct dispensing.

Throughout this proceeding, Respondent has vigorously argued that it is unfair to fault it for failing to analyze the URs to determine whether the pharmacies' dispensing ratios were consistent with the figures discussed at the August 2009 review (which had also been published several years earlier in *Southwood*) [167] because the Government did not specifically identify this as a deficiency in its policies and procedures as part of the Compliance Review.

While I have previously rejected Respondent's contention that the Government should be estopped from faulting it for failing to use the URs for this purpose, as well as the ALJ's discussion that the MOA bars sanctioning Respondent for failing to use the URs for this purpose, the ALJ also opined that the Government had not proved that Respondent's failure to use the URs for this purpose ''rendered [its] anti-diversion program ineffective under 21 CFR 1301.71(a).'' R.D. at 190.

The ALJ explained that ''the parties seem to agree that controlled substance ratios are an important aspect that should be investigated prior to shipping controlled substances.'' *Id.* at 188. Noting Ms. Seiple's declaration that Respondent ''was aware of the dispensing ratio of controlled to non-controlled substances'' of the seven pharmacies, *id.* (citing RX 103, at ¶¶ 158, 177, 204, 225, 244, 284, 303, 319), the ALJ then noted that ''[r]ather than using URs for every customer . . . Respondent used the information reported by site visits, phone surveys, and initial due diligence to estimate the ratios.'' *Id.* at 188.

The ALJ then explained that the issue appears to be ''whether Respondent's failure to analyze URs every time an order was held violated Respondent duties under DEA regulations.'' *Id.* at 189. The ALJ opined:

> The Government has offered no evidence that accurate information regarding controlled substance ratios can *only* be acquired through URs. In fact, the Government's own guidance it provided to Respondent specifically instructed Respondent to conduct this inquiry via questionnaires. This is precisely what Respondent has done. It is contradictory for DEA to instruct Respondent at the Compliance Review that it should ask its customers about their controlled substance ratios, and now insist that *only* URs can be the basis for such information.
>
> The fact that Respondent actually analyzed URs on several occasions to determine customers' controlled substance ratios is evidence that such analysis is helpful. Respondent does not dispute that. But the fact that a certain method of gathering and analyzing information is *helpful* does not force the conclusion that the method is

[165] As found above, the UR only listed the top 200 drugs dispensed. While the UR likely did not reflect all of the dispensings, Respondent could have asked Tru Valu for a complete UR. Thus, it cannot now hide behind its failure to do so.

[166] As noted previously, *Southwood* was published in the **Federal Register** in 2007, as well as on the Agency's Web site. As a participant in a highly regulated industry, Respondent is properly charged with knowledge of the contents of the decision, which involved an entity registered as a distributor which was charged with similar violations. *See United States* v. *Southern Union Co.,* 630 F.3d 17, 31 (1st Cir. 2010) (''[T]hose who manage companies in highly regulated industries are not unsophisticated . . . . It is part of [a company's] business to keep abreast of government regulations.''); *cf. Fed. Crop Ins. Corp.* v. *Merrill,* 332 U.S. 380, 384–85 (1947) (''Just as everyone is charged with knowledge of the United States Statutes at Large, Congress has provided that the appearance of rules and regulations in the **Federal Register** gives legal notice of their contents.'') (citations omitted); *California* v. *FERC,* 329 F.3d 700, 707 (9th Cir. 2003) (''Publication in the **Federal Register** is legally sufficient notice to all interested or affected persons regardless of actual knowledge or hardship resulting from ignorance, except those who are legally entitled to personal notice.'').

[167] The ALJ opined that *Southwood* ''includes no mention of controlled substance ratios as a red flag for diversion.'' R.D. at 188. However, as explained above, *Southwood* did discuss the ratio of controlled to non-controlled dispensing at a typical retail pharmacy. *Southwood* did not further discuss the ratio as an indicator of diversion because there were ample other red flags presented by Southwood's customers, including the quantities of hydrocodone that the distributor was selling to various internet pharmacies and its retail pharmacy customers, as well as evidence that the pharmacies were engaged in filling unlawful prescriptions. Moreover, in the September 2006 letter, the Deputy Assistant Administrator specifically advised distributors (including Respondent) that they should be asking their customers ''[w]hat percentage of the . . . business does dispensing controlled substances constitute?'' GX 3, at 3.

absolutely necessary to provide effective controls against diversion. This is especially true when there are other methods of gathering necessary information, as is the case here.

Id.

I agree with the ALJ that using the URs to actually determine a customer's controlled to non-controlled dispensing ratio ''is helpful'' in assessing whether a pharmacy's dispensing patterns are consistent with legitimate pharmacy dispensing practices. Indeed, because the URs are compiled from a pharmacy's dispensing records, the URs should typically present an accurate report as to the pharmacy's actual dispensings.

By contrast, surveys and questionnaires typically rely on nothing more than estimates, and it is certainly within the realm of possibility (if not likely) that a pharmacist who was diverting drugs would report substantially lower levels of controlled substance dispensings than he was actually engaged in; indeed, as discussed throughout, this appears to have been the case with respect to several of the pharmacies. The distribution of controlled substances is a highly regulated industry for good reason. Those who choose to engage in the distribution of controlled substances are not free to ignore relevant information, and indeed are obligated to make distribution decisions based on the most accurate information they have obtained. I thus reject the ALJ's reasoning. [168]

So too, the ALJ also rejected the Government's contention that Respondent ignored large increases in the quantities of oxycodone being dispensed, such as the increase in Tru-Valu's oxycodone dispensings between the April and December 2008 URs. *See* R.D. at 191–95. Framing the issue as ''whether increases in monthly dispensing volumes are indicative of diversion,'' the ALJ noted that ''*Southwood* does not indicate that increases in monthly dispensing volumes could indicate diversion or that comparing URs is a necessary method of due diligence.'' *Id.* at 192–93. The ALJ also noted that while the 2006 letter to distributors addressed various circumstances that may be indicative of diversion, it only ''list[ed] 'characteristics in [illegitimate pharmacies'] pattern[s] of ordering controlled substances.' '' *Id.* at 193 (quoting GX 3, at 3). According to the ALJ, the list provided in the letter was ''unhelpful . . . because the comparisons . . . do not involve monitoring *ordering* patterns, but *dispensing* patterns.'' *Id.* The ALJ then reasoned that because there is no evidence ''that DEA told Respondent to compare URs in order to identify increases in monthly dispensing volumes,'' it would be unfair to sanction Respondent for failing to do so. *Id.* at 194.[169]

It is true that *Southwood* did not discuss whether an increase in the monthly dispensing volume for a particular drug is an indicator of diversion. Yet in holding that the distributor's due diligence program was ineffective, *Southwood* did note that in the case of several of the pharmacies, ''Respondent actually distributed even

[168] As found above with respect to each of the pharmacies, some (but not all) of the survey and site visit forms used by Respondent phrased the question in terms of the percentage of prescriptions that were for controlled substances (and schedule II controlled substances) rather than in terms of the percentage of dosage units or ratio of controlled to non-controlled drugs. Of further note, the ALJ rejected the testimony of a DI that Respondent should have been comparing the pharmacies' statements as to the percentage of the prescriptions comprised by controlled substances (and schedule II drugs) with the information on the URs to look for inconsistencies. Notwithstanding that she ''recognize[d] that inconsistencies in information provided by a customer during the due diligence process can be a red flag that should at least trigger further investigation,'' R.D. at 190 (citing *Southwood*), she then concluded that using the URs ''would not be helpful because it would amount to an 'apples and oranges' comparison.'' *Id.* at 191.

However, while the URs provided by Tru-Valu did not provide data as to the number of prescriptions filled for each drug, the ALJ ignored that the URs provided by five of the pharmacies (Drug Shoppe, Englewood, City View, Medical Plaza, and Morrison's) did provide the data and yet Respondent never compared the figures. And while making those calculations may have required totaling the respective number of prescriptions for schedule II drugs and all controlled substances, given the predominance of controlled substances in the dispensings, an accurate estimate generally could have been made by simply totaling up the controlled substances on the first few pages of the URs.

Most significantly, the ALJ entirely ignored that the URs provided by Englewood actually totaled the number of prescriptions for each schedule of controlled substances as well as for the non-controlled prescription drugs, and yet Respondent failed to compare the data with what Englewood's pharmacist reported.

Respondent contends that comparing a pharmacy's representation as to the percentages of prescriptions comprised by controlled substances and schedule II drugs to the UR data showing the volume of dosages is an apples to oranges comparison. This begs the question of to what Respondent intended to compare the prescription percentages provided by each pharmacy to determine if it was engaged in illegitimate dispensing. Of note, in the case of City View, Ms. Seiple documented her ''concerns regarding [the number] of doses dispensed as opposed to noncontrols'' and that she had spoken with the pharmacy ''multiple times regarding ratio of controls [sic] & noncontrols [sic].''

So too, on several occasions, Respondent's inspector submitted a site visit report and a recommendation, noting that the dispensing percentages reported by a pharmacy were either ''a little high'' or ''high,'' and recommended that the Compliance Department obtain a new UR and compare it with the information obtained during the site visit. As found above, these recommendations were not followed. According to Ms. Seiple, this was because Respondent's Policies did not ''specify any particular percentage of controlled drugs to non-controlled drugs that the Company considers 'high' or 'a little high.' '' RX 103A, at 45. Ms. Seiple did not, however, address what percentage, if any, Respondent considered to be suspicious. This suggests that Respondent's purpose in asking the question was to create the illusion that it was conducting due diligence.

Notwithstanding that the dispensing ratio figures provided in *Southwood* and during the August 2009 briefing refer to dosage units, generally for most of these pharmacies, the percentage of prescriptions for controlled substances would actually be lower than the percentage of dispensings when calculated using dosage units, due in part, to the large quantities of oxycodone being dispensed per prescription. Moreover, in 2008, DEA noted that ''controlled substances constitute between 10 percent and 11 percent of all prescriptions written in the United States.'' DEA, *Electronic Prescriptions for Controlled Substances,* 73 FR 36722 (2008) (Notice of Proposed Rulemaking).

Thus, while a comparison of the percentages reported by Tru-Valu to the 20/80 ratio figure is not a precise comparison, when a pharmacist reports that the percentage of the prescriptions comprised by controlled substances is well above the 20 percent figure, it nonetheless is an indicator (red flag) of diversion. As explained above, in May 2008, Tru-Valu told Respondent's consultant that controlled substances comprised 40 percent of the prescriptions it dispensed (more than double the figure) and in July 2010, Tru-Valu told Respondent's inspector that 60 percent of the prescriptions were for schedule II drugs and that 60 to 80 percent of the prescriptions were for all controlled substances.

[169] The ALJ also asserted that ''it appears that the only evidence that increases in a pharmacy's monthly sales are indicative of diversion was [the DI's] opinion, which was based solely on his experience as a diversion investigator. This is not sufficient to put the industry on notice of DEA's position that such conduct is sanctionable.'' R.D. at 194. The ALJ's reasoning conflates the issue of whether an increase in a pharmacy's dispensings of a particular drug is an indicator of diversion with that of whether the Agency was required to provide notice.

As for whether the DI's testimony is enough to establish that an increase in a pharmacy's dispensing volume of a particular drug is an indicator of diversion, at least one federal appeals court has held that a diversion investigator with sufficient experience can testify as an expert regarding the ''common red flags suggestive of an illicit pharmaceutical operation.'' *United States* v. *Lovern,* 590 F.3d 1095, 1102 (10th Cir. 2009). According to the DI's declaration, at the time of the hearing, he had ten years of experience as a DI and had investigated nine distributors. GX 49B, at 1. Moreover, while there may be a legitimate explanation for why a pharmacy has experienced an increase in the volume of its controlled substance dispensings, it is hardly assailable that a large increase is an indicator of diversion, especially when the increase involves a drug highly sought after by drug abusers. Indeed, it is within the Agency's experience that drug-seeking patients and drug-dealing doctors seek out those pharmacies that will fill their prescriptions with no questions asked. *See East Main Street Pharmacy,* 75 FR 66,149, 66,152 (2010) (discussing relationship between physician convicted of drug dealing and pharmacy, pursuant to which physician directed all of his patients to fill their prescriptions at the pharmacy); *see also Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62,316, 62,321 (2012) (discussing patients travelling 200 miles from doctor's office to pharmacy).

larger quantities of the drug [hydrocodone] to them'' after it had received information that pharmacies were likely engaged in unlawful dispensing. 72 FR at 36,500.[170]

As for the 2006 letter, it is true that the letter did not specifically identify increases in a pharmacy's dispensings of highly abused controlled substances as an indicator of diversion. However, the letter did not purport to set forth an all-inclusive list of the circumstances present with those pharmacies engaged in diversion, and some red flags are so obvious that no one who engages in the legitimate distribution of controlled substances can reasonably claim ignorance of them. *See Holiday CVS, L.L.C., d/b/a/CVS/Pharmacy Nos. 219 and 5195,* 77 FR 62,316, 62,322 (2012). This is especially true when the drug is a potent narcotic which is known to be highly sought after by drug abusers, and even a cursory review of the pharmacy's dispensing data would establish that the pharmacy's already high levels of dispensing have increased even more.[171]

The ALJ further expressed her hesistancy ''to recommend sanctions based on a method of due diligence that has never been identified by DEA in any regulation, guidance, training, or case.'' R.D. at 194. To the extent the ALJ's opinion suggests that DEA has not provided the industry with sufficient notice ''that such conduct is sanctionable,'' *id.,* as discussed previously, the suspicious order rule provides fair notice to distributors as to their obligation to notify the Agency of suspicious orders they receive. Due Process does not require the Government to identify every conceivable circumstance which may render an order suspicious, or to identify every step a distributor must take to determine whether a particular order is suspicious. I therefore respectfully reject her reasoning.

I acknowledge that prior to April 1, 2009, Respondent engaged in various due diligence efforts, including conducting a site visit and a phone survey in response to Tru-Valu's request for an increase in the amount of oxycodone. I find, however, that these measures did not sufficiently dispel the suspicion created by the other information Respondent had obtained from Tru-Valu, particularly the December 2008 UR data (that being the most recently obtained UR until October 2009). That UR showed that Tru-Valu's dispensing of oxycodone 30 alone accounted for nearly 64 percent of its dispensings and represented an increase of more than 50 percent from the level of its previous UR. Thus, Tru-Valu's dispensings of this single dosage (which is also the strongest dosage of immediate release oxycodone which is commercially available) were more than three times the level of all controlled substances dispensed by a typical retail pharmacy.

The UR also showed that, with the exception of carisoprodol, which was then controlled only under Florida law (and which subsequently was federally controlled, based in part on its abuse potential when used as part of a drug cocktail which included narcotics and benzodiazepines),[172] each of the top ten drugs dispensed was controlled under the CSA, including alprazolam 2 mg. These facts alone created not merely a suspicion, but a strong one at that, that Tru-Valu was diverting controlled substances. Also, the 2008 site visit, which was the only time Respondent obtained information as to the names of the pain management doctors whose prescriptions were being filled by Tru-Valu, revealed that two of them were doctors Respondent terminated when its CEO decided to cut off sales to direct dispensers because of their unethical marketing practices.

Moreover, at the 2008 visit, the PIC disclosed that he was actively seeking out the business of area pain doctors. Unexplained by Respondent is why a pharmacist who was actively seeking out the business of physicians prescribing narcotics would then risk alienating those physicians by refusing to fill their illegitimate prescriptions. Yet Respondent simply ignored this potential conflict on the part of Tru-Valu's PIC.

As noted above, from April 1, 2009, through the date of the Compliance Review, Respondent filled monthly orders for oxycodone products totaling 25,300 du (April), 25,000 du (May), and 24,000 du (both June and July). None of the orders were reported to DEA as suspicious. For reasons explained previously, I hold that they were suspicious.

Even were I to ignore the existence of these red flags (which I decline to do), I further find that even after Respondent implemented the SOMS and its new policies and procedures, Respondent continued to fail to report suspicious orders. As noted above, on November 30, 2009, Tru-Valu placed orders for 7,200 du of oxycodone 30; 14,400 du of oxycodone 15; and 1,000 du of oxycodone 10/325, bringing its total monthly orders to 26,200 du and exceeding the 25,000 du CSL. Yet there is no evidence that the orders were held for review and they were not reported as suspicious.

Moreover, in February 2010, Tru-Valu's orders totaled 46,800 du, thus exceeding the CSL by nearly 22,000 du. While Respondent's Compliance Department documented that it contacted Tru-Valu and was told by its pharmacist that a local supermarket had closed and that he was ''getting some of [its] business,'' Respondent failed to comply with its Policies and Procedures by independently verifying the pharmacist's explanation. It also failed to obtain a new UR as required by its Policies and Procedures and did not do so until April 1, 2010.[173]

[170] While *Southwood* did not specifically note the preceding months' orders in that portion of the decision which held that the distributor had violated the suspicious order rule when it failed to report the orders placed by a pharmacy which had ordered 2.1 million du in a single month, the opinion had earlier set forth the quantity of the distributions made to the pharmacy each month. *See* 72 FR 36,489 (listing monthly orders); *id.* at 36,501 (observing that distributor ''did not report any of [pharmacy's] purchases as suspicious. . . . It did not do so even in November 2006, when it distributed more than 2.1 million dosage units of hydrocone to'' the pharmacy).

