

P-WAG-0001

**EXHIBIT**  
*Walgreens*  
*Swords 7*  
*12-21-18-*

PLAINTIFFS TRIAL  
EXHIBIT  
**P-00015\_EXb**

## SETTLEMENT AND MEMORANDUM OF AGREEMENT

This Memorandum of Agreement (“Agreement”) is entered into by and between the United States Department of Justice (“DOJ”), the United States Drug Enforcement Administration (“DEA”), and Walgreen Co. and its wholly owned subsidiaries (“Walgreens”) (each a “Party” and collectively the “Parties”).

### APPLICABILITY

This Agreement shall be applicable to Walgreens Corporate and any facility owned or operated by Walgreens that is or was registered with DEA to dispense, distribute, or otherwise handle controlled substances or List I chemicals. Unless explicitly stated herein, nothing contained in this Agreement will lessen, supplant or expand Walgreens’ legal obligations under any statute, regulation, or law.

### PROCEDURAL BACKGROUND

1. Walgreens owns or operates (or has previously owned or operated) distribution centers that are or were registered with DEA as distributors of Schedule II-V controlled substances under provisions of the Controlled Substances Act, 21 U.S.C. §§ 801 et seq., (“CSA” or “the Act”) (each a “Distribution Center,” collectively the “Distribution Centers”).
2. Walgreens owns or operates (or has previously owned or operated) pharmacies that are or were registered with DEA as Retail/Chain Pharmacies to handle Schedule II-V controlled substances under the CSA (each a “Pharmacy,” collectively the “Pharmacies”). Walgreens owns or operates (or has previously owned or operated) Central Pharmacy Operations facilities that are or were registered with DEA as Retail/Chain Pharmacies or Central Fill Pharmacies to handle Schedule II-V controlled substances under the CSA (each a “CPO Facility,” collectively the “CPO Facilities”).
3. On April 7, 2011, Walgreens entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with DEA. See Appendix A.
4. Walgreens’ Jupiter Distribution Center (“Walgreens Jupiter”) is registered with DEA as a distributor of Schedule II-V controlled substances at 15998 Walgreens Drive, Jupiter, Florida 33478 (Registration RW0277752).
5. On September 13, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration (“OTSC/ISO”) to Walgreens Jupiter. See Appendix B. After Walgreens requested an administrative hearing before DEA, the Administrative Law Judge (“ALJ”) docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-1.
6. On November 26, 2012, the DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued three OTSCs to Walgreens Retail Pharmacy (1) #03629, 12028 Majestic Boulevard, Hudson, Florida 34667 (Registration BW4713992); (2) #04727, 4950 South U.S. Highway 1, Fort Pierce, Florida 34952 (Registration BW6561270); and

- (3) #06997, 785 Lockwood Boulevard, Oviedo, Florida 32765 (Registration BW8487438). See Appendix C. After Walgreens requested an administrative hearing on each of these three matters, the ALJ docketed each case, *In the Matter of Walgreen Co.*, respectively Docket Nos. 13-9, 13-10, and 13-11.
7. On February 4, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens Retail Pharmacy #03836, 9332 U.S. Highway 19, Port Richey, Florida 34668 (Registration AW8830247). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-16.
  8. On February 11, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens #04391, 2501 Virginia Avenue, Fort Pierce, Florida 34981 (Registration BW5872494). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-18.
  9. Finally, on February 19, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens #03099, 1525 Colonial Boulevard, Fort Myers, Florida 33907 (Registration AW1366877). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-20.
  10. On February 22, 2013, the ALJ consolidated the seven cases into one consolidated proceeding that was scheduled for an Administrative Hearing initially on January 7, 2013, and then continued until February 25, 2013, and again until April 23, 2013.

#### STIPULATION AND AGREEMENT

The facts alleged in the OTSC/ISO issued to Walgreens Jupiter, as well as the facts alleged in the government's filings in *In the Matter of Walgreen Co.*, Docket No. 13-1, as listed in Appendix B, would, if proven, constitute grounds under which DEA could revoke the DEA registration of Walgreens Jupiter. The facts alleged in the OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, as well as the facts alleged in the government's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20, as listed in Appendix C, would, if proven, constitute grounds under which DEA could revoke the DEA registrations of Walgreens #03629, #04727, #06997, #03836, #04391, and #03099.

Walgreens acknowledges that suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007. Furthermore, Walgreens acknowledges that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA (21 U.S.C. §§ 801 et seq.) and its implementing regulations (21 C.F.R. Part 1300 et seq.). Finally, Walgreens acknowledges that its

recordkeeping practices regarding the dispensing of controlled substances from certain retail pharmacies utilizing its CPO Facilities as central-fill pharmacies did not require such original prescriptions to be marked "CENTRAL FILL."

Walgreens, DEA, and DOJ agree as follows:

#### I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in these administrative matters is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority and civil penalty matters arising under the CSA and its implementing regulations relating to (1) the conduct described in the OTSC/ISO issued to Walgreens Jupiter, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket No. 13-1; (2) the conduct described in the OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20; (3) recordkeeping obligations of the CPO Facilities and Pharmacies; (4) other allegations regarding Covered Conduct identified in Section I.2 of this Agreement involving any other Walgreens DEA registrant; and (5) any other allegations relating to conduct arising under the CSA or its implementing regulations which DEA or DOJ knows or has reason to know of as of the effective date of this Agreement, regardless of whether DEA or DOJ has notified Walgreens of such allegations, including conduct at any Walgreens registrant where DEA or DOJ has an open investigation. This includes the open civil investigation into the above-referenced conduct in the United States Attorney's Office for the Southern District of Florida, as well as open civil investigations in the United States Attorney's Offices for the District of Colorado, the Eastern District of Michigan, and the Eastern District of New York. This also includes civil investigations by DEA Field Offices nationwide. The Parties further believe that the terms and conditions of this Agreement as set forth below represent a complete resolution of these matters.
2. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following, whether it occurred at a specific Walgreens DEA registrant or elsewhere within Walgreens:
  - a. Distribution Centers
    - (1) Conduct alleged in the September 13, 2012 OTSC/ISO issued to Walgreens Jupiter, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket 13-1, as listed in Appendix B, and similar allegations regarding any other Walgreens Distribution Center, occurring on or before the effective date of this Agreement;
    - (2) Failure regarding any Distribution Center to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific and industrial channels, as required by 21 U.S.C. §§

823(b) and (e), including any failures to conduct adequate due diligence to ensure that controlled substances were not diverted into other than legitimate channels, on or before the effective date of this Agreement;

- (3) Failure regarding any Distribution Center to timely detect and report suspicious orders of controlled substances as required by 21 U.S.C. § 823 and/or 21 C.F.R. § 1301.74(b) on or before the effective date of this Agreement;
- (4) Distributing controlled substances to pharmacies by any Distribution Center that the Distribution Center knew or should have known were engaged in any of the Covered Conduct listed in Section I.2.b of this Agreement on or before the effective date of this Agreement;
- (5) Failure regarding any Distribution Center to make complete and accurate ARCOS reports, on or before the effective date of this Agreement;
- (6) Refusal or negligent failure by any Distribution Center to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under the CSA and its implementing regulations, on or before the effective date of this Agreement; and
- (7) Conduct regarding any Distribution Center inconsistent with the CSA and its implementing regulations on or before the effective date of this Agreement.

b. Walgreens Pharmacies and CPO Facilities

- (1) Conduct alleged in the November 26, 2012, February 4, 2013, February 11, 2013, and February 19, 2013 OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20, as listed in Appendix C, and similar allegations regarding any other Walgreens Pharmacy or CPO Facility, occurring on or before the effective date of this Agreement;
- (2) Failure of Walgreens Pharmacists at any Pharmacy or CPO Facility to exercise their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a), and dispensing by any Pharmacy, or CPO Facility, of controlled substances pursuant to purported prescriptions that were otherwise invalid under 21 C.F.R. Part 1306, on or before the effective date of this Agreement;

- (3) Dispensing by any Pharmacy or CPO Facility of controlled substances to individuals Walgreens knew or should have known were diverting controlled substances on or before the effective date of this Agreement;
  - (4) Dispensing by any Pharmacy or CPO Facility of controlled substances pursuant to prescriptions issued by a physician who did not have a current, valid DEA registration on or before the effective date of this Agreement;
  - (5) Refusal or negligent failure by any Pharmacy or CPO Facility to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under the CSA and its implementing regulations, including, but not limited to, failure by any Pharmacy or CPO Facility to maintain accurate records pursuant to 21 C.F.R. Part 1304 and to properly label and/or mark prescriptions pursuant to 21 C.F.R. Part 1306, on or before the effective date of this Agreement;
  - (6) Conduct inconsistent with the CSA and its implementing regulations on or before the effective date of this Agreement, by any Pharmacy or CPO Facility; and
  - (7) Failure by any Walgreens registrant, including any Pharmacy or CPO Facility, to adhere to the provisions of the April 7, 2011 Administrative Memorandum of Agreement between Walgreen Co. and DEA (the "2011 MOA").
3. Effect of 2011 MOA. The obligations contained in the 2011 MOA are superseded by the obligations contained within this Agreement.
  4. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of three (3) years from the effective date of this Agreement unless the Parties agree in writing to an earlier termination, provided, however, that the releases in Paragraphs II.6 and II.8 in this Agreement extend beyond the effective date.

## II. Terms and Conditions

1. Obligations of Walgreens Distribution Centers.
  - a. Walgreens will continue to review, and where reasonable and appropriate, to revise its processes and practices for conducting suspicious order monitoring and reporting suspicious orders from Walgreens' pharmacies, as set forth in the attached Addendum.
  - b. Walgreens shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties.
  - c. Walgreens agrees to the surrender of Walgreens Jupiter's DEA Registration RW027752 for controlled substances Schedules II-V, until September 13, 2014.

2. Obligations of Walgreens Pharmacies and CPO Facilities.

- a. Walgreens agrees to maintain a compliance program in an effort to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations, as set forth in the attached Addendum. This program shall include procedures to identify the common signs associated with the diversion of controlled substances. The program shall also include the routine and periodic training of all Walgreens pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA and applicable DEA regulations. This compliance program shall apply to all Walgreens Pharmacies and CPO Facilities.
- b. Walgreens shall implement and maintain policies and procedures in an effort to ensure that prescriptions for controlled substances are only dispensed to authorized ultimate users pursuant to federal and state law and regulations. Walgreens shall maintain its current policy that requires all customers to provide identifying information and shall also require valid photo identification as required by and in accordance with controlling state law where the pharmacy is located. Documents maintained by Walgreens pursuant to any obligation under federal and/or state law regarding the verification of an ultimate user's identity shall be kept readily available by the pharmacy, and shall be produced to DEA agents, task force officers or investigators on request.
- c. Walgreens shall direct and train its pharmacists that their corresponding responsibility under federal law requires them not to fill a prescription that such pharmacist knows or has reason to know was issued for other than a legitimate medical purpose or by a practitioner acting outside the usual course of professional practice.
- d. In connection with Walgreens' recordkeeping obligations, Walgreens agrees to maintain records regarding the dispensing of controlled substances in electronic format, in addition to the regularly maintained paper files, including records relating to which Distribution Center and/or CPO Facility shipped the controlled substance to the Pharmacy. These records shall be made available to DEA agents, task force officers or investigators, upon demand, without the need for a warrant or subpoena, provided that the DEA agents, task force officers or investigators present appropriate identification. Walgreens shall provide electronic reports of dispensing on an ad hoc basis in response to DEA requests within a reasonable time.
- e. Walgreens agrees to the surrender of the DEA registrations to dispense controlled substances for Schedules II-V at the following facilities until May 26, 2014: BW4713992 (#03629), BW6561270 (#04727), BW5872494 (#04391), AW8830247 (#03836), AW1366877 (#03099), and BW8487438 (#06997).

3. Walgreens General Obligations.

- a. Walgreens' policy and procedure is to cooperate with the government in any investigation. Walgreens agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other law enforcement agency investigating or prosecuting customers of Walgreens' pharmacies for alleged violations or activities related to the Covered Conduct, unless such matters would affect the rights or obligations of Walgreens in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews as reasonable and appropriate with reasonable notice in advance. However, nothing in this paragraph shall be construed as a waiver by Walgreens, its directors, officers or employees of any constitutional rights or rights that they would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.
- b. Walgreens agrees that it will promptly move to dismiss, with prejudice, the pending lawsuit by Walgreens in Case No. 12-1397 in the United States Court of Appeals for the District of Columbia Circuit.
- c. Walgreens agrees to pay the United States eighty million dollars (\$80,000,000.00) ("the Settlement Amount") within ten (10) days of the effective date of this Agreement by electronic funds transfer pursuant to written instructions provided to Walgreens by the United States Attorney's Office for the Southern District of Florida.

4. Obligations of DEA.

- a. DEA agrees to accept at DEA Field Offices the information regarding suspicious orders as required under 21 C.F.R. § 1301.74(b) in the manner described in the attached Addendum.
- b. Within five (5) business days of the effective date of this Agreement, DEA agrees to unlock the controlled substances storage area at Walgreens Jupiter and make its contents available to Walgreens for any lawful transfer or reverse distribution of the inventory contained therein to an appropriate DEA registrant(s).
- c. Provided that Walgreens submits a re-application for each of the above-listed facilities at least four (4) months prior to the end of the applicable surrender period, DEA agrees that, upon application by Walgreens, it will grant (1) a DEA registration to distribute controlled substances in Schedules II-V for Walgreens Jupiter on or before September 13, 2014, and (2) DEA registrations to dispense controlled substances in Schedules II-V for the Walgreens Pharmacies listed in Paragraph II.2.e on or before May 26, 2014.



5. Joint Obligations of the Parties.
  - a. Walgreens and DEA agree that upon the execution of this Agreement, DEA and Walgreens shall promptly file a joint motion with the ALJ to terminate all pending administrative proceedings against Walgreens.
  
6. Release by the United States. In consideration of the fulfillment of the obligations of Walgreens under this Agreement, the United States agrees to:
  - a. Release Walgreens and all Walgreens facilities, including Walgreens subsidiary entities, affiliates, and registrants, along with their respective officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims related to Covered Conduct prior to the effective date of this Agreement within DEA's enforcement authority under the CSA and its implementing regulations, and any corresponding DOJ authority for civil penalty claims under 21 U.S.C. § 842.
  - b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under the CSA and its implementing regulations based on the Covered Conduct, or other noncompliant conduct to the extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of investigations and inspections in existence as of the effective date of this Agreement, or the review of the reports and records Walgreens submitted to DEA prior to the effective date of this Agreement; and
  - c. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct, or other noncompliant conduct to the extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of investigations and inspections in existence as of the effective date of this Agreement, or the review of the reports and records Walgreens submitted to DEA prior to the effective date of this Agreement.
  
7. Notwithstanding the releases by the United States in Paragraph #6 above, DEA reserves the right to seek to admit evidence of Covered Conduct for proper evidentiary purposes in any future administrative proceeding against Walgreens for non-Covered Conduct. Further, nothing in this Agreement shall prohibit or limit any other agency within DOJ, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiated an investigation, action, or proceeding involving Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any component of DOJ, based on the Covered Conduct. At Walgreens' request, DEA and DOJ agree to disclose the terms of this Agreement to any other agency and will represent, assuming

Walgreens is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed.

8. Release by Walgreens. Walgreens fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Walgreens has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.
9. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Walgreens) are the following:
  - a. Any potential criminal liability;
  - b. Any civil, criminal or administrative liability arising under Title 26, United States Code (Internal Revenue Code); or
  - c. Any liability based upon such obligations as are created by this Agreement.
  - d. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the settlement amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.
10. Walgreens agrees that any and all costs it has or will incur in connection with this matter—including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, and remedial action—shall be unallowable costs for government contracting accounting and for Medicare, Medicaid, TriCare, and FEHBP (or any other government reimbursement program) for reimbursement purposes.

### III. Miscellaneous

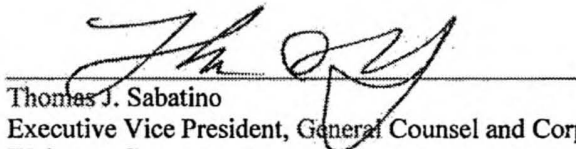
1. Binding on Successors. This Agreement is binding on Walgreens, and its respective successors, heirs, transferees, and assigns.
2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Parties.
4. Incorporation of Addendum. This Agreement incorporates a separate document, entitled "Addendum: Prospective Compliance," containing additional compliance measures to be undertaken by Walgreens.

5. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the Parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.  
  
Walgreens represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Walgreens further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.
6. Execution of Agreement. This Agreement shall become effective on the date of signing by the last signatory (the "Effective Date"). The United States agrees to notify Walgreens immediately when the final signatory has executed this Agreement.
7. Notices. All communications and notices to Walgreens pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by Walgreens providing written notification to DEA:
  - a. Dwayne A. Piñon, Director, Pharmacy Law, Operations & Services, Walgreen Co., 104 Wilmot Road, MS #1434, Deerfield, Illinois 60015; fax: 847-315-4660; email: [dwayne.pinon@walgreens.com](mailto:dwayne.pinon@walgreens.com).
8. Disclosure. Walgreens and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.
9. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.
10. Authorizations. The individuals signing this Agreement on behalf of Walgreens represent and warrant that they are authorized by Walgreens to execute this Agreement. The individuals signing this Agreement on behalf of DEA and DOJ represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA and DOJ to execute this Agreement.
11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and any Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties relating to this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Walgreens facilities and/or registrations at issue are located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA.


IN WITNESS WHEREOF, the Parties hereto have duly executed this Memorandum of Agreement.

On Behalf of Walgreen Co.:



  
Thomas J. Sabatino  
Executive Vice President, General Counsel and Corporate Secretary  
Walgreen Co.

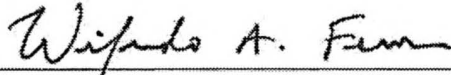
Dated: 6/10/13

  
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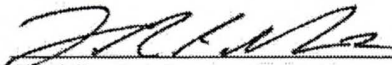
Dated: June 10, 2013

On Behalf of the United States Department of Justice:



Wifredo A. Ferrer  
United States Attorney  
Southern District of Florida

Dated: 6/11/13



Franklin G. Monsour, Jr.  
Assistant United States Attorney  
Southern District of Florida

Dated: 6/11/13

**On Behalf of the United States Drug Enforcement Administration:**



Michele M. Leonhart  
Administrator  
United States Drug Enforcement Administration

Dated: 6/10/13

### Addendum: Prospective Compliance

The Parties agree that Walgreens will maintain the following specific compliance measures for the duration of this Agreement. To the extent any compliance measures identified below are not yet in place, Walgreens commits to implement such measures within the timeframes specified herein.

#### A. General

1. Walgreens will maintain a Department of Pharmaceutical Integrity, composed of personnel with pharmacy-related training and managerial personnel, who shall be trained in relevant diversion-related issues, to coordinate compliance efforts related to controlled substances. Within one (1) month of the effective date of this Agreement, Walgreens will identify a dedicated contact point (including a dedicated email address) for DEA within the Department of Pharmaceutical Integrity to facilitate Walgreens' responses to DEA requests for information and documents, specifically including responses to requests for dispensing log data and pseudoephedrine data.

#### B. Pharmacies

1. Upon request by DEA to Walgreens' Department of Pharmaceutical Integrity, within two (2) business days Walgreens will provide to DEA, via appropriate secure means of electronic transmission, controlled substance dispensing logs consisting of those categories of information the regulations require dispensers to maintain as records, *see* 21 C.F.R. § 1304.22(c). DEA understands and agrees that additional reasonable time may be required to the extent DEA seeks additional data or information not regularly maintained for such logs.
2. For all Schedule II controlled substance prescriptions, Walgreens currently affixes a sticker to each paper prescription containing certain dispensing information such as: a serial number unique to each prescription (which includes a suffix identifying the dispensing retail pharmacy); the prescriber's name, address, telephone number, and DEA registration number; the patient's name, address, and telephone number; the prescription issue date; the drug and quantity dispensed; and the fill date. Walgreens currently also affixes such stickers to Schedule III-V controlled substance paper prescriptions in certain states, but not others, depending upon state law requirements. Within three (3) months of the effective date of this Agreement, Walgreens pharmacies will affix such a sticker to all paper controlled substance prescriptions in each state, regardless of the requirements of state law. Walgreens will maintain a paper file of such prescriptions organized chronologically by fill date. In the event that DEA requests an electronic list of such prescriptions in sequential order by prescription number, Walgreens' Department of Pharmaceutical Integrity will provide such a list upon request within a reasonable time. Paper prescriptions will be maintained at the registered location of the pharmacy that dispensed them for a period of the longer of two (2) years or that required by applicable state law.

3. Walgreens' retail pharmacies utilize a computer application for the storage and retrieval of refill information for original paper prescriptions. For prescription refills, Walgreens will follow the procedures outlined in 21 C.F.R. § 1306.22(f). To the extent that DEA wishes to retrieve electronic records regarding refills, Walgreens' Department of Pharmaceutical Integrity will facilitate responses to such requests, including by providing such information to DEA upon request in a manner that is sortable and retrievable by prescriber name, prescriber DEA registration number, patient name, patient address, drug dispensed, date filled, and last name of dispensing pharmacist.
4. Walgreens remains committed to properly training its pharmacy personnel to deal with evolving diversion-related issues. Walgreens will continue to enhance its Good Faith Dispensing Policy and training materials to identify "red flags" of potential diversion for pharmacists to consider in making professional judgments regarding dispensing of controlled substances. Walgreens will train its pharmacy personnel at least annually on Good Faith Dispensing and will update the Good Faith Dispensing Policy and training materials to respond to changing diversion threats of which Walgreens is aware. DEA will share information with Walgreens periodically regarding circumstances that may present "red flags" of potential diversion. Walgreens' training program will also instruct pharmacists and supervisory personnel to contact the Department of Pharmaceutical Integrity, as appropriate, to address specific problematic issues arising with particular patients or physicians, so that the Department of Pharmaceutical Integrity can assess and respond to such issues. Pharmacist training will also cover instruction on how to assist DEA in obtaining records as required by this Agreement or any regulations.
5. Walgreens will maintain procedures to verify that the DEA registration number for the issuing prescriber of a controlled substance is a current, valid registration number. Such verification shall be performed using information from the National Technical Information Service (NTIS) database or similarly reliable third party database where DEA registration changes are recorded. Walgreens agrees to maintain a system integrating NTIS data with Walgreens' computer system that will: (1) update NTIS registration data on a weekly basis; and (2) prevent a pharmacy from filling a controlled substance prescription using a registration number not listed in such NTIS data until such prescriber's valid registration number is confirmed.
6. Beginning in 2014, Walgreens will exclude any accounting for controlled substance prescriptions dispensed by a particular pharmacy from bonus computations for pharmacists and pharmacy technicians at that pharmacy.
7. For each retail pharmacy, Walgreens will maintain, either electronically or in paper form, a log of pseudoephedrine purchases that can be made available upon request to authorized DEA personnel. To the extent that printing or copying of such a log from electronic records at a pharmacy would be unduly laborious or time-consuming, DEA agrees that Walgreens' Department of Pharmaceutical



Integrity will facilitate transmission of such information, including through transmission of electronic records to DEA.

C. Distribution Centers

1. Within one (1) week of the effective date of this Agreement, Walgreens will designate a DEA contact point in its Department of Pharmaceutical Integrity to address inquiries regarding suspicious order monitoring and reporting. At least one (1) existing employee at each Walgreens distribution center that distributes controlled substances will receive appropriate training on suspicious order monitoring requirements and on reporting relevant issues to the Department of Pharmaceutical Integrity.
2. For purposes of complying with suspicious order monitoring and reporting requirements for orders to be supplied by a Walgreens distribution center, Walgreens will maintain the tolerance threshold, ceiling limits, and other elements of its current suspicious order monitoring and reporting system, either for the duration of this Agreement or until Walgreens distribution activities are transitioned to a third party. Walgreens will endeavor to conduct its evaluations of "orders of interest" identified by its tolerance thresholds and ceiling limits within four (4) business days in most cases, and shall inform DEA Field Offices of orders that Walgreens has determined are "suspicious" within two (2) business days of making any such determination. Walgreens agrees not to ship any "order of interest" or "suspicious order" in whole or in part unless and until Walgreens resolves the reason(s) that caused it to designate the order as an "order of interest" or a "suspicious order." Within ninety (90) days of the effective date of this Agreement, suspicious order reports shall identify reason(s) an order was determined to be suspicious, and the registration number for the specific Walgreens distribution center that would have received the order at issue.
3. Within eighteen (18) months of the effective date of this Agreement, Walgreens will initiate enrollment in and operationally implement DEA's Controlled Substance Ordering System (CSOS) for orders of all Schedule II controlled substances placed by its retail pharmacies to its distribution centers.



## SETTLEMENT AND MEMORANDUM OF AGREEMENT

This Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice ("DOJ"), the United States Drug Enforcement Administration ("DEA"), and Walgreen Co. and its wholly owned subsidiaries ("Walgreens") (each a "Party" and collectively the "Parties").

### APPLICABILITY

This Agreement shall be applicable to Walgreens Corporate and any facility owned or operated by Walgreens that is or was registered with DEA to dispense, distribute, or otherwise handle controlled substances or List I chemicals. Unless explicitly stated herein, nothing contained in this Agreement will lessen, supplant or expand Walgreens' legal obligations under any statute, regulation, or law.

### PROCEDURAL BACKGROUND

1. Walgreens owns or operates (or has previously owned or operated) distribution centers that are or were registered with DEA as distributors of Schedule II-V controlled substances under provisions of the Controlled Substances Act, 21 U.S.C. §§ 801 et seq., ("CSA" or "the Act") (each a "Distribution Center," collectively the "Distribution Centers").
2. Walgreens owns or operates (or has previously owned or operated) pharmacies that are or were registered with DEA as Retail/Chain Pharmacies to handle Schedule II-V controlled substances under the CSA (each a "Pharmacy," collectively the "Pharmacies"). Walgreens owns or operates (or has previously owned or operated) Central Pharmacy Operations facilities that are or were registered with DEA as Retail/Chain Pharmacies or Central Fill Pharmacies to handle Schedule II-V controlled substances under the CSA (each a "CPO Facility," collectively the "CPO Facilities").
3. On April 7, 2011, Walgreens entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with DEA. See Appendix A.
4. Walgreens' Jupiter Distribution Center ("Walgreens Jupiter") is registered with DEA as a distributor of Schedule II-V controlled substances at 15998 Walgreens Drive, Jupiter, Florida 33478 (Registration RW0277752).
5. On September 13, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration ("OTSC/ISO") to Walgreens Jupiter. See Appendix B. After Walgreens requested an administrative hearing before DEA, the Administrative Law Judge ("ALJ") docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-1.
6. On November 26, 2012, the DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued three OTSCs to Walgreens Retail Pharmacy (1) #03629, 12028 Majestic Boulevard, Hudson, Florida 34667 (Registration BW4713992); (2) #04727, 4950 South U.S. Highway 1, Fort Pierce, Florida 34952 (Registration BW6561270); and

- (3) #06997, 785 Lockwood Boulevard, Oviedo, Florida 32765 (Registration BW8487438). See Appendix C. After Walgreens requested an administrative hearing on each of these three matters, the ALJ docketed each case, *In the Matter of Walgreen Co.*, respectively Docket Nos. 13-9, 13-10, and 13-11.
7. On February 4, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens Retail Pharmacy #03836, 9332 U.S. Highway 19, Port Richey, Florida 34668 (Registration AW8830247). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-16.
  8. On February 11, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens #04391, 2501 Virginia Avenue, Fort Pierce, Florida 34981 (Registration BW5872494). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-18.
  9. Finally, on February 19, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens #03099, 1525 Colonial Boulevard, Fort Myers, Florida 33907 (Registration AW1366877). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-20.
  10. On February 22, 2013, the ALJ consolidated the seven cases into one consolidated proceeding that was scheduled for an Administrative Hearing initially on January 7, 2013, and then continued until February 25, 2013, and again until April 23, 2013.

#### STIPULATION AND AGREEMENT

The facts alleged in the OTSC/ISO issued to Walgreens Jupiter, as well as the facts alleged in the government's filings in *In the Matter of Walgreen Co.*, Docket No. 13-1, as listed in Appendix B, would, if proven, constitute grounds under which DEA could revoke the DEA registration of Walgreens Jupiter. The facts alleged in the OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, as well as the facts alleged in the government's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20, as listed in Appendix C, would, if proven, constitute grounds under which DEA could revoke the DEA registrations of Walgreens #03629, #04727, #06997, #03836, #04391, and #03099.

Walgreens acknowledges that suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007. Furthermore, Walgreens acknowledges that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA (21 U.S.C. §§ 801 et seq.) and its implementing regulations (21 C.F.R. Part 1300 et seq.). Finally, Walgreens acknowledges that its

recordkeeping practices regarding the dispensing of controlled substances from certain retail pharmacies utilizing its CPO Facilities as central-fill pharmacies did not require such original prescriptions to be marked "CENTRAL FILL."

Walgreens, DEA, and DOJ agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in these administrative matters is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority and civil penalty matters arising under the CSA and its implementing regulations relating to (1) the conduct described in the OTSC/ISO issued to Walgreens Jupiter, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket No. 13-1; (2) the conduct described in the OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20; (3) recordkeeping obligations of the CPO Facilities and Pharmacies; (4) other allegations regarding Covered Conduct identified in Section I.2 of this Agreement involving any other Walgreens DEA registrant; and (5) any other allegations relating to conduct arising under the CSA or its implementing regulations which DEA or DOJ knows or has reason to know of as of the effective date of this Agreement, regardless of whether DEA or DOJ has notified Walgreens of such allegations, including conduct at any Walgreens registrant where DEA or DOJ has an open investigation. This includes the open civil investigation into the above-referenced conduct in the United States Attorney's Office for the Southern District of Florida, as well as open civil investigations in the United States Attorney's Offices for the District of Colorado, the Eastern District of Michigan, and the Eastern District of New York. This also includes civil investigations by DEA Field Offices nationwide. The Parties further believe that the terms and conditions of this Agreement as set forth below represent a complete resolution of these matters.
2. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following, whether it occurred at a specific Walgreens DEA registrant or elsewhere within Walgreens:
  - a. Distribution Centers
    - (1) Conduct alleged in the September 13, 2012 OTSC/ISO issued to Walgreens Jupiter, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket 13-1, as listed in Appendix B, and similar allegations regarding any other Walgreens Distribution Center, occurring on or before the effective date of this Agreement;
    - (2) Failure regarding any Distribution Center to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific and industrial channels, as required by 21 U.S.C. §§

823(b) and (e), including any failures to conduct adequate due diligence to ensure that controlled substances were not diverted into other than legitimate channels, on or before the effective date of this Agreement;

- (3) Failure regarding any Distribution Center to timely detect and report suspicious orders of controlled substances as required by 21 U.S.C. § 823 and/or 21 C.F.R. § 1301.74(b) on or before the effective date of this Agreement;
- (4) Distributing controlled substances to pharmacies by any Distribution Center that the Distribution Center knew or should have known were engaged in any of the Covered Conduct listed in Section I.2.b of this Agreement on or before the effective date of this Agreement;
- (5) Failure regarding any Distribution Center to make complete and accurate ARCOS reports, on or before the effective date of this Agreement;
- (6) Refusal or negligent failure by any Distribution Center to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under the CSA and its implementing regulations, on or before the effective date of this Agreement; and
- (7) Conduct regarding any Distribution Center inconsistent with the CSA and its implementing regulations on or before the effective date of this Agreement.

b. Walgreens Pharmacies and CPO Facilities

- (1) Conduct alleged in the November 26, 2012, February 4, 2013, February 11, 2013, and February 19, 2013 OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20, as listed in Appendix C, and similar allegations regarding any other Walgreens Pharmacy or CPO Facility, occurring on or before the effective date of this Agreement;
- (2) Failure of Walgreens Pharmacists at any Pharmacy or CPO Facility to exercise their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R. § 1306.04(a), and dispensing by any Pharmacy, or CPO Facility, of controlled substances pursuant to purported prescriptions that were otherwise invalid under 21 C.F.R. Part 1306, on or before the effective date of this Agreement;

- (3) Dispensing by any Pharmacy or CPO Facility of controlled substances to individuals Walgreens knew or should have known were diverting controlled substances on or before the effective date of this Agreement;
  - (4) Dispensing by any Pharmacy or CPO Facility of controlled substances pursuant to prescriptions issued by a physician who did not have a current, valid DEA registration on or before the effective date of this Agreement;
  - (5) Refusal or negligent failure by any Pharmacy or CPO Facility to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under the CSA and its implementing regulations, including, but not limited to, failure by any Pharmacy or CPO Facility to maintain accurate records pursuant to 21 C.F.R. Part 1304 and to properly label and/or mark prescriptions pursuant to 21 C.F.R. Part 1306, on or before the effective date of this Agreement;
  - (6) Conduct inconsistent with the CSA and its implementing regulations on or before the effective date of this Agreement, by any Pharmacy or CPO Facility; and
  - (7) Failure by any Walgreens registrant, including any Pharmacy or CPO Facility, to adhere to the provisions of the April 7, 2011 Administrative Memorandum of Agreement between Walgreen Co. and DEA (the "2011 MOA").
3. Effect of 2011 MOA. The obligations contained in the 2011 MOA are superseded by the obligations contained within this Agreement.
  4. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of three (3) years from the effective date of this Agreement unless the Parties agree in writing to an earlier termination, provided, however, that the releases in Paragraphs II.6 and II.8 in this Agreement extend beyond the effective date.

## II. Terms and Conditions

1. Obligations of Walgreens Distribution Centers.
  - a. Walgreens will continue to review, and where reasonable and appropriate, to revise its processes and practices for conducting suspicious order monitoring and reporting suspicious orders from Walgreens' pharmacies, as set forth in the attached Addendum.
  - b. Walgreens shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties.
  - c. Walgreens agrees to the surrender of Walgreens Jupiter's DEA Registration RW0277752 for controlled substances Schedules II-V, until September 13, 2014.

2. Obligations of Walgreens Pharmacies and CPO Facilities.

- a. Walgreens agrees to maintain a compliance program in an effort to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations, as set forth in the attached Addendum. This program shall include procedures to identify the common signs associated with the diversion of controlled substances. The program shall also include the routine and periodic training of all Walgreens pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA and applicable DEA regulations. This compliance program shall apply to all Walgreens Pharmacies and CPO Facilities.
- b. Walgreens shall implement and maintain policies and procedures in an effort to ensure that prescriptions for controlled substances are only dispensed to authorized ultimate users pursuant to federal and state law and regulations. Walgreens shall maintain its current policy that requires all customers to provide identifying information and shall also require valid photo identification as required by and in accordance with controlling state law where the pharmacy is located. Documents maintained by Walgreens pursuant to any obligation under federal and/or state law regarding the verification of an ultimate user's identity shall be kept readily available by the pharmacy, and shall be produced to DEA agents, task force officers or investigators on request.
- c. Walgreens shall direct and train its pharmacists that their corresponding responsibility under federal law requires them not to fill a prescription that such pharmacist knows or has reason to know was issued for other than a legitimate medical purpose or by a practitioner acting outside the usual course of professional practice.
- d. In connection with Walgreens' recordkeeping obligations, Walgreens agrees to maintain records regarding the dispensing of controlled substances in electronic format, in addition to the regularly maintained paper files, including records relating to which Distribution Center and/or CPO Facility shipped the controlled substance to the Pharmacy. These records shall be made available to DEA agents, task force officers or investigators, upon demand, without the need for a warrant or subpoena, provided that the DEA agents, task force officers or investigators present appropriate identification. Walgreens shall provide electronic reports of dispensing on an ad hoc basis in response to DEA requests within a reasonable time.
- e. Walgreens agrees to the surrender of the DEA registrations to dispense controlled substances for Schedules II-V at the following facilities until May 26, 2014: BW4713992 (#03629), BW6561270 (#04727), BW5872494 (#04391), AW8830247 (#03836), AW1366877 (#03099), and BW8487438 (#06997).



3. Walgreens General Obligations.

- a. Walgreens' policy and procedure is to cooperate with the government in any investigation. Walgreens agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other law enforcement agency investigating or prosecuting customers of Walgreens' pharmacies for alleged violations or activities related to the Covered Conduct, unless such matters would affect the rights or obligations of Walgreens in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews as reasonable and appropriate with reasonable notice in advance. However, nothing in this paragraph shall be construed as a waiver by Walgreens, its directors, officers or employees of any constitutional rights or rights that they would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.
- b. Walgreens agrees that it will promptly move to dismiss, with prejudice, the pending lawsuit by Walgreens in Case No. 12-1397 in the United States Court of Appeals for the District of Columbia Circuit.
- c. Walgreens agrees to pay the United States eighty million dollars (\$80,000,000.00) ("the Settlement Amount") within ten (10) days of the effective date of this Agreement by electronic funds transfer pursuant to written instructions provided to Walgreens by the United States Attorney's Office for the Southern District of Florida.

4. Obligations of DEA.

- a. DEA agrees to accept at DEA Field Offices the information regarding suspicious orders as required under 21 C.F.R. § 1301.74(b) in the manner described in the attached Addendum.
- b. Within five (5) business days of the effective date of this Agreement, DEA agrees to unlock the controlled substances storage area at Walgreens Jupiter and make its contents available to Walgreens for any lawful transfer or reverse distribution of the inventory contained therein to an appropriate DEA registrant(s).
- c. Provided that Walgreens submits a re-application for each of the above-listed facilities at least four (4) months prior to the end of the applicable surrender period, DEA agrees that, upon application by Walgreens, it will grant (1) a DEA registration to distribute controlled substances in Schedules II-V for Walgreens Jupiter on or before September 13, 2014, and (2) DEA registrations to dispense controlled substances in Schedules II-V for the Walgreens Pharmacies listed in Paragraph II.2.e on or before May 26, 2014.

5. Joint Obligations of the Parties.
  - a. Walgreens and DEA agree that upon the execution of this Agreement, DEA and Walgreens shall promptly file a joint motion with the ALJ to terminate all pending administrative proceedings against Walgreens.
6. Release by the United States. In consideration of the fulfillment of the obligations of Walgreens under this Agreement, the United States agrees to:
  - a. Release Walgreens and all Walgreens facilities, including Walgreens subsidiary entities, affiliates, and registrants, along with their respective officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims related to Covered Conduct prior to the effective date of this Agreement within DEA's enforcement authority under the CSA and its implementing regulations, and any corresponding DOJ authority for civil penalty claims under 21 U.S.C. § 842.
  - b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under the CSA and its implementing regulations based on the Covered Conduct, or other noncompliant conduct to the extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of investigations and inspections in existence as of the effective date of this Agreement, or the review of the reports and records Walgreens submitted to DEA prior to the effective date of this Agreement; and
  - c. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct, or other noncompliant conduct to the extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of investigations and inspections in existence as of the effective date of this Agreement, or the review of the reports and records Walgreens submitted to DEA prior to the effective date of this Agreement.
7. Notwithstanding the releases by the United States in Paragraph #6 above, DEA reserves the right to seek to admit evidence of Covered Conduct for proper evidentiary purposes in any future administrative proceeding against Walgreens for non-Covered Conduct. Further, nothing in this Agreement shall prohibit or limit any other agency within DOJ, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiated an investigation, action, or proceeding involving Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any component of DOJ, based on the Covered Conduct. At Walgreens' request, DEA and DOJ agree to disclose the terms of this Agreement to any other agency and will represent, assuming

Walgreens is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed.

8. Release by Walgreens. Walgreens fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Walgreens has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.
9. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Walgreens) are the following:
  - a. Any potential criminal liability;
  - b. Any civil, criminal or administrative liability arising under Title 26, United States Code (Internal Revenue Code); or
  - c. Any liability based upon such obligations as are created by this Agreement.
  - d. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the settlement amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.
10. Walgreens agrees that any and all costs it has or will incur in connection with this matter—including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, and remedial action—shall be unallowable costs for government contracting accounting and for Medicare, Medicaid, TriCare, and FEHBP (or any other government reimbursement program) for reimbursement purposes.

### III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Walgreens, and its respective successors, heirs, transferees, and assigns.
2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Parties.
4. Incorporation of Addendum. This Agreement incorporates a separate document, entitled "Addendum: Prospective Compliance," containing additional compliance measures to be undertaken by Walgreens.

5. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the Parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.

Walgreens represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Walgreens further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

6. Execution of Agreement. This Agreement shall become effective on the date of signing by the last signatory (the "Effective Date"). The United States agrees to notify Walgreens immediately when the final signatory has executed this Agreement.
7. Notices. All communications and notices to Walgreens pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by Walgreens providing written notification to DEA:
- a. Dwayne A. Pifon, Director, Pharmacy Law, Operations & Services, Walgreen Co., 104 Wilmot Road, MS #1434, Deerfield, Illinois 60015; fax: 847-315-4660; email: [dwayne.pinon@walgreens.com](mailto:dwayne.pinon@walgreens.com).
8. Disclosure. Walgreens and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.
9. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.
10. Authorizations. The individuals signing this Agreement on behalf of Walgreens represent and warrant that they are authorized by Walgreens to execute this Agreement. The individuals signing this Agreement on behalf of DEA and DOJ represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA and DOJ to execute this Agreement.
11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and any Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties relating to this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Walgreens facilities and/or registrations at issue are located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA.

**Addendum: Prospective Compliance**

The Parties agree that Walgreens will maintain the following specific compliance measures for the duration of this Agreement. To the extent any compliance measures identified below are not yet in place, Walgreens commits to implement such measures within the timeframes specified herein.

**A. General**

1. Walgreens will maintain a Department of Pharmaceutical Integrity, composed of personnel with pharmacy-related training and managerial personnel, who shall be trained in relevant diversion-related issues, to coordinate compliance efforts related to controlled substances. Within one (1) month of the effective date of this Agreement, Walgreens will identify a dedicated contact point (including a dedicated email address) for DEA within the Department of Pharmaceutical Integrity to facilitate Walgreens' responses to DEA requests for information and documents, specifically including responses to requests for dispensing log data and pseudoephedrine data.

**B. Pharmacies**

1. Upon request by DEA to Walgreens' Department of Pharmaceutical Integrity, within two (2) business days Walgreens will provide to DEA, via appropriate secure means of electronic transmission, controlled substance dispensing logs consisting of those categories of information the regulations require dispensers to maintain as records, *see* 21 C.F.R. § 1304.22(c). DEA understands and agrees that additional reasonable time may be required to the extent DEA seeks additional data or information not regularly maintained for such logs.
2. For all Schedule II controlled substance prescriptions, Walgreens currently affixes a sticker to each paper prescription containing certain dispensing information such as: a serial number unique to each prescription (which includes a suffix identifying the dispensing retail pharmacy); the prescriber's name, address, telephone number, and DEA registration number; the patient's name, address, and telephone number; the prescription issue date; the drug and quantity dispensed; and the fill date. Walgreens currently also affixes such stickers to Schedule III-V controlled substance paper prescriptions in certain states, but not others, depending upon state law requirements. Within three (3) months of the effective date of this Agreement, Walgreens pharmacies will affix such a sticker to all paper controlled substance prescriptions in each state, regardless of the requirements of state law. Walgreens will maintain a paper file of such prescriptions organized chronologically by fill date. In the event that DEA requests an electronic list of such prescriptions in sequential order by prescription number, Walgreens' Department of Pharmaceutical Integrity will provide such a list upon request within a reasonable time. Paper prescriptions will be maintained at the registered location of the pharmacy that dispensed them for a period of the longer of two (2) years or that required by applicable state law.

3. Walgreens' retail pharmacies utilize a computer application for the storage and retrieval of refill information for original paper prescriptions. For prescription refills, Walgreens will follow the procedures outlined in 21 C.F.R. § 1306.22(f). To the extent that DEA wishes to retrieve electronic records regarding refills, Walgreens' Department of Pharmaceutical Integrity will facilitate responses to such requests, including by providing such information to DEA upon request in a manner that is sortable and retrievable by prescriber name, prescriber DEA registration number, patient name, patient address, drug dispensed, date filled, and last name of dispensing pharmacist.
4. Walgreens remains committed to properly training its pharmacy personnel to deal with evolving diversion-related issues. Walgreens will continue to enhance its Good Faith Dispensing Policy and training materials to identify "red flags" of potential diversion for pharmacists to consider in making professional judgments regarding dispensing of controlled substances. Walgreens will train its pharmacy personnel at least annually on Good Faith Dispensing and will update the Good Faith Dispensing Policy and training materials to respond to changing diversion threats of which Walgreens is aware. DEA will share information with Walgreens periodically regarding circumstances that may present "red flags" of potential diversion. Walgreens' training program will also instruct pharmacists and supervisory personnel to contact the Department of Pharmaceutical Integrity, as appropriate, to address specific problematic issues arising with particular patients or physicians, so that the Department of Pharmaceutical Integrity can assess and respond to such issues. Pharmacist training will also cover instruction on how to assist DEA in obtaining records as required by this Agreement or any regulations.
5. Walgreens will maintain procedures to verify that the DEA registration number for the issuing prescriber of a controlled substance is a current, valid registration number. Such verification shall be performed using information from the National Technical Information Service (NTIS) database or similarly reliable third party database where DEA registration changes are recorded. Walgreens agrees to maintain a system integrating NTIS data with Walgreens' computer system that will: (1) update NTIS registration data on a weekly basis; and (2) prevent a pharmacy from filling a controlled substance prescription using a registration number not listed in such NTIS data until such prescriber's valid registration number is confirmed.
6. Beginning in 2014, Walgreens will exclude any accounting for controlled substance prescriptions dispensed by a particular pharmacy from bonus computations for pharmacists and pharmacy technicians at that pharmacy.
7. For each retail pharmacy, Walgreens will maintain, either electronically or in paper form, a log of pseudoephedrine purchases that can be made available upon request to authorized DEA personnel. To the extent that printing or copying of such a log from electronic records at a pharmacy would be unduly laborious or time-consuming, DEA agrees that Walgreens' Department of Pharmaceutical

Integrity will facilitate transmission of such information, including through transmission of electronic records to DEA.

C. Distribution Centers

1. Within one (1) week of the effective date of this Agreement, Walgreens will designate a DEA contact point in its Department of Pharmaceutical Integrity to address inquiries regarding suspicious order monitoring and reporting. At least one (1) existing employee at each Walgreens distribution center that distributes controlled substances will receive appropriate training on suspicious order monitoring requirements and on reporting relevant issues to the Department of Pharmaceutical Integrity.
2. For purposes of complying with suspicious order monitoring and reporting requirements for orders to be supplied by a Walgreens distribution center, Walgreens will maintain the tolerance threshold, ceiling limits, and other elements of its current suspicious order monitoring and reporting system, either for the duration of this Agreement or until Walgreens distribution activities are transitioned to a third party. Walgreens will endeavor to conduct its evaluations of "orders of interest" identified by its tolerance thresholds and ceiling limits within four (4) business days in most cases, and shall inform DEA Field Offices of orders that Walgreens has determined are "suspicious" within two (2) business days of making any such determination. Walgreens agrees not to ship any "order of interest" or "suspicious order" in whole or in part unless and until Walgreens resolves the reason(s) that caused it to designate the order as an "order of interest" or a "suspicious order." Within ninety (90) days of the effective date of this Agreement, suspicious order reports shall identify reason(s) an order was determined to be suspicious, and the registration number for the specific Walgreens distribution center that would have received the order at issue.
3. Within eighteen (18) months of the effective date of this Agreement, Walgreens will initiate enrollment in and operationally implement DEA's Controlled Substance Ordering System (CSOS) for orders of all Schedule II controlled substances placed by its retail pharmacies to its distribution centers.

P-WAG-0001

# APPENDIX A



## ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration (hereinafter "DEA") and Walgreen Co., on its behalf as well as on behalf of its subsidiaries that operate walk-in, retail pharmacies under the name Walgreens (hereinafter "Walgreens") (each a "Party" and collectively hereinafter referred to as the "Parties").

### I. APPLICABILITY

This Agreement shall be applicable to all current and future Walgreens walk-in, retail pharmacy locations registered with the DEA to dispense controlled substances.

### II. BACKGROUND

On September 30, 2009, the Deputy Assistant Administrator, Office of Diversion Control, DEA, issued an Order to Show Cause ("OTSC"), proposing to revoke DEA Certificate of registration BW8002759 of Walgreens #06094 located at 3005 Midway Drive, San Diego, California 92110.

The OTSC alleged that Walgreens #06094 (1) dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances to individuals located in California based on Internet prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice in violation of federal and state law; and (3) dispensed controlled substances to individuals that Walgreens #06094 knew or should have known were diverting the controlled substances. *See* Appendix A (OTSC dated September 30, 2009). In addition to the allegations raised in the OTSC, DEA's investigation also reveals that Walgreens #06094 was allegedly refilling prescriptions for controlled substances too early and had allegedly filled several prescriptions that were issued using expired DEA registration numbers.

The OTSC was served via Certified Mail, Return Receipt Requested on October 5, 2009. On October 26, 2009, Walgreens #06094, through counsel, filed a hearing request with the Administrative Law Judge, wherein Walgreens #06094 generally disputed the factual allegations of the OTSC and disagreed with DEA's position that the DEA registration of Walgreens #06094 should be revoked. *See* Appendix B (Request for Hearing dated October 26, 2009).

The facts alleged above and in the OTSC could, if proven at hearing, constitute a basis to revoke the DEA registration of Walgreens #06094. The Parties, however, desire to settle the administrative matter pending against Walgreens #06094. Moreover, the Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest and entering into this Agreement will ensure nationwide compliance by Walgreens with respect to its pharmacy operations.

In consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, and intending to be legally bound hereby, the Parties hereto agree as follows:

### III. TERMS AND CONDITIONS

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, the Parties agree to resolve this matter according to the Terms and Conditions below.
2. No Admission or Concession. This Agreement is neither an admission by Walgreens of liability or of any allegations made by DEA in the OTSC and its investigation of Walgreens Pharmacy #06094, nor a concession by DEA that its allegations in the OTSC and its investigation of Walgreens Pharmacy #06094 are not well-founded.
3. Covered Conduct for Purposes of this Agreement. "Covered Conduct" shall mean the conduct alleged in the OTSC and described in Section II of this Agreement against Walgreens #06094.
4. Obligations of Walgreens:
  - a. Walgreens agrees to maintain a compliance program to detect and prevent diversion of controlled substances as required under the Controlled Substances Act ("CSA") and applicable DEA regulations. This program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping and requests for early refills. The program shall also include the routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA. This compliance program shall apply to all current and future Walgreens walk-in, retail pharmacies registered with the DEA in the United States and its territories and possessions.
  - b. Walgreens shall implement a system to notify the local DEA office within two business days of a refusal to fill a prescription for controlled substances where such refusal is based on the Walgreens pharmacist's determination that the prescription was forged, altered, and/or issued for other than a legitimate medical purpose by a practitioner acting outside the usual course of professional practice. However, in no case shall Walgreens be required to maintain a record of such refusals. An unintentional failure to meet the two-day notification deadline shall not be deemed a material breach of this Agreement.
  - c. Walgreens shall implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations. Walgreens shall maintain its current policy that requires all customers to provide identifying information such as name, date of birth and/or address when picking up a prescription and shall also require individuals obtaining prescriptions for controlled substances to present valid photo identification as required by and in accordance with controlling state law where the pharmacy is located. Walgreens shall also annotate the prescription file or other record to document the type of identification presented and the number, if any, associated with the identification, if required by state law. Documents maintained by Walgreens pursuant to any obligation under applicable state law regarding the verification of an ultimate user's identity shall be

readily retrievable by the pharmacy, and shall be produced to DEA agents, task force officers or investigators upon request.

- d. Walgreens shall not knowingly fill an invalid prescription or a prescription that it reasonably believes was issued for other than a legitimate medical purpose or by a practitioner acting outside the usual course of professional practice. Walgreens shall comply with state law with regard to dispensing controlled substances based on a prescription written by a prescriber located outside of the state where the patient and pharmacy are located. Walgreens pharmacists shall comply with state law, if applicable, and, where circumstances lead the pharmacist in his or her professional judgment to reasonably doubt the validity of the prescription, verify that a valid prescriber/patient relationship exists before filling a prescription for a controlled substance.
- e. Walgreens shall implement procedures to verify that the DEA registration number for the issuing prescriber of each controlled substance prescription is a valid, active DEA registration number, independent of calling the local DEA office. Such verification shall be performed periodically using the NTIS or similarly-reliable third-party database where DEA registration changes are recorded. Walgreens is not precluded from contacting any DEA office to verify the legitimacy of a DEA registration, however, it is understood that verification of a DEA number does not fulfill all of the obligations of a pharmacist's corresponding responsibility.
- f. In connection with Walgreens' record keeping requirements pursuant to 21 C.F.R. § 1304, Walgreens agrees to maintain records regarding the dispensing of controlled substances in electronic format, in addition to the regularly-maintained, official paper files. These records shall be made available to DEA agents, task force officers or investigators, upon demand, without the need for a warrant or subpoena, provided that the DEA agents, task force officers or investigators present an appropriate form of identification. Walgreens shall provide electronic reports of dispensing on an ad hoc basis in response to requests by DEA within a reasonable time. The paper records shall continue to be the official record and shall be consulted when there is any question as to the accuracy of the electronic records.
- g. All dispensing records submitted by Walgreens to Prescription Monitoring Programs (PMPs) (in those states that have or will implement such a system) shall, to the extent required under applicable state law, contain a prescriber's valid, active DEA registration number. Such information submitted to state Prescription Monitoring Programs shall be extracted from Walgreens' electronic records of dispensing, which shall be available for review by DEA agents, task force officers or investigators.
- h. Walgreens shall provide pharmacists with access to state PMPs and pharmacists shall be required to follow state guidelines and requirements for use and review of information provided by the state PMP on dispensing controlled substances. It is agreed and understood that the pharmacist is ultimately responsible to use his or her professional judgment on whether the information will be useful in determining the appropriateness of filling a prescription for a controlled substance.

- i. Walgreens shall maintain a system to only dispense refills of controlled substances in schedules III – V that are valid and appropriately-authorized. Within six months of execution of this Agreement, Walgreens shall also implement a system to identify and prevent early refills of controlled substances for all cash payments of controlled substances. A pharmacist who, in the exercise of his/her professional judgment determines that a prescription may be refilled early must do so consistent with federal and state laws, regulations or guidelines and provide a reasonable explanation for the early refill. Walgreens shall maintain records regarding the pharmacist's rationale for dispensing such early refill in a manner consistent with other records required to be kept by the pharmacy. These records shall be readily retrievable by the pharmacy and shall be produced to DEA agents and/or investigators upon demand.
  - j. Walgreens currently maintains cameras at every walk-in retail pharmacy, which capture images of the front door and/or the pharmacy counters. Walgreens shall continue to maintain all currently-installed security cameras in these locations. Walgreens understands and takes seriously the need for security in its locations, and will continue to monitor security and make modifications as needed to maintain store security. Walgreens shall implement and maintain procedures to retain recordings from security cameras for at least 30 days. These recordings shall be readily retrievable at pharmacy locations, and shall be produced to DEA agents and/or DEA investigators upon request. To the extent a particular pharmacy's security camera has the technical capability to record beyond the required 30-day period, Walgreens shall endeavor to produce such additional recordings upon request. Nothing in this paragraph, however, shall be construed to require Walgreens to maintain any camera recording beyond the 30-day period described herein.
  - k. Walgreens shall report to the local DEA office, within twenty calendar days after discovery, the initiation of any adverse legal proceeding relating to its pharmacy permit, license or registration, that is known to Walgreens, and is conducted or brought by a government entity or licensing board regarding the dispensing of controlled substances or sale of scheduled listed chemical products.
5. Release by DEA. In consideration of the fulfillment of the obligations of Walgreens under this Agreement, DEA hereby releases and agrees to refrain from filing any administrative actions against Walgreens' DEA registrations based on the Covered Conduct or similar conduct at any other Walgreens pharmacy on or before the effective date of this agreement, within DEA's enforcement authority under 21 U.S.C. §§ 823 and 824. Notwithstanding the release by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct in any other administrative proceedings. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State or political subdivision thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement agency that initiates an investigation, action, or proceeding, involving the Covered Conduct. At Walgreens' request, DEA agrees to disclose the terms of this

Agreement to any other law enforcement agency and will represent that Walgreens' compliance with this Agreement adequately addressed the allegations raised in the administrative proceedings by DEA as defined in the Covered Conduct.

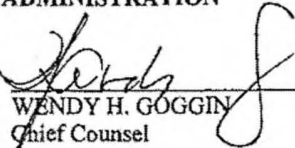
6. Release by Walgreens. Walgreens fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Walgreens has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.
7. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Walgreens) are the following:
  - a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
  - b. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct subject to paragraph 5 of the Agreement;
  - c. Any liability based upon such obligations as are created by this Agreement.
8. Binding on Successors. This Agreement shall inure to the benefit of and is binding on Walgreens, and its respective successors, heirs, transferees and assigns.
9. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
10. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and Released Parties only and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.
11. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the Parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Walgreens represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Walgreens further represents that this Agreement is voluntarily entered into in order to avoid litigation, without duress or compulsion.
12. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"), and remain in effect for a period of three years from the Effective Date. DEA agrees to notify Walgreens immediately when the final signatory has executed this Agreement.

13. Breach of Agreement. Only material and systemic violations of the provisions of this Agreement may constitute a breach of the agreement. Parties shall have a reasonable time to cure any such violation.
14. Effect of Breach. A material breach shall render the Agreement voidable; however, such breach may be waived by the Parties.
15. Disclosure. Walgreens and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.
16. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which constitute one and the same agreement.
17. Authorizations. The individuals signing this Agreement on behalf of Walgreens represent and warrant that they are authorized by Walgreens to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

THE UNITED STATES DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

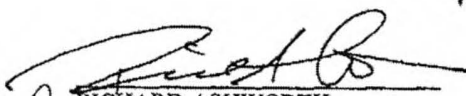
  
JOSEPH T. RANNAZZISI  
Deputy Assistant Administrator  
Office of Diversion Control

Dated: 4/7/11

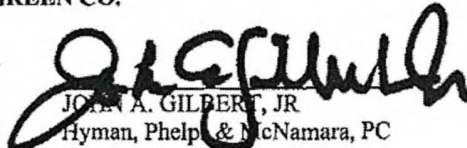
  
WENDY H. GOGGIN  
Chief Counsel

Dated: 4/1/11

WALGREEN CO.

  
RICHARD ASHWORTH  
Divisional Vice President, Pharmacy Services  
Walgreen Co.

Dated: 3/18/2011

  
JOHN A. GILBERT, JR.  
Hyman, Phelps & McNamara, PC  
Attorney for Walgreen Co.

Dated: 3/24/11

# APPENDIX B





Office of the Administrator

Springfield, VA 22152

September 13, 2012

**IN THE MATTER OF**

Walgreen Co.  
15998 Walgreens Drive  
Jupiter, Florida 33478

**ORDER TO SHOW CAUSE AND  
IMMEDIATE SUSPENSION OF REGISTRATION**

**PURSUANT** to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

**NOTICE** is hereby given to inform Walgreen Corporation (“Walgreens” or “Respondent”) of the immediate suspension of Drug Enforcement Administration (“DEA”) Certificate of Registration RW0277752, pursuant to 21 U.S.C. § 824(d), because such registration constitutes an imminent danger to the public health and safety. Notice is also given to afford Walgreens an opportunity to show cause before DEA in Arlington, Virginia, or a location designated by the Administrative Law Judge, on November 13, 2012 (if Walgreens requests such a hearing), as to why DEA should not revoke Walgreens’s DEA Certificate of Registration RW0277752, pursuant to 21 U.S.C. § 824(a)(4), deny any pending applications for renewal or modification of such registration, and deny any applications for additional registration, pursuant to 21 U.S.C. § 823(b) & (e), because Walgreens’ continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(b) & (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following nonexhaustive summary of facts and law (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which DEA construes *in pari materia* in this context.)

1. Walgreens’ Jupiter Florida Distribution Center is registered with DEA as a distributor in Schedules II-V pursuant to DEA Certificate of Registration RW0277752 at 15998 Walgreens Drive, Jupiter, Florida 33478. DEA Certificate of Registration RW0277752 expires by its terms on May 31, 2013. The Jupiter Distribution Center is one of 12 Distribution Centers owned and operated by the Walgreen Corporation,

headquartered in Deerfield, Illinois. Walgreens also operates more than 7800 Walgreens retail pharmacies in the United States.

2. Since at least 2009, the State of Florida has been the epicenter of a notorious, well-documented epidemic of prescription drug abuse. In July 2011, the Florida Surgeon General declared a Public Health Emergency based on the prescription pill epidemic which results in an average of seven overdose deaths per day in Florida. The drugs most commonly associated with this epidemic are typically prescribed at unscrupulous pain clinics by physicians acting outside the usual course of professional practice and include Schedule II pain relievers, such as oxycodone; Schedule IV benzodiazepines such as alprazolam, and Schedule IV muscle relaxers, such as carisoprodol. Frequently, these drugs are prescribed in large amounts and in combination with each other as "cocktails" popular with drug seeking individuals. *See East Main Street Pharmacy*, 75 Fed. Reg. 66149, 66153, (2010); *Paul H. Volkman*, 73 FR 30630, 30633-34, 30639 (2008), *pet. for rev. denied*, *Volkman v. DEA*, 567 F.3d 1215 (6th Cir. 2009).
3. Oxycodone is a dangerously addictive Schedule II controlled substance which is known to be highly abused and diverted in the State of Florida. According to the 2010 Florida Medical Examiner's Commission Drug Report, the drug that caused the most deaths in the state of Florida for 2010 was oxycodone (1,516 deaths), followed by benzodiazepines (1,304 deaths of which 981 were caused by alprazolam.)
4. Since 2009, Walgreens' Jupiter, Florida Distribution Center has been the single largest distributor of oxycodone products in Florida. At about the same time as the abuse of prescription drugs became an epidemic in Florida, Walgreens' Florida retail pharmacies, supplied by Respondent, commanded an increasingly large percentage of the state's growing oxycodone business. In 2010, only 3 Walgreens retail pharmacies were in the top 100 purchasers of oxycodone within Florida. In 2011, 38 Walgreens pharmacies made the top 100 and 6 were in the top 10. Through May 2012, 44 Walgreens pharmacies are in the top 100 oxycodone purchasers, all of them supplied by Respondent.
5. According to DEA records, in 2011, Walgreens operated 7,862 retail pharmacies in the United States. Sixteen of the top 25 largest Walgreens retail oxycodone purchasers, including the top 6 purchasers, were in Florida and supplied by Respondent. The following table shows these 6 stores and their yearly oxycodone purchases for 2009 through 2011:

<u>Store # Location</u>	<u>Oxycodone Purchases by Dosage Unit</u>		
	<u>2009</u>	<u>2010</u>	<u>2011</u>
1. 03629 Hudson, FL	388,100	913,900	2,211,700
2. 03099 Ft. Myers, FL	95,800	496,100	2,165,900
3. 06997 Oviedo, FL	80,900	223,500	1,684,900
4. 03836 Port Richey, FL	344,000	849,000	1,406,000
5. 04391 Ft. Pierce, FL	250,000	881,400	1,329,600
6. 04727 Ft. Pierce, FL	153,500	507,100	1,192,000

6. An ongoing DEA investigation of Respondent's distribution practices and policies, combined with both a general examination of dispensing at Walgreens Florida pharmacies as well as a detailed investigation of the dispensing practices at the six pharmacies identified above, demonstrates that Respondent has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). Respondent failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487 (2007) (revocation based in part on the respondent's recurring distributions of extraordinary quantities of controlled substances to entities that likely diverted the controlled substances by filling unlawful prescriptions, as well as the respondent's failure to conduct due diligence sufficient to protect against the diversion of the controlled substances it distributed).
7. DEA's investigation of Respondent also revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. §1301.74(b). 21 C.F.R. § 1301.74(b) (distributors are required to "design and operate a system to disclose to the registrant suspicious orders of controlled substances . . . suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."); *see also Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,502 (finding that the respondent repeatedly violated federal regulations by failing to report suspicious orders). Walgreens knew or should have known about their obligations to report suspicious orders, as such obligations were spelled out in detail in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Respondent, on September 27, 2006, February 7, 2007, and December 27, 2007. The purpose and proper implementation of suspicious order reporting programs was further discussed in the industry's own trade association, the

Healthcare Distribution Management Association (HDMA), in "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" published in 2008.<sup>1</sup>

8. Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at Respondent's customer pharmacies. *See* 21 C.F.R. § 1301.74(b); *see also Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487 (2007).
9. Respondent's practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled "Suspicious Control Drug Orders." Two reports were provided, one for suspicious orders of Schedule II drugs, another for suspicious orders of drugs in Schedules III through V. These reports were transmitted on Respondent's behalf from Walgreens Corporate headquarters in Deerfield, Illinois. Respondent's suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico. The reports are based on a formula that assigns an average monthly order for a particular drug, which is then multiplied by a "DEA factor" (which is always 3, regardless of the drug or the average order amount), resulting in a "Trigger" amount, above which orders for the month are reported as suspicious, along with a listing of all orders placed for the particular drug by the reported pharmacy for the month in which the "Trigger" amount was exceeded. This report from the Jupiter Distribution Center covers pharmacies in multiple states and Puerto Rico, yet the average order and trigger amount is the same for a particular drug regardless of the pharmacy's location, the population it serves, or the number of other pharmacies in the area.
10. As made clear in 21 CFR §1301.74(b), *Southwood*, and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported *as discovered*, not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place *before* the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order's legitimacy is concluded. As such, Respondent's reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title Respondent attached to these reports.

<sup>1</sup> See [http://www.healthcaredistribution.org/gov\\_affairs/pdf\\_controlled/20081113\\_icg.pdf](http://www.healthcaredistribution.org/gov_affairs/pdf_controlled/20081113_icg.pdf).

