

L. MITCHELL JONES (U.S.B. 5979)
Assistant Attorney General
JOHN E. SWALLOW (U.S.B. 5802)
Attorney General
Commercial Enforcement Division
Heber M. Wells Building
Box 146741
Salt Lake City, UT 84114-6741
TEL: (801) 366-0310

**BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING
OF THE DEPARTMENT OF COMMERCE
OF THE STATE OF UTAH**

IN THE MATTER OF THE LICENSES OF ROY WINEGAR'S PHARMACY TO OPERATE AS A PHARMACY AND TO DISPENSE CONTROLLED SUBSTANCES IN THE STATE OF UTAH))))))	STIPULATION AND ORDER CASE NO. DOPL 2013- 425
--	----------------------------	---

ROY WINEGAR'S PHARMACY ("Respondent") and the **DIVISION OF
OCCUPATIONAL AND PROFESSIONAL LICENSING** of the Department of Commerce of
the State of Utah ("Division") stipulate and agree as follows:

1. Respondent admits the jurisdiction of the Division over Respondent and over the subject matter of this action. Lloyd J. Thomas is the president and pharmacist-in-charge of Respondent pharmacy. Lloyd J. Thomas is an agent for, and is authorized to enter into binding agreements on behalf of Respondent pharmacy.

2. Respondent acknowledges that Respondent enters into this Stipulation knowingly and voluntarily.

3. Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that Respondent is entitled to a hearing before the State of Utah's Board of Pharmacy ("Board"), or other Division Presiding Officer, at which time Respondent may present evidence on Respondent's own behalf, call witnesses, and confront adverse witnesses. Respondent understands that by signing this document Respondent hereby waives the right to a hearing, the right to present evidence on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent hereby waives all administrative and judicial review as set forth in Utah Code Ann. §§ 63G-4-301 through 63G-4-405, and Utah Administrative Code R151-46b-12 through R151-46b-15. Respondent and the Division hereby express their intent that this matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent waives the right to the issuance of a Petition and a Notice of Agency Action in this matter.

6. Respondent understands that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document. The Division may release this Stipulation and Order, and will release other information about this disciplinary action against Respondent's license, to other persons and entities.

7. Respondent admits the following facts are true:
- A. Respondent was first licensed to operate as a pharmacy and to dispense controlled substances in the State of Utah on or about October 24, 1996.
 - B. On or about July 17, 2013 a random inspection was performed by Division investigators at Respondent pharmacy and the following violations were found:
 - a. The Division had not been notified of a designated e-mail address for self- audits or alerts for the pharmacy;
 - b. Three pharmacy technicians were not wearing name tags when inspectors presented at the pharmacy;
 - c. The pharmacy did not have current and retrievable editions of required pharmacy literature, including any state laws or rules. The Code of Federal Regulations available to staff was the outdated 2004 edition;
 - d. The pharmacy was not clean. There was rust above the sink area where medications were stored, dusty bays, stained carpet, and a lack of space for the amount of drugs and personnel present;
 - e. The sink did not have hot water during the inspection and was full of dirty dishes;
 - f. The pharmacy is located within a grocery store and has different hours from the rest of the store. Security concerns existed regarding the amount of glass around the counter. The pharmacy does not have metal gates or other barriers that slide in front of the glass after hours when the pharmacy is closed;
 - g. One of the pharmacy technicians knows the alarm code and routinely enters the pharmacy in mornings without a pharmacist present;
 - h. The pharmacy does not have temperature logs for the room temperature of the pharmacy. The refrigerator temperature logs were inconsistently recorded;
 - i. Investigators found expired food sitting on top of prescription medications in the refrigerator. The pharmacy did not have a separate refrigerator for food storage, so food was intermingled with drugs;

- j. Offers to counsel customers were not documented. The pharmacy has a place for patients to check off accepted or declined on the signature pick up label, but none of the records inspected had this information recorded;
- k. Inspectors found the following problems when reviewing controlled substance prescription records:
 - i. Required information was missing from the prescription records including DEA numbers, patient date of birth, and patient address;
 - ii. Prescriptions were not manually signed, but had digital images of signatures;
 - iii. The pharmacy processed and dispensed Tramadol with an e-prescription after it had become a controlled substance in the State of Utah, did not meet the requirements of the Code of Federal Regulations, and did not have certification authority.
- l. The pharmacy had misbranded drugs sitting on the inventory shelves. Some drugs were in amber containers with no labeling at all and others had handwritten markings, but no expiration dates;
- m. Prescription files for the past five years were not immediately retrievable in written or electronic format. The pharmacy only stores hard copies on site back until 2012. The current computer system could only access records electronically back to 2009. The pharmacy has a computer with the older profile records, but it was unhooked on the pharmacy floor;
- n. The following concerns were found with the pharmacy's annual controlled substance inventory:
 - i. The annual inventories were not performed with the specified time frame of four days from the initial inventory date each year;
 - ii. The 2008 inventory was performed on June 14, 2008 for the CII's and the CIII-V inventory was not done until June 24, 2008. There was no signature of the person taking the inventory or the PIC recorded;
 - iii. The 2009 inventory was performed on July 12, 2009. The pharmacy only did a CII inventory. There was no inventory for CIII-Vs and there were no signatures on the inventories performed;