[171] Citing *Holiday CVS,* the ALJ also reasoned that ''DEA has recognized that increased sales by a pharmacy, alone, are not necessarily indicative of diversion.'' R.D. at 193 (citing 77 FR at 62,324 n.33). However, the ALJ then acknowledged that ''[t]he Administrator stopped short of stating that increased controlled substance sales are *never* a red flag, but emphasized that such increases could be 'explained by an increase in legitimate prescriptions.' '' *Id.*

In *Holiday CVS,* the Government took exception to the ALJ's ruling which barred it from admitting evidence of the pharmacy's oxycodone purchases. The Administrator upheld the ALJ's ruling, noting that the evidence did not establish a violation of the CSA's prescription requirement, 21 CFR 1306.04(a), which requires proof by reference to a specific prescription that a pharmacist knowingly (or with willful blindness) dispensed a prescription which lacked a legitimate medical purpose and was issued outside of the usual course of professional practice. *See* 77 FR at 62,324 n.33.

Here, however, the issue is simply whether the oxycodone orders placed by the seven pharmacies were suspicious. Certainly a substantial increase in a pharmacy's oxycodone orders is an indicator of suspicious activity, notwithstanding that upon investigating the orders, the pharmacy may have a legitimate explanation for the increase, which ultimately dispels the suspicion.

[172] *See Placement of Carisoprodol into Schedule IV,* 76 FR 77,330, 77,338 (2011) (noting that ''the drugs most frequently used in combination with carisoprodol that presented in [Emergency Department] visits were opioids (hydrocodone, oxycodone), benzodiazepines (alprazolam, diazepam, clonazepam), alcohol, and illicit drugs (marijuana, cocaine)); *see also id.* at 77,342–43 (testimony of various law enforcement officials regarding use of carisoprodol in combination with narcotics and benzodiazepines); *Paul H. Volkman,* 73 FR 30,630, 30,637 (2008) (testimony of expert in pain management noting that physician's prescribing of drug cocktails which included an opioids, a benzodiazepine, and carisoprodol ''greatly increased the chance for drug abuse, diversion, [and]/or addiction'').

[173] The ALJ rejected the Government's contention that Respondent did not follow its policies and

Not only does this evidence support a finding that Respondent failed to comply with its Policies and Procedures, it also supports a finding that Respondent failed to report suspicious orders. As Respondent represented to the Agency, ''[t]he purpose of the [SOMS] is to ensure that potentially suspicious orders are flagged and reviewed by the compliance department.'' RX 78, at 59. As Respondent further represented, the SOMS' function was to ''[h]old all orders for controlled drugs that meet or exceed the criteria set out in 21 CFR 1301.74(b),'' those being ''orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.'' *Id.* at 32. Thus, where Respondent failed to comply with its policies and procedures and obtain an explanation for an order which it independently verified, as well as a new UR, those orders are properly deemed suspicious. I therefore find that Respondent violated 21 CFR 1301.74(b) when it failed to report those orders in February 2010 which placed Tru-Valu over its CSL.

The following month, Respondent shipped an even larger quantity of oxycodone to Tru-Valu (55,200 du, including 43,200 du of 30 mg and 12,000 du of 15 mg). Tru-Valu's orders exceeded even the new CSL and were again justified on the ground that a supermarket had closed, yet Respondent still had not independently verified this explanation. Nor did it obtain a new UR until April 1, 2010, after it had filled the March orders. Moreover, the evidence shows that on March 31, 2010, Respondent deleted an order for oxycodone 15. However, none of these orders were reported as suspicious even though Tru-Valu had again exceeded the CSL and placed orders of unusual size.

These episodes provide a further reason to conclude that Respondent did not maintain effective controls against diversion. As found above, the SOMS calculated a customer's CSL based on ''[t]he highest monthly total [invoiced to the customer] from the preceding six months.'' RX 78, at 60. Thus, if Respondent approved an increase in the quantity of a drug family, regardless of whether it had complied with its Policies and Procedures by obtaining an explanation for the order, independently verifying that explanation, and obtaining a new UR, the increased amount would become the new CSL and thus allow the customer to order even larger quantities of controlled substances without even triggering a SOMS hold and further review.

Thus, in April 2010, Respondent filled orders totaling 48,000 du. While these orders were apparently held for review because they violated either the pattern or frequency parameter (as they were the first orders placed for the month and placed on the 27th day), Respondent deemed the orders non-excessive because they were under the previous month's total of 55,200, even though the previous month's orders were never properly investigated and justified. I conclude, however, that the orders were suspicious because they violated either the frequency or pattern parameter and were never properly justified.

Of further note, several weeks prior to filling the April 27 orders, Respondent obtained a UR for the month of February 2010. This UR showed that Tru-Valu had dispensed more than 192,000 du of oxycodone 30; 38,563 du of oxycodone 15; and 30,655 du of alprazolam 2 mg; these drugs alone accounted for more than 81 percent of Tru-Valu's dispensings. The UR also showed that the top ten drugs dispensed were formulations of oxycodone, methadone, or alprazolam, and 17 of the top 20 drugs were controlled. Yet the April 27 orders were not reported as suspicious.

The SOMS notes show that Tru-Valu placed additional oxycodone orders in May 2010, which were flagged for review because its orders were increasing and there was a change in its buying pattern because another distributor had cut back its allocation. While notes in the MFRs suggest that Respondent obtained this explanation from the pharmacist, there is no evidence that Respondent ever independently verified this explanation, as required by its Policies and Procedures.

According to Respondent's records, on May 18, 2010, Tru-Valu placed another order which clearly placed it over its CSL. While Respondent deleted the order, it failed to report the order as suspicious. Later, it also edited an order for oxycodone 15 (May 27), reducing it from 12,000 to 7,200 du, while again failing to report it. Indeed, Respondent frequently deleted or edited orders to bring a customer within its CSL and yet never reported the original orders as suspicious.

However, the suspicious order regulation requires the reporting of an *order,* regardless of whether the order is rejected entirely or edited by reducing the amount that is actually shipped. As explained in *Southwood,* the purpose of the regulation is ''to provide investigators in the field with information regarding potential illegal activity in an expeditious manner.'' 72 FR at 36,501. That purpose was undermined by Respondent when it either entirely deleted orders—thus treating them as if they had never been placed—or edited the orders by reducing their size to place the customer at or below the CSL—thus treating them as if they had been placed in smaller amounts than those that would trigger reporting. I thus find that Respondent repeatedly violated the regulation by failing to report those orders which it either deleted entirely or edited downwards in size.[174]

procedures by independently verifying the pharmacist's explanation, reasoning that ''by relying solely on the lack of documentation, the Government is attempting to improperly shift the burden of proof to Respondent.'' R.D. at 173. As explained in my discussion of the Government's Exceptions, I respectfully reject the ALJ's reasoning.

[174] The Government argued ''that Respondent regularly edited and/or deleted held orders in order to keep the particular customer within their CSL.'' Gov. Proposed Findings of Fact and Conclusions of Law, at 123. Rejecting this contention, the ALJ explained:

> This argument meets the common sense test, but fails to rise to the level of proving a violation of a legal requirement. First, the Respondent's witnesses affirmatively asserted that their actions to edit or delete an order were not linked to the suspicious nature of the order itself. Rather, orders were edited and deleted for business reasons, not diversion-avoidance reasons. This testimony was not contradicted by any other witnesses in this matter. Next, the record establishes that due diligence was done upon the order prior to making the determination to edit or delete it. Accordingly, I find that the Government has failed to prove that the Respondent's practice of editing and deleting orders violated [its] duty to maintain effective controls against diversion or the duty to detect suspicious orders. R.D. at 196.

I respectfully disagree with the ALJ's reasoning. As for the assertion that the compliance department's ''actions to edit or delete an order were not linked to the suspicious nature of the order itself'' but were done for business reasons, as found above, in nearly every instance in which an order was edited or deleted, the original order placed the respective pharmacy over its CSL and thus rendered the order to be of unusual size. RX 78, at 60. Moreover, there are comparatively few instances in which Respondent documented that an order was edited or deleted for such reasons as that the customer had not purchased enough non-controlled products to meet its ''ratio'' or because product was being allocated due to a market shortage.

As for the ALJ's further assertion that ''[t]his testimony was not contradicted by any other witnesses,'' R.D. at 196, earlier in her decision the ALJ specifically noted the testimony of both Mssrs. Corona and Schulze on this issue. *Id.* at 98. Mr. Corona testified, however, that ''[i]t was common practice for [the] Compliance Department to either edit or delete orders for controlled substances if the order was above the customer's threshold and there was not a reason to increase the threshold. Though this was not intentionally done to subvert [Respondent's] responsibility to report suspicious order [sic], in effect, this practice did just that.'' GX 51B, at 9 ¶ 30.

To similar effect, Mr. Schulze testified that ''[i]t was a common practice for compliance clerks to reduce orders or delete orders to keep a customer within its CSL for the rolling 30 day period, as can be seen in the due diligence file Memo For Record

Continued

Moreover, Respondent failed to report the May 18 and May 27 orders as suspicious notwithstanding that: (1) It had shipped 65,200 du of oxycodone during the month; (2) it had deleted entirely the May 18 order; (3) it had reduced the May 27 order; and (4) several days later, it noted in the Memo for Records, that the May 27 orders, which resulted in the shipment of 24,000 du of oxycodone 30 and 7,2000 du of oxycodone 15, had been released without committee review and been filled by mistake and that 25,000 du was the level at which Tru-Valu's oxycodone orders were to be reviewed.

Notwithstanding the above, in June 2010, Respondent filled orders totaling 33,600 du. While the June 15 order for 12,000 du of oxycodone 30 placed Respondent over its CSL, the order was released with reservation by the committee and not reported as suspicious. Likewise, Tru-Valu placed additional orders on June 21 and June 30 which placed it over the CSL; while the June 21 order (for 12,000 du of oxycodone 30) was cancelled by the pharmacist, it still was suspicious and should have been reported for the reasons set forth above.

Although Respondent deleted the June 30 order because it was placed too early, even assuming that Respondent contacted the pharmacist because the order was apparently re-submitted the next day, there is no documentation as to what explanation was offered by Tru-Valu's pharmacist. Nor was a new UR obtained. Here again, Respondent violated the regulation by failing to report the order as suspicious.

While based on the June orders Respondent filled, Tru-Valu's CSL was increased from the 25,000 du level noted in the June 2nd MFR entry to 33,600 du, Tru-Valu's July orders totaled 46,800 du. Yet Respondent again failed to obtain an explanation for the order and a new UR. Nor did it report the order as suspicious.

In August 2010, Respondent conducted a site visit. During the visit, Respondent developed significant additional information which reinforces the conclusion that Tru-Valu was engaged in suspicious activity. This included the pharmacy's report that 60 to 80 percent of the prescriptions it filled were for controlled substances, and that 60 percent of the total prescriptions were for schedule II drugs. The inspector also reported that while it was the middle of the afternoon, the pharmacy was ''very busy'' with a ''long line of mostly younger people'' (reporting that there were 10 persons) who were ''thin, tattooed, [and] casually dressed'' and that ''more [were] coming in.'' The inspector further noted that the pharmacy had posted signs imposing a ''pill limit'' of 180 du on oxycodone 30 and 90 du on oxycodone 15; that it did not accept insurance on certain oxycodone products; and that patients ''must have a recent MRI report.'' All of these were indicia of illegitimate activity.

Ten days after the site visit, Respondent deleted an order, documenting that the order was deleted ''per review until [the] review completed.'' Yet notwithstanding all of the additional information its inspector had documented during the site visit, the order was not reported as suspicious. Moreover, on September 1, 2010, Respondent filled orders for 24,000 du of oxycodone 30 and 2,400 du of oxycodone 15. While there is evidence documenting that Respondent's compliance department spoke with Tru-Valu's PIC regarding why he did not accept insurance on certain oxycodone products, there is no documentation that Respondent inquired about the signs imposing pill limits and requiring an MRI, or about the clientele observed by the inspector. And here again, Respondent failed to report the orders as suspicious.

Nearly three weeks later, Tru-Valu ordered 26,400 oxycodone 30, thus placing it over its CSL. While Respondent edited the order by reducing it to 7,200 du, here again, Respondent failed to obtain an explanation for the order and a new UR. And here again, it failed to report the order as suspicious even though it noted that additional product should not be released until ''reservations [were] addressed.''

Yet the following day, Respondent shipped an additional 13,200 du of oxycodone 30 to Tru-Valu. While Respondent contacted the pharmacy and asked the PIC if he got a lot of out-of- state customers, it did not further inquire as to why he had posted the signs imposing pill limits and requiring an MRI. Nor did it question the PIC regarding the inspector's observation of the pharmacy's customers.

Moreover, the same day, Respondent's compliance committee conducted an account review, which included reviewing the site visit and its most recent UR, which covered the month of July 2010. This UR showed that Tru-Valu's dispensings of oxycodone 30 totaled more than 206,000 du, which was 61 percent of its total dispensings, and with its dispensings of oxycodone 15 of 32,441 du, its dispensings of these two drugs were 70.7 percent of all dispensings. The UR also showed that Tru-Valu had dispensed more than 31,000 du of alprazolam 2 mg and that nine of the top ten drugs dispensed were federally controlled substances such as oxycodone, methadone, alprazolam 2 mg (the other being carisoprodol). In addition, 18 of the top 20 were federally controlled drugs and included 11 oxycodone products, three alprazolam products, two diazepam products, methadone, and Dilaudid (hydromorphone).

Notwithstanding the information provided by the UR and the recent site visit, Respondent approved the order for 13,200 du and increased the amount of oxycodone Tru-Valu could purchase ''to the pattern high of 46,800.'' Respondent further documented that the 46,800 du figure was only 42 percent of Tru-Valu's UR, in essence using the UR as a one-way ticket to justify making additional distributions while ignoring the significant information it contained which raised a strong suspicion as to the illegitimacy of its dispensings. Here again, Respondent did not report the order as suspicious.

Moreover, upon filling an order for 14,400 du of oxycodone 30 on October 5, 2010, Respondent had shipped 58,800 du to Tru-Valu on a rolling 30-day basis, and exceeded the 46,800 du CSL. Here again, there is no evidence that Respondent contacted the pharmacy and yet the order was released with

('MFR') and SOMS shipping notes.'' GX 53, at 2–3. Mr. Schulze also testified that he was ''aware that Ms. Seiple also explicitly stated that Masters never cancelled, deleted, or edited orders to bring customers within the limits established by SOMS. That statement is simply not true.'' *Id.* at 2. *See also* GX 52, at 14 (''In the beginning of SOMS implementation, we deleted orders that exceeded the CSL and informed the customers when they could place another order. Later on, when an order was held by SOMS due to size of the order exceeding the established limit, we would edit the orders, reducing the total amount shipped to keep the customers within the CSL.''); *id.* at 15 (''In practice, we did not analyze a customer's orders to determine if they were 'suspicious' and as such were required to be reported to DEA. We were looking at orders to determine what we could justify shipping out. If the order needed to be edited to justify shipment, we would do that.'').

As explained above, because the purpose of the CSL was to determine whether a customer's orders were of unusual size and thus suspicious, Respondent's practice of editing or deleting those orders which placed a customer over its CSL subverted the SOMS. Whether Respondent's employees edited or deleted orders with the intent to subvert its obligation to report suspicious orders is irrelevant because the regulation does not require proof of any level of scienter.

As for the ALJ's statement that ''the record establishes that due diligence was done upon the order prior to making the determination to edit or delete it,'' R.D. at 196, as found above, the evidence shows that while the pharmacies submitted numerous oxycodone orders which placed them over their respective CSLs, Respondent only rarely contacted the pharmacies and obtained an explanation for why they were ordering these quantities.

reservation. Nor was the order reported as suspicious.

Only eight days later, Respondent edited an order (placed the day before) to 6,000 du (60 bottles) to keep Tru-Valu at its CSL. Yet on filling the order, Respondent had actually shipped 64,800 du of oxycodone on a rolling 30-day basis. Once again, Respondent did not contact the pharmacy and obtain an explanation for the order. Here again, it failed to report the order as suspicious.

Moreover, Respondent filled additional orders on November 1, 2010 (for 24,000 du of oxycodone 30 and 2,400 du of oxycodone 15) as well as on November 8, 2010 for 14,400 du of oxycodone 30. While these orders apparently were not held by the SOMS, given the extensive red flags raised by Tru-Valu's business practices, the orders were suspicious and should have been reported. Indeed, the evidence shows that Respondent placed Tru-Valu on non-control status only after Respondent received a letter from Mallinckrodt raising concerns about Tru-Valu.

Yet, even before April 1, 2009, Respondent had ample evidence that raised a strong suspicion as to the legitimacy of Tru-Valu's business practices and this evidence became even stronger over time. While Ms. Seiple justified Respondent's failure to report Tru-Valu's orders as suspicious on the ground that the pharmacy was actively marketing to nearby pain clinics and had provided Respondent with the names of several doctors who were writing the prescriptions, it bears noting that Respondent had previously cut off sales to two of the physicians. It also bears noting that because only a practitioner (*i.e.,* in this case, a licensed physician) can issue a prescription, the fact that Respondent was provided with the names of several doctors who were practicing pain management says nothing about whether those doctors were issuing legitimate prescriptions. Moreover, while Respondent's CEO and former Vice-President acknowledge that the company was well aware of the oxycodone crisis then ongoing in the State of Florida, Respondent took no further steps to verify the credentials of the physicians (indeed, while it obtained their names at the initial site visit, it did not subsequently update this information) and whether they had any specialty training in pain management, physical medicine, and/or addiction, all of which was readily accessible at the Florida Department of Health's Web site.

Respondent further justifies its failure to report the orders, asserting that the orders were consistent with the pharmacy's business model as represented by the PIC and confirmed during the May 2008 site visit. However, the fact that ''the URs and other information provided by Tru-Valu were consistent with the pharmacy's business model as explained by [its] PIC and confirmed in the May 2008 site inspection'' says nothing about whether the pharmacy was engaged in legitimate dispensing.