11. A review of the documents Respondent provided as evidence of its "due diligence" on the above listed six pharmacies, demonstrates that Respondent failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels. In response to DEA requests, Respondent has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores.
12. Respondent's employee with overall responsibility for Schedule II drug operations (the "CII Function Manager"), raised questions within the corporation about what she correctly identified as unusually large orders for Schedule II narcotics placed regularly by several customer pharmacies. Based on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy. For example:
- a. In January 2011, Jupiter's CII Function Manager expressed concern about the enormous volume of 30 mg oxycodone being ordered by three stores, Walgreens #'s 7298, 3836, and 5018, concluding in an email to the "Manager, Rx Inventory Drug Stores" at Walgreens' Corporate Headquarters in Deerfield, Illinois, that she felt the stores needed "to justify the large quantity." With regard to store # 3836 in Port Richey, Florida, she noted that Respondent had shipped this store 3271 bottles of 100 count 30 mg oxycodone (i.e., 327,100 dosage units) in the 40 day period from 12/1/10 to 1/10/11, causing her to question "*how they can even house this many bottle[s].*" She then inquired of the same corporate manager: "*How do we go about checking the validity of these orders?*"
  - b. Despite having raised these concerns from the distributor to a supervisor at corporate headquarters, none of these orders were reported as suspicious and there appears to have been no other inquiry conducted into the circumstances of the enormous amount of narcotics being shipped to store # 3836 in Port Richey, a town of less than 3000 people in a county with a population of only approximately 475,000. Despite the fact that a distribution center manager had raised questions about this store's ordering volume to a corporate manager in January 2011, the very next month, Respondent filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy. Again, there is no evidence of any due diligence conducted by Respondent or anyone else within the corporation to verify the legitimacy of these orders in order to fulfill their obligation to maintain effective controls against diversion.
13. According to documents received from Walgreens Corporate Headquarters, on April 2, 2012, Walgreens revised its suspicious order policy, but made the policy retroactively effective to January 1, 2012. The policy states, in pertinent part, that "Effective calendar year 2012, the Controlled Substance Order Monitoring and Prevention System prevents suspicious control drugs from being shipped to the stores. In calendar year 2012, because of the program mentioned, suspicious control drug reports are no longer generated as their shipment is prevented by the system."

14. This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to *orders*, not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood*, is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." 72 FR at 36501.
15. Respondent's local DEA field office within the Miami Field Division has not received a suspicious order report for any orders placed in 2012, despite the fact that Respondent has received and shipped multiple orders this year that, using the criteria Walgreens employed in 2011, would have exceeded the trigger amount previously used to report these sales.
16. The available evidence suggests that Respondent's abdication of its responsibilities as an individual registrant was at least facilitated by a push from Walgreens Corporate headquarters to increase oxycodone sales at its Florida retail pharmacies, all of which received their Schedule II controlled substances from Respondent. I also note that during the relevant time herein, Walgreens had in effect compensation programs for pharmacy employees in which bonuses were based on the number of prescriptions filled at the pharmacy. This bonus program, combined with a concerted, corporate directed effort to increase oxycodone sales, served as an incentive for pharmacists and pharmacy technicians to ignore the "red flags" of diversion presented by these prescriptions, many of which, in the proper exercise of the pharmacist's corresponding responsibility under 21 CFR §1306.04(a), should have resulted in a refusal to fill.
- a. In July 2010, Walgreens' corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11 page spreadsheet, ranking all Florida stores by the number of oxycodone prescriptions dispensed in June. The spreadsheet was sent to Walgreens' market pharmacy supervisors in Florida on July 29, 2010, with the admonition that they "*look at stores on the bottom end ... We need to make sure we aren't turning legitimate scripts away. Please reinforce.*" A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their "*busiest store in Florida*" was filling almost 18 oxycodone prescriptions per day, yet "*We also have stores doing about 1 a day. Are we turning away good customers?*"
- b. At roughly the same time as Walgreens' supervisors were urging its Florida pharmacies to increase their oxycodone sales, Florida enacted new laws to combat the prescription drug abuse problem, particularly the devastating effects of oxycodone and other abused drugs dispensed directly from rogue pain clinics, commonly known as "pill mills." These new laws went into effect on October 1, 2010 and severely restricted the ability of pain clinics and physicians to dispense controlled substances directly from the clinics. The purpose of these legislative changes was to stem the overwhelming tide of controlled substances being

diverted from pill mills and into illicit channels for sale and recreational abuse. As a result, Florida pharmacies and the distributors who served them knew or should have known that starting in late 2010, there would be a significant increase in requests to dispense pursuant to prescriptions issued by physicians associated with the pain clinics.

- c. Walgreens store # 06997 in Oviedo, Florida, was ranked 444<sup>th</sup> on the above-referenced Walgreens' ranking of oxycodone sales generated at its Florida retail pharmacies, filling on average only 4 oxycodone prescriptions per day in June 2010. DEA tracks pharmacy activity not by prescriptions but by dosage units of a particular drug purchased by the pharmacy for retail sales. In 2010, the national average for oxycodone sales to retail pharmacies was 70,395 dosage units per year, or about 5,866 dosage units per month. This store's oxycodone sales began to increase drastically, as shown by the fact that in June 2010, Walgreens store #06997 purchased just 6,600 dosage units of oxycodone products. One year later, in June 2011, this same pharmacy purchased 169,700 dosage units of oxycodone.
- d. Oviedo is a town of about 34,000 people and is home to two Walgreens retail pharmacies. Beginning in late 2010, these two pharmacies became the site of multiple arrests by the local police for drug offenses. The local Chief of Police began writing letters to the pharmacies after each arrest stemming from prescriptions they filled. These letters informed the pharmacy of the circumstances of the arrest and that the dispensed drugs were not being used for treatment. They further provided the pharmacy with the name and date of birth not only of the person whose prescription they filled, but also of others associated with the illegal distribution of the dispensed drugs. These letters then concluded with a request for the pharmacy's help in "dealing with the prescription medication epidemic" by soliciting a commitment to stop further incidents.
- e. The Oviedo Police Chief's concerns reached the highest levels of Walgreens' Loss Prevention Operations, with the Director of Divisional Loss Prevention noting in an email on January 28, 2011 that "*[e]vidently the Chief of Police is concerned that we are filling too many C2 prescriptions.... From what I've been told, he is referencing 100 plus incidents/arrests in his jurisdiction.*" Walgreens' response was to "*take a look at this market . . . and see if we have an increase in dispensing.*"
- f. The Oviedo Police Chief convened a meeting with Walgreens Loss Prevention officials on February 10, 2011, in an effort to further bring awareness of the problems he was seeing at their stores and to brief them on the number of arrests at each location. On March 15, 2011, he sent identical letters to both the Chairman and CEO of Walgreens, asking them for their support and assistance in combating the prescription drug epidemic, informing them that Oviedo "*has seen the parking lots of your stores become a bastion of illegal drug sales and drug use*" where once the prescriptions are filled, "*the drugs are sold, distributed as payment, crushed and snorted, liquefied and injected, or multiple pills swallowed while in the parking lot of your pharmacies.*"

- g. Despite being informed at the highest levels of ongoing diversion and drug-related criminal activity directly stemming from dispensing at these pharmacies, and bearing in mind that the average U.S. retail pharmacy in 2011 purchased only 73,000 dosage units of *all formulations of oxycodone for the entire year*, the Walgreens corporation, through Respondent, responded to this information about one of its stores by shipping the following quantities of 30 milligram formulation oxycodone to Oviedo store 06997:

(i) February 2011	75,300 dosage units
(ii) March 2011	72,900 dosage units
(iii) April 2011	101,700 dosage units
(iv) May 2011	133,900 dosage units
(v) June 2011	115,200 dosage units
(vi) July 2011	145,300 dosage units

- h. Perhaps even more significant than the enormous amount of oxycodone Respondent shipped to this store despite the information provided by the Chief of Police to its pharmacists and most senior leaders, is the fact that the dispensing records for both Oviedo Walgreens pharmacies show that on multiple occasions, they each dispensed additional prescriptions of commonly diverted narcotics to the same individuals who they knew had been previously arrested for drug offenses at their pharmacies. I find this to be a staggering disregard of Walgreens' obligations under the Controlled Substances Act.

17. While the detailed information provided by the Chief of Police put Respondent and its parent company on notice of actual diversion occurring at the two Oviedo pharmacies, Respondent had ample other indications that its pharmacies were direct and significant contributors to the epidemic of prescription drug abuse and diversion in Florida, yet it largely ignored these indicators, at all levels of the corporate structure. An inexhaustive description of some of these indicators are the following:

- a. On September 27, 2010, a pharmacist working at Walgreens # 04727 in Ft. Pierce reported to law enforcement that he mistakenly provided an extra 120 dosage units of 15 milligram oxycodone to a customer. When the pharmacist tried to call the customer to request he return the mistakenly dispensed oxycodone, he was told by the customer's girlfriend that the customer was an addict who sells his pills and views the extra oxycodone as a "pot of gold" which he would not return. Despite this incident, Walgreens # 04727 filled several additional oxycodone prescriptions issued to this customer in December 2010 and January 2011.



- b. On November 4, 2010, a Walgreens # 04727 pharmacist reported to police that she dispensed a prescription for 60 dosage units of oxycodone 15mg to a twenty-four year old male who she then witnessed transfer the drugs to a female in the store. The female entered the pharmacy restroom, leaving behind evidence indicating she had smoked the oxycodone. Despite this incident, Walgreens # 04727 continued to fill the same customer's oxycodone and alprazolam prescriptions on several occasions in November and December 2010 and January 2011.
- c. On December 21, 2010, a pharmacist employed by Walgreens Pharmacy # 3629 in Hudson, Florida reported to the Pasco County (Florida) Sheriff's Office that an individual had attempted to fill a prescription for 270 dosage units of thirty milligram oxycodone, but ran from the pharmacy after learning the pharmacy had contacted law enforcement, suspecting the prescription was a forgery. Despite this incident, the same pharmacy that reported this customer to the Sheriff's Office in December continued to fill the same customer's oxycodone prescriptions in February, March, April, May and October of 2011.
18. On or about March 2011, corporate officials at Walgreens headquarters in Illinois initiated a Florida pharmacy store review initially entitled "Focus on Profit" and later changed to "Focus on Compliance." The purpose of this review was to address the "significant increase in the number of [Schedule II controlled substance] prescriptions we are filling in [Florida]" after the October 2010 change in Florida law regarding pain clinics. The initial pilot survey asked the following questions, amongst others: "Do pain management clinic patients come all at once or in a steady stream?" and "Do you see an increase in pain management prescriptions on the day the warehouse order is received?" On May 17, 2011, in an email with the subject heading "Florida Focus on Profit," a Walgreen Co. corporate attorney reviewed the survey and regarding these two questions, stated "*If these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance.*" The surveys that ultimately were used in the Focus on Compliance initiative did not contain those questions. By omitting these questions in order to avoid gathering information pertinent to whether or not pain clinic patients were engaged in diversion, the Walgreens Corporation and Respondent as a corporate subsidiary, ignored its statutory and regulatory obligation to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. See 21 U.S.C. § 823(b) and (e).
19. Apparently as part of this "Focus On Compliance," Walgreens sought to develop and implement "Oxycodone Action Plans" within its districts in Florida in an attempt to reduce the volume of oxycodone dispensing on behalf of pain clinics. For store # 3629 in Hudson, the plan devised by District Pharmacy and Loss Prevention supervisors in a memo dated August 23, 2011 included "*contacting the Jupiter warehouse and designating order limits for Oxycodone.*" The plan, effective immediately, was to "limit" the Hudson store to orders of no more than 100 bottles of 100 count 30 milligram oxycodone. Notwithstanding the memo and the plan to limit store #3629's purchases to no more than 100 bottles, Respondent subsequently

shipped the following orders to store 3629:

<u>Date</u>	<u>Bottles</u>	<u>Dosage Units</u>
09/26/11	331	33,100
10/10/11	371	37,100
11/29/11	200	20,000
12/06/11	113	11,300
12/13/11	150	15,000

Respondent's inability to enforce a very simple, modest limitation on this one pharmacy is further evidence of its failure to maintain effective controls against diversion, even in the rare instance when it tried to do so.

20. In mid to late 2011 and continuing into 2012, Walgreens undertook to reduce the volume of oxycodone dispensing at its high-volume pharmacies and in some cases, did, in fact, achieve a relatively significant reduction in Schedule II dispensing at these stores. Additionally, in late May, 2012, approximately seven weeks after Administrative Inspection Warrants were served on six Walgreens retail pharmacies and Respondent, Walgreens suspended dispensing of Schedule II drugs as well as Alprazolam and Carisoprodol at these six pharmacies and two others. In my assessment of the imminent danger posed by Respondent's continued registration, I have considered these remedial measures, as well as Walgreens' claims that it continues to revise its suspicious order reporting system to prevent the excesses that occurred in 2010 and 2011. In my judgment, and in the exercise of the discretion afforded me by 21 U.S.C. § 824(d), the danger posed by Respondent's continued registration is only slightly mitigated by the dispensing restrictions enacted at these eight pharmacies.
21. To reiterate, my concerns with Respondent's distribution practices are not limited to the six Walgreens pharmacies discussed herein. Respondent distributes to over 800 other retail pharmacies in Florida alone, many of which dispense oxycodone in amounts far in excess of the U.S. and Florida averages and which also experienced dramatic increases in their distribution of oxycodone from at least 2009 to the present. No fewer than 43 Walgreens pharmacies in Florida purchased in excess of 500,000 dosage units of oxycodone in 2011, despite a national average of approximately 74,000 dosage units for all U.S. pharmacies and an average of approximately 110,00 dosage units for all Florida Walgreens pharmacies. Florida remains the epicenter of this country's prescription drug abuse problem and notwithstanding the cessation of Schedule II dispensing at eight of its retail customers, Respondent remains the top distributor of the most dangerous prescription drugs in Florida, and still has not made a single suspicious order report in calendar year 2012.

22. Through May of this year, Respondent's customers included 44 Walgreens retail pharmacies on the list of the 100 top oxycodone purchasing pharmacies in Florida.<sup>2</sup> Respondent continues to distribute large amounts of oxycodone while it appears to continue to misunderstand or ignore its obligation to maintain effective controls against diversion by reporting suspicious orders and conducting due diligence on its customer stores to verify the legitimacy of their orders. Thus, the fact that Walgreens stopped selling Schedule II controlled substances to a handful of retail pharmacies – virtually all of which Walgreens also knew were themselves under DEA investigation at the time Walgreens stopped distributing to these pharmacies – does little to mollify my concerns about the danger posed by Respondent's continued operation. The nature and significance of the problems revealed by DEA's investigation indicate that Respondent's anti-diversion measures are inadequate generally; the problems do not appear to be limited to the pharmacies discussed herein. Consequently, I believe that Respondent's continued operation poses an imminent danger to public health and safety.
23. Voluntary dispensing restrictions enacted either in anticipation of, or in reaction to regulatory action, do not indicate to me that Respondent and its parent company have recognized and adequately reformed the systemic shortcomings discussed herein. On the contrary, when a company undertakes to survey its stores for regulatory compliance, then selectively edits that survey for the explicit purpose of avoiding evidence of its own non-compliance, as Walgreens apparently did in May 2011, claims of effective remedial measures have less credibility. I gave significant weight to the fact that Walgreens appears to have deliberately structured certain of its anti-diversion measures to avoid learning about and/or documenting evidence consistent with diversion. At best, I regard this as deliberate indifference on Walgreens' part as to its obligations as a DEA registrant.
24. My confidence in Walgreens' remedial measures is lessened further by the fact that this manipulation of the compliance survey occurred just one month after Walgreens entered into a nationwide Memorandum of Agreement (MOA) with DEA to resolve an Order to Show Cause issued to a San Diego Walgreens pharmacy based on allegations of unlawful dispensing. Walgreens pledged in this MOA to enact a compliance program at all of its retail pharmacies to detect and prevent diversion of controlled substances and to implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations. Walgreens' effort to enact such a program in Florida appears to have been, in part, intentionally skewed to avoid actually detecting certain evidence of possible diversion. That Walgreens would actively seek to avoid documenting evidence of possible diversion in its "Focus on Compliance" in Florida immediately after entering this MOA, further contributes to my preliminary finding that Respondent's continued registration during

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<sup>2</sup> By way of comparison, only two other national or regional chain pharmacies have stores on this list, one of which has four stores in the top 100, while the other has three.

the pendency of this proceeding constitutes an imminent danger to the public health and safety.

IN view of the foregoing, and based on information before the Agency as of the issuance of this notice, it is my preliminary finding pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), that Walgreens' continued registration is inconsistent with the public interest. Under the summarized facts and circumstances described herein, it is also my preliminary finding, significantly in light of the rampant and deadly problem of prescription controlled substance abuse in Florida, that Respondent's continued registration while these proceedings are pending constitutes an imminent danger to the public health and safety. See 21 U.S.C. § 824(d). Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0277752 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.<sup>3</sup>

**PURSUANT** to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Walgreens possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession Walgreens's DEA Certificate of Registration RW0277752 and any unused order forms.

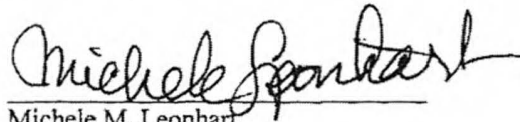
**THE** following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Walgreens may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. See 21 C.F.R. § 1301.43(a). If Walgreens fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Walgreens may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. See 21 C.F.R. § 1301.43(c).
3. Should Walgreens decline to file a request for a hearing or, should Walgreens request a hearing and then fail to appear at the designated hearing, Walgreens shall be deemed to have waived the right to a hearing and the DEA may cancel

<sup>3</sup> I have primarily addressed Schedule II controlled substances based on Walgreens' representations that Respondent no longer distributes controlled substances other than Schedule II. This should not be construed as an indication that DEA has concluded that Respondent's distribution practices relating to non-schedule II controlled substances conform to all applicable requirements and obligations. To the contrary, many of the problematic distribution practices noted herein would raise imminent danger concerns with respect to non-Schedule II controlled substances if Respondent were to continue to distribute them.

such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrisette Drive, Springfield, VA 22152.



Michele M. Leonhart  
Administrator  
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges  
Scott Lawson, Counsel for the Government  
Jonathan Novak, Counsel for the Government

**REQUEST FOR HEARING**

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters  
Office of the Administrative Law Judges  
Hearing Clerk  
8701 Morrisette Drive  
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant  
or attorney]

**Note:** Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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**UNITED STATES DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION**

**IN THE MATTER OF**

**WALGREEN, CO.**

**DOCKET NO. 13-01**

**ADMINISTRATIVE LAW JUDGE  
JOHN J. MULROONEY, II**

**GOVERNMENT'S PREHEARING STATEMENT**

Scott Lawson  
Jonathan Novak  
Attorneys  
Diversion & Regulatory Litigation  
Office of Chief Counsel  
8701 Morrisette Drive  
Springfield, VA 22152  
Tel: 202.307.8038  
Fax: 202.307.4946

Date: October 31, 2012

[https://www.dea.gov/divisions/mia/2013/mia061113\\_appendixb.pdf](https://www.dea.gov/divisions/mia/2013/mia061113_appendixb.pdf)



Pursuant to the October 15, 2012 Order for Prehearing Statements, as modified by the October 18, 2012 Order Granting the Respondent's Motion For a Continuance and Amending the Order for Prehearing Statements, the United States Department of Justice, Drug Enforcement Administration (DEA or Government), hereby submits its Prehearing Statement.<sup>1</sup>

### I. ISSUE

Whether DEA should revoke DEA Certificate of Registration RW0277752 issued to Walgreen Co. ("Respondent"), pursuant to 21 U.S.C. §§ 824(a)(4) and 823(b) and (e) and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(b) and (e).

### II. REQUESTED RELIEF

The Government requests revocation of Respondent's DEA Certificate of Registration RW0277752.

### III. PROPOSED STIPULATIONS OF FACT<sup>2</sup>

1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA Registration RW0277752 at 15998 Walgreens Drive, Jupiter, Florida 33478.
2. DEA Registration Number RW0277752 expires by its terms on May 31, 2013.

### IV. PROPOSED WITNESSES<sup>3</sup>

1. Joseph Rannazzisi  
Deputy Assistant Administrator for Diversion Control  
DEA Headquarters  
8701 Morrissette Drive

<sup>1</sup> The Government is filing separately a Motion For an Extension of Time to file this Prehearing Statement, which was originally due on October 29, 2012. The Government was unable to file by this date due to Hurricane Sandy and the resulting closure of the federal government on October 29 and 30, 2012.

<sup>2</sup> The Government anticipates discussing additional stipulations with Respondent.

<sup>3</sup> At this time the Government has not noticed an expert witness. The Government requests the opportunity to supplement its intended witnesses and testimony if it determines that such an expert is necessary in the presentation of its case, and particularly, if Respondent intends to utilize an expert witness.

Springfield, Virginia 22152

2. Susan Langston  
Diversion Program Manager  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
3. Kyle Wright  
Chief, Targeting and Analysis Unit  
DEA Headquarters  
8701 Morrissette Drive  
Springfield, Virginia 22152
4. Donna Richards  
Acting Diversion Group Supervisor  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
5. Phyllis Garrett  
Diversion Investigator  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
6. Chief Jeffrey Chudnow  
Oviedo Police Department  
300 Alexandria Boulevard  
Oviedo, Florida 32766
7. Robert Varno  
Walgreen Co.  
15998 Walgreens Drive  
Jupiter, Florida 33478
8. Christine Atwell  
Walgreen Co.  
15998 Walgreens Drive  
Jupiter, Florida 33478
9. Kathy L. Federico  
Diversion Group Supervisor  
Milwaukee District Office  
4725 West Electric Avenue  
West Milwaukee, Wisconsin 53219

10. George Corripio  
Pharmacist  
Walgreen Co. Store # 5079  
2423 Orange Ave.  
Ft. Pierce, Florida
11. Edward J. Lanzetti  
Walgreen Co. Market Loss Prevention Director  
7003 Presidents Dr., #250  
Orlando, Florida 32809

## V. SUMMARY OF TESTIMONY

### 1. Deputy Assistant Administrator Joseph Rannazzisi

Deputy Assistant Administrator Rannazzisi will describe his background, education and training as a DEA Deputy Assistant Administrator, a law enforcement officer, and a licensed pharmacist. He will further testify substantially as follows:

Prescription drug abuse occurs in the United States at an alarming rate. The 2010 National Survey on Drug Use and Health reveals that approximately 7 million Americans abuse controlled substance pharmaceuticals for non-medical purposes. Second only to marijuana, controlled substance prescription drugs are abused by more people than cocaine, heroin, hallucinogens and inhalants combined. Of all prescription drugs, narcotic pain relievers such as oxycodone, hydrocodone, and oxymorphone are abused most frequently. Each year, roughly 5.1 million people abuse narcotic pain relievers in the United States.

Beginning in late 2008 and continuing to the present, there has been a significant rise in the number of rogue pain clinics whose complicit doctors were initially permitted to dispense millions of dosage units of oxycodone and other abused drugs directly from the clinics. Florida is the epicenter for these illegal pain clinics. DEA, State and local law enforcement investigations reveal that thousands of drug seekers flock to these Florida-based pain clinics to obtain their supply of oxycodone, and other controlled substances such as alprazolam, which is

in turn illegally redistributed in states along the entire east coast and Midwest.

The illicit pain clinics, the pharmacies that fill their scripts, and the wholesale distributors who supply pharmacies without appropriate due diligence (including Respondent), have caused, and continue to cause, millions of dosage units of oxycodone and other controlled substances to be diverted, posing a serious threat to the public health and safety. According to the Florida Medical Examiner's Office, they have seen a 345.9% increase in the number of overdose deaths associated with oxycodone between 2005 and 2010. For 2010, their data showed that approximately 4,091 persons died in Florida alone from an overdose caused by just five drugs: methadone, oxycodone, hydrocodone, benzodiazepines, or morphine.

Furthermore, the abuse of prescription drugs is not isolated to just one drug. Abusers and addicts routinely abuse prescription drugs in combination with one another to enhance the effects. This activity significantly increases the risk of potential harm to the individual. This combination is often referred to as a "cocktail" of hydrocodone or oxycodone used in combination with alprazolam (a benzodiazepine) and carisoprodol. According to the Florida Medical Examiner's Office, they have seen a 127% increase in the number of deaths associated with benzodiazepines in the State of Florida between 2005 and 2010.

On July 1, 2011, the State Health Officer and Surgeon General, Dr. Frank Farmer issued a statewide public health emergency declaration in response to the ongoing problem of prescription drug abuse and diversion in Florida. The press release accompanying this emergency declaration noted more oxycodone is dispensed in the state of Florida than in all remaining states combined. It further stated that in 2010, "98 of the top 100 doctors dispensing Oxycodone nationally were in Florida"; and that "126 million oxycodone pills were dispensed through the top 100 dispensing pharmacies in Florida".

Following changes in Florida law aimed at curbing the problematic dispensing direct from the pain clinics, drug abusers have found other ways to obtain oxycodone and other “cocktail” drugs. Rather than dispensing the drugs directly to “patients,” pain clinics and complicit doctors are now forced to write prescriptions for oxycodone and other abused drugs. Drug abusers wanting their prescriptions filled must take their prescriptions to a retail pharmacy. The result was that law enforcement saw immediate and significant increases in the volume of oxycodone dispensed from retail pharmacies across the state of Florida. Retail pharmacies are generally supplied by a DEA-registered wholesale distributor. The doctors and clinics that prescribe oxycodone inappropriately, the pharmacies that dispense their prescriptions, and the wholesale distributors who supply them have caused, and continue to cause, millions of dosage units of oxycodone to be diverted for unlawful use thereby creating an imminent threat to the public health and safety.

Deputy Assistant Administrator Rannazzisi will authenticate and describe the purpose behind three letters sent by DEA to all distributors and manufacturers, including Respondent, on September 27, 2006, February 7, 2007, and December 27, 2007. These letters explained to distributor registrants their obligations to maintain effective controls against diversion and report suspicious orders as part of their duties within the closed system established by the Controlled Substances Act (CSA). He will describe the purpose of the suspicious order requirement of 21 C.F.R. §1301.74(b) and its relationship to the statutory obligation of all distributors to maintain effective controls against diversion of controlled substances pursuant to 21 U.S.C. §§ 823(b)(1) & 823(d)(1). Consistent with the guidance of these letters, he will describe a distributor’s obligation to devise and implement an effective system to identify suspicious orders and the obligation to report suspicious orders to DEA as they are discovered. He will further testify that

a distributor has an obligation under the statutory and regulatory scheme to determine the legitimacy of any order it identifies as suspicious prior to fulfilling that order.

He will further testify that distributors have a statutory obligation to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels and that the exercise of this obligation requires a distributor to confirm the legitimacy of all orders prior to filling. He will describe the general ways in which distributors commonly perform and document this due diligence and will describe common indicators of diversion that all distributors should be alert to at their customer pharmacies. He will testify that these obligations apply equally to distributor registrants regardless of whether their customers are independent or chain pharmacies and regardless of whether the distributor and its customers are under common ownership.

Based on the evidence of its' suspicious order program provided by Respondent, he will testify that the Walgreen Co.'s suspicious order program fails to comply with Respondent's obligations under 21 C.F.R. §1301.74(b). He will testify that the "Suspicious Control Drug Orders" report provided to DEA on Respondent's behalf monthly by Walgreen Co. corporate headquarters constitutes nothing more than a monthly report of completed transactions and therefore does not meet the regulatory requirement to report suspicious orders as discovered, as is spelled out in his December 27, 2007 letter to Respondent. In other words, despite the title attached to these compilations of completed transactions, he will testify that they are not suspicious order reports under the regulation. Furthermore, he will testify that based on the documents provided by Walgreen Co., Respondent appears to have conducted little to no investigation or analysis of the orders it reported as suspicious prior to completing the sale of these orders, despite the fact that on a single day, many of these orders greatly exceeded the

monthly threshold established by Respondent for reporting orders of a particular controlled substance as suspicious.

Moreover, he will testify that the monthly reports of completed "suspicious" transactions reported by Respondent were misleading in that they did not report each order received and shipped by Respondent, but instead aggregated the orders shipped on any given day. Further, he will testify that the reports made by Respondent are flawed in that they include all orders for a particular controlled substance shipped to a particular pharmacy in a given month and do not indicate which of these orders are being reported as suspicious. He will testify that based on the foregoing, Respondent did not make a single proper suspicious order report, despite a history of supplying its customers, particularly but not limited to its Florida retail pharmacies, incredibly large amounts of the most commonly abused and diverted controlled substances.

He will testify regarding the Walgreen Co.'s current suspicious order policy, applicable to all of its distribution centers, including Respondent, which indicates that as of January 1, 2012, the company will no longer make suspicious order reports as a result of a system that supposedly prevents shipment of any suspicious orders. He will testify that such a policy evidences a misunderstanding of the suspicious order reporting requirement, which is triggered by suspicious orders for controlled substances, not only when such an order is actually shipped. He will testify that this operating statement on behalf of Respondent is further evidence of the lack of an appropriate system under 21 C.F.R. § 1301.74(b) and is indicative of ineffective controls against the diversion of controlled substances.

Finally, he will discuss the additional requirements imposed upon the Walgreen Co.'s operation of its retail pharmacies by the Memorandum of Agreement entered into between DEA and Walgreen Co. in April, 2011.

**2. Susan Langston, Diversion Program Manager (“DPM”), Miami Field Division (MFD)**

DPM Langston will testify to her background, education and training as a DEA Diversion Investigator, Diversion Group Supervisor, and Diversion Program Manager. She will testify substantially as follows:

Since at least 2009, the State of Florida has been the epicenter of a notorious, well-documented epidemic of prescription drug abuse. In July 2011, the Florida Surgeon General declared a Public Health Emergency based on the prescription pill epidemic which results in an average of seven overdose deaths per day in Florida. The controlled substances most commonly associated with this epidemic are typically prescribed at unscrupulous pain clinics by physicians acting outside the usual course of professional practice and include Schedule II pain relievers, such as oxycodone (which is highly addictive and known to be highly abused and diverted in the State of Florida); Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol. Frequently, these controlled substances are prescribed in large amounts and in combination with each other as “cocktails” popular with drug seeking individuals. According to the 2010 Florida Medical Examiner’s Commission Drug Report, the drug that caused the most deaths in the State of Florida for 2010 was oxycodone (1,516 deaths), followed by benzodiazepines (1,304 deaths of which 981 were caused by alprazolam). DPM Langston will testify regarding changes to Florida law aimed at curbing this problem that restricted the ability of practitioners to dispense controlled substances to patients and how the epidemic of controlled substance drug abuse and diversion has now shifted to pharmacies.

DPM Langston will explain why Respondent and 6 of its retail pharmacy customers were targeted for investigation. She will testify about statistical information compiled by DEA’s



ARCOS (“Automation of Reports and Consolidated Orders System”) unit, identifying the largest distributors of oxycodone and related controlled substances in Florida, as well as the largest retail pharmacy purchasers of these substances in Florida from 2008 to the present. She will introduce charts showing these pharmacies’ oxycodone purchases from at least 2008 to the present and describe why the size and frequency of these purchases should have created suspicion within Walgreen Co. and Respondent that these pharmacies were diverting controlled substances.

She will testify that on August 19, 2011, DEA met with Walgreens personnel at the DEA MFD offices in Weston, Florida to apprise them of relevant ARCOS information about Walgreens’ sales of oxycodone in Florida. Present from Walgreens were Dwayne Pinon (corporate in-house counsel), Ed Forbes (Market Loss Prevention Director), Wesley Rohn (Pharmacy District Supervisor), Joan Bustelo (Pharmacy District Supervisor), Anne-Marie Aldrich (Pharmacy District Supervisor), Cesar Cedeno (Pharmacy District Supervisor), Georgia Lehoczky (Market Pharmacy Director), Robert Espinosa (Pharmacy Supervisor), Lakeisha Axem (Pharmacy Supervisor), Sandra Vazquez (Pharmacy Supervisor) and Susan Thompson, Loss Prevention Manager. She will testify that the Walgreens officials at this meeting were told, amongst other things, that 20 Florida Walgreens pharmacies were in the top 300 of oxycodone purchasers in the United States for the first half of 2011 and within the State of Florida over the same time frame, 100 of the top 300 pharmacy oxycodone purchasers were Walgreens retail pharmacies. Moreover, Florida Walgreens pharmacies purchased more than double the average amount of oxycodone purchased by Florida pharmacies.

DPM Langston will discuss the “Suspicious Control Drug Order” reports received by DEA from Walgreens. She will testify that these reports were sent to DEA from Walgreens Loss

Prevention officials at corporate headquarters in Illinois on behalf of the Jupiter Distribution Center. She will discuss the contents of these reports, how frequently they were submitted, and what DEA was able to glean from an examination of these reports. DPM Langston will testify that the reports were not in compliance with DEA's clear edict regarding what should and should not be contained in a suspicious order report. She will also testify that in 2012, DEA has not received a single suspicious order report from either Walgreens Corporate Headquarters or from the Jupiter distribution center.

DPM Langston will discuss the execution of Administrative Inspection Warrants (AIW), on April 4, 2012 at six Walgreens pharmacies and Respondent, along with the service of an administrative subpoena for additional records from Respondent, the six pharmacies, and their corporate headquarters. She will testify regarding the meaning of the subpoena's request for "due diligence" files and her efforts to communicate this concept to Respondent. Further, she will testify to the types of information traditionally found within such files maintained by distributor registrants and the traditional steps distributors undertake to monitor their customers and assess whether or not they are involved in diversion.

She will also introduce emails produced by Walgreens in response to the subpoena, in which the corporation urges its Florida pharmacy supervisors to increase their oxycodone sales and she will discuss other emails indicating that Walgreens' officials were aware of excessive dispensing at some of these 6 pharmacies, all of whom received their Schedule II controlled substances from Respondent. She will discuss Walgreen Co.'s dispensing guidelines for its Florida pharmacies and the development and results of a survey entitled "Focus on Compliance", the purpose of which was to assess the scope of the diversion problem at Walgreen's Florida pharmacies.

DPM Langston will testify about multiple specific suspicious orders placed by the six related Walgreens pharmacies during 2011, which were filled despite their suspicious nature and without Respondent conducting any due diligence to ensure these orders were not being diverted. DPM Langston will discuss the specific order dates, the objective suspicious factors related to the orders, such as size and quantity, as well as the subjective factors creating a situation in which Walgreens knew or should have known that the orders were suspicious and that these pharmacies' dispensing practices posed an unreasonable risk of diversion. DPM Langston will discuss due diligence steps that could have and should have been taken before the distribution center shipped the orders. She will also describe numerous "red flags" of diversion evident from a review of the records available to Respondent from the individual pharmacies it served.

### **3. Office of Diversion Control, Unit Chief Kyle Wright**

Mr. Wright will testify to his background, education and training as the Targeting and Analysis Unit Chief in the Office of Diversion Control. He will further testify as follows:

Mr. Wright will testify regarding the Automation of Reports and Consolidated Orders System ("ARCOS") data regarding Respondent's sales of controlled substances. He will testify to the background of ARCOS, its purpose, the information ARCOS contains, and how the information is used by DEA to identify potential diversion of controlled substances. He will testify that he used ARCOS information to conduct an analysis of Respondent's sales of controlled substances. Specifically, he will testify with respect to the ARCOS information for Respondent's top six retail pharmacy customers. Wright will further authenticate charts showing comparative levels of controlled substance purchases among Respondent's various retail chain customers from 2008 to the present, to include the average oxycodone purchasing by all of Respondent's customers; its Florida customers; and the six targeted Walgreens pharmacies.

Wright will further testify to the importance of accurate and complete reporting to ARCOS and will testify that a distributor who reports in a manner that consolidates multiple orders under separate DEA Forms 222 into a single Form 222 is not making a complete and accurate report. Wright will authenticate documents showing Respondent's ARCOS reporting on a number of occasions and compare this reporting to the actual sales information from the source documents.

#### **4. Acting Group Supervisor ("A/GS") Donna Richards**

A/GS Donna Richards will testify to her background, education and training as a DEA Diversion Investigator and Group Supervisor. She will testify substantially as follows:

A/GS Richards conducted a thorough review of the materials provided by Walgreens in response to the administrative subpoena issued by DEA. She will testify that her review of these documents produced no actual showing of any due diligence exercised by Respondent to verify the legitimacy of their increasingly frequent and large orders for highly abused controlled substances. The one exception A/GS Richards will note are several emails from the Jupiter distribution center CII Function Manager, Christine Atwell, questioning the size and frequency of orders from particular pharmacies. Richards will testify that despite Respondent's apparent concern about the orders it was fulfilling on behalf of these pharmacies, Respondent continued to ship suspiciously large quantities of controlled substances to these pharmacies and did not properly report any of the orders that Atwell questioned, or that were subsequently shipped to these pharmacies as suspicious. Richards will testify that based on the Walgreen Co.'s response to DEA's request for due diligence files, Respondent filled these orders without adequately resolving Atwell's concerns or otherwise conducting any investigation of these orders to determine that they were not being diverted.

Richards will further testify about several particular incidents occurring at Respondent's customer pharmacies that should have increased Respondent's scrutiny of these customers, all of whom were already purchasing unusually large quantities of the most commonly abused and diverted controlled substances. One of these incidents occurred in December 2010, at Walgreens store 03629 in Hudson, Florida. An individual attempted to fill a prescription for 270 thirty milligram oxycodone tablets but abruptly left the pharmacy without the narcotics he was seeking after apparently learning that pharmacy personnel, who had reviewed the prescription and suspected it was a forgery, had contacted law enforcement. Despite being put on notice that this customer was likely diverting, Walgreens 03629 continued filling prescriptions for the customer through October 2011. All of the prescriptions were for oxycodone, hydromorphone and/or alprazolam, were paid for in cash and issued by physicians located a significant distance from Walgreens 03629. She will further testify that efforts by Walgreens to impose order limits on this particular store in light of its problematic dispensing did not succeed.

Similarly, Richards will testify that on September 27, 2010, a pharmacist at Walgreens store 04727 in Ft. Pierce, Florida, reported to local law enforcement that he mistakenly provided an extra 120 dosage units of oxycodone 15mg to a customer. The pharmacist stated that when he spoke to the customer's girlfriend to request the return of the oxycodone, the girlfriend said that the customer was an addict who sold his pills and viewed the extra prescription as a "pot of gold." Despite this incident, Walgreens 04727 continued to fill this customer's prescriptions for oxycodone 15mg and oxycodone 30mg on December 30, 2010 and January 26, 2011.

On November 4, 2010, a Walgreens 04727 pharmacist reported to local law enforcement that she dispensed a prescription for 60 dosage units of oxycodone 15mg to a customer. The pharmacist witnessed the customer hand the prescription to a female in the store. The female

entered the restroom with the prescription and upon leaving the restroom, left evidence (aluminum foil with burn marks and pill residue) indicating that she had used the oxycodone in an illicit manner. Despite this incident, Walgreens 04727 continued to fill the customer's oxycodone and alprazolam prescriptions on November 30, 2010, December 13, 2010, December 27, 2010, and January 24, 2011. Additionally, on two of these occasions, the pharmacist noted on the prescription that the customer did not have identification and/or a passport.

On October 28, 2011, the Sheriff of St. Lucie County notified Walgreens 04727 by letter that it needed to take action to stem the tide of prescription drug diversion. St. Lucie County Sheriff Ken Mascara requested Walgreens 04727's "help in dealing the with prescription painkiller epidemic" in St. Lucie County and Florida by "closely scrutinizing" prescriptions for Schedule II narcotics, written by out-of-town physicians and/or written for out-of town individuals. Nevertheless, Walgreens 04727 continued its practice of filling numerous opiate/opioid prescriptions issued by out-of-town physicians through early 2012. Several of these out-of town physicians subsequently surrendered their registrations for cause and/or were subject to state action for their conduct involving controlled substances prescriptions.

She will also provide additional examples of orders for controlled substances received by Respondent that, given the information available to the Walgreen Co., including the above-related police incidents and the below-summarized testimony of Oviedo Police Chief Chudnow, should have been considered suspicious. She will provide testimony that despite clear "red flags" of diversion at some of its customer pharmacies, the distribution center shipped suspicious orders to these pharmacies without executing any due diligence to resolve the potential for diversion.

**5. Diversion Investigator (“DI”) Phyllis Garrett**

DI Phyllis Garrett will testify to her background, education and training as a DEA Diversion Investigator. She will testify as follows:

A review of the ARCOS information reported by the Jupiter distribution center to DEA revealed failures to report complete and accurate information to ARCOS. Specifically, DI Garrett will point to examples where Walgreens reported a single ordered quantity of Schedule II controlled substances, while the actual amounts were ordered over several DEA 222 forms, amounting to several separate transactions instead of one. DI Garrett’s testimony, along with that of Kyle Wright, will be used to admit documents showing these failures to report completely and accurately.

She will introduce evidence of particular shipments of 30mg oxycodone to the six pharmacies named in the Order to Show Cause and will describe the characteristics of these orders that should have triggered both a suspicious order report and additional investigation from Respondent prior to shipping.

**6. Oviedo Chief of Police Jeffrey Chudnow**

Chief Chudnow will testify about his background, training and experience as a police officer and as the Chief of Police for Oviedo, Florida. Chief Chudnow will testify about the very tangible effects that the diversion of controlled substances has had on the city of Oviedo, as evidenced by increases in, among other things, crime rates and overdoses. Chief Chudnow will testify about his department’s knowledge of Walgreens 06997, as well as another Walgreens within the city limits, as centers for illicit controlled substance sales and use.

The Oviedo Police Department (OPD) made numerous arrests for illegal distribution of

controlled substances in 2010 and 2011 related to controlled substances dispensed at the two Walgreens pharmacies, with many of the illicit transactions preceding these arrests occurring in the parking lots of the stores. Chief Chudnow will testify that it was his practice following one of these arrests to send a letter to the pharmacy which dispensed the controlled substance being diverted, notifying them of the details and asking for the pharmacy's assistance in preventing future diversion. Chief Chudnow sent dozens of these letters, at least five of which will be offered into evidence because, as noted in the ISO, Walgreens Store 06997 continued to dispense to some of these individuals even after being notified of their arrest.<sup>4</sup>

On February 10, 2011, Chief Chudnow met with Ed Lanzetti, Walgreens Market Loss Prevention Director, and another Walgreens official. At the meeting, Chief Chudnow presented Mr. Lanzetti with numerous statistics and facts regarding controlled substance arrests related to Walgreens' two Oveido pharmacies. These statistics included numbers and types of drug-related arrests, types of controlled substances seized per arrest, and statistics showing the names of doctors whose prescriptions were related to diversion arrests. Despite being given this information, Walgreens 06997 continued to fill prescriptions for these associated doctors subsequent to the February meeting with Chief Chudnow.

On March 15, 2011, Chief Chudnow sent letters to Alan G. McNally, Chairman of Walgreens Corporation and to Gregory D. Wasson, President and CEO of Walgreens Corporation, informing them about the numerous controlled substance arrests taking place at the Oveido Walgreens pharmacies and the effects on the community of Oveido, and asking for their assistance in stopping these problems. Chief Chudnow never received any response to his request for assistance from anyone at Walgreens Corporation.

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<sup>4</sup> DEA will offer the evidence of subsequent dispensing to the subjects of Chudnow's letters through a Diversion Investigator and will specify these individuals and supporting documents in a Supplemental Prehearing Statement, after moving for a protective order concerning the personal information to be disclosed in these exhibits.



**7. Robert Varno**

Varno will be asked to testify about his experience as Respondent's Distribution Center Manager in Jupiter, Florida from June 2001 until June 2012. Varno will testify about his responsibilities as the manager of the distribution center, including the filling of orders for all of the Walgreens retail pharmacies serviced by the Jupiter distribution center. Varno will be asked to explain the distribution of controlled substances to the Walgreens retail pharmacies, including the use of DEA Form 222 for filling orders for Schedule II controlled substances. Varno will testify regarding his knowledge and use of shipping information reported to ARCOS, as well as Suspicious Order Reports, his understanding of their creation and his use of these reports in managing the distribution center. He will discuss how these reports were received and stored at the distribution center, his utilization of these reports, and how these reports impacted shipping operations at the distribution center. Varno will testify about his training in anti-diversion measures by Walgreen's Headquarters and/or Loss Prevention officials, particularly those portions of his training focusing on Florida's well-known epidemic of prescription drug abuse. He will also testify about his own knowledge of the prescription drug problem in Florida and how that awareness impacted operations at Respondent, particularly with regard to identifying and verifying suspicious orders of commonly abused painkillers.

**8. Christine Atwell**

Christine Atwell will be asked to testify about her more than six years of experience as the CII Function Manager at the Walgreens distribution center in Jupiter, Florida. Atwell will explain the role of the CII Function Manager as part of the distribution center operations, including her functions while serving in that role. She will explain the system for filling orders for Schedule II controlled substances in place in 2010 and 2011, including the filling of standard

orders, the filling of "PDQ<sup>5</sup>" orders and the filling of orders for a quantity beyond the stock on hand at the distribution center. Atwell will discuss how the Distribution Center handled orders placed directly by pharmacy employees in addition to the automated system. She will testify about the process of reviewing orders for controlled substances received at the distribution center, as well as about the guidance and training she received from Walgreen Co. on how to evaluate special orders. Atwell is expected to testify that she had full approval authority on all special orders placed by pharmacies. She will testify about how the automated system handled DEA Form 222 documentation of orders filled by the distribution center, as well as any controlled substances ordered but not filled by the distribution center.

Atwell will testify regarding her knowledge and use of information reported to ARCOS, as well as Suspicious Order Reports, to include her understanding of their creation and her use of these reports in managing the distribution center's CII functions. She will testify about her training in anti-diversion measures by Walgreen's Headquarters and/or Loss Prevention officials, particularly those portions of this training focusing on Florida's well-known epidemic of prescription drug abuse. She will also testify about her own knowledge of the prescription drug problem in Florida and how that awareness impacted operations at Respondent, particularly with regard to identifying and verifying suspicious orders of commonly abused painkillers.

As the CII Function Manager, Atwell will testify regarding emails she sent to Walgreens corporate personnel, including Barbara Martin and Distribution Center Manager Rob Varno, voicing concerns about the unusual size and frequency of orders being placed by several pharmacies. She will testify about Walgreens response to those concerns and her awareness of any efforts by Walgreens to address the prescription drug problem both nationally and within

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<sup>5</sup> PDQ is internal vernacular used by Walgreens for "Pretty Darn Quick," or for orders received daily at the distribution center for fast turnaround outside the regular weekly orders.

Florida.

Atwell will discuss changes to the automated filling systems implemented at the Jupiter Distribution Center in 2012. She will also discuss her understanding of the suspicious order reports produced by Walgreens, including that she has no input into the creation of these reports and she never utilized these reports as part of her role as CII Function Manager at the distribution center. She will testify that during her tenure as the CII Function Manager at the Jupiter distribution center, she has never stopped an order from being filled and distributed.<sup>6</sup>

**9. Group Supervisor (“GS”) Kathy Federico**

GS Federico will testify to her background, education and training as a DEA Group Supervisor. She will testify as follows:

On June 14, 2012, GS Federico, of the DEA Milwaukee District Office, spoke with Dwayne Pinon, in-house corporate counsel for Walgreen, Co., in a telephone interview. During the interview, Pinon stated that Walgreens’ prior suspicious order reporting system was based on a formula for Pseudoephedrine reporting in the DEA Chemical Handlers Handbook. Pinon stated that the old system automatically reported any orders for quantities above the algorithm’s threshold limit. He stated that DEA had informed Walgreens that this algorithm reporting system was outdated and that Walgreens needed to establish their own system for reporting suspicious orders. Pinon stated that the old reports were not suspicious orders, but were in fact just orders that “bounced off” the old reporting system. Pinon informed Federico that Walgreens had implemented a new system which they hoped to present to DEA at some point. The new system set limits on a pharmacy ordering controlled substances based on their sales history, and

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<sup>6</sup> Both Ms. Atwell and Mr. Varno were interviewed by DEA in August, 2012, with counsel for Respondent present. The Government reserves the right to present evidence of their statements through the testimony of DI’s Richards and/or Garrett, particularly if either or both do not testify at the hearing.

any order over the set limit would trigger an alert to Walgreens Loss Prevention. Loss Prevention would then resolve the order. Pinon stated that any orders that Loss Prevention could not resolve would be reported to DEA. However, he stated that initial implementation of this new version of the Suspicious Order Monitoring System had produced “thousands” of allegedly suspicious orders, and was thus still being adjusted to produce different results.

#### **10. George Corripio**

George Corripio will testify about his thirty-one (31) years of experience as a pharmacist, and his current position as a Walgreen’s Staff Pharmacist at Walgreens #5079 at 2423 Orange Avenue, Ft. Pierce, Florida 34950. Corripio will testify about a brief period in 2011 when he worked at Walgreens #4727, also located in Ft. Pierce, Florida. Corripio will testify as follows:

Unlike the customers at The clientele at Walgreens #4727 was “heavy CII traffic,” and that “80% of the clientele was oxy[codone].” In his professional opinion, the diagnoses did not match the customers, as most of the clientele were young people and most of the diagnoses were for back pain. He felt that most of the customers were not telling the truth. The customers were young, they seemed to all know each other, and they often appeared to be under the influence. Often the clientele would present “cocktail prescriptions.” On one occasion, a female customer presented a prescription for ten opiates, which is the type of prescription dispensed to a patient suffering from terminal illness.

Corripio will testify about his general discomfort at filling oxycodone prescriptions at Walgreens #4727, and about how supervising pharmacist did not seem bothered by the clientele and offered to fill prescriptions for Corripio that he felt uncomfortable filling. She suggested that as long as the pharmacy had a diagnosis code for the prescription, they were fine to fill. When Corripio refused to fill a prescription, the customer would often ask when the female pharmacist

was coming back.

Corripio will testify that in his professional opinion, any reasonable pharmacist and technician would know that something was not right with the situation going on at the pharmacy. Corripio brought the situation to the attention of the local police department to seek help with the problems. Corripio will further testify that he believed his District pharmacy supervisor knew about the dispensing practices at Store # 4727.<sup>7</sup>

**11. Edward J. Lanzetti**

Mr. Lanzetti will testify about his employment and duties at Walgreens as a Market Loss Prevention Director. He will be asked to describe his knowledge of the prescription drug abuse problem in Florida and about Walgreens' efforts to combat these issues. He will be asked to describe the Loss Prevention program as it pertains to anti-diversion measures and the methods used by Walgreens' Loss Prevention program to detect and prevent diversion at its pharmacies. Lanzetti will be asked about the increases in oxycodone sales at Walgreens pharmacies in 2010. He will also be questioned about his meeting with Chief Jeffrey Chudnow of the Oviedo Police Department, and about any actions taken in response by the Walgreen Corporation.

**VI. PROPOSED DOCUMENTS**

Exhibit	Description	Approx. # Pages
1.	DEA Certificate of Registration RW0277752 (attached hereto)	1
2.	Sep 27, 2006 Letter from Deputy Asst. Administrator to Respondent	4
3.	Feb 7, 2007 Letter from Deputy Asst. Administrator to Respondent	2

<sup>7</sup> Mr. Corripio was also interviewed by DEA in August, 2012, with counsel for Respondent present. The Government reserves the right to present evidence his statements through the testimony of DI's Richards and/or Garrett, particularly if Corripio does not testify at the hearing.

Exhibit	Description	Approx. # Pages
4.	Dec 27, 2007 Letter from Deputy Asst. Administrator to Respondent	4
5.	2011 Memorandum of Agreement between DEA and Walgreen Co.	7
6.	Florida Declaration of Public Health Emergency	3
7.	HDMA Guidance on Suspicious Order Reporting	16
8.	Walgreen Policy: Handling Suspicious Drug Orders, Revised 2/15/05	1
9.	Walgreen Policy: Handling Suspicious Orders and Loss of Controlled Drugs, Revised 2/15/05	1
10.	Walgreen: Handwritten Revisions to Suspicious Order Policies, undated	2
11.	Walgreen Policy: Handling Suspicious Drug Orders, Revised 04/02/202 (sic)	1
12.	Walgreen Policy: Handling Suspicious Orders and Loss of Controlled Drugs, Revised 04/02/2012	1
13.	"Controlled Substance Threshold" Project P09002, Feb. 2009	18
14.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Dec. 30, 2011	1500+ *
15.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Nov. 30, 2011	1500+ *
16.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Oct. 31, 2011	1500+ *
17.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Sep. 30, 2011	1500+ *
18.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated July 31, 2011	1500+ *
19.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated May 5, 2011	1500+ *
20.	Chart of Top Oxycodone Dispensing Florida Pharmacies, 2008-2012.	5
21.	Chart of Oxycodone Sales to Selected Walgreens Pharmacies, 2006-2012	7
22.	Chart of Oxycodone Average Sales: US average, Florida average, Walgreens Nationwide Average, Walgreens Florida Average.	2
23.	Chart of Oxycodone 30 mg Orders Shipped to Selected Pharmacies	5

Exhibit	Description	Approx. # Pages
24.	2011 MOA between Walgreens and DEA	7
25.	Chart and Supporting Documents – Inaccurate ARCOS Reporting	10
26.	Excerpts from DEA Pharmacist Manual	5
27.	Chart: Oxycodone Sales Comparisons of Selected Walgreens Pharmacies	4
28.	Oviedo Police Department Letters to Walgreens	10
29.	Walgreen Emails Re: Oxycodone Sales **	2
30.	Walgreens Emails re: pharmacy orders **	15
31.	Walgreens Emails re: Ft. Pierce Pharmacies 4727 & 4391 **	8
32.	Walgreens Email about Oviedo Police Chief **	2
33.	Walgreens Emails re: Focus on Compliance **	25
34.	Walgreens Emails re: Oxycodone Action Plans **	8
35.	Walgreens Emails re: Dispensing Guidelines **	10
36.	Selected DEA Forms 222 From Respondent	25
37.	ARCOS Information Submitted by Respondent for the transactions in Exhibit 33.	5
38.	Police Reports re: individual incidents at selected pharmacies	15

\* The Government will seek to only use excerpts from these reports in order to limit the size of each exhibit well below the number of pages contained within the original report.

\*\* Respondent has informed the Government that it will be providing a Bates-stamped replica of the material it originally provided in response to a subpoena without any numeration. Once received, the Government will use these materials to specify exactly which documents are being used and provide a more detailed exhibit list in subsequent filings.

## VII. OTHER MATTERS

As this and related matters not currently before the Court are part of an ongoing investigation, the Government requests the opportunity to supplement this Prehearing Statement as necessary with additional witnesses and documentary evidence. There may also be a need to supplement or revise in response to ongoing litigation brought by Respondent in both the Eastern District of Virginia and the Court of Appeals for the District of Columbia.

Pursuant to the Court's Amended Order for Prehearing Statements, the Government's position at this time is that paragraph 20 of the OTSC/ISO is the only portion of the charging document that is *solely* relevant to the Administrator's findings of an imminent danger to the public health and safety. While other portions of the OTSC/ISO also support this finding, they are also relevant to the issues to be determined herein, particularly at this stage of the proceeding, where the Government is not yet aware of the particular defenses to be raised by Respondent.

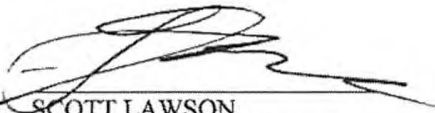
#### VIII. POSITION REGARDING HEARING SITUS

At this time, the Government does not request a change of location for the hearing, though this position is subject to clarification of the means and method of securing the presentation of testimony by civilian witnesses located more than 500 miles from the site of the hearing. *See* 21 U.S.C. § 876. This concern would be substantially alleviated should Respondent agree to produce in person any current employee requested in this Prehearing Statement or supplements thereto.

#### IX. BEST ESTIMATE AS TO TIME REQUIRED TO PRESENT CASE

The Government anticipates requiring no more than four (4) days to present its case-in-chief, exclusive of cross-examination and rebuttal.

Respectfully submitted,



SCOTT LAWSON  
JONATHAN P. NOVAK  
Attorneys  
Diversion & Regulatory Litigation  
Office of Chief Counsel

Date: October 31, 2012



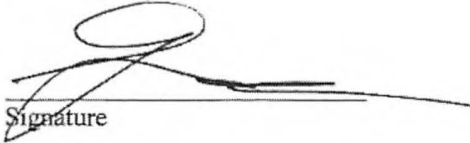
**CERTIFICATE OF SERVICE**

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **GOVERNMENT'S PREHEARING STATEMENT**, to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* to counsel for Respondent at the following addresses:

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3/01/12  
Date

  
Signature

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**UNITED STATES DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION**

**IN THE MATTER OF**

**WALGREEN, CO.**

**DOCKET NO. 13-01**

**ADMINISTRATIVE LAW JUDGE  
JOHN J. MULROONEY, II**

**GOVERNMENT'S SUPPLEMENTAL PREHEARING STATEMENT**

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Date: December 7, 2012

[https://www.dea.gov/divisions/mia/2013/mia061113\\_appendixb.pdf](https://www.dea.gov/divisions/mia/2013/mia061113_appendixb.pdf)

Pursuant to the November 20, 2012 Prehearing Ruling, the Government hereby submits its Supplemental Prehearing Statement.

The Government supplements the proposed testimony of its previously disclosed witnesses as follows:

**1. Deputy Assistant Administrator Joseph Rannazzisi**

Both the ISO and the Government's Prehearing Statement refer to three letters issued by Deputy Administrator Rannazzisi. The second of these two letters, dated February 7, 2007, is identical to the first, dated September 27, 2006. The Government therefore will not be referencing the February 7, 2007 letter in its proposed testimony and has removed this document from its exhibit list.

Deputy Administrator Rannazzisi will further testify in response to Respondent's contention in its Prehearing Statement that its suspicious orders program was modeled on guidance from DEA's website. He will testify that Respondent's reliance on this website is misplaced, as it applies to DEA's Chemical Program only and is designed to implement separate statutes and regulations than those involving suspicious orders for controlled substances.

**2. DPM Langston:**

Ms. Langston will further testify to her review of the materials provided by Respondent in response to a subpoena request for the distributor's due diligence and customer files. Utilizing her training and experience in investigating manufacturers and distributors of controlled substances, she will testify that she found little to no evidence that Respondent or any part of its vertically integrated corporate structure undertook any efforts to assess the reasonableness or legitimacy of the orders it was shipping to Walgreens stores, despite the fact that it routinely identified these orders as suspicious. (To the extent this testimony is duplicative of that

proffered for A/GS Richards, Ms. Langston's testimony on these matters will be in place of Ms. Richards.) Correcting her proffered testimony in the government's Prehearing Statement, Ms. Langston will testify that the last suspicious control drug orders report received by DEA on behalf of Respondent was in February 2012, covering orders through January 2012.

**3. Diversion Investigator ("DI") Phyllis Garrett:**

DI Garrett (or, in the alternative, GS Richards) will additionally testify that Respondent's Suspicious Order Reports frequently failed to fully report all orders that, pursuant to their own criteria, should have been reported as suspicious. She will identify and describe a chart with supporting documentation, showing examples of these failures, some of which also include failures to report orders of Schedule II drugs to ARCOS. She will similarly identify and describe a summary of orders shipped by Respondent in early 2012, after it adopted a policy of no longer making suspicious order reports on the basis that it would not ship them, that exceeded its 2011 and January 2012 criteria for reporting those orders as suspicious.

DI Garrett (or, in the alternative GS Richards) will identify Walgreens "Oxycodone Action Plan" Memo for District 227 and compare the plan's intent to impose immediate order limits on three stores with the actual orders shipped by Respondent subsequent to this plan.

**4. George Corripio**

Pharmacist George Corripio will testify that he was temporarily transferred from Fort Pierce Walgreens 5079 to Walgreens Store # 4727, Fort Pierce, Florida, for a brief period in late 2010 (vice 2011 as stated in the Government's Prehearing Statement.) He will testify to the sharp contrast in clientele and dispensing practices between 4727 and 5079, despite their relative close proximity. He will testify that much of Store #4727's oxycodone customers appeared to be young, healthy individuals, whose appearance did not correspond with the medication they were

seeking or the diagnosis codes he obtained from the offices of the clinics issuing the prescriptions. Many times, the customers seeking the pain medications would arrive in groups who all seemed to know each other and they often appeared to be under the influence of something, which was suspicious to him based on his years of experience as a pharmacist. He will testify that the pharmacy supervisor, Andrea Cohen, told him that all he had to do to in order to fill a prescription was to get a diagnosis code from the issuing office. Because of his own discomfort in filling these prescriptions which he readily identified as suspicious, Andrea Cohen offered to fill them for him. He will testify that the offices whose customers presented pain prescriptions at 4727 generally provided the same diagnosis, usually low back pain, and that he observed that if 4727 filled one of these questionable prescriptions, they would soon see several more customers presenting similarly questionable prescriptions. He will testify that many times when he refused to fill these prescriptions, the customers would get angry and ask when the female pharmacist was coming back. He will testify that the majority of these customers paid cash and were encouraged to return to the pharmacy by Supervisor Andrea Cohen, who would offer these customers Walgreens discount cards. He will testify that he told law enforcement officers that the situation at 4727 with regards to the pill-seeking customers was out of control and that he needed help.

He will testify about an incident he reported to the police after he mistakenly provided extra oxycodone to customer Richard Hanson. Upon trying to call Hanson to tell him to return the oxycodone, Hanson's girlfriend told him that Hanson was an addict who sells his pills. He will be asked about whether there is anything in Walgreens dispensing system to note such an incident in order to flag a customer such as Hanson should he present prescriptions in the future for similar substances.

**Proposed Exhibits:**

Pursuant to the Court's Prehearing Ruling, the Government produced the following proposed exhibits to Respondent on November 30, 2012:

<b>Exhibit</b>	<b>Description</b>	<b># Pages</b>
1.	DEA Certificate of Registration RW0277752	1
2.	September 27, 2006 Guidance Letter From DEA Deputy Assistant Administrator Joseph T. Rannazzisi to Walgreen Co.	8
3.	December 27, 2007 Guidance Letter From DEA Deputy Assistant Administrator Joseph T. Rannazzisi to Walgreen Co.	4
4.	April 2011 Memorandum of Agreement Between Walgreen Co. and DEA	7
5.	July 1, 2011 Florida State Department of Health Declaration of Public Health Emergency Regarding Prescription Drug Abuse Epidemic	5
6.	October 17, 2008 Healthcare Distribution Management Association Guidance with Attached Letter for DEA Chief Counsel Wendy Goggin	17
7.	February 15, 2005 Walgreens Policy: "Handling Suspicious Drug Orders"	2
8.	Notes on Walgreens Proposed Suspicious Order Policy	2
9.	April 4, 2012 Walgreens Policy: "Handling Suspicious Orders and Loss of Controlled Drugs"	1
10.	April 4, 2012 Walgreens Policy: "Handling Suspicious Drug Orders"	1
11.	Walgreens "Controlled Substance Threshold" Project P09002, February 2009	18
12.	December 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	1626
13.	December 2011 Walgreens Jupiter Distribution Center C3-5 Suspicious Order Report	384

14.	Excerpt of December 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	25
15.	Excerpt of August 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
16.	Excerpt of July 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
17.	Excerpt of June 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
18.	Excerpt of December 2010 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	36
19.	Excerpt of Suspicious Orders for Walgreens #3099	14
20.	Excerpt of Suspicious Orders for Walgreens #3629	64
21.	Excerpt of Suspicious Orders for Walgreens #3836	49
22.	Excerpt of Suspicious Orders for Walgreens #4391	34
23.	Excerpt of Suspicious Orders for Walgreens #4727	19
24.	Excerpt of Suspicious Orders for Walgreens #6997	15
25.	Walgreens Ft. Pierce Comparison of ARCOS Data and Chart	1
26.	Walgreens Oviedo Comparison of ARCOS Data and Chart	1
27.	Walgreens Port Richey and Hudson Comparison of ARCOS Data and Chart	1
28.	Walgreens Ft. Myers Comparison of ARCOS Data and Chart	1
29.	Top 100 Walgreens Purchasers of Oxycodone from Jupiter Distribution Center	3
30.	Yearly Sales of Oxycodone to Select Walgreens Pharmacies from All Sources, 209-2011	1
31.	Orders for 30mg Oxycodone (100 count bottles) in 2012 Exceeding Walgreens 2011 "Trigger Amount" for Reporting Suspicious Transactions, with Attached DEA Forms 222	23
32.	Walgreens Ft. Pierce (#4391) ARCOS Reporting Discrepancies	28
33.	Walgreens Ft. Pierce (#4727) ARCOS Reporting Discrepancies	21
34.	Walgreens Ft. Meyers (#3099) ARCOS Reporting Discrepancies	25
35.	Walgreens Hudson (#3629) ARCOS Reporting Discrepancies	41



36.	Walgreens Oviedo (#6997) ARCOS Reporting Discrepancies	22
37.	Walgreens Port Richey (#3836) ARCOS Reporting Discrepancies	30
38.	Suspicious Order Report Discrepancies	39
39.	DEA Guidance "A Pharmacist's Guide to Prescription Fraud"	2
40.	September 27, 2010 Ft. Pierce Police Incident Report for Richard Frederick Hanson	5
41.	Copies of Prescriptions Filled for Richard Frederick Hanson by Walgreens #4727	10
42.	November 4, 2011 Ft. Pierce Police Incident Report from Walgreens #4727	6
43.	Copies of Prescriptions Filled for Carlo Pastor by Walgreens #4727	18
44.	December 24, 2010 Police Incident Report Regarding James McCune and Accompanying Prescriptions	18
45.	Dispensing Log of Prescriptions Filled by Walgreens #3629 for James McCune	1
46.	Letters sent from Oviedo Police Department to Walgreens	16
47.	Summary of Arrests Made at Walgreens Pharmacies in Oviedo, Florida	1
48.	Summary of Surveillance Conducted at Walgreens Oviedo Pharmacies and Law Enforcement Results	2
49.	Oviedo Clinton and Valerie Brekke Exhibit	30
50.	Oviedo Staci Starling Exhibit	17
51.	March 19, 2012 Administrative Subpoena for Walgreens Due Diligence Files	2
52.	Letters from Walgreens Legal Counsel to DPM Susan Langston Outlining Walgreens' Response to DEA Due Diligence Subpoena	6
53.	Email: FW: The Two Minute Oxy-Refusal [WAG00000368]	2
54.	Email: re_oxycodone 30 mg [WAG00000460]	2
55.	Email: Re_Please advise on Pain Manag [WAG00000462]	2
56.	Email: Standards of Practice for the Disp [WAG00000464]	2
57.	Email: Re_Handling Pain Management RX [WAG00000660]	2

58.	Email: 0969_001a [WAG00000742]	22
59.	Email: 0969_001a [WAG00000742]	22
60.	Email: Fw_DEA issue at 6094 with attachment [WAG00000813]****	8
61.	Email: _ Oxycodone sales with attachment [WAG00000829]	12
62.	Email: District Notes and Focus Points [WAG00000845]	1
63.	Email: Margate FL Schedule II limitations (Svihra) [WAG00000846]	4
64.	Email: Re: High Quantity Stores 682971 [WAG00000869]	11
65.	Email: Ft Pierce.msg 2 [WAG00000889]	13
66.	Email: Rx Numbers – Oviedo FL (Svihra) [WAG00000902]	2
67.	Email: Oviedo FL (Stahmann) [WAG00000904]	3
68.	Email: Re Fw 682971 - OXYCODONE HCL 30MG TAB [WAG00000908]	11
69.	Email: Fw_3099 Oxycodone Issue [WAG00000919]	2
70.	Email: Re Store #3836 [WAG00000921]	4
71.	Email: Re Fw INC000002834005 Store #3836 WIC#682971 order qty 148 [WAG00000925]	4
72.	Email: 1412 - CII Dispensing Action Plan [WAG00000929]	1
73.	Email: 3525 - CII Dispensing Action Plan [WAG00000930]	1
74.	Email: Fw_Stores with many adjustments [WAG00000948]	2
75.	Email: STORE 3099 – RxS Due Diligence [WAG00001042]	3
76.	Email: Re Store #06997 [WAG00001057]	2
77.	Email: Re Fw Oxycontin question [WAG00001064]	8
78.	Email: Re Fw CII Order [WAG00001087]	17
79.	Email: Florida Focus on Profit (Svihra) [WAG00001107] ****	7
80.	Email: Store 4706 [WAG00001125]	7
81.	Email: Dist #227 Oxycodone Memo August 2011 [WAG00001212]	2

82.	Email: Store 3099 [WAG00001256]	1
83.	Email: Re_3099 [WAG00001260]	2
84.	Email: 1009_001 [WAG00001326]	40
85.	Email: REQUEST REVIEW Florida Pain Management Visits (Merten) [WAG00001638]	1

\*\*\*\* Government Exhibits 60 and 79 are subject to the ongoing litigation involving Respondent's privilege claims. They are produced here as redacted by Respondent pending a resolution of the privilege issue.