- iv. The 2010 inventory was performed on November 27, 2010. The pharmacy only did a CII inventory. There was no inventory for the CIII-Vs and there were no signatures on the inventories performed;
 - v. The 2011 inventories were performed on September 19, 2011;
 - vi. The 2012 inventory was performed on July 1, 2012. The CIII-V inventory was not hand counted or verified. It was just a printout of what the computer said was on hand;
 - vii. The pharmacy had not done a 2013 inventory at the time of the inspection nor did they perform a Tramadol inventory in May when Tramadol became a controlled substance in the State of Utah;
 - viii. The pharmacy did not reconcile inventories to account for shortages of theft or loss.
- o. Power of attorney forms authorizing pharmacists to sign DEA 222 order forms were not available for inspection.
 - p. On multiple occasions the pharmacy failed to submit positive identification of persons receiving controlled substances to the Utah Controlled Substance database.
 - q. The pharmacy has engaged in compounding practices that are not compliant with USP 795 or 797, including:
 - i. Garbing material was not present at the pharmacy for the inspection. A staff pharmacist stated he stores it at his home;
 - ii. There were no training records available for the staff engaged in compounding;
 - iii. The pharmacy did not have the required library reference materials for compounding on site and available to staff.
 - iv. The pharmacy had patient specific compounds on their inventory shelves with beyond use dates back to 2011.

- v. The pharmacy had a large amount of outdated compounding ingredients with no expiration dates at all, or as far as back as 1996, on the inventory shelves;
- vi. The pharmacy did not have master worksheets, prep worksheets, lot numbers, or end product evaluation with actual yield to anticipated yields documented. There was no documentation of personnel involved in the compounding process;
- vii. The pharmacy had no standard operating procedures, training manual, quality assurance program, or Material Safety Data Sheet files;
- viii. There was no documentation for how the pharmacy determines beyond use dating. The label generated by the pharmacy defaults to a one year beyond use date.
- ix. The pharmacy had a scale that has to be moved any time it is used and no calibration records.
- x. The pharmacy had an amber bottle on its shelf marked with hand drawn on Sharpie lines indicating graduated ounces with no calibration.
- xi. The pharmacy had an empty amber bottle on its shelf with a post-it note taped to the outside with a formula for "Standford's Solution" that had mold growing in the bottom.
- xii. Inspectors found that a staff pharmacist had prepared compounded products at his home, which is not licensed as a pharmacy, and brought the end product to the pharmacy for sale and distribution. Additionally:
 - 1. The staff pharmacist admitted to preparing a transdermal hormone prescription for a family member at his home on at least two occasions.
 - 2. The staff pharmacist prepared a sterile ophthalmic solution in April 2013 at his home where there is no clean room or hood. The staff pharmacist said he microwaved the solution to boiling two times to ensure sterility. The beyond use date printed on the label dispensed to the patient had a one year date, well beyond USP 797

standards of immediate use requirements, since the compound was made outside of a hood. At room temperature, the compound would need to be administered within one hour of it being compounded.

- xiii. Prescription labels did not bear the minimum requirements of a lot number, storage instructions, or language indicating “this is a compounded preparation.”
- xiv. There was no purified water for hand and equipment washing available in the pharmacy.
- r. The Division investigated a staff pharmacist employed at the pharmacy for prescription fraud and the unlicensed practice of medicine. The staff pharmacist admitted to self medicating and altering or issuing prescriptions for himself and his wife without the prescribing practitioner’s authorization.
- s. The pharmacy was served with a subpoena for original prescription records for the staff pharmacist and his spouse. Ten prescriptions could not be located at the pharmacy and six records obtained were just duplicates of the label prepared, and not a prescription itself.