As for Ms. Seiple's contention that ''[b]ased on its extensive investigation, it determined that the orders it shipped to Tru-Valu were not suspicious,'' the fact remains that Respondent repeatedly failed to obtain an explanation for those orders that were held by the SOMS. And even in those few instances in which it did contact the pharmacy, it did not independently verify the pharmacy's explanation and it only rarely obtained a new UR.

As for Respondent's failure to obtain a new UR every time an order was held, the ALJ found that the Government had proved the allegation, noting that ''very few URs were collected, despite SOMS holding hundreds of orders over several years.'' R.D. at 201. However, the ALJ then explained that ''the relevant question . . . is not simply whether Respondent failed to follow its policies, but whether such failure rendered Respondent's system ineffective (factor one) and/or constituted negative experience distributing controlled substances so as to justify revocation (factor four).'' *Id.* (citing 21 U.S.C. 823(e)).[175]

Citing *Southwood,* the ALJ opined ''that an anti-diversion system is ineffective if 'the direct and foreseeable consequence of the manner in which Respondent conducted its due diligence program was the likely diversion of [controlled substances].'' *Id.* (quoting 72 FR at 36,502). The ALJ then explained that in contrast to *Southwood,* the Government had ''made no showing that Respondent's failure to order a recent UR for every SOMS-held order would likely result in diversion,'' noting that ''the record is void of evidence that *any* controlled substances distributed by Respondent ha[ve] been diverted.'' *Id.* at 201–02. The ALJ further reasoned that ''[t]here is also no evidence that updated URs, had they been requested, would have indicated that the drugs were likely to be diverted.'' *Id.* at 202.

The ALJ then characterized the Government's argument as being that ''*any* failure to follow *every* policy, no matter how minute, renders the Policies and Procedures *per se* ineffective, regardless of whether such failure would likely result in [the] diversion of controlled substances.'' *Id.* In the ALJ's view, ''[t]his argument falls short of the standard set forth in *Southwood* that due diligence efforts are ineffective when their 'direct and foreseeable consequence' '' is the 'likely diversion of' controlled substances.'' *Id.* (quoting 72 FR at 36,500). The ALJ thus concluded that the Government had not proved that Respondent's due diligence program was rendered ineffective by its failure to obtain a UR every time an order was held by the SOMS. *Id.*

While it is true that *Southwood* noted that the ''direct and foreseeable consequence of the manner in which [the distributor] conducted its due diligence programs was the likely diversion of'' large quantities of controlled substances, this discussion occurred in the context of describing the company's conduct in continuing to distribute the drugs even after it had obtained information from the Agency and some of its customers that the latter were likely filling unlawful prescriptions. 72 FR at 36,500; *see also id.* (noting that ''in several cases, Respondent actually distributed even larger quantities of [hydrocodone] to'' the pharmacies). *Southwood* did not, however, address whether a distributor's failure to follow its procedures for detecting and reporting suspicious orders must be shown to have resulted in the likely diversion of controlled substances in order to be actionable misconduct.

Respondent's Policy 6.2 served the purpose of identifying both: (1) Those orders which could be shipped notwithstanding that they met the criteria of unusual size, unusual pattern, or unusual frequency, because the suspicion created by the order itself was sufficiently dispelled through the procedures set forth by the policy, and (2) those orders which were to be considered as suspicious because the information obtained through those procedures did not dispel the suspicion. However, as explained above, an order can still be suspicious even if the evidence available to the distributor does not establish that the order is likely to be diverted. Thus, the Government was not required to show that Respondent's failure to follow its policy and obtain a UR was likely to result in diversion in order to establish liability. It need only show that the failure to follow the policy resulted in Respondent's failure to report suspicious orders.

As explained above, the ALJ characterized as ''minute'' the

[175] Because Respondent was distributing schedule II drugs, the correct section is 823(b), which uses the same factors as 823(e).

requirement that a new UR be obtained whenever an order was held by the SOMS. However, the record is replete with numerous instances in which orders held by the SOMS were nonetheless released without any investigation, based solely on the fact that the order was supported by the UR. Indeed, this occurred even when a new UR had not been obtained in months. And it also occurred even after Respondent's inspector noted, with respect to several of the pharmacies, that their controlled substance dispensing ratios seem high and that a new UR should be obtained and compared with the figure reported by the pharmacy.

To be sure, Respondent may well have ignored any information on those URs raising a suspicion of diversion, as it did with the few URs that were obtained. But as noted throughout this decision, the URs it did obtain contained significant information that raised a strong suspicion that the each of the pharmacies was engaged in illegitimate dispensing practices. I therefore also hold that Respondent's repeated failure to obtain a new UR whenever orders were held by the SOMS rendered its system for detecting suspicious orders ineffective.[176]

The Drug Shoppe

Prior to April 1, 2009, Respondent had acquired information raising a strong suspicion as to the legitimacy of The Drug Shoppe's dispensing practices. While The Drug Shoppe was a community pharmacy, it had previously reported that 40 percent of the prescriptions it filled were for controlled substances and 20 percent of the prescriptions were for schedule II drugs.

Moreover, the first UR obtained by Respondent showed that The Drug Shoppe's monthly dispensings of oxycodone 30 totaled 38,689 du and its dispensings of all oxycodone products totaled 56,600 du out of total dispensings of 165,068, or more than 34 percent of the pharmacy's dispensings. While The Drug Shoppe's PIC had stated that he had refused to fill prescriptions when the quantity was ''too high,'' the UR previously obtained showed that the average quantity of oxycodone 30 dispensed per prescription was 214 du.

Also, while during a site visit, the pharmacy reported that it filled for various pain management physicians and provided the names of five of the physicians, there is no evidence that Respondent even verified that the physicians were licensed and registered. Nor did it verify whether these physicians had specialty training or board certification in pain management or another related specialty.

According to Respondent's records, as of April 1, 2009, The Drug Shoppe's monthly purchasing limit was set at 50,000 du for all oxycodone products. Yet Respondent allowed The Drug Shoppe to exceed the purchasing limit by more than 5,000 du in April 2009.

In the middle of July 2009, Respondent obtained a new UR which covered the period of May 14 through July 14. Of note, the UR showed that The Drug Shoppe's monthly dispensings of oxycodone 30 had increased to nearly 53,000 du. Yet Respondent did not find this suspicious, and approved an increase from 50,000 to 62,000 du on The Drug Shoppe's oxycodone purchasing limit and filled orders totaling that amount during July.

Thereafter, the SOMS went into effect. However, even as early as the first month that the SOMS was operational, Respondent filled orders, which were held for review because they exceeded The Drug Shoppe's oxycodone CSL, without obtaining an explanation for the orders and a new UR while failing to report the orders as suspicious. For example, on August 13, 2009, Respondent filled an order for 1,000 Endocet which placed The Drug Shoppe over its CSL. While the SOMS was supposed to hold an order even if it resulted from a pharmacy's orders exceeding the CSL by a single dosage unit, the order was approved because it was ''ok to ship within current limit.'' As previously explained, if Respondent had actually contacted the pharmacy, one would expect the explanation it obtained from it to have been documented in the SOMS notes, rather than that the order was ''ok to ship within current limit.'' I therefore conclude that Respondent did not contact the pharmacy and obtain an explanation for the order, and that the order, which was not reported, was suspicious.

Further, only days later during the Compliance Review, a DEA Investigator specifically identified Respondent's distributions of oxycodone to The Drug Shoppe as ''potentially problematic.'' GX 48A, at 3, 5; GX 12, at 23. This information obviously had no impact on Respondent's evaluation of the oxycodone orders thereafter placed by The Drug Shoppe.

One week later, Respondent deleted an order because it placed The Drug Shoppe over its current limit. Yet Respondent did not report the order as suspicious. Moreover, the next day, Respondent filled an order for 19,500 du of oxycodone 30, bringing The Drug Shoppe's orders to 74,000 du of oxycodone products, with 72,500 du being for 30 mg tablets. While Respondent justified filling the order, documenting that there was a ''Large # RX's For HIV Disease State,'' there is no evidence that it independently verified that The Drug Shoppe was filling a large number of prescriptions for HIV patients as well as whether HIV patients would necessarily require oxycodone 30. Here again, while the order placed The Drug Shoppe over its CSL by 12,000 du, it was not reported as suspicious.

As noted in my findings, throughout the course of its relationship with The Drug Shoppe, the pharmacy repeatedly placed orders which, on a rolling 30-day basis, resulted in the pharmacy exceeding its oxycodone CSL by a large amount. Invariably, Respondent failed to contact the pharmacy and obtain an explanation for the order and it rarely obtained a new UR. Instead, it typically justified shipping the order, noting that the order was under the current size limit, even when the order placed The Drug Shoppe over its CSL by tens of thousands of dosage units. And it never reported any of the orders as suspicious.

Moreover, during November 2009, Respondent purportedly reduced The Drug Shoppe's oxycodone CSL to 46,500 du, yet Respondent continued to fill orders which placed The Drug Shoppe over the CSL, while also failing to contact the pharmacy and obtain an explanation for the orders and a new UR. And it failed to report the orders as suspicious.

Likewise on December 23, 2009, Respondent deleted an order for 15,500 du of oxycodone 30 because the pharmacy was already at the CSL. While Respondent contacted the pharmacy and was told that its sales representative had said that it was allotted 62,000 du, Respondent did not obtain a new UR. Moreover, the next day, Respondent shipped 13,500 du of oxycodone 30, thus bringing its shipments since December 3, 2009 to 60,000 du (of which 58,600 were for oxycodone 30). Respondent's records contain no explanation as to why it ignored that The Drug Shoppe was nearly 14,000 du over its CSL and it did not obtain a new UR. Nor did it report the order as suspicious.

As found above, throughout January 2010, Respondent filled orders that placed Respondent above the 46,500 du

[176] Where, in a given month, multiple orders were held, it would have sufficed if Respondent had obtained a new UR following the first held order, as it said it would. If that were the case, I would not find liability for failing to obtain additional URs.

CSL on nine occasions, and on several occasions, the orders even placed it above the previous CSL of 62,000. Respondent generally justified shipping the orders, reasoning that the amount ordered during the calendar month was under the CSL, notwithstanding that the determination of whether the orders exceeded the CSL was supposed to be calculated on a rolling 30-day basis. Here again, while the SOMS notes typically contained this explanation, Respondent did not document that it obtained an explanation for the order from the pharmacy and a new UR. I conclude that the orders were suspicious and should have been reported but were not.

Moreover, in the middle of January, Respondent conducted a site visit. On the report, the inspector noted in multiple places that The Drug Shoppe's dispensing ratio of 40 percent was ''a little high.'' He recommended that Respondent obtain a new UR and compare it with the site visit. Respondent did not, however, obtain a new UR for another five months. Nor did it follow its inspector's recommendation to compare the pharmacy's representation of its dispensing ratio with even the previous UR.

On January 25, 2010, The Drug Shoppe's CSL was raised to 60,000 du. Only four days later, Respondent filled more oxycodone orders, notwithstanding that they placed the pharmacy at 15,000 du over the new CSL. According to various notes, Respondent's Compliance Committee approved the increase because the order was supported by the ''ur plus 10%'' ''per company policy.'' Here again, Respondent treated the UR as a one-way ticket to justify increasing the amount it could ship, while ignoring that the UR was incomplete because it did not list The Drug Shoppe's total dispensings, as well as the significant information it contained.

As found above, on multiple occasions thereafter through June 15, 2010, Respondent filled The Drug Shoppe's oxycodone orders notwithstanding that the orders placed it over its CSL (and on some occasions because the orders were of unusual frequency). Here again, Respondent released the orders on the basis of one of three reasons: (1) That the order was under the CSL, (2) that the order was supported by the UR, or (3) that the frequency was not excessive, even though the SOMS had apparently flagged some of the orders for this reason as well. However, with the exception of an order placed on May 7, 2010, which was apparently held by the SOMS because The Drug Shoppe had placed four orders each for 9,600 du between May 3 and 7 and thus were of an unusual pattern, Respondent failed to obtain an explanation for any of these orders from the pharmacy and a new UR.[177] Nor did it report any of the orders as suspicious.

On June 15, 2010, Respondent edited an oxycodone 30 order from 9,600 du to 5,400 du. Nonetheless, this resulted in The Drug Shoppe's orders totaling 67,600 du and placing it over its CSL. While Respondent finally obtained a new UR, there is no evidence that Respondent actually obtained an explanation for the order. Nor did it report the order as suspicious.

Still later on June 25, Respondent filled an order for 6,000 du of oxycodone 30. Yet it documented in the SOMS notes that ''oxy edited to zero per csl and policy.'' Respondent offered no evidence to explain the inconsistency and did not report the order as suspicious. And several days later, The Drug Shoppe placed a further order for 3,600 du of oxycodone which was held by the SOMS. While Respondent deleted the order, noting that it could be placed after June 30, it did not investigate the order and did not report the order as suspicious.

According to the SOMS note dated July 19, 2010, The Drug Shoppe's oxycodone CSL was then at 42,420 du. Yet on this date, Respondent filled an order for 9,600 du of oxycodone 30, thus placing the total of filled orders at 46,800 du on a rolling 30-day basis and over the CSL. Of note, while the order was held by the SOMS, Respondent did not contact the pharmacist and obtain an explanation for the order. Nor did it obtain a new UR. And it did not report the order as suspicious.

Moreover, one week later, Respondent edited an order to 1,600 du ''to meet the CSL for July.'' Notwithstanding that the order (and not simply the filled amount) placed The Drug Shoppe over its CSL, there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order. Nor did it obtain a new UR. It did not report the order as suspicious. And the deleted amount was treated as if it had never been ordered.

As found above, on multiple occasions throughout August, Respondent filled The Drug Shoppe's orders notwithstanding that the orders exceeded the CSL referred to in the July 19 SOMS note on a rolling 30-day basis. Here again, while the orders were held by the SOMS, several of them were approved because Respondent counted them on a calendar month basis and deemed the size not excessive, thus changing its own rule. Respondent did not contact the pharmacy and obtain an explanation for the orders or a new UR. And later on August 24, 2010, Respondent filled an order, notwithstanding that the order placed The Drug Shoppe over the CSL, documenting the reason as ''RWR'' (release with reservation). Yet Respondent's Policy 6.2 contained no provision that allowed for the release of an order on this basis.[178] RX 78, at 32. Respondent did not obtain an explanation from the pharmacy for any of these orders, it did not obtain a new UR, and it failed to report any of the orders as suspicious.

On each date in September 2010 on which it filled The Drug Shoppe's oxycodone orders, the pharmacy exceeded the CSL. The explanations offered for releasing the orders included: (1) That the orders were ''within [the] monthly buying pattern'' even though the orders exceeded the CSL (Sept. 1 and 2 orders); (2) the orders were ''under csl [and] supported by ur'' or ''rwr under csl'' even when the orders placed the pharmacy more than 9,000 du over its csl (Sept. 7), or nearly 8,000 du over (Sept. 20); or (3) merely ''rwr'' even when the orders placed the pharmacy over the CSL by nearly 10,000 du (Sept. 13) and 13,000 du (Sept. 23). Of note, Respondent did not document that it had contacted the pharmacy and obtained an explanation for any of the orders and I find that it did not do so. Respondent also did not obtain a new UR. And it failed to report any of the orders as suspicious.

October 2010 brought more of the same, with The Drug Shoppe's orders exceeding the CSL on four occasions and Respondent filling the orders, typically justifying its doing so by counting the orders on a calendar-month basis. However, here again,

[177] However, while Respondent contact The Drug Shoppe at the time of the May 7 order, it did not obtain a new UR.

[178] The ALJ rejected the Government's contention that Respondent's compliance department used the notation of ''release with reservation'' or ''RWR'' to document its objection to the release of a held order. R.D. at 168–69. The ALJ rejected the contention, reasoning that ''Ms. Seiple credibly explained that RWR was actually used to identify orders that were not suspicious, but about which Respondent desired to collect more information.'' *Id.*

I conclude, however, that it is not necessary to determine what the purpose was of these notations, because in those instances in which orders were held by the SOMS, the orders already met the criteria of a suspicious order. Accordingly, even if Respondent used the notations because it ''desired to collect more information'' about the customer, *id.,* the order was still suspicious and subject to reporting.

Respondent failed to contact the pharmacy and obtain an explanation for the order and a new UR. And it failed to report the orders as suspicious.

While November 2010 brought a substantial decrease in the volume of oxycodone Respondent shipped to The Drug Shoppe, both the November 1 and November 9 orders placed the pharmacy over its CSL on a rolling 30-day basis, with the first order placing The Drug Shoppe nearly 8,700 du over its CSL. The order was released, notwithstanding that Respondent failed to obtain an explanation for the order from the pharmacy and a new UR. Again, it failed to report the order as suspicious. Nor did Respondent obtain an explanation for the November 9 order and a new UR. And it did not report the order as suspicious.

On November 18, Respondent conducted a site visit during which its inspector was told that 40 percent of the prescriptions were for controlled drugs and ten percent were for schedule II drugs. The inspector was also told that 85 percent of the controlled substance prescriptions it filled were paid for with cash. Both of these were additional indicia that the pharmacy was engaged in in suspicious dispensing practices. *See* GX 51, at 4 ¶ 12 (declaration of Wayne Corona).