**Proposed Supplemental Exhibits:**

- 86. Email: Actions Taken in District 21 about CII Dispensing WAG0001740 – 2 pages
- 87. Email: New Florida Prescribing Law – 3 pages
- 88. Email: Focus on Compliance Survey – 6 pages
- 89. Focus on Compliance Survey Results – Excel Spreadsheet – 48 pages
- 90. List of items produced in response to Administrative Subpoena – 13 pages

**OTHER MATTERS**

**1. Testimony by VTC:**

The Government has moved to exclude the proffered testimony of DEA employees and/or Task Force Officers Amber Baginski, Roberta Goralczyk, William Schwartz and Roger Kernicky, witnesses 19-22 in Respondent's Prehearing Statement. Should the Court deny the Government's motion as to any of these witnesses, we request that they be allowed to testify by VTC. It is the Government's intention to have Oviedo Police Chief Jeffrey Chudnow testify in

person, however, given his position, we request the opportunity to present his testimony by VTC only if some currently unforeseen circumstance requires that he remain in Florida. We similarly request the opportunity to present the testimony of George Corripio by VTC if necessary to accommodate his employment schedule.

**2. Notice of Additional Basis For Revocation:**

The ISO and Prehearing Statement allege that Respondent violated federal statutes and regulations by failing to implement a system to properly identify and investigate suspicious orders. The failure to conduct adequate due diligence as part of a distributor's obligation to maintain effective controls against diversion is further alleged as conduct that would render Respondent's registration inconsistent with the public interest under 21 U.S.C. § 824(a)(4). Florida law imposes similar requirements on wholesale distributors to conduct due diligence and develop a program to identify suspicious orders and prevent suspicious transactions. Florida Statutes (FS) 499.0121 (15). In particular, a wholesale distributor must assess the reasonableness of orders in excess of 5,000 unit doses of any one controlled substance in any one month. FS 499.0121 (15)(b). The Government hereby notifies Respondent that the same evidence and testimony already disclosed may therefore also demonstrate that Respondent has failed to comply with applicable State law under 21 U.S.C. §§ 823(b)(2) & § 823(e)(2).

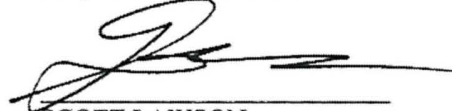
**3. Courtroom presence of Government Expert Witness:**

The Government requests that its noticed expert, Prof. Paul Doering be permitted to observe all aspects of the hearing in the event he is called in rebuttal.

**4. Respondent's Witnesses:**

Similar to Respondent's notice at fn 1 of its Prehearing Statement, the Government reserves the right to call any of Respondent's Witnesses on the matters listed in their proposed testimony.

Respectfully submitted,



SCOTT LAWSON  
JONATHAN P. NOVAK  
Attorneys  
Diversion & Regulatory Litigation  
Office of Chief Counsel


Date: December 7, 2012

**CERTIFICATE OF SERVICE**

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **GOVERNMENT'S SUPPLEMENTAL PREHEARING STATEMENT**, to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* to counsel for Respondent at the following addresses:

Phil Perry  
Allen M. Gardner  
Nathan H. Seltzer  
Latham & Watkins LLP  
555 Eleventh Street, NW  
Suite 1000  
Washington, DC 20004-2232  
Fax: 202.637.2201  
Email: [Phil.Perry@lw.com](mailto:Phil.Perry@lw.com)  
[Allen.Gardener@lw.com](mailto:Allen.Gardener@lw.com)  
[Nathan.Seltzer@lw.com](mailto:Nathan.Seltzer@lw.com)

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# APPENDIX C





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Springfield, Virginia 22152

NOV 26 2012

**IN THE MATTER OF**

Walgreen Co.  
d/b/a Walgreens # 03629  
12028 Majestic Boulevard  
Hudson, Florida 34667

**ORDER TO SHOW CAUSE**

**PURSUANT** to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

**NOTICE** is hereby given to afford Walgreen Co. d/b/a Walgreens # 03629 ("Walgreens 03629") an opportunity to show cause before the Drug Enforcement Administration ("DEA") at DEA Hearing Facility ("DEAHF"), 1550 Crystal Drive, Suite 901, Arlington, VA 22202, or a location designated by the Administrative Law Judge on March 26, 2013 (if Walgreens 03629 requests such a hearing), or at such time designated by the Administrative Law Judge, as to why the DEA should not revoke Walgreens 03629's DEA Certificate of Registration BW4713992 and deny any pending applications to modify or renew such registration pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4) for reason that the continued registration of Walgreens 03629 is inconsistent with the public interest as that term is defined in 21 U.S.C. § 823(f). The basis for this Order to Show Cause is set forth in the following non-exhaustive summary of facts and law.

1. Walgreens 03629 is registered with the DEA as a chain pharmacy authorized to handle controlled substances in Schedules II -V under DEA registration number BW4713992 at 12028 Majestic Boulevard, Hudson, Florida 34667. DEA registration BW4713992 expires by its terms on May 31, 2013.
2. Walgreens 03629 has consistently failed to exercise its corresponding responsibility to ensure that controlled substances it dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice. Walgreens 03629 ignored readily identifiable red flags that controlled substances prescribed were being diverted and dispensed controlled substances despite unresolved red flags. *See* 21 C.F.R. § 1306.04(a); *see also Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315, 62,319 (2012).
3. From late 2010 to November 2011, Walgreens 03629 dispensed oxycodone to customers who presented prescriptions with addresses and locations from 26 states outside of the State of Florida. In addition, Walgreens 03629 dispensed controlled substances, primarily in suspicious

cocktail combinations of oxycodone, alprazolam and carisoprodol, to patients of at least twenty (20) practitioners who were subjected to disciplinary action for dispensing illegitimate prescriptions for controlled substances. Most of these practitioners' registered locations were significant distances from Walgreens 03629. These practitioners include, but are not limited to, the following:

- a. Three hundred fifty four (354) prescriptions for controlled substances prescribed by Ramiro Abaunza, M.D, of Miami, Florida. On November 7, 2011, Dr. Abaunza voluntarily surrendered his DEA registration for cause. Walgreens 03629 is over 300 miles from Miami, Florida.
- b. One-thousand five-hundred fifty (1,550) prescriptions for controlled substances prescribed by Robert R. Reppy, M.D., whose DEA Certificate of Registration was revoked effective November 2, 2011.
- c. Fifty-two (52) prescriptions for controlled substances prescribed by Christopher Wayne, M.D., of Delray Beach, Florida. Dr. Wayne voluntarily surrendered his DEA Certificate of Registration for cause on July 15, 2011, following the emergency suspension of his Florida medical license. Walgreens 03629 is approximately 272 miles from Delray Beach, Florida.
- d. Eight (8) prescriptions for controlled substances prescribed by John T. Legowik, M.D., of Ft. Myers, Florida. Dr. Legowik voluntarily surrendered his DEA Certificate of Registration for cause on November 7, 2011, following the issuance of an Immediate Suspension Order. Dr. Legowik was arrested on April 27, 2012, and charged with illegal distribution of oxycodone and Xanax. Walgreens 03629 is approximately 178 miles from Ft. Myers, Florida.
- e. Eighteen (18) prescriptions for controlled substances prescribed by Randall Wolff, M.D., of Deerfield Beach, Florida. Dr. Wolff's DEA Certificates of Registration were revoked by DEA on February 1, 2011. Walgreens 03629 is approximately 265 miles from Deerfield Beach, Florida.
- f. Three-hundred thirty-five (335) prescriptions for controlled substances prescribed by TJ McNichol, M.D., of Brandon, Florida. Dr. McNichol's DEA Certificate of Registration was revoked by DEA on September 17, 2012. Walgreens 03629 is approximately 57 miles from Brandon, Florida.
- g. Forty (40) prescriptions for controlled substances prescribed by Paul J. Glusman, D.O. of Deerfield Beach, Florida. Dr. Glusman voluntarily surrendered his DEA Certificate of Registration for cause on February 2, 2011, following the issuance of an Immediate Suspension Order. Walgreens 03629 is approximately 265 miles from Deerfield Beach, Florida.

4. On December 21, 2010, a pharmacist employed by Walgreens 03629 notified the Pasco County (Florida) Sheriff's Office to report an individual ("JAM") who attempted to fill a prescription for 270 dosage units of 30mg oxycodone. The prescription, purportedly issued by a Tampa, Florida physician, was later determined to be a forgery. JAM, who at the time of this transaction was a resident of New Port Richey, Florida, abruptly departed from the Walgreens 03629 pharmacy location without filling the forged prescription after learning that pharmacy personnel had contacted local law enforcement. After this incident, Walgreens 03629 filled the following prescriptions for JAM:
  - a. On February 28, 2011, Walgreens 03629 filled a prescription for 150 dosage units of oxycodone 30mg issued to JAM. The prescription was issued to JAM by Ronald Heromin, M.D. (Dr. Heromin), a purported pain management physician practicing in Miami, Florida. JAM paid for the above prescription in cash. JAM's residence in New Port Richey, Florida, is located approximately 304 miles from Miami, Florida, and approximately 308 miles from Walgreens 03629.
  - b. On March 30, 2011, Walgreens 03629 filled prescriptions for 180 dosage units of oxycodone 30mg, 90 dosage units of hydromorphone 8mg (Schedule II controlled substance) and 60 dosage units of alprazolam 2mg issued to JAM by Dr. Heromin. JAM paid for the prescriptions in cash.
  - c. On April 28, 2011, Walgreens 03629 filled prescriptions issued to JAM for 90 dosage units of hydromorphone 8mg and 60 dosage units of alprazolam 2mg. The following day, Walgreens 03629 filled a prescription issued to JAM for 180 dosage units of oxycodone 30mg. These prescriptions were issued by Ramiro Abaunza, M.D. (Dr. Abaunza), a purported pain management physician practicing in Miami, Florida. JAM paid for the above prescriptions in cash.
  - d. On May 27, 2011, Walgreens 03629 filled a prescription issued to JAM for 90 dosage units of hydromorphone 8mg. The following day, Walgreens 03629 filled a prescription issued to JAM for 60 dosage units of alprazolam 2mg. These prescriptions were issued by Dr. Abaunza and JAM paid for the prescriptions in cash.
  - e. On October 11, 2011, Walgreens 03629 filled a prescription issued to JAM for 90 dosage units of diazepam 10mg (Schedule IV controlled substance). On October 13, 2011, Walgreens 03629 filled a prescription issued to JAM for 120 dosage units of oxycodone 30mg. JAM paid for these prescriptions in cash. These prescriptions were issued by Albert Ford, M.D. (Dr. Ford), a purported pain management physician practicing in Tampa, Florida. Walgreens 03629 is approximately 45 miles from Tampa.
5. As noted above, on October 3, 2011, DEA issued a final order revoking Robert R. Reppy, D.O.'s DEA Certificate of Registration. See *Robert Raymond Reppy, D.O.*, 76 Fed. Reg. 61,154 (2011).

The effective date of the final order was November 2, 2011. Nevertheless, on November 2, 2011, Dr. Reppy issued a prescription for 220 dosage units of oxycodone 30 mg, which Walgreens 03629 filled on the same day. Walgreens 03629 filled this prescription in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.05.

6. On November 3, 2011, Donald H. Pritchard, M.D. issued a prescription for 60 dosage units of oxycodone 15mg. While the written prescription indicated that it was issued by Dr. Pritchard, the dispensing label affixed to the back of the prescription stated that the prescription was filled by Walgreens 03629 on November 3, 2011, under the [revoked] DEA registration of Dr. Reppy. Walgreens 03629's filling of a Schedule II controlled substance with an improperly affixed prescription label was in violation of 21 C.F.R. § 1306.14(a). *See Rocco's Pharmacy*, 62 Fed. Reg. 3,056, 3,063 (1997).

**THE** following procedures are available to Walgreens 03629 in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 03629 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens 03629 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show, Walgreens 03629 may file with the DEA a waiver of hearing together with a written statement regarding Walgreens 03629's respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should Walgreens 03629 decline to file a request for a hearing or should Walgreens 03629 request a hearing and then fail to appear at the designated hearing, Walgreens 03629 shall be deemed to have waived the right to a hearing, and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. See 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government Counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrisette Drive, Springfield, VA 22152.

  
\_\_\_\_\_  
Joseph T. Rannazzisi  
Deputy Assistant Administrator  
Office of Diversion Control  
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges  
Robert W. Walker, Counsel for the Government  
Scott Lawson, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters  
Office of the Administrative Law Judges  
Hearing Clerk  
8701 Morrisette Drive  
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant  
or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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[www.dea.gov](http://www.dea.gov)

Springfield, Virginia 22152

NOV 26 2012

**IN THE MATTER OF**

Walgreen Co.  
d/b/a Walgreens # 04727  
4950 South U.S. Highway 1  
Fort Pierce, Florida 34952

**ORDER TO SHOW CAUSE**

**PURSUANT** to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

**NOTICE** is hereby given to afford Walgreen Co. d/b/a Walgreens # 04727 ("Walgreens 04727") an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at DEA Hearing Facility ("DEAHF"), 1550 Crystal Drive, Suite 901, Arlington, VA 22202, or a location designated by the Administrative Law Judge on March 12, 2013 (if Walgreens 04727 requests such a hearing), or at such a time designated by the Administrative Law Judge, as to why DEA should not revoke Walgreens 04727's DEA Certificate of Registration BW6561270 pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. § 823(f), because its registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The bases for this Order to Show Cause are set forth in the following non-exhaustive summary of facts and law.

1. Walgreens 04727 is registered with the DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number BW6561270 at 4950 South U.S. Highway 1, Fort Pierce, Florida 34952. DEA Certificate of Registration BW6561270 will expire by its terms on May 31, 2013.
2. Walgreens 04727 consistently failed to exercise its corresponding responsibility to ensure that controlled substances it dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice. Walgreens 04727 ignored readily identifiable red flags that controlled substances prescribed were being diverted and dispensed controlled substances despite unresolved red flags. See 21 C.F.R. § 1306.04(a). See also *Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315, 62,319 (2012).



3. Walgreens 04727 dispensed controlled substances when it knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacy knew or should have known that the controlled substances were abused and/or diverted by the customer.
  - a. On September 27, 2010, a Walgreens 04727 pharmacist reported to local law enforcement that he mistakenly provided an extra 120 dosage units of oxycodone (Schedule II) 15mg to a customer. When the pharmacist tried to call the customer to request that he return the mistakenly dispensed oxycodone, he was told by the customer's girlfriend that the customer was an addict who sells his pills and viewed the extra oxycodone as a "pot of gold" which he would not return. Despite this incident, Walgreens 04727 filled several additional oxycodone prescriptions issued to this customer in December 2010 and January 2011.
  - b. On November 4, 2010, a Walgreens 04727 pharmacist reported to police that she dispensed a prescription for 60 dosage units of oxycodone 15mg to a twenty-four year old male who she then witnessed transfer the drugs to a female in the store. The female entered the pharmacy restroom with the prescription and upon leaving the restroom, left evidence indicating that she had used the oxycodone in an illicit manner. Despite this incident, Walgreens 04727 continued to fill the same customer's oxycodone and alprazolam (Schedule IV) prescriptions on several occasions in November 2010, December 2010 and January 2011.
4. Starting in at least 2010, Walgreens 04727 filled numerous controlled substance prescriptions despite customers exhibiting multiple "red flags" of controlled substance diversion that were never resolved before dispensing. Such "red flags" included multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor; individuals with the same address presenting substantially similar prescriptions; individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone and alprazolam; individuals presenting prescriptions for controlled substances issued by practitioners located long distances from the pharmacy; and individuals paying for prescriptions for controlled substances with cash and non-insurance discount cards. Walgreens 04727's practice of dispensing controlled substances despite unresolved red flags includes but is not limited to the following dispensing events.
  - a. On June 1, 2011, within a 10 minute period, Walgreens 04727 dispensed nearly identical prescriptions for oxycodone 15mg, oxycodone 30mg, and alprazolam 2mg, to five (5) customers, B.A., E.C., N.C., R.O., J.B., all residing at 1205 Seaway Drive, Apartment 4, Fort Piece, Florida. The prescriptions were all issued by Dr. Carrozzella, located in Kissimmee, Florida, which is 138 miles away from Walgreens 04727. All prescriptions were paid for with non-insurance discount cards.

- b. On June 28, 2011, Walgreens 04727 dispensed oxycodone 30mg, oxycodone 15mg and alprazolam 2mg to R.O. and N.C. (formerly residing at 1205 Seaway Drive, Apartment 4, Fort Pierce, Florida, newly residing at 1910 Wyoming Avenue, Fort Pierce Florida), E.C. (formerly residing at 1205 Seaway Drive, Apartment 4, newly residing at 9319 Breakers Row, Fort Pierce, Florida), and B.A. (residing at 1205 Seaway Drive, Apartment 4). All prescriptions were issued by Dr. John Carrozzella located in Kissimmee, Florida, which is 138 miles away from Walgreens 04727. All prescriptions were paid for with non-insurance discount cards.
- c. On September 21, 2011, Walgreens 04727 dispensed prescriptions for oxycodone 15mg, oxycodone 30mg, and alprazolam 2mg to three (3) customers B.A., E.C., and M.H. All three patients provided new Florida identification cards indicating the same new place of residence: 7500 Pensacola Rd., Fort Pierce, Florida. Walgreens 04727 dispensed the controlled substances despite noting the following red flags on the customers' prescription:
- i. B.A.: *"uses the same house"* address as E.C. and M.H. Replacement Florida Identification Card was *"replaced same day as pickup???"*
  - ii. E.C.: *"I.D. replaced on today's date?? Strange."* *"Lives @ same house as [B.A. and M.H.]."*
  - iii. M.H.: Florida Identification Card *"issued same day as oxy pickup?? Strange."* *"Lives @ same house as [E.C. and B.A.]."*

These prescriptions were all issued by Dr. John Carrozzella located in Kissimmee, Florida, and were paid for with non-insurance discount cards. Notably, this dispensing event occurred one month after DEA investigators met with Walgreens representatives regarding the spike in its Florida pharmacies' oxycodone purchases and diversion red flags.

5. Walgreens 04727 knew or should have known that the vast increase of customers seeking controlled substance prescriptions created a suspicious situation requiring increased scrutiny, and nonetheless failed in carrying out its responsibilities as a DEA registrant. Accordingly, Walgreens 04727 failed to exercise its corresponding responsibility regarding the proper prescribing and dispensing of controlled substances, in violation of 21 C.F.R. § 1306.04(a). Walgreens 04727 knew, or should have known, that a large number of the prescriptions for controlled substances that it filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. *See Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, supra; Sun & Lake Pharmacy, Inc. d/b/a The Medicine Shoppe, 76 Fed. Reg. 24,523 (2011); East Main Street Pharmacy, 75 Fed. Reg. 66,149 (2010); Paul H. Volkman, 73 Fed. Reg. 30,630 (2008), pet. for rev. denied, Volkman v. DEA, 567 F.3d 1215 (6th Cir. 2009).*

**THE** following procedures are available to Walgreens 04727 in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 04727 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens 04727 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 04727 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should Walgreens 04727 request a hearing and then fail to appear at the designated hearing, it shall be deemed to have waived the hearing and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing and based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrisette Drive, Springfield, VA 22152.

  
\_\_\_\_\_  
Joseph T. Rannazzisi  
Deputy Assistant Administrator  
Office of Diversion Control

cc: Hearing Clerk, Office of Administrative Law Judges  
Michelle F. Gillice, Counsel for the Government  
Scott Lawson, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters  
Office of the Administrative Law Judges  
Hearing Clerk  
8701 Morrissette Drive  
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant  
or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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[www.dea.gov](http://www.dea.gov)

Springfield, Virginia 22152

NOV 26 2012

**IN THE MATTER OF**

Walgreen Co.  
d/b/a Walgreens # 06997  
785 Lockwood Blvd.  
Oviedo, Florida 32765

**ORDER TO SHOW CAUSE**

**PURSUANT** to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

**NOTICE** is hereby given to afford Walgreen Co. d/b/a Walgreens # 06997 ("Walgreens 06997") an opportunity to show cause before the Drug Enforcement Administration ("DEA") at the DEA Hearing Facility ("DEAHF") at 1550 Crystal Drive, Suite 901, Arlington, Virginia 22202, or at a location designated by the Administrative Law Judge on March 12, 2013 (if Walgreens 06997 requests such a hearing), or at such time designated by the Administrative Law Judge, as to why the DEA should not revoke Walgreens 06997's DEA Certificate of Registration as a retail pharmacy pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. § 823(f), because its registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The bases for this Order to Show Cause are set forth in the following non-exhaustive summary of facts and law.

1. Walgreens 06997 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number BW8487438 at 785 Lockwood Boulevard, Oviedo, Florida 32765. DEA registration BW8487438 expires by its terms on May 31, 2013.
2. Since at least 2010, Walgreens 06997 has dispensed controlled substances based on prescriptions issued by physicians who lacked authority to do so, in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.05. These include, but are not limited to, the following circumstances:
  - a. Between December 2010 and July 2011, Walgreens 06997 filled at least two hundred sixty-eight (268) controlled substance prescriptions under an out-of-state registration number for Anthony Wicks, M.D. Dr. Wicks was registered with DEA under

Registration BW7987184 at Visalia, California, until his registration expired on May 31, 2011. Despite the fact that Dr. Wicks was registered out-of-state and that for three months he prescribed controlled substances using an expired registration number, Walgreens 06997 filled his prescriptions, which included more than 27,000 dosage units of 30mg oxycodone (Schedule II) tablets. At least sixty-four (64) of these prescriptions were filled after Dr. Wicks' DEA registration had expired.

- b. On January 20, 2011, DEA registration BL6686541, issued to Ronald Lynch, M.D., was revoked. On June 6, 2011, Walgreens 06997 dispensed 30 dosage units of vyvanse (Schedule II) 30mg tablets as prescribed by Dr. Lynch, despite Dr. Lynch not having a valid DEA registration.
3. Walgreens 06997 has consistently failed to exercise its corresponding responsibility to ensure that controlled substances it dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice. Walgreens 06997 ignored readily identifiable red flags that controlled substances prescribed were being diverted and dispensed controlled substances despite unresolved red flags. Such red flags included multiple patients coming with prescriptions for the same drugs in the same quantities coming from the same doctor; patients traveling long distances to the pharmacy; patients with the same address presenting substantially similar prescriptions; and, patients presenting combinations of controlled substances known to be highly abused, such as oxycodone and alprazolam. *See Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, 77 Fed. Reg. 62,315, 62,319 (2012).*
  4. Walgreens 06997 dispensed controlled substances when it knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacy knew or should have known that the controlled substances were abused and/or diverted by the customer.
    - a. Between August 10, 2010, and November 9, 2011, local law enforcement documented seventeen (17) incidents taking place at Walgreens 06997 involving controlled substances, resulting in the arrest of thirty-five (35) individuals for controlled substance-related charges. The Police Chief of the local police department, Jeffrey Chudnow, discussed concerns with Walgreens, both in person and in writing, regarding the association of Walgreens 06997 with these controlled substance incidents. In multiple letters sent to Walgreens 06997, as well as to Walgreens Corporate Headquarters, Chief Chudnow noted controlled substance-related arrests of Walgreens 06997 customers and requested Walgreens' assistance in "dealing with the prescription medication epidemic" by soliciting a commitment to stop further incidents.
      - i. By letter dated November 23, 2010, Chief Chudnow advised Walgreens 06997 of the November 11, 2010 arrest of Steven Sean Reynolds for illegal distribution of Xanax (alprazolam, Schedule IV). Reynolds had obtained the Xanax through a

prescription filled by Walgreens 06997, and Chief Chudnow advised the pharmacy that the controlled substance was not used for treatment of injury or illness.

- ii. By letter dated January 19, 2011, Chief Chudnow advised Walgreens 06997 of the January 12, 2011 arrest of Frederick J. Goepel for illegal distribution of oxycodone. The letter stated that Goepel had obtained the oxycodone from Walgreens 06997.
- iii. By letter dated January 21, 2011, Chief Chudnow advised Walgreens 06997 of the January 20, 2011 arrest of Clinton Brekke for possession of oxycodone with intent to sell. The letter stated that Brekke had obtained the oxycodone from Walgreens 06997. Despite notification by law enforcement that Brekke was diverting his oxycodone prescription, Walgreens 06997 again dispensed oxycodone to Brekke on March 13, 2011, April 7, 2011 and April 11, 2011. In addition, the January 21, 2011 letter also identified Valerie Brekke as being involved in the oxycodone-related arrest. Nevertheless, Walgreens 06997 filled prescriptions for Valerie Brekke on March 16, 2011 and April 25, 2011.
- iv. By letter dated January 25, 2011, Chief Chudnow advised Walgreens 06997 of the January 21, 2011 arrest of Matthew S. Miller and Timothy Kemp Dawson for illegal distribution of oxycodone. The letter stated that Miller and Dawson obtained the oxycodone from Walgreens 06997.
- v. By letter dated January 27, 2011, Chief Chudnow advised Walgreens 06997 of the January 26, 2011 arrest of Brian Lee Kemm for illegal distribution of oxycodone. The letter stated that Kemm obtained the oxycodone from Walgreens 06997. The letter further stated that the pills were illegally distributed to Staci Lynn Starling and Anna Marie Girst. Despite the content of the letter, Walgreens 06997 distributed alprazolam, hydromorphone (Schedule II), and oxycodone to Staci Lynn Starling on February 15, 2011, March 14, 2011, and April 13, 2011.
- vi. On February 10, 2011, Chief Chudnow and other representatives of the Oviedo Police Department met with Walgreens Regional Loss Prevention Manager Ed Lanzette in order to discuss his police department's concerns with criminal activities associated with Walgreens 06997. Chief Chudnow provided Walgreens with controlled substance arrest statistics as well as names of practitioners whose names were associated with diversion.
- vii. On November 17, 2011, Walgreens 06997 contacted the Oviedo Police Department to complain about large crowds of people waiting for the pharmacy to open.



- b. Additionally, on February 10, 2011, Chief Chudnow met with Walgreens Loss Prevention officials in an effort to bring further awareness to the problems arising from the Oviedo Walgreens pharmacies and to brief them on the number of drug-related arrests at each of the pharmacies. On March 15, 2011, Chief Chudnow sent identical letters to both the Chairman and CEO of Walgreens, asking them for their support and assistance in combating the prescription drug epidemic, informing them that Oviedo *"has seen the parking lots of your stores become a bastion of illegal drug sales and drug use"* where once the prescriptions are filled, *"the drugs are sold, distributed as payment, crushed and snorted, liquefied and injected, or multiple pills swallowed while in the parking lot of your pharmacies."*
5. Based on the above, Walgreens 06997 had an abundance of information available, under which it knew or should have known that the vast increase of customers seeking controlled substance prescriptions created a suspicious situation requiring increased scrutiny. Despite the specific guidance provided to Walgreens Corporation by DEA and local law enforcement, and despite the public information readily available regarding the oxycodone epidemic in Florida, Walgreens 06997 nonetheless failed in carrying out its responsibilities as a DEA registrant. Based on the facts as outlined above, Walgreens 06997 has failed to exercise its corresponding responsibility regarding the proper prescribing and dispensing of controlled substances in violation of 21 C.F.R. § 1306.04(a). Walgreens 06997 knew, or should have known, that a large number of the prescriptions for controlled substances that it filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice.

**THE** following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 06997 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens 06997 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 06997 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should Walgreens 06997 request a hearing and then fail to appear at the designated hearing, it shall be deemed to have waived the hearing and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing and based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrissette Drive, Springfield, VA 22152.



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Joseph T. Rannazzisi  
Deputy Assistant Administrator  
Office of Diversion Control

cc: Hearing Clerk, Office of Administrative Law Judges  
Jonathan P. Novak, Counsel for the Government  
Scott Lawson, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters  
Office of the Administrative Law Judges  
Hearing Clerk  
8701 Morrissette Drive  
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant  
or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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**U.S. Department of Justice  
Drug Enforcement Administration**

[www.dea.gov](http://www.dea.gov)

Springfield, Virginia 22152

**FEB 04 2013**

**IN THE MATTER OF**

Walgreen Corporation d/b/a  
Walgreens 03836  
9332 U.S. Highway 19  
Port Richey, Florida 34668

**ORDER TO SHOW CAUSE**

**PURSUANT** to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

**NOTICE** is hereby given to inform Walgreens Corporation d/b/a Walgreens #03836 ("Walgreens 03836") an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at the DEA Hearing Facility ("DEAHF"), 1550 Crystal Drive, Suite 901, Arlington, VA 22202, or at a location designated by the Administrative Law Judge on April 16, 2013 (if Walgreens 03836 requests such a hearing), or at such subsequent time designated by the Administrative Law Judge, why DEA should not revoke Walgreens 03836's Certificate of Registration AW8830247, pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. § 823(f), because Walgreens 03836's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The bases for this Order to Show Cause are set forth in the following *non-exhaustive summary* of facts and law.

1. Walgreens 03836 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number AW8830247 at 9332 U.S. Highway 19, Port Richey, Florida 34668. DEA Certificate of Registration AW8830247 will expire by its terms on May 31, 2013.
2. Walgreens 03836 pharmacists repeatedly failed to exercise their corresponding responsibility to ensure that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual

course of their professional practice. Walgreens pharmacists ignored readily identifiable red flags that controlled substances prescribed were being diverted, and they dispensed controlled substances despite unresolved red flags. *See* 21 C.F.R. § 1306.04(a). *See also Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315, 62,319 (2012).

3. Walgreens 03836 pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacists knew or should have known that the controlled substances were abused and/or diverted by the customer.

4. Starting in at least 2010, Walgreens 03836 pharmacists filled numerous controlled substance prescriptions despite customers exhibiting multiple "red flags" of controlled substance diversion that were never resolved before dispensing. Such "red flags" included multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor; individuals with the same address presenting substantially similar prescriptions; individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone and alprazolam; individuals presenting prescriptions for controlled substances issued by practitioners located long distances from the pharmacy; individuals paying for prescriptions for controlled substances with cash and non-insurance discount cards; individuals residing long distances from the pharmacy; and individuals residing long distances from the practitioners from whom the prescriptions were obtained. Walgreens 03836's practice of dispensing controlled substances despite unresolved red flags includes, but is not limited to, the following dispensing events:

a. From April 2011 through July 2011, Walgreens 03836 pharmacists dispensed oxycodone, alprazolam, and hydrocodone to persons residing in Pensacola, Florida, who had obtained their prescriptions for controlled substances from Ramiro Abaunza, M.D., ("Dr. Abaunza"), a practitioner practicing in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel approximately 1397 miles roundtrip. The individuals to whom the controlled substances were dispensed during this time period are J.C., M.S. (April 9, 2011); H.R. (April 15, 2011); H.N. (April 19, 2011); V.J. (April 23, 2011); J.B., M.J., A.J. (April 26, 2011); A.F., D.D., D.S. (April 28, 2011); C.B., Z.S. (May 4, 2011); C.J. (May 5, 2011); C.C., S.C., J.E. (May 7, 2011); J.M., C.T. (May 9, 2011); R.C., C.G., H.P., T.M. (May 11, 2011); A.F. (May 23, 2011); L.J., A.J., C.S. (May 24, 2011); A.J., L.J., P.J. (June 21, 2011); A.J., L.J. (July 18, 2011).

b. On May 5, 2011, a Walgreens 03836 pharmacist dispensed thirty-milligram tablets of oxycodone to C.C. and S.C., both of whom lived at the same Pensacola, Florida, address and both of whom obtained the prescriptions from Dr. Abaunza.

c. On June 21, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to L.J. and P.J., both of whom lived at the same Pensacola, Florida, address and both of whom obtained the prescriptions from Dr. Abaunza.

d. On April 29, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to J.A. and R.E., both of whom lived in Frankfort,

Kentucky, and both of whom obtained their prescriptions from Dr. Abaunza. Additionally, on May 27, 2011, one or more Walgreens 03836 pharmacists dispensed hydrocodone and alprazolam to J.A. and R.E. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 2242 miles roundtrip.

e. From April 9, 2011, through May 13, 2011, a Walgreens 03836 pharmacist dispensed controlled substances to customers who lived in Decatur, Tennessee, and obtained their prescriptions for controlled substances from Dr. Abaunza in Miami, Florida. On April 9 and May 13 of 2011, a Walgreens 03836 pharmacist dispensed oxycodone to S.M. On April 12, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to J.M. On April 20, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to F.M. and A.R. On April 23, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to Z.F. On April 30, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to T.H. On May 2, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to M.M. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 1760 miles roundtrip.

f. From April 12, 2011, through May 26, 2011, a Walgreens 03836 pharmacist dispensed controlled substances to customers who lived in Riceville, Tennessee, and obtained their prescriptions for controlled substances from Dr. Abaunza in Miami, Florida. On April 12 and May 9 of 2011, a Walgreens 03836 pharmacist dispensed oxycodone to J.G. On May 3, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to B.S. On May 26, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to B.S. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 1733 miles roundtrip.

g. From April 12, 2011, through May 26, 2011, a Walgreens 03836 pharmacist dispensed controlled substances to customers who lived in Athens, Tennessee, and obtained their prescriptions for controlled substances from Dr. Abaunza in Miami, Florida. On April 13, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to K.I. and M.L., who also lived at the same address. On May 11, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to K.I. and M.L. On May 4, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and alprazolam to M.G. On May 9, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to C.H. On May 26, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to M.K. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 1750 miles roundtrip.

h. On April 15, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to M.L. and C.P., both of whom resided at the same address in Etowah, Tennessee. The next day, a Walgreens 03836 pharmacist dispensed oxycodone to M.L. and C.P. Both M.L. and C.P. obtained their prescriptions for controlled substances from Dr. Abaunza in Miami, Florida, and obtained the prescriptions for alprazolam and

oxycodone on the same day. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 1688 miles roundtrip.

i. On or about April 23, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to G.R., pursuant to prescriptions issued by Dr. Abaunza in Miami, Florida. At the time these controlled substances were distributed, G.R. resided in Spring City, Tennessee. In order to obtain these prescriptions and have them filled at Walgreens 03836, G.R. would have had to travel approximately 1762 miles roundtrip.

j. On April 25, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to J.M., pursuant to a prescription issued by Dr. Abaunza in Miami, Florida. At the time these controlled substances were distributed, J.M. resided in Elora, Tennessee. In order to obtain this prescription and have it filled at Walgreens 03836, J.M. would have had to travel approximately 1829 miles roundtrip.

k. On or about April 30, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to L.S. According to dispensing records provided by Respondent, on or about May 4, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to L.S. and dispensed oxycodone, alprazolam, and hydrocodone to J.S. At the time these controlled substances were distributed, L.S. and J.S. resided in Sweetwater, Tennessee, and obtained their prescriptions from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, L.S. and J.S. would have had to travel approximately 1773 miles roundtrip.

l. On May 4, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to R.D., a resident of Cleveland, Tennessee, pursuant to prescriptions issued by Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, R.D. would have had to travel approximately 1665 miles roundtrip.

m. In April 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to R.M., a resident of Cedartown, Georgia. On May 19, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to R.M. The prescriptions for controlled substances were obtained from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, R.M. would have had to travel approximately 1544 miles roundtrip.

n. On April 30, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and hydrocodone to C.G. On May 3, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and hydrocodone to J.M. At the time these controlled substances were distributed, both C.G. and J.M. resided at the same address in Lilburn, Georgia, and obtained their prescriptions from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 1457 miles roundtrip.



o. On May 2, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, and alprazolam to C.M. and K.S., residents of Columbus, Ohio. The prescriptions for controlled substances were obtained from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 2490 miles roundtrip.

p. On May 3, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, and alprazolam to A.N., and oxycodone, hydrocodone, and alprazolam to D.N., both of whom resided at the same address in Hamersville, Ohio. The prescriptions for controlled substances were obtained from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 2390 miles roundtrip.

q. On April 19, 2011, a Walgreens 03836 pharmacist dispensed hydrocodone and alprazolam to D.E., a resident of Dothan, Alabama. On April 26, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to D.E. The prescriptions for controlled substances were obtained from Dr. Abaunza in Miami, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, D.E. would have had to travel approximately 1219 miles roundtrip.

r. On April 21, 2011, a Walgreens 03836 pharmacist dispensed controlled substances, including large quantities of fifteen-milligram tablets of oxycodone and two-milligram tablets of alprazolam, to seven individuals, L.J., C.J., J.W., C.S., D.S., J.I. and C.W., all of whom were residents of the State of Kentucky and two of whom, L.J. and C.J., resided at the same address. Two days later, on April 23, 2011, two Walgreens 03836 pharmacists dispensed controlled substances, including large quantities of thirty-milligram tablets of oxycodone, to the same seven individuals. All of these individuals obtained their prescriptions for the controlled substances from either Charles Kessler, M.D. ("Dr. Kessler"), who was practicing in Plantation, Florida, or Richard Vitalis, D.O. ("Dr. Vitalis"), who was practicing in North Lauderdale, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these seven individuals would have had to travel between approximately 1987 and 2189 miles roundtrip. Moreover, in order to return to Respondent's location on April 23, 2011, and obtain thirty-milligram tablets of oxycodone, these individuals would have had to stay in Port Richey, Florida, for two nights or made a second trip from Kentucky to Respondent's location on April 23, 2011, for which the distance travelled would have been approximately between 1524 and 1724 miles roundtrip. Finally, on April 21 and April 23 of 2011, oxycodone was distributed to L.J. despite dispensing information indicating that L.J. was allergic to opioid analgesics.

s. On April 14, 2011, Walgreens 03836 pharmacists dispensed large quantities of oxycodone and alprazolam to four individuals, M.C., C.D., K.J., and M.J., all of whom resided at the same address in Kissimmee, Florida. The oxycodone prescriptions for M.C. and C.D. were dispensed by the same pharmacist within five minutes of each other. The oxycodone prescriptions for K.J. and M.J. were dispensed by the same pharmacist

within ten minutes of each other. These individuals obtained their prescriptions for controlled substances from Dr. Vitalis, whose office was located in North Lauderdale, Florida, approximately 288 miles from Walgreens 03836. In order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel approximately 578 miles roundtrip.

t. On April 28 and May 5 of 2011, Walgreens 03836 pharmacists dispensed controlled substances in nearly identical amounts to four individuals, P.W., T.S., J.N., and L.B., all of whom resided at the same address in Kissimmee, Florida. Specifically, on April 28, 2011, the same Walgreens 03836 pharmacist distributed fifteen-milligram tablets of oxycodone to P.W. and J.N. These prescriptions were dispensed within six minutes of each other. On May 5, 2011, the same Walgreens 03836 pharmacist distributed both fifteen and thirty-milligram tablets of oxycodone, and alprazolam to L.B. and T.S. The oxycodone prescriptions were dispensed within eight minutes of each other. All of these prescriptions were obtained from Dr. Vitalis in North Lauderdale, Florida, approximately 288 miles from Walgreens 03836. In order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel approximately 603 miles roundtrip.

u. From April 12 through May 25, 2011, a Walgreens 03836 pharmacist dispensed controlled substances to six individuals, B.M., J.W., B.T., J.G., D.S., and C.S., all of whom resided at the same address in Tampa, Florida, and all of whom obtained their prescriptions from either Dr. Kessler or Dr. Vitalis. Specifically, on April 12, 2011, a Walgreens 03836 pharmacist dispensed two oxycodone prescriptions and a prescription for alprazolam to J.W. On April 18, 2011, a Walgreens 03836 pharmacist dispensed two oxycodone prescriptions and a prescription for alprazolam to C.S. On April 21, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and alprazolam to B.T. On April 23, 2011, a Walgreens 03836 pharmacist dispensed a second oxycodone prescription to B.T. On April 27, 2011, the same Walgreens 03836 pharmacist dispensed two oxycodone prescriptions and a prescription for alprazolam to both D.S. and J.G. The alprazolam prescriptions were dispensed within nine minutes of each other. The oxycodone prescriptions for D.S. and J.G. were dispensed within two minutes of each other. With respect to the oxycodone prescriptions for D.S. and J.G., the controlled substances were packaged in a container bearing an incorrect dispensing date in violation of 21 C.F.R. § 1306.14(a). On May 11, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and alprazolam to J.W. On May 12, 2011, a Walgreens 03836 pharmacist dispensed oxycodone, hydrocodone, alprazolam, and carisoprodol to C.S. On May 18, 2011, a Walgreens 03836 pharmacist dispensed oxycodone to B.M. On May 25, 2011, a Walgreens 03836 pharmacist dispensed oxycodone and alprazolam to J.G. In order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel between approximately 583 and 587 miles roundtrip.

v. From April 9, 2011, through May 18, 2011, Walgreens 03836 pharmacists dispensed approximately 61 prescriptions for oxycodone, 31 prescriptions for alprazolam, and 7 prescriptions for methadone to persons who obtained their prescriptions from Dr. Kessler and who were residing in the State of Kentucky. Moreover, on May 12, 2011,

one or more Walgreens 03836 pharmacists dispensed oxycodone to five Kentucky residents and two residents of Pensacola, Florida, all of whom obtained their prescriptions from Dr. Kessler. With respect to three of the Kentucky residents who obtained controlled substances from Walgreens 03836 pharmacists on May 12, 2011, C.S., H.J., and T.K, their oxycodone prescriptions were dispensed within a 17 minute period.

w. An analysis of patients who obtained prescriptions for controlled substances from Dr. Kessler and had them filled at Walgreens 03836 shows that, out of 140 different customers, 72% of the customers resided more than 250 miles from Walgreens 03836, 60% resided more than 400 miles from Walgreens 03836, and 51% resided more than 700 miles from Walgreens 03836.

x. From April 8, 2011, through July 20, 2011, Walgreens 03836 pharmacists dispensed controlled substances including, but not limited to, oxycodone, hydrocodone, and alprazolam, on 55 occasions to persons who obtained their prescriptions from Dr. Ronald Heromin, M.D. ("Dr. Heromin"). At the time these controlled substances were distributed, Dr. Heromin was practicing at offices in Miami and Doral, Florida:

i. Of the 55 prescriptions dispensed, at least 16 prescriptions for Schedule II controlled substances contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.11(a), as well as FLA. STAT. § 893.04(1)(c)(1). At least nine prescriptions for Schedule IV controlled substances contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.21(a), as well as FLA. STAT. § 893.04(1)(c)(1);

ii. Of the 25 prescriptions which lacked a patient address, eleven prescriptions for oxycodone and five prescriptions for alprazolam were issued to persons residing in Pensacola, Florida, which is approximately 412 miles from Walgreens 03836, and at least 670 miles from either of Dr. Heromin's offices in Doral and Miami, Florida. Moreover, on April 30, 2011, a Walgreens 03836 pharmacist distributed thirty milligram tablets to five individuals who obtained their prescriptions from Dr. Heromin, four of whom were residing in Pensacola, Florida, and one of whom was residing in Wetumpka, Alabama. The prescriptions were for quantities of either 180 or 210 tablets each, and all five prescriptions were filled within a 12 minute period by the same pharmacist. In order for the four Pensacola residents to obtain these prescriptions and have them filled at Walgreens 03836, they would have had to travel approximately 1388 miles roundtrip and the patient from Wetumpka, Alabama, would have had to travel approximately 1438 miles roundtrip.

y. From April 25, 2011, through November 5, 2011, one or more Walgreens 03836 pharmacists distributed controlled substances to E.P. and K.P., both of whom resided at the same address in Dothan, Alabama. Specifically, on April 25, 2011, a Walgreens 03836 pharmacist dispensed 60 tablets of Adderall to E.P. On May 25, 2011, a Walgreens 03836 pharmacist dispensed 180-ten milligram tablets of methadone to E.P. On April 27 and August 19 of 2011, a Walgreens 03836 pharmacist dispensed

hydrocodone to K.P., and on October 10 and November 5 of 2011, a Walgreens 03836 pharmacist dispensed Adderall to K.P. On June 22, 2011, the same Walgreens 03836 pharmacist dispensed Adderall and Methadone to E.P. and hydrocodone to K.P. Of the prescriptions described in this paragraph, at least five of them contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.11(a), as well as F.S.A. § 893.04(1)(c)(1).

z. From April 9, 2011, through July 19, 2011, Walgreens 03836 pharmacists dispensed controlled substances including, but not limited to, oxycodone, hydrocodone, and alprazolam, pursuant to 138 different prescriptions issued to individuals residing in Pensacola, Florida. All but three of these prescriptions had been issued by physicians practicing in South Florida, including Drs. Abaunza, Kessler, Vitalis, and Heromin. In order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel between approximately 1341 and 1397 miles roundtrip.

aa. From April 9, 2011, through February 28, 2012, Walgreens 03836 pharmacists dispensed approximately 81 prescriptions for controlled substances to individuals residing in Tennessee. The majority (68%) of those prescriptions were issued by physicians practicing in either Doral or Miami, Florida, both of which are more than 270 miles from Walgreens 03836.

bb. From April 9, 2011, through January 28, 2012, Walgreens 03836 pharmacists dispensed approximately 149 prescriptions for controlled substances to individuals residing in Kentucky. Approximately 92% of those prescriptions were issued by physicians practicing in South Florida cities located more than 250 miles from Walgreens 03836.

cc. On April 29, 2011, a Walgreens 03836 pharmacist dispensed 300 four-milligram tablets of hydromorphone to W.W. On May 13, 2011, a Walgreens 03836 pharmacist dispensed hydromorphone to C.W. On June 1, 2011, a Walgreens 03836 pharmacist dispensed 1080 four-milligram tablets of hydromorphone and 300 forty-milligram tablets to oxycodone to C.W. All of the above described controlled substances in this paragraph were dispensed pursuant to prescriptions that contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.11(a), as well as FLA. STAT. § 893.04(1)(c)(1). Additionally, the controlled substances provided to C.W. on May 13, 2011, were mislabeled insofar as the container displayed an incorrect dispensing date in violation of 21 C.F.R. § 1306.14(a) and FLA. STAT. § 893.04(1)(e)(2).

dd. In addition to the hydromorphone dispensed to W.W. on April 29, 2011, a Walgreens 03836 pharmacist also dispensed hydromorphone to W.W. on July 27, 2011, and on January 12, 2012. A Walgreens 03836 pharmacist also dispensed hydromorphone to W.W. on January 18, 2010, February 16, 2010, March 16, 2010, April 13, 2010, May 11, 2010, June 9, 2010, July 7, 2010, August 4, 2010, September 29, 2010, October 28, 2010, November 29, 2010, December 28, 2010, January 25, 2011, and February 22, 2011. At the time these controlled substances were dispensed, W.W. resided in Adams,

Kentucky. In order to obtain these prescriptions and have them filled at Walgreens 03836, Respondent's location, W.W. would have had to travel approximately 1814 miles roundtrip.

ee. During January 2011, one or more Walgreens 03836 pharmacists dispensed controlled substances to approximately twenty-two different individuals who presented fraudulent prescriptions that contained no patient address in violation of 21 C.F.R. § 1306.124(a) and FLA. STAT. § 893.04(1)(e)(2). During December 2010, one or more Walgreens 03836 pharmacists dispensed controlled substances to approximately six individuals who presented fraudulent prescriptions that contained no patient address.

ff. Walgreens 03836 pharmacists also filled prescriptions for controlled substances in 2010 and during the first three months of 2011 when they knew or should have known that the prescriptions were not for a legitimate medical purpose and/or were issued outside the usual course of professional practice. This includes, but is not limited to, dispensing oxycodone and alprazolam from December 2010 through February 2011 to customers who resided in Ocala, Florida, and who obtained their prescriptions from Christopher Wayne, D.O., whose offices were located in Ft. Lauderdale and Pembroke Park, Florida. In order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel between more than 650 miles roundtrip.

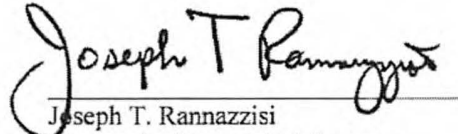
5. Walgreens 03836 pharmacists knew or should have known that the vast increase of customers seeking controlled substance prescriptions and the large number of customers residing long distances from Walgreens 03836 and/or their respective physicians created a suspicious situation requiring increased scrutiny, and Walgreens 03836 nonetheless failed in carrying out its responsibilities as a DEA registrant. Accordingly, Walgreens 03836 pharmacists failed to exercise their corresponding responsibility regarding the proper prescribing and dispensing of controlled substances, in violation of 21 C.F.R. § 1306.04(a). Walgreens 03836 pharmacists knew, or should have known, that a large number of the prescriptions for controlled substances that they filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. See *Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195, supra*; *Sun & Lake Pharmacy, Inc., d/b/a The Medicine Shoppe*, 76 Fed. Reg. 24,523 (2011); *East Main Street Pharmacy*, 75 Fed. Reg. 66,149 (2010); *Paul H. Volkman*, 73 Fed. Reg. 30,630 (2008); *pet. for rev. denied, Volkman v. DEA*, 567 F.3d 1215 (6<sup>th</sup> Cir. 2009).

**THE** following procedures are available to Walgreens 03836 in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 03836 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. See 21 C.F.R. § 1301.43(a). If Walgreens 03836 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 03836 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. See 21 C.F.R. § 1301.43(c).

3. Should Walgreens 03836 decline to file a request for a hearing or, should Walgreens 03836 request a hearing and then fail to appear at the designated hearing, Walgreens 03836 shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrisette Drive, Springfield, VA 22152.

  
Joseph T. Rannazzisi  
Deputy Assistant Administrator  
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges  
Frank W. Mann, Counsel for the Government

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U.S. Department of Justice  
Drug Enforcement Administration

[www.dea.gov](http://www.dea.gov)

Springfield, Virginia 22152

FEB 11 2013

**IN THE MATTER OF**

Walgreen Co.  
d/b/a Walgreens # 04391  
2501 Virginia Avenue  
Fort Pierce, Florida 34981

**ORDER TO SHOW CAUSE**

**PURSUANT** to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

**NOTICE** is hereby given to afford Walgreen Co. d/b/a Walgreens # 04391 ("Walgreens 04391") an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at DEA Hearing Facility ("DEAHF"), 1550 Crystal Drive, Suite 901, Arlington, VA 22202, or a location designated by the Administrative Law Judge on April 23, 2013, (if Walgreens 04391 requests such a hearing), or at such subsequent time designated by the Administrative Law Judge, as to why the DEA should not revoke Walgreens 04391's DEA Certificate of Registration BW5872494 pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. § 823(f), because its registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The bases for this Order to Show Cause are set forth in the following *non-exhaustive summary* of facts and law.

1. Walgreens 04391 is registered with the DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number BW5872494 at 2501 Virginia Avenue, Fort Pierce, Florida 34981. DEA Certificate of Registration BW5872494 will expire by its terms on May 31, 2013.
2. Walgreens 04391 pharmacists repeatedly failed to exercise their corresponding responsibility to ensure that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their



professional practice. Walgreens pharmacists ignored readily identifiable “red flags” that controlled substances were being diverted and/or abused, and they dispensed controlled substances despite unresolved “red flags”. See 21 C.F.R. § 1306.04(a). See also *Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315, 62,319 (2012).

3. Between January 1, 2010 and April 4, 2012, Walgreens 04391 pharmacists filled numerous prescriptions for controlled substances despite “red flags” indicating a risk of controlled substance diversion and/or abuse. Such “red flags” included multiple individuals presenting prescriptions for the same drugs in the same quantities from the same practitioner; individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone and benzodiazepines; individuals presenting prescriptions for controlled substances issued by practitioners located long distances from the pharmacy; individuals presenting prescriptions for controlled substances issued by multiple practitioners, or “doctor shoppers”; and warnings documented by pharmacy employees regarding physicians prescribing illegitimately. Walgreens 04391’s practice of dispensing controlled substances despite unresolved “red flags” includes, but is not limited to the following incidents:
  - a. Between July 6, 2010 and March 22, 2012, Walgreens 04391 pharmacists filled at least forty prescriptions for hydrocodone, oxycodone 30 mg, oxycodone 60 mg, and oxycodone 80 mg for customer A.R., who obtained these prescriptions from ten different physicians, seven of whom were located in Miami, Florida, approximately 144 miles away from Walgreens 04391. At least four of the above-referenced oxycodone prescriptions were issued by Dr. Armando Falcon and were dispensed to A.R. on November 7, 2011, November 30, 2011, January 20, 2012, and February 28, 2012, despite the following warning printed on the prescription label beneath Dr. Falcon’s name and recorded in the pharmacy’s electronic dispensing log: “FAKE CII DO NOT FILL CANDY DR.”
  - b. On February 3, 2012 and February 11, 2012, Walgreens 04391 pharmacists filled two prescriptions for oxycodone issued by Dr. Dustin Lee despite the following warning printed on the prescription label beneath Dr. Lee’s name and recorded in the pharmacy’s electronic dispensing log: “FAKE CII DO NOT FILL CANDY DR\*\*\*FAKE.”
  - c. Between February 28, 2011 and February 3, 2012, Walgreens 04391 pharmacists filled at least twenty-eight prescriptions for oxycodone and Schedule IV benzodiazepines for customer E.O., who obtained the prescriptions from four different physicians, three of whom were located in Miami, Florida, approximately 140 miles away from the pharmacy. On January 4, 2012 and February 3, 2012, Walgreens 04391

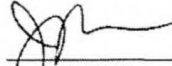
dispensed oxycodone to E.O. despite the following warning printed on the prescription label underneath Dr. John Wolf's name and recorded in the pharmacy's electronic dispensing log: "DO NOT FILL ANY FILL ANY CII."

- d. On January 19, 2011, a Walgreens 04391 pharmacist(s) filled eleven prescriptions for oxycodone and alprazolam cocktails to five different customers, all prescribed by Dr. Ralph Miniet, who is located in Fort Lauderdale, Florida, approximately 100 miles away from the pharmacy. According to the time stamp on the prescription labels, all six of the oxycodone prescriptions were dispensed within a ten minute time period.
- e. On November 23, 2010, Walgreens 04391 dispensed 383 dosage units of oxycodone 30 mg and 63 dosage units of alprazolam 2 mg to customer S.W. prescribed by John Davison, M.D. On November 24, 2010, Walgreens 04391 dispensed 483 dosage units of oxycodone 15 mg and 100 dosage units of oxycodone 30 mg prescribed by Dr. Davison. On December 14, 2010, Walgreens 04391 dispensed oxycodone and alprazolam to S.W. *ten days early* pursuant to prescriptions from Leonard Harman, D.O. More specifically, Walgreens 04391 dispensed to S.W. the following controlled substances pursuant to seven prescriptions from Dr. Harman: 210 dosage units of oxycodone 30 mg, 210 dosage units of oxycodone 30 mg; 210 dosage units of oxycodone 15 mg, 210 dosage units of oxycodone 15 mg; 84 dosage units of methadone 10 mg; 84 dosage units of methadone 10 mg; and 63 dosage units of alprazolam 2 mg.

**THE** following procedures are available to Walgreens 04391 in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 04391 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens 04391 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 04391 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should Walgreens 04391 request a hearing and then fail to appear at the designated hearing, it shall be deemed to have waived the hearing and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing and based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrisette Drive, Springfield, VA 22152.



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Joseph T. Rannazzisi  
Deputy Assistant Administrator  
Office of Diversion Control

cc: Hearing Clerk, Office of Administrative Law Judges  
Michelle F. Gillice, Counsel for the Government

**REQUEST FOR HEARING**

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters  
Office of the Administrative Law Judges  
Hearing Clerk  
8701 Morrissette Drive  
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant  
or attorney]

**Note:** Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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**U.S. Department of Justice  
Drug Enforcement Administration**

[www.dea.gov](http://www.dea.gov)

Springfield, Virginia 22152

FEB 19 2013

**IN THE MATTER OF**

Walgreen Co.  
d/b/a Walgreens # 03099  
1525 Colonial Boulevard  
Fort Myers, Florida 33907

**ORDER TO SHOW CAUSE**

**PURSUANT** to Sections 303 and 304 of the Controlled Substances Act, Title 21,  
United States Code, Sections 823 and 824,

**NOTICE** is hereby given to afford Walgreen Co. d/b/a Walgreens # 03099 ("Walgreens 03099"), an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at the DEA Hearing Facility ("DEAHF") 1550 Crystal Drive, Suite 901, Arlington, VA 22202, or a location designated by the Administrative Law Judge, on April 23, 2013 (if Walgreens 03099 requests such a hearing), or at such subsequent time designated by the Administrative Law Judge, as to why DEA should not revoke Walgreens 03099's DEA Certificate of Registration AW1366877 pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registration, and deny any applications for any new DEA registrations pursuant to 21 U.S.C. § 823(f), because its registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(f). The bases for this Order to Show Cause are set forth in the following *non-exhaustive summary* of facts and law.

1. Walgreens 03099 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number AW1366877 at 1525 Colonial Boulevard, Fort Myers, Florida 33907. DEA registration AW1366877 expires by its terms on May 31, 2013.
2. Walgreens 03099 pharmacists repeatedly failed to exercise their corresponding responsibility to ensure that controlled substances they dispensed were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting within the usual course of their professional practice. Walgreens 03099 pharmacists ignored readily identifiable red flags that controlled substances prescribed were being

diverted, and they dispensed despite unresolved red flags. *See* 21 C.F.R. § 1306.04(a). *See also Holiday CVS, L.L.C., d/b/a CVS Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62,315, 62,319 (2012).

3. Walgreens 03099 pharmacists dispensed controlled substances when they knew or should have known that the prescriptions were not issued in the usual course of professional practice or for a legitimate medical purpose, including circumstances where the pharmacists knew or should have known that the controlled substances were abused and/or diverted by the customer.
  - a. On September 27, 2010, Fort Myers police received a 911 call from Walgreens 03099 regarding a customer, whose identity was known to Walgreens 03099, who appeared to be under the influence of drugs and was trying to buy syringes. A trespass warning was issued to the customer. Despite this incident, Walgreens 03099 pharmacists filled oxycodone, morphine and alprazolam prescriptions for this customer on numerous occasions between February 3, 2011 and October 10, 2011.
  - b. On September 28, 2010, Fort Myers police documented that a Walgreens 03099 customer, whose identity was known to Walgreens 03099, engaged in a drug deal on the premises of Walgreens 03099 by selling for money controlled substances he had just purchased from Walgreens 03099. The customer had just filled prescriptions for oxycodone and alprazolam that he paid for using cash and with a Walgreens discount card. Nevertheless, Walgreens 03099 pharmacists filled oxycodone and alprazolam prescriptions for this customer on numerous occasions between September 28, 2010 and June 13, 2011.
4. Since at least 2010, Walgreens 03099 pharmacists filled numerous controlled substance prescriptions despite customers exhibiting multiple "red flags" of controlled substance diversion that were not resolved before dispensing. Such "red flags" included: multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor; individuals with the same address presenting substantially similar prescriptions; individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone, alprazolam and carisoprodol; individuals from out-of-state or who had travelled significant distances within state to fill prescriptions at Walgreens 03099; and filling new oxycodone prescriptions for customers when fewer than 30 days had elapsed since the customer had filled their previous prescription for a 30-day supply of oxycodone. Walgreens 03099's practice of dispensing controlled substances despite unresolved red flags includes, but is not limited to, the following dispensing events:
  - a. From January 5, 2011 through October 11, 2011, Walgreens 03099 pharmacists filled approximately forty-two prescriptions for oxycodone 15 mg and 30 mg, alprazolam 2 mg, carisoprodol 350 mg, morphine sulfate 30 mg and 60 mg and zolpidem 10 mg for customer JVL. JVL was ages 35 and 36 during the period of these dispensings. From December 20, 2010 through October 24, 2011,

Walgreens 03099 pharmacists filled approximately thirty-four prescriptions for oxycodone 15 mg and 30 mg, alprazolam 2 mg, carisoprodol 350 mg, morphine sulfate 30 mg and diazepam 5 mg and 10 mg for customer LVL. LVL was ages 33 and 34 during the period of these dispensings. JVL and LVL both resided at the same address in Fort Myers, Florida and both received their prescriptions from the same physician, Emiliya Hill, M.D.

- b. From August 8, 2011 through October 31, 2011, Walgreens 03099 pharmacists filled approximately twelve prescriptions for oxycodone 15 mg and 30 mg, morphine sulfate 30 mg, and diazepam 10 mg for customer GG. GG was age 44 during the period of these dispensings. From August 13, 2011 through October 11, 2011, Walgreens 03099 pharmacists filled approximately nine prescriptions for oxycodone 15 mg and 30 mg, morphine sulfate 30 mg, and diazepam 10 mg for customer RT. RT was ages 43 and 44 during the period of these dispensings. From August 13, 2011 through October 11, 2011, Walgreens 03099 pharmacists filled approximately eight prescriptions for oxycodone 15 mg and 30 mg, morphine sulfate 30 mg, and diazepam 5 mg for customer TT. TT was age 47 during the period of these dispensings. GG, RT and TT all resided at the same address in Fort Myers, Florida and all received their prescriptions from the same physician, Emiliya Hill, M.D.
- c. On April 12, 2011, a Walgreens 03099 pharmacist filled a prescription for 120 dosage units of oxycodone 15 mg for customer CA pursuant to a prescription written by Emiliya Hill, M.D., on April 11, 2011. On April 15, 2011, a Walgreens 03099 pharmacist filled a prescription for 210 dosage units of oxycodone 30 mg for customer CA pursuant to a prescription written by Emiliya Hill, M.D., on April 11, 2011. Walgreens 03099 pharmacists also filled alprazolam and carisoprodol prescriptions for customer CA in April 2011. On May 9, 2011, a Walgreens 03099 pharmacist again filled a prescription for 120 dosage units of oxycodone 15 mg for customer CA pursuant to a prescription written by Emiliya Hill, M.D., on May 9, 2011. On May 12, 2011, a Walgreens 03099 pharmacist again filled a prescription for 210 dosage units of oxycodone 30 mg for customer CA pursuant to a prescription written by Emiliya Hill, M.D., on May 9, 2011. Walgreens 03099 pharmacists also filled alprazolam and carisoprodol prescriptions for customer CA in May 2011.
- d. On May 12, June 9, July 5, July 25, August 22 and October 17, 2011, Walgreens 03099 pharmacists filled prescriptions for 230 dosage units of oxycodone 30 mg for customer MS pursuant to prescriptions written by Emiliya Hill, M.D. In addition to the early dispensings of several of these prescriptions before MS's previous prescriptions had run their course, Walgreens 03099 pharmacists also dispensed alprazolam and carisoprodol to customer MS.
- e. On December 19, 2010, and January 14, February 11, March 11, April 7, May 5, June 2, June 30, July 28, and August 24, 2011, Walgreens 03099 pharmacists filled prescriptions for 90 dosage units of oxycodone 15 mg for customer KW.



All of these prescriptions were written by Emiliya Hill, M.D., except for the April 7 prescription which was written by Natalya Verbinskaya, M.D. On December 18, 2010, and January 15, 2011, Walgreens 03099 pharmacists filled prescriptions for 42 dosage units of alprazolam 2 mg for customer KW pursuant to prescriptions written by Emiliya Hill, M.D. On February 11, March 11, April 7, May 5, June 2, June 30, July 28, and August 24, 2011, Walgreens 03099 pharmacists filled prescriptions for 56 dosage units of alprazolam 2 mg for customer KW. All of these prescriptions were written by Emiliya Hill, M.D., except for the April 7 prescription which was written by Natalya Verbinskaya, M.D.