8. Respondent admits that Respondent’s conduct described above is unprofessional conduct as defined in Utah Code Ann. § 58-1-501(2)(a) and (h); § 58-17b-502(3) and (8); § 58-17b-603(1); R156-17b-605(1)(b), (f), (h), (k) and (3); R156-17b-610(4); R156-17b-612 (4); R156-17b-614a(1)(a), (b), and (e), (2), (3), (4), (7), (8), and (11); R156-37-502(5); and 21 CFR 1311; and unlawful conduct as defined in Utah Code Ann. § 58-1-501(1)(a) and § 58-17b-501(10). Respondent agrees by engaging in such conduct the Division is justified in taking disciplinary action against Respondent’s license pursuant to Utah Code Ann. § 58-1-401(2)(a). Respondent agrees that an Order, which constitutes disciplinary action against Respondent’s license by the Division pursuant to Utah Administrative Code R156-1-102(6) and Utah Code

Ann. § 58-1-401(2), may be issued in this matter providing for the following action against

Respondent's license:

- (1) Respondent's licenses to operate as a pharmacy and to dispense controlled substances shall be revoked. Those revocations shall be immediately stayed. Respondent's licenses shall be subject to a term of probation for a period of five years. The period of probation shall commence on the date the Division Director signs the attached Order. During the period of probation Respondent's license shall be subject to all of the following terms and conditions. If the Board or Division later deems any of the conditions unnecessary such deletions may be made by an amended order issued unilaterally by the Division.
 - a. **Meeting with Compliance Specialist.** Respondent's pharmacist in charge (PIC) shall meet with the Division Compliance Specialist Connie Call within two weeks of the effective date of this Order to schedule a meeting for the purpose of discussing the terms and conditions of this Stipulation and Order. An appointment with Ms. Call can be scheduled by contacting her by phone at (801) 530-6295 or by email at c_call@utah.gov.
 - b. **Written Practice Plan.** Respondent shall submit a written practice plan along with policies and procedures to the Division and Board, within 30 days of the effective date of this Stipulation and Order. The plan shall outline changes made and how Respondent plans on coming into compliance with Class A pharmacy operating standards.
 - c. **Meetings with the Board.** Respondent's pharmacist-in-charge (PIC) shall meet with the Board at the Board's next scheduled meeting following the signing of the accompanying Order. The PIC shall meet with a Division staff person prior to the PIC's first meeting with the Board to review this agreement. For the remainder of the duration of probation, the PIC shall meet with the Board or with the Division, as directed by the Division, annually or at such other greater or lesser frequency as the Division may direct.
 - d. **Compliance with Laws Governing Pharmacies.** Respondent shall come into compliance with all statutes and administrative rules governing pharmacies in the State of Utah within 90 days of the date of this Stipulation and Order. Respondent shall have a clean sink with hot water; security and anti-theft deterrent barriers

in place; and a separate refrigerator for food storage.

- e. **Inspections.** Respondent shall undergo periodic inspections conducted by a Division approved inspector.
- f. **Cease and Desist From All Compounding.** Respondent shall not perform any compounding, including simple, moderate, and complex, sterile, and non-sterile compounding.
- g. **Fine.** Respondent shall pay a fine of \$50,000.00 (fifty-thousand dollars) to the Division, pursuant to Utah Code Ann. § 58-17b-504 and Utah Administrative Code R156-17b-402. \$35,000.00 (thirty-five thousand dollars) of the fine, shall be stayed. If Respondent violates any provision of this Stipulation and Order the Division may move to remove the stayed portion of the fine. \$15,000.00 (fifteen-thousand dollars) shall be paid to the Division within 90 days of the effective date of this Stipulation and Order.
- h. **Supervised Practice.** Respondent shall hire a pharmacist supervisor, pre-approved by the Division and Board, to assist Respondent with compliance with all Class A pharmacy operating standards established in state and federal law. Respondent shall provide a copy of this Stipulation and Order to the supervisor and cause the supervisor to notify the Division in writing that a copy of the Stipulation and Order has been received. Respondent shall cause the supervisor to write the Division to confirm his or her understanding of the terms of the Stipulation and Order.
- i. **Supervisor Visits to Pharmacy.** Respondent shall cause Respondent's supervisor to physically visit Respondent's pharmacy on at least a quarterly basis during the first year of probation. During the supervisor's visits to the pharmacy, the supervisor shall check to see that Respondent is complying with state and federal law and complying with the terms and conditions of this Stipulation and Order. After the first year the supervisor shall visit in-person the pharmacy on an as needed basis, as determined by the Division and Board.
- j. **Supervisor Reports.** Respondent shall cause Respondent's supervisor to submit reports to the Board and Division assessing Respondent's compliance with the terms and conditions of this Stipulation and Order. The reports shall be submitted quarterly or at such frequency as directed by the Board and Division. Failure to

timely submit a report, or the receipt of an unfavorable report, may be considered a violation of probation.