Moreover, while Respondent obtained a new UR on December 15, 2010, (for the month of October), that UR showed that Respondent's dispensings of oxycodone 30 alone (49,637 du) comprised 27 percent of all drugs dispensed, and its dispensings of all oxycodone products totaled 57,601 du, or more than 31 percent of all drugs dispensed. Yet even after acquiring this additional information, Respondent continued to ship oxycodone to The Drug Shoppe through February 8, 2011, the date on which DEA Investigators went to Respondent's Kemper Springs facility and requested its file on The Drug Shoppe. Respondent failed to report any of these orders as suspicious.

I find unpersuasive Ms. Seiple's justifications for why Respondent failed to report any of The Drug Shoppe's orders as suspicious. From early on in its relationship with The Drug Shoppe, Respondent acquired substantial information raising a strong suspicion that the pharmacy was engaged in illegitimate dispensing practices. Moreover, during the August 2009 DEA briefing, Respondent's distributions to The Drug Shoppe were specifically identified as being potentially problematic.

Regarding Ms. Seiple's claim that Respondent believed that the volume of pain medications being dispensed was accounted for because the pharmacy was filling for AIDS patients, Respondent simply accepted this assertion without any further inquiry as to how many HIV/AIDS patients the pharmacy had, let alone how many of these patients were actually being prescribed oxycodone 30. Nor did Ms. Seiple address the many instances in which orders were held by the SOMS and yet Respondent filled the orders without contacting the pharmacy and obtaining an explanation (let alone then independently verifying the explanation) and a new UR.

Nor do I find persuasive Ms. Seiple's explanation as to why it took until February 2011 for Respondent to discover that The Drug Shoppe's PIC had been criminally charged with an offense related to controlled substances. Even assuming that Respondent was unaware of Mr. Agravat's criminal charge until February 2011, the due diligence file establishes that the form for the 2008 site visit included a question which asked, in part, whether any of the staff pharmacists had ever been criminally prosecuted. Notably, Respondent's consultant left the answer blank and there is no evidence that Respondent ever followed up on the omission. Moreover, none of the forms Respondent subsequently used to document its due diligence and site visits even asked this question. And in any event, there were sufficient other circumstances present that created a strong suspicion that The Drug Shoppe was engaged in illegitimate dispensing practices. I therefore reject Respondent's justifications as to why it did not report any of The Drug Shoppe's orders as suspicious prior to February 2011.

Englewood Specialty Pharmacy

Prior to April 1, 2009, Respondent had obtained substantial information creating a strong suspicion as to the legitimacy of Englewood Specialty Pharmacy's dispensing practices. For example, in a due diligence review conducted in March 2008 because Englewood was seeking an increase in its purchasing limits for oxycodone and hydrocodone, Englewood reported that 30 percent of the prescriptions it filled were for controlled substances and 15 percent of the prescriptions were for schedule II drugs. Yet the UR provided by Englewood, which covered the month of January 2008, also showed the number of prescriptions for each drug and even totaled the prescriptions for the various schedules and the non-controlled prescriptions. Notably, as found above, schedule II drugs actually comprised more than 32 percent and all controlled substances comprised 51 percent of the prescriptions dispensed.

In terms of dosage units, the UR showed that out of Englewood's total dispensings of 342,760 du for all prescription drugs, schedule II drugs comprised 161,279 du, or 47 percent of its total dispensings. Moreover, controlled substances comprised 67 percent of its total dispensings, even after counting carisoprodol as a non-controlled drug. Of further note, while a Dan Farris was the owner of the pharmacy and listed as the Pharmacist-in-Charge by the consultant who performed the September 2008 site visit, there is no evidence that Respondent ever verified Dan Farris' licensure status with the Florida Department of Health.

In September 2008, Englewood sought a further increase in its oxycodone purchasing limit, with its PIC reporting that 30 percent of the prescriptions it filled were for controlled drugs and 20 percent were for schedule IIs. However, the UR Englewood submitted showed that it filled 9,928 schedule II prescriptions and 5,595 schedule III through V prescriptions (after subtracting out carisoprodol), out of a total of 22,315 prescriptions. Thus, schedule II prescriptions comprised 44.5 percent of all prescriptions and all controlled substances prescriptions comprised nearly 70 percent of all prescriptions the pharmacy dispensed.

Moreover, in terms of dosage units, the UR showed that schedule II drugs comprised 57 percent of the total dispensings and all controlled substances (again after subtracting carisoprodol) comprised 75 percent of the total dispensings. Even assuming that the pharmacist's representations as to the percentage of the prescriptions comprised by schedule II and all controlled substances were estimates, the disparity between these statements and the actual figures as shown in the UR was too large to be ignored. Yet there is no evidence that Respondent compared the prescriptions levels on the UR with the pharmacist's statement.[179]

Most significantly, in early November 2008, Respondent finally conducted a

[179] Throughout the proceeding Respondent has argued that is unfair to fault it for failing to compare the dispensing percentages as reported by the pharmacies with those shown by the URs because neither before, nor as part of the August 2009 compliance review, did the Agency identify this as a deficiency in its procedures. While it is true that, in some instances, the pharmacy's URs did not include the number of prescriptions, in Englewood's case, the URs did and yet the information was still ignored. This suggests that Respondent's purpose in asking these questions was simply to go through the motion of conducting due diligence.

site visit at Englewood, during which its PIC reported that all controlled substance prescriptions comprised only 25 percent of the prescriptions it filled. Tellingly, Respondent's consultant wrote in his report that ''[h]e [the PIC] appears to be doing a larger narcotic business than he admits to.'' RX 2C, at 78. Yet even this did not prompt Respondent to review the information provided by the UR and compare it with the various statements the PIC had made, and most incredibly, Respondent subsequently approved Englewood to purchase 50,000 du of oxycodone per month.

Notwithstanding the purchasing limit, Respondent filled orders for more than 80,000 du in the April (30,000 over the purchasing limit), and 102,000 du in both June and July 2009 (52,000 over the purchasing limit).[180] Respondent, however, had not obtained a new UR since September 2008, and even then the June and July orders exceeded its average monthly dispensings of oxycodone 30 and 15 mg (approximately 74,000 for the two dosages combined) as shown on that report by approximately 28,000 du. Yet there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the orders and there is no evidence explaining why Respondent ignored the purported purchasing limit. Based on the circumstances presented, I conclude that the orders during these months were suspicious and that Respondent violated 21 CFR 1301.74(b) by failing to report them.

While the SOMS became operational in August 2009, Respondent filled orders placed on August 3 for 90,000 oxycodone 30 and 12,000 oxycodone 15, totaling 102,000 du, and on September 28, it filled orders for 90,000 du of oxycodone 30 and 10,000 du of oxycodone 15. Yet the SOMS notes show that neither set of orders were held for review. GX 18, at 163. As previously explained, because the SOMS recalculated the CSL every month based on the highest monthly total of doses invoiced in the preceding six months, the CSL was increased even where the orders were never properly reviewed such as in the months of June and July 2009. Here again, this supports a finding that as implemented, the SOMS was not an effective control against diversion. Moreover, with respect to the September 28 orders, Englewood was specifically identified during the August 2009 DEA briefing as a customer whose oxycodone purchases were problematic. GX 48A, at 3; GX 12, at 23. Yet Respondent even failed to report the September orders as suspicious.

In early October 2009, Respondent finally obtained a new UR (for the month of September), 11 months after it had obtained the previous UR. Of note, by du, the UR showed that schedule II drugs comprised 62 percent and all controlled substances comprised 77 percent of Englewood's total dispensings. Moreover, Englewood's monthly dispensings of oxycodone 30 had increased from 51,341 to 123,476 du.

Ms. Seiple noted that Englewood's account was ''showing usage of 150k on oxy in [the] month of September'' [181] and that the pharmacy was also purchasing from Amerisource Bergen, another distributor. Ms. Seiple further documented that she was ''very concerned w/quantity dispensed per UR'' and was recommending that Englewood be limited to 50,000 du of oxycodone until the Compliance Committee reviewed the account.[182]

While the Compliance Committee reviewed the account and adopted Ms. Seiple's recommendation to reduced Englewood's oxycodone CSL to 50,000 du, on October 27, Englewood ordered 100,000 du of oxycodone 30 and 20,000 of oxycodone 15. While the order for 30 mg was reduced to 50,000 du and the order for 15 mg was deleted, neither order was reported as suspicious as it should have been. Indeed, Ms. Seiple's documented concern over the quantity of oxycodone being dispensed by Englewood begs the question of exactly what additional evidence was required to render the orders suspicious.

On December 3, Englewood placed orders for 50,000 du of oxycodone 30 and 24,000 du of methadone. This, however, was only three days after Respondent had filled an oxycodone order for 37,500 du which placed Englewood at its CSL, which apparently had been reduced due to supply issues. While Respondent deleted the order and told the PIC that it would not fill the order until there was a review by the Compliance Committee, it did not obtain an explanation for the order or a new UR and it failed to report the orders as suspicious.

However, two weeks later, Englewood placed more orders for 50,000 oxycodone 30 and 24,000 du of methadone. While Ms. Seiple documented that she called the pharmacy and told the PIC that order would not be shipped but could be resubmitted in four days, here again, there is no evidence that Ms. Seiple asked the PIC why his pharmacy needed so much oxycodone. She also failed to obtain a new UR and failed to report the order as suspicious.

Notwithstanding the extensive evidence that Englewood was engaged in illegitimate dispensing practices, on December 28, Respondent's compliance committee conducted a new review and approved the pharmacy to purchase 50,000 du of oxycodone 30 and 24,000 du of methadone. However, the orders were not reported as suspicious. Based on the evidence, I conclude that the orders were suspicious and should have been reported.

Moreover, on Jan. 12, 2010, Respondent conducted a second site visit at Englewood. While the inspector (Mr. Chase) documented that Dan Farris was the owner and that he had never had his license suspended, there is no evidence that Respondent ever verified this information. Mr. Chase further noted that 40 percent of the prescriptions filled by Englewood were for any controlled substances and that this was ''a little high'' and that ''25 [percent] were for schedule II drugs.''

While Chase recommended that Respondent obtain a new UR and compare it with the figures provided by the pharmacist, it did not obtain a new UR until August 11, 2010, seven months later. Moreover, as found above, the most recent UR showed that schedule II drugs comprised 45 percent and all controlled substances comprised 66 percent of the prescriptions Englewood dispensed. Yet there is no evidence that Respondent's Compliance Department even examined the previous UR.

Thereafter, beginning in late January 2010, Englewood repeatedly placed oxycodone orders that exceeded the CSL on a rolling 30-day basis. While the orders were held by the SOMS, the evidence shows that the orders were filled, with the typical justification being that the orders were supported by Englewood's UR, which was already three months old (as of January) and which had prompted Ms. Seiple to

[180] As found above, the June 2009 orders were comprised entirely of 30 mg tablets, and the July orders included 100,000 du of the 30 mg tablets.

[181] This would be accurate if one only counted Englewood dispensings of oxycodone 30 and 15 (26,097 du). As found above, Englewood's dispensings of all oxycodone products, including extended release drugs, totaled nearly 216,000 du, or 44 percent of its total dispensings.

[182] Ms. Seiple also documented that she was very concerned with the quantities of methadone being dispensed by Englewood and had discussed with its PIC the size of the prescriptions and been told that they averaged 480 to 600 du per script. Yet the UR showed that the prescriptions averaged only 258 du, provided one actually bothered to add up the two line items on the UR and calculate the average per prescription. RX 2C, at 41. This was another example of Englewood's PIC providing information, the falsity of which was easily ascertainable, which Respondent ignored.

initially limit the account because of her concern with the quantities being dispensed. *See, e.g.,* RX 2C, at 2 (MFR note of Jan. 26; ''Ship per UR per Committee signed by Wayne''). And in other instances, the orders were justified as being within the CSL, even though they clearly were not. *See, e.g.,* GX 18, at 164 (April 15 order for 50,000 du of oxycodone 30 approved as ''under CSL'' even though the order placed Englewood's oxycodone orders at 139,600 du on a rolling 30-day basis); *id.* (May 26 SOMS notes: ''release order under CSL'' even though filled orders totaled 80,000 du on both a rolling 30-day and calendar month basis and subsequent notes indicate the CSL was set at 63,000). None of these orders were reported as suspicious. I hold that they were.

Indeed, the evidence shows that at Mr. Corona's direction, Respondent adopted a policy of filling Englewood's orders as long as the quantity was supported by the UR and without obtaining an explanation from the pharmacy, which was independently verified, and a new UR. *See* RX 2C, at 2. This was contrary to the representations made by Respondent to this Agency as to how its SOMS program would be operated and resulted in Respondent's failure to report numerous suspicious orders. And I further hold that this policy rendered the SOMS an ineffective system for disclosing suspicious orders. 21 CFR 1301.74(b).

Thereafter, on June 28, 2010, Respondent, which had filled an order for 50,000 du of oxycodone 30 three days earlier, edited an order from 40,000 du (400 bottles) to 13,000 (du). While the SOMS notes indicate that the order was edited down to keep Englewood at its CSL, there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order. It did not obtain a new UR, even though the last UR was then nine months old. Nor did it report the order as suspicious. I hold that it was.

So too, only two days later, Englewood placed another order, this being for 9,600 du of oxycodone, which Respondent deleted. While Respondent attempted to contact the pharmacy's PIC, it was unable to get a hold of him and it failed to obtain an explanation for the order. It also failed to report the order as suspicious. I hold that it was.

On July 13, Respondent filled an order for 50,000 du of oxycodone, bringing the rolling 30-day total of filled orders to 113,000 du, nearly double the CSL of 63,000. While Ms. Seiple documented that the PIC had stated that he was no longer ordering his allotment at the end of the month, the evidence shows that Englewood had been ordering large quantities (typically 50,000 du) in the middle of March, April and May 2010. Thus, although Respondent could have verified the PIC's statement simply by reviewing its own records, there is no evidence that it did so and it again failed to obtain a new UR. Nor did it report the order as suspicious even though the order placed Englewood at more than 50,000 du over its CSL. I hold that the order was suspicious.

Also, notwithstanding the PIC's statement that he was no longer ordering his allotment at the end of the month, on July 27, 2010, Englewood ordered 30,000 du, which again placed its orders over the CSL. While Respondent edited the orders to 13,000 du, it did not contact the pharmacy and obtain an explanation for the order. Nor did it obtain a new UR. And while under its policies, Respondent was required to review the entire file on Englewood before filling an order that was held by the SOMS, there is no evidence that it questioned why Englewood had ordered 30,000 du, given the PIC's statement that he was no longer ordering at the end of the month. Respondent did not report the order as suspicious. Here again, I conclude that the order was suspicious.

On August 10, 2010, Respondent filled an order for 50,000 du, bringing the total of Englewood's filled orders to 113,000 du on a rolling 30-day basis. Respondent did not contact the pharmacy and obtain an explanation for the order. Instead, Ms. Seiple released the order ''with reservation''—''pending updated UR.'' Notably, Respondent had not obtained a new UR in ten months (even though Respondent's policy required it to obtain a new UR every time an order was held by the SOMS) and it had been seven months since its inspector had recommended that it obtain a new UR. The order was not reported as suspicious. I hold that the order was suspicious.

Respondent finally obtained a UR (for July 2010) *the day after it filled the order.* The UR showed that Englewood had dispensed more than 204,000 du of oxycodone 30 during the month. The dispensings of oxycodone 30 alone comprised more than 39 percent of the pharmacy's total dispensings, and the July 2010 dispensings of oxycodone 30 showed an increase of more than 80,000 du from the prior UR. The UR also showed that with the exception of carisoprodol, the top ten drugs dispensed by volume included six oxycodone products, methadone, and two alprazolam products. Moreover, 18 of the top 20 drugs were federally controlled substances.

Yet even after obtaining this UR, which showed an even higher level of oxycodone dispensing than the September UR which had prompted Ms. Seiple's concern over Englewood's dispensing levels, Respondent continued to fill the pharmacy's orders for large quantities of oxycodone. On both August 23 and September 27, 2010, Englewood submitted orders which placed it over its oxycodone CSL, and yet on both occasions Respondent failed to obtain an explanation for the orders. While Respondent edited the August 23 order from 25,000 du to 13,000 du, Englewood's orders were still over the CSL by 13,000 du and yet Respondent did not report the order as suspicious. And while Respondent edited the September 27 order from 18,000 to 13,000 du and brought Englewood within its CSL, here again, Respondent failed to obtain an explanation for the order. Instead, Respondent treated the 5,000 du that was edited off the order as if Englewood had never ordered this additional amount and failed to report the order. I hold, however, that the order was also suspicious and that Respondent was required to report both the August 23 and September 27, 2010 orders.[183]

Respondent only terminated Englewood as a customer after a subsequent site visit, during which its inspector observed cars with both Kentucky and Tennessee license plates in the parking lot and documented that there was ''suspicious activity outside of the pharmacy.'' Yet Englewood had repeatedly presented numerous other suspicious circumstances during the course of Respondent's dealings with it.

As for Ms. Seiple's explanations as to why Respondent did not report any of Englewood's orders as suspicious, Ms. Seiple failed to address why Respondent did not verify the status of the PIC's license. While Ms. Seiple asserted that Respondent was aware of the volume of oxycodone and other controlled substances being dispensed and the percentage of controlled to non-controlled drugs, her claim that these were accounted for by the pharmacy's 'business model'' of servicing patients from two large hospitals, a number of physician's offices and ''several nearby pain clinics'' is unpersuasive. As

[183] The next day, Respondent placed additional orders for 1,200 oxycodone 20 and 600 du of oxycodone 10, bringing Englewood's rolling 30-day total to 64,800 du and over the CSL. Respondent filled the orders, notwithstanding that it failed to obtain an explanation for the orders and did not report them as suspicious, noting that this was the ''first time purchase [sic] on Oxy since 2009.''

previously explained, hospitals have their own pharmacies, and in any event, Respondent produced no evidence to support the conclusion that a pharmacy's mere proximity to a hospital would result in controlled substances being dispensed at a level more than three times (by ratio) than that of a typical retail pharmacy. So too, even if there were a number of physician's offices near the pharmacy, this does not explain why controlled substances would be dispensed at a ratio more than three times that of a typical retail pharmacy.