- f. From December 2010 through October 2011, Walgreens 03099 pharmacists filled identical, or nearly identical, prescriptions for oxycodone for three family members, YH, VH and DH. YH and VH sometimes filled their prescriptions at Walgreens 03099 on the same day. These prescriptions were issued by three physicians who practiced at Southwest Medical Solutions, a pain clinic in Bonita Springs, Florida. The physicians are Lawrence Giventer, M.D. (an ophthalmologist), Connie C. Lee, M.D. and Anthony Posca, M.D. YH was ages 45 and 46 at the time of the dispensings. VH was age 28 at the time of the dispensings and DH was age 24 at the time of the dispensings. Some examples of these dispensings are:
    - i. On July 14, August 11 and October 11, 2011, Walgreens 03099 pharmacists filled identical prescriptions for 120 dosage units of oxycodone 30 mg and 60 dosage units of oxycodone 15 mg that were issued to YH and VH by Dr. Posca.
    - ii. On September 12, 2011, Walgreens 03099 pharmacists filled oxycodone prescriptions that were issued to YH and VH by Dr. Lee. YH's prescription was for 150 dosage units of oxycodone 30 mg and VH's prescription was for 140 dosage units of oxycodone 30 mg.
    - iii. On August 23, 2011, Walgreens 03099 pharmacists filled prescriptions for 120 dosage units of oxycodone 30 mg and 75 dosage units of oxycodone 15 mg that were issued to DH by Dr. Lee. On September 22, 2011, a Walgreens 03099 pharmacist filled a prescription for 150 dosage units of oxycodone 30 mg that was issued to DH by Dr. Posca. On September 24, 2011, a Walgreens pharmacist filled a prescription for 60 dosage units of oxycodone 15 mg that was issued to DH by Dr. Posca.
5. Beginning in 2010, the number of customers seeking to fill controlled substance prescriptions and the number of controlled substance prescriptions filled at Walgreens 03099 increased sharply. Walgreens 03099 pharmacists knew or should have known that this vast increase created a suspicious situation requiring increased scrutiny, and Walgreens 03099 nonetheless failed in carrying out its responsibilities as a DEA registrant. Accordingly, Walgreens 03099 pharmacists failed to exercise their

corresponding responsibility regarding the proper dispensing of controlled substances, in violation of 21 C.F.R. § 1306.04(a). Walgreens 03099 pharmacists knew or should have known that a large number of the prescriptions for controlled substances they filled were not issued for a legitimate medical purpose or were issued outside the usual course of professional practice. *See Holiday CVS, L.L.C. d/b/a CVS Pharmacy Nos. 219 and 5195, supra; Sun & Lake Pharmacy, Inc. d/b/a The Medicine Shoppe*, 76 Fed. Reg. 24,523 (2011); *East Main Street Pharmacy*, 75 Fed. Reg. 66,149 (2010); *Paul H. Volkman*, 73 Fed. Reg. 30,630 (2008), *pet. for rev. denied, Volkman v. DEA*, 567 F.3d 1215 (6th Cir. 2009).

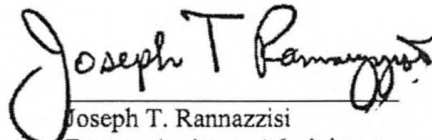
6. On October 30, 2012, pursuant to a Notice of Inspection, DEA Diversion Investigators conducted an inspection of Walgreens 03099 and found the following recordkeeping violations:
  - a. Prescriptions lacking annotations that they were filled by Walgreens' central fill pharmacy, in violation of 21 C.F.R. § 1306.27(a);
  - b. Prescriptions that were not readily retrievable and lacking the red "C" which is required when storing controlled substance prescriptions with non-controlled prescriptions, in violation of 21 C.F.R. § 1304.04(h)(4); and
  - c. Prescriptions lacking the DEA registration number of the prescriber and the address of the patient, in violation of 21 C.F.R. §§ 1306.21(a), 1306.05(a) and 1306.27(a)(2).

**THE** following procedures are available to Walgreens 03099 in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 03099 may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens 03099 fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.
2. Within 30 days after the date of receipt of this Order to Show Cause, Walgreens 03099 may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).
3. Should Walgreens 03099 decline to file a request for a hearing or should it request a hearing and then fail to appear at the designated hearing, it shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing, and the Administrator may enter her final order in this matter without a hearing based upon the evidence presented to her. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Matters are

deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrisette Drive, Springfield, VA 22152.

  
Joseph T. Rannazzisi  
Deputy Assistant Administrator  
Office of Diversion Control

cc: Hearing Clerk, Office of Administrative Law Judges  
Paul E. Soeffing, Counsel for the Government

**REQUEST FOR HEARING**

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters  
Office of the Administrative Law Judges  
Hearing Clerk  
8701 Morrissette Drive  
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

- (A) [State with particularity the interest of the person in the proceeding.]
- (B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]
- (C) [State briefly the position of the person with regard to the particular objections or issues.]
- (D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant  
or attorney]

**Note:** Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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UNITED STATES DEPARTMENT OF JUSTICE  
Drug Enforcement Administration

In the Matters of

**Walgreen Co.**  
**d/b/a Walgreens #03629**

Docket No. 13-9

**Walgreen Co.**  
**d/b/a Walgreens #04727**

Docket No. 13-10

**Walgreen Co.**  
**d/b/a Walgreens #06997**

Docket No. 13-11

PREHEARING STATEMENT ON BEHALF OF  
THE GOVERNMENT

Drug Enforcement Administration  
Office of Chief Counsel  
8701 Morrisette, Drive  
Springfield, Virginia 22152  
(202) 307-8010 (office)  
(202) 307-4946 (facsimile)  
Email: [Robert.Walker@usdoj.gov](mailto:Robert.Walker@usdoj.gov)

Dated: January 9, 2013

[https://www.dea.gov/divisions/mia/2013/mia061113\\_appendixc.pdf](https://www.dea.gov/divisions/mia/2013/mia061113_appendixc.pdf)

Pursuant to the Order of the Administrative Law Judge dated December 31, 2012, the United States Department of Justice, Drug Enforcement Administration (DEA), by and through the undersigned attorney, respectfully submits the following pre-hearing statement:

**I. ISSUE**

Whether the record as a whole establishes that the continued registration of Walgreen Company, d/b/a Walgreens #03629 (Walgreens #03629), as a retail pharmacy under 21 U.S.C. §§ 824(a)(4) and 823(f), would be inconsistent with the public interest.

**II. REQUESTED RELIEF**

The Government requests: (a) an expedited hearing at a time and place convenient to the respective parties; and (b) a recommended ruling by the Administrative Law Judge favorable to the Government's contention that the DEA Certificate of Registration of the Walgreens #03629 should be revoked and any pending application for renewal or modification of such registration be denied.

**III. PROPOSED STIPULATIONS OF FACT**

1. Walgreens #03629 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II -V under DEA registration number BW4713992 at 12028 Majestic Boulevard, Hudson, Florida 34667. DEA registration BW4713992 expires by its terms on May 31, 2013.

2. The driving distance between Miami and Hudson, Florida is approximately 307 miles or a more than five hour drive.<sup>1</sup>

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<sup>1</sup>All driving times are approximated by a driving speed of 65 miles per hour.

3. The driving distance between Delray Beach and Hudson, Florida is approximately 272 miles or a four hour and 10 minute drive.

4. The driving distance between Fort Myers and Hudson, Florida is approximately 155 miles or a nearly three hour drive.

5. The driving distance between Deerfield Beach and Hudson, Florida is approximately 274 miles or a more than four hour drive.

6. The driving distance between Fort Lauderdale and Hudson, Florida is approximately 292 miles or a nearly five hour drive.

7. The driving distance between Brandon and Hudson, Florida is approximately 57 miles or a one hour drive.

8. The driving distance between Tampa and Hudson, Florida is approximately 45 miles.

9. Hydromorphone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(12).

10. Oxycodone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(13).

11. Alprazolam is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(1).

12. Diazepam is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(14).

13. Soma is a brand name for carisoprodol, a drug typically used legitimately as a muscle relaxant. While carisoprodol was not a controlled drug prior to January 2012, it has nevertheless been a highly abused pharmaceutical agent, particularly when used in



combination with certain narcotic and benzodiazepine drugs. Effective January 11, 2012, carisoprodol was placed in Schedule IV as a controlled substance pursuant to 21 C.F.R.

§ 1308.14.

**IV. PROPOSED WITNESSES<sup>2</sup>**

1. Susan Langston  
Diversion Group Supervisor  
Drug Enforcement Administration  
Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
2. Gayle Lane  
Diversion Group Supervisor  
Drug Enforcement Administration  
Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
3. Janet E. Pascalli  
Task Force Officer  
Drug Enforcement Administration  
Tampa District Office  
4950 West Kennedy Blvd.  
Suite 400  
Tampa, Florida 33609
4. Donna G. Richards  
Diversion Investigator  
Drug Enforcement Administration  
Fort Lauderdale District Office  
1475 West Cypress Creek Road, Suite 301  
Fort Lauderdale, Florida 33309
5. Peter Flagg  
Diversion Investigator  
Drug Enforcement Administration  
Tampa District Office  
4950 West Kennedy Blvd.  
Suite 400  
Tampa, Florida 33609

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<sup>2</sup> The Government reserves the opportunity to call any person listed as a witness on behalf of Walgreens #03629.

6. Caren Cohalla  
Pharmacist  
Walgreens Corporation  
Walgreens Company  
d/b/a Walgreens #03629  
12028 Majestic Boulevard  
Hudson, Florida 34667
7. Stuart Eakins  
Pharmacy Manager  
Walgreens Corporation  
Walgreens Company  
d/b/a Walgreens #03629  
12028 Majestic Boulevard  
Hudson, Florida 34667
8. Patricia Gibson  
Pharmacy Manager  
Walgreens Corporation  
Walgreens Company  
d/b/a Walgreens #03629  
12028 Majestic Boulevard  
Hudson, Florida 34667
9. Mary E. Chmielewski Ph.D.  
Senior Personnel Psychologist  
Research & Analysis (HRN), Human Resources Division  
Drug Enforcement Administration  
600 Army-Navy Drive, W-3114-4  
Arlington, Virginia 22202
10. Paul L. Doering  
Distinguished Service Professor of Pharmacy Practice, Emeritus  
College of Pharmacy  
University of Florida  
101 South Newell Drive  
HPNP Bldg 212  
Room # 3307  
Gainesville, Florida 32611

#### IV. SUMMARY OF TESTIMONY

##### 1. Susan Langston, Diversion Program Manager (“DPM”), Miami Field Division<sup>3</sup>

Following testimony regarding her experience and qualifications as DEA Diversion Program Manager Susan Langston (DPM Langston) will testify regarding the diversion of controlled substances in Florida and the proliferation of “pill mills” employing unscrupulous doctors who dispense controlled substances outside the usual course of professional practice or for other than legitimate medical purposes. In response to this ongoing health threat, on August 18, 2011, DPM Susan Langston, GS Gayle Lane and other DEA investigators met with representatives from Walgreens Corporation to discuss oxycodone diversion and abuse issues in Florida. DPM Langston will testify that DEA investigators advised Walgreens about specific red flags for diversion related to patients, specifically, out-of-state patients, questionable Florida identification cards, cocktail prescriptions for oxycodone 15mg, oxycodone 30mg, alprazolam 2mg, and carisoprodol, customers under the age of 45 and customers paying for prescriptions with cash. DPM Langston will testify that Walgreens #03629 was put on notice that there would be a vast increase of customers seeking controlled substance prescriptions, particularly those involving oxycodone, for no legitimate medical purpose.

DPM Langston will testify to DEA findings that Walgreens #03629 has dispensed controlled substances to customers residing in numerous states and commonwealths outside of Florida. She will testify that Walgreens #03629’s dispensing to out of state customers is particularly problematic when one considers information developed by DEA that as a result of long-standing prescription monitoring programs in Kentucky and Ohio,

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<sup>3</sup>In the event DPM Langston is unable to testify, GS Lane will offer the proposed testimony set forth below.

and with the increased difficulty in obtaining controlled substances from licensed physicians in these jurisdictions, many individuals have found creative ways to circumvent state prescription monitoring programs. As a result of the restricted access to controlled substances in their states, many individuals from Ohio, Kentucky and other states have travelled by the carloads to “pain” clinics located Florida to obtain prescriptions for oxycodone, alprazolam, and carisoprodol. This troublesome trend is particularly acute in the Appalachia region where individuals return to the region with drugs dispensed or prescribed by physicians working at Florida clinics. Because of the easy availability of drugs from these cash-only clinics, drug seeking individuals in the Appalachia region have obtained these drugs and abuse or sell them on the streets both to support drug habits and finance later car trips to Florida. The financing of these trips include the costs charged by the clinics for doctor visits and for drugs dispensed by the clinics. DPM Langton will testify that Walgreens #03629 knew or should have known of these trends before dispensing controlled substances to individuals residing outside of the State of Florida.

**2. Gayle Lane, Group Supervisor (“GS”), Miami Field Division<sup>4</sup>**

Following testimony regarding her experience and qualifications as a Diversion Group Supervisor, GS Lane will testify to the background of the investigation into Walgreens #03629, which stemmed from Walgreens #03629 and other Walgreens pharmacies’ dramatic spike in oxycodone purchases.

GS Lane will testify that on August 19, 2011, DEA met with Walgreens representatives. GS Lane will testify that she and DPM Langston advised Walgreens of

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<sup>4</sup> GS Lane may testify to portions of DPM Langston’s testimony, in lieu of DPM Langston, as outlined above.

customer and physician specific red flags to look for prior to dispensing prescriptions for controlled substances. These red flags identified addressed both patient and physician conduct, including physicians prescribing the same commonly abused controlled substances, utilizing the same diagnosis, not certified in pain management and/or practicing outside their specialty.

GS Lane will testify that on April 4, 2012, an Administrative Inspection Warrant (AIW) was executed at Walgreens #03629. Pursuant to the AIW, investigators obtained inventory records, prescriptions for all Schedule II controlled substances, prescription labels for all dispensed Schedule II controlled substances, and an electronic dispensing log for all Schedule II-IV controlled substances dispensed by Walgreens #03629 between January 1, 2010 and April 4, 2012. GS Lane will introduce Walgreens #03629's dispensing log and summary charts which will show that Walgreens #03629 dispensed controlled substances pursuant to prescriptions that presented obvious red flags.

GS Lane will testify that Respondent's dispensing log reveals that it filled prescriptions issued by doctors who routinely prescribed oxycodone and alprazolam "cocktails", who were located significant distances away from the pharmacy, and whose patients paid for their prescriptions with cash.

**3. DEA Task Force Officer Janet E. Pascalli's proposed testimony:**

Following testimony regarding her experience and qualifications as a DEA Task Force Officer, Janet E. Pascalli (TFO Pascalli) will testify that in her capacity as Detective for the Pasco County Sheriff's Office (PCSO), her office received numerous reports regarding individuals that frequented Respondent to fill prescriptions. Among the reports received by the PSCO were that addicts and "dopers" would frequent Walgreens

#03629 because of the ease with which they could get combination controlled substance prescriptions filled. She will further testify that the PCSO received additional information that Walgreens #03629 became a favorite location with traffickers of prescription drugs and some of these individuals would travel great distances to fill questionable prescriptions, primarily for oxycodone and alprazolam. TFO Pascalli will testify to numerous calls received by local law enforcement from Walgreens #03629 about individuals who attempted to fill phony prescriptions.

TFO Pascalli will testify that on December 21, 2010, the PCSO received a call from Walgreens #03629 pharmacist Caren Cohalla (Ms. Cohalla) regarding an individual who attempted fill a fraudulent oxycodone prescription. The individual, later identified as James A. McCune (Mr. McCune), attempted to pass a prescription for 270 oxycodone 30mg tablets purportedly issued by Steven Mazer, M.D. (Dr. Mazer), a physician practicing at a Tampa pain clinic. According to Ms. Cohalla, the print on the prescription appeared suspicious (blurry) and the address for the prescribing doctor was misspelled. Ms. Cohalla further informed PCSO that there was an alert in Walgreens #03629's system for Dr. Mazer which stated "Verify, our prescription...pad stolen." When Mr. McCune later returned to the store to pick up the prescription, he apparently overheard a pharmacy technician tell Ms. Cohalla to call 911. Mr. McCune then ran out of the pharmacy without attempting to pick up the prescription.

TFO Pascalli will testify that on April 9, 2011, Mr. McCune was arrested and charged with attempt to obtain a controlled substance by fraud relating to his aforementioned attempt to fill a forged prescription at Walgreens #03629. She will testify that Mr. McCune subsequently entered a guilty plea to one count of attempt to

obtain a controlled substance by fraud in the Sixth Judicial District of Pasco/Pinellas and on June 15, 2012, was sentenced to three years of drug offender probation for this offense.

**4. Diversion Investigator Donna Richards' Proposed Testimony:**

Following testimony of her background and qualifications, DEA Diversion Investigator Donna Richards (Investigator Richards) will testify regarding DEA's investigation of Mr. McCune's attempt at prescription forgery. Investigator Richards will testify that Mr. McCune attempted to fill a prescription for 270 thirty milligram oxycodone tablets at Walgreens #03629. The prescription, purportedly issued by a Tampa, Florida physician, was later determined to be a forgery. Mr. McCune was a resident of New Port Richey, Florida at the time of this transaction.

Investigator Richards will testify despite being put on notice that he was a prescription forger Walgreens #03629 continued filling prescriptions for Mr. McCune through October 2011. All of the prescriptions were for oxycodone, hydromorphone and/or alprazolam, were paid for in cash and issued by physicians located a significant distance from Walgreens #03629. Investigator Richards will testify to specific prescriptions filled by Walgreens #03629 and Mr. McCune's method of payment in obtaining these medications.

**5. Diversion Investigator Peter Flagg's Proposed Testimony:**

Investigator Flagg will testify that on April 4, 2012, DEA executed an Administrative Inspection Warrant (AIW) at Walgreens #03629. During the execution of the AIW, investigators obtained inventory records, copies of all Schedule II prescriptions, and dispensing records for Schedule II-IV controlled substances dispensed between

January 1, 2010 and April 4, 2012. Investigator Flagg will testify that a review of the records revealed that Walgreens #03629 filled prescriptions that should have raised concerns or red flags to the pharmacists. Specifically, Walgreens #03629 filled prescriptions issued by doctors who routinely prescribed oxycodone, alprazolam and Soma (carisoprodal) cocktails, practiced outside their specialties and located significant distances away from the pharmacy as demonstrated by the following:

- a. From June 5, 2010 through August 11, 2010, Walgreens #03629 filled eight prescriptions for the aforementioned drug cocktail (oxycodone, alprazolam and Soma) issued by John T. Legowik, M.D. (Dr. Legowik) of Fort Myers, Florida. Fort Myers is approximately 178 miles from Walgreens #03629. Following a DEA investigation into his unlawful handling of controlled substances, on November 7, 2011, Dr. Legowik voluntarily surrendered his DEA Certificate of Registration;
- b. From September 3, 2010 through February 5, 2011, Walgreens #03629 filled 40 prescriptions for the aforementioned drug cocktail issued by Paul J. Glusman, D.O. of Deerfield Beach, Florida. Deerfield Beach is approximately 272 miles from Walgreens #03629. Following a DEA investigation into his unlawful handling of controlled substances, on February 11, 2011, Dr. Glusman voluntarily surrendered his DEA Certificate of Registration. On or about September 29, 2011, in the United States District Court, Southern District of Florida, Dr. Glusman entered a plea of guilty to ten counts of felony distribution of a controlled substance in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2. Dr. Glusman was sentenced to 46-months of incarceration followed by 36-months of supervised probation;
- c. From January 9, 2010 through November 7, 2011, Walgreens #03629 filled 1,550 controlled substance prescriptions issued by Robert R. Reppy, D.O. (Dr. Reppy) of Tampa, Florida. Of that total, the pharmacy filled 1,094 prescriptions for the aforementioned drug cocktail.<sup>5</sup>

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<sup>5</sup> See proposed testimony of Prof. Paul Doering outlined below.



Investigator Flagg will further testify to DEA investigative findings showing that on November 2, 2011, Dr. Reppy issued a prescription for 220 oxycodone 30 mg. tablets to "LF" of Hudson, Florida and the prescription was filled by Walgreens #03629 that same day. Walgreens #03629 unlawfully filled the aforementioned prescription issued by Dr. Reppy when the latter was no longer authorized to issue prescriptions for controlled substances because on October 3, 2011, DEA issued a final order revoking Dr. Reppy's DEA Certificate of Registration and the effective date of the final order was November 2, 2011. See *Robert Raymond Reppy, D.O.*, 76 FR 61154 (2011).

Investigator Flagg will further testify that on November 3, 2011, Donald H. Pritchard, M.D. (Dr. Pritchard) of Crystal River, Florida issued a prescription for 60 oxycodone 15mg tablets to a patient residing in New Port Richey, Florida. The prescription was issued from Dr. Pritchard's practice location in Spring Hill, Florida. While the written prescription revealed that it was issued by Dr. Pritchard, the dispensing label affixed to the back of the prescription revealed that it was filled by Walgreens #03629 on November 3, 2011 under the revoked DEA registration of Dr. Reppy. Investigator Flagg will testify that Walgreens #03629's filling of a Schedule II controlled substance with an improperly affixed prescription label was in violation of 21 C.F.R. § 1306.14(a).

Investigator Flagg will testify to his review of Walgreens #03629's purchases of oxycodone from January 1, 2010 through April 4, 2012, and his comparison of the pharmacy's purchases of oxycodone with 14 pharmacies within the same zip code area (zip code 34667). Investigator Flagg will testify that from January 1, 2010 through December 31, 2010, Walgreens #03629 purchased 913,900 dosage units of oxycodone.

During the same time period the other 14 pharmacies purchased a combined total of 3,417,000 dosage units of oxycodone. From January 1, 2011 through December 31, 2011, Walgreens #03629 purchased 2,211,700 dosage units of oxycodone. During the same time period the other 14 pharmacies purchased a combined total of 2,396,020 dosage units of oxycodone.<sup>6</sup>

Investigator Flagg will testify that his further review of dispensing records of Walgreens #03629 revealed that the pharmacy dispensed oxycodone to customers who presented prescriptions with addresses and locations outside the state of Florida. Specifically, Walgreens #03629 dispensed to customers who resided in 26 states and/or commonwealths including the Appalachia regions of Kentucky, Ohio and Tennessee.

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<sup>6</sup> The Government will present expert testimony of Mary E. Chmielewski regarding the above purchases by Walgreens #03629 as well as the oxycodone purchases of 14 area pharmacies in the 34667 zip code from January 2010 through December 2011. Mary E. Chmielewski will further testify that the above oxycodone purchases by Walgreen #03629 as well as the pharmacy's oxycodone purchases in the period of January 2006 through December 2011 were statistically significant.

Investigator Flagg will testify that pursuant to an administrative subpoena served on Walgreen Co. headquarters in 2012, the company produced a dispensing log from its central fill facility, Central Pharmacy Operations (CPO) located in Orlando, Florida. Investigator Flagg will testify that he identified 25 controlled substance prescriptions in Schedule III-IV from CPO's dispensing log that indicated they were filled by Walgreens #03629. Investigator Flagg will testify that for purposes of verifying the above prescriptions, on October 29, 2012, DEA personnel conducted an inspection of Walgreens #03629 and subsequently obtained copies of the 25 selected prescriptions, as well as the pharmacy's CPO Fill Interstore Transfer Claim Form and a copy of the computer screen printout of the "RX View" for each of the 25 prescriptions. Investigator Flagg will testify that his review of prescriptions obtained from Walgreens #03629 revealed numerous violations, including, but not limited to:

- a. None of the selected 25 prescriptions obtained from Walgreens #03629 contained the word "CENTRAL FILL" written on the face of the original as required by 21 C.F.R. § 1306.27(a);
- b. At least seven of the selected prescriptions did not contain the full address of the patient as required by 21 C.F.R. § 1306.05(a). In addition, one of the aforementioned prescriptions did not contain the DEA registration number of the practitioner as required by 21 C.F.R. § 1306.05(a).
- c. Walgreens #03629 filled a prescription for a controlled substance with a name of the practitioner stamped on the prescription in violation of 21 C.F.R. § 1306.05(d) ("...a computer-generated prescription that is printed out or faxed by the practitioner must be manually signed.").

**6. Caren Cohalla's proposed testimony:**

Caren Cohalla (Ms. Coholla) will testify to her training and experience as a registered pharmacist and her employment history with Walgreens #03629. Ms. Cohalla will testify that on December 21, 2010, she placed a call to the aforementioned PSCO regarding Mr. McCune's attempt to fill a fraudulent oxycodone prescription. She will

testify to her reason for refusing to fill the prescription. Ms. Cohalla is expected to testify to what procedures, if any, were implemented in light of Mr. McCune's attempt at filling a fraudulent prescription. She is also expected to testify regarding Walgreens #03629's filling of subsequent prescriptions for Mr. McCune through October 2011 despite Mr. McCune's previous history of prescription fraud and despite the latter travelling a long distance to fill these prescriptions. Ms. Cohalla is expected to testify to prescriptions filled by Walgreens #03629 by other individuals residing in faraway locations such as Ohio, Kentucky, Tennessee, Colorado and Missouri. She will testify to whether prescriptions presented by these individuals presented any red flags for the on-duty pharmacist and whether pharmacy personnel attempted to resolve these red flags.

**7. Stuart Eakins' proposed testimony:**

Stuart Eakins (Mr. Eakins) will testify to his training and experience as Pharmacy Manager for Walgreens #03629. Mr. Eakins is expected to testify to what procedures, if any, were implemented in light of Mr. McCune's attempt at filling a fraudulent prescription. He is also expected to testify regarding Walgreens #03629's filling of subsequent prescriptions for Mr. McCune through October 2011 despite Mr. McCune's previous history of prescription fraud and despite the latter travelling a long distance to fill these prescriptions.

Mr. Eakins is expected to testify regarding guidelines and procedures for filling questionable controlled substance prescriptions. He will be asked to testify about red flags for diversion and abuse and how pharmacy personnel would try to resolve those red flags.

**8. Patricia Gibson's proposed testimony:**

Patricia Gibson (Ms. Gibson) will testify to her training and experience as Pharmacy Manager for Walgreens #03629. Ms. Gibson is expected to testify regarding Walgreens #03629's procedure for filling central filled prescriptions. She will be asked specifically about 25 prescriptions randomly selected by Investigator Flagg, and the pharmacy's failure to properly execute these prescriptions with the "CENTRAL FILL" designation as required by 21 C.F.R. § 1306.27(a). Ms. Gibson is also expected to testify to Walgreens #03629's filling of additional prescriptions for controlled substances that did not comport to the requirements of 21 C.F.R. § 1306.05 (i.e., prescriptions that did not contain the DEA registration number, full address and manual signature of the practitioner).

**9. Mary E. Chmielewski's proposed testimony:**

Mary E. Chmielewski (Dr. Chmielewski) will testify regarding her education, background, training, and experience as Senior Personnel Psychologist in the Research and Analysis (HRN), Human Resources Division of DEA. Dr. Chmielewski will be offered as an expert on relevant statistical data involving the sale and purchase of controlled substances by a DEA registered pharmacy.

Dr. Chmielewski will testify that in the course of her official duties, she frequently performs statistical analysis and interpretation. She has performed a statistical analysis of the ARCOS data related to oxycodone purchased by Walgreens #03629 for the period of January 2006 through December 2011. She is also expected to testify to her review of data compiled by Investigator Flagg regarding oxycodone purchases by 14 pharmacies in the 34997 zip code where Walgreens #03629 conducts business.

Dr. Chmielewski will testify that in analyzing the purchase data of Walgreens

#03629, she employed the Chi Square (Goodness of Fit) test. The Chi Square test is an inferential statistical test used to detect group differences using frequency (count) data and is among the most frequently reported analyses in research journal articles. In short, the Chi Square test is used to evaluate the number of observations that fall in two or more categories. Goodness-of-fit refers to whether a significant difference exists between a given set of observations and an expected number of observations based on chance. The expected number of observations is the likelihood to occur by chance and the actual observations are the collected data. Dr. Chmielewski will testify that with regard to her analysis of oxycodone purchase data by Walgreens #03629, it was determined that a statistically significant difference for orders from 2006 through 2011 was greater than what would be expected to occur due to chance or probability. She will therefore conclude that the volume increase of Walgreen #03629's purchases of oxycodone over this period of time was statistically significant.

**10. Professor Paul Doering's proposed testimony:**

Professor Paul Doering, M.S. (Prof. Doering) will testify regarding his education, background, training, and experience as a pharmacist. Prof. Doering will testify that he (1) is a registered pharmacist in the states of Florida and North Carolina, (2) is certified as a Consultant Pharmacist in Florida, (3) previously practiced in the community pharmacy setting (4) has been a professor at the University of Florida's School of Pharmacy for the past 35 years, (5) currently serves at the University of Florida's College of Pharmacy as Distinguished Service Professor of Pharmacy Practice, Emeritus, and (6) for 28 years was either Director or Co-Director of the University of Florida's Drug Information and Pharmacy Resource Center, a telephone access service through which

health professionals can get obtain information about drugs or drug therapy. Prof. Doering will further testify about his experiences serving as an expert consultant and witness in a number of criminal, civil, and administrative proceedings. Prof. Doering will provide expert witness testimony as detailed below.

Prof. Doering will testify about the education and training pharmacists receive in pharmacy school, including learning the fundamentals of both state and federal pharmacy law as it relates to the filling and dispensing of prescription drugs in general, and controlled substances in particular. He will further testify about training pharmacists receive in the application of those laws to real life situations. He also will discuss the coverage of these topics in Florida's pharmacist licensing exam.

Prof. Doering will testify about the epidemic of prescription drug diversion and abuse in the state of Florida. He will discuss the 2011 State of Emergency declared by the Florida Surgeon General which was issued in effort to prevent the many drug overdose deaths from controlled substances. The controlled substances commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol. Prof. Doering will testify about the overdose deaths due to oxycodone and benzodiazepines identified by the 2011 Florida Medical Examiners Report. He will testify that pharmacists are in a key position to reverse the trend of this epidemic.

Prof. Doering will further testify about the pharmacist's role in the distribution of prescription drugs that are controlled substances. He will testify about the dangerous propensities of certain controlled substances, in particular opiates and opioids such as oxycodone and benzodiazepines such as diazepam (Valium) and alprazolam (Xanax).

Prof Doering will testify that when controlled release opiate products are prescribed correctly, patients should not need to be on concurrent around the clock opiates for break through pain.

Prof. Doering will discuss the responsibilities of pharmacists in filling controlled substances prescriptions. He will testify about the review and analysis pharmacists should undertake before certifying any such prescription for release to the patient, including checking the licensing status of prescribers and evaluating whether the prescription presented to them is for a legitimate medical purpose and issued by a properly registered practitioner in the usual course of professional practice.

Prof. Doering will further testify about the "red flags" used by pharmacists as indicators of diversion and abuse. Because of the enormous abuse and diversion associated with oxycodone, the mere fact that an oxycodone prescription is being presented should put the pharmacist on full-alert to ensure that the prescription is valid. Oxycodone prescribed in combination with alprazolam and/or with carisoprodol, a popular "cocktail" combination in illicit use, should raise even more scrutiny with a pharmacist.

Prof. Doering will discuss certain patterns or circumstances that are consistent with drug diversion schemes that, in his opinion, a diligent pharmacist can observe, as well as the techniques that help the pharmacist detect drug diversion. Examples of such patterns or circumstances include, but are not limited to, patients who pay with cash, patients who are prescribed large quantities of controlled substances, patients who share the same address, patients who are prescribed the same numbers and types or combinations of drugs, and patients who live a distance from the prescribing practitioner



and/or pharmacy, including out-of-state patients and/or practitioners. His testimony will also cover the criteria appearing in the 2010 Edition of the Drug Enforcement Administration's Pharmacist's Manual, which provided guidance to pharmacists of indicators that a prescription was not issued for a legitimate medical purpose. Prof. Doering will testify that when taken together these "red flags" create enough suspicion that the reasonable and prudent pharmacist would refuse to fill the prescriptions.

Additionally, Prof. Doering will testify about the information he was provided by the DEA to review and analyze concerning Walgreens #03629. This information included, but is not limited to: Walgreens #03629's dispensing log, copies of prescriptions and prescription labels for Schedule II controlled substances dispensed by Walgreens #03629.

Prof. Doering will testify that based on his education, training, and experience as a pharmacist, his review and analysis of the DEA information he received shows that dispensing pharmacists at Walgreens #03629 ignored "red flags" of drug diversion or abuse and filled prescriptions that were issued outside the usual course of medical practice. He will testify that some, but not all red flags can be resolved by a pharmacist. In those instances when red flags are unresolvable, a reasonable pharmacist exercising due care would refuse to fill the prescription.

Prof. Doering will discuss his analysis of Walgreens #03629's controlled substance dispensing between January 1, 2010 and April 4, 2012. He will testify that while the number of dosage units ordered by a pharmacy does not confirm illegal activity, the larger the number of dosage units ordered and dispensed, the more suspicion is aroused. He will testify that the sheer number of controlled substance prescriptions

filled per day can be an indicator that something might be awry. Prof. Doering will discuss the increase in Walgreens #03629's average daily dispensing of controlled substances. Prof. Doering will testify that a pharmacy such as Walgreens #03629 would have expected its customer base to reach a plateau. Any drastic change in volume should cause a pharmacy to step back and figure out why. Professor Doering will testify that the rise in oxycodone dispensing by Walgreens #03629 in 2010-2011, coincides with the change in Florida law, which restricted controlled substance dispensing by practitioners.

Professor Doering will testify about various other categories of red flags that appear in the dispensing logs of Walgreens #03629, including the pharmacy's filling of prescriptions for physicians (i.e., Dr. Reppy) who issue an unusually large percentage of their total prescriptions for the aforementioned drug cocktail (oxycodone, alprazolam and Soma)<sup>6</sup> and customers traveling from distances over 50 miles away to have their prescriptions filled. Prof. Doering will cite as a further example the prescription forgery incident involving James McCune and how the red flags presented by that incident were not resolved by Walgreens #03629 before the pharmacy filled controlled substances prescriptions for Mr. McCune.

#### V. PROPOSED DOCUMENTS

1. Facsimile of DEA Certificate of Registration (attached).
2. Certified registration history for Walgreens #03629 (two pages).
3. Certified registration histories – Drs. Abanza, Reppy, Wayne, Legowick, Wolff, McNichol and Glusman (14 pages).
4. Administrative MOA dated April 7, 2011 (seven pages).

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<sup>6</sup> See proposed testimony of Investigator Flagg outlined above concerning Walgreen's #03629's filling of "drug cocktail" prescriptions issued by Dr. Reppy.

5. ARCOS Report of Respondent's Oxycodone Purchases, 2006-2012
6. Printout of prescriptions filled by Walgreens #03629 (140 pages).
7. Pasco County Sheriff's Office Incident Report for James McCune (eight pages).  
Prescriptions filled for James McCune (10 pages).
8. Prescription printout for James McCune (two pages).
9. Copy of prescription issued by Dr. Reppy on November 2, 2011 and filled by Walgreens #03629 (one page).
10. Copy of prescription issued by Dr. Pritchard on November 3, 2011 (one page).
11. Copy of dispensing label dated November 3, 2011 for 60 dosage units of oxycodone (listing Dr. Reppy as prescribing physician) (one page).
12. Dispensing log of Walgreens #03629's central filled prescriptions.
13. Copies of 25 randomly selected prescriptions (re: central fill prescriptions) (25 pages).
14. CV- Mary E. Chmielewski Ph.D.
15. Charts: Comparison of Total Dosages Oxycodone by Year - Walgreens #03629
16. CV – Professor Paul Doering, M.S.
17. Report - Professor Paul Doering, M.S.

**VI. OTHER MATTERS WHICH MAY AID IN THE EXPEDITIOUS DISPOSITION OF THE HEARING**

- a. The Government reserves the opportunity to amend its instant pleading at a time and date specified by the presiding Administrative Law Judge;
- b. The Government requests the issuance of a protective order to prevent disclosure of the identities of Walgreens #03629's customers wherever such names and records are used in this proceeding;

- c. The Government requests that due to the location of its witnesses, the Respondent, and counsel(s) for the Walgreens #03629, the hearing be held at the DEA Hearing Facility (DEAHF) located at 1550 Crystal Drive, Suite 901, Arlington, Virginia.
- d. The Government incorporates by reference its statement regarding consolidation and *res judicata*.

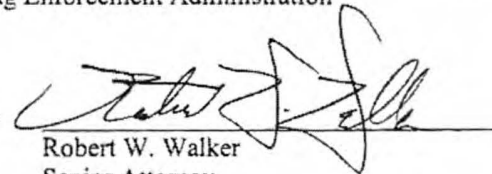
**ESTIMATED TIME FOR PRESENTATION OF THE GOVERNMENT'S CASE**

Three to four business days, exclusive of cross-examination and rebuttal.

Respectfully submitted,

UNITED STATES DEPARTMENT OF JUSTICE  
Drug Enforcement Administration

By:



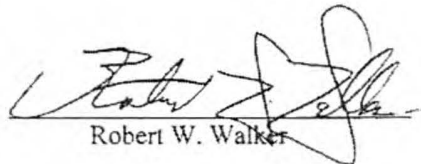
Robert W. Walker  
Senior Attorney  
Drug Enforcement Administration  
Office of Chief Counsel  
8701 Morrisette, Drive  
Springfield, Virginia 22152

Attachment

**CERTIFICATE OF SERVICE**

This is to certify that a true and correct copy of the foregoing was this day sent via facsimile with a second copy placed in the United States Mail addressed to counsel for the Respondents, Phillip J. Perry, Esq., Nathan H. Selzer, Esq., and Allen M. Gardner, Esq., Lantham & Watkins, LLP, 55 Eleventh Street, NW, Suite 1000, Washington, D.C. 20004.

This ninth day of January 2013.



Robert W. Walker

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BW4713992	05-31-2013	\$551
SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5	CHAIN PHARMACY	05-12-2010
WALGREEN CO. DBA: WALGREENS # 03629 12028 MAJESTIC BLVD. HUDSON, FL 34667		

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**  
 UNITED STATES DEPARTMENT OF JUSTICE  
 DRUG ENFORCEMENT ADMINISTRATION  
 WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

**THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.**

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**  
 UNITED STATES DEPARTMENT OF JUSTICE  
 DRUG ENFORCEMENT ADMINISTRATION  
 WASHINGTON, D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
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SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
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WALGREEN CO. DBA: WALGREENS # 03629 12028 MAJESTIC BLVD. HUDSON, FL 34667		

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Form DEA-223 (05/04)

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UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

In the Matter of

**Walgreen Co.  
d/b/a Walgreens #04727**

**Docket No. 13-10**

**CHIEF ADMINISTRATIVE LAW JUDGE  
JOHN J. MULROONEY, II**

**PREHEARING STATEMENT ON BEHALF OF  
THE GOVERNMENT**

Michelle F. Gillice  
Scott Lawson  
Attorneys  
Diversion and Regulatory Litigation  
Office of Chief Counsel  
Drug Enforcement Administration  
8701 Morrissette Drive  
Springfield, Virginia 22152  
(202) 307-8010 (office)  
(202) 307-4946 (facsimile)

Dated: January 9, 2013

Pursuant to the December 31, 2012 Orders for Prehearing Statements, the United States Department of Justice, Drug Enforcement Administration (DEA or Government), hereby submits its Prehearing Statement.

### I. ISSUE

Whether DEA should revoke DEA Certificate of Registration BW6561270 issued to Walgreen Co. 04727 ("Respondent"), pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f) and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(f).

### II. REQUESTED RELIEF

The Government requests a recommended ruling by the Administrative Law Judge favorable to the Government's contention that the Respondent's Certificate of Registration BW6561270 should be revoked and any pending application for renewal or modification of such registration be denied.

### III. PROPOSED STIPULATIONS OF FACT<sup>1</sup>

1. Respondent is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number BW6561270 at 4950 South U.S. Highway 1, Fort Pierce, Florida 34952. DEA registration BW6561270 expires by its terms on May 31, 2013.
2. Respondent has been licensed by the Florida Department of Health as a pharmacy under license number PH16392 since October 22, 1999.
3. Oxycodone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(13).
4. Alprazolam is a Schedule IV controlled substance pursuant to

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<sup>1</sup> The Government anticipates discussing additional stipulations with Respondent.



21 C.F.R. § 1308.14(c)(1).

5. Soma is a brand name for carisoprodol, a drug typically used legitimately as a muscle relaxant. While carisoprodol was not a controlled drug prior to January 2012, it has nevertheless been a highly abused pharmaceutical agent, particularly when used in combination with certain narcotic and benzodiazepine drugs. Effective January 11, 2012, carisoprodol was placed in Schedule IV as a controlled substance pursuant to 21 C.F.R. § 1308.14.

6. Respondent is in Walgreen Co.'s Pharmacy District 112.

7. The driving distance between Respondent and the office of Dr. Charles Kessler located at 660 North State Road 7, Plantation, Florida 33317 is approximately 99 miles or an approximately one hour and forty-five minute drive.

8. The driving distance between Respondent and the office Dr. John Carrozzella located at 2921-A Vineland Road, Kissimmee, Florida 34746 is approximately 109 miles or an approximately one hour and fifty minute drive.

9. The driving distance between Respondent and the office of Dr. Ralph Miniet located at 935 Intercoastal Drive, Fort Lauderdale, Florida 33304 is approximately 98 miles or an approximately two hour drive.

10. The driving distance between Respondent and the office of Dr. Alexandra Taylor located at 660 Linton Boulevard, Del Ray Beach, Florida 33444 is approximately 72 miles or an approximately one hour drive.

**IV. PROPOSED WITNESSES<sup>2</sup>**

1. Susan Langston  
Diversion Program Manager  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
2. Gayle Lane  
Diversion Group Supervisor  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
3. Diversion Investigator Linda Stocum (or Group Supervisor Susan Skyer )  
DEA Orlando District Office  
300 International Parkway, Suite 424  
Heathrow, Florida 32746
4. Dianne Williams or Allison King  
Diversion Investigator  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
5. Mary E. Chmielewski, Ph.D.  
Senior Personnel Psychologist  
Research & Analysis (HRN), Human Resources Division  
Drug Enforcement Administration  
600 Army-Navy Drive, W-3114-4  
Arlington, VA 22202
6. George Corripio  
Pharmacist  
Walgreen Co. Store # 5079  
2423 Orange Avenue  
Fort Pierce, Florida
7. Andrea Cohen  
Pharmacy Manager, Store #5335  
Walgreen Co.  
7620 South U.S. Highway 1  
Port St. Lucie, Florida 34952

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<sup>2</sup> In addition to the witnesses identified below, DEA reserves the right to call any of the witnesses listed by Respondent on matters identified by Respondent.

8. Melissa Kayes  
Pharmacy Technician, Store 04727  
Walgreen Co.  
4950 South U.S. Highway 1  
Fort Pierce, Florida 34952
9. Joseph Berdie  
Assistant Store Manager, Store 04727  
Walgreen Co.  
4950 South U.S. Highway 1  
Fort Pierce, Florida 34952
10. Wesley Rohn  
Pharmacy District Supervisor, Palm Beach North  
Walgreen Co.  
901 Northpoint Parkway, Suite 105  
West Palm Beach, Florida 33407
11. Ed Svihra, RPH, CHC  
Director, HealthCare Loss Prevention  
1411 Lake Cook Road, MS #413  
Deerfield, Illinois 60015
12. Doug Lemmons  
Director, Divisional Loss Prevention Operations  
Walgreen Co.  
200 Wilmot Road, 2<sup>nd</sup> Floor  
Deerfield, Illinois, 60015
13. Ed Lanzanetti  
Market Loss Prevention Director  
Walgreen Co.  
1411 Lake Cook Road, 4<sup>th</sup> Floor  
Deerfield, Illinois 60015
14. Paul L. Doering, M.S.  
Distinguished Service Professor of Pharmacy Practice, Emeritus  
College of Pharmacy  
University of Florida  
101 South Newell Drive  
HPNP Bldg 212  
Room 3307  
Gainesville, Florida 32611

## V. SUMMARY OF TESTIMONY

### 1. Susan Langston, Diversion Program Manager (“DPM”), Miami Field Division<sup>3</sup>

DPM Langston will testify to her background, education and training as a DEA Diversion Investigator, Diversion Group Supervisor, and Diversion Program Manager. DPM Langston will testify about the problem of prescription painkiller diversion and abuse in Florida and the proliferation of “pill mills” employing unscrupulous doctors who prescribe controlled substances outside the usual course of professional practice or for other than legitimate medical purposes. DPM Langston will testify that since at least 2009, the State of Florida has been epicenter of a notorious, well-documented epidemic of prescription drug abuse. The controlled substances most commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol.

DPM Langston will testify that in response to the prescription pill epidemic, in 2010, the Florida legislature passed a law that restricted the ability of pain clinics to dispense controlled substances on site. DPM Langston will testify that once illicit prescriptions could not be filled at the pain clinic, pain clinic patients had to go to pharmacies to have their prescriptions filled. DPM Langston will testify that with the new law, came a wave of new pharmacy applicants for DEA registrations.

DPM Langston will testify that upon receiving applications from retail pharmacy owners in South Florida, DEA regularly conducts pre-registration interviews to discuss pharmaceutical drug diversion. In June 2011, Walgreens Co. submitted an application

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<sup>3</sup> In the event DPM Langston is unable to testify, GS Lane will offer the proposed testimony set forth below.

for a new pharmacy DEA registration in Miami. In response to Walgreen's new pharmacy application, DEA scheduled a meeting with Walgreens pharmacy representatives on August 19, 2011. DPM Langston will testify that in preparation for the meeting, DEA conducted a search of Walgreens Florida pharmacies' oxycodone purchases through DEA's Automation of Reports and Consolidated Orders System (ARCOS) which revealed that Respondent had significantly increased its oxycodone purchases between 2009 and 2011. DPM Langston will introduce an ARCOS report which shows that in 2009, Respondent had purchased a total of approximately 153,000 dosage units of oxycodone. In 2010, Respondent increased its purchases to 494,300 in 2010.<sup>4</sup> DPM Langston will introduce a chart prepared for the meeting with Walgreens entitled "2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone." The chart shows that by July 31, 2011, in just seven months, Respondent surpassed its 2010 oxycodone purchases, having purchased 781,000 dosage units of oxycodone. DPM Langston will testify that such a dramatic increase in oxycodone purchases is an indication to DEA investigators that pharmaceutical diversion might be occurring and, coupled with the timing of the state law changes regarding pill mill dispensing, should have been an indication or "red flag" to Respondent that it was likely dispensing oxycodone pursuant to illegitimate prescriptions.

DPM Langston will testify that at the August 19, 2011 meeting, DEA investigators met with Walgreen Co. officials to discuss Walgreens' oxycodone sales in Florida and oxycodone diversion in Florida. Present on behalf of Walgreen Co. were Dwayne Pinon (corporate in-house counsel), Ed Forbes (Market Loss Prevention

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<sup>4</sup> A more recent compilation from ARCOS indicates Respondent purchased approximately 507,100 dosage units of oxycodone in 2010.

Director), Wesley Rohn (Pharmacy District Supervisor), Joan Bustelo (Pharmacy District Supervisor), Anne-Marie Aldrick (Pharmacy District Supervisor), Cesar Cedeno (Pharmacy District Supervisor), Lakeisha Axem (Pharmacy Supervisor), Sandra Vazquesz (Pharmacy Supervisor), and Susan Thompson (Loss Prevention Manager).

DPM Langston will testify that she and Group Supervisor (GS) Gayle Lane discussed in detail suspicious activity or "red flags" indicating that a controlled substance prescription may have come from a rogue pain management clinic, may not have been issued for a legitimate medical purpose, and/or may have been issued outside the usual course of professional practice. DPM Langston will testify that she and GS Lane identified suspicious activity or red flags related to customers indicating a risk of diversion. Such red flags included the following: people from out-of-state using questionable Florida Identification Cards, groups of patients with the same prescriptions for the more common drugs of abuse (typically oxycodone 30mg, oxycodone 15mg, Alprazolam 2mg and Soma, and one or two non-controlled prescriptions), groups of patients receiving the same prescriptions and same diagnosis, patients between 22 and 45 years old, patients traveling significant distances to the pharmacy and/or to the pain management physician, and patients paying with cash. DPM Langston will testify that patients paying with non-insurance discount cards to pay for controlled substance prescriptions are considered the equivalent of cash payments.

DPM Langston will testify that DEA also discussed physician red flags or suspicious conduct indicating the prescriptions were not issued for legitimate medical purposes or were issued outside the usual course of professional practice including: doctors writing prescriptions for the same common drugs of abuse, doctors using the same diagnosis for multiple prescriptions, and doctors whose specialties are unrelated to

pain management (e.g., obstetrics, pediatrics, or ophthalmology) prescribing large quantities of Schedule II controlled substances.

DPM Langston will testify that she and GS Lane informed Walgreens representatives of information compiled by ARCOS pertaining to Respondent and other Walgreens pharmacies' purchases of oxycodone. DPM Langston will testify that Walgreens representatives were told that the average US pharmacy purchased 69,500 dosage units of oxycodone in 2010, whereas the average Florida pharmacy purchased 134,000 dosage units of oxycodone in 2010. DPM Langston will testify that the summary chart entitled "2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone" was discussed at the meeting and provided to Walgreens official Dwayne Pinon. DPM Langston will testify that Walgreens representatives were told that all of its pharmacies identified on the first page of the chart had, in the first seven months of 2011, ordered more than double the amount of oxycodone purchased by the average Florida pharmacy in 2010. Respondent was identified on the first page of the chart as having purchased 781,000 dosage units of oxycodone in the first seven months of 2011 and ranked #39 in the US for top purchasers of oxycodone. The ARCOS report will show that by the end of 2011, Respondent's oxycodone purchases increased to approximately 1,192,000 dosage units.

**2. Gayle Lane, Group Supervisor ("GS"), Miami Field Division<sup>5</sup>**

Following testimony regarding her experience and qualifications as a Diversion Group Supervisor, GS Lane will testify to the background of the investigation into

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<sup>5</sup> GS Lane may testify to portions of DPM Langston's testimony, in lieu of DPM Langston, as outlined above.

Respondent, which stemmed from Respondent and other Walgreens pharmacies' dramatic spike in oxycodone purchases.

GS Lane will testify that on August 19, 2011, DEA met with Walgreens representatives. GS Lane will testify that she and DPM Langston advised Walgreens of customer and physician specific red flags to look for prior to dispensing prescriptions for controlled substances. These red flags pertained to both patient and physician conduct, including physicians prescribing the same commonly abused controlled substances, utilizing the same diagnosis, not certified in pain management and/or practicing outside their specialty.

GS Lane will testify that on April 4, 2012, an Administrative Inspection Warrant (AIW) was executed at Walgreens # 04727. Pursuant to the AIW, investigators obtained inventory records, prescriptions for all Schedule II controlled substances, prescription labels for all dispensed Schedule II controlled substances, and an electronic dispensing log for all Schedule II-IV controlled substances dispensed by Respondent between January 1, 2010 and April 4, 2012.<sup>6</sup> GS Lane will introduce Respondent's dispensing log and summary charts which will show that Respondent dispensed controlled substances pursuant to prescriptions that presented obvious red flags.

GS Lane will testify that Respondent's dispensing log reveals that it filled prescriptions issued by doctors who routinely prescribed oxycodone and alprazolam "cocktails", who practiced outside their specialties, who were located significant distances away from the pharmacy, and whose patients paid for their prescriptions with cash or using non-insurance discount cards.

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<sup>6</sup> Prescription labels are affixed to the back of the prescriptions by Respondent on date of dispensing.



GS Lane will testify that between January 1, 2010 and March 21, 2012, Respondent filled 723 controlled substance prescriptions issued by Dr. Kenneth Pearlberg, an ophthalmologist<sup>7</sup>, located approximately 69 miles from Respondent in Boca Raton. Dr. Pearlberg surrendered his DEA registration for cause on March 21, 2012. Through her testimony and use of a chart that she prepared summarizing data from Respondent's dispensing log, GS Lane will show that approximately 73% of Dr. Pearlberg's prescriptions were for oxycodone and alprazolam cocktails. Approximately 50% of Dr. Pearlberg's patients paid for these prescriptions with cash or using non-insurance discount cards such as the WellCard, Familywise Card, Age & Agility Card, and Walgreens Card ("WCard").

GS Lane will testify that between January 1, 2010 and April 2012, Respondent dispensed at least 657 controlled substance prescriptions issued by Dr. Alexandra Taylor, certified in obstetrics and gynecology<sup>8</sup>, located in Del Ray Beach, Florida. GS Lane will introduce a chart she prepared summarizing data from Respondent's dispensing log, showing that approximately 78% of Dr. Taylor's prescriptions were for oxycodone and alprazolam cocktails.

GS Lane will testify that between January 1, 2010 and April 2012, Respondent dispensed at least 745 controlled substance prescriptions issued by Dr. Ralph Miniet, a pediatrics specialist<sup>9</sup>, located approximately 90 miles from Respondent in Fort Lauderdale, of which 73% of the prescriptions were for oxycodone and alprazolam cocktails. GS Lane will testify that approximately 86% of Dr. Miniet's patients paid for

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<sup>7</sup> GS Lane will introduce documents from the Florida Department of Health's medical license verification website showing that Dr. Pearlberg is an ophthalmologist.

<sup>8</sup> GS Lane will introduce documents from the Florida Department of Health's medical license verification website showing that Dr. Taylor is certified in obstetrics and gynecology.

<sup>9</sup> GS Lane will introduce documents from the Florida Department of Health's medical license verification website showing that Dr. Miniet specializes in pediatrics.

these prescriptions with cash or non-insurance discount cards. GS Lane will introduce prescription copies, prescription labels and a summary chart she prepared from Respondent's dispensing log regarding customers who were prescribed oxycodone by Dr. Miniet dispensed by Respondent on August 10, 2011 and October 4, 2011.<sup>10</sup>

GS Lane will testify about and introduce a sampling of 20 prescriptions for oxycodone dispensed by Respondent between March 2011 and December of 2011 despite its own pharmacists' warnings or noted "red flags" concerning the physicians. These warnings appear on the prescription labels under the physician's name as well as in Respondent's dispensing log. The physicians and the warnings on the prescription labels for filled oxycodone prescriptions include the following: Ramiro Abaunza, M.D., "DO NOT FILL CONTROL. MID UNDER INVESTIGAT"; Dr. Astrid Febre, "FAKE CII, VERIFY ALL, CANDY DR CHECK FOR"; John Wolf, M.D., "DO NOT FILL ANY CII"; Ronald Heromin, M.D., "DO NOT FILL CONTROLS"; and Barry Schultz, M.D.; "MD HAS HX OVERPRESCRIBE".<sup>11</sup>

GS Lane will introduce an Emergency Suspension Order from the Florida Department of Health showing that on April 13, 2011, it suspended the medical license of Barry Schultz, M.D. for excessive and inappropriate prescribing of controlled substances. GS Lane will introduce an excerpt from Respondent's dispensing log showing that it dispensed oxycodone pursuant to Dr. Schultz's prescriptions after his medical license was suspended on April 18 and 19, 2011. GS Lane will also discuss the pharmacist's notes in the dispensing log on the aforementioned dates which state "LIC. SUSP'D 4.14.11." GS Lane will introduce prescriptions issued by Dr. Schultz and Respondent's prescription

<sup>10</sup> The red flags associated with Dr. Miniet's prescriptions dispenses on these dates will be expanded upon through the proposed expert testimony of Paul Doering, M.S.

<sup>11</sup> The red flags associated with these prescriptions will be expanded upon through the expert testimony Paul Doering, M.S.

labels showing that it dispenses oxycodone pursuant to Dr. Schultz's prescriptions on April 18 and 19, 2011. The April 19, 2011 prescription label contains the following language under Dr. Schultz's name "13550 JOG RD.....LIC SUSP'D 4.14.11."

Through the testimony of GS Lane, the Government will introduce prescriptions, prescription labels, and a summary chart showing that Respondent filled oxycodone and alprazolam cocktail prescriptions on several occasions for a group of customers sharing the same addresses, prescribed by the same out town physician on May 4, June 1, June 28, July 26 and September 21, 2011.<sup>12</sup>

Through the testimony GS Lane, the Government will introduce a letter she obtained from St. Lucie County Sherriff's Office dated October 28, 2011 from Sherriff Ken Mascara to Respondent requesting Respondent's "*help in dealing the with prescription painkiller epidemic*" in St. Lucie County and Florida by "*closely scrutinizing*" prescriptions for Schedule II narcotics, written by out-of-town physicians and/or written for out-of town individuals.

GS Lane will testify that during the execution of the AIW on April 4, 2012, she spoke with Wesley Rohn, the District Pharmacy Supervisor for Palm Beach North. GS Lane recalled that Wesley Rohn attended the August 19, 2011 meeting with DEA Diversion management and investigators. GS Lane will testify that Mr. Rohn reviewed the AIW and then pointed to it and said they "don't do this anymore", and that they stopped "last month". When GS Lane asked Mr. Rohn why Respondent did not not take action after meeting with DEA eight months earlier, Mr. Rohn did not respond.

GS Lane will testify that on August 23, 2012, she and other DEA investigators

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<sup>12</sup> Red flags of diversion and abuse associated with the prescriptions dispensed on these dates will be expanded upon through the expert testimony Paul Doering, M.S.

and DEA Chief Counsel attorneys interviewed Walgreens pharmacist George Corripio. Mr. Corripio stated that he was transferred from Walgreens #5079 in Fort Pierce to Respondent for a period of about six months in 2010/2011.<sup>13</sup> GS Lane will testify that Mr. Corripio said that as soon as he was transferred to the store he immediately wanted to leave due to the heavy oxycodone traffic. Mr. Corripio said that "80% of clientele was oxy" and that he thought it was "terrible." Mr. Corripio said the oxycodone prescriptions were mainly for young people with diagnoses of lower back pain, that the pain clinics all gave the same lower back pain diagnosis for patients, and that the customers appeared to be under the influence of controlled substances. Mr. Corripio said that "nothing felt right" and he did not think the customers or the doctors were being truthful about the prescriptions.

Mr. Corripio stated that Respondent's Pharmacy Manager, Andrea Cohen, tried to alleviate his concerns regarding filling the oxycodone prescriptions. She told him to call the doctor, write a diagnosis code, and then "we will be fine." Mr. Corripio said he did not believe the diagnosis codes fit the customers. Mr. Corripio said he would fill one person's prescriptions, and immediately three to four other customers would come to the pharmacy with similar prescriptions. Moreover, when he would call the doctor's office, some person at the clinic who was not the doctor would rattle off the same diagnosis for all the patients. Mr. Corripio said Ms. Cohen filled the Schedule II narcotic prescriptions that he felt uncomfortable filling. Mr. Corripio said testify Ms. Cohen also filled the prescriptions that the floater pharmacists would not fill. Mr. Corripio told DEA investigators that when he refused to fill a prescription, customers would get angry and ask when the 'lady' pharmacist was coming back.

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<sup>13</sup> At the time of the interview, Mr. Corripio was working at Walgreens #5079 in Fort Pierce, Florida.

3. **Mary Chmielewski, Ph.D.**

Dr. Chmielewski is a Senior Personnel Psychologist who works in the Research & Analysis Group of DEA's Human Resources Division. In the course of her official duties, Dr. Chmielewski frequently performs statistical analysis and interpretation. Dr. Chmielewski will provide expert testimony regarding statistical analysis of ARCOS data related to the oxycodone purchased by Respondent between January 1, 2006 and December 31, 2011. Dr. Chmielewski will testify that the volume increase of oxycodone purchases observed over this period of time was statistically significant.

4. **Linda Stocum, Diversion Investigator<sup>14</sup>**

Following testimony about her experience and qualifications as a Diversion Investigator DI Stocum, will testify about the investigation into controlled substances filled by Walgreen Co.'s central fill facility located in Orlando, Florida. As part of the existing investigation into several Florida Walgreens pharmacies, including Respondent, and the Walgreens Distribution Center in Jupiter, Florida, DEA obtained hard copies of prescriptions filled at those pharmacies between January 2010 and April 2012. DEA also obtained controlled substances dispensing logs from the pharmacies. Based on a review of the documents obtained from the AIWs as well as the continuing DEA investigation into Walgreens, DEA requested copies of all controlled substance prescriptions filled by the Walgreens Mail Order facility out of Orlando, Florida. DEA obtained copies of all prescriptions filled by the facility between January 1, 2010 and April 2012.

After a review of the Mail Order prescriptions and a comparison to ARCOS information on controlled substance purchases made under the Mail Order DEA registration, DEA contacted the facility to inquire about large discrepancies between

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<sup>14</sup> In the event DI Stocum is unable to testify, GS Susan Slkyer will offer the proposed testimony below.

controlled substances ordered and prescriptions filled. At this time, Walgreens informed DEA that in addition to operating a mail order facility, Walgreens also runs their central pharmacy operations ("Central Fill") out of the same Orlando facility. DI Stocum will explain how the Central Fill facility operates: namely, that a Walgreens pharmacy will send certain prescriptions to the facility to be filled, and the facility will then send the filled prescription back to the pharmacy for dispensing to the ultimate customer.

DI Stocum and DI Deborah George conducted an on-site visit to the Central Fill facility on June 19 and June 21, 2012. DI Stocum will testify about the site visit and what she learned about the facility and operations at that time. She will testify that the Walgreens Central Fill staff provided verbal explanations of the operations conducted at the facility, but were unable to provide DEA with documentation regarding filled prescriptions.

DI Stocum will introduce an administrative subpoena issued on July 27, 2012 to Walgreen Co. for dispensing records from Central Fill. DI Stocum will testify that pursuant to an administrative subpoena, on October 25, 2012, Walgreen Co. produced dispensing log spreadsheets from Central Fill. DI Stocum will introduce a summary spreadsheet of Central Fill's prescriptions dispensed for Respondent between January 1, 2010 and June 12, 2012, indicating that Central Fill dispensed 648 prescriptions in Schedule III-V for Respondent.

DI Stocum will testify that pharmacies sending prescriptions to a central fill facility must notate "CENTRAL FILL" on the face of the original prescriptions as required under 21 C.F.R. § 1306.27(a)(1). DI Stocum will testify about the effect of non-compliance with this provision of the CFR; namely the complications created in

attempting to perform an audit or otherwise capture the full picture of tracking controlled substance distributions and dispensing.

**5. Dianne Williams, Diversion Investigator<sup>15</sup>**

Following testimony about her experience and qualifications as a Diversion Investigator, DI Williams will testify that she reviewed the Central Fill dispensing spreadsheet identifying 648 prescriptions filled for Respondent. DI Williams and DI Allison King reviewed prescription obtained pursuant to the AIW and noted that none of the prescriptions appeared to bear the notation "CENTRAL FILL".

On October 30, 2012, DI Williams and DI King visited Respondent and presented a Notice of Inspection to Pharmacy Manger Patrick Haro. DI Williams and DI King requested that Mr. Haro provide approximately twenty (20) controlled substances prescriptions filled for Respondent by the Central Fill. In addition, DI Williams requested copies of the computer print screen called "RX View" for each prescription. DI Williams will testify that that the RX View provides an image of the prescription accompanied with the prescription and dispensing information. DI Williams will introduce copies of 20 prescriptions and accompanying RX Views for the controlled substances prescriptions filled by Central Fill that were provided by Respondent following the inspection. The documents will show that Respondent failed write "CENTRAL FILL" on the face of any of the original prescriptions.

DI Williams will testify that per her request, Pharmacist Haro provided twenty (20) CPO FILL INTERSTORE TRANSFER CLAIM forms to support Respondent's receipt of the requested prescriptions which were filled by Central Fill. The transfer claims fail to identify the prescription number, patient name or any other way for DEA to

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<sup>15</sup> In the event DI Williams is unable to testify, DI Allison King will offer the proposed testimony below.

determine which prescription goes with which transfer claim. On eleven of the twenty Central Fill transfer claims, Respondent failed to record the date of receipt and the pharmacy employee accepting delivery of the filled prescriptions.

**6. George Corripio, Walgreens Pharmacist**

George Corripio will testify that he has been a pharmacist for 31 years and is a staff pharmacist at Walgreens 05079. Mr. Corripio was transferred to Respondent for a period of approximately six months in 2010/2011. He will testify that Walgreens 04727 had "heavy CII traffic" and after filling a few oxycodone prescriptions, he refused to fill more. Mr. Corripio will testify that "80% of clientele was oxy" and that he thought it was "terrible." Mr. Corripio will testify that there was a huge difference in clientele between Walgreens 04727 and his former pharmacy (Walgreens 05079) even though they were less than five miles apart. Mr. Corripio will testify that the oxycodone prescriptions were mainly for young people with diagnoses of lower back pain, that the pain clinics all gave the same lower back pain diagnosis for patients, that the customers appeared to be under the influence of controlled substances. Mr. Corripio will testify that "nothing felt right" and he did not think the customers or the doctors were being truthful about the prescriptions.

Mr. Corripio will testify that the Respondent's Pharmacy Manager, Andrea Cohen, tried to alleviate his concerns regarding filling oxycodone prescriptions. She told him to write a diagnosis code, call the doctor and then "we will be fine." However, Mr. Corripio did not believe the diagnosis codes fit the customers. He will testify that if he would fill one person's prescriptions, immediately three to four other customers would come to the pharmacy with similar prescriptions. Moreover, when he would call the doctor's office, some person at the clinic who was not the doctor would rattle of the same



diagnosis for all the patients. Eventually, Andrea Cohen told Mr. Corripio that she would fill the Schedule II narcotic prescriptions. Mr. Corripio will testify Andrea Cohen also filled the oxycodone prescriptions that Respondent's floater pharmacists would not fill. He will further testify that when he refused to fill a prescription, customers would get angry and ask when the "lady" pharmacist was coming back.

Mr. Corripio will testify that oxycodone dispensing at Walgreens 04727 was "out of control" and he told Fort Pierce police that he needed help. He said pharmacy personnel were aware of the problem, especially after receiving a letter from the St. Lucie County Sheriff's Office.