- k. **Payment of Costs.** Failure of Respondent to pay the costs associated with this Stipulation and Order constitutes a violation of the Stipulation and Order.
- l. **Active License.** Respondent shall maintain active licenses at all times during the period of this agreement.
- m. **Address Changes.** Respondent shall immediately notify the Division in writing of any change in Respondent's residential or business address.
- n. **Cease and Desist Unprofessional Conduct.** Respondent shall cease and desist from all unprofessional conduct described in paragraph 7 above.

9. Upon approval by the Director of the Division, this Stipulation and Order shall be the final compromise and settlement of this non-criminal administrative matter, and that any hearings or prehearing conferences currently scheduled are hereby vacated. Respondent acknowledges that the Director is not required to accept the terms of this Stipulation and Order and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and the Respondent waive any claim of bias or prejudice they might otherwise have with regard to the Director by virtue of his having reviewed this Stipulation, and this waiver shall survive such nullification.

10. Respondent shall abide by and comply with all applicable federal and state laws, regulations, rules and orders related to the Respondent's licensed practice. If the Division files a Petition alleging that Respondent has engaged in new misconduct or files an Order to Show Cause Petition alleging that Respondent has violated any of the terms and conditions contained in this Stipulation and Order, the period of Respondent's probation shall be tolled during the period

that the Petition or Order to Show Cause Petition has been filed and is unresolved.

11. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order. There are no verbal agreements that modify, interpret, construe or affect this Stipulation. Respondent agrees not to take any action or make any public statement, that creates, or tends to create, the impression that any of the matters set forth in this Stipulation and Order are without factual basis. A public statement includes statements to one or more Board members during a meeting of the Board. Any such action or statement shall be considered a violation of this Stipulation and Order.

12. The accompanying Order becomes effective immediately upon the approval of this Stipulation and signing of the Order by the Division Director. Respondent shall comply with all the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order page of this Stipulation and Order. Respondent shall comply with and timely complete all the terms and conditions of probation. If a time period for completion of a term or condition is not specifically set forth in the Stipulation and Order, Respondent agrees that the time period for completion of that term or condition shall be set by the Division or Board. Failure to comply with and timely complete a term or condition shall constitute a violation of the Stipulation and Order and may subject Respondent to revocation or other sanctions.

13. If Respondent violates any term or condition of this Stipulation and Order, the Division may take action against Respondent, including imposing appropriate sanction, in the manner provided by law. Such sanction may include revocation or suspension of Respondent's license, or other appropriate sanction.

14. Respondent understands that the disciplinary action taken by the Division in this Stipulation and Order may adversely affect any license that Respondent may possess in another state or any application for licensure Respondent may submit in another state.

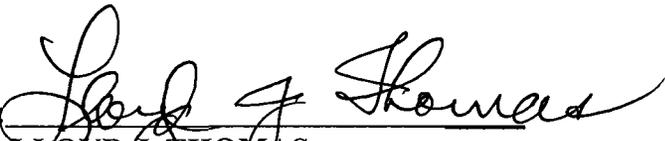
15. Respondent shall practice only under Respondent's name as set forth in the caption of this Stipulation and Order. If Respondent intends to practice under any other name, then, prior to practicing under any other name, Respondent shall inform the Division in writing, and Respondent and the Division shall enter into an Amended Stipulation and Order, which consists of the new name Respondent intends to practice under, along with all the same terms and conditions in the original Stipulation and Order.

16. Respondent has read each and every paragraph contained in this Stipulation and Order. Respondent understands each and every paragraph contained in this Stipulation and Order. Respondent has no questions about any paragraph or provision contained in this Stipulation and Order.

DIVISION OF OCCUPATIONAL &
PROFESSIONAL LICENSING

RESPONDENT

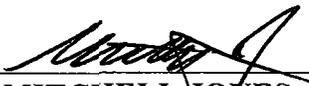
BY: 
RICHARD J. OBORN
Bureau Manager

BY: 
LLOYD J. THOMAS
President and Pharmacist-in-Charge

DATE: 10/7/13

DATE: 10/4/13

JOHN E. SWALLOW
ATTORNEY GENERAL

BY: 
L. MITCHELL JONES
Counsel for the Division

DATE: 4 Oct 2013

ORDER

THE ABOVE STIPULATION, in the matter of **ROY WINEGAR'S PHARMACY**, is hereby approved by the Division of Occupational and Professional Licensing, and constitutes my Findings of Fact and Conclusions of Law in this matter. The issuance of this Order is disciplinary action pursuant to Utah Administrative Code R156-1-102(6) and Utah Code Ann. § 58-1-401(2). The terms and conditions of the Stipulation are incorporated herein and constitute my final Order in this case.

DATED this 8th day of October, 2013.

DIVISION OF OCCUPATIONAL AND
PROFESSIONAL LICENSING



MARK B. STEINAGEL
Director

Investigator Brittany Butsch