To be sure, Ms. Seiple also contended that Englewood ''filled prescriptions for patients from several nearby pain clinics and identified the physicians,'' and that ''[t]his accounted for the volume of pain medications and other controlled substances, including oxycodone, being dispensed relative to other drugs.'' Yet two of the doctors were located in Sarasota, a distance of approximately 47 miles from Port Charlotte, which is hardly ''nearby,'' and which begs the question as to why the pharmacy's patients were travelling this distance to get their prescriptions. And while filling prescriptions written by doctors working at pain clinics may well have accounted for the high volume of controlled substances being dispensed by Englewood, it says nothing about the legitimacy of those prescriptions. Respondent did not, however, conduct any inquiry into whether these physicians even held licenses, let alone whether they had any training or board certification in pain management or other related specialties.

Moreover, in the initial site visit report, Respondent's consultant specifically noted that Englewood's PIC ''appears to be doing a larger narcotics business then he admits to.'' Ms. Seiple totally failed to address what action, if any, she took in response to this observation as well as the other instances in which Englewood's PIC represented that the percentage of its dispensings comprised by both schedule II and all controlled substances were substantially lower than what the URs showed. This was so even though Englewood's URs showed the total number of prescriptions for each schedule of controlled substance as well as for non-controlled prescriptions drugs.

So too, putting aside that the SOMS was not even operational until August 2009, Ms. Seiple did not claim that for every order held by the SOMS, Respondent obtained an explanation for the order, let alone that it independently verified the explanation, and a new UR. Indeed, Respondent rarely obtained an explanation for the orders, and it obtained only four URs during the course of its relationship with Englewood, as Ms. Seiple conceded in her declaration. Notably, during the period from April 1, 2009 through Respondent's termination of Englewood in October 2010, it obtained a new UR only twice: Once in October 2009 (for Sept.), more than one year after it had obtained the previous UR, and again in August 2010, ten months later. Respondent also disregarded its inspector's recommendation to get a new UR following the January 2010 site visit.

Ms. Seiple's explanation for why it did not get a UR notwithstanding the inspector's recommendation was that Respondent's policies and procedures did ''not specify any particular percentage of controlled drugs to non-controlled drugs that the Company considers 'high' or 'a little high.'' While that may be, Respondent's policies and procedures did require that a new UR be obtained whenever an order was held for review by the SOMS, and as found above, the SOMS held numerous orders after October 2009, and this continued through the following year. However, Ms. Seiple offered no explanation for why Respondent failed to comply with its Policy and Procedures applicable to the review of held orders.

Moreover, the controlled substance percentage (40) reported by the inspector was double the percentage discussed at the August 2009 compliance review, as well as double the figure noted by the Agency in *Southwood.* Unexplained by Ms. Seiple is what level of controlled substance dispensing was required to induce her to follow the inspector's recommendation. I therefore find Ms. Seiple's explanation for why it failed to obtain a new UR unpersuasive. And I further find that none of the reasons offered by Ms. Seiple for failing to report Englewood's orders as suspicious excuse Respondent's failure to do so.

City View Pharmacy

More than one year before April 1, 2009, Respondent had acquired substantial information which created a suspicion as to the legitimacy of City View's dispensing practices. More specifically, in March 2008, City View requested an increase in the quantity of solid dose oxycodone it could purchase to 20,000 du per month. In reviewing City View's request, Respondent documented that 60 percent of the prescriptions filled by the pharmacy were for controlled substances and 40 percent were for schedule II drugs. These figures placed City View well above the controlled to non-controlled dispensing ratio of a typical retail pharmacy as discussed in *Southwood.*

As part of the review, City View provided a UR for the month of February 2008. Notably, the UR showed that oxycodone 30 alone accounted for more than 24 percent of its total dispensings and oxycodone products alone accounted for more than 35 percent. Of note, during a site visit by its consultant done three months later, City View reported that all controlled substances comprised 35 to 40 percent of the prescriptions it filled and that it had purchased drugs from five different distributors during the previous 24 months.

During the site visit, City View also reported that it filled prescriptions for pain management physicians, identifying six such physicians by name and providing their DEA numbers. Yet there is no evidence that Respondent verified the credentials of these physicians.

Shortly after the site visit, Respondent approved City View to purchase 25,000 du of oxycodone per month while at the same time rejecting its request to purchase alprazolam because it was ''too new'' a customer. Unexplained is why City View was also not too new to purchase oxycodone.

Notwithstanding that City View's oxycodone purchasing limit was set at 25,000 du, in both June and July 2009, Respondent filled orders by the pharmacy totaling more than 31,000 du. Respondent did not document that it obtained any explanation for why it allowed City View to exceed the purchasing limit. Moreover, Respondent had not obtained a new UR since the March 2008 UR, more than one year earlier.

After Respondent filled an order (Aug. 3, 2009) for 20,000 du of oxycodone 30 and 2,400 du of oxycodone 15, Ms. Seiple made an entry in the Ship to Memos stating ''8/3/09 please keep on hold until UR is received per file.'' GX 19, at 111. Yet on August 25, one week after Respondent had represented to DEA that when an order was held by the SOMS, it would contact the pharmacy and obtain an explanation for the order (which it would purportedly then independently verify) as well as a new UR, Respondent filled an order for 7,600 du (which placed it at 33,000 du on a rolling 30-day basis), notwithstanding that it did not contact the pharmacy and obtain an explanation for the order and still had not obtained a new UR. Instead, it released the order on the ground that it was at the pharmacy's ''oxy limit for the month.''

Indeed, Respondent did not obtain a new UR until October 5, even though City View submitted orders on both September 1 and 14, 2009, which placed it over its CSL (according to the SOMS notes) on a rolling 30-day basis. Respondent did not contact City View and obtain an explanation for either order. Instead, it released the September 1 order, the explanation being that the order placed City View ''under current limit,'' and it released the September 14 order, the explanation being that the order placed it ''at their [sic] current limit.'' Neither order was reported as suspicious, even though they had triggered the SOMS review because they were of unusual size. However, I conclude that they were suspicious.

Still later in the month, City View placed an order for 10,000 du, which Respondent deleted, noting that its limit was 30,000 du and that it had ''already received 37,600 within 30 days.'' Moreover, while Ms. Seiple contacted the pharmacy the same date, the pharmacist did not provide the information she sought and hung up on her. While Respondent went so far as to place City View on compliance hold, it did not report the order as suspicious. I conclude that the order was suspicious.

On October 1, City View placed an order for 10,000 du of oxycodone 30. While Respondent deleted the order and left a message for the pharmacist that it would not ship without a new UR, it did not report the order as suspicious.

On October 5, Respondent finally obtained a new UR, more than 17 months after it had obtained the previous UR. The UR showed that during the month of September 2009, City View had dispensed 47,472 du of oxycodone 30. City View's dispensings of oxycodone 30 alone comprised 41 percent of its dispensings of all prescription products. With the exception of carisoprodol, the top ten drugs dispensed by quantity were comprised of three oxycodone products (30 mg, 15 mg, and 10/325 mg), four different manufacturers' alprazolam 2 mg products, one manufacturer's alprazolam 1 mg product, and a combination hydrocodone 10/500 mg product. All of these are highly abused drugs. The UR thus created a strong suspicion that City View was not engaged in legitimate dispensing practices.

Notwithstanding the information provided by the UR, on October 5, 2009, Respondent filled an order for 10,000 du of oxycodone 30. Based on the information provided by the UR, I hold that the order was suspicious, notwithstanding that the order was not held by the SOMS. GX 19, at 119. Respondent did not, however, report the order as suspicious. For the same reason, I also hold that the orders for 10,000 du which Respondent filled on October 12 and 20 were suspicious and should have been reported.[184]

On October 29, City View placed a further order for oxycodone 30, which placed its orders over its CSL on a rolling 30-day basis. While Respondent contacted the PIC and told him that the order was being deleted, it did not obtain an explanation for the order and it failed to report the order as suspicious, which it was based on the information provided by the recent UR alone.

Thereafter, the evidence shows that City View submitted orders for 10,000 du on November 2, 6, and 16, as well as December 1, 2009, each of which placed its oxycodone orders above the CSL (whether it was set at 30,000 du or 22,500 du) on a rolling 30-day basis, and in some cases at 40,000 du. While the November 16 order was edited to 2,500 du, Respondent failed to obtain an explanation for the orders from the pharmacy and a new UR. It also failed to report the orders as suspicious. I hold that the orders were suspicious based on both the information Respondent had obtained which raised a strong suspicion as to the legitimacy of City View's dispensings practices, and Respondent's failure to investigate why City View was placing orders which the SOMS had flagged for being of unusual size.

Through the rest of December 2009 and January 2010, City View's oxycodone orders did not place it over the CSL (whether it was set at 30,000 or 22,500 du). However, on February 1 and 8, Respondent filled orders for 10,000 du on each date, thus placing City View's orders at 32,500 du on a rolling 30-day basis and over the CSL. Respondent approved both orders, documenting the reason as being that the orders were under the CSL, when they clearly were not. Respondent did not contact the pharmacy on either occasion and obtain an explanation for the order and it did not obtain a new UR. Nor did it report the orders as suspicious even though the orders were flagged by the SOMS for being of unusual size. I hold that the orders were suspicious based on the information Respondent had obtained regarding City View's dispensing practices and Respondent's failure to investigate the orders.

On February 17, Respondent conducted a site visit, during which its inspector was told that schedule II drugs comprised 15 percent and all controlled substances comprised 30 percent of the prescriptions dispensed by City View. The inspector did not, however, note that City View was servicing any pain clinics. And while he recommended that a new UR be obtained and compared with the dispensing ratio reported at the site visit,[185] Respondent did not obtain a new UR until April 26, 2010, more than two months later.

The evidence shows that on February 18, as well March 3, 12, 18, and 24, 2010, City View placed orders for 10,000 du of oxycodone 30 which were held by the SOMS, typically because the orders placed the pharmacy over its CSL on a rolling 30-day basis and typically by thousands of dosage units. Invariably, the orders were filled, notwithstanding that Respondent failed to contact the pharmacy and obtain an explanation for the order, with the reason given being either that the order was under the CSL (because Respondent counted the orders on a calendar-month basis) or that the order was supported by the dispensing levels shown on the UR, which had not been obtained since early October. Respondent did not report any of the orders as suspicious. Based on Respondent's failure to investigate the orders and the information it had obtained regarding the pharmacy's dispensing levels, I hold that the orders were suspicious.

Moreover, while a March 24, 2010 SOMS note states that the CSL was 22,500 du, on March 27 (a Saturday), City View placed two orders totaling 20,000 du, resulting in its rolling 30-day orders being 61,200 du, nearly three times the CSL listed in the note. While the evidence shows that Respondent contacted the pharmacist and was told that he placed the second order to be released on April 1, there is no evidence that Respondent questioned him as to why City View's orders during March had increased by 70 percent from the previous month. Instead, it approved the first order on the ground that the ''UR supports release-places CSL @ 51,200 for current period,'' even though it had not obtained a new UR in more

[184] The SOMS notes show that multiple orders were placed on October 12. GX 19, at 119. However, only one of the entries lists the name of a reviewer and a reason for why the order was shipped and the note does not state what drug was ordered. As for the October 20 order, the SOMS notes do not list a reviewer and a reason, thus suggesting that the order was not held for review.

[185] While on the Pharmacy Evaluation form, the questions which asked for the percentage of controlled drugs and the percentage of schedule II drugs, followed the questions: ''What is the average number of prescriptions filled per day?'' the Site Visit Recommendation form simply states: ''Control/Non-control ratio of 30%.''

than five months. Nor did it report the order as suspicious. Here again, I hold that the order was suspicious for the reasons stated above. Moreover, this was another example of the CSL having been increased based on Respondent's having filled orders even though it failed to properly review those orders.

As found above, on seven occasions during April, Respondent filled orders by City View which placed its rolling 30-day total at between 61,200 and 64,000 du (depending on the date), when its CSL was 51,200. With the exception of the April 26 (the last April) order, when it finally obtained a new UR, Respondent did not even contact City View, let alone obtain an explanation for the orders. And even with respect to the April 26 order, there is no evidence that Respondent obtained an explanation for the order.

Here again, Respondent's records show that the orders were approved, the typical reason being that the UR (from seven months earlier) supported the order, although in one instance (April 1), the reason given was that the order was ''within csl for period,'' GX 19, at 114, and in the instance of the April 5 order, there is no evidence that the order was even held for review. *Id.*

As for the UR, which it finally obtained on April 26, it showed that during the period of March 1–30, 2010, City View had dispensed 93,943 du of oxycodone 30, an amount which was nearly double what it had dispensed during September 2009. Indeed, City View's dispensings of oxycodone 30 alone now comprised more than 52.5 percent of its total dispensings. Moreover, the UR showed that City View's dispensings of alprazolam 2 mg, another drug highly sought after by drug abusers for use as a part of a drug cocktail with narcotics such as oxycodone, totaled 19,738 du, more than double the amount (9,722) it dispensed during September 2009.

Aside from the fact that the April 26 order placed City View's orders at 64,000 du on a rolling 30-day basis and nearly 13,000 du above the CSL and was not properly investigated, I find that the March 2010 UR alone created a strong suspicion that City View was engaging in illegitimate dispensing practices and rendered the April 26 order suspicious. I further find that Respondent failed to report the order as suspicious.

Although this UR alone establishes that all of City View's subsequent orders through the termination of the account—nearly eight months later—were suspicious, the evidence establishes that City View continued to place oxycodone orders which were held by the SOMS and were not properly investigated. Nor were any of the orders reported as suspicious. These include orders on May 10 and 18 which placed City View's orders at 65,000 du, thus exceeding the 51,200 du CSL set by the compliance committee, both of which were released, with the reasons given that the orders were either within or under the CSL.

While on May 18, 2010, Respondent conducted a due diligence survey by telephone, during which City View again represented that its dispensing ratio was 30 percent controlled to 70 percent non-controlled, there is no evidence that Respondent compared this statement with the recent UR as its inspector had previously recommended.[186] Nor is there any evidence that it compared the UR with the information DEA had previously published and provided during the August 2009 briefing as to the dispensing ratio.

Although City View also stated that it was servicing two small nursing homes and was near a medical center, Respondent did not even obtain the names of the homes, let alone inquire as to how many residents they had and the types and quantities of various controlled substance prescriptions the pharmacy claimed it was filling for their residents. In short, these superficial explanations do nothing to dispel the strong suspicion created by the March UR.

On June 28, 2010, Respondent performed another site visit at City View. While City View's pharmacist reported a dispensing ratio consistent with what he had previously told Respondent, I hold that this does not dispel the strong suspicion created by the amounts of oxycodone 30 and alprazolam 2 being dispensed by the pharmacy. Nor do I find the inspector's notations that City View was two blocks from a hospital and that there were pain clinics in the area sufficient to dispel the strong suspicion created by the UR that the pharmacy was engaged in illegitimate dispensing practices.

On July 7, 2010, Respondent reviewed the site visit and lowered City View's CSL to 28,700 du; it also placed it on compliance hold pending the receipt of an updated UR. However, Respondent did not obtain a new UR until December. Yet on July 13, it removed the compliance hold. That same day, it filled an order for 10,000 du of oxycodone 30, bringing City View's rolling 30-day total to 37,000 du. While this order placed City View at more than 8,000 du above the new CSL, the explanation provided in the SOMS merely states: ''rwr order sitevisit [sic] and ur on fiel'' [sic]. Here again, I conclude that Respondent failed to obtain an explanation for the order. Based on both the information provided by the UR, and the fact that the order was placed on hold because it was of unusual size and Respondent failed to properly investigate the order, I conclude that the order was suspicious. However, the order was not reported.

Later, on July 28, Respondent edited an oxycodone order to meet the CSL. Here again, there is no evidence that Respondent obtained an explanation for the order (and a new UR) and it failed to report the order. For the same reasons as stated above, I hold that the order was suspicious but was not reported.

On September 28, Respondent filled an order for 5,000 du of oxycodone 30 and 1,600 du of oxycodone 15, bringing the total of its filled orders to 34,700 on a rolling 30-day basis and exceeding the CSL of 28,700 du. Likewise, on five different dates in October, Respondent filled orders which brought City View's rolling 30-day total to between 34,900 and 35,900 du, again exceeding the CSL which remained at 28,700. GX 19, at 117 (SOMS note entry for 10/26/10).

With respect to each of these orders, Respondent failed to obtain an explanation from the pharmacy and a new UR. Here again, the orders were typically filled with Respondent documenting the reason as the orders were under the CSL, even though they were not. As explained previously, I hold that the orders were suspicious and should have been reported but were not.

Finally, in November 2010, Respondent filled oxycodone orders on four separate dates, each of which placed City View's orders over its CSL on a rolling 30-day basis. On November 2 and 9, City View's orders totaled 36,300 du, and on November 18, its orders totaled 37,000 du. For both the November 2 and 18 orders, Ms. Seiple noted only ''rwr'' as the reason for releasing them. As for the November 9 order, Ms. Seiple noted that the order was ''being released with reservation'' and that the oxycodone was ''within buying pattern'' and ''under [the] CSL.'' Here again, I conclude that Respondent failed to obtain an explanation from the pharmacy for each of the orders and a new UR. And as explained previously, I hold that the orders were suspicious and should have been reported but were not.