Mr. Corripio will testify that Andrea Cohen would almost always ask the "Oxy customers" if they would like to purchase the Walgreens cash discount card. Mr. Corripio will testify about the purpose of the cash discount cards and how it used with pharmacy prescriptions.

#### **7. Melissa Kayes, Pharmacy Technician**

Ms. Kayes will be asked to testify about oxycodone prescriptions filled while she was under the supervision of pharmacy manager Andrea Cohen. She will be asked to testify about red flags for diversion and abuse and how she would try to resolve those red flags. Ms. Kayes will be asked to testify about any guidance she received from Andrea Cohen on how to identify and handle suspicious prescriptions for controlled substances. Ms. Kayes will be asked to testify about the practice of refusing to fill prescriptions for controlled substances under her supervisor Andrea Cohen. Ms. Kayes will be asked to testify about specific oxycodone and alprazolam prescriptions she dispensed on May 4, 2011, June 28, 2011, and July 21, 2011.

**8. Andrea Cohen, Pharmacy Manager**

Ms. Cohen will be asked to testify about her experience as pharmacy manager and her role in dispensing oxycodone and other controlled substances as well as her supervision of pharmacists and pharmacy technicians. She will be asked about the explosive growth of oxycodone ordering and dispensing while she was pharmacy manager at Respondent's location.

Ms. Cohen will be asked about dispensing guidelines and practices while she was the manager at Respondent's location. Ms. Cohen will be asked about red flags for diversion and abuse and how she resolved those red flags prior to dispensing. She will be asked about guidance she received with respect to the growth of oxycodone customers in 2010 and 2011 and dispensing guidance from her supervisors.

She will be asked about the guidance she provided to other pharmacy staff on how to resolve red flags pertaining to controlled substance prescriptions. Ms. Cohen will be asked about filling oxycodone prescriptions for other pharmacists who declined to fill prescriptions. Ms. Cohen will be asked about specific prescriptions she dispensed and that were dispensed by other pharmacists and/or technicians under her supervision on May 4, 2011 and June 28, 2011 and July 26, 2011.

Ms. Cohen will be asked about any bonuses and salary raises while at Respondent's location. Ms. Cohen will be asked to testify about the circumstances concerning her transfer from Respondent to another Walgreen Co. pharmacy in Port Saint Lucie, Florida.

**9. Joseph Berdie, Assistant Store Manager**

Mr. Berdie will be asked about the oxycodone customer traffic at Respondent's location between 2010 through 2011. Mr. Berdie will be asked about an email he sent to

Wesley Rohn on January 5, 2011 entitled "C2 ID requirements" seeking advice about dispensing an oxycodone prescription to a customer without a proper ID. He will be asked to testify as to the direction he received from Wesley Rohn and/or other management. Mr. Berdie will be asked to testify about the guidance he received from Andrea Cohen, Wesley Rohn and other management on how to handle prescriptions or customers that present red flags for diversion and abuse. Mr. Berdie will be asked to testify about the controlled substances dispensing practices of other pharmacists and technicians that he observed.

**10. Wesley Rohn, Pharmacy District Supervisor**

Mr. Rohn will be asked to testify about inquiring about ordering a new CII safe for Respondent in December 2010. Mr. Rohn will be asked to testify about an email he sent to his district pharmacies on November 23, 2010 entitled "Professionalism and CII's" with instructions to "\*\*\*PLEASE POST ON CII CABINET\*\*". Mr. Rohn will be asked to testify about his response to concerns raised by Respondent's assistant store manager Joseph Berdie about concerns with dispensing controlled substances for a customer without a valid ID. He will be asked to discuss his response to concerns raised by Respondent's Store Manager Lori Bellino about Andrea Cohen and "C2" scripts. He will be asked to testify about guidance he emailed to his district following the August 22, 2011 meeting with DEA.

**11. Edward Svihra, RPH, Health Care Loss Prevention Director**

Mr. Svihra will be asked to testify about his Florida pharmacy "pain management" visits in early 2012 with Doug Lemmons and specifically, his visit to Respondent's store. Mr. Svihra will be asked to testify about concerns he, Doug Lemmons and Ken Amos discussed in January 2011 regarding Respondent's oxycodone

dispensing. Mr. Svihra will also be asked to testify about a pharmacist's hotline complaint received in 2011 regarding Respondent's pharmacists being asked to fill prescriptions they were uncomfortable filling.

**12. Doug Lemmons, Loss Prevention Operations Director**

Mr. Lemmons will be asked to testify his Florida pharmacy "pain management" visits in early 2012 with Edward Svihra, and specifically, his visit to Respondent's store in 2012. Mr. Lemmons will be asked to testify about concerns identified in January 2011 and discussed with Mr. Svihra and Ken Amos regarding Respondent's oxycodone dispensing.

**13. Edward J. Lanzetti, Market Loss Prevention Director**

Mr. Lanzetti will be asked about his role as a Market Loss Prevention Director and its relation to Respondent and other Walgreen's pharmacies' dispensing of controlled substances. He will be asked to testify about an email he sent dated May 19, 2011 in which he attached a "Special Focus on Profit for Florida Market" regarding Walgreens "CII" dispensing in Florida. He will be asked to testify about the red flags identified in the focus report. He will be asked to testify about his email dated June 21, 2011 raising concerns about the "Focus on Compliance" program (renamed from "Focus on Profit.")

**14. Paul Doering, M.S.**

Professor Doering will testify regarding his education, background, training, and experience as a pharmacist. In this regard, among other matters, Prof. Doering will testify that he (1) is a registered pharmacist in the states of Florida and North Carolina, (2) is certified as a Consultant Pharmacist in Florida, (3) previously practiced in the community pharmacy setting, (4) has been a professor at the University of Florida's

School of Pharmacy for the past 35 years, (5) currently serves at the University of Florida's College of Pharmacy as Distinguished Service Professor of Pharmacy Practice, Emeritus, and (6) for 28 years was either Director or Co-Director of the University of Florida's Drug Information and Pharmacy Resource Center, a telephone access service through which health professionals can obtain information about drugs or drug therapy. Prof. Doering will further testify about his experiences serving as an expert consultant and witness in a number of criminal, civil, and administrative proceedings. Prof. Doering will provide expert witness testimony as detailed below.

Prof. Doering will testify about the education and training pharmacists receive in pharmacy school, including learning the fundamentals of both state and federal pharmacy law as it relates to the filling and dispensing of prescription drugs in general, and controlled substances in particular. He will further testify about training pharmacists receive in the application of those laws to real life situations. He also will discuss the coverage of these topics in Florida's pharmacist licensing exam.

Prof. Doering will testify about the epidemic of prescription drug diversion and abuse in the state of Florida. He will discuss the in 2011 State of Emergency declared by the Florida Surgeon General which was issued in effort to prevent the many drug overdose deaths from controlled substances. The controlled substances commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol. Prof. Doering will testify about the overdose deaths due to oxycodone and benzodiazepines identified by the 2011 Florida Medical Examiners Report. He will testify that pharmacists are in a key position to reverse the trend of this epidemic.

Prof. Doering will further testify about the pharmacist's role in the distribution of prescription drugs that are controlled substances. He will testify about the dangerous propensities of certain controlled substances, in particular opiates and opioids such as oxycodone and benzodiazepines such as diazepam (Valium) and alprazolam (Xanax). Prof. Doering will testify that when controlled release opiate products are prescribed correctly, patients should not need to be on concurrent around the clock opiates for break through pain.

Prof. Doering will discuss the responsibilities of pharmacists in filling controlled substances prescriptions. Prof. Doering will testify about the review and analysis pharmacists should undertake before certifying any such prescription for release to the patient, including checking the licensing status of prescribers and evaluating whether the prescription presented to them is for a legitimate medical purpose and issued by a properly registered practitioner in the usual course of professional practice.

Moreover, Prof. Doering will testify about the "red flags," or, in other words, indicators of diversion and abuse, used by pharmacists to detect drug diversion. Because of the enormous abuse and diversion associated with oxycodone, the mere fact that an oxycodone prescription is being presented should put the pharmacist on full-alert to ensure that the prescription is valid. He will testify that oxycodone prescribed in combination with alprazolam and/or with carisoprodol, a popular "cocktail" combination in illicit use, should raise even more scrutiny with a pharmacist.

He will discuss certain patterns or circumstances that are consistent with drug diversion schemes that, in his opinion, a diligent pharmacist can observe, as well as the techniques that help the pharmacist detect drug diversion. Examples of such patterns or circumstances include, but are not limited to, patients who pay with cash, patients who

are prescribed large quantities of controlled substances, patients who share the same address, patients who are prescribed the same numbers and types or combinations of drugs, and patients who live a distance from the prescribing practitioner and/or pharmacy, including out-of-state patients and/or practitioners. His testimony also will cover the criteria appearing in the 2010 Edition of the Drug Enforcement Administration's Pharmacist's Manual, which provided guidance to pharmacists of indicators that a prescription was not issued for a legitimate medical purpose. Prof. Doering will testify that when taken together these "red flags" create enough suspicion that the reasonable and prudent pharmacist would refuse to fill the prescriptions.

Additionally, Prof. Doering will testify about the information he was provided by the DEA to review and analyze concerning Respondent. This information included, but is not limited to: Respondent's dispensing log, copies of prescriptions and prescription labels for Schedule II controlled substances dispensed by Respondent, specialty status for prescribers from the Florida Department of Health, spreadsheets for prescription dispensing activity, and copies of electronic mail messages dispatched to Respondent and other parties in the Walgreens organization.

Prof. Doering will testify that based on his education, training, and experience as a pharmacist, his review and analysis of the DEA information he received shows that Respondent's pharmacists ignored "red flags" of drug diversion or abuse and filled prescriptions that were issued outside the usual course of medical practice. He will testify that some, but not all, red flags can be resolved by a pharmacist. In those instances, when red flags are unresolvable, a reasonable pharmacist exercising due care would refuse to fill the prescription.

Prof. Doering will discuss his analysis of Respondent's controlled substance dispensing between January 1, 2010 and April 4, 2012. He will testify that while the number of dosage units ordered by a pharmacy does not confirm illegal activity, the larger the number of dosage units ordered and dispensed, the more suspicion is aroused. He will testify that the sheer number of controlled substance prescriptions filled per day can be an indicator that something might be awry. Prof. Doering will introduce a chart to illustrate the increase in Respondent's average daily dispensing of controlled substances. In the first six months of 2010, Respondent dispensed on average 35.3 controlled substance prescriptions per day. In the first six months of 2011, that number rose to an average of 72.5 prescriptions dispensed per day. For example, on June 28, 2011, Respondent filled 156 controlled substances prescriptions of which 42 prescriptions alone were for oxycodone 30mg. Prof. Doering will testify that a pharmacy that has been licensed since 1999, such as Respondent, would have expected its customer base to reach a plateau. Any drastic change in volume should cause a pharmacy to step back and figure out why. Professor Doering will testify that the rise oxycodone dispensing by Respondent in 2010-2011, coincides with the change in Florida law, which restricted controlled substance dispensing by practitioners.

#### **Candy Doctor Prescriptions**

Prof. Doering will testify about oxycodone dispensed by Respondent pursuant to prescriptions which Respondent's pharmacists noted on the prescription labels warnings about the legitimacy of the prescription and/or the prescriber. Prof. Doering will discuss the red flag notations in the dispensing log and appearing on the prescription labels. Such with warnings include: DO NOT FILL CONTROL. MD UNDER INVESTIGAT', "FAKE CII, VERIFY ALL, CANDY DR CHECK FOR", "DO NOT FILL CONTROLS", etc. Prof. Doering will



testify that despite these noted red flags that oxycodone prescriptions were illegitimate, Respondent dispensed oxycodone anyway.

#### **Dr. Miniet's Prescriptions**

Prof Doering will testify that he identified 13 high volume prescribers who make up only 0.7% of Respondent's controlled substance prescribers, but accounted for 17.7% of all controlled substances filled by Respondent. Prof. Doering will discuss Dr. Ralph Miniet (ranking #4 on the high volume prescriber chart). Dr. Ralph Miniet, a pediatrics specialist, located approximately 98 miles from Respondent in Fort Lauderdale, issued 745 prescriptions that were dispensed by Respondent. Prof Doering will testify that he analyzed two days of dispensing involving Dr. Miniet's oxycodone and alprazolam prescriptions.

Prof. Doering will testify that it is a red flag when more than one patient presents similar controlled substance prescriptions on the same day issued by the same physician. He will testify that a pharmacist should have heightened concern when seemingly unrelated persons present similar prescriptions from prescriber located far away within a short time period. Prof. Doering will introduce summary charts for two dispensing days showing prescriptions issued by Dr. Ralph Miniet. On August 10, 2011, Respondent filled 12 prescriptions for oxycodone 30mg, oxycodone /acetaminophen 10-325 mg, and alprazolam 2mg, for five patients, S.A., C.A., C.B., J.P, and R.B. The prescription labels indicate that four of the five patients had their prescriptions dispensed within the same two minute time frame. On October 4, 2011, Respondent filled 15 prescriptions for oxycodone 30 mg, oxycodone /acetaminophen 10-325 mg, alprazolam 2mg, issued by Dr. Miniet to six patients, S.A., C.A., C.B, J.P., S.M., and M.L. Prof. Doering will testify that the timing of dispensing indicates the prescriptions for each patient were filled on the

heels of the other. Prof. Doering will testify that on several of the customers' prescription labels, the pharmacist indicated that prescription could only be picked up by the patient. This indicates that a pharmacist already had some concerns about customer or the prescription. Prof. Doering will testify that on August 10 and October 4, 2011, Respondent dispensed the aforementioned prescriptions despite unresolved red flags.

#### **1205 Seaway Drive Customers**

Prof. Doering will testify that patients arriving in groups and or sharing the same address present a huge "red flag" to a pharmacist. This is because patients who learn of "pill mill" doctors in distance places from their homes will share transportation costs in traveling to those doctors and share transportation to pharmacies known to fill purported prescriptions without a hassle. Prof. Doering will discuss in detail twenty controlled substance prescriptions for oxycodone and alprazolam filled by Respondent on May 4, 2011 for 6 patients, B.A., J.B., M.H., N.C. R.O., and E.C., all of whom resided the same address, 1205 Seaway Drive, Apt. 4, Fort Pierce, Florida 34949. Additional red flags include the prescriptions being filled within minutes of each other, and that all prescriptions were issued by Dr. Charles Kessler, located approximately 99 miles away from Respondent in Plantation, Florida. Prof. Doering will testify that Respondent dispensed these controlled substance prescriptions to B.A., J.B., M.H., N.C., and E.C. in spite of unresolved red flags. He will testify that similar dispensing, despite multiple unresolved red flags, occurred with respect to these and additional patients residing at 1205 Seaway Drive, Apt. 4., or new shared addresses on June 1, 2011, June 28, 2011, July 26, 2011 and September 21, 2011.

On June 1, 2011, B.A, J.B., E.C., N.C., and R.O. presented oxycodone and alprazolam prescriptions all issued by Dr. John Carrozzella, a physician located

approximately 109 miles away from Respondent in Kissimmee, Florida. The prescription labels reveal that all five patients shared the same address at 1205 Seaway Drive Apt. 4, and all ten oxycodone prescriptions were dispensed within minutes of each other. Prof. Doering will testify Respondent dispensed these prescriptions for controlled substances despite multiple unresolved red flags.

On June 28, 2011, Respondent filled 12 controlled substance prescriptions for oxycodone and alprazolam for customers B.A., E.C., N.C. and R.O. all prescribed by Dr. John Carrozzella. The prescription labels reveal the N.C. and R.O. shared a new address at 1910 Wyoming Avenue in Fort Pierce. Additionally, Professor Doering will testify that on this date, Respondent dispensed an enormous volume of controlled substances, 155 prescriptions total.

On July 26, 2011, Respondent filled 15 controlled substances prescriptions for oxycodone and alprazolam for customers B.A., E.C., N.C., R.O., and M.H. All prescriptions were issued by Dr. John Carrozzella. All prescriptions were filled within minutes of each other. E.C. and M.H. shared the same address at 9319 Breakers Row, Fort Pierce, Florida. N.C. and R.O. shared the same address at 1910 Wyoming Avenue. Prof. Doering will testify that despite multiple unresolved red flags, Respondent dispensed controlled substances to these customers.

Prof Doering will discuss that on September 21, 2011, Respondent filled oxycodone and alprazolam prescriptions for M.H., E.C. and N.C., all prescribed by Dr. John Carrozzella. All three patients presented new Florida Identification cards picked up the same day and had changed their address from 1205 Seaway Dr. to 7500 Pensacola Road. Respondent's pharmacist handwrote concerns which identified red flags on the oxycodone prescription labels for M.H., E.C., and N.C. The pharmacist noted it was

“strange” that these three customers all picked up new Florida Identification Cards on the same day they presented their oxycodone prescriptions for filling, and the new identification cards showed they all shared the same new address. Prof. Doering will testify that these red flags were not resolved prior to Respondent dispensing controlled substances to these customers.

#### **Unauthorized Prescriptions**

Prof. Doering will testify that on several occasions, Respondent filled prescriptions by persons not authorized to prescribe controlled substances. He will testify that under Florida law, advanced registered nurse practitioners and physician assistants are not authorized to prescribe controlled substances. On at least four occasions, Respondent filled controlled substance prescriptions written by physician assistants. On at least two of those occasions, Respondent’s dispensing log showed that the physician assistant used a DEA registration assigned to a medical doctor. Prof. Doering will introduce a summary chart based on Respondent’s dispensing log showing on four occasions, Respondent dispensed controlled substances prescribed by the following physician assistants: Larry James, Michael Carpino, Peter Vo, and Jeffrey Patane. Through the testimony of Prof. Doering, the Government will introduce documentation from the Florida Department of Health showing the aforementioned individuals are licensed as physician assistants.

Prof. Doering will testify that in his opinion, Respondent’s pharmacists failed to exercise that degree of professional judgment that a reasonable and prudent pharmacist would have done in like or similar circumstances when dispensing controlled substances. He will opine that some red flags presented with prescriptions were unresolvable and that a prudent pharmacist would not have dispensed under those circumstances. He will opine

that Respondent's pharmacists failed to execute their duty to verify whether or not the large number of prescriptions written and dispensed were for a legitimate medical need and demonstrated a reckless indifference for the consequences of their actions or inactions.

#### VI. PROPOSED DOCUMENTS

Exhibit	Description	Approx. # Pages
1	DEA Certificate of Registration BW6561270 (attached hereto)	1
2	Walgreens Attendee List , DEA Meeting on August 19, 2011	2
3	Chart of Respondent's Oxycodone Sales & Ranking in 2010 and 2011 provided to Walgreens officials at August 19, 2011 DEA meeting	3
4	ARCOS Report of Respondent's Oxycodone Purchases, 2006-2012	5
5	Summary Chart of Respondent's Oxycodone Purchases	2
6	Curriculum Vitae of Mary E. Chmielewski, Ph.D	5
7	Copy of the Administrative Inspection Warrant dated April 3, 2012	12
8	DEA Receipt for Cash and Other Items dated April 4, 2012 identifying receipt of 4 boxes of Schedule II prescriptions	1
9	Administrative Subpoena dated March 19, 2012	1
10	Walgreens Response to Admin Subpoena dated May 4, 2012	6
11	Respondent's Controlled Substances Dispensing Log, January 2010 – April 4, 2012.	(CD ROM) 1,060
12	Florida Department of Health, Physician Profiles for physicians Alexandra Taylor M.D., Kenneth Pearlberg, M.D., and Ralph Miniet, M.D.	4
13	Summary Chart of Dr. Pearlberg's prescriptions	1
14	Summary Chart of Dr. Miniet's prescriptions	1
15	Summary Chart of Dr. Taylor's prescriptions	1
16	Dispensing Log Summary: Dr. Schultz	1
17	Florida Department of Health Emergency Suspension Order, Barry Schultz M.D., April 13, 2011	65
18	Copies of Prescriptions <sup>16</sup> re: Candy Drs., etc.	40

<sup>16</sup> All copies of prescriptions identified as Exhibits include copies of the prescription label affixed to the back of the prescription by Respondent on date of dispensing.

19	Copies of Prescriptions issued by Barry Schultz M.D.	4
20	Prescription copies for B.A., J.B., E.C., N.C., M.H., and R.O. dispensed on May 4, 2011	28
21	Prescription copies for B.A., J.B., E.C., N.C., and R.O. dispensed on June 1, 2011	20
22	Prescription copies for B.A., E.C., N.C., and J.B., dispensed on June 28, 2011	16
23	Prescription copies for B.A., E.C., N.C., M.H., and R.O. dispensed on July 26, 2011	20
24	Prescription copies for B.A., J.B., M.H., E.C. and N.C. dispensed on September 21, 2011	16
25	Prescription copies for S.A., C.A., C.B., J.P. and R.B. dispensed on August 10, 2011	20
26	Prescription copies for S.A., C.A., C.B., J.P., S.M., and M.L., dispensed on October 4, 2011	22
27	St. Lucie County Sherriff Ken Mascara Letter to Respondent, dated October 28, 2011	1
28	Administrative Subpoena issued July 27, 2012	6
29	Central Fill CII Dispensing Log	196
30	Notice of Inspection, October 30, 2012	1
31	Central Fill: 20 Prescription Copies, RX View, CPO Interstore Transfer Claims	60
32	Email from Pharmacy Manager 04727 forwarding Wesley Rohn email dated November 23, 2010 re: "Professionalism and CII's*** PLEASE POST ON CII CABINET****"	1
33	Email from Wesley Rohn dated December 2, 2010 re: "C-II Safe"	1
34	January 5, 2011 email exchange between Store 4727, Joseph Berdie, and Wes Rohn re: "C2 ID requirements?"	2
35	January 6, 2011 email exchange between Andrea Cohen and Wesley Rohn re: "CII procedures"	1
36	Email from Ed Lanzetti dated May 19, 2011 re: "Focus on Profit for Florida Market" with Attachment	8
37	Email from Store Manager 04727 dated January 12, 2011 re: "C2 Concerns"	1
38	Email chain dated January 17- 20, 2011, Subject: "Fort Pierce" (WAG00000889-0901)	13
39	Email from Wesley Rohn dated August 22, 2011 re: "DEA Meeting Best Practices"	1
40	Email dated March 22, 2012, "REQUEST REVIEW: Florida Pain Management Visits" (WAG00001638)	1
41	Curriculum Vitae of Paul L. Doering, M.S.	31
42	Chart of High Volume Prescribers	2
43	Summary Chart: Average Daily Dispensing of	1

	Controlled Substances, Six Month Increments (January 2010 – April 4, 2012)	
44	Summary Chart of Dr. Miniet's Filled Prescriptions on August 10, 2011 and October 4, 2011	2
45	Summary Chart Dispensing to 1205 Seaway Dr. Customers on May 4, June 1, June 28, July 26 and Sept 21, 2011	4
46	Summary Chart of Dispensing Physician Assistants' Controlled Substances Prescriptions	2
47	Florida Department of Health Licensure Verification re: Physician Assistants Larry James, Michael Carpino, Peter Vo and Jeffrey Patane	4

#### VII. POSITION REGARDING HEARING SITUS

The Government requests to hold the hearing at the DEA Hearing Facility (DEAHF) located at 1550 Crystal Drive, Suite 901, Arlington, Virginia.

#### VIII. OTHER MATTERS

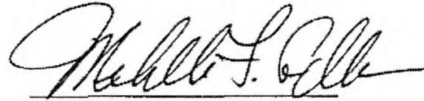
The Government reserves the opportunity to amend its instant pleading at a time and date specified by the presiding Administrative Law Judge. The Government requests the issuance of a protective order to prevent disclosure of the identities of Respondent's customers wherever such names and records are used in this proceeding.

The December 31, 2012 Orders for Prehearing Statements ordered the Government to present its position regarding the issue of consolidation and the possible *res judicata* effect of final factual and/or legal findings made by the Agency under Docket No. 13-1. The Government hereby incorporates by reference the separate filing on this issue regarding Docket Nos. 13-1, 13-9, 13-10, and 13-11.

**IX. BEST ESTIMATE AS TO TIME REQUIRED TO PRESENT CASE**

The Government anticipates requiring no more than three (3) days to present its case-in-chief, exclusive of cross-examination and rebuttal.

Respectfully submitted,



MICHELLE F. GILLICE  
SCOTT LAWSON  
Attorneys  
Diversion & Regulatory Litigation  
Office of Chief Counsel  
Drug Enforcement Administration  
8701 Morrisette Drive  
Springfield, Virginia 22152

Dated: January 9, 2013

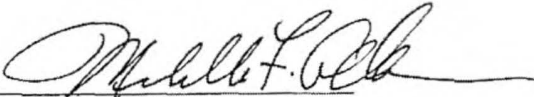


CERTIFICATE OF SERVICE

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **GOVERNMENT'S PREHEARING STATEMENT** to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* and first class mail to counsel for Respondent at the following addresses:

Phil Perry  
Allen M. Gardner  
Nathan H. Seltzer  
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Washington, DC 20004-2232  
Fax: 202.637.2201  
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Jan 9, 2013

  
Michelle F. Gillice  
Diversion & Regulatory Litigation  
Office of Chief Counsel  
Drug Enforcement Administration  
8701 Morrisette Drive  
Springfield, Virginia 22152

DEA REGISTRATION NUMBER		THIS REGISTRATION FEE	
BW6561270		EXPIRES	PAID
		05-31-2013	\$551
SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED	
2,2N,3 3N,4,5	CHAIN PHARMACY	05-12-2010	
WALGREEN CO. DBA: WALGREENS # 04727 4950 S US HWY 1 FT PIERCE, FL 34952			

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**  
 UNITED STATES DEPARTMENT OF JUSTICE  
 DRUG ENFORCEMENT ADMINISTRATION  
 WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**  
 UNITED STATES DEPARTMENT OF JUSTICE  
 DRUG ENFORCEMENT ADMINISTRATION  
 WASHINGTON, D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BW6561270	05-31-2013	\$551
SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5	CHAIN PHARMACY	05-12-2010
WALGREEN CO. DBA: WALGREENS # 04727 4950 S US HWY 1 FT PIERCE, FL 34952		

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (05/04)

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UNITED STATES DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF

WALGREEN, CO.  
D/B/A WALGREENS #06997

DOCKET NO. 13-11

ADMINISTRATIVE LAW JUDGE  
JOHN J. MULROONEY, II

GOVERNMENT'S PREHEARING STATEMENT

Jonathan Novak  
Scott Lawson  
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Date: January 9, 2013

[https://www.dea.gov/divisions/mia/2013/mia061113\\_appendixc.pdf](https://www.dea.gov/divisions/mia/2013/mia061113_appendixc.pdf)

Pursuant to the December 31, 2012 Order for Prehearing Statements, the United States Department of Justice, Drug Enforcement Administration (“DEA” or “Government”), hereby submits its Prehearing Statement.

### I. ISSUE

Whether DEA should revoke DEA Certificate of Registration BW8487438 issued to Walgreen Co. (“Respondent” or “Walgreens #06997”), pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f) and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(f).

### II. REQUESTED RELIEF

The Government requests revocation of Respondent’s DEA Certificate of Registration BW8487438.

### III. PROPOSED STIPULATIONS OF FACT

1. Walgreens #06997 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA Registration BW8487438 at 785 Lockwood Boulevard, Oviedo, Florida 32765.
2. DEA Registration Number BW8487438 expires by its terms on May 31, 2013.

### IV. PROPOSED WITNESSES<sup>1</sup>

1. Susan Langston  
Diversion Program Manager  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
2. Susan Slyker  
Group Supervisor  
DEA Orland District Office  
300 International Parkway, Suite 424

<sup>1</sup> In addition to those witnesses noted in the Government’s Prehearing Statement, the Government reserves the right to call any witnesses noted on Respondent’s proposed witness list.

Heathrow, Florida 32746

3. Deborah George  
Diversion Investigator  
DEA Orland District Office  
300 International Parkway, Suite 424  
Heathrow, Florida 32746
4. Linda Stocum  
Diversion Investigator  
DEA Orland District Office  
300 International Parkway, Suite 424  
Heathrow, Florida 32746
5. Jeffrey Chudnow  
Chief of Police  
Oviedo Police Department  
300 Alexandria Boulevard  
Oviedo, Florida 32766
6. Mary E. Chmielewski, Ph.D.  
Senior Personnel Psychologist  
DEA Research & Analysis Group, Human Resources Division  
600 Army Navy Drive  
Arlington, Virginia 22202
7. Paul L. Doering, M.S.  
Distinguished Service Professor of Pharmacy Practice, Emeritus  
College of Pharmacy  
University of Florida  
101 South Newell Drive  
HPNP Bldg 212  
Room 3307  
Gainesville, Florida 32611

## V. SUMMARY OF TESTIMONY

### 1. Diversion Program Manager Susan Langston

DPM Langston will testify to her background, education and training as a DEA Diversion Investigator, Diversion Group Supervisor, and Diversion Program Manager. DPM Langston will testify about the problem of prescription painkiller diversion and abuse in Florida and the

proliferation of "pill mills" employing unscrupulous doctors who prescribe controlled substances outside the usual course of professional practice or for other than legitimate medical purposes. DPM Langston will testify that since at least 2009, the State of Florida has been epicenter of a notorious, well-documented epidemic of prescription drug abuse. The controlled substances most commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol.

DPM Langston will testify that in response to the prescription pill epidemic, the Florida legislature passed a law in 2010 that restricted the ability of pain clinics to dispense controlled substances on site. DPM Langston will testify that once illicit prescriptions could not be filled at the pain clinic, pain clinic patients had to go to pharmacies to have their prescriptions filled. DPM Langston will testify that with the new law came a wave of new pharmacy applicants for DEA registrations.

DPM Langston will testify that upon receiving applications from retail pharmacy owners in South Florida, DEA regularly conducts pre-registration interviews to discuss pharmaceutical drug diversion. In June 2011, Walgreen Co. submitted an application for a new pharmacy DEA registration in Miami. In response to Walgreen's new pharmacy application, DEA scheduled a meeting with Walgreens pharmacy representatives on August 19, 2011. DPM Langston will testify that in preparation for the meeting, DEA conducted a search of Walgreens Florida pharmacies oxycodone purchases through DEA's Automation of Reports and Consolidated Orders System (ARCOS) which showed Walgreens #06997 significantly increased its oxycodone purchases between 2009 and 2011. DPM Langston will testify that such a dramatic increase in oxycodone purchases in such a short period of time is an indication to DEA

investigators that pharmaceutical diversion might be occurring and, coupled with the timing of the state law changes regarding pill mill dispensing, should have been an indication or "red flag" to Walgreens #06997 that it was likely dispensing oxycodone pursuant to illegitimate prescriptions.

DPM Langston will testify that at the August 19, 2011 meeting, DEA investigators met with Walgreens Co. officials to discuss Walgreens' oxycodone sales in Florida and oxycodone diversion in Florida. Present on behalf of Walgreen Corporation were Dwayne Piñon (corporate in-house counsel), Ed Forbes (Market Loss Prevention Director), Wesley Rohn (Pharmacy District Supervisor), Joan Bustelo (Pharmacy District Supervisor), Anne-Marie Aldrick (Pharmacy District Supervisor), Cesar Cedeno (Pharmacy District Supervisor), Lakeisha Axem (Pharmacy Supervisor), Sandra Vazquez (Pharmacy Supervisor), and Susan Thompson (Loss Prevention Manager).

DPM Langston will testify that at the August 19, 2011 meeting with Walgreens, she and Group Supervisor Gayle Lane discussed suspicious activity or "red flags" indicating that a controlled substance prescription may have come from a rogue pain management clinic, may not have been issued for a legitimate medical purpose, and/or may have been issued outside the usual course of professional practice. DPM Langston will testify that she and GS Lane identified suspicious activity or red flags related to customers indicating a risk of diversion. Such red flags included the following: people from out-of-state using questionable Florida Identification Cards, groups of patients with the same prescriptions for the more common drugs of abuse (typically oxycodone 30mg, oxycodone 15mg, Alprazolam 2mg and Soma, and one or two non-controlled prescriptions), groups of patients receiving the same prescriptions and same diagnosis, patients between 22 and 45 years old, patients traveling significant distances to the pharmacy and/or to



the pain management physician, and patients paying with cash. DPM Langston will testify that patients using with non-insurance discount cards to pay for controlled substance prescriptions is considered the equivalent of cash payments.

DPM Langston will testify that DEA also discussed physician red flags or suspicious conduct indicating the prescriptions were not issued for legitimate medical purposes or were issued outside the usual course of professional practice including: doctors writing prescriptions for the same common drugs of abuse, doctors using the same diagnosis for multiple prescriptions, and doctors whose specialties are unrelated to pain management (e.g., obstetrics, pediatrics, or ophthalmology) prescribing large quantities of Schedule II controlled substances. DPM Langston will testify that she and GS Lane informed Walgreens representatives of information compiled by ARCOS pertaining to Walgreens #06997 and other Walgreens pharmacies' purchases of oxycodone. DPM Langston will testify that Walgreens representatives were told that the average US pharmacy purchased 69, 500 dosage units of oxycodone in 2010, whereas the average Florida pharmacy purchased 134,000 dosage units of oxycodone in 2010. DPM Langston will testify that the summary chart entitled "2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone" was discussed at the meeting and provided to Walgreens official Dwayne Piñon. The ARCOS report will show that by then end of 2011, Walgreens #06997's oxycodone purchases increased to approximately 1,684,900 dosage units.

## **2. Group Supervisor Susan Slyker**

DEA Diversion Group Supervisor ("GS") Slyker will testify about her training, background, and her experience as a Diversion Investigator and Group Supervisor. She will further testify substantially as follows:

In April 2012, as part of a larger investigation into the controlled substance dispensing practices of multiple pharmacies and other distributors of controlled substances owned by Walgreen Co., GS Slyker participated in the execution of an Administrative Inspection Warrant at Walgreens Store #06997 located at 785 Lockwood Boulevard, Oviedo, Florida 32765. During the execution of the warrant, GS Slyker conducted interviews with pharmacy staff and technicians, as well as supervised the collection of prescriptions for Schedule II controlled substances. During the execution of the warrant, DEA obtained hard copies of all Schedule II prescriptions on hand at the pharmacy. Subsequent to the execution of the warrant, DEA obtained electronic copies of Walgreens #06997 dispensing logs from Walgreens corporate headquarters.

During the course of the continuing investigation into the dispensing practices of Walgreens #06997, GS Slyker became aware of prescriptions that had been filled under DEA registrations belonging to Dr. Ronald Lynch (BL6686541) and Dr. Anthony Wicks (BW7987184). Both Lynch and Wicks were known to DEA due to other investigations. GS Slyker will testify that an examination of the dispensing logs for Walgreens #06997, provided to DEA by Walgreens, revealed two hundred sixty eight (268) prescriptions for controlled substances filled for Dr. Anthony Wicks under registration BW7987184 between December 2010 and July 2011. During this period of time, Dr. Wicks was registered at an address in Visalia, California, until his registration expired on May 31, 2011. Walgreens #06997 filled at least sixty four (64) prescriptions for Dr. Wicks subsequent to the expiration of his registration. Similarly, the dispensing log showed that on June 6, 2011, Walgreens 06997 dispensed 30 dosage units of vyvanse, a Schedule II controlled substance under the registration of Dr. Ronald Lynch. Dr. Lynch's DEA registration BL6686541 was revoked by the Administrator on January

20, 2011.

In the event of witness unavailability or unforeseen issues, GS Slyker may be called upon to testify to parts of the proposed testimony of Diversion Investigators Linda Stocum and Deborah George.

### **3. Diversion Investigator Deborah George**

Diversion Investigator ("DI") George will testify to her background, education and training as a DEA Diversion Investigator. She will testify substantially as follows:

Subsequent to the execution of the Administrative Inspection Warrant at Walgreens #06997, DEA became aware of related investigations into criminal activity related to customers of Walgreens #06997. On April 18, 2012, DI George contacted the Oviedo Police Department to discuss any police investigations into activity at the pharmacy. On that date, DI George received, from the Oviedo Police Department, copies of multiple letters sent from the chief of police, Jeffrey Chudnow, to Walgreens #06997 informing the pharmacy that customers, to whom they had dispensed controlled substances, were arrested and charged criminally with illegal distribution of the very controlled substances dispensed by Walgreens #06997. Additionally, DI George obtained copies of the same letters, as sent from Chief Chudnow to the Chairman and to the CEO of Walgreens, informing Walgreens corporate headquarters of the arrests taking place at Walgreens #06997.

Upon receiving and examining the letters, DI George then compared the names of the arrestees identified in the Chudnow letters to the dispensing logs for Walgreens #06997 in order to corroborate the information provided in the letters. DI George was able to corroborate that the arrestees were in fact supplied with controlled substances from Walgreens #06997. These

customers of Walgreens #06997 included: Sean Reynolds, arrested November 11, 2010 for illegal distribution of Xanax; Frederick J. Goepel, arrested January 12, 2011 for illegal distribution of oxycodone; Clinton Brekke, arrested January 20, 2011 for possession with intent to sell oxycodone; Valerie Brekke, involved in the arrest of Clinton Brekke for possession with intent to sell oxycodone; Matthew S. Miller and Timothy Kemp Dawson, arrested January 21, 2011 for illegal distribution of oxycodone; Brian Lee Kemm, arrested on January 26, 2011 for illegal distribution of oxycodone; and, Staci Lynn Starling and Anna Marie Girst, involved in the arrest of Kemm as the customers purchasing illegal controlled substances.

DI George also found that despite the content of the letters from Chief Chudnow, Walgreens #06997 filled controlled substance prescriptions for some of the arrested customers subsequent to these arrests and notifications to Walgreens #06997. Clinton Brekke was arrested on January 20, 2011 and Chief Chudnow notified Walgreens in a letter dated January 21, 2011. Subsequently, Walgreens #06997 filled prescriptions for Mr. Brekke on March 13, April 7 and April 11, 2011. In the same letter regarding the arrest of Clinton Brekke, Valerie Brekke was identified as involved in the oxycodone-related arrest. Nonetheless, Walgreens #06997 filled prescriptions for Valerie Brekke for oxycodone on March 16 and April 25, 2011. In Chief Chudnow's January 27, 2011 letter, Staci Lynn Starling was noticed as a party purchasing oxycodone from Brian Lee Klemm. Nonetheless, Walgreen's #06997 dispensed alprazolam, hydromorphone and oxycodone to Ms. Starling on February 15, March 14 and April 13, 2011.

In the event of witness unavailability or unforeseen issues, DI George may be called upon to testify to parts of the proposed testimony of Diversion Investigator Linda Stocum and GS Slyker.

#### 4. Diversion Investigator Linda Stocum

Diversion Investigator (“DI”) Stocum will testify to her background, education and training as a Diversion Investigator with the Drug Enforcement Administration. She will further testify as follows:

As part of the existing investigation into several Walgreens pharmacies in Florida and the Walgreens Distribution Center in Jupiter, Florida, DEA obtained hard copies of prescriptions filled at those pharmacies between January 2010 and April 2012. DEA also obtained controlled substances dispensing logs from the pharmacies. Based on a review of the documents obtained from the Administrative Inspection Warrants as well as the continuing DEA investigation into Walgreens, DEA requested copies of all controlled substance prescriptions filled by the Walgreens Mail Order facility out of Orlando, Florida. DEA obtained copies of all prescriptions filled by the facility between January 1, 2010 and April 2012.

After a review of the Mail Order prescriptions and a comparison to ARCOS information on controlled substance purchases made under the Mail Order DEA registration, DEA contacted the facility to inquire about large discrepancies between controlled substances ordered and prescriptions filled. At this time, Walgreens informed DEA that in addition to operating a mail order facility, Walgreens also runs their central pharmacy operations (“Central Fill”) out of the same Orlando facility. DI Stocum will explain how the Central Fill facility operates: namely, that a Walgreens pharmacy will send certain prescriptions to the facility to be filled, and the facility will then send the filled prescription back to the pharmacy for dispensing to the ultimate customer.

DI Stocum and DI Deborah George conducted an on-site visit to the Central Fill facility on June 19 and June 21, 2012. DI Stocum will testify about the site visit and what she learned

about the facility and operations at that time. She will testify that the Walgreens Central Fill staff provided verbal explanations of the operations conducted at the facility, but were unable to provide DEA with documentation regarding filled prescriptions.

Subsequent to the on-site visit to Central Fill, DEA obtained the dispensing logs for Central Fill from Walgreens. DI Stocum compared the information in the Central Fill dispensing log to the prescriptions obtained from Walgreens #06997 during the execution of the April 2012 Administrative Inspection Warrant. DI Stocum found that the prescriptions sent from Walgreens #06997 to Central Fill lacked notation stating that the prescription was sent to Central Fill, as required under 21 C.F.R. § 1306.27(a)(1).

On October 25, 2012, DI Stocum visited Walgreens #06997 to review the pharmacy's prescription records pertaining to prescriptions reported as filled by Central Fill. DI Stocum will testify that she presented a Notice of Inspection to Pharmacy Manager Dan Heinis, and that Heinis assisted DEA in its inspection. DI Stocum requested to see prescriptions that she knew to have been filled by Central Fill based on the Central Fill dispensing log, and she testify about these prescriptions. Heinis assisted DI Stocum by providing the prescriptions. None of the prescriptions were marked as having been filled by Central Fill. Heinis stated that he could not identify which prescriptions were filled by Central Fill and which were filled by Walgreens #06997. Heinis discussed with DEA how and why a prescription might be filled by Central Fill instead of Walgreens #06997. Heinis also noted that when a prescription was filled by Central Fill but was not picked up by the ultimate customer, the controlled substance is automatically added to the retail store's inventory.

DI Stocum will testify about the practical effect of this aspect of Walgreens' practice; namely the complications created in attempting to perform an audit or otherwise capture the full

picture of tracking controlled substance distributions and dispensing.

In the event of witness unavailability or unforeseen issues, DI Stocum may be called upon to testify to parts of the proposed testimony of Diversion Investigator George and GS Slyker.

**5. Oviedo Police Department Chief of Police Jeffrey Chudnow**

Chief Chudnow will testify about his background, training and experience as a police officer and as the Chief of Police for Oviedo, Florida. Chief Chudnow will testify about the effects that the diversion of controlled substances has had on the city of Oviedo, as evidenced by increases in, among other things, crime rates and overdoses. Chief Chudnow will testify about his department's knowledge of Walgreens #06997, as well as another Walgreens store within the city limits, as centers for illicit controlled substance sales and use.

The Oviedo Police Department (OPD) made numerous arrests for illegal distribution of controlled substances in 2010 and 2011 related to controlled substances dispensed at the two Walgreens pharmacies, Walgreens #06997 and Walgreens #04251, with many of the illicit transactions preceding these arrests occurring in the parking lots of the stores. Chief Chudnow will testify that it was his practice following one of these arrests to send a letter to the pharmacy which dispensed the controlled substance being diverted, notifying them of the details and asking for the pharmacy's assistance in preventing future diversion. Chief Chudnow sent dozens of these letters, at least five of which will be offered into evidence, because Walgreens #06997 continued to dispense to some of these individuals even after being notified of their arrest.

On February 10, 2011, Chief Chudnow met with Ed Lanzetti, Walgreens Market Loss Prevention Director, and another Walgreens official. At the meeting, Chief Chudnow presented Mr. Lanzetti with numerous statistics and facts regarding controlled substance arrests related to

Walgreens' two Oveido pharmacies. These statistics included numbers and types of drug-related arrests, types of controlled substances seized per arrest, and statistics showing the names of doctors whose prescriptions were related to diversion arrests. Despite being given this information, Walgreens #06997 continued to fill prescriptions for these associated doctors subsequent to the February meeting with Chief Chudnow.

On March 15, 2011, Chief Chudnow sent letters to Alan G. McNally, Chairman of Walgreens Corporation and to Gregory D. Wasson, President and CEO of Walgreens Corporation, informing them about the numerous controlled substance arrests taking place at the Oveido Walgreens pharmacies and the effects on the community of Oveido, and asking for their assistance in stopping these problems. Chief Chudnow never received any response to his request for assistance from anyone at Walgreens.

**6. Mary E. Chmielewski, Ph.D.**

Mary E. Chmielewski, Ph.D., is a Senior Personnel Psychologist who works in the Research & Analysis Group of DEA's Human Resources Division. Dr. Chmielewski will be offered by the Government as an expert in statistical analysis related to the purchase of controlled substances by a registered pharmacy. In the course of her official duties, Dr. Chmielewski frequently performs statistical analysis and interpretation. Dr. Chmielewski has performed a statistical analysis of the ARCOS data related to the oxycodone purchased by Walgreens #06997 from January 2006 through December 2011. Dr. Chmielewski will testify that the volume increase of oxycodone purchases observed over this period of time was statistically significant.



## 7. Professor Paul Doering

Professor Doering will testify regarding his education, background, training, and experience as a pharmacist. Prof. Doering will testify that he (1) is a registered pharmacist in the states of Florida and North Carolina, (2) is certified as a Consultant Pharmacist in Florida, (3) previously practiced in the community pharmacy setting (4) has been a professor at the University of Florida's School of Pharmacy for the past 35 years, (5) currently serves at the University of Florida's College of Pharmacy as Distinguished Service Professor of Pharmacy Practice, Emeritus, and (6) for 28 years was either Director or Co-Director of the University of Florida's Drug Information and Pharmacy Resource Center, a telephone access service through which health professionals can get obtain information about drugs or drug therapy. Prof. Doering will further testify about his experiences serving as an expert consultant and witness in a number of criminal, civil, and administrative proceedings. Prof. Doering will provide expert witness testimony as detailed below.

Prof. Doering will testify about the education and training pharmacists receive in pharmacy school, including learning the fundamentals of both state and federal pharmacy law as it relates to the filling and dispensing of prescription drugs in general, and controlled substances in particular. He will further testify about training pharmacists receive in the application of those laws to real life situations. He also will discuss the coverage of these topics in Florida's pharmacist licensing exam.

Prof. Doering will testify about the epidemic of prescription drug diversion and abuse in the state of Florida. He will discuss the in 2011 State of Emergency declared by the Florida Surgeon General which was issued in effort to prevent the many drug overdose deaths from

controlled substances. The controlled substances commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol. Prof. Doering will testify about the overdose deaths due to oxycodone and benzodiazepines identified by the 2011 Florida Medical Examiners Report. He will testify that pharmacists are in a key position to reverse this trend of this epidemic.

Prof. Doering will further testify about the pharmacist's role in the distribution of prescription drugs that are controlled substances. He will testify about the dangerous propensities of certain controlled substances, in particular opiates and opioids such as oxycodone and benzodiazepines such as diazepam (Valium) and alprazolam (Xanax). Prof. Doering will testify that when controlled release opiate products are prescribed correctly, patients should not need to be on concurrent around the clock opiates for break through pain.

Prof. Doering will discuss the responsibilities of pharmacists in filling controlled substances prescriptions. Prof. Doering will testify about the review and analysis pharmacists should undertake before certifying any such prescription for release to the patient, including checking the licensing status of prescribers and evaluating whether the prescription presented to them is for a legitimate medical purpose and issued by a properly registered practitioner in the usual course of professional practice.

Prof. Doering will testify about the "red flags" used by pharmacists as indicators of diversion and abuse. Because of the enormous abuse and diversion associated with oxycodone, the mere fact that an oxycodone prescription is being presented should put the pharmacist on full-alert to ensure that the prescription is valid. Oxycodone prescribed in combination with alprazolam and/or with carisoprodol, a popular "cocktail" combination in illicit use, should raise

even more scrutiny with a pharmacist.

He will discuss certain patterns or circumstances that are consistent with drug diversion schemes that, in his opinion, a diligent pharmacist can observe, as well as the techniques that help the pharmacist detect drug diversion. Examples of such patterns or circumstances include, but are not limited to, patients who pay with cash, patients who are prescribed large quantities of controlled substances, patients who share the same address, patients who are prescribed the same numbers and types or combinations of drugs, and patients who live a distance from the prescribing practitioner and/or pharmacy, including out-of-state patients and/or practitioners. His testimony also will cover the criteria appearing in the 2010 Edition of the Drug Enforcement Administration's Pharmacist's Manual, which provided guidance to pharmacists of indicators that a prescription was not issued for a legitimate medical purpose. Prof. Doering will testify that when taken together these "red flags" create enough suspicion that the reasonable and prudent pharmacist would refuse to fill the prescriptions.

Additionally, Prof. Doering will testify about the information he was provided by the DEA to review and analyze concerning Walgreens #06997. This information included, but is not limited to: Walgreens #06997's dispensing log, copies of prescriptions and prescription labels for Schedule II controlled substances dispensed by Walgreens #06997, and copies of the letters sent by Chief Jeffrey Chudnow of the Oviedo Police Department to Walgreens #06997.

Prof. Doering will testify that based on his education, training, and experience as a pharmacist, his review and analysis of the DEA information he received shows that Walgreens #06997's pharmacists ignored "red flags" of drug diversion or abuse and filled prescriptions that were issued outside the usual course of medical practice. He will testify that some, but not all red flags can be resolved by a pharmacist. In those instances, when red flags are unresolvable, a

reasonable pharmacist exercising due care would refuse to fill the prescription.

Prof. Doering will discuss his analysis of Walgreens #06997's controlled substance dispensing between January 1, 2010 and April 4, 2012. He will testify that while the number of dosage units ordered by a pharmacy does not confirm illegal activity, the larger the number of dosage units ordered and dispensed, the more suspicion is aroused. He will testify that the sheer number of controlled substance prescriptions filled per day can be an indicator that something might be awry. Prof. Doering will discuss the increase in Walgreens #06997's average daily dispensing of controlled substances. Prof. Doering will testify that a pharmacy such as Walgreens #06997 would have expected its customer base to reach a plateau. Any drastic change in volume should cause a pharmacy to step back and figure out why. Professor Doering will testify that the rise oxycodone dispensing by Walgreens #06997 in 2010-2011, coincides with the change in Florida law, which restricted controlled substance dispensing by practitioners.

Professor Doering will testify about various other categories of red flags that appear in the dispensing logs, including customers arriving on the same day, living at the same address, and presenting prescriptions from the same doctor; customers traveling from distances over 50 miles away to have their prescriptions filled; customers prescribed a cocktail of highly abused controlled substances; and large numbers of customers presenting prescriptions from the same doctors, who primarily or exclusive prescribe highly abused controlled substances.

## VI. PROPOSED DOCUMENTS

1. DEA Certificate of Registration BW8487438 (1 page)
2. Chart entitled "2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone" (1 page)

3. Administrative Inspection Warrant (14 pages)
4. Certification of Registration History for DEA Certificate of Registration BW7987184 (2 pages)
5. Certification of Registration History for DEA Certificate of Registration BL6686541 (2 pages)
6. Dispensing Log for Walgreens #06997 (944 pages)
7. Excerpts of Dispensing Log: Wicks (8 pages)
8. Excerpts of Dispensing Log: Cocktail (20 pages)
9. Excerpts of Dispensing Log: Distances Traveled (12 pages)
10. Excerpts of Dispensing Log: Customers Coming From the Same Address (10 pages)
11. Copies of prescriptions sent from Walgreens #06997 to the Walgreens Central Fill facility
12. Letters from Oviedo Police Department to Walgreens (9 pages)
13. Chudnow Desktop Notes (2 pages)
14. Brekke Letters, Dispensing Logs and Prescriptions (30 pages)
15. Starling Letters, Dispensing Logs and Prescriptions (17 pages)
16. Oviedo Police Department Surveillance Statistics (2 pages)
17. Oviedo Police Department Arrest Statistics (1 page)
18. Curriculum Vitae of Mary E. Chmielewski, Ph.D. (5 pages)
19. Comparison of Total Dosages of Oxycodone by Year: Walgreens #06997 (2 pages)
20. Curriculum Vitae of Professor Paul Doering (31 pages)

#### **VII. OTHER MATTERS**

The Government reserves the opportunity to amend its instant pleading at a time and date specified by the presiding Administrative Law Judge. The Government requests the issuance of

a protective order to prevent disclosure of the identities of Walgreens #06997's customers wherever such names and records are used in this proceeding.

The December 31, 2012 Orders for Prehearing Statements ordered the Government to present its position regarding the issue of consolidation and the possible *res judicata* effect of final factual and/or legal findings made by the Agency under Docket No. 13-1. The Government hereby incorporates by reference the separate filing on this issue regarding Docket Nos. 13-1, 139, 13-10, and 13-11.

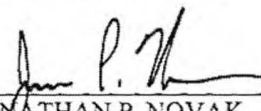
#### VIII. POSITION REGARDING HEARING SITUS

At this time, the Government does not request a change of location for the hearing.

#### IX. BEST ESTIMATE AS TO TIME REQUIRED TO PRESENT CASE

The Government anticipates requiring no more than two (2) days to present its case-in-chief, exclusive of cross-examination and rebuttal.

Respectfully submitted,

  
\_\_\_\_\_  
JONATHAN P. NOVAK  
Attorney  
Diversion & Regulatory Litigation  
Office of Chief Counsel

Date: January 9, 2013

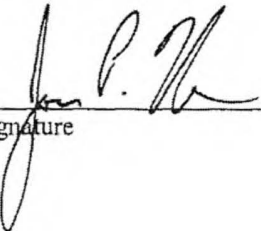
**CERTIFICATE OF SERVICE**

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **GOVERNMENT'S PREHEARING STATEMENT**, to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* to counsel for Respondent at the following addresses:

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4/9/13  
Date

  
\_\_\_\_\_  
Signature

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BW8487438	05-31-2013	\$551
SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5	CHAIN PHARMACY	05-12-2010
WALGREEN CO. DBA: WALGREENS # 06997 785 LOCKWOOD BLVD OVIEDO, FL 32765		

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**  
 UNITED STATES DEPARTMENT OF JUSTICE  
 DRUG ENFORCEMENT ADMINISTRATION  
 WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**  
 UNITED STATES DEPARTMENT OF JUSTICE  
 DRUG ENFORCEMENT ADMINISTRATION  
 WASHINGTON, D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
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SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
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WALGREEN CO. DBA: WALGREENS # 06997 785 LOCKWOOD BLVD OVIEDO, FL 32765		

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Form DEA-223 (05/04)



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UNITED STATES DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of  
  
**Walgreen Co.;**  
  
**Walgreen Co.**  
**d/b/a Walgreens #03629;**  
  
**Walgreen Co.**  
**d/b/a Walgreens #04727;**  
  
**Walgreen Co.**  
**d/b/a Walgreens #06977**

**Docket No. 13-1**

**Docket No. 13-9**

**Docket No. 13-10**

**Docket No. 13-11**

**CHIEF ADMINISTRATIVE LAW JUDGE  
JOHN J. MULROONEY, II**

**SUPPLEMENTAL PREHEARING STATEMENT  
ON BEHALF OF THE GOVERNMENT**

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Dated: February 8, 2013

[https://www.dea.gov/divisions/mia/2013/mia061113\\_appendixc.pdf](https://www.dea.gov/divisions/mia/2013/mia061113_appendixc.pdf)

Pursuant to the Administrative Law Judge's January 24, 2013 Amended and Consolidated Pre-Hearing Ruling and Protective Order, the United States Department of Justice, Drug Enforcement Administration ("DEA" or "Government") by and through its undersigned counsel, hereby respectfully submits the following supplement to its January 9, 2013, pre-hearing statements:

#### SUMMARY OF TESTIMONY

In addition to the summary of testimony provided in the Government's Prehearing Statements, the following witnesses will additionally testify as detailed below.

##### **Donna Richards, Diversion Investigator**

Diversion Investigator Donna Richards will testify to her further review of controlled substance prescriptions obtained from the Walgreens Corporation, specifically those dispensed by Walgreens #03629. She will testify that several of the seized prescriptions did not contain the full addresses of the patient as required by 21 C.F.R. § 1306.05(a); nevertheless, these prescriptions were filled by Walgreens #03629. She will testify to other violations noted in the manner in which prescriptions were issued by a practitioner and eventually filled by Walgreens #03629.

As noted in the Government's January 9, 2013 pre-hearing statement, Investigator Richards was expected to testify to her review of Walgreens #03629's dispensing logs which revealed that prescriptions were filled for physicians located significant distances from the pharmacy. Investigator Richards (or alternatively Investigator Flagg) will further testify to Walgreens #03629's dispensing pursuant to prescriptions issued by Miami-based physicians. These physicians issued prescriptions to patrons from distant locations like Ohio, Kentucky, Texas and Oklahoma. Investigator Richards will testify that what distinguished these out of state patrons from the "snowbirds" that typically

descend upon southern Florida was the unusual manner in which they obtained prescriptions from a physician in Miami, only to make the four and a half hour trip to Hudson, Florida to fill the prescriptions. Prof. Doering will also weigh in on these anomalous events and further posit that they presented red flags to the pharmacists at Walgreens #03629 that could not be resolved.

**Peter Flagg, Diversion Investigator**

Diversion Investigator Peter Flagg will further testify to Walgreens #03629's dispensing of controlled substances to customers from distant locations within Florida, including, but not limited to, Pensacola (approximately 405 miles or a six and one half hours from Hudson, Florida), Miami (approximately 307 miles or a five hour drive from Hudson, Florida) and Fort Lauderdale (approximately 292 miles or a nearly five hour drive from Hudson, Florida). Investigator Flagg will testify to his further review of Walgreens #03629's dispensing records, including those of December 2010, and corroborate testimony of TFO Pascalli that the pharmacy did not dispense controlled substances to James McCune when the latter attempted to pass a forged prescription on December 21, 2010.

Investigator Flagg (or alternatively Investigator Richards) will further testify to his review of dispensing logs of prescriptions issued by various practitioners, including those identified in the Government's January 9, 2013 pre-hearing statement, including, but not limited to, Drs. Abaunza, Wayne, Reppy, and McNichol. Investigator Flagg will testify that in preparation for his testimony, several prescriptions issued by the above physician were randomly selected. He will testify to some of his observations, including the distances travelled by pharmacy customers and identical prescriptions issued to persons residing in the same household. Specifically, Investigator Flagg will testify to

oxycodone prescriptions issued by Ronald Heromin, M.D. (Dr. Heromin) of Miami, Florida to customers residing in Somerset and surrounding areas in Kentucky. These customers would then make the four and a half hour trip to Hudson, Florida where the prescriptions would be filled by Walgreens #03629. Investigator Flagg will further testify to his further review of prescriptions issued by Dr. Reppy where the dispensing label for several of his prescriptions identified the physician's practice as a "Pill Mill." At least one Walgreens #03629 dispensing label alternatively referred to Dr. Reppy as an "Internet MD." Prof. Doering is expected to weigh in on these red flags that were not resolved by pharmacists at Walgreens #03629.

Investigator Flagg will further testify regarding Walgreens #03629 customers James and Peggy Norris who in late 2010 travelled more than four hours from their residence in Springhill (Florida) to Miami to obtain oxycodone prescriptions from Dr. Abaunza; they then made the return trip to Hudson to fill the prescriptions at Walgreens #03629. During the same period and into 2011, James Norris apparently engaged in doctor-shopping by obtaining oxycodone prescriptions from the aforementioned Dr. Heromin and these prescriptions were also filled at Walgreens #03629. Investigator Flagg will also testify that between December 2010 and March 15, 2011, Walgreens #03629 customer William Padgett doctor-shopped between Drs. Abaunza and Heromin and obtained prescriptions for oxycodone from both physicians where they were filled at Walgreens #03629. He will testify regarding additional instances of doctor-shopping by customers of Walgreens #03629. Prof. Doering is expected to testify that Walgreens #03629 did not resolve these obvious red flags before filling prescriptions for the Misters Norris and Padgett.

In addition, a cursory review of Walgreens #03629's dispensing spreadsheet and the pharmacy's dispensing label for an oxycodone prescription issued to James Norris on December 21, 2010 revealed discrepancies in the spelling of the customer's street address (*Tike* Avenue as opposed to the apparently correct address of *Pike* Avenue in Springhill, Florida). Investigator Flagg found the same issues with prescriptions dispensed for Blake Gumm, a then 22 year old individual who also obtained oxycodone prescriptions from Dr. Heromin and filled them at Walgreens #03629. The pharmacy's dispensing labels dated December 29, 2010 and January 8, 2011 (both for oxycodone 30mg.) revealed an Ocala, Florida address<sup>1</sup> for the customer. However, Walgreens #03629's dispensing log reveals a Somerset, Kentucky address for Blake Gumm. Investigator Flagg will testify that Walgreens #03629's failure to maintain a complete and accurate record of each controlled substance dispensed was in violation of 21 C.F.R. § 1304.21. Investigator Flagg will further testify that on July 31, 2010, Walgreens #03629 filled a prescription for oxycodone under the retired DEA registration number of Michael Romano in violation of 21 C.F.R. § 1306.03.

**Professor Paul Doering**

Testimony pertaining to Walgreens 03629 (Hudson)

Prof. Doering will testify regarding the large volume prescribing of oxycodone and other "cocktail" drugs by Michael Strobe, M.D. and Daniel Bender, M.D., in addition to practitioners outlined in the Government's January 9, 2013 pre-hearing statement. Prof. Doering will explain why he considers the above physicians as "suspect

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<sup>1</sup>Walgreen's # 03629 dispensing log reveals that this address in Ocala, Florida was the same address for an individual by the name of Robert Gumm, who also obtained prescriptions for oxycodone (80mg and 30mg) from Dr. Heromin and filled them at Walgreen's #03629 on January 7 and 8, 2011. It is unclear the relationship between Robert and Blake Gumm, however, Prof. Doering will testify that the circumstances of these prescriptions presented yet another red flag that was not resolved by Walgreen's #03629.

doctors,” based in relevant part upon their large volume prescribing of oxycodone and other drugs of abuse. Prof. Doering will testify that such large volume prescribing is yet another red flag to a pharmacist and because of the heightened scrutiny that should be given to these types of prescribers, pharmacies should exercise caution when filling their prescriptions. Prof. Doering will testify that Walgreens #03629 did not resolve the red flags presented by the prescriptions issued by Drs. Strobe and Bender before filling prescriptions issued by these practitioners.

Testimony pertaining to Walgreens 04727 (Fort Pierce)

Prof. Doering will testify about oxycodone Respondent dispensed pursuant to prescriptions issued by Dr. Barry Schultz despite red flags noted by Walgreens employees. Prof. Doering will also testify about two prescriptions for oxycodone that Respondent’s pharmacists dispensed after Dr. Schultz’s medical license was suspended by the State of Florida on April 13, 2011. Prof. Doering will testify that one of the two oxycodone prescriptions, which was dispensed on April 19, 2011, includes the notation: “LIC SUSP’D 4.14.11” next to Dr. Schultz’s address. Prof. Doering will testify that the red flags presented by Dr. Schultz’s prescriptions due to his medical license suspension were not resolved prior to dispensing controlled substances on April 18 and 19, 2011.

Prof. Doering will testify that pattern prescribing of controlled substances, particularly prescriptions for oxycodone and alprazolam, is a “red flag” indicating a risk of illegitimate prescriptions. Prof. Doering will testify that physicians that prescribe large volumes of controlled substances whose training are in areas other than pain management, is a “red flag”.

**Group Supervisor Gayle Lane<sup>1</sup>**

Through the testimony of GS Lane, the Government will introduce additional prescriptions obtained pursuant to the AIW at Respondent's pharmacy on April 4, 2012. GS Lane will introduce a prescription for oxycodone/acetaminophen prescribed by Michael Carpino on October 14, 2011 under DEA registration AD9312353. GS Lane will also introduce a prescription for oxycodone/acetaminophen prescribed by Peter Vo on October 27, 2011 under DEA registration number AF1972086.

Through the testimony of GS Lane, the Government will introduce emails pertaining to controlled substance dispensing at Walgreens 04727 produced by Respondent in response to an Administrative Subpoena dated March 19, 2012.

**George Corripio, Pharmacist**

Mr. Corripio will be asked to testify about Walgreens corporate and regional management oversight, guidance, and on-site visits pertaining to controlled substance dispensing at Walgreens 04727.

**Andrea Cohen, Pharmacy Manager**

Ms. Cohen will be asked to testify about red flags pertaining to additional prescriptions to which she initialed and signed her pharmacy license number including prescriptions issued by Drs. Ralph Miniet, Astrid Febre, Ramiro Abaunza, and Barry Schultz. Ms. Cohen will be asked to testify about Walgreens corporate and regional management oversight, guidance, and on-site visits pertaining to controlled substance dispensing at Walgreens 04727.

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<sup>1</sup> Diversion Investigator Gonzales and DPM Susan Langston may testify to portions of GS Lane's proposed testimony, in lieu of GS Lane, as outlined below and in the Government's Prehearing Statement, Docket 13-10, dated January 9, 2013.



**Melissa Kayes, Pharmacy Technician**

Ms. Kayes will be asked to testify about Walgreens corporate and regional management oversight, guidance, on-site visits pertaining to controlled substance dispensing at Walgreens 04727.

**Wesley Rohn, Pharmacy District Supervisor**

Mr. Rohn will be asked to testify about guidance he provided to Walgreens 04727 as well as his oversight of the pharmacy and on-site visits to examine and monitor the controlled substance dispensing.

**PROPOSED ADDITIONAL WITNESSES and TESTIMONY**

30. Domingo Gonzales, Diversion Investigator  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
31. Timothy Martin  
Diversion Investigator  
DEA Tucson District Office  
6970 South Palo Verde Road  
Tucson, AZ 85756-5006
32. Dwayne Pinon  
Senior Attorney  
Litigation and Regulatory Law  
Walgreen Co.  
104 Wilmot Rd., MS 1434  
Deerfield, IL 60015

**30. Domingo Gonzales, Diversion Investigator**

Following testimony about his experience and qualifications as a Diversion Investigator, DI Gonzales will testify as follows.

Testimony pertaining to Walgreens # 04727 (Fort Pierce)<sup>2</sup>

DI Gonzales will introduce several spreadsheets which he excerpted from Respondent's electronic dispensing log for Walgreens 04727 which summarize dispensing to particular customers on May 4, June 1, June 28, July 26, and September 21, 2011, as well as dispensing pursuant to prescriptions issued by Dr. Ralph Miniet on August 10, 2011 and October 4, 2011.

