## Message

From: pharmacyservices@walgreens.com [pharmacyservices@walgreens.com]

**Sent**: 2/19/2013 2:02:11 PM

To: Polster, Tasha [tasha.polster@walgreens.com]

**Subject**: Attached Image **Attachments**: 2582\_001.pdf

PLAINTIFFS TRIAL EXHIBIT
P-19651\_00001

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# 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:

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## III. TERMS AND CONDITIONS

- 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.
- 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.
- 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.
- Walgreens shall implement a system to notify the local DEA office within two business this is in days of a refusal to fill a prescription for controlled substances where such refusal is additionally used based on the Walgreens pharmacist's determination that the prescription was forged, have feel supervisor altered, and/or issued for other than a legitimate medical purpose by a practitioner acting fellowing 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

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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 This is 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 retarkon the accuracy of the electronic records Net

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.

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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 determines that a prescription may be retified early must do so consistent with rederal a 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.

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period described herein.

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.

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

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

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- 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. <u>Binding on Successors</u>. This Agreement shall inure to the benefit of and is binding on Walgreens, and its respective successors, heirs, transferees and assigns.
- 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.

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- 13. <u>Breach of Agreement</u>. 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. <u>Effect of Breach</u>. A material breach shall render the Agreement voidable; however, such breach may be waived by the Parties.
- 15. <u>Disclosure</u>. 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. <u>Authorizations</u>. 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.

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Depyty Assistant Administrator

Office of Diversion Control

Dated:

WENDY H. GOGGIN Chief Counsel

WALGREEN CO.

Divisional Vice President, Pharmacy Services

Walgreen Co.

Dated: 3/18/2011

Hyman, Phelp & NcNamara, PC Attorney for Walgreen Co.

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