On December 2, Respondent finally obtained another UR, eight months after

[186] Of note, this question did not refer to the percentage of prescriptions. Rather, the question simply stated: ''What is your Daily ratio of controlled to non-controls?'' GX 19, at 38.

it had obtained the previous UR. However, the UR was incomplete. Nonetheless, on December 6, Respondent filled orders for 8,000 du of oxycodone 30 and 1,000 du of oxycodone 15, before placing City View on compliance hold three days later. While it is unclear whether these orders were held by the SOMS, I hold that the orders were suspicious based on the information provided by the previous UR. However, Respondent failed to report the orders.

On or about December 15, 2010, City View placed a further order for controlled substances which, based on the various notes made by Ms. Seiple, was likely for oxycodone. Respondent placed the order on hold, with Ms. Seiple documenting that she had called the PIC and her ''concerns regarding # of doses dispensed as opposed to noncontrols'' and how the pharmacy made a profit (apparently because insurance did not reimburse at a high enough rate given the cost of the drugs). RX 2D, at 2. The following day, Ms. Seiple noted that she had spoken to City View ''on phone multiple times regarding ratio of controls & noncontrols,'' as well as ''in regards to ratio cash vs. insurance,'' and that the pharmacy was ''placed in noncontrolled status due to customer indicating cash in OXY.'' *Id.* While Respondent apparently deleted the December 15 order, it did not report the order as suspicious. I hold that the order was suspicious.

Significantly, Respondent had information that the ratio of controlled to non-controlled drugs being dispensed by City View was suspiciously high well before April 1, 2009, and each of the URs it obtained thereafter corroborated this. This information alone was enough to establish a strong suspicion as to the legitimacy of City View's dispensing practices.[187]

As for Ms. Seiple's declaration, none of the reasons she offered dispelled the strong suspicion created by the information Respondent had obtained. While Ms. Seiple asserted that City View's business model involved marketing to nursing homes, hospice programs, and in-patient medical facilities, at the time of 2008 site visit, the pharmacy did not identify any actual customer and nearly two years later, the pharmacy reported that it serviced only two small nursing homes with 20 to 30 beds; Respondent also obtained no information as to how many of the nursing homes residents were being prescribed oxycodone 30. Although Ms. Seiple also asserted that City View was located within two blocks of two hospitals, Respondent produced no evidence as to why this justified the pharmacy's dispensing levels of oxycodone and other highly abused drugs relative to non-controlled drugs.

To be sure, City View also reported that it filled prescriptions for patients from several pain clinics. While this undoubtedly accounted for both the large volume of pain medications and the high percentage of oxycodone dispensed by City View, this does not establish that the dispensings were legitimate. Indeed, notwithstanding that Respondent's CEO had earlier decided to cut off sales to pain physicians in Florida who were engaged in direct dispensing, it conducted no further investigation into the qualifications of the physicians that were identified by the pharmacy as writing the oxycodone prescriptions. It did not even verify if they were licensed by the State, let alone whether they had any training or board certification in pain management or another related specialty. Nor did it ask the pharmacy as to the nature of the prescriptions that these physicians were writing and whether they included such cocktails as oxycodone and alprazolam.

Moreover, putting aside Ms. Seiple's misleading statement that after City View's account was approved, the SOMS held any order that met the suspicious order criteria and that these orders were released only after review, the evidence shows that while numerous orders were held, Respondent rarely, if ever, contacted the pharmacy and obtained an explanation for the order, which it then independently verified. Also, Ms. Seiple did not address why Respondent failed to obtain a new UR whenever an order was held, nor did she explain why Respondent ignored the information which showed that City View's dispensings of oxycodone 30 had nearly doubled between September 2009 and March 2010. And finally, while Ms. Seiple asserted that Respondent terminated City View after it developed concerns over the pharmacy's dispensing volumes and ratio of controlled to non-controlled drugs, the same concerns were present well before April 1, 2009. I thus conclude that none of Ms. Seiple's explanations refute the conclusion that the various orders were suspicious.

Medical Plaza Pharmacy

On March 24, 2009, Respondent conducted a due diligence survey for Medical Plaza's request to purchase controlled substances. During the survey, the PIC reported that 35 to 40 percent of the prescriptions filled by the pharmacy were for schedule II controlled substances but that he was unsure of the percentage of dispensings comprised by all controlled substances. He also represented that 70 to 80 percent of the prescriptions he filled were paid for by insurance.

Thereafter, Respondent approved Medical Plaza to purchase controlled substances, and while the date of this decision is unclear, the evidence shows that Respondent filled the pharmacy's orders for oxycodone 30 as early as April 10, 2009. Notably, Respondent approved Medical Plaza without having performed a site visit or having obtained a UR.

On June 18, 2009, Respondent finally performed a site visit. As found above, prior to the site visit, Respondent had filled orders for 14,800 du of oxycodone 30. During the site visit, Respondent's inspector noted that the pharmacy did not fill prescriptions for physicians who were primarily engaged in pain management. Yet the inspector also noted that schedule II drugs comprised 20 percent and all controlled substances comprised 60 percent of the pharmacy's prescriptions, this being the second time that Respondent had received information that Medical Plaza's dispensing ratio of controlled to non-controlled drugs was suspicious. He also noted that 25 percent of the prescriptions were paid for with cash.

Nonetheless, Respondent did not obtain a UR until August 11, after Medical Plaza sought an increase in the amount of controlled substances it could purchase, apparently after orders for 5,000 oxycodone 15 and 3,600 oxycodone 10/325 were held by the SOMS. Prior to this date, Respondent had filled orders for 19,800 du of 30 mg tablets.[188] Given the acknowledgement of Respondent's CEO and former Vice-President that they were aware of the oxycodone abuse crisis ongoing in Florida during this time period, as well

[187] Given that the record does not contain evidence as to how much Respondent charged City View for the drugs and how much City View was paid by insurers, I do not address whether the concern as to how City View could make a profit on its oxycodone dispensings was present prior to December 2010.

[188] It is noted that under Respondent's Policies and Procedures, it did not bind itself to obtaining a UR prior to selling controlled substances to a new customer. *See* RX 78, at 30–31 (Policy 6.1). Moreover, while its Policy mandates the performance of additional due diligence in various circumstances including where there are ''[i]ndications that the customer is or may be diverting controlled drugs,'' even then its Policy does not require that a UR be obtained. *Id.* at 30–31 (''Additional due diligence may include any or all of the following steps, as determined by a Compliance Manager: i. Drug Utilization Records.'').

as the information Medical Plaza provided the pharmacy during the March 2009 survey, which included that schedule II drugs comprised 35 to 40 percent of the prescriptions it dispensed, I conclude that Respondent's failure to obtain a UR prior to approving Medical Plaza to purchase controlled substances was reckless and a breach of its due diligence duty to conduct a meaningful investigation of its customer. *Southwood,* 72 FR at 36,498–99.

As for the UR, which covered the month of July, it showed that Medical Plaza had dispensed 61,130 du of oxycodone 30 and 27,122 du of oxycodone 15, out of the pharmacy's total dispensings of 201,445 du. Thus, oxycodone 30 alone accounted for more than 30 percent of Medical Plaza's dispensings and the combined dispensings of oxycodone 30 and 15 accounted for nearly 44 percent of its dispensings. Also, as found above, Medical Plaza's dispensings of all oxycodone products accounted for more than 51 percent of its total dispensings. Thus, even ignoring that during the June 2009 site visit, Medical Plaza had changed its story (from what it told during the March 2009 due diligence survey) regarding the level of its schedule II dispensings, the level of the pharmacy's oxycodone dispensings was more than sufficient to create a strong suspicion as to the illegitimacy of the pharmacy's dispensing practices.

The UR also provided other indicia that Medical Plaza was engaged in illegitimate dispensing activity. As found above, whether by looking at the number of prescriptions or the quantity of dosage units, even a cursory review of the UR shows that controlled substances were predominant among the most highly dispensed drugs. Also, as found above, Medical Plaza blacked out the financial data (which included its costs and profits) for nearly all of the controlled substances it dispensed. Yet Medical Plaza had previously represented that 70 to 80 percent of the prescriptions it filled were paid for by insurance and Respondent's former Vice-President testified that ''DEA advised us to focus on whether a customer had a high percentage of cash for controlled substance prescriptions (as compared to third-party insurance payments) [and] refused to accept insurance for the payment of controlled substance prescriptions.'' GX 51B, at 4 ¶ 12. In short, the blacked-out financial data begged the question, which Respondent did not ask until seventeen months later (when it ignored the answer anyway), what was the pharmacy hiding? I hold, however, that the blacked-out data provided an additional basis of suspicion as to the legitimacy of Medical Plaza's dispensing practices.[189]

As noted above, on August 11, Medical Plaza placed orders for 5,000 du of oxycodone 15 and 3,600 du of Endocet 10, thus triggering holds by the SOMS. While the notations on a form (used to review requests to increase a customer's controlled substances purchasing limits) state that Medical Plaza was ''[i]n a medical building of 60 doctors, and next to a hospital,'' Respondent conducted no further inquiry into the practice specialties of these physicians and whether they would be prescribing such powerful narcotics as oxycodone 30 in the course of their medical practices.

While this review prompted Respondent to obtain a UR, the following day Respondent filled the orders. Moreover, while Ms. Seiple documented that Medical Plaza's request to increase its purchasing limit was to be reviewed by the Compliance Committee, Respondent filled the orders before the review was even conducted. For the reasons explained above, I hold that the information Respondent obtained provided multiple grounds to suspect that Medical Plaza was engaged in illegitimate dispensing practices and that the two orders were suspicious and should have been reported. Respondent did not, however, report the orders. It also failed to report various orders placed by Medical Plaza in October, including an order for 10,000 du of oxycodone 30.

On November 17, Medical Plaza placed orders for 7,000 du of oxycodone 30; 3,000 du of oxycodone 15; 1,200 du of OxyContin 80; 1,200 du of Endocet 10/325; and 200 du of Endocet 5/325. As found above, these orders placed Medical Plaza's oxycodone orders at 23,600 du on a rolling 30-day basis, which was 5,000 du over its CSL. While Respondent filled the orders for OxyContin and Endocet, it held the orders for the 30 and 15 mg tablets.

The next day, Respondent conducted a new due diligence survey. Respondent's representative noted that Medical Plaza's ''primary customer base'' was as a community pharmacy and did not check the form's boxes for either pain management or workers compensation. Respondent's representative also noted that Medical Plaza did not do any institutional or closed-door business. Medical Plaza further represented that its ''ratio of controls [sic] to non controls [sic]'' [190] was ''40/60'' and that ''70 to 80'' percent of the prescriptions were paid by insurance.

There is, however, no evidence that Respondent questioned why Medical Plaza was dispensing the quantities of oxycodone as shown on the last UR (July 2009) or why the ratio of controlled to non-controlled dispensings reported by the pharmacy was double the level discussed in the August 2009 briefing.

Moreover, there is no evidence that Respondent's employee obtained an explanation for the orders and it also failed to obtain a new UR. However, Respondent filled the orders, noting that they were shipped with reservation and that an updated UR was requested. Based on the various information Respondent had obtained, which raised a strong suspicion as to the legitimacy of Medical Plaza's dispensing practices, as well as the fact that these orders were held by the SOMS because they were of unusual size and yet Respondent failed to obtain an explanation for the orders and a new UR, I conclude that the orders were suspicious and should have been reported but were not.

On December 14, Medical Plaza placed an order for 15,000 du of oxycodone, which placed it over CSL by 9,000 du on a rolling 30-day basis. As found above, while Respondent obtained a new UR, it failed to obtain an explanation for the order. Moreover, as explained previously, while Respondent did not fill the order, it was nonetheless required to report it, because it was suspicious based on both the information Respondent had obtained regarding Medical Plaza's dispensing practices and because the order was held by the SOMS based on its unusual size.

As for the UR, which covered the month of November, it showed that Medical Plaza's dispensings of oxycodone 30 had increased by 31,274 du (51 percent) from the level of the previous UR to 92,404 du. The UR also showed that Medical Plaza's dispensings of oxycodone 15 had increased by 16,929 (62.4 percent) from the previous level to 44,051 du. Thus, Medical Plaza's dispensings of oxycodone 30 amounted to 37.5 percent,

[189] It also noted that the pharmacy had represented that it did not fill prescriptions for physicians who were primarily engaged in pain management. The pharmacy's representation and the quantity of oxycodone and other narcotics it was dispensing begged the questions of who were the physicians writing these prescriptions and what were their practice specialties? There is, however, no evidence that Respondent asked these questions.

[190] Here again, the question did not refer to percentages of prescriptions but was simply phrased as: ''What is your daily ratio of controls [sic] to non controls [sic]?''

its dispensings of the 15 mg tablets amounted to 17.9 percent, and its dispensings of all oxycodone products amounted to 63 percent of its total dispensings for all drugs (246,255 du).

Moreover, the UR again showed that controlled substance were predominant among the most dispensed drugs, whether this was determined by the number of prescriptions or quantity of dosage units, with only carisoprodol being among the top 15 drugs dispensed. And once again, the financial data for the most highly dispensed controlled substances were blacked out.

In sum, the UR provided nothing to dispel the strong suspicion that Medical Plaza was engaged in illegitimate dispensing activities. Indeed, as it showed that the pharmacy's dispensing of oxycodone had increased by a large margin from the previous UR, it should have reinforced this conclusion. Yet Respondent failed to report the December 14 order as suspicious.

Thereafter, Respondent did not ship any more oxycodone until February 24, 2010, when Medical Plaza placed orders for 3,600 du of 30 mg and 6,000 du of 15 mg. As Respondent had not obtained any new information since the previous UR, I find that these orders, which were not reported, were suspicious.

In March 2010, Medical Plaza's oxycodone orders increased dramatically, with Respondent filling orders placed on six dates totaling 49,000 du of oxycodone 30 and 31,500 du of oxycodone. Significantly, the highest monthly total of orders filled during the previous six months was 12,600 du (November 2009), and with each successive order from March 18 through March 25, Medical Plaza's orders on a rolling 30-day basis exceeded the CSL by a factor which increased from three to seven times.

While each of these orders was held by the SOMS because it exceeded the CSL, with the possible exception of the March 16 order (the notes for which refer to problems with AR [191]), in each other instance there is no evidence that Respondent contacted the pharmacy and obtained an explanation for the order. Nor did it obtain a UR on reviewing any of the March orders. Indeed, the orders were typically released with the explanation being that the UR supported the order. Based on both the information Respondent had obtained regarding Medical Plaza's dispensing practices and the fact that the orders were held by the SOMS because they were of unusual size and were not properly investigated, I conclude that the orders were suspicious and should have been reported but were not.

As found above, in April, Medical Plaza continued to place orders, which, even if the CSL was increased based on the March orders (notwithstanding that they were not properly reviewed), still exceeded the CSL on a rolling 30-day basis. Indeed, on April 15, Medical Plaza placed orders for 42,000 du of oxycodone 30 and 10,000 du of oxycodone 15, bringing its rolling 30-day total to 138,200 du, which was nearly 58,000 du over the CSL. As with the previous orders (April 1 and 8), Respondent approved the orders but did not obtain an explanation for the orders and a new UR. Instead, the justification for filling the orders was that they were within the CSL (April 1 order), the size was ''not excessive'' (April 8 orders) and that the ''ur supports order'' (April 15). None of these orders were reported as suspicious. For the same reasons as stated above, I conclude that these orders were suspicious.

On April 23, Medical Plaza placed an order for 15,000 du of oxycodone 30 and 15,000 du of oxycodone 15, thus bringing its rolling 30-day total to 140,700 du, more than 60,000 over the March shipments. Respondent contacted the pharmacy, and was initially told that the order was placed because of price, that the pharmacy's business was about the same, and that the pharmacy was stocking up. While Respondent asked for a new UR, Respondent's PIC replied that ''nothing changed'' and did not provide a new UR. (Indeed, Respondent did not obtain a new UR until August 19). Moreover, in a subsequent phone call, Medical Plaza now claimed that it was promoting its business.

While Respondent deleted the orders, it failed to report them as suspicious. I hold that they were suspicious based on the information Respondent had obtained regarding Medical Plaza's controlled substance dispensing levels. I further hold that the orders were suspicious because they were clearly of unusual size and Medical Plaza's pharmacist gave inconsistent explanations for the orders.

On May 3, Medical Plaza placed orders for 30,000 oxycodone 30 and 20,000 oxycodone 15, thus bringing its rolling 30-day total of orders to 115,700 du, 40,000 du over its CSL (notwithstanding that the SOMS would recalculate the CSL based on the filled orders which were never properly reviewed). While Respondent documented having called the pharmacy, it is unclear whether it ever obtained an explanation for the order. What is clear is that it did not obtain a new UR. And while the evidence shows that Respondent reduced both orders to 10,000 du, it did not report the orders as suspicious. For the reasons stated previously, I hold that the orders were suspicious.

Thereafter, Respondent did not fill any oxycodone orders until June 28, when it shipped 14,000 oxycodone 30 to Medical Plaza. According to a SOMS note, Respondent had reduced Medical Plaza's CSL to 14,000 du. RX 2F, at 4 (MFR entry for June 28). Yet this order had actually been for 20,000 du and while Respondent called the pharmacy, there is no evidence as to what explanation Medical Plaza provided and it did not obtain a new UR. Moreover, three days later on July 1, Medical Plaza placed another order for 20,000 du. Thus, on a rolling 30-day basis, Medical Plaza had placed orders that were more than double its CSL. Here again, while Respondent edited the order to 14,000 du, it did not obtain an explanation for the order and a new UR. Moreover, it did not report the orders.