DI Gonzales will also introduce spreadsheets he created from Respondent's electronic dispensing log for prescriptions issued by Drs. Barry Schultz, Ralph Miniet, Kenneth Pearlberg, and Alexandra Taylor. With respect to spreadsheets pertaining to prescriptions issued by Drs. Miniet, Pearlberg, and Taylor, DI Gonzales will testify as to how he calculated the percentage of "cocktail prescriptions" and oxycodone 30mg prescriptions paid for by cash (including payment through use of non-insurance discount cards.)<sup>3</sup>

More specifically, DI Gonzales will testify that between January 1, 2010 and March 21, 2012, Respondent dispensed 723 prescriptions for controlled substances prescribed by Dr. Kenneth Pearlberg, of which 523 prescriptions or 72 percent were for "cocktail" controlled substances (oxycodone, alprazolam, and carisprodol) which are highly sought for illicit use. DI Gonzales will testify that 62 percent of the prescriptions for oxycodone 30mg were paid for with cash (including use of non-insurance discount cards).

DI Gonzales will testify that between October 20, 2010 and October 31, 2011, Respondent dispensed 745 prescriptions for controlled substances prescribed by Dr.

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<sup>2</sup> GS Lane may testify to portions of DI Gonzales testimony, in lieu of DI Gonzales, as outlined below.

<sup>3</sup> The proposed testimony pertaining to cocktail prescriptions and cash payments for prescriptions issued by Drs. Pearlberg, Miniet and Taylor revises the proposed testimony of GS Lane in the Government's Prehearing Statement Docket 13-10, at 11-12.

Ralph Miniet of which 542 or 73 percent were for “cocktail” controlled substances: oxycodone, alprazolam and carisoprodol. DI Gonzales will testify that 86 percent of the prescriptions for oxycodone 30mg were paid for with cash (including use of non-insurance discount cards.)

DI Gonzales will testify that between March 30, 2010 and March 20, 2012, Respondent dispensed 657 prescriptions for controlled substances prescribed by Dr. Alexandra Taylor, of which 514 prescriptions or 78 percent were for “cocktail” controlled substances (oxycodone, alprazolam and carisoprodol). DI Gonzales will testify that 82 percent of the prescriptions for oxycodone 30mg were paid for with cash (including use of non-insurance discount cards.)

Through the testimony of DI Gonzales, the Government will introduce a spreadsheet excerpted from Respondent’s electronic dispensing log for dispensing events that correspond to controlled substance prescriptions issued by Drs. John Wolf, Astrid Febre, Barry Schultz, Ronald Heromin and Ramiro Abaunza in which pharmacists’ warnings about the prescriber are printed on the prescription label.

Through the testimony of DI Gonzales, the Government will introduce professional licensure verification from the Florida Department of Health identifying Peter Vo and Michael Carpino as physician assistants. DI Gonzales will introduce a summary chart he created from Respondent’s dispensing log showing that on October 14, 2011, Respondent dispensed 90 dosage units of oxycodone/acetaminophen prescribed by Michael Carpino under DEA registration number AD9312353. On October 27, 2011, Respondent dispensed 60 dosage units of oxycodone/acetaminophen prescribed by Peter Vo under DEA registration number AF1972086. DI Gonzales will introduce DEA certificate of registration AD 9312353 identifying Richard Allen Dube, M.D., as the

registrant and DEA certificate of registration AF1972086 identifying Gerard Quincy C Flores, M.D., as the registrant.

Testimony Pertaining to Walgreens #03629 (Hudson)

DI Gonzales will testify to his preparation of several spreadsheets excerpted from Walgreens #03629's electronic dispensing log. Specifically, he will testify to his preparation of spreadsheets of Walgreens #03629's dispensing pursuant to prescriptions issued by Michael Strobee, M.D., Daniel Bender, M.D., and Ronald Heromin, M.D., as well as Drs. Abaunza, Reppy, McNichol, Wayne, Wolffe, Legowik and Glusman.

Investigator Gonzales will further testify to his preparation of a chart showing the distances travelled by customers of Walgreens #03629. The distances measured and charted will not only cover travel from the practice locations of the prescribing physicians to Walgreens #03629, but the distances travelled by these customers from their residential locations to physician locations. In at least one instance, the distance travelled by a customer from his listed residence in Pensacola, Florida to his physician's office in Miami was approximately 674 miles or a nine hour drive. The above distance and travel times were calculated based on Walgreens #03629's dispensing and prescription data.

Investigator Gonzales will further testify to his preparation of spreadsheets showing Walgreen's #03629's Customer Dispensing History by Drug. The spreadsheets will show Walgreen's #03629's dispensing for Michael Strobee, M.D., Daniel Bender, M.D., and Ronald Heromin, M.D., as well as the aforementioned Drs. Abaunza, Reppy, McNichol, Wayne, Wolffe, Legowik and Glusman. The spreadsheets will provide a history of prescriptions issued by the above physicians. Investigator Gonzales will also identify instances where prescriptions issued by the above physicians included drug

cocktails consisting of oxycodone, alprazolam and/or carisoprodol. Again, Investigator Gonzales will testify that these dispensing history spreadsheets were derived from Walgreens #03629 dispensing and prescription data. Professor Paul Doering will also testify to these drug combinations and how they should inform a pharmacist's decision on whether or not such prescriptions should be filled.

**31. Timothy Martin, Diversion Investigator**

DI Martin, after describing his training and experience, will testify about his investigation of the Walgreens Tempe Central Pharmacy Operations (Tempe CPO) facility at 8350 S. River Parkway, Tempe, AZ 85284. This facility is registered with DEA as Walgreen's Mail Service, Inc., under DEA number BW4197883. The Tempe CPO facility performs central fill activities coincident to its registration as a retail chain pharmacy.

DI Martin will describe the basis for his investigation of this facility and the interviews he conducted while inspecting this registrant. He will testify that in March 2011, he informed Matt Cook, the Pharmacy Operations Manager at the Tempe CPO, that a review of central fill prescription records at Walgreens retail pharmacy #4102 in Tucson revealed that the words "Central Fill" were not written on the face of prescriptions that pharmacy #4102 sent to the Tempe CPO for filling, in violation of 21 C.F.R. § 1306.27(a)(1). DI Martin will testify that he has subsequently visited a number of Walgreens pharmacies in the Tucson area and confirmed that they also do not comply with the regulation when submitting prescriptions to the central-fill facility.

DI Martin (or alternatively DI Linda Stocum) will testify that since May of 2011, Mr. Cook has been the Pharmacy Operations Manager at the Orlando Central Fill facility

that provides central-fill services for Walgreens Florida retail pharmacies, including each of the Respondent pharmacies in the consolidated hearing.

**32. Dwayne Pinon, Senior Attorney, Walgreen Co.**

The Government requests to call Walgreens' attorney Dwayne Pinon as a witness.

The basis for requesting Mr. Pinon as a substantive witness is as follows:

In the documents Respondent provided on February 1, 2013 pursuant to the Court's order concerning exchange of proposed exhibits for the pharmacy matters, Docket Nos. 13-9, 13-10, and 13-11, Respondent provided a number of proposed exhibits that relate not to pharmacy matters, but to the allegations concerning suspicious order reporting raised only in the original, Jupiter Distribution Center matter, Docket No. 13-1. Notwithstanding that additional documents for the distribution center matter were to be exchanged with Supplemental Prehearing Statements on December 7, 2012, Respondents Proposed Exhibits 295 – 300 are only relevant, if at all, to the suspicious order issue.

Surprisingly, a number of these documents are communications from attorney Dwayne Pinon and appear to be offered as evidence of the defense, previously raised in Respondent's Prehearing Statement, that their suspicious order reporting system is based on DEA's guidance for the reporting of suspicious List I chemical transactions. (See Respondent's Prehearing Statement for Docket No. 13-1, Proposed Testimony of Denny Murray, p. 11.) Respondent's Proposed Exhibit 298 purports to be a letter from Mr. Pinon to a DEA official in Detroit, in which he advises that Walgreens is revising its controlled substance suspicious order system in accordance with formulas taken from DEA's Chemical Handlers Manual, which itself is listed as Respondent's Proposed Exhibit 296. In its Proposed Exhibit 299, Respondent offers an email sent by Mr. Pinon on March 26, 2008, in which he also discusses the propriety of using the chemical

suspicious order system for controlled substances. Respondent has previously offered a similar email from Mr. Pinon as Proposed Exhibit 250.

By offering Exhibits 250, 298, and 299, communications from Mr. Pinon to DEA officials, as purported evidence of Walgreens' reliance on the chemical handlers program for designing its controlled substance suspicious orders program, Walgreens has made the reasonableness of any conclusions or advice drawn from these documents a matter in controversy. Rather than accept the hearsay nature of these documents, the Government is entitled to elicit testimony from Mr. Pinon about his role in the development of Walgreens' suspicious order systems, the context of these communications, whether or not he made or received any other communications from DEA on this issue, and whether or not Mr. Pinon considered the ample countervailing sources of information that refute his supposition that the Chemical Program should be used as guidance for controlled substance suspicious order reporting.

Department of Justice policy requires approval of the Criminal Division prior to serving an attorney with a subpoena. See United States Attorney Manual, § 9-13.410. The Government has submitted the request seeking this approval through the Office of Enforcement Operations (OEO). Attached hereto is a proposed subpoena for Mr. Pinon. The Government will not serve such unless and until OEO provides the necessary approval.

**OTHER MATTERS WHICH MAY AID IN THE EXPEDITIOUS DISPOSITION  
OF THE HEARING**

The Government hereby notices this tribunal of its intent to offer the testimony of TFO Janet Pascalli via VTC. The expected VTC location and contact information is as follows:

Drug Enforcement Administration  
Tampa District Office  
4950 West Kennedy Blvd.  
Suite 400  
Tampa, Florida 33609  
Contact point: TDO Tech Ops Special Agent Ken Harris, (813) 287-4761.

**PROPOSED ADDITIONAL DOCUMENTARY EXHIBITS**

- Gov't. Ex. 177, James McCune prescription dated December 16, 2010
- Gov't. Ex. 178, Pasco County Police report, continuation sheet and attached affidavit
- Gov't. Ex. 96-101, 176, and 204-206, Excerpts - Walgreen's #03629's dispensing log of selected practitioners
- Gov't. Ex. 109, 189-197, Copies of randomly selected prescriptions filled by Walgreens 03629
- Gov't. Ex. 184, 185, Prescriptions issued by Michael E. Romano, M.D.
- Gov't. Ex. 189-197, Walgreen's #03629 – Customer Dispensing History by Drug
- Gov't. Ex. 198, Chart – Customer Distance/Travel Time
- Gov't. Ex. 200, Prescriptions - James and Peggy Norris
- Gov't. Ex. 201, Robert Reppy, D.O. "Internet MD" prescription
- Gov't. Ex. 202, Robert Reppy, D.O. "Pill Mill" prescriptions
- Gov't. Ex. 203, Certified registration history – Michael E. Romano, M.D. (retired DEA registration number FR0695722
- Gov't. Ex. 207, Andrea Cohen DOH License Verification
- Gov't. Ex. 208, DEA Certificate of Registration, No. AD9312353, Richard Allan



Dube, M.D.

Gov't. Ex. 209, DEA Registration Certificate of Registration, No.AF1972086, Gerard Quincy Flores, M.D.


Gov't. Ex. 210, Walgreens 04727 Dispensing Log Excerpt Corresponding to Ex. 125 prescriptions

Gov't. Ex. 211, Physician Assistant Oxycodone Prescriptions

Respectfully submitted,

UNITED STATES DEPARTMENT OF JUSTICE  
Drug Enforcement Administration

By:



Scott Lawson  
Attorney  
Office of Chief Counsel  
Drug Enforcement Administration  
8701 Morrissette Drive  
Springfield, Virginia 22152

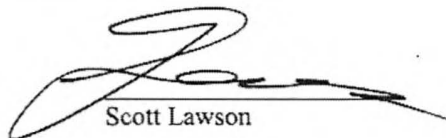
Dated: February 8, 2013

**CERTIFICATE OF SERVICE**

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **SUPPLEMENTAL PREHEARING STATEMENT ON BEHALF OF THE GOVERNMENT** to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent *via e-mail* and first class mail to counsel for Respondent at the following address:

Phillip J. Perry  
Nathan H. Selzer  
Allen M. Gardner  
Lantham & Watkins, LLP  
555 Eleventh Street, NW  
Suite 1000,  
Washington, D.C. 20004  
Email: [Phi.Perry@lw.com](mailto:Phi.Perry@lw.com)  
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[Nathan.Seltzer@lw.com](mailto:Nathan.Seltzer@lw.com)

2/8/13

  
Scott Lawson

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**UNITED STATES DEPARTMENT OF JUSTICE  
Drug Enforcement Administration**

<p><b>IN THE MATTER OF</b></p> <p><b>WALGREEN, CO.</b></p> <p><b>WALGREEN, CO.</b> <b>D/B/A WALGREENS #03629,</b></p> <p><b>WALGREEN, CO.</b> <b>D/B/A WALGREENS #04727,</b></p> <p><b>WALGREEN, CO.</b> <b>D/B/A WALGREENS #06997,</b></p> <p><b>WALGREEN, CO.</b> <b>D/B/A WALGREENS #03836,</b></p> <p><b>WALGREEN, CO.</b> <b>D/B/A WALGREENS #04391,</b></p> <p><b>WALGREEN, CO.</b> <b>D/B/A WALGREENS #03099</b></p>	<p><b>DOCKET NO. 13-1</b></p> <p><b>DOCKET NO. 13-9</b></p> <p><b>DOCKET NO. 13-10</b></p> <p><b>DOCKET NO. 13-11</b></p> <p><b>DOCKET NO. 13-16</b></p> <p><b>DOCKET NO. 13-18</b></p> <p><b>DOCKET NO. 13-20</b></p>
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**GOVERNMENT'S PREHEARING STATEMENT FOR  
WALGREENS #03836**

**FRANK W. MANN**  
Senior Attorney  
Diversion and Regulatory Litigation  
Office of Chief Counsel  
Drug Enforcement Administration  
8701 Morrisette Drive  
Springfield, Virginia 22152  
(202) 353-9647 (office)  
(202) 307-4946 (facsimile)

Dated: March 8, 2013

[https://www.dea.gov/divisions/mia/2013/mia061113\\_appendixc.pdf](https://www.dea.gov/divisions/mia/2013/mia061113_appendixc.pdf)

Pursuant to the February 12, 2013 Order for Prehearing Statements and the February 27, 2013, Order Granting the Government's Unopposed Motion for Enlargement of Prehearing Statement Deadlines in Docket No. 13-16, the United States Department of Justice, Drug Enforcement Administration (DEA or Government), hereby submits its Prehearing Statement regarding Walgreens 03836.

### I. ISSUE

Whether DEA should revoke DEA Certificate of Registration AW8830247 issued to Walgreen Co. 03836 ("Respondent"), pursuant to 21 U.S.C. §§ 824(a)(4) and 823(?) and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(f).

### II. REQUESTED RELIEF

The Government requests a ruling by the Administrative Law Judge recommending that the Respondent's Certificate of Registration AW8830247 be revoked, and that any pending application for renewal or modification of such registration be denied.

### III. PROPOSED STIPULATIONS OF FACT<sup>1</sup>

1. Respondent is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number AW8830247 at 9332 U.S. Highway 19, Port Richey, Florida 34668. DEA registration AW8830247 expires by its terms on May 31, 2013.
2. Respondent is licensed by the Florida Department of Health as a pharmacy under license number PH7367.
3. Oxycodone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(xiii).

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<sup>1</sup> The Government anticipates discussing additional stipulations with Respondent.

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4. Methadone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(c)(15).
5. Hydromorphone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(vii).
6. Alprazolam is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(1).

#### IV. PROPOSED WITNESSES<sup>2</sup>

1. Susan Langston  
Diversion Program Manager  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
2. Gayle Lane  
Diversion Group Supervisor  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
3. Domingo Gonzales and/or Dianne Williams  
Diversion Investigator  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
4. Paul L. Doering, M.S.  
Distinguished Service Professor of Pharmacy Practice, Emeritus  
College of Pharmacy  
University of Florida  
101 South Newell Drive  
HPNP Bldg 212  
Room 3307  
Gainesville, Florida 32611
5. Cassie Mulvey  
2667 Sabal Springs Circle  
Apt 204  
Clearwater, FL 33761
6. Tara Karavicus  
8102 N. Sheldon Road  
Apt. 1008  
Tampa, FL 33615

<sup>2</sup> In addition to the witnesses identified below, DEA reserves the right to call any of the witnesses listed by Respondent on matters identified by Respondent.

- 7. Shane Van Gordon  
11438 Rohrman Road  
Port Richey, FL 34668
- 8. Jade Leppi  
9118 Ruger Drive  
New Port Richey, FL 34655
- 9. Kate Wilson  
8851 Candlewick Lane  
Port Richey, FL 34668
- 10. Sanjay Patel  
1524 Stipule Court  
Trinity, FL 34655
- 11. Fred Casale  
1473 Mallard Place  
Palm Harbor, FL 34683
- 12. Michael Nunez  
7815 Talisman Road  
Port Richey, FL 34668
- 13. Terrence Myers  
18511 US Highway 41 N  
Lutz, FL 33549
- 14. Dale Randall  
21216 Snow Hill Road  
Brooksville, FL 34601
- 15. Quang Tran  
2432 Mountain Ash Way  
New Port Richey, FL 34655

**V. SUMMARY OF TESTIMONY**

- 1. **Susan Langston, Diversion Program Manager (“DPM”), Miami Field Division<sup>3</sup>**

DPM Langston will testify to her background, education and training as a DEA

Diversion Investigator, Diversion Group Supervisor, and Diversion Program Manager.

<sup>3</sup> In the event DPM Langston is unable to testify, GS Lane will offer the proposed testimony set forth below.

DPM Langston will testify about the problem of prescription painkiller diversion and abuse in Florida and the proliferation of "pill mills" employing unscrupulous doctors who prescribe controlled substances outside the usual course of professional practice or for other than legitimate medical purposes. DPM Langston will testify that since at least 2009, the State of Florida has been epicenter of a notorious, well-documented epidemic of prescription drug abuse. The controlled substances most commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol.

DPM Langston will testify that in response to the prescription pill epidemic, in 2010, the Florida legislature passed a law in 2010 that restricted the ability of pain clinics to dispense controlled substances onsite. DPM Langston will testify that once illicit prescriptions could not be filled at the pain clinics, patients of the pain clinics had to go to pharmacies to have their prescriptions filled. DPM Langston will testify that with the new law came a wave of new pharmacy applicants for DEA registrations.

DPM Langston will testify that upon receiving applications from retail pharmacy owners in South Florida, DEA regularly conducts pre-registration interviews to discuss pharmaceutical drug diversion. In June 2011, Walgreens Co. submitted an application for a new pharmacy DEA registration in Miami. In response to Walgreen's new pharmacy application, DEA scheduled a meeting with Walgreens pharmacy representatives on August 19, 2011. DPM Langston will testify that in preparation for the meeting, DEA conducted a search of Walgreens Florida pharmacies' oxycodone purchases through DEA's Automation of Reports and Consolidated Orders System (ARCOS), which revealed that Respondent had significantly increased its oxycodone



purchases between 2009 and 2011. DPM Langston will introduce an ARCOS report which shows that in 2010 Respondent had purchased a total of approximately 826,500 dosage units of oxycodone. For the first seven months of 2011, Respondent had purchased 1,284,200 dosage units of oxycodone. DPM Langston will introduce a chart prepared for the meeting with Walgreens entitled "2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone." The chart shows that by July 31, 2011, in just seven months, Respondent surpassed its 2010 oxycodone purchases, having purchased 1,284,200 dosage units of oxycodone. DPM Langston will testify that such a dramatic increase in oxycodone purchases is an indication to DEA investigators that pharmaceutical diversion might be occurring and, coupled with the timing of the state law changes regarding pill mill dispensing, should have been an indication or "red flag" to Respondent that it was likely dispensing oxycodone pursuant to illegitimate prescriptions.

DPM Langston will testify that at the August 19, 2011, meeting, DEA investigators met with Walgreen Co. officials to discuss Walgreens' oxycodone sales in Florida and oxycodone diversion in Florida. Present on behalf of Walgreen Co. were Dwayne Pinon (corporate in-house counsel), Ed Forbes (Market Loss Prevention Director), Wesley Rohn (Pharmacy District Supervisor), Joan Bustelo (Pharmacy District Supervisor), Anne-Marie Aldrick (Pharmacy District Supervisor), Cesar Cedeno (Pharmacy District Supervisor), Lakeisha Axem (Pharmacy Supervisor), Sandra Vazquez (Pharmacy Supervisor), and Susan Thompson (Loss Prevention Manager).

DPM Langston will testify that she and Group Supervisor (GS) Gayle Lane discussed in detail suspicious activity or "red flags" indicating that a controlled substance prescription may have come from a rogue pain management clinic, may not have been issued for a legitimate medical purpose, and/or may have been issued outside the usual

course of professional practice. DPM Langston will testify that she and GS Lane identified suspicious activity or red flags related to customers indicating a risk of diversion. Such red flags included the following: people from out-of-state using questionable Florida Identification Cards, groups of patients with the same prescriptions for the more common drugs of abuse (typically oxycodone 30mg, oxycodone 15mg, Alprazolam 2mg and Soma, and one or two non-controlled prescriptions), groups of patients receiving the same prescriptions and same diagnosis, patients between 22 and 45 years old, patients traveling significant distances to the pharmacy and/or to the pain management physician, and patients paying with cash. DPM Langston will testify that patients paying with non-insurance discount cards to pay for controlled substance prescriptions are considered the equivalent of cash payments.

DPM Langston will testify that DEA also discussed physician red flags, or suspicious conduct, indicating the prescriptions were issued outside the usual course of professional practice or for other than a legitimate medical purpose including: doctor: writing prescriptions for the same common drugs of abuse; doctors using the same diagnosis for multiple prescriptions; and doctors whose specialties are unrelated to pain management (e.g., obstetrics, pediatrics, or ophthalmology) prescribing large quantities of Schedule II controlled substances.

DPM Langston will testify that she and GS Lane informed Walgreens representatives of information compiled by ARCOS pertaining to Respondent and other Walgreens pharmacies' purchases of oxycodone. DPM Langston will testify that Walgreens representatives were told that the average US pharmacy purchased 69,500 dosage units of oxycodone in 2010, whereas the average Florida pharmacy purchased 134,000 dosage units of oxycodone in 2010. DPM Langston will testify that the

summary chart entitled "2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone" was discussed at the meeting and provided to Walgreens official Dwayne Pinon. DPM Langston will testify that Walgreens representatives were told that all of its pharmacies identified on the first page of the chart had, in the first seven months of 2011, ordered more than double the amount of oxycodone purchased by the average Florida pharmacy in 2010. Respondent was identified on the first page of the chart as having purchased 781,000 dosage units of oxycodone in the first seven months of 2011 and ranked #39 in the US for top purchasers of oxycodone. The ARCOS report will show that by the end of 2011, Respondent's oxycodone purchases increased to approximately 1,192,000 dosage units.

DPM Langston will also testify regarding an electronic disk that was provided by Walgreens Corporation that captured the dispensing records for Schedule II-V controlled substances from January 1, 2010, through April 4, 2012 ("03836 database"). DPM Langston will testify that Respondent represented the 03836 database to be a true and accurate documentation of controlled substances sold by Respondent during the above described time period.

**2. Gayle Lane, Group Supervisor ("GS"), Miami Field Division<sup>4</sup>**

Following testimony regarding her experience and qualifications as a Diversion Group Supervisor, GS Lane will testify to the background of the investigation into Respondent, which stemmed from Respondent and other Walgreens pharmacies' dramatic spike in oxycodone purchases.

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<sup>4</sup> GS Lane may testify to portions of DPM Langston's testimony, in lieu of DPM Langston, as outlined above.

GS Lane will testify that on August 19, 2011, DEA met with Walgreens representatives. GS Lane will testify that she and DPM Langston advised Walgreens of customer and physician specific red flags to look for prior to dispensing prescriptions for controlled substances. These red flags pertained to both patient and physician conduct, including physicians (1) prescribing the same commonly abused controlled substances; (2) utilizing the same diagnosis; and (3) who were not certified in pain management and/or practicing outside their specialty.

GS Lane will testify that on April 4, 2012, an Administrative Inspection Warrant (AIW) was executed at Walgreens # 03836. Pursuant to the AIW, investigators obtained inventory records, and prescriptions for all Schedule II controlled substances dispensed from January 1, 2010, through April 4, 2012, as well as DEA Forms 222, inventories, and copies of Schedule III-V prescriptions dispensed from January 1, 2010, through April 4, 2012. GS Lane will also testify that on May 7, 2012, the Miami Diversion Group received an electronic disk ("03836 database") provided by the Walgreens Corporation which captures Respondent's dispensing records for Schedule II-V controlled substances from January 1, 2010, through April 4, 2012. She will testify that a review of the data on the 03836 database revealed that Respondent dispensed 1,807,353 dosage units of oxycodone from January 1, 2010, through April 4, 2012, and dispensed 24,193 Schedule II prescriptions during that same time period. Of the 24,193 Schedule II prescriptions, 1,449 were dispensed for oxycodone 15 mg, with a total dispensing of 165,020 dosage units. The 03836 database also revealed that Respondent dispensed 9,043 prescriptions for oxycodone 30 mg, for a total of 1,642,333 dosage units.

GS Lane will introduce the 03836 database and summary charts which will show that Respondent dispensed controlled substances pursuant to prescriptions that presented

obvious red flags. GS Lane will also testify that the 03836 database revealed that numerous prescriptions filled by Respondent were written by practitioners in South Florida. GS Layne will testify that these practitioners were located well outside reasonable commuting distances for customers utilizing Respondent's pharmacy. Based on the 03836 database and the prescriptions obtained pursuant to the ATW, GS Lane will testify that many of the customers appeared to frequent these practitioners as a group and had their prescriptions for controlled substances filled on the same date and around the same time as each other.

GS Lane will testify that Respondent's dispensing log reveals that it filled prescriptions issued by doctors who routinely prescribed oxycodone and alprazolam "cocktails" who practiced outside their specialties, who were located significant distances away from the pharmacy, and whose patients paid for their prescriptions with cash or were using non-insurance discount cards.

**4. Domingo Gonzales, Diversion Investigator<sup>5</sup>**

Following testimony about his experience and qualifications as a Diversion Investigator, DI Gonzales will testify about his review of Respondent's prescription records, including the actual prescriptions and prescription labels, and the 03836 database. DI Gonzales will testify that these materials indicated that Respondent dispensed controlled substances on numerous occasions despite the existence of multiple red flags for diversion, including, but not limited to: (1) customers paying cash; (2) customers using cash discount cards; (3) customers presenting prescriptions for common drug "cocktails" such as oxycodone and alprazolam; hydrocodone and alprazolam;

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<sup>5</sup> In the event DI Gonzales is unable to testify, DI Dianne Williams will offer the proposed testimony below.

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hydrocodone, oxycodone, and alprazolam; and oxycodone, alprazolam, and carisoproclicol;

(4) customers obtaining prescriptions for controlled substances from physicians with offices located outside reasonable commuting distances from Respondent's pharmacy

(5) customers residing outside reasonable commuting distances from their physicians' offices and/or Respondent's pharmacy; (6) multiple customers obtaining identical or nearly identical prescriptions for controlled substances from the same physician on the same day and presenting those prescriptions to Respondent's pharmacy at the same time; and (7) customers residing outside reasonable commuting distances from their physicians and/or Respondent's pharmacy who reside at the same address; and (8) customers presenting Florida identification cards.

DI Gonzales will testify that the 03836 database and prescriptions revealed the following:

a. From April 2011 through July 2011, Walgreens 03836 pharmacists and/or pharmacy technicians Cassie Mulvey, Shane Van Gordon, Tara Karpavicus, Jude Leppi, Kate Wilson, Sanjay Patal, and Fred Casale dispensed controlled substances, including oxycodone, alprazolam, hydrocodone, and hydromorphone, to persons residing in Pensacola, Florida, who had obtained their prescriptions for controlled substances from Ramiro Abaunza, M.D., ("Dr. Abaunza"), a practitioner practicing in Miami, Florida. DI Gonzales will testify that, in order to obtain these prescriptions and have them filled at Walgreens 03836, customers living in Pensacola, Florida, who obtained prescriptions from Dr. Abaunza would have had to travel approximately 1397 miles roundtrip in order to get the prescriptions filled at Walgreens 03836.<sup>6</sup> The persons who obtained the controlled substances, the dates of dispensing, the controlled substances obtained, and the Walgreens 03836 employee who dispensed the controlled substances are as follows:

Date	Customer	Residence	Controlled substances dispensed	Pharmacist tech

<sup>6</sup>

The Government will seek to obtain a stipulation from Walgreens regarding the distances involved in the various transactions noticed in this matter.

<sup>11</sup>  
[https://www.dea.gov/divisions/mia/2013/mia061113\\_appendixc.pdf](https://www.dea.gov/divisions/mia/2013/mia061113_appendixc.pdf)

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4.9.11	J.C.	Pensacola	Alprazolam, oxycodone, hydrocodone	Mulvey
4.9.11	M.S.	Pensacola	Alprazolam, oxycodone	Mulvey
4.14.11	J.M.	Pensacola	Oxycodone	Casale
4.15.11	H.R.	Pensacola	Alprazolam, hydromorphone	Van Gordon
4.19.11	H.N.	Pensacola	Alprazolam, hydrocodone	Van Gordon
4.23.11	V.J.	Pensacola	Oxycodone	Karpavicus
4.23.11	A.B.	Pensacola	Oxycodone	Karpavicus
4.23.11	J.M.-1	Pensacola	Oxycodone	Karpavicus
4.26.11	J.B.	Pensacola	Oxycodone, alprazolam	Leppi, Van Gordon
4.26.11	M.J.	Pensacola	Oxycodone, alprazolam	Van Gordon
4.26.11	A.J.	Pensacola	Oxycodone, alprazolam, hydrocodone	Van Gordon
4.28.11	A.F.	Pensacola	Oxycodone, alprazolam	Wilson
4.28.11	D.D.	Pensacola	Oxycodone, alprazolam	Mulvey, Wilson
4.28.11.	D.S.	Pensacola	Oxycodone, alprazolam	Mulvey
5.2.11	M.B.	Pensacola	Oxycodone, alprazolam, hydrocodone	Karpavicus
5.4.11	C.B.	Pensacola	Oxycodone, alprazolam	Wilson
5.4.11	Z.S.	Pensacola	Oxycodone,	Wilson

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			alprazolam	
5.5.11	C.J.	Pensacola	Oxycodone, alprazolam, hydrocodone	Mulvey
5.7.11	C.C.	Pensacola	Oxycodone	Leppi
5.7.11	S.C.	Pensacola	Oxycodone	Leppi
5.7.11	J.E.	Pensacola	Oxycodone	Leppi
5.9.11	J.M.-2	Pensacola	Oxycodone, alprazolam	Karpavicus
5.9.11	C.T.	Pensacola	Oxycodone, alprazolam, hydrocodone	Mulvey
5.11.11	R.C.	Pensacola	Oxycodone, alprazolam, hydrocodone	Wilson
5.11.11	C.G.	Pensacola	Oxycodone, alprazolam, hydrocodone	Wilson
5.11.11	H.P.	Pensacola	Oxycodone, alprazolam, hydrocodone	Wilson
5.11.11	T.M.	Pensacola	Oxycodone, alprazolam, hydrocodone	Wilson
5.23.11	A.F.	Pensacola	Hydrocodone, alprazolam	Mulvey
5.24.11	A.J.	Pensacola	Hydrocodone, alprazolam	Patel
5.24.11	L.J.	Pensacola	Hydrocodone, alprazolam	Patel
5.24.11	C.S.	Pensacola	Hydrocodone, alprazolam	Patel
6.21.11	A.J.	Pensacola	Hydrocodone,	Van Gordon



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			alprazolam	
6.21.11	L.J.	Pensacola	Hydrocodone, alprazolam	Van Gordon
6.21.11	P.J.	Pensacola	Hydrocodone, alprazolam	Van Gordon
7.18.11	A.J.	Pensacola	Hydrocodone, alprazolam	Leppi, Van Gordon
7.18.11	L.J.	Pensacola	Hydrocodone, alprazolam	Van Gordon

b. Additionally, DI Gonzales will testify that the 03836 database/prescriptions revealed that on May 7, 2011, Jade Leppi dispensed thirty-milligram tablets of oxycodone to C.C. and S.C., both of whom lived at the same Pensacola, Florida, address and both of whom obtained the prescriptions from Dr. Abaunza on May 6, 2011. DI Gonzales will testify that the 03836 database/prescriptions and the prescription labels show that both of these prescriptions were dispensed within a two minute period.

c. DI Gonzales will testify that the 03836 database/prescriptions revealed that on June 21, 2011, Shane Van Gordon dispensed hydrocodone and identical amounts of alprazolam to L.J. and P.J., both of whom lived at the same Pensacola, Florida, address and both of whom obtained the prescriptions from Dr. Abaunza on June 20, 2011. DI Gonzales will testify that the database/prescription labels show that all of these controlled substances were dispensed during a six minute period.

d. DI Gonzales will testify that the 03836 database/prescriptions revealed that on April 29, 2011, two Walgreens 03836 pharmacists and/or pharmacy technicians dispensed oxycodone, hydrocodone, and alprazolam to J.A. and R.E., both of whom lived in Frankfort, Kentucky, and both of whom obtained their prescriptions from Dr. Abaunza on April 29, 2011. Specifically, Michael Nunez dispensed hydrocodone to both J.A. and R.E. and alprazolam to J.A. Jade Leppi dispensed oxycodone to J.A. and R.E. and alprazolam to R.E. DI Gonzales will testify that the database/prescription labels show that the oxycodone prescriptions were dispensed to both J.A. and R.E. during a 3 minute period. Additionally, on May 27, 2011, during a seven minute period, Shane Van Gordon dispensed hydrocodone and alprazolam to J.A. and R.E. who obtained their prescriptions from Dr. Abaunza on May 27, 2011. DI Gonzales will testify that, in order to obtain these prescriptions from Dr. Abaunza and have them filled at Walgreens 03836, customers living in Frankfort, Kentucky would have to travel approximately 2242 miles roundtrip.

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e. DI Gonzales will testify that the 03836 database/prescriptions revealed that (1) from April 9, 2011, through May 13, 2011, a Walgreens 03836 pharmacist dispensed controlled substances to customers who lived in Decatur, Tennessee, and obtained their prescriptions for controlled substances from Dr. Abaunza in Miami, Florida; (2) on April 9, 2011, Cassie Mulvey dispensed oxycodone to S.M.; (3) on May 13, 2011, Shane Van Gordon dispensed alprazolam to S.M.; and (4) on April 12, 2011, Fred Casale dispensed oxycodone to J.M. DI Gonzales will testify that the database/prescription labels show that on April 20, 2011, Shane Van Gordon, during a five minute period, dispensed hydrocodone and alprazolam to F.M. and A.R. DI Gonzales will testify that the 03836 database/prescriptions revealed that on April 23, 2011, (1) Jade Leppi dispensed oxycodone to Z.F.; (2) on April 30, 2011, Jade Leppi dispensed oxycodone, hydrocodone, and alprazolam to M.M. DI Gonzales will testify that, in order to obtain these prescriptions from Dr. Abaunza and have them filled at Walgreens 03836, customers residing in Decatur, Tennessee, would have to travel approximately 1760 miles roundtrip.

f. DI Gonzales will testify that the 03836 database/prescriptions revealed that from April 12, 2011, through May 26, 2011, a Walgreens 03836 pharmacist dispensed controlled substances to customers who lived in Riceville, Tennessee, and obtained their prescriptions for controlled substances from Dr. Abaunza in Miami, Florida. On April 12 and May 9 of 2011, Fred Casale dispensed oxycodone to J.G. On May 9, 2011, Cassie Mulvey dispensed oxycodone to J.G. On May 3, 2011, Cassie Mulvey dispensed oxycodone to B.S. On May 26, 2011, Shane Van Gordon dispensed hydrocodone and alprazolam to B.S. DI Gonzales will testify that, in order to obtain these prescriptions from Dr. Abaunza and have them filled at Walgreens 03836, customers residing in Riceville, Tennessee, would have to travel approximately 1733 miles roundtrip.

g. DI Gonzales will testify that the 03836 database/prescriptions revealed that from April 12, 2011, through May 26, 2011, a Walgreens 03836 pharmacist dispensed controlled substances to customers who lived in Athens, Tennessee and obtained their prescriptions for controlled substances from Dr. Abaunza in Miami, Florida. On April 13, 2011, Tara Karpavicus dispensed oxycodone, hydrocodone, and alprazolam to K.I. and M.L., both of whom lived at the same address and obtained their prescriptions from Dr. Abaunza on the same day. According to the database/prescription labels, both prescriptions for oxycodone were dispensed during a four minute period and both prescriptions for alprazolam were dispensed during a ten minute period. On May 11, 2011, Michael Nunez dispensed hydrocodone and alprazolam to K.I. and Tara Karpavicus dispensed hydrocodone and alprazolam to M.L. According to the database/prescription labels, both the hydrocodone and alprazolam prescriptions were dispensed during a seven minute period. On May 4, 2011, Kate Wilson dispensed oxycodone and alprazolam to M.G. On May 9, 2011, Cassie Mulvey dispensed oxycodone to C.H. On May 26, 2011, Shane Van Gordon dispensed hydrocodone and alprazolam to M.K. DI Gonzales will testify that, in order to obtain these prescriptions from Dr. Abaunza

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and have them filled at Walgreens 03836, customers residing in Athens, Tennessee, would have had to travel approximately 1750 miles roundtrip.

h. DI Gonzales will testify that the 03836 database/prescriptions revealed that on April 15, 2011, Shane Van Gordon, during a seven minute period, dispensed hydrocodone and alprazolam to M.L. and C.P., both of whom resided at the same address in Etowah, Tennessee, and had obtained their prescriptions from Dr. Abaunza on the same day. The next day, Jade Leppi dispensed oxycodone to M.L. and C.P., both of whom obtained their prescriptions from Dr. Abaunza on the same day. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, customers residing in Etowah, Tennessee, would have to travel approximately 1688 miles roundtrip.

i. DI Gonzales will testify that on or about April 23, 2011, Tara Karpavicus dispensed oxycodone, hydrocodone, and alprazolam to G.R., pursuant to prescriptions issued by Dr. Abaunza in Miami, Florida. At the time these controlled substances were distributed, G.R. resided in Spring City, Tennessee. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, G.R. would have had to travel approximately 1762 miles roundtrip.

j. DI Gonzales will testify that on April 25, 2011, Kate Wilson dispensed oxycodone to J.M., pursuant to a prescription issued by Dr. Abaunza in Miami, Florida, and mislabeled the prescription by entering the wrong date on which the prescription was written by Dr. Abaunza. At the time these controlled substances were dispensed, J.M. resided in Elora, Tennessee. DI Gonzales will testify that in order to obtain this prescription and have it filled at Walgreens 03836, J.M. would have had to travel approximately 1829 miles roundtrip.

k. DI Gonzales will testify that on or about April 30, 2011, Fred Casale dispensed oxycodone and Tara Karpavicus dispensed hydrocodone and alprazolam to L.S. According to dispensing records provided by Respondent, on or about May 4, 2011, Fred Casale dispensed oxycodone, alprazolam, and hydrocodone to J.S. and oxycodone to L.S. At the time these controlled substances were distributed, both L.S. and J.S. resided in Sweetwater, Tennessee, and obtained their prescriptions from Dr. Abaunza in Miami, Florida. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, L.S. and J.S. would have had to travel approximately 1773 miles roundtrip.

l. DI Gonzales will testify that on May 4, 2011, Kate Wilson dispensed oxycodone, hydrocodone, and alprazolam to R.D., a resident of Cleveland, Tennessee, pursuant to prescriptions issued by Dr. Abaunza in Miami, Florida. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, R.D. would have had to travel approximately 1665 miles roundtrip.

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m. DI Gonzales will testify that according to the 03836 database, on April 26, 2011, Kate Wilson dispensed oxycodone, hydrocodone, and alprazolam to R.M., a resident of Cedartown, Georgia.<sup>7</sup> On May 19, 2011, Shane Van Gordon dispensed hydrocodone and alprazolam to R.M. The prescriptions for controlled substances were obtained from Dr. Abaunza in Miami, Florida. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, R.M. would have had to travel approximately 1544 miles roundtrip.

n. DI Gonzales will testify that, on April 30, 2011, Tara Karpavicus dispensed oxycodone and hydrocodone to C.G. On May 3, 2011, Fred Casale dispensed oxycodone and Kate Wilson dispensed hydrocodone to J.M. At the time these controlled substances were distributed, both C.G. and J.M. resided at the same address in Lilburn, Georgia, and obtained their prescriptions for controlled from Dr. Abaunza in Miami, Florida. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, these customers would have had to travel approximately 1457 miles roundtrip.

o. DI Gonzales will testify that, on May 2, 2011, Terrence Myers dispensed oxycodone and alprazolam and Tara Karpavicus dispensed hydrocodone to C.M. Also, on May 2, 2011, Terrence Myers dispensed oxycodone and Tara Karpavicus dispensed alprazolam and hydrocodone to K.S. According to the 03836 database/prescription labels, both oxycodone prescriptions were dispensed during a five minute period. According to the 03836 database, at the time the controlled substances were dispensed, both C.M. and K.S. were residents of Columbus, Ohio, who had obtained their prescriptions from Dr. Abaunza in Miami, Florida. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, C.M. and K.S. would have had to travel approximately 2490 miles roundtrip.

p. DI Gonzales will testify that on May 3, 2011, Shane Van Gordon dispensed oxycodone and Kate Wilson dispensed alprazolam to A.N. Also, on May 3, 2011, Shane Van Gordon dispensed oxycodone and Kate Wilson dispensed hydrocodone, and alprazolam to D.N. At the time these controlled substances were dispensed, both A.N. and D.N. resided at the same address in Hamersville, Ohio, and had obtained their prescriptions from Dr. Abaunza in Miami, Florida. According to the 03836 database/prescription labels, the prescriptions for oxycodone were filled in a six minute period and the prescriptions for alprazolam and hydrocodone were filled during a twenty minute period. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, A.N. and D.N. would have had to travel approximately 2390 miles roundtrip.

q. DI Gonzales will testify that on April 19, 2011, Shane Van Gordon dispensed hydrocodone and alprazolam to D.E., a resident of Dothan, Alabama.

<sup>7</sup> Prescription information indicates alprazolam and hydrocodone were dispensed on April 20, 2011.

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On April 26, 2011, Kate Wilson dispensed oxycodone to D.E. The prescriptions for controlled substances were obtained from Dr. Abaunza in Miami, Florida. DI Gonzales will testify that, in order to obtain these prescriptions and have them filled at Walgreens 03836, D.E. would have had to travel approximately 1219 miles roundtrip.

r. DI Gonzales will testify that, on April 21, 2011, Kate Wilson dispensed the following: (1) oxycodone (15mg), alprazolam, methadone, and carisoprodol to L.J.; (2) oxycodone (15mg), alprazolam, and carisoprodol to C.J.; (3) oxycodone (15mg) and alprazolam to J.W.; (4) oxycodone (15mg) to C.S.; (5) oxycodone (15mg) to D.S.; (6) oxycodone (15mg) and alprazolam to J.I.; and (7) oxycodone (15mg) and alprazolam to C.W. According to the prescriptions and/or the 03836 database, at the time these controlled substances were dispensed, L.J., C.J., J.W., C.S., D.S., J.I., and C.W. were residents of the State of Kentucky and L.J. and C.J. resided at the same address. Two days later, on April 23, 2011, Tara Karpavicus dispensed oxycodone (30mg) to L.J. and Jade Leppi dispensed oxycodone (30mg) to C.J., J.W., C.S., D.S., J.I., and C.W. DI Gonzales will testify that L.J., C.J., J.W., C.S., and D.S. obtained their prescriptions from Charles Kessler, M.D. ("Dr. Kessler"), who was practicing in Plantation, Florida. DI Gonzales will further testify that J.I. and C.W. obtained their prescriptions from Richard Vitalis, D.O. ("Dr. Vitalis"), who was practicing in North Lauderdale, Florida. The prescriptions issued by Dr. Kessler were all issued on the same day, April 20, 2011. The prescriptions issued by Dr. Vitalis were all issued on the same day, April 21, 2011. According to the 03836 database/prescription labels, the prescriptions for 15mg oxycodone issued by Dr. Kessler were all dispensed in a twenty-two minute period. The prescriptions for 15mg oxycodone issued by Dr. Vitalis were dispensed during a five minute period. All the prescriptions for 30mg oxycodone were dispensed between 10:59 and 1:15 on April 23, 2011. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, these seven individuals would have had to travel between approximately 1987 and 2189 miles roundtrip. Moreover, in order to return to Walgreens 03836 on April 23, 2011 and fill the prescriptions for the thirty-milligram tablets of oxycodone, these individuals would have had to stay in Port Richey, Florida, for two nights, or made a second trip from Kentucky to Respondent's location on April 23, 2011. The distance travelled for this trip would have been approximately an additional 1524 to 1724 miles roundtrip. DI Gonzales will also testify that on April 21 and April 23 of 2011, oxycodone was distributed to L.J. despite dispensing information possessed by Respondent that indicated L.J. was allergic to opioid analgesics.

s. DI Gonzales will testify that, on April 14, 2011, Fred Casale dispensed 210-thirty milligram and 120 fifteen-milligram tablets of oxycodone each to four individuals, M.C., C.D., K.J., and M.J, all of whom resided at the same address in Kissimmee, Florida. According to the database/prescription labels, the oxycodone prescriptions for M.C. and C.D. were dispensed within five minutes of each other and the oxycodone prescriptions for K.J. and M.J. were dispensed within ten minutes of each other. Also, on April 14, 2011, Michael Nunez

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dispensed identical amounts of alprazolam and carisoprodol to K.J. and M.J. and Shane Van Gordon dispensed identical amounts of alprazolam to M.C. and C.D. These individuals obtained their prescriptions for controlled substances on the same day from Dr. Vitalis, whose office was located in North Lauderdale, Florida, approximately 288 miles from Walgreens 03836. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel approximately 578 miles roundtrip.

t. DI Gonzales will testify that on April 28 and on or about May 5<sup>8</sup> of 2011, Walgreens 03836 pharmacists dispensed controlled substances in nearly identical amounts to four individuals, P.W., T.S., J.N., and L.B., all of whom were listed, according to the prescriptions, as residing at the same address in Kissimmee, Florida. Specifically, on April 28, 2011, Cassie Mulvey distributed fifteen-milligram tablets of oxycodone to P.W. and J.N. Also, on April 28, 2011, Kate Wilson dispensed alprazolam to P.W. According to the 03836 database/prescription labels, the prescriptions to P.W. and J.N. were all dispensed within six minutes of each other. On May 5, 2011, Kate Wilson dispensed fifteen and thirty-milligram tablets of oxycodone to L.B. and T.S., and also dispensed alprazolam to T.S. The oxycodone prescriptions were dispensed within eight minutes of each other. All of the prescriptions described in this paragraph were obtained from Dr. Vitalis in North Lauderdale, Florida, approximately 288 miles from Walgreens 03836. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, P.W., T.S., J.N., and L.B. would have had to travel approximately 603 miles roundtrip. DI Gonzales will also testify that, according to the 03836 database, P.W. was listed as residing in Columbus, Ohio, at the time Cassie Mulvey and Kate Wilson provided him with oxycodone. The 03836 database also showed that L.B. and T.S. were living together at the same address in Tampa, Florida.

u. DI Gonzales will testify that from April 12 through May 25, 2011, various Walgreens 03836 pharmacists and/or pharmacy technicians dispensed controlled substances to six individuals, B.M., J.W., B.T., J.G., D.S., and C.S., all of whom resided at the same address in Tampa, Florida, and all of whom obtained their prescriptions from either Dr. Kessler or Dr. Vitalis. Specifically, on April 12, 2011, Dale Randall dispensed oxycodone (30mg) and alprazolam to J.W. Also, on April 12, 2011, Cassie Mulvey dispensed oxycodone (15mg) to J.W. On April 18, 2011, Fred Casale dispensed two oxycodone prescriptions (15mg and 30mg) and a prescription for alprazolam to C.S. On April 21, 2011, Kate Wilson dispensed oxycodone and alprazolam to B.T. On April 23, 2011, Jade Leppi dispensed a second oxycodone prescription (30mg) to B.T. According to the 03836 database/prescriptions labels, on April 26 or 27 of 2011,<sup>9</sup> Kate Wilson dispensed two oxycodone prescriptions (15mg and 30mg) each to D.S. and J.G. within a two minute period and she also dispensed alprazolam to both D.S. and

<sup>8</sup> According to the 03836 database, prescriptions for T.S. were dispensed on May 6, 2011. However, the prescription labels indicate a dispensing date of May 5, 2011.

<sup>9</sup> According to the 03836 database, the dispensing date is April 27, 2011. However, the prescription labels generated by Respondent indicate the date is April 26, 2011.

J.G. within a nine minute period. The oxycodone prescriptions for D.S. and J.Q. were packaged in a container bearing an incorrect dispensing date in violation of 21 C.F.R. § 1306.14(a). On May 11, 2011, Michael Nunez dispensed oxycodone and alprazolam to J.W. On May 12, 2011, Fred Casale dispensed oxycodone, alprazolam, and carisoprodol to C.S., and Cassie Mulvey dispensed hydrocodone to C.S. On May 18, 2011, Kate Wilson dispensed oxycodone to B.M. On May 25, 2011, Kate Wilson dispensed oxycodone and alprazolam to J.G. Based on the 03836 database and the prescriptions, all of the customers referenced in this paragraph except J.G. obtained their prescriptions from Dr. Kessler in Plantation, Florida. J.G. obtained his prescriptions from Dr. Vitalis in North Lauderdale, Florida. DI Gonzales will testify that in order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel between approximately 583 and 587 miles roundtrip.

v. DI Gonzales will testify that he reviewed the 03836 database and the prescriptions obtained during the AIW and found that from April 9, 2011, through May 18, 2011, various Walgreens 03836 pharmacists dispensed approximately 62 prescriptions for oxycodone, 31 prescriptions for alprazolam, and 7 prescriptions for methadone to persons who obtained their prescriptions from Dr. Kessler and who were residing in the State of Kentucky. The individuals receiving oxycodone are: L.C. (four prescriptions); N.B. (four prescriptions); S.B. (four prescriptions); C.S. (five prescriptions); W.O. (three prescriptions); C.S.-1 (three prescriptions); L.J. (two prescriptions); C.J. (two prescriptions); J.W. (two prescriptions); C.S.-2 (two prescriptions); D.S. (two prescriptions); K.W. (one prescription); J.Q. (two prescriptions); J.C. (one prescription); A.H. (two prescriptions); F.S. (two prescriptions); W.M. (two prescriptions); J.H. (two prescriptions); P.W. (two prescriptions); S.B. (one prescription); M.L. (two prescriptions); M.K. (one prescription); E.C. (three prescriptions); M.P. (one prescription); J.H.-1 (two prescriptions); B.B. (one prescription); H.J. (one prescription); T.K. (one prescription); C.P. (one prescription); and P.V. (one prescription).

The individuals receiving alprazolam are: L.C. (two prescriptions); N.B. (two prescriptions); S.B. (two prescriptions); C.S. (two prescriptions); W.O. (two prescriptions); C.S.-1 (two prescriptions); L.J. (one prescription); C.J. (one prescription); J.W. (one prescription); J.Q. (one prescription); A.H. (one prescription); F.S. (one prescription); W.M. (one prescription); J.H. (one prescription); P.W. (one prescription); M.L. (one prescription); E.C. (one prescription); M.P. (one prescription); J.H.-1 (one prescription); B.B. (one prescription); H.J. (one prescription); C.P. (one prescription); P.V. (one prescription); J.M. (one prescription); and H.P. (one prescription).

The individuals receiving methadone are: M.P.; L.J.; W.M.; P.W.; E.C.; J.H. - ; and L.C.

DI Gonzales will further testify that on the same day (May 12, 2011), four different Walgreens 03836 pharmacists dispensed oxycodone to five Kentucky residents and two residents of Pensacola, Florida, all of whom obtained their

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prescriptions from Dr. Kessler. Specifically, Fred Casale dispensed oxycodone, hydrocodone, and alprazolam to C.S. Fred Casale dispensed oxycodone and alprazolam and Cassie Mulvey dispensed hydrocodone to C.S.-1. Fred Casale dispensed oxycodone and alprazolam to H.J. and dispensed oxycodone to T.K. Tara Karparvicus dispensed oxycodone and alprazolam to C.P. At the time these controlled substances were dispensed, C.S., C-S -1, H.J., T.K. and C.P. were listed as Kentucky residents who had obtained their prescriptions from Dr. Kessler in Plantation, Florida. Also, on May 12, 2011, Kate Wilson dispensed oxycodone and alprazolam to K.B. and D.M. At the time these controlled substances were dispensed, K.B. and D.M. were listed as residing in Pensacola, Florida, and had obtained their prescriptions from Dr. Kessler. Moreover, the oxycodone prescriptions dispensed to C.S.-1, H.J., and T.K. were dispensed within seventeen minutes of each other by Fred Casale.

w. DI Gonzales will testify that he reviewed the 03836 database and the prescriptions obtained during the AIW and determined that 66 different customers obtained prescriptions for controlled substances from Dr. Kessler and had them filled at Walgreens 03836 during the period between April 9, 2011, and May 18, 2011. Based on his analysis, DI Gonzales found that only 27% of these customers resided within 50 miles of Walgreens 03836. In addition, he found that approximately 72% resided more than 250 miles from Walgreens 03836, 60% resided more than 400 miles from Walgreens 03836, and 51% resided more than 700 miles from Walgreens 03836.

x. DI Gonzales will testify that based on his analysis of the 03836 database and the prescriptions obtained pursuant to the AIW that, from April 8, 2011, through July 20, 2011, Walgreens 03836 pharmacists dispensed controlled substances including, but not limited to, oxycodone, hydrocodone, and alprazolam, on 55 occasions to persons who obtained their prescriptions from Dr. Ronald Heromin, M.D. ("Dr. Heromin"). At the time these controlled substances were distributed, Dr. Heromin was practicing at offices in Miami and Doral, Florida. DI Gonzales will testify that of the 55 prescriptions dispensed, at least 16 prescriptions for Schedule II controlled substances contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.11(a), as well as FLA. STAT. § 893.04(1)(c)(1). He also will testify that at least nine prescriptions for Schedule IV controlled substances contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.21(a), as well as FLA. STAT. § 893.04(1)(c)(1). DI Gonzales will further testify that eleven unaddressed prescriptions for oxycodone were issued to persons residing in Pensacola, Florida (J.A. D.B., B.C., J.F., M.H. C.I., L.J., J.K., H.O., J.S., and J.W.) and filled by Walgreens 03836. Also, based on his analysis, five unaddressed prescriptions for alprazolam were issued to persons residing in Pensacola, Florida (to R.C., W.G., A.J., T.M., and L.S.) which is approximately 412 miles from Walgreens 03836, and at least 670 miles from either of Dr. Heromin's offices in Doral and Miami, Florida. Moreover, on April 30, 2011, Tara Karpavicus dispensed oxycodone (30 mg) pursuant to unaddressed prescriptions issued to five individuals who obtained their prescriptions from Dr. Heromin, four of whom were residing in Pensacola, Florida (J.A., J.F., H.O., and



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J.S.) and one of whom was residing in Wetumpka, Alabama (D.G.). All five prescriptions were filled within a 12 minute period. DI Gonzales will testify that in order for the four Pensacola residents to obtain these prescriptions and have them filled at Walgreens 03836, they would have had to travel approximately 1388 miles roundtrip and the patient from Wetumpka, Alabama, would have had to travel approximately 1438 miles roundtrip.

y. DI Gonzales will testify that from April 25, 2011, through November 5, 2011, various Walgreens 03836 pharmacists distributed controlled substances to E.P. and K.P., both of whom resided at the same address in Dothan, Alabama, and who obtained their prescriptions for controlled substances from a physician practicing in New Port Richey, Florida. Specifically, on April 25, 2011, Terrence Myers dispensed 60 tablets of Adderall to E.P. On May 25, 2011, Tara Karpavicus dispensed 180-ten milligram tablets of methadone to E.P. On April 27, 2011, Kate Wilson dispensed hydrocodone to K.P. On June 22, 2011, Michael Nunez dispensed hydrocodone to K.P. and dispensed Adderall and methadone to E.P. On August 19, 2011, Cassie Mulvey dispensed hydrocodone to K.P. and on October 10, 2011, and November 5, 2011, Sean Francisco dispensed Adderall to K.P. Of the prescriptions described in this paragraph, at least five of them contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.11(a), as well as F.S.A. § 893.04(1)(c)(1). DI Gonzales will testify that, in order to obtain the above prescriptions and have them filled at Walgreens 03836, E.P. and K.P. would have had to travel approximately 653 miles roundtrip.

z. DI Gonzales will testify that from April 9, 2011, through July 19, 2011, Walgreens 03836 pharmacists dispensed controlled substances including, but not limited to, oxycodone, hydrocodone, and alprazolam, pursuant to 138 different prescriptions issued to individuals residing in Pensacola, Florida. All but three of these prescriptions had been issued by physicians practicing in South Florida, including Drs. Abunza, Kessler, Vitalis, and Heromin. In order to obtain these prescriptions and have them filled at Walgreens 03836, these individuals would have had to travel between approximately 1341 and 1397 miles roundtrip.

aa. DI Gonzales will testify that from April 9, 2011, through February 28, 2012, Walgreens 03836 pharmacists dispensed approximately 81 prescriptions for controlled substances to individuals residing in Tennessee. The majority (68%) of those prescriptions were issued by physicians practicing in either Doral or Miami, Florida. DI Gonzales will testify that both of those cities are located more than 270 miles from Walgreens 03836.

bb. DI Gonzales will testify that from April 9, 2011, through January 28, 2012, Walgreens 03836 pharmacists dispensed approximately 149 prescriptions for controlled substances to individuals residing in Kentucky. Approximately 92% of those prescriptions were issued by physicians practicing in South Florida cities which are located more than 250 miles from Walgreens 03836.

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cc. DI Gonzales will testify that on April 29, 2011, Kate Wilson dispensed 300 four-milligram tablets of hydromorphone to W.W. On May 13, 2011, Kate Wilson dispensed hydromorphone to C.W. pursuant to a prescription written on April 12, 2011. On June 1, 2011, Shane Van Gordon dispensed 1080 four-milligram tablets of hydromorphone and 300 forty-milligram tablets to oxycodone to C.W. All of the above described controlled substances in this paragraph were dispensed pursuant to prescriptions that contained no patient address in violation of 21 C.F.R. §§ 1306.05(a) and 1306.11(a), as well as FLA. STAT. § 893.04(1)(c)(1). Additionally, the controlled substances provided to C.W. on May 13, 2011, were mislabeled insofar as they were listed as having been prescribed and dispensed on April 29, 2011. DI Gonzales will testify that this violates 21 C.F.R. § 1306.14(a) and FLA. STAT. § 893.04(1)(e)(2).

dd. DI Gonzales will testify that, in addition to the hydromorphone dispensed to W.W. on April 29, 2011, Kate Wilson dispensed hydromorphone to W.W. on July 27, 2011. On January 12, 2012, also Kate Wilson dispensed 260 four-milligram tablets of hydromorphone and Michael Nunez dispensed 40 four-milligram tablets of hydromorphone to W.W. At the time these controlled substances were dispensed, W.W. was listed as residing in Adams, Kentucky. Moreover, W.W. had been receiving controlled substances from Walgreens 03836 since at least January 18, 2010. DI Gonzales will testify that, in order to obtain these prescriptions and have them filled at Walgreens 03836, W.W. would have had to travel approximately 1814 miles roundtrip.

DI Gonzales will also testify that many of the customers identified above who received controlled substances from Walgreens 03836 after presenting facially suspicious prescriptions also had a history of presenting equally suspicious prescriptions prior to the time periods described above. Accordingly, DI Gonzales will testify that even after the execution of an Administrative Memorandum of Agreement between DEA and Walgreens Co.<sup>10</sup> regarding similar conduct at Walgreens Pharmacy 06094, Walgreens 03836 pharmacists and pharmacy technicians continued to dispense controlled substances when they knew or should have known that the prescriptions were issued for other than a legitimate medical purpose by a practitioner acting outside the usual course of professional practice.

#### 14. Paul Doering, M.S.

<sup>10</sup> Executed April 7, 2011.

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Professor Doering will testify regarding his education, background, training, and experience as a pharmacist. In this regard, among other matters, Prof. Doering will testify that he (1) is a registered pharmacist in the states of Florida and North Carolina, (2) is certified as a Consultant Pharmacist in Florida, (3) previously practiced in the community pharmacy setting, (4) has been a professor at the University of Florida's School of Pharmacy for the past 35 years, (5) currently serves at the University of Florida's College of Pharmacy as Distinguished Service Professor of Pharmacy Practice, Emeritus, and (6) for 28 years was either Director or Co-Director of the University of Florida's Drug Information and Pharmacy Resource Center, a telephone access service through which health professionals can obtain information about drugs or drug therapy. Prof. Doering will further testify about his experiences serving as an expert consultant and witness in a number of criminal, civil, and administrative proceedings. Prof. Doering will provide expert witness testimony as detailed below.

Prof. Doering will testify about the education and training pharmacists receive in pharmacy school, including learning the fundamentals of both state and federal pharmacy law as it relates to the filling and dispensing of prescription drugs in general, and controlled substances in particular. He will further testify about training pharmacists receive in the application of those laws to real life situations. He also will discuss the coverage of these topics in Florida's pharmacist licensing exam.

Prof. Doering will testify about the epidemic of prescription drug diversion and abuse in the state of Florida. He will discuss the State of Emergency declared by the Florida Surgeon General in 2011 which was issued in effort to prevent the many drug overdose deaths from controlled substances. The controlled substances commonly associated with this epidemic are Schedule II pain relievers, such as oxycodone; Schedule

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IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol. Prof. Doering will testify about the overdose deaths due to oxycodone and benzodiazepines identified by the 2011 Florida Medical Examiners Report. He will testify that pharmacists are in a key position to reverse the trend of this epidemic.

Prof. Doering will further testify about the pharmacist's role in the distribution of prescription drugs that are controlled substances. He will testify about the dangerous propensities of certain controlled substances, in particular opiates and opioids, such as oxycodone, benzodiazepines, such as diazepam (Valium), and alprazolam (Xanax). Prof. Doering will testify that when controlled release opiate products are prescribed correctly patients should not need to be on concurrent around the clock opiates for break through pain.

Prof. Doering will discuss the responsibilities of pharmacists in filling controlled substances prescriptions. Prof. Doering will testify about the review and analysis pharmacists should undertake before certifying any such prescription for release to the patient, including checking the licensing status of prescribers and evaluating whether the prescription presented to them is for a legitimate medical purpose and issued by a properly registered practitioner in the usual course of professional practice.

Moreover, Prof. Doering will testify about the "red flags," or, in other words, indicators of diversion and abuse used by pharmacists to detect drug diversion. Because of the enormous abuse and diversion associated with oxycodone, the mere fact that an oxycodone prescription is being presented should put the pharmacist on full-alert to ensure that the prescription is valid. He will testify that oxycodone prescribed in combination with alprazolam and/or with carisoprodol, a popular "cocktail" combination in illicit use, should raise even more scrutiny with a pharmacist.

He will discuss certain patterns or circumstances that are consistent with drug diversion schemes that, in his opinion, a diligent pharmacist can observe, as well as the techniques that help the pharmacist detect drug diversion. Examples of such patterns or circumstances include, but are not limited to, patients who pay with cash, patients who are prescribed large quantities of controlled substances, patients who share the same address, patients who are prescribed the same numbers and types or combinations of drugs, and patients who live a distance from the prescribing practitioner and/or pharmacy, including out-of-state patients and/or practitioners. His testimony also will cover the criteria appearing in the 2010 Edition of the Drug Enforcement Administration's Pharmacist's Manual, which provided guidance to pharmacists of indicators that a prescription was not issued for a legitimate medical purpose. Prof. Doering will testify that these "red flags" signal that a prescription may have been issued outside the usual course or professional practice and/or for other than a legitimate medical purpose.

Additionally, Prof. Doering will testify about the information he was provided by the DEA to review and analyze concerning Respondent. This information included, but is not limited to: Respondent's dispensing log, copies of prescriptions and prescription labels for Schedule II-IV controlled substances dispensed by Respondent, and spreadsheets for prescription dispensing activity.

Prof. Doering will testify that based on his education, training, and experience as a pharmacist, his review and analysis of the DEA information he received shows that Respondent's pharmacists ignored readily apparent "red flags" of drug diversion or abuse, and filled prescriptions that were issued outside the usual course of medical practice without first conclusively resolving those red flags. He will testify that some, but not all, red flags can be resolved by a pharmacist. In those instances when red flags

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are unresolvable, a reasonable pharmacist exercising due care should and would refuse to fill the prescription.