Notwithstanding that the June 28 and July 1 orders were substantially less than Medical Plaza's orders during March and April, I nonetheless hold that the orders were suspicious based on Respondent's failure to properly investigate the orders (by obtaining an explanation and a new UR), as well as the information it had previously obtained which raised a strong suspicion as to the legitimacy of Medical Plaza's dispensing practices.

While on July 22, Ms. Seiple documented that she had requested an updated UR, on July 30, Respondent filled an order for 10,300 du of oxycodone 30 even though it had not obtained a new UR. As found above, the order again placed Medical Plaza over its CSL by 10,000 du and yet no explanation was obtained from the pharmacy.[192] *See* GX 22, at 145 (SOMS note of 8/17/2010 indicating that CSL was still 14,000). And only four days later, Respondent filled an order for 12,200 du of oxycodone 30, which again resulted in Medical Plaza exceeding its CSL by more than 8,000 du. Yet according to the SOMS, the order was

[191] While this may be an abbreviation for accounts receivable, the record does not establish this.

[192] The SOMS notes for this date indicate that this order was not held for review. *See* GX 22, at 145. According to a note in the Ship to Memos, the July 1 order was returned. *Id.* at 141. However, according to the materials Respondent provided on the SOMS, ''[t]he rolling 30 day invoice history will include invoices and credit memos from the past 30 days.'' RX 78, at 60. Thus, even if the July 1 order was returned, it still should have been counted in determining whether Medical Plaza's orders placed it over the CSL.

not even held for review. *Id.* Respondent did not report either order as suspicious. For the reasons as discussed above, I hold that the July 30 and August 3 orders were suspicious.

On August 17, 2010, Medical Plaza placed an order for 20,000 du of oxycodone 30. While Respondent deleted the order, the order placed Respondent at 42,500 du, more than three times (and more than 28,000 du over) its CSL as reflected in the SOMS notes of the same date. While Respondent called the PIC and requested a new UR, told him that the order was being deleted but that he could re-order after the UR was reviewed, Respondent failed to obtain an explanation for the order and it did not report the order as suspicious. For the reasons discussed above, I hold that the order was suspicious.

On August 19, Medical Plaza finally provided a new UR (eight months after the previous UR), which covered the month of July 2010. The UR showed that the pharmacy had dispensed 118,908 du of oxycodone 30 and 41,160 du of oxycocodone 15; its total dispensings of all prescription products were 285,977.85 du. Thus, oxycodone 30 amounted to 41.6 percent of its total dispensings, its dispensing of oxycodone 15 comprised 14.4 percent, and its dispensings of all oxycodone products were 63.58 percent. Also, as with the previous UR, controlled substances were predominant among the most highly dispensed drugs (the only exception in the top ten being carisoprodol) and once again, Medical Plaza had blacked out the financial data for oxycodone 30 and 15, as well as alprazolam 2. As with the previous URs, the July 2010 UR raised a strong suspicion as to the legitimacy of Medical Plaza's dispensing practices which Respondent ignored.

The same day, Medical Plaza place an order for 20,000 du of oxycodone 30, bringing its rolling 30-day total to 42,500 du, again exceeding the CSL (as noted in the 8/17 SOMS note) by a factor of three. Respondent edited the order to 6,400 du, thus bringing the total filled orders to 28,900 du. Respondent did not, however, obtain an explanation for the order. Nor did it report the order, which I hold was suspicious.

As found above, Respondent filled orders on September 1 (10,000 du) and 7 (8,600 du), as well as October 1 (16,800 du), each of which placed Medical Plaza over its CSL, even if the CSL had been recalculated based on the July orders. Respondent did not obtain an explanation for any of these orders or a new UR. According to the SOMS notes, the September 1 order was released because it was within the ''monthly buying pattern'' and the order left 8,600 du which could be filled. However, with the September 1 order, Medical Plaza's orders came to 28,600 du on a rolling 30-day basis. Moreover, Respondent did not report the order as suspicious.

As for the September 7 order, the SOMS note shows that it was ''edited to meet CSL,'' even though upon filling the order, Medical Plaza's filled orders on a rolling 30-day basis came to 25,000 du.[193] Here again, the order was not reported as suspicious. And on filling the October 1 order, Medical Plaza's filled orders totaled 25,400 du on a rolling 30-day basis. Yet the only entries in the SOMS note which could correspond with this order merely states ''rwr,'' an abbreviation for release with reservation. Respondent did not report the order as suspicious. Based on the information Respondent had obtained which raised a strong suspicion as to the legitimacy of Medical Plaza's dispensing practices, as well the evidence showing that each of these three orders exceeded the CSL and was held by the SOMS but that Respondent failed to investigate the orders, I hold that the orders were suspicious.

Thereafter, Respondent filled Medical Plaza's orders for oxycodone 30 each month through March 4, 2011, shipping 16,800 du each month with the exception of November (when it shipped only half this amount). While the evidence supports a finding that each of these orders was suspicious based on the information provided by the URs alone, several of the orders were held by the SOMS. Here again, however, the evidence shows that the orders were released without Respondent obtaining an explanation for the orders. None of the orders was reported as suspicious.

More specifically, the December 1 orders brought Medical Plaza's rolling 30-day total to 25,200 du. Yet according to a note in the MFR, Medical Plaza's oxycodone CSL was still at 14,000 du. As for why the orders were released, the SOMS notes merely include the abbreviation for release with reservation.

In January, Medical Plaza ordered 20,000 du. Respondent edited the order to 16,800. MFR notes show that Respondent contacted the pharmacy and was told that the pharmacy ''use[s] quite a bit of insurance on oxy,'' prompting Ms. Seiple to question how the pharmacy could be making a profit when insurance reimbursed at a lower rate ($32) than what Master's charged for oxycodone ($39) and then noting that the pharmacy would be ''losing money.''

The same day, Respondent obtained a new UR from Medical Plaza. While that UR showed that Medical Plaza's dispensing of oxycodone had declined from the previous UR, in contrast to the previous URs, the financial data for the oxycodone and other highly abused drugs were not blacked out. Tellingly, the data showed that far from ''losing money'' on its oxycodone 30 dispensings, Medical Plaza was making profits that were approximately three times its acquisition costs. Yet even then, Respondent failed to report Medical Plaza's order as suspicious. I hold that the order was suspicious.

Moreover, on February 1 (10,000 du) and 2 (6,800 du), Respondent filled more orders by Medical Plaza. Remarkably, the most recent UR contains a handwritten note by Ms. Seiple which indicates that she reviewed the UR on ''2–2–11,'' and in an MFR note of the same date, Ms. Seiple wrote that ''63K of 190K dispensing is 33% of sales is oxy 30 & 15 mg.'' Yet the same day, Respondent's compliance committee released the order for 6,800 du. Here again, Respondent failed to report the orders as suspicious. I hold that both orders were suspicious.

Finally, on March 2, Medical Plaza placed an order for 16,800 du. While an MFR note of March 3 states that the account was placed on compliance hold pending the pharmacy providing a physician's list and the performance of a site visit, Respondent filled the order the next day. Respondent did not, however, report the order as suspicious. I hold that it was. And I further hold that Respondent repeatedly violated 21 CFR 1301.74(b) by failing to report suspicious orders.

As for Ms. Seiple's assertions that Respondent did not report Medical Plaza's orders because the pharmacy was located in a medical center with 60 physicians and was adjacent to a medical center, and that this accounted for the large of volume of pain medication being dispensed and the percentage of oxycodone being dispensed relative to other drugs, Respondent's inspector specifically noted that pharmacy did not fill prescriptions for physicians who were primarily engaged in pain management. So too, in a subsequent survey, Respondent's representative did not document that Medical Plaza's primary customer based was comprised of either

[193] As found above, whether the CSL was recalculated based on the July orders (including the one that was returned) or based on the August orders, the September order still exceeded the CSL.

workers compensation or pain management patients.

As explained above, the mere presence of 60 doctors in the same building, without any investigation into their specialties and the drugs they would prescribe in the course of their respective medical practices does not remotely justify either the volume of pain medications or the percentage of oxycodone being dispensed by Medical Plaza relative to other drugs. Indeed, while a pharmacy's presence in a building with a large number of doctor's offices might explain why a pharmacy dispenses a larger volume of *all* prescription products than a pharmacy not located in the building, unexplained is why this would render the pharmacy more likely to dispense a much greater percentage of controlled substances, especially of oxycodone 30, a drug highly sought after by drug abusers, than any other pharmacy.

As for Ms. Seiple's statement regarding the SOMS, even ignoring that her statement misleadingly suggests that all of Medical Plaza's orders post-April 1 were reviewed, the evidence shows that there were numerous instances in which orders were held by the SOMS but were released without Respondent obtaining an explanation for the order, which it independently verified, as well as a new UR. Moreover, while Medical Plaza represented that 70 to 80 percent of the prescriptions it filled were paid for with insurance, Ms. Seiple entirely failed to address why she did not question Medical Plaza as to why the financial data for its controlled substance dispensings were blacked out on the URs. And she also failed to address why Respondent continued selling oxycodone to Medical Plaza even after she questioned how the pharmacy could be making a profit on oxycodone given that insurance paid less than the cost of the product and the UR she then obtained showed that Medical Plaza was obviously making substantial profits.

Temple Terrace Pharmacy D/B/A Superior Pharmacy

In June 2008, Respondent conducted a due diligence survey in response to Superior's request for an increase in the amount of solid dose oxycodone it could purchase. Notably, the answers provided by Superior were not indicative of illegitimate dispensing practices as Superior represented that twenty (20) percent of the prescriptions it filled were for controlled substances, and that 90 to 95 percent of the prescriptions were paid for by insurance. Superior also apparently represented that it did not have ''relationships with specific doctors/clinics,'' and maintained that it had a variety of policies in place to prevent diversion. Yet even in this period, Superior began to present various indicia that it was not all that it claimed to be.

Specifically, while Respondent requested a complete UR showing its dispensings of both controlled and non-controlled drugs, Superior provided a report showing only the top 100 drugs it dispensed. Moreover, during a site visit conducted several weeks later, Respondent's consultant found that the pharmacy shared its waiting area with a clinic that specialized in pain management and weight loss and that ''[m]any of their prescriptions originate within the clinic.'' The consultant's report also included two photographs showing the signage on the pharmacy's storefront. On top, the sign read: ''SUPERIOR PHARMACY • WALK IN CLINIC''; below that the sign read: ''Pain Management & Weight Loss.''

Moreover, within days of the site visit, Respondent visited Superior's Web page. As found above, the Web page included blurbs promoting Superior as both a pain management clinic (''Don't live in pain. Trust the medical professionals at Superior Pain Clinic to help you enjoy life again!'') and weight loss clinic, as well as a pharmacy.

As found above, Respondent's owner/CEO testified that in early 2009, he had decided to cut off sales to Florida pain management physicians who were engaged in the direct dispensing of controlled substances, in part because of his putative concern over their unethical marketing practices. Yet here was a pharmacy and pain clinic occupying the same space and Respondent's compliance department failed to investigate the relationship between the two. This was all the more remarkable given that during the due diligence survey conducted by Respondent in June 2008, its employee had entered scribble in the answer blank with regard to the question of whether the pharmacy had ''[r]elationships with specific doctors/clinics,'' thus suggesting that there were no such relationships. Indeed, the evidence suggests that Respondent did not even inquire as to the relationship between the pharmacy and the pain clinic until November 2009.

Thus, as of April 1, 2009, Respondent had obtained substantial information which raised a strong suspicion as to the legitimacy of Superior's dispensing practices. As found above, in April 2009, Respondent filled various orders totaling 28,800 du of oxycodone products; in May 2009, it filled orders totaling 25,000 du of oxycodone 30; and in June, it filled orders totaling 65,000 du of oxycodone products (of which 55,000 du were for oxycodone 30) and which included a June 24 order for 30,000 du of 30 mg, as well as 5,000 du of both 15 mg and 10/325 mg. Respondent did not report any of these orders as suspicious. Based on the information Respondent had previously obtained, I hold that these orders were suspicious.

Moreover, six days before it filled the June 24 order, Respondent finally obtained a second UR from Superior. Notably, with the exception of carisoprodol, each of the top twenty-five drugs dispensed was a controlled substance under the CSA and three of the top four drugs were different manufacturers' oxycodone 30 products. Also among the most dispensed drugs were the stronger formulations of alprazolam (1 and 2 mg) and diazepam (5 and 10 mg), as well as other narcotics including oxycodone 15 and combination hydrocodone drugs. The UR further showed that Superior's dispensings of oxycodone 30 alone totaled more than 60,000 du, nearly 29 percent of its total dispensings, and combined with its dispensings of oxycodone 15 and Endocet 10, these three products alone accounted for more than 37 percent of its total dispensings.

Also, on June 23, Respondent conducted a due diligence assessment by phone during which the pharmacy was asked about its primary customer base and denied that it was comprised of pain management or bariatric patients. Yet during the site visit conducted a year earlier, Respondent's consultant had noted that ''many of the prescriptions originate within the clinic.'' Moreover, during the assessment, Superior apparently acknowledged that controlled substances comprised 50 percent of its dispensings.

Superior also provided the names of two physicians (written as a Dr. Mercedes and Dr. Hubang) who were working at the Superior Pain Clinic. While Respondent obtained a printout from the Florida DOH's license verification Web page, the printout was for a Dr. Merced, whose address was listed as being in North Carolina, and not a Dr. Mercedes. Moreover, there is no evidence that Respondent verified the licensure status of a Dr. Hubang, or of any of the doctors previously identified by its consultant as being pain management physicians whose prescriptions were being filled at Superior. While several months later, Respondent eventually determined that the doctor's name was actually Dr.

Mubang, there is no evidence that Respondent verified the latter's licensure status.[194]

Even putting aside the substantial information Respondent had acquired regarding the suspicious nature of Superior's dispensings, Superior's June orders were 40,000 du (and 2.6 times) above its May orders and its purported 25,000 du purchasing limit (as well as 36,000 du greater than its April orders). The June orders were thus of unusual size, and therefore suspicious for this reason as well. Yet the orders were not reported to the Agency.

As for the oxycodone orders Superior placed in July (totaling 65,000 oxycodone 30 and 65,200 total du of oxycodone) and August (totaling 75,000 oxycodone 30), I hold that aside from whether the orders were of unusual size, pattern or frequency, the circumstances surrounding the Superior's operation establishes that the orders were suspicious. The orders were not, however, reported as suspicious.

The next month, Respondent filled an order (September 14) for 30,000 du of oxycodone 30 but did not report the order as suspicious. Moreover, as found above, on September 24, Superior placed orders for another 30,000 oxycodone 30 and 5,000 Endocet 10. While the latter order was filled, the former order triggered a compliance hold which was conducted by Ms. Seiple. Of note, Ms. Seiple documented that she had reviewed the file and noted that the pharmacy was located inside the clinic and that she had called the pain clinic and been told that if she came in, there was a pharmacy inside the clinic. Ms. Seiple then documented that the orders for 30,000 oxycodone 30 were being deleted ''per Web site'' and the photographs. Yet even then, Respondent failed to report the orders as suspicious. And of further note, Respondent had known for fourteen months that the pharmacy and pain clinic shared the same space and jointly marketed themselves as a sort of one-stop shop.

As found above, Respondent did obtain a new UR for the previous month. Notably, the UR showed that Superior's dispensings of oxycodone 30 alone accounted for 33 percent of its total dispensings, and 19 of the top 25 drugs dispensed were controlled under the CSA. Moreover, while notations in Ms. Seiple's September 24 note indicated that Superior had either been placed on non-controlled status or had its oxycodone limit reduced to 25,000 du, on September 30, Respondent filled three orders totaling 30,000 du of oxycodone. Yet the orders were not even held by the SOMS for review and Respondent provided no explanation for why the orders were shipped. I find, however, that the orders were suspicious and that Respondent violated the suspicious order rule when it failed to report the orders.

Respondent continued to fill numerous orders placed by Superior for oxycodone (as well as other controlled substances) through December 7, 2009. Indeed, on November 30, Respondent filled two orders for 20,000 du of oxycodone 30 and on December 2, it filled an additional order for 10,000 du, even though it had determined on November 19 that Superior's pharmacist owned both the pharmacy and the pain clinic.

Based on the circumstances presented by Superior, I find that each of these orders was suspicious and that Respondent violated 21 CFR 1301.74(b) by failing to report the orders. As for Ms. Seiple's proffered explanations for why Superior's orders were not reported, as explained in my factual findings, I reject her explanations and find it especially noteworthy that she entirely failed to address why, in light of the information she had obtained as early as June 2008, which showed, *inter alia,* that the pharmacy and pain/weight loss clinic were located in the same space and that Superior marketed itself as both a pharmacy and pain/weight management clinic, Respondent continued to distribute oxycodone and other controlled substances to it thereafter. Indeed, Ms. Seiple's statement that the ''weight-loss and pain management facility [were] located in an adjacent office'' is downright misleading.

Ms. Seiple further asserted that the volume and percentage of Superior's dispensings of controlled substances and oxycodone were accounted for (in part) because Superior was ''filling prescriptions for a juvenile in-patient facility.'' However, Respondent obtained no information as to the type of treatment being provided by the facility, the number of patients it had, and whether its patients would even be treated with drugs such as oxycodone 30. Indeed, this is just another example of Respondent's willingness to accept any superficial explanation which it believed would justify its continued filling of the pharmacies' oxycodone orders.