Prof. Doering will discuss his analysis of Respondent's controlled substance dispensing between April 8, 2011 and April 4, 2012. Specifically, he will testify that with respect to prescriptions issued by Drs. Abaunza, Kessler, Vitalis, and Heromin, there was a distinct pattern of prescribing which is consistent with diversion. Prof. Doering will discuss how a various combination of factors, viewed collectively, created red flags for diversion that could not be resolved. For example, Prof. Doering will discuss how many of the patients described above (1) presented prescriptions for identical controlled substances in identical or similar amounts and dosages; (2) obtained their prescriptions from the same physician; (3) travelled long distances from their residences to a physician's office to obtain the prescriptions; and then (4) travelled long distances to Port Richey, Florida, to fill the prescriptions while bypassing many other pharmacies, including Walgreens pharmacies, that were located either closer to their physicians' offices, their residences, or were more aligned with the routes they travelled to obtain the prescriptions from their respective doctors. Prof. Doering will testify that with respect to customers who traveled well outside their reasonable commuting distances to obtain their prescriptions and then continued to travel outside their reasonable commuting distances to have them filled in Port Richey, no reasonable pharmacist would agree to fill the prescription absent a plausible explanation for the customer's unusual behavior. He will testify, for instance, that the existence of multiple patients travelling from places such as Pensacola, Florida,<sup>11</sup> to obtain prescriptions from a physician in Miami, and then heading

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<sup>11</sup> This also includes customers residing in Kentucky, Ohio, Tennessee, Georgia, Alabama, or cities such as Kissimmee, Florida.

to Port Richey to have those prescription filled constitute “dealbreakers” that should cause any reasonable pharmacist to refuse to fill those prescriptions. He will testify that these situations, when combined with other “red flags” such as customers presenting similar or identical prescriptions for the same controlled substances, or residing together at the same address, simply increase the necessity for either refusing to serve the customer or at least conducting a thorough investigation in an attempt to explain such unusual behavior.

Prof. Doering will also testify regarding Walgreens 03836 failure to correctly report the physician’s instructions on some prescriptions. For instance, he will discuss prescriptions J.A. on April 29, 2011, as described above in subparagraph d above.<sup>12</sup> Prof. Doering will testify that the physician’s instructions for hydrocone are incongruous inasmuch as the customer is directed to take “as needed” for “baseline pain.” Prof. Doering will also testify that Walgreens 03836 personnel misrepresented these directions when it created a label for the customer and incorrectly stated that the prescription was for “bilateral pain.”

Prof. Doering will testify, based on the evidence described in the proposed testimony of DI Gonzales and DI Williams above, that subparagraphs a-dd all contain evidence of red flags for diversion that were never adequately resolved. In fact, after reviewing copies of the individual prescriptions and the 03836 database, Prof. Doering will testify that there was little or no evidence of any attempt on the part of any Walgreens 03836 employee to resolve the red flags summarized in subparagraphs a-c d.

15-24. Cassie Mulvey  
Tara Kapavicus  
Shane Van Gordon

<sup>12</sup> See proposed testimony of DI Gonzales and DI Williams.

28  
[https://www.dea.gov/divisions/mia/2013/mia061113\\_appendixc.pdf](https://www.dea.gov/divisions/mia/2013/mia061113_appendixc.pdf)

**Jade Leppi  
Kate Wilson  
Sanjay Patel  
Fred Casale  
Michael Nunez  
Terrence Myers  
Dale Randall**

All of these individuals in section 15-24 will be asked to testify regarding their specific experience and training in the field in pharmacy. They each will be asked to discuss the pharmacy's process and procedures for filling a controlled substance prescription. Each will be asked to testify about the specific dispensing of controlled substances which are attributed to them in the proposed testimony of DI Gonzales and DI Williams. Each will be asked to describe the role they played in each dispensing attributed to them, and to identify what "red flags" for diversion, if any, they noted prior to dispensing the controlled substances to the individual customer. Accordingly, each will be asked to describe the steps he or she took to resolve those red flags and to explain how, in the course of dispensing the controlled substances, they minimized the risk of diversion. They will also be asked about the pharmacy's process and procedures for ordering controlled substances from the distribution center and oversight of the process by pharmacy and corporate supervisors.

25. **Quang Tran**

Quang Tran will be asked to testify regarding his role as the supervisor of those pharmacists and/or pharmacy technicians who dispensed the controlled substances described in the proposed testimony of DI Gonzales and DI Williams. Accordingly, he will be asked, with respect to any dispensing described above that he supervised and/or approved, to identify what red flags for diversion, if any, he noted prior to the dispensing



and what steps, if any, he carried out or ordered to be carried out, to resolve those red flags and minimize the risk of diversion.

#### VI. PROPOSED DOCUMENTS

Exhibit	Description	Approx. # Pages
1	DEA Certificate of Registration BW6561270 (attached hereto)	1
2	Respondent's Controlled Substances Dispensing Log, January 2010 – April 4, 2012.	(CD ROM)
3	Prescriptions issued by Ramiro Abaunza, M.D. (A-G)	150
4	Prescriptions issued by Ramiro Abaunza, M.D. (H-M)	137
5	Prescriptions issued by Ramiro Abaunza, M.D. (N-W)	138
6	03836 Database printouts showing prescription history of: J.C., M.S., J.M., H.R., H.N., V.J., A.B., J.M.-1, J.B., M.J., A.J., A.F., D.D., D.S, M.B., C.B., Z.S., C.J., C.C., S.C, J.E., J.M.-2, C.T., R.C., C.G., H.P., T.M., A.F., A.J., L.J., C.S., and P.J	36
7	Map and mileage information re: Pensacola to Miami to Port Richey to Pensacola	2-3
8	03836 Database printout showing prescription history for C.C. and S.C. on May 7, 2011	1
9	Map and mileage information re: Pensacola address of C.C. and S.C. to Miami to Port Richey to Pensacola address of C.C. and S.C.	2-3
10	03836 Database printout showing prescription history for L.J. and P.J. on June 21, 2011	1
11	Map and mileage information re: Pensacola address of L.J. and P.J. to Miami to Port Richey to Pensacola address of L.J. and P.J.	2-3
11	03836 Database printout showing prescription history for J.A. and R.E. on April 29, 2011 and May 27, 2011	1
12	Map and mileage information re: Frankfort, Kentucky to to Miami to Port Richey to Frankfort, Kentucky	2-3
10	03836 Database printout showing prescription history for S.M. on April 9, 2011, and May 13, 2011.	1
11	03836 Database printout showing prescription history for J.M. on April 12, 2011	1
12	03836 Database printout showing prescription history for F.M. and A.R. on April 20, 2011	1
13	03836 Database printout showing prescription history for Z.F. on April 23, 2011	1
14	03836 Database printout showing prescription history for	1

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	T.H. on April 30, 2011	
15	03836 Database printout showing prescription history for M.M. on May 2, 2011	1
16	Map and mileage information re: Decatur, Tennessee to Miami to Port Richey to Decatur, Tennessee	2-3
17	03836 Database printout showing prescription history for J.G. on April 12, 2011, and May 9, 2011	1
18	03836 Database printout showing prescription history for B.S. on May 3, 2011, and May 26, 2011	1
19	Map and mileage information re: Riceville, Tennessee to Miami to Port Richey to Riceville, Tennessee	2-3
20	03836 Database printout showing prescription history for K.I. and M.L. on April 13, 2011, and May 11, 2011	1
21	03836 Database printout showing prescription history for M.G. on May 4, 2011	1
22	03836 Database printout showing prescription history for C.H. on May 9, 2011	1
23	03836 Database printout showing prescription history for M.K. on May 26, 2011	1
24	Map and mileage information re: Athens, Tennessee to Miami to Port Richey to Athens, Tennessee	2-3
25	03836 Database printout showing prescription history for M.L. and C.P. on April 15-16, 2011	1
26	Map and mileage information re: Etowah, Tennessee to Miami to Port Richey to Etowah, Tennessee	2-3
27	03836 Database printout showing prescription history for G.R. on April 23, 2011	1
28	Map and mileage information re: Spring City, Tennessee to Miami to Port Richey to Spring City, Tennessee	1-3
29	03836 Database printout showing prescription history for J.M. on April 25, 2011	1
30	Map and mileage information re: Elora, Tennessee to Miami to Port Richey to Elora, Tennessee	1-3
31	03836 Database printout showing prescription history for L.S. and J.S. on April 30, 2011, and May 4, 2011	1
32	Map and mileage information re: Sweetwater, Tennessee to Miami to Port Richey to Sweetwater, Tennessee	1-3
33	03836 Database printout showing prescription history for R.D. on May 4, 2011	1
34	Map and mileage information re: Cleveland, Tennessee to Miami to Port Richey to Cleveland, Tennessee	1-3
35	03836 Database printout showing prescription history for R.M. for April 26, 2011, and May 19, 2011	1
36	Map and mileage information re: Cedartown, Georgia to Miami to Port Richey to Cedartown, Georgia	1-3
37	03836 Database printout showing prescription history for	1

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	C.G. and J.M. on April 30, 2011, and May 3, 2011	
38	Map and mileage information re: Lilburn, Georgia to Miami to Port Richey to Lilburn, Georgia	1-3
28	03836 Database printout showing prescription history for C.M. and K.S. on May 2, 2011	1
29	Map and mileage information re: Columbus, Ohio to Miami to Port Richey to Columbus, Ohio	1-3
30	03836 Database printout showing prescription history for A.N. and D.N. on May 3, 2011	1
31	Map and mileage information re: Hamersville, Ohio to Miami to Port Richey to Hamersville, Ohio	1-3
32	03836 Database printout showing prescription history for D.E. on April 19, 2011, and April 26, 2011	1
33	Map and mileage information re: Dothan, Alabama to Miami to Port Richey to Dothan, Alabama	1-3
34	Prescriptions of Dr. Kessler A-L	175
35	Prescriptions of Dr. Kessler M-P	57
36	Prescriptions of Dr. Kessler Q-Z	172
37	Prescriptions of Dr. Vitalis	116
38	03836 Database printout showing prescription history for L.J., C.J., J.W., C.S., D.S., J.I., and C.W. for April 21, 2011, and April 23, 2011	1-2
39	Map and mileage information re: Frankfort, Kentucky to Plantation, Florida, to Port Richey to Frankfort, Kentucky (L.J., C.J., J.W., and D.S.)	1-3
40	Map and mileage information re: Stamping Ground, Kentucky to Plantation, Florida, to Port Richey to Stamping Ground Kentucky (C.S.)	1-3
41	Map and mileage information re: London, Kentucky to North Lauderdale, Florida, to Port Richey to London, Kentucky (J.I.)	1-3
42	Map and mileage information re: East Bernstadt, Kentucky to North Lauderdale, Florida, to Port Richey to East Bernstadt, Kentucky (C.W.)	1-3
43	03836 Database printout showing prescription history for M.C., C.D., K.J., and M.J. for April 14, 2011	1-2
44	Map and mileage information re: Kisseemee, Florida to North Lauderdale, Florida, to Port Richey to Kisseemee, Florida	1-3
45	03836 Database printout showing prescription history for P.W., T.S., J.N., and L.B. on April 28, 2011, and May 5-6, 2011	1-2
46	Map and mileage information re: Columbus, Ohio, to North Lauderdale, Florida, to Port Richey to Columbus, Ohio (P.W.)	1-3
47	03836 Database printout showing prescription history for	2-3

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	B.M., J.W., B.T., J.G., D.S., and C.S. on April 12, 18, 21, 23, and 26-27 of 2011, and May 11, 18, and 25 of 2011	
48	Map and mileage information re: Tampa, Florida, to Plantation, Florida, to Port Richey to Tampa, Florida (B.M., J.W., B.T., D.S., and C.S.)	1-3
49	Map and mileage information re: Tampa, Florida, to North Lauderdale, Florida, to Port Richey, to Tampa, Florida (J.G.)	1-3
50	03836 Database printout showing prescription history of Kentucky residents receiving prescriptions from Dr. Kessler	1-2
51	03836 Database printout showing prescription history for C.S., C.S.-1, H.J., T.K., C.P., K.B. and D.M. on May 12, 2011	1-2
52	Map and mileage information re: Glasgow, Kentucky to Plantation, Florida, to Port Richey to Glasgow, Kentucky (C.S.-1)	1-3
53	Map and mileage information re: Owenton, Kentucky to Plantation, Florida, to Port Richey to Owenton, Kentucky (H.J.)	1-3
54	Map and mileage information re: Pensacola, Florida, to Plantation, Florida, to Port Richey to Pensacola, Florida (K.B. and D.M.)	1-3
55	03836 Database printout showing prescription history for individuals obtaining prescriptions from Dr. Kessler between April 9, 2011, and May 18, 2011	1-2
56	Chart showing location of persons obtaining prescriptions from Dr. Kessler	1-2
57	Prescriptions of Dr. Heromin	69
58	Map and mileage information re: Pensacola, Florida to Doral, Florida, to Port Richey to Pensacola, Florida (Dr. Heromin)	1-3
59	Map and mileage information re: Pensacola, Florida to Miami, Florida, to Port Richey to Pensacola, Florida (Dr. Heromin)	1-3
60	Map and mileage information re: Wetumpka, Alabama to Doral, Florida, to Port Richey to Doral, Alabama	1-3
61	Map and mileage information re: Wetumpka, Alabama to Miami, Florida, to Port Richey to Wetumpka, Alabama	1-3
62	Prescriptions for K.P. and E.P.	11
63	03836 Database printout showing prescription history for K.P. and E.P.	1
64	Map and mileage information re: Dothan, Alabama to New Port Richey, Florida, to Port Richey to Dothan, Alabama	1-3
65	03836 Database printout showing prescription history for	1-2

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	residents of Pensacola, Florida, who received controlled substances from April 9, 2011, through July 19, 2011	
66	Map and mileage information re: Pensacola, Florida, to Miami, Florida, to Port Richey to Pensacola, Florida (Dr. Abaunza)	1-3
67	Map and mileage information re: Pensacola, Florida, to Plantation, Florida, to Port Richey to Pensacola, Florida (Dr. Kessler)	1-3
68	Map and mileage information re: Pensacola, Florida, to North Lauderdale, Florida, to Port Richey to Pensacola, Florida (Dr. Vitalis)	1-3
69	03836 Database printout showing prescription history for residents of Tennessee who received controlled substances from April 9, 2011, through February 28, 2012	1-2
70	03836 Database printout showing prescription history for residents of Kentucky who received controlled substances from April 9, 2011, through January 28, 2012	1-2
71	Prescriptions for W.W. and C.W.	8
71	03836 Database printout showing prescription history for W.W. and C.W.	1
72	Map and mileage information re: Adams, Kentucky, to Odessa, Florida, to Port Richey to Adams, Kentucky (W.W.)	2

**VII. POSITION REGARDING HEARING SITUS**

The Government requests to hold the hearing at the DEA Hearing Facility (DEAHF) located at 1550 Crystal Drive, Suite 901, Arlington, Virginia.


**VIII. OTHER MATTERS**

The Government reserves the opportunity to amend its instant pleading at a time and date specified by the presiding Administrative Law Judge. The Government requests the issuance of a protective order to prevent disclosure of the identities of Respondent's customers wherever such names and records are used in this proceeding.

**IX. BEST ESTIMATE AS TO TIME REQUIRED TO PRESENT CASE**

The Government anticipates requiring no more than three (3) days to present its case-in-chief, exclusive of cross-examination and rebuttal.

Respectfully submitted,

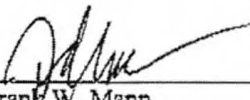
  
FRANK W. MANN  
SCOTT LAWSON  
Attorneys  
Diversion & Regulatory Litigation  
Office of Chief Counsel  
Drug Enforcement Administration  
8701 Morrisette Drive  
Springfield, Virginia 22152

Dated: March 8, 2013

**CERTIFICATE OF SERVICE**

I hereby certify that on the date signed below, I caused the original and nine copies of the foregoing **GOVERNMENT'S PREHEARING STATEMENT** to be hand delivered and one copy to be faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* and first class mail to counsel for Respondent at the following addresses:

Phil Perry  
Allen M. Gardner  
Nathan H. Seltzer  
Latham & Watkins LLP  
555 Eleventh Street, NW  
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\_\_\_\_\_  
Frank W. Mann  
Diversion & Regulatory Litigation  
Office of Chief Counsel  
Drug Enforcement Administration  
8701 Morrisette Drive  
Springfield, Virginia 22152

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DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
AW8830247	05-31-2013	\$551
SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5	CHAIN PHARMACY	05-12-2010
<b>WALGREEN CO.</b> DBA: WALGREENS # 03836 9332 US HIGHWAY 19 PORT RICHEY, FL 34668		

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**  
 UNITED STATES DEPARTMENT OF JUSTICE  
 DRUG ENFORCEMENT ADMINISTRATION  
 WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 856) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**  
 UNITED STATES DEPARTMENT OF JUSTICE  
 DRUG ENFORCEMENT ADMINISTRATION  
 WASHINGTON, D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
AW8830247	05-31-2013	\$551
SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5	CHAIN PHARMACY	05-12-2010
<b>WALGREEN CO.</b> DBA: WALGREENS # 03836 9332 US HIGHWAY 19 PORT RICHEY, FL 34668		

Sections 304 and 1008 (21 U.S.C. 824 and 856) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (05/04)



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UNITED STATES DEPARTMENT OF JUSTICE  
Drug Enforcement Administration

IN THE MATTER OF WALGREEN, CO.	DOCKET NO. 13-1
WALGREEN, CO. D/B/A WALGREENS #03629,	DOCKET NO. 13-9
WALGREEN, CO. D/B/A WALGREENS #04727,	DOCKET NO. 13-10
WALGREEN, CO. D/B/A WALGREENS #06997,	DOCKET NO. 13-11
WALGREEN, CO. D/B/A WALGREENS #03836,	DOCKET NO. 13-16
WALGREEN, CO. D/B/A WALGREENS #04391,	DOCKET NO. 13-18
WALGREEN, CO. D/B/A WALGREENS #03099	DOCKET NO. 13-20

GOVERNMENT'S PREHEARING STATEMENT FOR  
WALGREENS #04391 & #03099

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Dated: March 1, 2013

Pursuant to the Orders for Pre-hearing Statements dated February 14, 2013, and February 22, 2013, the the United States Department of Justice, Drug Enforcement Administration (DEA or Government), hereby submits its Prehearing Statement for Walgreens #04391 and Walgreens #03099.

### ISSUES

Whether DEA should revoke DEA Certificates of Registration BW5872494 and AW1366877, issued to Walgreen Co. d/b/a Walgreens #04391 (“Walgreens 04391”) and Walgreen Co. d/b/a Walgreens #03099 (“Walgreens 03099”), respectively, pursuant to 21 U.S.C. §§ 824(a)(4) and 823(f), and deny any pending applications for renewal or modification of such registrations, pursuant to 21 U.S.C. § 823(f).

### REQUESTED RELIEF

The Government requests a ruling by the Administrative Law Judge recommending the revocation of the Respondent’s Certificates of Registration BW5872494 and AW1366877, and the denial of any pending application for renewal or modification of such registrations.

### PROPOSED STIPULATIONS OF FACT<sup>1</sup>

1. Respondent Walgreens 04391 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number BW5872492 at 2501 Virginia Avenue, Fort Pierce, Florida 34981. This registration expires by its terms on May 31, 2013.
2. Respondent Walgreens 03099 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number AW1366877 at 1525 Colonial Blvd., Fort Myers, Florida 33907. This registration expires by its terms on May 31, 2013.

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<sup>1</sup> The Government anticipates discussing additional stipulations with Respondent.

3. Hydromorphone is a Schedule II controlled substance pursuant to 21 C.F.R. § 1308.12(b)(1)(vii).
4. Clonazepam is a Schedule IV controlled substance pursuant to 21 C.F.R. § 1308.14(c)(10).

**I. WALGREENS #04391 (FORT PIERCE 2 PHARMACY)**

**PROPOSED WITNESSES<sup>2</sup>**

1. Susan Langston  
Diversion Program Manager  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
2. Martin Ramirez  
Diversion Investigator  
DEA Miami Field Division  
Tallahassee Resident Office  
1510 Commonwealth Business Drive  
Tallahassee, Florida 32303
3. Linda Stocum, Diversion Investigator (or Group Supervisor Susan Slyker)  
DEA Orlando District Office  
300 International Parkway, Suite 424  
Heathrow, Florida 32746
4. Dianne Williams  
Diversion Investigator (or Diversion Investigator Alison King)  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
5. Marc Cohen, Pharm. CPh.  
Pharmacy Manager  
Walgreens 04391  
2501 Virginia Avenue,  
Fort Pierce, Florida 34981
6. Lloyd Wright, Pharmacist  
Walgreens 04391

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<sup>2</sup> In addition to the witnesses identified below, DEA reserves the right to call any of the witnesses listed by Respondent on matters identified by Respondent.

2501 Virginia Avenue,  
Fort Pierce, Florida 34981

7. Wesley Rohn, Pharm. D.  
Pharmacy District Supervisor, Palm Beach North  
Walgreen Co.  
901 Northpoint Parkway, Suite 105  
West Palm Beach, Florida 33407
  
8. Ed Svihra, RPH, CHC  
Director, HealthCare Loss Prevention  
Walgreen Co.  
1411 Lake Cook Road, MS #413  
Deerfield, Illinois 60015
  
9. Doug Lemmons  
Director, Divisional Loss Prevention Operations  
Walgreen Co.  
200 Wilmot Road, 2<sup>nd</sup> Floor  
Deerfield, Illinois, 60015
  
10. Paul L. Doering, M.S.  
Distinguished Service Professor of Pharmacy Practice, Emeritus  
College of Pharmacy  
University of Florida  
101 South Newell Drive  
HPNP Bldg. 212  
Room 3307  
Gainesville, Florida 32611

#### SUMMARY OF TESTIMONY

**1. Susan Langston, Diversion Program Manager (“DPM”), Miami Field Division**

DPM Langston will testify to her background, education, and training as a DEA Diversion Investigator, Diversion Group Supervisor, and Diversion Program Manager. DPM Langston will testify about the problem of prescription painkiller diversion and abuse in Florida, and the proliferation of “pill mills” employing unscrupulous doctors who prescribe controlled substances outside the usual course of professional practice or for other than legitimate medical purposes. DPM Langston will testify that since at least

2009, the State of Florida has been epicenter of a notorious, well-documented epidemic of prescription drug abuse. The controlled substances most commonly associated with this epidemic are Schedule II pain relievers, such as oxycodone, Schedule IV benzodiazepines, such as alprazolam, and Schedule IV muscle relaxers, such as carisoprodol.

DPM Langston will testify that in response to the prescription pill epidemic, the Florida legislature passed a law in 2010 that restricted the ability of pain clinics to dispense controlled substances on site. DPM Langston will testify that, as a result of the new law, illicit prescriptions could no longer be filled at pain clinics, and pain clinic patients now had to go to pharmacies to have their prescriptions filled. DPM Langston will testify that with the new law came a wave of new pharmacy applicants for DEA registrations.

DPM Langston will testify that upon receiving applications from retail pharmacy owners in South Florida, DEA regularly conducts pre-registration interviews with new applicants to discuss pharmaceutical drug diversion. In June 2011, Walgreens Co. submitted an application for a new pharmacy DEA registration in Miami. In response to Walgreen's new pharmacy application, DEA scheduled a meeting with Walgreens pharmacy representatives on August 19, 2011. DPM Langston will testify that in preparation for the meeting, DEA conducted a search of Walgreens Florida pharmacies' oxycodone purchases through DEA's Automation of Reports and Consolidated Orders System (ARCOS), which revealed that Walgreens 04391 had significantly increased its oxycodone purchases between 2006 and 2011. DPM Langston will introduce an ARCOS report which shows that in 2006, Respondent purchased a total of approximately 237,400 dosage units of oxycodone. By the end of 2010, Walgreens 04391 had increased it

oxycodone purchases to 881,000 dosage units. By the end of 2011, Walgreens 04391 increased its oxycodone purchases to 1,329,600 dosage units.

DPM Langston will testify that at the August 19, 2011 meeting, DEA investigators met with Walgreen Co. officials to discuss, generally, oxycodone diversion in Florida, and specifically, Walgreens' oxycodone sales in Florida. Present on behalf of Walgreen Co. were Dwayne Pinon (corporate in-house counsel), Ed Forbes (Market Loss Prevention Director), Wesley Rohn (Pharmacy District Supervisor), Joan Bustelo (Pharmacy District Supervisor), Anne-Marie Aldrick (Pharmacy District Supervisor), Cesar Cedeno (Pharmacy District Supervisor), Lakeisha Axem (Pharmacy Supervisor), Sandra Vazquez (Pharmacy Supervisor), and Susan Thompson (Loss Prevention Manager).

DPM Langston will also introduce a chart prepared for the August 19, 2011 meeting with Walgreen Co. entitled "2010 Top 100 Florida Walgreens Pharmacy Buyers of Oxycodone." The chart reveals that in the first seven months of 2011, Walgreens 04391 had already purchased at 802,500 dosage units for oxycodone, nearly matching the 881,000 dosage units of oxycodone purchased for the entire year of 2010. DPM Langston will testify that such a dramatic increase in oxycodone purchases is an indication to DEA investigators that pharmaceutical diversion might be occurring and, coupled with the timing of the state law changes regarding pill mill dispensing, should have been an indication or "red flag" to Respondent that it was likely dispensing oxycodone pursuant to illegitimate prescriptions. DPM Langston will testify that this chart was provided to Dwayne Pinon, Walgreen Co.'s counsel, at the meeting.

DPM Langston will testify that she and Group Supervisor ("GS") Gayle Lane detailed for Walgreens representatives at the meeting, suspicious activity or "red flags"

indicating that a controlled substance prescription may have come from a rogue pain management clinic, may not have been issued for a legitimate medical purpose, and/or may have been issued outside the usual course of professional practice. DPM Langston will testify that she and GS Lane identified suspicious activity or red flags related to customers indicating a risk of diversion. Such red flags included the following: "cocktail" prescriptions or combinations of controlled substance prescriptions for oxycodone, alprazolam and carisoprodol; people from out-of-state using questionable Florida Identification Cards; groups of patients with the same prescriptions for the more common drugs of abuse (including oxycodone 30mg, oxycodone 15mg, Alprazolam 2mg and carisoprodol, and one or two non-controlled prescriptions); groups of patients receiving the same prescriptions and same diagnoses, patients between 22 and 45 years old; patients traveling significant distances to the pharmacy and/or to the physician; and patients paying with cash. DPM Langston will testify that patients using non-insurance discount cards to pay for controlled substance prescriptions are considered the equivalent of cash payments.

DPM Langston will testify that she and GS Lane also informed Walgreen Co. representatives of physician red flags or suspicious conduct indicating that prescriptions were not issued for legitimate medical purposes or were issued outside the usual course of professional practice including: doctors writing prescriptions for the same common drugs of abuse; doctors using the same diagnoses for multiple prescriptions; and doctors whose specialties are unrelated to pain management (e.g., obstetrics, pediatrics, or ophthalmology) prescribing large quantities of Schedule II controlled substances.

DPM Langston will testify that on May 7, 2012, pursuant to an administrative subpoena, Walgreen Co. provided her with an electronic dispensing log of all Schedule



II-IV controlled substances dispensed by Walgreen 04391 between January 1, 2010 and April 4, 2012.

**2. Martin Ramirez, Diversion Investigator**

Following testimony regarding his experience and qualifications as a Diversion Investigator, DI Ramirez will testify that on April 4, 2012, an Administrative Inspection Warrant (AIW) was executed at Walgreens 04391. Pursuant to the AIW, he and other DEA investigators conducted a closing inventory of all oxycodone products, obtained inventory records, and prescriptions of all Schedule II controlled substances dispensed between January 1, 2010 and April 4, 2012.<sup>3</sup>

DI Ramirez will testify that his review and analysis of Walgreens 04391's electronic dispensing log revealed that Walgreens 04391 routinely dispensed prescriptions issued by doctors for oxycodone and Schedule IV benzodiazepine "cocktails" in the face of "red flags" for risk of diversion or abuse, including customer doctor shopping, prescribers practicing outside their specialty, cash payments for oxycodone, and significant geographical distances between the physician and Walgreens 04391.<sup>4</sup>

**A. Prescriptions**

DI Ramirez will testify that when Respondent's pharmacists dispense a controlled substance, they generate a label from the electronic dispensing log and attach it to the back of the prescription. DI Ramirez will testify that numerous labels generated from the dispensing log that were attached to oxycodone prescriptions dispensed by Walgreens

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<sup>3</sup> DI Ramirez will testify that upon review of the prescriptions collected, he was not provided with any Schedule II prescriptions dispensed between May 1, 2011 and August 25, 2011.

<sup>4</sup> "Red Flags" for risk of diversion or abuse associated with the prescriptions introduced by DI Ramirez will be expanded upon through the proposed expert testimony of Prof. Paul Doering, M.S.

04391 contain commentary about the prescriber indicating the pharmacy staff who received and processed the prescriptions for dispensing knew or should have known that the prescriptions were suspect. For example, DI Ramirez will introduce summary dispensing spreadsheets and several prescriptions issued by Dr. Dustin Lee, in which commentary under Dr. Lee's name on the label states, "FAKE CII DO NOT FILL CANDY DR\*\*\*FAKE." DI Ramirez will introduce several prescriptions issued by Dr. Armando Falcon, in which the commentary under Dr. Falcon's name on the label states, "FAKE CII DO NOT FILL CANDY DR."

Through the testimony of DI Ramirez, the Government will introduce summary spreadsheets excerpted from Respondent's dispensing log showing Walgreens 04391's dispensing of cocktail prescriptions prescribed by Dr. Ralph Miniet, a pediatrics specialist located in Fort Lauderdale, Florida.<sup>5</sup> DI Ramirez will introduce prescriptions for oxycodone in which the label attached to the prescription describes Dr. Miniet's prescriptions as "PAY FOR PLAY."<sup>6</sup>

DI Ramirez will introduce a spreadsheet summarizing Respondent's controlled substance dispensing to eight customers (R.A., M.W., S.C., C.W., L.K., L.S., and P.L.) on October 14, 2011. The evidence will show that on that date, Walgreens 04391 pharmacists filled oxycodone, hydromorphone, and other controlled substances for these customers, and that Dr. Miniet was the prescribing physician for each prescription. DI Ramirez will introduce evidence that on October 14, 2011, Respondent dispensed

<sup>5</sup> Either DI Ramirez or Miami Field Division, Diversion Group Supervisor Gayle Lane will introduce documents from the Florida Department of Health's medical license verification website showing that Dr. Miniet specializes in pediatrics. DI Ramirez will also testify that Fort Lauderdale is approximately 105 miles away from the pharmacy.

<sup>6</sup> The "PAY FOR PLAY" prescriptions were dispensed between November 2010 and January 2011. In light of the Court's February 14, 2013, Order Granting Respondent's Motion In Limine regarding the Memorandum of Agreement, these prescriptions are not offered as evidence of violative dispensing, but are rather offered to show what Walgreens 04391 pharmacists knew or should have known about the validity of Dr. Miniet's controlled substance prescriptions dispensed after April 7, 2011.

customer L.S. a twenty-even year old residing in Port St. Lucie on October 14, 2011 for 180 dosage units of oxycodone 30 mg, 84 dosage units of hydromorphone 8mg, 28 dosage units of alprazolam 2mg, and 28 dosage units of carisprodol 350mg who paid cash for the drugs. DI Ramirez will introduce a map showing that after customer L.S. drove approximately 105 miles south to Fort Lauderdale to get her prescriptions, she drove at least 12 miles north of her home in Port St. Lucie to fill the prescriptions at Respondent's location. Additionally, DI Ramirez will introduce documentation from the Florida Department of Health and Walgreens dispensing log identifying Walgreens 04391 pharmacist Gladys Murrow. The evidence will show Ms. Murrow signed at least seven Schedule II controlled substance prescriptions (indicating she reviewed and filled the prescriptions) issued by Dr. Miniet which were filled on October 14, 2011.

The Government also will introduce through DI Ramirez, a spreadsheet summarizing the dispensing of controlled substances, almost exclusively combinations of oxycodone 30 mg and clonazepam 1mg or 2 mg, to male and female patients, pursuant to prescriptions issued by Dr. Ronald Thompson, a board certified obstetrician/gynecologist located in Miami, Florida.<sup>7</sup> Pharmacy generated labels attached to multiple prescriptions issued by Dr. Thompson that were dispensed in December 2011 and January 2012 contain the following commentary below Dr. Thompson's name, "FAKE CII DO NOT FILL ANY CII CANDY DR." DI Ramirez will also introduce documentation from the Florida Department of Health and Walgreens 04391 dispensing log identifying Walgreens pharmacist Lloyd Wright. The evidence will show that Mr. Wright signed at least 7 oxycodone prescriptions (indicating he reviewed and filled the prescriptions)

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<sup>7</sup> DI Ramirez will introduce documents from the Florida Department of Health's medical license verification website showing that Dr. Thompson is a board certified obstetrician/gynecologist. He will also testify that Miami is approximately 114 miles away from the pharmacy.

issued by Dr. Thompson for customers who were also dispensed clonazepam between Dec 30, 2011 and January 18, 2012.

In addition, the Government will introduce through the testimony of DI Ramirez, prescriptions and a summary spreadsheet excerpted from Respondent's dispensing log showing oxycodone dispensed to customer A.R. between April 21, 2011 and March 22, 2012, pursuant to prescriptions issued by five different physicians. On April 21 and 29, 2012, Walgreens 04391 pharmacists dispensed 60 dosage units of Oxycontin 60 mg and 90 dosage units of oxycodone 30 mg, respectively, prescribed by Dr. John Spencer Archinihu, whose office was located in Kissimmee, Florida. On August 17, and August 25, 2011, Walgreens 04391 pharmacists dispensed 60 dosage units of Oxycontin 60 mg, 60 dosage units of Oxycontin 80 mg, and 150 dosage units of oxycodone 30 mg prescribed by Dr. Robert Besen, whose office was located in Miami, Florida. On September 27 and September 30, 2011, Walgreens 04391 pharmacists dispensed 60 dosage units of Oxycontin 60 mg and 150 dosage units of oxycodone 30 mg prescribed by Dr. Besen's colleague, Dr. Carmen Alfonso. On October 27, 2011, November 7, 2011, November 30, 2011, January 4, 2012, January 20, 2012, and February 28, 2012, Respondent dispensed prescriptions for Oxycontin 60 mg and oxycodone 30 mg to A.R. issued by Dr. Armando Falcon, whose office was located in Miami, Florida. The pharmacy labels attached to the prescription at the time of dispensing include the following warning underneath Dr. Falcon's name "FAKE CII DO NOT FILL CANDY DR."

On March 22, 2012, Respondent dispensed 180 dosage units of oxycodone-acetaminophen to A.R. prescribed by Dr. Dustin Lee, whose office was located in Miami Florida. DI Ramirez will testify that a Walgreens 04391 employee had attached a Florida

Prescription Data Monitoring Program ("PDMP") patient history report for A.R. dated March 22, 2012. DI Ramirez will testify that the PDMP report reveals that during the same time period that customer A.R. was filling his oxycodone prescriptions at Walgreens 04391, he was also filling hydrocodone and carisoprodol prescriptions issued by a completely different physician at another pharmacy located in Fort Pierce.

DI Ramirez will introduce a summary spreadsheet and prescriptions dispensed by Walgreens 04391 to customer E.O., a resident of Port St. Lucie, Florida, which will show that between April 22, 2011 and February 3, 2012, Walgreens 04391 pharmacists dispensed oxycodone and alprazolam to E.O. issued by five different physicians. DI Ramirez will testify that E.O.'s residence in Port Saint Lucie is approximately 16 miles south of Walgreens 04391.<sup>8</sup> Additionally, the evidence will show that several of the oxycodone prescriptions dispensed to E.O. contain the following commentary on the label under Dr. Wolf's name, "DO NOT FILL ANY FILL ANY CII."

DI Ramirez will introduce prescriptions Walgreens 04391 filled for customer A.W. who resided in Port St. Lucie, Florida. The evidence will show that on November 9, 2011, Walgreens 04391 dispensed A.W. 180 dosage units of oxycodone 30 mg and 60 dosage units of alprazolam 2 mg, each of which were issued by Dr. Aaron Boorstein, whose office was located in Fort Lauderdale, Florida.<sup>9</sup> On November 23, 2011, Walgreens 04391 filled A.W.'s prescription for 60 dosage units of oxycodone 15 mg prescribed by Dr. Boorstein. One week later, on December 1, 2011, Walgreens 04391

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<sup>8</sup> DI Ramirez will introduce documentation showing Walgreens has at least eight pharmacies located in Port St. Lucie. DI Ramirez will also introduce a map showing the approximate distance and route traveled by customer E.O. from Port St. Lucie to Miami area physicians, and back past Port St. Lucie to Respondent's location in Fort Pierce.

<sup>9</sup> DI Ramirez will also introduce a map showing the approximate distance and route traveled by customer A.W. from Port St. Lucie to Fort Lauderdale, and back past Port St. Lucie to Respondent's location approximately 11 miles north of her residence in Port St. Lucie.

dispensed 20 dosage units of hydromorphone 2 mg to A.W. which had been prescribed by Dr. Gonzalo Oria, whose office was in Port St. Lucie, Florida. On December 6, 2011, five days after A.W. received hydromorphone, Walgreens 04391 filled a prescription for customer A.W. for 180 dosage units of oxycodone 30 mg issued by Dr. Boorstein.

**B. Interviews with Walgreens Pharmacists**

DI Ramirez will testify that on August 22, 2012, he and other DEA investigators interviewed Walgreens 04391 pharmacy manager Marc Cohen in the presence of DEA and Walgreens attorneys. At the interview, Mr. Cohen stated that he filled controlled substance prescriptions for "pain clinics" after validating the physician's DEA number in their system, checking customers' identification cards, calling doctor's offices and receiving a diagnosis code from a nurse. Mr. Cohen also stated that it was important to know the specialty of a physician writing prescriptions for oxycodone, to ensure they are not writing prescriptions which are out of the scope of their practices, however, he did not verify the prescribing physician's specialty/specialties prior to filing oxycodone prescriptions.

DI Ramirez will testify that when Mr. Cohen was questioned about the commentary regarding certain physicians which appears in Respondent's electronic dispensing log and on the labels attached to prescriptions, Mr. Cohen stated that he did not know how the remarks got into the dispensing log. Mr. Cohen further stated that he would not see these remarks unless he went into "another view" of the pharmacy data. Consequently, if the dispensing log included comments that a doctor's prescription pad was stolen, Mr. Cohen said he would not know to look out for customers attempting to use a stolen prescription pad. With respect to "red flags" of diversion or abuse, Mr. Cohen stated that amounts of controlled substances prescribed are not a "red flag," as

there is no maximum dose that can be prescribed and that the elderly build up a tolerance to controlled substances. DI Ramirez will testify that Mr. Cohen stated he did not fill any "cocktail" prescriptions although he also commented that was unfamiliar with the term "cocktail" prescriptions until a meeting with DEA.

DI Ramirez will testify that on August 23, 2012, he and other DEA investigators interviewed Walgreens 04391 pharmacist Lloyd Wright in the presence of DEA and Walgreens attorneys. DI Ramirez will testify that Mr. Wright stated that 90% of the customers were from pain management clinics and the prescriptions were for controlled substance "cocktails." Mr. Wright explained his procedure for filling controlled substance prescriptions for pain clinic customers consisted of validating the doctor's DEA registration, checking customer identification cards, and calling the doctor's office to obtain a diagnosis code from the nurse. Mr. Wright stated that at some point he stopped filling for patients who lived out of the Ft. Pierce and Port St. Lucie area. DI Ramirez asked Mr. Wright what his thoughts were as he looked back at the dispensing of controlled substances from Walgreens 04391. Mr. Wright replied, "We should not have filled them."

**4. Linda Stocum, Diversion Investigator<sup>10</sup>**

Following testimony about her experience and qualifications as a Diversion Investigator, DI Stocum, will testify about the investigation into controlled substance prescriptions filled by Walgreen Co.'s central fill and mail order facility located in Orlando, Florida. As part of the existing investigation into several Florida Walgreens pharmacies, including Respondent, and the Walgreens Distribution Center in Jupiter, Florida, DEA obtained hard copies of prescriptions filled at those pharmacies between

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<sup>10</sup> In the event DI Stocum is unable to testify, GS Susan Slyker will offer the proposed testimony below.

January 2010 and April 2012. DEA also obtained controlled substances dispensing logs from the pharmacies. Based on a review of the documents obtained from the AIWs, as well as the continuing DEA investigation into Walgreens, DEA requested copies of all controlled substance prescriptions filled by the Walgreens Mail Order facility in Orlando, Florida. DEA obtained copies of all prescriptions filled by the Orlando facility between January 1, 2010, and April 2012.

After a review of the Mail Order prescriptions and a comparison to ARCOS information on controlled substance purchases made under the Mail Order facility's DEA registration, DEA contacted the facility to inquire about large discrepancies between controlled substances ordered and prescriptions filled. At this time, Walgreens informed DEA that in addition to operating a mail order facility, Walgreens also operates its central pharmacy operations ("Central Fill") out of the same Orlando facility.

DI Stocum and DI Deborah George conducted an on-site visit to the Central Fill facility on June 19 and June 21, 2012. DI Stocum will testify about the site visit and what she learned about the facility and operations at that time. She will testify that the Walgreens Central Fill staff provided verbal explanations of the operations conducted at the facility, but were unable to provide DEA with documentation regarding filled prescriptions. DI Stocum will explain how the Central Fill facility operates based on discussions with Walgreens pharmacy personnel. She will testify that Walgreens pharmacies will send certain prescriptions to the facility to be filled, and the facility will then send the filled prescription back to the pharmacy for dispensing to the ultimate customer.

DI Stocum will testify that pursuant to an administrative subpoena issued on July 27, 2012, on October 25, 2012, Walgreen Co. produced dispensing log spreadsheets from



Central Fill. DI Stocum will introduce a summary spreadsheet of Central Fill's prescriptions filled for Walgreens 04391 between January 1, 2010 and June 12, 2012. The evidence will show that Central Fill filled 547 prescriptions in Schedules III-V for Respondent.

DI Stocum will testify that pharmacies sending prescriptions to a central fill facility must notate "CENTRAL FILL" on the face of the original prescriptions as required under 21 C.F.R. § 1306.27(a)(1). DI Stocum will testify about the effect of non-compliance with this regulation, namely, the complications created in attempting to perform an audit or otherwise capture the full picture of tracking controlled substance distributions and dispensing.

**5. Dianne Williams, Diversion Investigator<sup>11</sup>**

Following testimony about her experience and qualifications as a Diversion Investigator, DI Williams will testify that on October 30, 2012, she and DI Alison King visited Walgreens 04391 and presented a Notice of Inspection to Pharmacy Manager Marc Cohen. DI Williams and DI King requested that Mr. Cohen provide approximately twenty-four (24) controlled substances prescriptions identified on a dispensing log spreadsheet provided by Respondent as prescriptions the Central Fill pharmacy filled for Walgreens 04391. DI Williams will introduce copies of the twenty-four prescriptions and accompanying RX Views and Interstore Transfer Claims provided by Mr. Cohen. The documents will show that Respondent failed to write "CENTRAL FILL" on the face of any of the original prescriptions. Also, on three of the interstore transfer claims, Walgreens 04391 failed to document a record of receipt of the filled prescription

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<sup>11</sup> In the event DI Williams is unable to testify, DI Alison King will offer the proposed testimony below.

including date of receipt, method of delivery, and name of retail pharmacy employee accepting delivery.

**6. Lloyd Wright, Pharmacist**

Mr. Wright will be asked to testify about Walgreens 04391's dispensing of controlled substances, including oxycodone. Mr. Wright will testify about "red flags" for controlled substance diversion and abuse, and his process for resolving "red flags" prior to dispensing. Mr. Wright will testify about verification and processing procedures for oxycodone and other controlled substance prescriptions, as well as any changes or modifications to this process over the last two years. Mr. Wright will testify about prescriptions for controlled substances that he filled prescribed by Drs. Wolf, Miniet, Thompson, Falcon, and Boorstein. Also, Mr. Wright will testify about Walgreen Co.'s corporate and regional management oversight, guidance, and on-site visits pertaining to controlled substance dispensing at Walgreens.

**7. Marc Cohen, Pharmacy Manager**

Mr. Cohen will be asked to testify about his training and experience as pharmacy manager, and his role in dispensing oxycodone and other controlled substances. He will also testify about his supervision of pharmacists and pharmacy technicians with respect to controlled substance dispensing. He will be asked about the increase in oxycodone ordering and dispensing while he was pharmacy manager at Respondent's location. Mr. Cohen will testify about verification and other procedures for dispensing oxycodone and other controlled substance prescriptions, as well as any changes or modifications to this process over the last two years. Mr. Cohen will testify about "red flags" for diversion and abuse and his process for resolving "red flags" prior to dispensing. He will be asked about the guidance he provided to other pharmacy staff on how to resolve "red flags"

pertaining to controlled substance prescriptions. Mr. Cohen will testify about Walgreens corporate and regional management oversight, guidance, and on-site visits pertaining to controlled substance dispensing at Walgreens.

**8. Wesley Rohn, Pharmacy District Supervisor**

Mr. Rohn will testify about controlled substance ordering and dispensing guidance he provided to Walgreens 04391 pharmacists, as well as his oversight of the pharmacy, and on-site visits to examine and monitor the controlled substance dispensing.

**9. Edward Svihra, RPH, Health Care Loss Prevention Director**

Mr. Svihra will about his visits concerning "pain management" to Walgreens pharmacies, and specifically, to Walgreens 04391, with Loss Prevention Operations Director, Doug Lemmons, in early 2012. Mr. Svihra will be asked to testify about concerns that he, Doug Lemmons and Division Vice President of Loss Prevention, Kenneth Amos, discussed in January 2011 regarding Respondent's oxycodone dispensing.

**10. Doug Lemmons, Loss Prevention Operations Director**

Mr. Lemmons will testify about his Florida pharmacy "pain management" visits in early 2012 with Edward Svihra, and specifically, his visit to Respondent's store in 2012. Mr. Lemmons will be asked to testify about concerns identified in January 2011 and discussed with Mr. Svihra and Mr. Amos regarding Respondent's oxycodone dispensing.

**11. Paul Doering, M.S.**

Professor Doering will testify regarding his education, background, training, and experience as a pharmacist. Prof. Doering will testify that he (1) is a registered pharmacist in the states of Florida and North Carolina, (2) is certified as a Consultant

Pharmacist in Florida, (3) previously practiced in the community pharmacy setting, (4) has been a professor at the University of Florida's School of Pharmacy for the past 35 years, (5) currently serves at the University of Florida's College of Pharmacy as Distinguished Service Professor of Pharmacy Practice, Emeritus, and (6) for 28 years was either Director or Co-Director of the University of Florida's Drug Information and Pharmacy Resource Center, a telephone access service through which health professionals can obtain information about drugs or drug therapy. Prof. Doering will further testify about his experiences serving as an expert consultant and witness in a number of criminal, civil, and administrative proceedings. Prof. Doering will provide expert witness testimony as detailed below.

Prof. Doering will testify about the education and training pharmacists receive in pharmacy school, including learning the fundamentals of both state and federal pharmacy law as it relates to the filling and dispensing of prescription drugs in general, and controlled substances in particular. He will further testify about training pharmacists receive in the application of those laws to real life situations. He also will discuss the coverage of these topics in Florida's pharmacist licensing exam.

Prof. Doering will testify about the epidemic of prescription drug diversion and abuse in the state of Florida. He will discuss the in 2011 State of Emergency declared by the Florida Surgeon General which was issued in effort to prevent the many drug overdose deaths from controlled substances. The controlled substances commonly associated with this epidemic are Schedule II pain relievers such as oxycodone; Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol. Prof. Doering will testify about the overdose deaths due to oxycodone and

benzodiazepines identified by the 2011 Florida Medical Examiners Report. He will testify that pharmacists are in a key position to reverse the trend of this epidemic.

Prof. Doering will further testify about the pharmacist's role in the distribution of controlled substances. He will testify about the dangerous propensities of certain controlled substances, in particular opiates and opioids such as oxycodone and benzodiazepines such as diazepam (Valium), alprazolam (Xanax), and clonazepam (Klonopin.)

Prof. Doering will discuss the responsibilities of pharmacists in filling controlled substances prescriptions. He will testify about the review and analysis pharmacists should undertake before certifying any such prescription for release to the patient, including checking the licensing status of prescribers and evaluating whether the prescription presented to them is for a legitimate medical purpose and issued by a properly registered practitioner in the usual course of professional practice.

Moreover, Prof. Doering will testify about the "red flags," or, in other words, indicators of diversion and abuse, which are used by pharmacists to detect drug diversion. Because of the enormous abuse and diversion associated with oxycodone, the mere fact that an oxycodone prescription is being presented should put the pharmacist on full-alert to ensure that the prescription is valid. He will testify that oxycodone prescribed in combination with alprazolam, or other benzodiazepines, and/or with carisoprodol, is a popular "cocktail" combination in illicit use, and when presented together by a customer should cause a pharmacist to more closely scrutinize the prescriptions.

He will discuss certain patterns or circumstances that are consistent with drug diversion schemes that a diligent pharmacist should observe, as well as the techniques that help the pharmacist detect drug diversion. Examples of such patterns or

circumstances include, but are not limited to, patients who share the same address, patients who are prescribed the same numbers and types or combinations of drugs, and patients who live a distance from the prescribing practitioner and/or pharmacy, including out-of-state patients and/or practitioners. He also will testify that the 2010 Edition of the Drug Enforcement Administration's Pharmacist's Manual, provides additional guidance to pharmacists of indicators that a prescription was not issued for a legitimate medical purpose. Prof. Doering will testify that when taken together, certain "red flags" create enough doubt about the validity of the prescription that a reasonable and prudent pharmacist would refuse to fill the prescription. Prof. Doering will also testify about the ways in which a reasonable pharmacist would attempt to conclusively resolve "red flags" of diversion or abuse.

Additionally, Prof. Doering will testify about the information he was provided by the DEA to review and analyze concerning Respondent. This information included, but is not limited to: Respondent's dispensing log, copies of prescriptions and prescription labels for Schedule II controlled substances dispensed by Respondent, specialty status for prescribers from the Florida Department of Health, spreadsheets for prescription dispensing activity, and copies of electronic mail messages dispatched to Respondent and other parties in the Walgreens organization.

Prof. Doering will testify that based on his education, training, and experience as a pharmacist, his review and analysis of the DEA information he received shows that Respondent's pharmacists filled prescriptions that contained one or more "red flags" of drug diversion and either did not or could not conclusively resolve those "red flags" before dispensing the drugs.

**A. "Candy Doctor" Prescriptions**

Prof. Doering will testify about oxycodone dispensed by Respondent pursuant to prescriptions which Walgreens 04391 pharmacy employees documented red flags by commenting on the legitimacy of the prescription and/or the prescriber. Prof. Doering will discuss the red flag commentary in dispensing log and appearing on the prescription labels, including Dr. Dustin Lee, "FAKE CII DO NOT FILL CANDY DR\*\*\*FAKE"; and Armando Falcon M.D., "FAKE CII DO NOT FILL CANDY DR." Prof. Doering will testify that this type of commentary pertains to the conduct of the physician, and consequently, a pharmacist's call to the physician's office could not resolve this type of red flag.

**B. Dr. Miniet's Prescriptions**

Prof. Doering will testify that he reviewed the prescriptions and summary spreadsheets of Dr. Miniet's prescription dispensed by Walgreens 04391. Prof. Doering will testify that the prescriptions with the commentary "PAY FOR PLAY" on the label indicate that pharmacists knew or should have known in early 2011 that Dr. Miniet's prescriptions may have been issued for other than legitimate medical purposes. Prof. Doering will testify that Dr. Miniet's prescriptions posed multiple red flags for risk of diversion including cocktail prescribing, significant distances between patient, pharmacy and prescriber, cash payments for prescriptions, physician practicing outside his specialty, and young patients in their twenties. Prof. Doering will testify about prescriptions issued by Dr. Miniet and filled by Walgreens 04391 on October 14, 2011 to customers R.A., M.W., S.C., C.W., L.K., P.L. and L.S. Prof. Doering will testify that these prescription presented several "red flags". For example, Prof. Doering will testify about four prescriptions dispensed to customer L.S., a twenty-even year old residing in

Port St. Lucie on October 14, 2011 for 180 dosage units of oxycodone 30 mg, 84 dosage units of hydromorphone 8mg, 28 dosage units of alprazolam 2mg, and 28 dosage units of carisprodol 350mg who paid cash for the drugs. Prof Doering will also testify that it appears that many of the prescriptions dispensed on October 14, 2011 were reviewed by the same pharmacist as indicated by the signature on the prescription. Prof. Doering will testify that given the nature of the red flags associated with the prescriptions for L.S. and other customers, a pharmacist would not be able to resolve the red flags merely by verifying the patient's identification and calling the physician.

#### **C. Dr. Thompson's Prescriptions**

Prof Doering will testify about several controlled substances dispensed pursuant to prescriptions issued by Dr. Ronald Thompson, a board certified obstetrician/gynecologist. Prof. Doering will discuss the multiple red flags associated with these prescriptions including: cocktail prescribing, male patients, significant distances between patient, pharmacy and prescriber, cash payments for prescriptions, physician practicing outside his specialty, and pharmacy commentary, "FAKE CII DO NOT FILL ANY CII CANDY DR". Prof. Doering will testify that given the nature of the red flags associated with these prescriptions, a pharmacist would not be able to resolve the red flags merely by verifying the patient's identification and calling the physician.

#### **D. Customer A.R.**

Prof. Doering will testify about his review of prescriptions dispensed to customer A.R. between late April 2011 and March 2012. Prof. Doering will testify that A.R.'s prescriptions presented multiple red flags for diversion including, frequent doctor changes, and multiple high volume, high strength oxycodone prescriptions. Prof.



Doering will discuss a Prescription Drug Monitoring Program (PDMP) report attached to a March 22, 2012 oxycodone prescription. The report revealed that for the past year, A.R. was doctor shopping, meant that he was filling prescriptions for hydrocodone and carisprodol prescribed by different physicians at different pharmacies. Prof. Doering will testify that Florida's PDMP was created to help pharmacists identify and prevent precisely this type of doctor shopping scenario. Prof. Doering will testify that the red flags associated with A.R.'s prescriptions should have prompted Walgreens 04391 pharmacists to run a PDMP report well before March 22, 2012. Had they done so, A.R.'s doctor shopping would have come to light much earlier. In addition, Prof. Doering will testify that even when Walgreens 04391 pharmacists did run the PDPM report, they still dispensed oxycodone to A.R. despite unresolved red flags indicating that A.R. was diverting or abusing the controlled substances.

**E. Customer E.O.**

Prof. Doering will testify about "red flags" associated with prescriptions filled for customer E.O., a twenty-nine year old Port St. Lucie resident. These red flags include cash payments for oxycodone and benzodiazepine "cocktails," and distances traveled from his Port St. Lucie residence to several physicians in the Miami area, and frequent prescriber changes. Prof. Doering will testify that it is also a "red flag" that E.O. traveled out of his way to have the prescriptions filled approximately 16 miles north of his Port St. Lucie home at Walgreens 04391 in Fort Pierce. Prof. Doering will testify that the commentary on labels attached to the prescriptions regarding Dr. Wolf is an additional "red flag". Prof. Doering will testify that given the multiple red flags associated with E.O.'s prescriptions, a pharmacist would not be able to resolve the "red flags" merely by verifying the patient's identification and calling the physician.

**F. Customer A.W.**

Prof Doering will testify about "red flags" associated with prescriptions filled for customer A.W., a twenty-three year old Port St Lucie resident, who traveled over 100 miles south to Fort Lauderdale to visit Dr. Boorstein and then filled her prescriptions over 11 miles north of her home in Port St. Lucie. Prof. Doering will testify about a prescription dispensed to A.W. issued by Dr. Oria for hydromorphone 2mg on December 1, 2011, while she was also being prescribed oxycodone 15 mg and 30 mg by Dr. Boorstein. Prof. Doering will testify that the hydromorphone prescription raises red flags of doctor shopping and health risks concerns due to multiple opioid prescriptions. Prof. Doering will testify that it may have been possible for a pharmacist to resolve the this "red flag" by calling Dr. Oria to inquire whether or not he was aware of oxycodone prescriptions issued by Dr. Boorstein. Prof. Doering will testify that there is no indication on the face of the prescription that a pharmacist contacted Dr. Oria to resolve the "red flags." On December 6, 2011, five days after receiving hydromorphone, customer A.W. presented a prescription for 180 dosage units oxycodone 30 mg. Prof. Doering will testify that there is no indication on the face of the prescription that a pharmacist contacted Dr. Boorstein to discuss the hydromorphone dispensed five days earlier.

Prof. Doering will testify that in his opinion, Respondent's pharmacists failed to exercise that degree of professional judgment that a reasonable and prudent pharmacist would have done in like or similar circumstances when dispensing controlled substances. He will opine that some red flags presented with prescriptions were unresolvable and that a prudent pharmacist would not have dispensed under those circumstances. He will opine that Respondent's pharmacists failed to execute their duty to verify whether or not the

large number of prescriptions they dispensed were for a legitimate medical need, and that they demonstrated a reckless indifference for the consequences of their actions or inactions.

#### PROPOSED DOCUMENTS

212. DEA Certificate of Registration BW5872494 (attached hereto), (1 page)
213. ARCOS Report of Walgreens 04391 Oxycodone purchases, 2006-2012, (2 pages)
214. Respondent's Dispensing Log, January 2010 – April 4, 2012, (6,740 pages)
215. Prescriptions with Label Commentary, (15 pages)
216. Summary Spreadsheet of Dispensing, Customer A.R., (2 pages)
217. Prescriptions for Customer A.R., (20 pages)
218. March 22, 2012 PDPM report for Customer A.R., (2 pages)
219. Summary Spreadsheet of Dispensing, Customer E.O., (3 pages)
220. Customer E.O. Travel Distance Map, (2 pages)
221. Prescription for Customer E.O., (13 pages)
222. Summary Spreadsheet of Dispensing, Customer A.W., (2 pages)
223. Customer A.W. Travel Distance Map, (2 pages)
224. Prescriptions for Customer, A.W., (6 pages)
225. Summary Spreadsheet of Dispensing, Dr. Dustin Lee, (3 pages)
226. Summary Spreadsheet of Dispensing, Dr. Armando Falcon, (16 pages)
227. Summary Spreadsheet of Dispensing, Dr. Ronald Thompson, (18 pages)
228. Prescriptions Issued by Dr. Thompson, filled December 2011 and January 2012, (30 pages)
229. Summary Spreadsheet of Dispensing, Dr. Ralph Miniet, (88 pages)
230. Summary Spreadsheet of Dispensing, October 14, 2011, Dr. Miniet, (3 pages)
231. Prescriptions filled on October 14, 2011, Dr. Miniet, (13 pages)
232. Customer L.S. Travel Distance Map, (2 pages)
233. Central Fill Dispensing Log for Walgreens 04391, (315 pages)
234. Notice of Inspection, October 30, 2012, (1 page)
235. Central Fill Prescriptions, RX View and CPO Interstore Transfer Claims, (120 pages)

- 236. Florida Department of Health, Pharmacist License Verification, Lloyd Wright, (2 pages)
- 237. Florida Department of Health, Pharmacist License Verification, Gladys Murrow, (2 pages)
- 238. Pharmacy- Physician Travel Distance Map, (1 page)
- 239. Walgreens pharmacies located in Port St. Lucie, Florida, (1 page)

**II. WALGREENS #03099 (FORT MYERS PHARMACY)**  
**PROPOSED WITNESSES<sup>12</sup>**

- 1. Susan Langston  
Diversion Program Manager  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
- 2. Donna Richards  
Acting Diversion Group Supervisor  
DEA Miami Field Division  
2100 North Commerce Parkway  
Weston, Florida 33326
- 3. Roberta Goralczyk  
Group Supervisor  
DEA Tampa District Office  
4950 West Kennedy Boulevard, Suite 400  
Tampa, Florida 33609
- 4. Megan Owens  
Pharmacist  
21579 Bella Terra Boulevard  
Estero, Florida 33928
- 5. Trudi-Ann Blackellar  
Pharmacist  
10200 Olivewood Way, #39  
Estero, Florida 33928
- 6. Keri Kratofil  
District Pharmacy Supervisor

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<sup>12</sup> In addition to the witnesses identified below, DEA reserves the right to call any of the witnesses listed by Respondent on matters identified by Respondent.

22011 Bridge Run Court  
Estero, Florida 33928

7. Professor Paul Doering, M.S.  
Consultant Pharmacist  
3723 SW 20<sup>th</sup> Street  
Gainesville, Florida 32608

### SUMMARY OF TESTIMONY

#### 1. Diversion Program Manager Susan Langston

DPM Langston will testify regarding the nature of diversion of controlled substances in Florida including the link between unscrupulous doctors at pain clinics, who prescribe oxycodone and other highly abused drugs to drug seekers, and pharmacies who willingly fill such prescriptions without exercising their corresponding duty to prevent diversion.

DPM Langston will testify that on August 18, 2011, she and GS Gayle Lane and other DEA investigators met with representatives from Walgreens Corporation to discuss oxycodone diversion and abuse issues in Florida. DPM Langston will testify that DEA investigators advised Walgreens about specific red flags for diversion related to patients, namely: out-of-state patients, questionable Florida identification cards, cocktail prescriptions for oxycodone 15 mg, oxycodone 30 mg, alprazolam 2 mg, and Soma (carisoprodol), patients under the age of 45 years old, and patients paying with cash. DPM Langston will testify that she discussed red flags or suspicious conduct to look for with respect to physicians: doctors writing for the same drugs; prescriptions from multiple individuals containing the same diagnosis; and doctors writing for large quantities of Schedule II prescriptions who had specialties unrelated to pain management, such as obstetricians, pediatricians and ophthalmologists.

## **2. Diversion Investigator Donna Richards**

DI Richards will testify that on April 4, 2012, DEA executed an AIW at Walgreens 03099. During execution of the AIW, investigators obtained inventory records, copies of all Schedule II prescriptions and dispensing records for Schedule II-IV controlled substances dispensed between January 1, 2010 and April 4, 2012. DI Richards will testify that a review of the records revealed that Walgreens 03099 filled prescriptions that should have raised concerns or red flags of diversion to the pharmacists. Specifically, Walgreens 03099 filled prescriptions issued by doctors who: prescribed to patients who had travelled either from out-of-state or from great distances within Florida to see the doctor and then have their prescriptions filled at Respondent's pharmacy; engaged in "pattern prescribing" by prescribing the same drugs and dosage amounts to multiple individuals, including some who lived at the same address; practiced outside their specialty; and issued prescriptions for controlled substance "cocktails" including combinations of oxycodone, alprazolam and carisoprodol. She will also testify regarding police reports of Walgreens 03099 customers under the influence of drugs or engaging in drug sales with other individuals at Walgreens 03099. Despite this activity, Walgreens 03099 continued to dispense controlled substances to these customers after these incidents.

## **3. Group Supervisor Roberta Goralczyk**

GS Goralczyk will testify regarding DEA's October 30, 2012, administrative inspection of Walgreens 03099 and the recordkeeping violations found during this inspection. Investigators found thirty-three prescriptions that lacked annotations that they were filled by Walgreens' central fill pharmacy, in violation of 21 C.F.R. § 1306.27(a), and that lacked the red "C" which is required when storing controlled substance

prescriptions with non-controlled prescriptions, in violation of 21 C.F.R. § 1304.04(h)(4) (these thirty-three prescriptions were also not readily retrievable). Investigators also found three prescriptions that lacked the DEA registration number of the prescriber and eight “call-in” prescriptions that lacked the address of the patient and the DEA registration number of the prescriber, in violation of 21 C.F.R. §§ 1306.21(a), 1306.05(a) and 1306.27(a)(2).

#### 4. Megan Owens, Pharmacist<sup>13</sup>

Ms. Owens will testify that she was employed as a pharmacist by Walgreens beginning in 2007 and became the Pharmacy Manager at Walgreens 03099 in March 2010. She held this position until February 2012 when she left her employment with Walgreens due to scheduling issues. She is currently the Pharmacy Manager at a CVS Pharmacy in Bonita Springs, Florida.

She will testify that Walgreens 03099 filled a high volume of oxycodone prescriptions because the pharmacy was surrounded by numerous pain clinics. She will testify that she had weekly phone calls with her District Manager, Keri Kratofil, but seldom met with her in person. During the weekly calls she was told to “follow the law” and sometimes “red flags” of diversion were discussed. She will testify that there was no Walgreens manual providing further guidance on this and that she would resolve red flags by calling the prescriber. Someone from Loss Prevention came to the store approximately four times per year.

Ms. Owens will testify that she would check the identification of customers filling controlled substance prescriptions, call the offices of prescribers to verify oxycodone

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<sup>13</sup> In the event Ms. Owens does not testify, DEA will call either GS Donna Richards or DI Jennifer Jimenez to testify to the statements Ms. Owens made to investigators during her January 24, 2013, interview discussed below.

prescriptions and obtain the patient's diagnosis, whether the patient was a regular patient and whether the patient had a recent MRI, and check Florida's prescription drug monitoring program (E-FORCSE) to identify doctor-shoppers. She would not otherwise look for indications of diversion and if the patient had identification, the doctor's office verified the prescription and she did not discover evidence of doctor-shopping from the PDMP, she would generally fill the prescription. She would not, however, fill prescriptions for customers or prescribers outside of the pharmacy's service area, which she defined as Lee and Collier Counties. If she was not able to verify a prescription she would not fill it and there were also occasions where she was unable to fill oxycodone prescriptions because the pharmacy had run out of oxycodone.

She will testify that the pain clinic customers came in with prescriptions for oxycodone 15 mg, oxycodone 30 mg, Xanax, occasionally Soma and quite a lot also had ibuprofen prescriptions. She will testify that she was not suspicious of customers getting oxycodone 15 mg and 30 mg together. She will testify that the customers told her that Publix would not fill their prescriptions because it couldn't get the medication. She received phone calls several times a week from people asking if Walgreens 03099 had oxycodone in stock, but she would not give out this information over the phone. Ms. Owens will be questioned regarding specific prescriptions that she filled that contained one or more red flags of diversion, including prescriptions she filled that were issued by Emiliya Hill, M.D.