Morrison's

Prior to April 1, 2009, Respondent had acquired substantial information that raised a strong suspicion as to the legitimacy of Morrison's dispensing practice. As early as its initial due diligence survey, Morrison's had reported that 60 percent of the prescriptions it filled were for controlled substances and 35 percent of the prescriptions were for schedule II drugs. Moreover, while the UR obtained in the spring of 2008 showed that Morrison's was dispensing an average of 63,315 du of oxycodone 30 per month (which accounted for 38 percent of the dispensings), the next UR (which was obtained on January 30, 2009) showed that the pharmacy's monthly dispensings had nearly doubled to 111,705 du.[195] Yet there is no evidence that Respondent found this to be suspicious.

In April 2009, Respondent filled Morrison's orders for 171,700 du of oxycodone 30 as well as its orders for 37,200 du of oxycodone 15 mg; in total, Respondent shipped to Morrison's nearly 218,000 du of oxycodone products. There is no evidence that Respondent questioned Morrison's as to why it was ordering 60,000 du more of oxycodone 30 than its average monthly dispensing level and it did not report the orders as suspicious. Based on the circumstances presented, I conclude that the orders were suspicious and should have been reported.

In May, Respondent obtained another UR. While the UR covered the period of January 1 through May 6, 2009, it showed that Morrison's was dispensing an average of 81,726 du per month of oxycodone 30. Yet during the month of May, Respondent shipped 141,200 du of oxycodone 30, 59,000 du more than the pharmacy's average monthly dispensing of the drug.

Here again, there is no evidence that Respondent questioned Morrison's as to why it was ordering this quantity and it did not report the orders as suspicious. Moreover, this was the second month in a row in which Morrison's had ordered substantially more oxycodone that what it was dispensing on a monthly basis. Based on the circumstances presented, I conclude that the orders were suspicious and should have been reported.

[194] Ms. Seiple also asserted that ''[b]ased on [Respondent's] extensive investigation, it determined that the orders it shipped to Superior were not suspicious.'' RX 103, at 75. Notwithstanding that Superior was also operating a pain clinic, Respondent's ''extensive investigation'' apparently did not uncover that Dr. Mubang had been criminally charged by the State of Florida with trafficking in prescription drugs, even though a Google Search would likely have revealed this.

[195] As found above, the UR obtain in the spring of 2008 covered the period of January 1 to April 1, 2008; the UR obtained on Jan. 30, 2009, covered the period of November 1, 2008 through January 30, 2009.

The UR also showed that Morrison's was dispensing an average of 19,463 du per month of oxycodone 15. While in June, Respondent filled orders totaling only 81,600 du of oxycodone 30, it also filled orders totaling 39,900 du of oxycodone 15, more than double the amount of its average monthly dispensings of this dosage. Here again, there is no evidence that Respondent questioned Morrison's regarding the quantity of oxycodone 15 it was ordering, and it did not report the orders as suspicious.

In July, Respondent filled orders totaling 141,300 du of oxycodone 30 and 48,000 du of oxycodone 15. Notwithstanding that Morrison's orders for the 30 mg dosage were 61,000 du (76 percent) larger and the orders for oxycodone 15 were nearly 2.5 times larger than its average monthly dispensings per the previous UR, Respondent failed to report the orders for either dosage as suspicious. Moreover, this was the third month in the last four in which Morrison's oxycodone 30 orders had exceeded its monthly dispensings by 60,000 du, and yet Respondent did not report the orders as suspicious.

As found above, on or about August 1, 2009, the SOMS became operational. *See* RX 78, at 59. While Respondent would eventually terminate Morrison's on or about August 18, the day after the DI identified it as a customer whose oxycodone orders were of concern, during the first seventeen days of the month, Respondent had filled orders totaling 101,600 du of oxycodone 30 and 39,600 du of oxycodone 15. Moreover, the SOMS notes establish that between August 5 and 14, multiple orders were held by the SOMS for review. GX 23, at 151. Yet in each instance the orders were released, with such reasons given as that the UR supported the order, the order was under the current size limit, or the order was ''ok to ship per'' Ms. Seiple.

Notably, in no instance did Respondent contact Morrison's and obtain an explanation for the order, and it did not obtain a new UR until the same day the DI identified Morrison's as a customer whose oxycodone orders were concerning. Nor did it report any of these orders as suspicious even though the purpose of the SOMS was to identify orders of unusual size, pattern or frequency.

As for the UR, it showed that during July 2009, Morrison's dispensings of oxycodone 30 had more than doubled to 196,069 du of oxycodone 30 (at an average prescription size of 195 du), an increase of more than 114,000 du from the average monthly dispensings per the previous UR. The UR also showed that Morrison's dispensings of oxycodone 15 had more than tripled to 63,658 du.

The next day, Morrison's placed orders for 8,400 du of oxycodone 30 and 1,200 du of oxycodone 15, as well as Endocet and methadone. While Respondent placed Morrison's on compliance hold and deleted the orders, it did not report the orders as suspicious. As explained above, deleting or refusing to fill an order does not excuse a distributor from its obligation to report a suspicious order.

As with the other pharmacies, Ms. Seiple offered the same set of unresponsive explanations as she did for the other pharmacies, even going so far as to declare under oath that ''after Morrison's account was approved, [the] SOMS system identified and held any orders for controlled substances placed by Morrison's that deviated from its typical volume pattern or frequency'' when the SOMS was not even operational during the months of April through July 2009. As explained previously, I do not find persuasive her explanations as to why Respondent failed to report the multiple suspicious orders placed by Morrison's.

Summary

The evidence shows that Respondent failed to report hundreds of suspicious orders placed by these pharmacies. With respect to each of the seven pharmacies, prior to April 1, 2009, Respondent had obtained information which created a strong suspicion that the pharmacies were engaged in dispensing illegitimate prescriptions, and while Respondent obtained additional information from the pharmacies at various points throughout the course of its dealings with them, this information corroborated rather than dispelled the already existing suspicion.[196] Indeed, in several cases, even after Ms. Seiple documented her concerns as to the legitimacy of a pharmacy's dispensing practices, those concerns were either ignored or discounted for months thereafter.

Moreover, even after the SOMS became operational and the pharmacies' orders were held because they exceeded one of the criteria set forth in 21 CFR 1301.74(b) (typically, because they were of unusual size), the evidence shows that Respondent rarely investigated any of the orders. Rather, the evidence shows that those orders were frequently released without contacting the pharmacy and obtaining an explanation for the order, let alone independently verifying that explanation. Indeed, those orders were frequently released with the justification being that the order was supported by the UR, even though the URs invariably reflected dispensing levels of oxycodone and other controlled substances that were highly suspicious.

Moreover, Respondent represented to the Agency that the SOMS would determine whether a pharmacy's orders were of unusual size by counting the orders on a rolling 30-day basis. While the evidence shows that in numerous instances, the SOMS held an order because it resulted in the pharmacy's orders exceeding its CSL on a rolling 30-day basis, many of the orders were subsequently filled because Respondent then counted the pharmacy's orders on a calendar-month basis. And again, Respondent filled the orders without obtaining an explanation from the pharmacy. Whether the orders were filled because they were supported by the UR, or because Respondent counted them on a calendar-month basis, this also frequently resulted in the CSL being increased even though Respondent had entirely failed to investigate whether there was a legitimate basis for the increase in the orders. This resulted in an even greater amount of oxycodone being shipped without being held by the SOMS for review.

So too, the evidence shows that in other instances, an order which placed a pharmacy over its CSL was entirely deleted. Respondent thus treated the order as if it had never existed rather than report it as suspicious and the SOMS did not include it in calculating the rolling 30-day total. And in still other instances, Respondent edited an order by reducing its size so that the pharmacy's orders did not place it over its CSL. Here again, Respondent failed to report these orders.

It is true—as the ALJ noted—that under 21 CFR 1301.71(b), ''[s]ubstantial compliance with the standards set forth in [21 CFR 1301.72–.76] may be deemed sufficient by the Administrator after evaluation of the overall security system and needs of the . . . registrant.'' R.D. at 199–201. Nor do I dispute the ALJ's conclusion that perfection is not the standard for assessing Respondent's compliance with 21 CFR 1301.74(b). *Id.*

[196] It is acknowledged that Respondent inquired as to the pharmacies' policies to prevent diversion. Certainly doing so is a necessary component of a distributor's due diligence obligations. However, even assuming that Respondent's inquiries were adequate, whether the pharmacies were actually following their policies is a totally different matter. Given the evidence discussed above, I hold that even assuming each of the pharmacies had adequate policies to prevent diversion, in no case did this dispel the strong suspicion that each of the pharmacies was engaged in illegitimate dispensing practices.

at 201 (''one minor oversight does not render the entire system ineffective'').

Here, however, the evidence with respect to the seven pharmacies establishes a wholesale failure on Respondent's part to comply with the regulation, both as to the manner in which Respondent actually operated its SOMS (including the manner in which it followed Policy 6.2) and in its failure to report hundreds of suspicious oxycodone orders.[197] As for the numerous suspicious order reports it did submit, Respondent produced no evidence explaining the circumstances which led it to file those reports, and as one of its former employees testified, ''the customers who were easily suspended or terminated from purchasing controlled substances from [it] were not the big money accounts.'' GX 52, at 7.

I thus conclude that Respondent has not substantially complied with 21 CFR 1301.74(b). I further conclude that the Government has proved that Respondent ''has committed such acts as would render [its] registration . . . inconsistent with the public interest.'' [198]

Sanction

Where, as here, the Government has met its *prima facie* burden of showing that a registrant has committed acts which ''render [its] registration . . . inconsistent with the public interest'' and thus subject to suspension or revocation, a respondent must come forward with '' ''sufficient mitigating evidence'' '' to show why it can continue to be entrusted with its registration. *Medicine Shoppe-Jonesborough,* 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson,* 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller,* 53 FR 21,931, 21,932 (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), [DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct.'' *Medicine Shoppe,* 73 FR at 387; *see also Jackson,* 72 FR at 23,853; *John H. Kennedy,* 71 FR 35,705, 35,709 (2006); *Prince George Daniels,* 60 FR 62,884, 62,887 (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).

Nor are these the only factors DEA considers in setting the appropriate sanction. *See, e.g., Southwood Pharmaceuticals, Inc.,* 72 FR 36,487, 36,504 (2007); *Joseph Gaudio,* 74 FR 10,083, 10,094 (2009). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *Cf. Jacobo Dreszer,* 76 FR 19,386, 19,387–88 (2011) (explaining that a respondent can ''argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation''); *see also Paul H. Volkman,* 73 FR 30,630, 30,644 (2008); *Gregory D. Owens,* 74 FR 36,751, 36,757 n.22 (2009).

Also, the Agency has held repeatedly that '' '[n]either *Jackson,* nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked,' '' or whether an application should be denied. *Gaudio,* 74 FR at 10,094 (quoting *Southwood,* 72 FR at 36,504 (2007)); *see also Robert Raymond Reppy,* 76 FR 61,154, 61,158 (2011); *Michael S. Moore,* 76 FR 45,867, 45,868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio,* 74 FR at 10,094 (quoting *Southwood,* 71 FR at 36,504). *Cf. McCarthy* v. *SEC,* 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoption of ''deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions'').

As found above, Respondent stipulated that it ''does not accept responsibility for any alleged wrongdoing in this matter'' and that ''any evidence . . . of changes, modifications, or enhancements [it] made to its internal Policies and Procedures in the ordinary course of business,'' whether of ''its own accord'' or ''based on alleged guidance or communications from [DEA] does not constitute evidence of remedial measures.'' ALJ Ex. 8. Respondent's failure to acknowledge its misconduct is reason alone to revoke its registration, especially given the evidence which shows that Respondent's failure to report suspicious orders placed by the seven pharmacies was both extensive and egregious. *See Holiday CVS,* 77 FR at 62,323; *see also MacKay* v. *DEA,* 664 F.3d 808, 820 (10th Cir. 2011); *Chein* v. *DEA,* 533 F.3d 828, 837 (D.C. Cir. 2007).

Indeed, the egregiousness of Respondent's misconduct is exacerbated by the acknowledgement of its senior officials that they were well aware of the oxycodone epidemic then ongoing in the State of Florida. It also exacerbated by the evidence which strongly supports the conclusion that with respect to the seven pharmacies, its Policies and Procedures for detecting and reporting suspicious orders were rarely, if ever, followed. And finally, I conclude that revocation is further supported by the Agency's interest in deterring future misconduct on the part of both Respondent, which retains a second distributor's DEA registration, and the community of registrants. *See Southwood,* 71 FR at 36,503 (citing *Butz* v. *Glover Livestock Comm'n Co., Inc.,* 411 U.S. 182, 187–88 (1973)).

Order

Pursuant to the authority vested in me by 21 U.S.C. 824(a)(4) and 823(b), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration RD0277409, issued to Masters Pharmaceuticals, Inc., be, and it hereby is, revoked. I further order that any application of Masters Pharmaceuticals, Inc., to renew or modify this registration be, and it hereby is, denied. This Order is effective October 15, 2015.

Dated: September 8, 2015.

Chuck Rosenberg,

Acting Administrator.

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BILLING CODE 4410–09–P

[197] Throughout this proceeding, Respondent has argued that because it is tertiary distributor, it lacks the data to ''reliably compar[e] either its oxycodone distribution[s] to other wholesalers' distributions or the oxycodone volumes purchased by a particular pharmacy to the volumes purchased by an average Florida pharmacy.'' RX 102, at 9–10; *see also* RX 104, at 8 (testimony of Respondent's owner that its ''business model tends to make its customers' purchasing patterns more difficult to predict and more variable than they would be if [it] were a full-line wholesaler''). Unexplained by Respondent is why it could not have obtained the information through the URs it acquired from all of its customers.

In the December 27, 2007 letter, the Deputy Assistant Administrator explained that ''[t]he determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the registrant's customer base.'' GX 4, at 1. The SOMS, however, did not compare a pharmacy's orders with those of Respondent's other customers, and thus does not appear to be a system that complies with 21 CFR 1301.74(b). Because the Government did not challenge the adequacy of Respondent's SOMS on this basis, I do not consider it.

[198] As explained above, I hold that the ALJ's pre-hearing order barring the Government from asserting any evidence of Respondent's failure to report suspicious orders between April 1, 2009 and the Compliance Review was error. However, even were the Court of Appeals to disagree, the scope of Respondent's failure to report suspicious orders following the compliance review is so extensive and egregious that I would come to the same conclusion that the revocation of Respondent's registration is warranted to protect the public interest.

Draft CDC Guideline for Prescribing Opioids for Chronic Pain

See website for complete information: http://www.cdc.gov/drugoverdose/prescribing/guideline.html

Draft CDC Guideline for Prescribing Opioids for Chronic Pain

Improving the Way Opioids are Prescribed for Safer Chronic Pain Treatment

The Problem

Existing guidelines vary in recommendations, and primary care providers say they receive insufficient training in prescribing opioid pain relievers. It is important that patients receive appropriate pain treatment, and that the benefits and risks of treatment options are carefully considered.

259 million

In 2012, health care providers wrote 259 million prescriptions for opioid pain relievers – enough for every American adult to have a bottle of pills.[1]

300% increase

Prescription opioid sales in the United States have increased by 300% since 1999,[2] but there has not been an overall change in the amount of pain Americans report.[3,4]

2 million

Almost 2 million Americans, age 12 or older, either abused or were dependent on opioid pain relievers in 2013.[5]

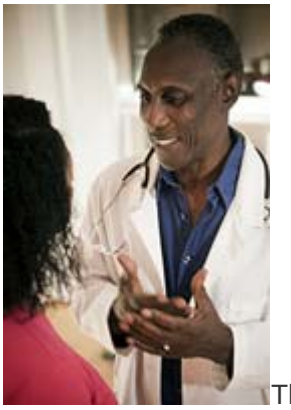
16 thousand

In 2013, more than 16,000 people died in the United States from overdose related to opioid pain relievers, four times the number in 1999.[6]

Improving Practice

Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these powerful drugs.

Draft CDC Guideline for Prescribing Opioids for Chronic Pain



The Centers for Disease Control and Prevention (CDC) is publishing new guideline for prescribing opioids for chronic pain. The agency is working for timely release of the guideline while ensuring that the development process:

- Meets scientific standards
- Includes expert consultation
- Allows for appropriate stakeholders to provide input
- Facilitates partnership development to enhance dissemination and uptake

Intended Purpose and Use of Guideline

The purpose of the CDC guideline is to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (i.e., pain lasting longer than 3 months or past the time of normal tissue healing) outside end-of-life care.

Clinical practices addressed in the guideline

Determining when to initiate or continue opioids for chronic pain outside end-of-life care

- Selection of opioid therapy, non-pharmacologic therapy, non-opioid pharmacologic therapy
- Establishment of treatment goals
- Discussion of risks and benefits of therapy with patients

Opioid selection, dosage, duration, follow-up, and discontinuation

- Selection of extended-release and long-acting opioids
- Dosage considerations
- Duration of treatment for acute pain and chronic opioid use
- Considerations for follow-up and discontinuation of opioid therapy

Assessing risk and addressing harms of opioid use

- Evaluation of risk factors for opioid-related harms and integration into the management plan
- Review of prescription drug monitoring program data
- Use of urine drug testing
- Considerations for concurrent use of opioids and benzodiazepines
- Arrangement of treatment for opioid use disorder

Guideline Development: Methods and Processes

CDC used the Grading of Recommendations Assessment, Development, and Evaluation method to guideline development (www.gradeworkinggroup.org). This method uses a transparent approach to grading quality of evidence and strength of recommendations. Four factors were used to determine the recommendations: 1) quality of evidence, 2) balance between benefits and harms, 3) values and preferences, and 4) costs. CDC also has developed a tiered approach to involve stakeholders in guideline development.