She will testify as to the process by which Walgreens 03099 filled prescriptions, including whether a prescription would be filled on site or by the Central Fill Pharmacy. In the fall of 2010, Walgreens 03099 started using the Central Fill Pharmacy. She will testify that every prescription is scanned into the computer and a scanned image is sent to



the Central Fill Pharmacy for data entry. The data entry person enters the information into the computer and the central fill pharmacist verifies that the information is correct. She will testify that if the prescription is for a Schedule II medication or the customer is waiting for the medication, the prescription is released back to Walgreens 03099 to be filled. The Central Fill Pharmacy fills all non-schedule II prescriptions, controlled and non-controlled, which are to be picked up the next day. She will testify that there is no way to distinguish a prescription filled by Walgreens 03099 from one filled by the Central Fill Pharmacy except when packaged, the label, receipt and bag were different. She will testify that the words "Central Fill" were not stamped on the prescriptions. She will testify as to notations made on Schedule II prescriptions filled by Walgreens 03099, including the initials of staff responsible for: scanning the prescription into the computer; computer screen verification; counting the pills; and verifying the prescription.

She will also testify regarding Walgreens 03099's ordering system for controlled substances. She will testify that orders were automatically generated by computer based on the previous weeks' usage, but that a pharmacist could change the order before it went through. The change could be made on the original line, or the pharmacist could add a line. She will testify that she was occasionally contacted about changing an order, but not routinely, and that she believes this was just protocol for Walgreens to call and check on the quantity. She will testify that she was not aware of any limits on oxycodone that could be ordered and that the computer automatically generated an order on a specific day, weekly. She will testify that she was not required to review the order and the distribution center never refused to send an order. She will testify that orders could be supplemented with "PDQ orders" that could be placed anytime through the computer system. She will testify that there were no limits placed on the PDQ orders and these

orders were never declined by the distribution center. She will testify that no one from the Walgreens distribution center had ever visited Walgreens 03099. She will testify that her annual bonuses during the years she worked for Walgreens ranged from approximately \$4,000 to approximately \$8,000 and were based on sales, number of prescriptions filled, which included all prescriptions, and management of inventory dollars.

**5. Trudi-Ann Blackellar, Pharmacist**

Ms. Blackellar will testify regarding her employment at Walgreens 03099 and the protocol she used to fill controlled substance prescriptions at Walgreens 03099. She will testify regarding specific controlled substance prescriptions that she filled, including whether she identified any red flags of diversion associated with those prescriptions, whether she took any actions to clear those red flags and why she ultimately filled the prescriptions.

**6. Keri Kratofil, District Pharmacy Supervisor**

Ms. Kratofil will testify regarding her employment as a Walgreens District Pharmacy Supervisor. She will testify regarding the substance of weekly conference calls she held with pharmacists at Walgreens pharmacies in her district. She will testify regarding any and all on-site visits she made to Walgreens pharmacies. She will testify regarding her knowledge of controlled substance prescriptions filled at Walgreens pharmacies in her district. She will testify regarding her knowledge of controlled substance orders placed by Walgreens 03099, including, but not limited to, orders for oxycodone. She will testify regarding how Walgreens 03099 received oxycodone products from the Walgreens distribution center both before and after October 2011. She will testify regarding when and why she made the decision to limit the supply of

oxycodone products at Walgreens 03099. Finally, she will testify regarding any and all communications she had with employees at Walgreens' distribution center regarding controlled substance orders by Walgreens 03099.

**7. Professor Paul Doering, M.S.**

Professor Paul Doering, M.S., ("Prof. Doering") will testify about his background, training and experience. He will then testify as a Florida pharmacy expert regarding the operations and procedures generally followed by pharmacies in Florida. Prof. Doering will testify about activity indicative of diversion or "red flags" of diversion that should be recognized by pharmacists, as well as the steps a reasonable pharmacist must take to resolve such red flags prior to dispensing. Prof. Doering will testify that some red flags cannot be resolved and that in those cases a pharmacist exercising his or her corresponding responsibility would not dispense controlled substances.

Prof. Doering will also testify about his review of prescriptions dispensed by Walgreens 03099 under suspicious circumstances including the following: multiple individuals presenting prescriptions for the same drugs in the same or similar quantities from the same doctor; individuals with the same address presenting substantially similar prescriptions; individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone and alprazolam; individuals presenting prescriptions for controlled substances issued by practitioners with specialties unrelated to pain management or oncology; individuals presenting prescriptions for controlled substances issued by practitioners located long distances from the pharmacy; and individuals paying for prescriptions for controlled substances with cash and non-insurance discount cards. Prof. Doering will testify that the combination of red flags associated with these prescriptions cannot be resolved such that a reasonable pharmacist,

in the exercise of his or her corresponding responsibility, could dispense the controlled substances prescribed.

#### PROPOSED DOCUMENTS

240. Copy of Walgreens #03099's DEA Certificate of Registration.<sup>14</sup> (1 page)
241. Administrative Inspection Warrant for Walgreens #03099 dated April 3, 2012. (2 pages)
242. Excerpts of Dispensing Log and Prescriptions for J.V.L. and L.V.L. dispensed by Walgreens #03099 pharmacists. (92 pages)
243. Excerpts of Dispensing Log and Prescriptions for G.G., R.T. and T.T. dispensed by Walgreens #03099 pharmacists. (58 pages)
244. Excerpts of Dispensing Log and Prescriptions for C.A. dispensed by Walgreens #03099 pharmacists. (60 pages)
245. Excerpts of Dispensing Log and Prescriptions for M.S. dispensed by Walgreens #03099 pharmacists. (44 pages)
246. Excerpts of Dispensing Log and Prescriptions for K.W. dispensed by Walgreens #03099 pharmacists. (6 pages)
247. Excerpts of Dispensing Log and Prescriptions for Y.H., V.H. and D.H. dispensed by Walgreens #03099 pharmacists. (92 pages)
248. Excerpts of Dispensing Log and Prescriptions for P.C. and M.C. dispensed by Walgreens #03099 pharmacists. (64 pages)
249. Excerpts of Dispensing Log and Prescriptions for T.T. and T.T. dispensed by Walgreens #03099 pharmacists. (82 pages)
250. Excerpts of Dispensing Log and Prescriptions for C.A., H.A. and T.W. dispensed by Walgreens #03099 pharmacists. (103 pages)
251. Excerpts of Dispensing Log for Prescriptions issued by Emiliya Hill, M.D., and dispensed by Walgreens #03099 pharmacists. (80 pages)
252. Bryon Wheeldon email chain dated 03/28/2011 re: "Fw: STORE 3099" [WAGS00001034-37]. (4 pages)

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<sup>14</sup> A copy is attached hereto,

- 253. "Store Manager 03099" email to Keri Kratofil dated 10/13/2011 [WAG00000467]. (1 page)
- 254. Emails from Matt McLaughlin dated 11/18/2011 and 11/21/2011 [WAG00000414-16]. (3 pages)
- 255. Notice of Inspection for Walgreens #03099 dated October 30, 2012. (1 page)
- 256. Copies of documentation and prescriptions with central fill and other violations from DEA's October 30, 2012, inspection of Walgreens #03099. (37 pages)
- 257. Police Report from 9/27/10 regarding trespass warning to Walgreens customer M.L. and Excerpts of Dispensing Log and Prescriptions for M.L. dispensed by Walgreens #03099 pharmacists. (15 pages)
- 258. Police Report from 9/28/10 regarding drug deal by Walgreens customer C.M. and Excerpts of Dispensing Log and Prescriptions for C.M. dispensed by Walgreens #03099 pharmacists. (8 pages)

**OTHER MATTERS**

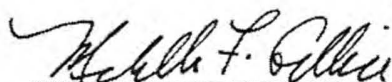
The Government reserves the right to supplement this Prehearing Statement upon receipt and review of Respondent's Prehearing Statement and documentary evidence and reserves the opportunity to amend its instant pleading at a time and date specified by the presiding Administrative Law Judge.

Additionally, the Government notifies the Court of its intent to submit a filing complying with the Courts order dated February 26, 2013 regarding the Government's documentary evidence. Such filing will be submitted on or before the Court's deadline of March 15, 2013.

**BEST ESTIMATE AS TO TIME REQUIRED TO PRESENT CONSOLIDATED CASES, INCLUDING THIS MATTER**

The Government anticipates that it will need seven days to present its case-in-chief, exclusive of cross-examination and rebuttal.

Respectfully submitted,



MICHELLE F. GILLICE  
PAUL E. SOEFFING  
Senior Attorneys  
Diversion & Regulatory Litigation  
Office of Chief Counsel  
Drug Enforcement Administration  
8701 Morrissette Drive  
Springfield, Virginia 22152

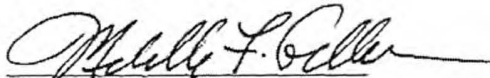
Dated: March 1, 2013

**CERTIFICATE OF SERVICE**

I hereby certify that on the date signed below, I caused the original and nine copies of the foregoing **GOVERNMENT'S PREHEARING STATEMENT** to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via first-class mail, and a courtesy copy via e-mail* to counsel for Respondent at the following addresses:

Phil Perry  
Allen M. Gardner  
Nathan H. Seltzer  
Latham & Watkins LLP  
555 Eleventh Street, NW  
Suite 1000  
Washington, DC 20004-2232  
Fax: 202.637.2201  
Email: [Phil.Perry@lw.com](mailto:Phil.Perry@lw.com)  
[Allen.Gardener@lw.com](mailto:Allen.Gardener@lw.com)  
[Nathan.Seltzer@lw.com](mailto:Nathan.Seltzer@lw.com)

3/1/2013



Michelle F. Gillice  
Diversion & Regulatory Litigation  
Office of Chief Counsel  
Drug Enforcement Administration  
8701 Morrissette Drive  
Springfield, Virginia 22152

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
AW1366877	05-31-2013	\$551
SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5	CHAIN PHARMACY	05-12-2010
WALGREEN CO. DBA: WALGREENS # 03099 1525 COLONIAL BLVD FT MYERS, FL 33907		

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**  
 UNITED STATES DEPARTMENT OF JUSTICE  
 DRUG ENFORCEMENT ADMINISTRATION  
 WASHINGTON, D.C. 20537

Sections 304 and 1006 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**  
 UNITED STATES DEPARTMENT OF JUSTICE  
 DRUG ENFORCEMENT ADMINISTRATION  
 WASHINGTON, D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
AW1366877	05-31-2013	\$551
SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5	CHAIN PHARMACY	05-12-2010
WALGREEN CO. DBA: WALGREENS # 03099 1525 COLONIAL BLVD FT MYERS, FL 33907		

Sections 304 and 1006 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (05/04)

DEA REGISTRATION NUMBER		THIS REGISTRATION FEE	
BW5872494		EXPIRES	PAID
		05-31-2013	\$551
SCHEDULES		BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,5		CHAIN PHARMACY	05-12-2010
WALGREEN CO. DBA: WALGREENS # 04391 2501 VIRGINIA AVE. FT PIERCE, FL 34981			

**CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE**  
 UNITED STATES DEPARTMENT OF JUSTICE  
 DRUG ENFORCEMENT ADMINISTRATION  
 WASHINGTON, D.C. 20537

Sections 304 and 1008 (21 U.S.C. 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

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Form DEA-223 (05/04)



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UNITED STATES DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTERS OF  
  
WALGREEN CO.

DOCKET NOS. 13-1, 13-9, 13-10, 13-11, 13-16, 13-18, 13-20

ADMINISTRATIVE LAW JUDGE  
JOHN J. MULROONEY, II

**GOVERNMENT'S CONSOLIDATED SUPPLEMENTAL PREHEARING STATEMENT**

The United States Department of Justice, Drug Enforcement Administration ("DEA" or "Government"), by and through its undersigned counsel, hereby files its Consolidated Supplemental Prehearing Statement.

**ADDITIONAL PROPOSED STIPULATIONS OF FACT**

1. Walgreen Co. d/b/a Walgreens #04391 is registered with DEA as a chain pharmacy authorized to handle controlled substances in Schedules II-V under DEA registration number BW5872494 at 2501 Virginia Avenue, Fort Pierce, Florida 34981. DEA registration BW5872494 expires by its terms on May 31, 2013.<sup>1</sup>

**PROPOSED WITNESSES**

Filed separately is the Government's comprehensive Witness List that includes each of the witnesses the Government intends to introduce during its case-in-chief for all the consolidated matters, as well as the location from where each witness will be testifying. In

<sup>1</sup> This proposed stipulation corrects Walgreens 04391's registration number which was misidentified in Government's Prehearing Statement filed on March 1, 2013.

addition to these witnesses, DEA reserves the right to call any of the witnesses listed by Respondent on matters identified by Respondent.

### SUMMARY OF TESTIMONY

#### 1. DEA Diversion Investigator Martin Ramirez

In addition to the testimony previously noticed, Diversion Investigator Martin Ramirez will testify to his preparation of Google maps showing distances travelled by customers to obtain and fill prescriptions for oxycodone and other controlled substances at Walgreens 04391.

Investigator Ramirez will further testify to his preparation of Google maps showing Walgreens pharmacies located in Port St. Lucie and Fort Pierce. In addition, the Government will introduce through the testimony of Investigator Ramirez, summary spreadsheets excerpted from Respondent's dispensing log showing oxycodone and other controlled substances dispensed to customers R.B and L.S.

#### 2. Lloyd Wright, Pharmacist (Walgreens #04391)

In addition to the testimony previously noticed, Mr. Wright will be asked to testify about his background and education. He will also be questioned about orders for controlled substances he placed with the Jupiter Distribution Center for Walgreens 04391. He will be asked about orders for controlled substances that Walgreens 04391 placed with the Jupiter Distribution Center that were reported to DEA as "suspicious orders." Mr. Wright will be questioned regarding how and when he was informed by Walgreens management, including but not limited to pharmacy district supervisors, and representatives from the Jupiter Distribution Center and/or Loss Prevention, that orders for controlled substances placed by Walgreens 04391 had been reported to DEA as "suspicious orders," as well as any and all subsequent communications and/or interactions he had

with the Walgreens corporate representatives concerning each order from Walgreens 04391 that Walgreens reported to DEA as suspicious.

**3. Marc Cohen, Pharmacy Manager (Walgreens #04391)**

In addition to the testimony previously noticed, Mr. Cohen will be questioned about orders for controlled substances he or his pharmacy staff placed with the Jupiter Distribution Center for Walgreens 04391. He will be asked about Walgreens 04391 orders Walgreens reported to DEA as "suspicious orders." Mr. Cohen will be questioned regarding how and when he was informed by Walgreens corporate representatives, including but not limited to pharmacy district supervisors, and representatives from the Jupiter Distribution Center and/or Loss Prevention, that orders placed for Walgreens 04391 had been reported to DEA as "suspicious orders," as well as any and all subsequent communications and/or interactions he had with the Walgreens corporate representatives concerning each order from Walgreens 04391 that Walgreens reported to DEA as suspicious.

**4. Andrea Cohen, Pharmacy Manager (Walgreens #04727)**

In addition to the testimony previously noticed, Ms. Cohen will be asked to testify about her background and education. Ms. Cohen will be questioned about orders for controlled substances she or her pharmacy staff placed with the Jupiter Distribution Center for Walgreens 04727. She will be asked about Walgreens 04727 orders that Walgreens subsequently reported to DEA as "suspicious orders." Ms. Cohen will be questioned regarding how and when she was informed by Walgreens corporate representatives, including but not limited to pharmacy district supervisors, and representatives from the Jupiter Distribution Center and/or Loss Prevention, that orders placed for Walgreens 04727 had been reported to DEA as "suspicious orders," as well as any and all subsequent communications and/or interactions she had with the Walgreens corporate

representatives concerning each order from Walgreens 04727 that Walgreens reported to DEA as suspicious.

**5. Jorge Corripio, Pharmacist (Walgreens #04727)**

In addition to the testimony previously noticed, Mr. Corripio will be asked to testify about his background and education. Mr. Corripio will be questioned about orders for controlled substances he placed with the Jupiter Distribution Center for Walgreens 04727. He will be asked about Walgreens 04727 orders that Walgreens subsequently reported to DEA as "suspicious orders." Mr. Corripio will be questioned regarding how and when he was informed by Walgreens management, including but not limited to pharmacy district supervisors, and representatives from the Jupiter Distribution Center and/or Loss Prevention, that orders placed for Walgreens 04727 had been reported to DEA as "suspicious orders," as well as any and all subsequent communications and/or interactions he had with the Walgreens corporate representatives concerning each order from Walgreens 04727 that Walgreens reported to DEA as suspicious.

**6. Melissa Kayes, Pharmacy Technician (Walgreens #04727)**

In addition to testimony previously noticed, Ms. Kayes will be asked to testify about her background and education. Ms. Kayes will be questioned about orders for controlled substances that she placed with the Jupiter Distribution Center for Walgreens 04727. She will be asked about Walgreens 04727 orders that Walgreens subsequently reported to DEA as a "suspicious orders." Ms. Kayes will be questioned regarding how and when she was informed by Walgreens management, including but not limited to pharmacy district supervisors, and representatives from the Jupiter Distribution Center and/or Loss Prevention, that orders placed for Walgreens 04727 had been reported to DEA as "suspicious orders," as well as any and all subsequent

communications and/or interactions she had with the Walgreens corporate representatives concerning each order from Walgreens 04727 that Walgreens reported to DEA as suspicious.

**7. DEA Diversion Investigator Domingo Gonzales**

In addition to testimony previously noticed, Diversion Investigator Domingo Gonzales will testify to a modified spreadsheet that he prepared showing the dispensing of controlled substance to customer "J.M." by Walgreens 03629. The modified spreadsheet, submitted in lieu of Government Proposed Exhibit 104, will include the patient address, the cash amount paid for each prescription, and dispensing pharmacist. He will further testify to his preparation of Google maps showing distances travelled by individuals while obtaining prescriptions for oxycodone and filling the prescriptions at Walgreens 03629.

**8. Caren Cohalla, Pharmacy Manager (Walgreens #03629)**

In addition to testimony previously noticed, Walgreens 03629 Pharmacy Manager Caren Cohalla will be asked to testify regarding her supervision of pharmacists and pharmacy technicians with respect to controlled substance dispensing. Ms. Cohalla will be asked to testify regarding her background and training on detecting "red flags" and other suspicious indicators of controlled substance diversion. She will also be asked to testify regarding similar training received by other pharmacists and pharmacy staff of Walgreens 03629 as well as guidance she provided to pharmacy staff on how to resolve "red flags" pertaining to controlled substance prescriptions. Ms. Cohalla will be asked to testify regarding Walgreens' Good Faith Dispensing procedures, modifications to those procedures, and whether these procedures were helpful in informing the determinations of pharmacy staff to fill, or not fill, a prescription for a controlled substance.

She will be asked about the increase in oxycodone ordering and dispensing while she

managed the Walgreens 03629 location. Specifically, Ms. Cohalla will be questioned about oxycodone orders placed for Walgreens 03629 with the Jupiter Distribution Center that Walgreens subsequently reported to DEA as "suspicious orders." Ms. Cohalla will be questioned regarding how and when her pharmacy was informed by Walgreens corporate representatives, including but not limited to pharmacy district supervisors, and representatives from the Jupiter Distribution Center and/or Loss Prevention, that the orders placed by the pharmacy had been reported to DEA as a "suspicious order." She will also be asked to testify to any and all subsequent communications and/or interactions she had with the Walgreens corporate representatives concerning each order from Walgreens 03629 that was subsequently reported to DEA as suspicious by Walgreens.

Ms. Cohalla will be asked to testify about verification and other procedures for dispensing oxycodone and other controlled substance prescriptions, as well as any changes or modifications to this process over the last two years. She will further testify about Walgreens corporate and regional management oversight, guidance, and on-site visits pertaining to controlled substance dispensing at Walgreens 03629. Ms. Cohalla will also be asked to address apparent inconsistencies between the dispensing logs of Walgreens 03629 and corresponding prescriptions.

**9. Terry Collins, Walgreens District Pharmacy Supervisor, District 227 (Tampa North)**

Following testimony of his background and qualifications as Walgreens District Pharmacy Supervisor, District 227 (Tampa North), Terry Collins will be asked to testify about controlled substance ordering and dispensing guidance he provided to Walgreens 03629

pharmacists, as well as his oversight of the pharmacy, and on-site visits to examine and monitor the controlled substance dispensing at that location.

Mr. Collins will be asked to address specific instances of controlled substance dispensing by Walgreens 03629. Specifically, Mr. Collins will be questioned regarding oxycodone dispensed to individuals travelling great distances from their residential locations to the locations of their treating physician and ultimately to Walgreens 03629 where the oxycodone prescriptions were filled. Mr. Collins will also be asked about Walgreens 03629's dispensing of controlled substances to customer "J.M." despite numerous red flags, and whether he or anyone affiliated with Walgreen corporate headquarters inquired about the dispensing of controlled substances to J.M. as well as other individuals.

Mr. Collins will be asked about the increase in oxycodone ordering and dispensing during his tenure as District Pharmacy Supervisor for District 227. Specifically, Mr. Collins will be questioned about oxycodone orders placed for Walgreens 03629 with the Jupiter Distribution Center that Walgreens subsequently reported to DEA as "suspicious orders." Mr. Collins will be questioned about whether he or representatives from the Jupiter Distribution Center and/or Loss Prevention ever informed pharmacy personnel at Walgreens 03629 that oxycodone orders placed by the pharmacy were reported to DEA as a "suspicious order." Mr. Collins will be further questioned about any and all subsequent communications and/or interactions he had with Walgreens 03629 personnel concerning each order from the pharmacy that was subsequently reported to DEA as suspicious.

**10. Amy Spiels-Hicks, Walgreens District Loss Prevention Manager, District 198  
(Tampa West)**



Following testimony of her background and qualifications as Walgreens District Loss Prevention Manager, District 198 (Tampa West), Amy Spiels-Hicks will be asked to testify regarding any visits she made to Walgreens 03629 to discuss “pain management” issues and the filling of questionable prescriptions for oxycodone and other highly abused controlled substances. Ms. Spiels-Hicks will be asked about the increase in oxycodone ordering and dispensing during her tenure as Loss Prevention Manager for District 198. Specifically, Ms. Spiels-Hicks will be questioned about oxycodone orders placed for Walgreens 03629 with the Jupiter Distribution Center that Walgreens subsequently reported to DEA as “suspicious orders.” Ms. Spiels-Hicks will be questioned about whether she or representatives from the Jupiter distribution facility and/or the District Pharmacy Supervisor ever informed pharmacy personnel at Walgreens 03629 that oxycodone orders placed by the pharmacy were reported to DEA as a “suspicious order.”

#### **11. DEA Diversion Investigator Peter Flagg**

DEA Diversion Investigator Peter Flagg testify regarding his background, education, and training as a DEA Diversion Investigator. Investigator Flagg will testify that, in the course of an investigation into Walgreens Mail Service, Inc., he obtained spreadsheets containing information about Schedule III through V controlled substances filled by Walgreens 03836 utilizing a central-fill pharmacy. Investigator Flagg will testify that he was selected 25 prescriptions at from the spreadsheet pertaining to Walgreens 03836 and sought to obtain those prescriptions from Walgreens 03836, as well as the “CPO Fill Interstore Transfer Claim Form” and a copy of the computer screen printout of the “RX View” for each of the 25 prescriptions.

Investigator Flagg will testify that, on October 29, 2012, he travelled to Walgreens 03836 and presented the spreadsheet with 25 prescriptions highlighted to Pharmacist Smitha Mekala,

and Senior Pharmacy Technician Kate Wilson. He then requested that Dr. Mekala and Ms. Wilson produce the prescriptions that were highlighted on the spreadsheet. Investigator Flagg will testify that, on the following day, Walgreens 03836 Store Manager Michael DeMaro provided Investigator Flagg with the requested documents.

Investigator Flagg will testify that, after reviewing the documents and speaking with Dr. Mekala, Ms. Wilson, and Assistant Store Manager Eric Perkins, he concluded that, of the 25 prescriptions selected: (1) none of them had the words "Central Fill" written on the face of the original prescriptions; (2) at least eleven prescriptions did not include the full address of the patient on the face of prescription; and (3) at least eight prescriptions did not contain the DEA registration number of the practitioner on the face of the prescription.

Investigator Flagg will also testify that, based on his conversations with Ms. Wilson, Dr. Mekala, and Mr. Perkins, that Walgreens 03836 placed no labels or other markings on its prescriptions to designate the prescriptions that were filled at a central fill pharmacy, nor did Walgreens 03836 maintain central filled prescriptions separately from the prescriptions that were filled at the actual retail (Walgreens 03836) store.

#### **12. Fred Casale, Pharmacy Manager (Walgreens #03836)**

In addition to the testimony previously noticed, Mr. Casale will also testify regarding any prescriptions he filled for controlled substances for Walgreens 03836 (as described in the Government's summarized testimony of DEA Diversion Investigators Domingo Gonzales and Dianne Williams disclosed in the previous prehearing statement for Walgreens 03836). Mr. Casale will be asked to explain the justification for filling each of the prescriptions attributed to him. He will be asked to discuss the pharmacy's process and procedures for filling a controlled substance prescription, including identifying any potential "red flags" for diversion. He will be

asked to discuss the procedure(s) for resolving, or attempting to resolve, any red flags for diversion.

As a pharmacy manager for Walgreens 03836, Mr. Casale will be asked to identify whether he approved the dispensing of any of the controlled substances identified in the Government's previously disclosed summarized testimony of Investigators Gonzalez and/or Williams as it relates to Walgreens 03836. To the extent that Mr. Casale approved the dispensing of these controlled substances, he will be asked to identify the specific steps he took to ensure that the prescriptions for controlled substances had been issued for a legitimate medical purpose within the usual course of professional practice.

With respect to prescriptions presented by customers who, in order to obtain the prescription and present it at Walgreens 03836, would have had to travel more than 100 miles roundtrip,<sup>2, 3</sup> Mr. Casale will be asked to identify what measures were taken to ensure that the prescriptions presented by these customers were for a legitimate medical purpose issued in the usual course of professional practice.

To the extent Mr. Casale was involved in the process of ordering controlled substances from a distributor, he will be questioned about orders placed for Walgreens 03836 with the Jupiter Distribution Center that Walgreens subsequently reported to DEA as "suspicious orders." He will be questioned regarding how and when he was informed by Walgreens corporate representatives, including but not limited to pharmacy district supervisors and representatives from the Jupiter Distribution Center and/or Loss Prevention, that the orders he had placed had been reported to DEA as a "suspicious order," as well as any and all subsequent

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<sup>2</sup> "Roundtrip" is defined as the distance travelled from the customer's residence (as listed on either on the prescription or in Walgreens 03836's dispensing logs) to the customer's physician's office, then to Walgreens 03836, and then back to the customer's residence.

<sup>3</sup> Based on the individual customer's home address listed either on the prescription and/or in the Walgreens 03836 dispensing log.

communications and/or interactions he had with the Walgreens corporate representatives concerning each order from Walgreens 03836 that Walgreens reported to DEA as suspicious.

**13. Peter Ventouris, Pharmacy Manager (Walgreens #03836)**

Peter Ventouris will be asked to testify regarding his background, education and training as a pharmacist and pharmacy manager. As a pharmacy manager for Walgreens 03836, Mr. Ventouris will be asked to identify whether he approved the dispensing of any of the controlled substances identified in the Government's previously disclosed summarized testimony of Investigators Gonzalez and/or Williams as it relates to Walgreens 03836. To the extent that Mr. Ventouris approved the dispensing of these controlled substances, he will be asked to identify the specific steps he took to ensure that the prescriptions for controlled substances had been issued for a legitimate medical purpose within the usual course of professional practice.

With respect to prescriptions presented by customers who, in order to obtain the prescription and present it at Walgreens 03836, would have had to travel more than 100 miles round trip, Mr. Ventouris will be asked to explain why Walgreens pharmacists and/or pharmacy technicians under his supervision dispensed controlled substances to these customers and identify what measures were taken to ensure that the prescriptions presented by these customers were for a legitimate medical purpose issued in the usual course of professional practice.

To the extent Mr. Ventouris was involved in the process of ordering controlled substances from a distributor, he will be questioned about orders placed for Walgreens 03836 with the Jupiter Distribution Center that Walgreens subsequently reported to DEA as "suspicious orders." He will be questioned regarding how and when he was informed by Walgreens corporate representatives, including but not limited to pharmacy district supervisors, and representatives

from the Jupiter Distribution Center and/or Loss Prevention, that the orders he had placed had been reported to DEA as a “suspicious order,” as well as any and all subsequent communications and/or interactions he had with the Walgreens corporate representatives concerning each order from Walgreens 03836 that Walgreens reported to DEA as suspicious.

**14. Quang Tran, Pharmacy Supervisor (Walgreens #03836)**

In addition to testimony previously disclosed, Mr. Tran will testify regarding prescriptions for controlled substances he filled at Walgreens 03836 (as described in the Government’s previously disclosed summarized testimony of Investigators Gonzalez and/or Williams as it relates to Walgreens 03836). Mr. Tran will be asked to explain the justification for filling each of the prescriptions attributed to him. He will be asked to discuss the pharmacy’s process and procedures for filling a controlled substance prescription, including identifying any potential “red flags” for diversion. He will be asked to discuss the procedure(s) for resolving, or attempting to resolve, any red flags for diversion.

Mr. Tran will be asked to identify whether he approved the dispensing of any of the controlled substances identified in the Government’s previously disclosed summarized testimony of Investigators Gonzalez and/or Williams as it relates to Walgreens 03836. To the extent that Mr. Tran approved the dispensing of these controlled substances, he will be asked to identify the specific steps he took to ensure that the prescriptions for controlled substances had been issued for a legitimate medical purpose within the usual course of professional practice.

With respect to prescriptions presented by customers who, in order to obtain the prescription and present it at Walgreens 03836, would have had to travel more than 100 miles roundtrip,<sup>4</sup> Mr. Tran will be asked to explain why Walgreens pharmacists and/or pharmacy technicians

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<sup>4</sup> Based on the individual customer’s home address listed either on the prescription and/or in the Walgreens 03836 dispensing log.

dispensed controlled substances to these customers and identify what measures were taken to ensure that the prescriptions presented by these customers were for a legitimate medical purpose issued in the usual course of professional practice.

To the extent Mr. Tran was involved in the process of ordering controlled substances from a distributor, he will be questioned about orders placed for Walgreens 03836 with the Jupiter Distribution Center that Walgreens subsequently reported to DEA as "suspicious orders." He will be questioned regarding how and when he was informed by Walgreens corporate representatives, including but not limited to pharmacy district supervisors and representatives from the Jupiter Distribution Center and/or Loss Prevention, that the orders he had placed had been reported to DEA as a "suspicious order," as well as any and all subsequent communications and/or interactions he had with the Walgreens corporate representatives concerning each order from Walgreens 03836 that Walgreens reported to DEA as suspicious.

#### **15. Tammy Benali**

Ms. Benali will be asked to testify regarding her background, education and training. She will be questioned about her role described in Government Exhibit 348 as "Product Verified User." Ms. Benali will be asked to describe in detail her duties as the "Product Verified User," and what role she played in ensuring that a prescription for a controlled substances was issued for a legitimate medical purpose and within the usual course of professional practice.

Specifically, Ms. Benali will be asked to discuss her role in approving and dispensing prescriptions for fifteen milligram tablets of oxycodone on April 21, 2011, to customers C.J. and L.J., both of whom resided at the same address in Frankfort, Kentucky, and obtained their prescriptions from a physician in Plantation, Florida. Ms. Benali will also be asked to discuss her role in approving the dispensing of thirty-milligram tablets of oxycodone to L.J. on April 23,

2011, as well as the dispensing of alprazolam to A.J., a resident of Pensacola, Florida, on July 8, 2011. She will also be asked to discuss her role in approving the dispensing of fifteen milligram tablets of oxycodone to B.J., a resident of Chillicothe, Ohio, who obtained his prescription from a physician in Doral, Florida (*see* Govt. Ex. 248).

With respect to the above prescriptions, Ms. Benali will be asked to describe what steps she took to ensure that these prescriptions were for issued for a legitimate medical purpose within the usual course of professional practice.

**16. Nancy Levi, RPh.**

Ms. Levi will be asked to testify regarding her background, education, and training. She will be questioned about her role described in Government Exhibit 348 as "Product Verified User." Ms. Levi will be asked to describe in detail her duties as the "Product Verified User," and what role she played in ensuring that a prescription for a controlled substances was issued for a legitimate medical purpose and within the usual course of professional practice.

Specifically, Ms. Levi will be asked to discuss her role in approving and dispensing prescriptions for thirty milligram tablets of oxycodone on April 23, 2011, to customer J.W., a resident of Frankfort, Kentucky, who obtained his prescription from a physician in Plantation, Florida. Ms. Levi will also be asked to discuss her role in approving the following additional prescriptions: (1) thirty-milligram oxycodone tablets to V.J., a resident of Pensacola, Florida, on April 23, 2011; (2) thirty-milligram oxycodone tablets to C.C., a resident of Pensacola, Florida, on May 7, 2011; (3) thirty-milligram tablets of oxycodone to E.C., a resident of Frankfort, Kentucky, on May 7, 2011; (4) thirty-milligram tablets of oxycodone to M.H, a resident of Pensacola, Florida, on May 7, 2011 (*see* Govt. Ex. 248).

With respect to the above prescriptions, Ms. Levi will be asked to describe what steps she took to ensure that these prescriptions for issued for a legitimate medical purpose within the usual course of professional practice.

**17 – 25. Cassie Mulvey  
Tara Kapavicus  
Shane Van Gordon  
Jade Leppi  
Kate Wilson  
Sanjay Patel  
Michael Nunez  
Terrence Myers  
Dale Randall**

To the extent the above individuals have been identified as filling prescriptions and dispensing controlled substances for Walgreens 03836 (as described in the Government's previously disclosed summarized testimony of Investigators Gonzalez and/or Williams as it relates to Walgreens 03836), each of the above individuals will be asked to explain the justification for filling each of the prescriptions attributed to them. They will each be asked to discuss the pharmacy's process and procedures for filling a controlled substance prescription, including identifying any potential "red flags" for diversion. They will each be asked to discuss the procedure(s) for resolving, or attempting to resolve, any red flags for diversion.

With respect to prescriptions presented by customers who, in order to obtain the prescription and present it at Walgreens 03836, would have had to travel more than 100 miles roundtrip, each of the above individuals will be asked to explain why they dispensed controlled substances to these customers and identify what measures were taken to ensure that the prescriptions presented by these customers were for a legitimate medical purpose issued in the usual course of professional practice.



To the extent any of the above individuals were involved in the process of ordering controlled substances from a distributor, he or she will be questioned about orders placed for Walgreens 03836 with the Jupiter Distribution Center that Walgreens subsequently reported to DEA as "suspicious orders." The individual will be questioned regarding how and when he or she was informed by Walgreens corporate representatives, including but not limited to pharmacy district supervisors, and representatives from the Jupiter Distribution Center and/or Loss Prevention, that the orders he or she had placed had been reported to DEA as a "suspicious order," as well as any and all subsequent communications and/or interactions he or she had with the Walgreens corporate representatives concerning each order from Walgreens 03836 that Walgreens reported to DEA as suspicious.

**26. Diversion Investigator Donna Richards**

In addition to the testimony previously noticed in its earlier Prehearing Statements, the Government will introduce through DI Richards three spreadsheets that she created from the Walgreens dispensing log. One of the spreadsheets will detail dispensings by store # 3099 pursuant to prescriptions issued by Dr. Lawrence Giventer. The second spreadsheet will detail dispensing by # 3099 pursuant to prescriptions issued by Dr. Giventer and two other practitioners located at the same address as Dr. Giventer in Bonita Springs, Florida, namely, Drs. Connie Lee and Anthony Posca. The Government also will introduce through DI Richards over 200 hundred prescriptions issued by Dr. Giventer that when filled by #3099 bore a sticker affixed by the pharmacy stating next to Dr. Giventer's street address, "ophthalmologist!!!," as well as prescriptions issued by Drs. Lee and Posca for individuals residing in Spring Hill, Bokeelia, Labelle, and Nokomis, Florida, all of which were filled by store #3099 in Ft. Myers. In addition, the Government will introduce through DI Richards several maps that she created identifying (1)

the number and locations of Walgreens pharmacies between Naples, Florida and Ft. Myers, Florida, (2) distances travelled by #3099 customers who obtained prescriptions from Drs. Giventer, Lee, and Posca in Bonita Springs, Florida, (3) the distance from Drs. Giventer, Lee, and Posca to three Walgreens pharmacies in Bonita Springs, Florida, and (4) several other Walgreens pharmacies located between Bonita Springs and Fort Myers that these customers bypassed to fill their prescriptions at #3099.

The Government also will introduce through DI Richards a third spreadsheet containing dispensing by store #3099 pursuant to prescriptions issued by Dr. Konstantine Yankopolus, who is identified on Walgreens' dispensing log as "OB/GYN." The Government will link this evidence to an email from Keri Kratofil dated October 13, 2011, and sent to the manager of #3099, which states in part, that they will be telling customers that "this is the last month we will be accepting pain prescription from Dr. Yankopolus . . . due to him prescribing outside of his scope of practice." Moreover, the Government will introduce through DI Richards a copy of Dr. Yankopolus prescriptions filled by #3099 subsequent to the above-referenced email and into 2012.

Furthermore, the Government will introduce through DI Richards license verification printouts from the Florida Department of Health website for Dr. Giventer and store # 3099 pharmacists Megan Owens and Trudi-Ann Blackellar.

#### **27. Prof. Paul Doering**

In addition to the testimony previously noticed in its earlier Prehearing Statement, Prof. Doering will testify about the red flags of diversion present in prescriptions issued by Drs. Giventer, Lee, Posca, and Yankopolus, including the nature of Drs. Giventer's and Yankopolus' practices which were identified by #3099 employees, and the distances travelled by individuals

who received prescriptions from Drs. Giventer, Lee, and Posca and filled at # 3099. Prof. Doering will opine that the red flags were not conclusively resolved by #3099 pharmacists before the controlled substances were dispensed.

**28. Megan Owens, pharmacist, store #3099**

In addition to the testimony previously noticed in its earlier Prehearing Statement, Ms. Owens will be questioned about her authority to place orders for controlled substances with the Jupiter distributor facility, any such controlled substances orders she placed, and those orders that Walgreens subsequently reported to DEA as a "suspicious order." Also, she will be questioned regarding how and when she was informed by Walgreens corporate representatives, including but not limited to pharmacy District Supervisors and representatives from the Jupiter distribution facility and Loss Prevention, that the orders she had placed had been reported to DEA as a "suspicious order," as well as any and all subsequent communications and/or interactions she had with the Walgreens corporate representatives concerning each order from store #3099 that Walgreens reported to DEA as suspicious.

**29. Trudi-Ann Blackellar, pharmacist, store #3099**

In addition to the testimony previously noticed in its earlier Prehearing Statement, Ms. Blackellar will be questioned about her authority to place orders for controlled substances with the Jupiter distributor facility, any such controlled substances orders she placed, and those orders that Walgreens subsequently reported to DEA as a "suspicious order." Also, she will be questioned regarding how and when she was informed by Walgreens corporate representatives, including but not limited to pharmacy District Supervisors and representatives from the Jupiter distribution facility and Loss Prevention, that the orders she had placed had been reported to DEA as a "suspicious order," as well as any and all subsequent communications and/or

interactions she had with the Walgreens corporate representatives concerning each order from store #3099 that Walgreens reported to DEA as suspicious.

**30. Marcie Ranick**  
Loss Prevention Department  
Walgreen Co.  
1417 Lake Cook Rd.  
Deerfield, IL 60015

The government supplements its previously noted witnesses with Marcie Ranick. Ms. Ranick is identified in Respondent's Proposed Exhibit 259-B as a Manager, Pharmacy Loss Prevention, at Respondent's corporate headquarters in Deerfield, Illinois. She is also the author of the letters identified in Respondent's Proposed Exhibit 259-E, transmitting a CD of suspicious control drug orders reports to DEA's Miami Field Division in Weston, Florida, from January 2010 through January 2012. Ms. Ranick will be asked to explain how these reports were created and distributed, what guidance she relied on for creating them, and what follow-up Respondent took in response to the orders it labeled as suspicious. She will be asked to explain her understanding of Respondent's suspicious order policies and the basis for any changes made to those policies from 2010 to the present.

#### **PROPOSED DOCUMENTS**

Filed separately with the Court is the Government's comprehensive Exhibit List that includes each of the exhibits the Government intends to introduce during its case-in-chief for all the consolidated matters. In the Record copy of exhibits to be produced to the Court, the Government will substitute unredacted exhibits 60 and 79 for the previously redacted copies provided to the Court during the pendency of the disputed privilege issue.

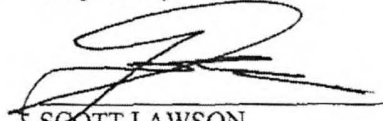
#### **OTHER MATTERS**

1. The Government has secured locations for witnesses to testify via video-conference (VTC). The VTC locations have been provided on the consolidated Witness List filed separately with the Court.

**BEST ESTIMATE AS TO TIME REQUIRED TO PRESENT CONSOLIDATED CASES**

The Government anticipates that it will need approximately ten (10) days to present its case-in-chief for all of the consolidated matters, exclusive of cross examination and rebuttal.

Respectfully submitted,



SCOTT LAWSON  
JONATHAN P. NOVAK  
Attorneys  
Diversion & Regulatory Litigation  
Office of Chief Counsel

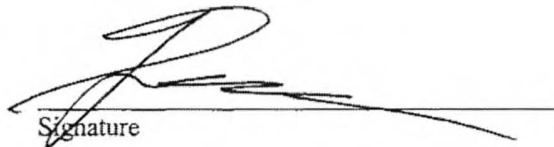
Date: April 5, 2013

**CERTIFICATE OF SERVICE**

I hereby certify that on the date signed below, I caused the original and seven copies of the foregoing **GOVERNMENT'S CONSOLIDATED SUPPLEMENTAL PRHEARING STATEMENT**, to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* to counsel for Respondent at the following addresses:

Phil Perry  
Allen M. Gardner  
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5 Apr 2013  
Date

  
Signature

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UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

In the Matter of	
<b>Walgreen Co. ; (Jupiter Distribution Facility)</b>	<b>Docket No. 13-1</b>
<b>Walgreen Co. d/b/a Walgreens #03629; (Hudson Pharmacy)</b>	<b>Docket No. 13-9</b>
<b>Walgreen Co. d/b/a Walgreens #04727; (Fort Pierce Pharmacy)</b>	<b>Docket No. 13-10</b>
<b>Walgreen Co. d/b/a Walgreens #06997; (Oviedo Pharmacy)</b>	<b>Docket No. 13-11</b>
<b>Walgreen Co. d/b/a Walgreens #03836; (Port Richey Pharmacy)</b>	<b>Docket No. 13-16</b>
<b>Walgreen Co. d/b/a Walgreens #04391; (Fort Pierce 2 Pharmacy)</b>	<b>Docket No. 13-18</b>
<b>Walgreen Co. d/b/a Walgreens #03099; (Fort Meyers Pharmacy)</b>	<b>Docket No. 13-20</b>
	<b>CHIEF ADMINISTRATIVE LAW JUDGE JOHN J. MULROONEY, II</b>

**GOVERNMENT'S CONSOLIDATED PROPOSED EXHIBITS LIST**



Pursuant to the March 26, 2013, Second Amended Supplemental Prehearing Ruling, the United States Department of Justice, Drug Enforcement Administration (DEA or Government), hereby submits its Consolidated Proposed Exhibit List.

### I. PROPOSED EXHIBITS

<b>Exhibit</b>	<b>Description</b>	<b># Pages</b>
1.	DEA Certificate of Registration RW0277752	1
2.	September 27, 2006 Guidance Letter From DEA Deputy Assistant Administrator Joseph T. Rannazzisi to Walgreen Co.	8
3.	December 27, 2007 Guidance Letter From DEA Deputy Assistant Administrator Joseph T. Rannazzisi to Walgreen Co.	4
4.	April 2011 Memorandum of Agreement Between Walgreen Co. and DEA	7
5.	July 1, 2011 Florida State Department of Health Declaration of Public Health Emergency Regarding Prescription Drug Abuse Epidemic	5
6.	October 17, 2008 Healthcare Distribution Management Association Guidance with Attached Letter for DEA Chief Counsel Wendy Goggin	17
7.	February 15, 2005 Walgreens Policy: "Handling Suspicious Drug Orders"	2
8.	Notes on Walgreens Proposed Suspicious Order Policy	2
9.	April 4, 2012 Walgreens Policy: "Handling Suspicious Orders and Loss of Controlled Drugs"	1
10.	April 4, 2012 Walgreens Policy: "Handling Suspicious Drug Orders"	1
11.	Walgreens "Controlled Substance Threshold" Project P09002, February 2009	18
12.	December 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	1626
13.	December 2011 Walgreens Jupiter Distribution Center C3-5 Suspicious Order Report	384
14.	Excerpt of December 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	25

Exhibit	Description	# Pages
15.	Excerpt of August 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
16.	Excerpt of July 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
17.	Excerpt of June 2011 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	46
18.	Excerpt of December 2010 Walgreens Jupiter Distribution Center C2 Suspicious Order Report	36
19.	Excerpt of Suspicious Orders for Walgreens #3099	14
20.	Excerpt of Suspicious Orders for Walgreens #3629	64
21.	Excerpt of Suspicious Orders for Walgreens #3836	49
22.	Excerpt of Suspicious Orders for Walgreens #4391	34
23.	Excerpt of Suspicious Orders for Walgreens #4727	19
24.	Excerpt of Suspicious Orders for Walgreens #6997	15
25.	Walgreens Ft. Pierce Comparison of ARCOS Data and Chart	1
26.	Walgreens Oviedo Comparison of ARCOS Data and Chart	1
27.	Walgreens Port Richey and Hudson Comparison of ARCOS Data and Chart	1
28.	Walgreens Ft. Myers Comparison of ARCOS Data and Chart	1
29.	Top 100 Walgreens Purchasers of Oxycodone from Jupiter Distribution Center	3
30.	Yearly Sales of Oxycodone to Select Walgreens Pharmacies from All Sources, 2009-2011	1
31.	Orders for 30mg Oxycodone (100 count bottles) in 2012 Exceeding Walgreens 2012 "Trigger Amount" for Reporting Suspicious Transactions, with Attached DEA Forms 222	23
32.	Walgreens Ft. Pierce (#4391) ARCOS Reporting Discrepancies	28
33.	Walgreens Ft. Pierce (#4727) ARCOS Reporting Discrepancies	21
34.	Walgreens Ft. Meyers (#3099) ARCOS Reporting Discrepancies	25
35.	Walgreens Hudson (#3629) ARCOS Reporting Discrepancies	41
36.	Walgreens Oviedo (#6997) ARCOS Reporting Discrepancies	22
37.	Walgreens Port Richey (#3836) ARCOS Reporting Discrepancies	30
38.	Suspicious Order Report Discrepancies	39
39.	DEA Guidance "A Pharmacist's Guide to Prescription Fraud"	2
40.	September 27, 2010 Ft. Pierce Police Incident Report for Richard Frederick Hanson	5

Exhibit	Description	# Pages
41.	Copies of Prescriptions Filled for Richard Frederick Hanson by Walgreens #4727	10
42.	November 4, 2011 Ft. Pierce Police Incident Report from Walgreens #4727	6
43.	Copies of Prescriptions Filled for Carlo Pastor by Walgreens #4727	18
44.	December 24, 2010 Police Incident Report Regarding James McCune and Accompanying Prescriptions	18
45.	Dispensing Log of Prescriptions Filled by Walgreens #3629 for James McCune	1
46.	Letters sent from Oviedo Police Department to Walgreens	16
47.	Will Not Be Used	
48.	Will Not Be Used	
49.	Will Not Be Used	
50.	Will Not Be Used	
51.	March 19, 2012 Administrative Subpoena for Walgreens Due Diligence Files	2
52.	May 4, 2012 Letters from Walgreens Legal Counsel to DPM Susan Langston Outlining Walgreens' Response to DEA Due Diligence Subpoena	6
53.	June 8, 2012 Letter from Walgreens Legal Counsel concerning final production of documents in response to subpoena	3
54.	Email: FW: The Two Minute Oxy-Refusal [WAG00000368]	2
55.	Email: re_oxycodone 30 mg [WAG00000460]	2
56.	Email: Re_Please advise on Pain Manag [WAG00000462]	2
57.	Email: Standards of Practice for the Disp [WAG00000464]	2
58.	Email: Re_Handling Pain Management RX [WAG00000660]	2
59.	Email: 0969_001a [WAG00000742]	22
60.	Email: Fw_DEA issue at 6094 with attachment [WAG00000813]****	8
61.	Email: _ Oxycodone sales with attachment [WAG00000829]	12
62.	Email: District Notes and Focus Points [WAG00000845]	1
63.	Email: Margate FL Schedule II limitations (Svihra) [WAG00000846]	4
64.	Email: Re: High Quantity Stores 682971 [WAG00000869]	11
65.	Email: Ft Pierce.msg 2 [WAG00000889]	13

Exhibit	Description	# Pages
66.	Email: Rx Numbers – Oviedo FL (Svihra) [WAG00000902]	2
67.	Email: Oviedo FL (Stahmann) [WAG00000904]	3
68.	Email: Re Fw 682971 - OXYCODONE HCL 30MG TAB [WAG0000908]	11
69.	Email: Fw_3099 Oxycodone Issue [WAG00000919]	2
70.	Email: Re Store #3836 [WAG00000921]	4
71.	Email: Re Fw INC000002834005 Store #3836 WIC#682971 order qty 148 [WAG00000925]	4
72.	Email: 1412 - CII Dispensing Action Plan [WAG00000929]	1
73.	Email: 3525 - CII Dispensing Action Plan [WAG00000930]	1
74.	Email: Fw_STORES with many adjustments [WAG00000948]	2
75.	Email: STORE 3099 – RxS Due Diligence [WAG00001042]	3
76.	Email: Re Store #06997 [WAG00001057]	2
77.	Email: Re Fw Oxycotin question [WAG00001064]	8
78.	Email: Re Fw CII Order [WAG00001087]	17
79.	Email: Florida Focus on Profit (Svihra) [WAG00001107] ****	7
80.	Email: Store 4706 [WAG00001125]	7
81.	Email: Dist #227 Oxycodone Memo August 2011 [WAG00001212]	2
82.	Email: Store 3099 [WAG00001256]	1
83.	Email: Re_3099 [WAG00001260]	2
84.	Email: 1009_001 [WAG00001326]	40
85.	Email: REQUEST REVIEW Florida Pain Management Visits (Merten) [WAG00001638]	1
86.	Email: Actions Taken in District 21 about CII Dispensing WAG0001740	2
87.	Email: New Florida Prescribing Law	3
88.	Email: Focus on Compliance Survey	6
89.	Focus on Compliance Survey Results – Excel Spreadsheet	48
90.	List of items produced in response to Administrative Subpoena	13
91.	Facsimile of DEA Certificate of Registration BW4713992	1
92.	Certified registration history for Walgreens #03629	2
93.	Certified registration histories – Drs. Abaunza, Reppy, Wayne, Legowick, Wolff, McNichol and Glusman	11
94.	ARCOS Report of Walgreens #03629's Oxycodone Purchases,	3

Exhibit	Description	# Pages
	2006-2012	
95.	Not Used	
96.	Prescription Printout Chart: Ramiro Abaunza, M.D.	31
97.	Prescription Printout Chart: Paul J. Glusman, D.O.	4
98.	Prescription Printout Chart: John T. Legowick, M.D.	1
99.	Prescription Printout Chart: TJ McNichol, M.D.	13
100.	Prescription Printout Chart: Christopher Wayne, M.D.	2
101.	Prescription Printout Chart: Randall Wolff, M.D.	2
102.	Will Not Be Used	
103.	Prescriptions filled for James McCune	14
104.	Will Not Be Used	
105.	Copy of prescription issued by Dr. Reppy on November 2, 2011 and filled by Walgreens #03629	1
106.	Copy of prescription issued by Dr. Pritchard on November 3, 2011	1
107.	Copy of dispensing label dated November 3, 2011 for 60 dosage units of oxycodone (listing Dr. Reppy as prescribing physician)	1
108.	Dispensing log of Walgreens #03629's central filled prescriptions and copies of selected centrally filled prescriptions	59
109.	Selected prescriptions from Walgreens #03629	52
110.	DEA Certificate of Registration BW6561270	1
111.	Walgreens Attendee List, DEA Meeting on August 19, 2011	2
112.	Chart of Walgreens #04727's Oxycodone Sales & Ranking in 2010 and 2011 provided to Walgreens officials at August 19, 2011 DEA meeting	3
113.	ARCOS Report of Walgreens #04727's Oxycodone Purchases, 2006-2012	8
114.	Copy of the Administrative Inspection Warrant dated April 3, 2012	2
115.	DEA Receipt for Cash and Other Items dated April 4, 2012 identifying receipt of 4 boxes of Schedule II prescriptions	1
116.	Not Used	
117.	Not Used	
118.	Not Used	
119.	Florida Department of Health, Physician Profiles for physicians Alexandra Taylor M.D., Kenneth Pearlberg, M.D., and Ralph Miniet, M.D.	3

Exhibit	Description	# Pages
120.	Summary Chart of Dr. Pearlberg's prescriptions	55
121.	Summary Chart of Dr. Miniet's prescriptions	58
122.	Summary Chart of Dr. Taylor's prescriptions	52
123.	Dispensing Log Summary: Dr. Schultz	6
124.	Florida Department of Health Emergency Suspension Order, Barry Schultz M.D., April 13, 2011	65
125.	Copies of Prescriptions <sup>1</sup> re: Candy Drs., etc.	22
126.	Copies of Prescriptions issued by Barry Schultz M.D.	4
127.	Prescription copies for B.A., J.B., E.C., N.C., M.H., and R.O. dispensed on May 4, 2011	28
128.	Prescription copies for B.A., J.B., E.C., N.C., and R.O. dispensed on June 1, 2011	20
129.	Prescription copies for B.A., E.C., N.C., and J.B., dispensed on June 28, 2011	16
130.	Prescription copies for B.A., E.C., N.C., M.H., and R.O. dispensed on July 26, 2011	20
131.	Prescription copies for B.A., J.B., M.H., E.C. and N.C. dispensed on September 21, 2011	14
132.	Prescription copies for S.A., C.A., C.B., J.P, and R.B dispensed on August 10, 2011	20
133.	Prescription copies for S.A., C.A., C.B. J.P., S.M., and M.L. , dispensed on October 4, 2011	22
134.	St. Lucie County Sherriff Ken Mascara Letter to Respondent, dated October 28, 2011	1
135.	Administrative Subpoena issued July 27, 2012	6
136.	Central Fill CII Dispensing Log	196
137.	Notice of Inspection, October 30, 2012	1
138.	Central Fill: 20 Prescription Copies, RX View, CPO Interstore Transfer Claims	60
139.	Will Not Be Used	
140.	Will Not Be Used	
141.	Will Not Be Used	
142.	Will Not Be Used	
143.	Email from Ed Lanzetti dated May 19, 2011 re: "Focus on Profit	3

<sup>1</sup> All copies of prescriptions identified as Exhibits include copies of the prescription label affixed to the back of the prescription by Respondent on date of dispensing.

Exhibit	Description	# Pages
	for Florida Market" with Attachment	
144.	Will Not Be Used	
145.	Will Not Be Used	
146.	Will Not Be Used	
147.	Will Not Be Used	
148.	Chart of High Volume Prescribers	2
149.	Summary Chart: Average Daily Dispensing of Controlled Substances, Six Month Increments (January 2010 – April 4, 2012)	1
150.	Summary Charts of Dr. Miniet's Filled Prescriptions on August 10, 2011 and October 4, 2011	6
151.	Summary Charts Dispensing to 1205 Seaway Dr. Customers on May 4, June 1, June 28, July 26 and Sept 21, 2011	4
152.	Summary Chart of Dispensing by P.A.'s Michael Carpino and Peter Vo	3
153.	Florida Department of Health Licensure Verification, Michael Carpino and Peter Vo	8
154.	DEA Certificate of Registration BW8487438	1
155.	Will Not Be Used	
156.	Administrative Inspection Warrant for Walgreens #06997	3
157.	Certification of Registration History for DEA Certificate of Registration BW7987184	2
158.	Certification of Registration History for DEA Certificate of Registration BL6686541	2
159.	Not Used	
160.	Excerpts of Dispensing Log: Wicks	8
161.	Excerpts of Dispensing Log: Cocktail	20
162.	Excerpts of Dispensing Log: Distances Traveled	12
163.	Excerpts of Dispensing Log: Customers Coming From the Same Address	10
164.	Copies of prescriptions sent from Walgreens #06997 to the Walgreens Central Fill facility	135
165.	Will Not Be Used	
166.	Chudnow Desktop Notes	2
167.	Brekke Dispensing Logs and Prescriptions	29
168.	Starling Dispensing Logs and Prescriptions	16
169.	Oviedo Police Department Surveillance Statistics	2

Exhibit	Description	# Pages
170.	Oviedo Police Department Arrest Statistics	1
171.	Curriculum Vitae of Mary E. Chmielewski, Ph.D.	5
172.	Comparison of Total Dosages of Oxycodone by Year: Walgreens #03629	2
173.	Comparison of Total Dosages of Oxycodone by Year: Walgreens #04727	2
174.	Comparison of Total Dosages of Oxycodone by Year: Walgreens #06997	2
175.	Curriculum Vitae of Professor Paul Doering	31
176.	RX Printout Excerpt - Reppy	60
177.	McCune Forged RX	1
178.	Pasco County Continuation Sheet and Attached Affidavit	8
179.	Spreadsheet for RX Under DEA # BH7849928	2
180.	RX# 1905003	2
181.	RX# 1905005	2
182.	RX# 1904633	2
183.	RX# 1904644	2
184.	Dr. M. Romano RX# 1791873	2
185.	Dr. M. Romano RX# 1769890	2
186.	06997 Cocktail Prescriptions	46
187.	06997 Long Distances Prescriptions	29
188.	06997 Wicks and Lynch Prescriptions	17
189.	Dispensing History: Glusman – Cocktail Drugs	2
190.	Dispensing History: Abaunza	16
191.	Dispensing History: Bender	36
192.	Dispensing History: Heromin	13
193.	Dispensing History: McNichol	14
194.	Dispensing History: Strobee	20
195.	Dispensing History: Wayne	2
196.	Dispensing History: Wolff	1
197.	Dispensing History: Reppy	47
198.	Distance-Travel Time Chart	1
199.	Heromin RX# 1841312-03629 to RX# 1860313-03629	14
200.	Norris RXs	6



Exhibit	Description	# Pages
201.	Reppy: Internet MD RX# 1859227-03629	2
202.	Reppy: Pill Mill RX# 1857824-03629 to RX# 1857810-03629	10
203.	Romano Certification	2
204.	RX Printout excerpt – Bender	82
205.	RX Printout excerpt – Heromin	20
206.	RX Printout excerpt – Strobe	102
207.	Andrea Cohen Department of Health License Verification	1
208.	Copy of DEA Registration AD9312353	1
209.	Copy of DEA Registration AF1972086	1
210.	Dispensing Log Excerpt, Ex 125 Rx	3
211.	Vo and Carpino oxycodone prescriptions	4
212.	DEA Certificate of Registration BW5872494	1
213.	ARCOS Report of Walgreens 04391 Oxycodone purchases, 2006-2012	5
214.	Not Used	
215.	Prescriptions with Label Commentary	33
216.	Summary Spreadsheet of Dispensing, Customer A.R	6
217.	Prescriptions for Customer A.R.	20
218.	Prescription and attached PDPM report for Customer A.R. dated March 22, 2012	3
219.	Summary Spreadsheet of Dispensing, Customer E.O.	3
220.	Customer E.O. Travel Distance Map	3
221.	Prescriptions for Customer E.O.	12
222.	Summary Spreadsheet of Dispensing, Customer A.W.	6
223.	Customer A.W. Travel Distance Map	5
224.	Prescriptions for Customer, A.W.	3
225.	Summary Spreadsheet of Dispensing, Dr. Dustin Lee	3
226.	Summary Spreadsheet of Dispensing, Dr. Armando Falcon	9
227.	Summary Spreadsheet of Dispensing, Dr. Ronald Thompson	24
228.	Prescriptions Issued by Dr. Thompson, filled December 2011 and January 2012	31
229.	Summary Spreadsheet of Dispensing, Dr. Ralph Miniuet	93
230.	Summary Spreadsheet of Dispensing, October 14, 2011, Dr.	2

Exhibit	Description	# Pages
	Miniet	
231.	Prescriptions filled on October 14, 2011, Dr. Miniet	13
232.	Customer L.S. Travel Distance Map	3
233.	Central Fill Dispensing Log for Walgreens 04391	312
234.	Notice of Inspection, October 30, 2012	1
235.	Central Fill Prescriptions, RX View and CPO Interstore Transfer Claims	126
236.	Florida Department of Health, Pharmacist License Verification, Lloyd Wright	1
237.	Florida Department of Health, Pharmacist License Verification, Gladys Murrow	1
238.	Not Used	
239.	Walgreens pharmacies located in Port St. Lucie, Florida	3
240.	Copy of Walgreens #03099's DEA Certificate of Registration	1
241.	Administrative Inspection Warrant for Walgreens #03099 dated April 3, 2012	2
242.	Excerpts of Dispensing Log and Prescriptions for J.V.L. and L.V.L. dispensed by Walgreens #03099 pharmacists	49
243.	Excerpts of Dispensing Log and Prescriptions for G.G., R.T. and T.T. dispensed by Walgreens #03099 pharmacists	32
244.	Excerpts of Dispensing Log and Prescriptions for C.A. dispensed by Walgreens #03099 pharmacists	30
245.	Excerpts of Dispensing Log and Prescriptions for M.S. dispensed by Walgreens #03099 pharmacists	22
246.	Excerpts of Dispensing Log and Prescriptions for K.W. dispensed by Walgreens #03099 pharmacists	9
247.	Excerpts of Dispensing Log and Prescriptions for Y.H., V.H. and D.H. dispensed by Walgreens #03099 pharmacists	49
248.	Excerpts of Dispensing Log and Prescriptions for P.C. and M.C. dispensed by Walgreens #03099 pharmacists	34
249.	Excerpts of Dispensing Log and Prescriptions for T.T. and T.T. dispensed by Walgreens #03099 pharmacists	43
250.	Excerpts of Dispensing Log and Prescriptions for C.A., H.A. and T.W. dispensed by Walgreens #03099 pharmacists	54
251.	Excerpts of Dispensing Log for Prescriptions issued by Emiliya Hill, M.D., and dispensed by Walgreens #03099 pharmacists	102
252.	Bryon Wheeldon email chain dated 03/28/2011 re: "Fw: STORE	4

Exhibit	Description	# Pages
	3099" [WAGS00001034-37]	
253.	"Store Manager 03099" email to Keri Kratofil dated 10/13/2011 [WAG00000467]	1
254.	Emails from Matt McLaughlin dated 11/18/2011 and 11/21/2011 [WAG00000414-16]	3
255.	Notice of Inspection for Walgreens #03099 dated October 30, 2012	1
256.	Copies of documentation and prescriptions with central fill and other violations from DEA's October 30, 2012, inspection of Walgreens #03099	241
257.	Police Report from 9/27/10 regarding trespass warning to Walgreens customer M.L. and Excerpts of Dispensing Log and Prescriptions for M.L. dispensed by Walgreens #03099 pharmacists	15
258.	Police Report from 9/28/10 regarding drug deal by Walgreens customer C.M. and Excerpts of Dispensing Log and Prescriptions for C.M. dispensed by Walgreens #03099 pharmacists	9
259.	DEA Certificate of Registration AW8830247	1
260.	Prescriptions issued by Ramiro Abaunza, M.D. (A-G)	150
261.	Prescriptions issued by Ramiro Abaunza, M.D. (H-M)	137
262.	Prescriptions issued by Ramiro Abaunza, M.D. (N-W)	138
263.	03836 Database printout showing prescription history of: J.C., M.S., J.M., H.R., H.N., V.J., A.B., J.M.-1, J.B., M.J., A.J., A.F., D.D., D.S, M.B., C.B., Z.S., C.J., C.C., S.C, J.E., J.M.-2, C.T., R.C., C.G., H.P., T.M., A.F., A.J., L.J., C.S., and P.J. This includes (1) history for C.C. and S.C. on May 7, 2011 and (2) history for L.J. and P.J. on June 21, 2011.b	2
264.	Map and mileage information re: Pensacola to Miami to Port Richey to Pensacola	3
265.	Map and mileage information re: Pensacola address of C.C. and S.C. to Miami to Port Richey to Pensacola address of C.C. and S.C.	3
266.	Map and mileage information re: Pensacola address of L.J. and P.J. to Miami to Port Richey to Pensacola address of L.J. and P.J.	3
267.	03836 Database printout showing prescription history for J.A. and R.E. on April 29, 2011, and May 27, 2011	1
268.	Map and mileage information re: Frankfort, Kentucky to Miami to Port Richey to Frankfort, Kentucky	4

Exhibit	Description	# Pages
269.	03836 Database printout showing prescription history for (1) S.M. on April 9, 2011, and May 13, 2011; (2) J.M. on April 12, 2011; (3) F.M. and A.R. on April 20, 2011; (4) Z.F. on April 23, 2011; (5) T.H. on April 30, 2011; (6) M.M. on May 2, 2011; (7) J.G. on April 12, 2011, and May 9, 2011; (8) B.S. on May 3, 2011, and May 26, 2011; (9) K.I. and M.L. on April 13, 2011, and May 11, 2011; (10) M.G. on May 4, 2011; (11) C.H. on May 9, 2011; (12) M.K. on May 26, 2011; (13) M.L.-I. and C.P. on April 15-16, 2011; (14) G.R. on April 23, 2011; (15) J.M.-1 on April 25, 2011; (15) L.S. and J.S. on April 30, 2011, and May 4, 2011; (16) R.D. on May 4, 2011;	1
270.	Map and mileage information re: Decatur, Tennessee to Miami to Port Richey to Decatur, Tennessee (SM, JM, FM, AR, ZF, TH, MM)	3
271.	Map and mileage information re: Riceville, Tennessee to Miami to Port Richey to Riceville, Tennessee (JG, BS)	3
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Respectfully submitted,



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Dated: April 5, 2013

**CERTIFICATE OF SERVICE**

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **GOVERNMENT'S CONSOLIDATED PROPOSED EXHIBITS LIST** to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* and first class mail to counsel for Respondent at the following addresses:

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