WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES



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STATE OF WISCONSIN BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY

PROCEEDINGS AGAINST

FINAL DECISION AND ORDER

STROHECKERS PHARMACY, RESPONDENT.

0004568

Division of Legal Services and Compliance Case No. 15 PHM 193

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

Stroheckers Pharmacy 2855-A SW Patton Road Portland, OR 97201

Wisconsin Pharmacy Examining Board P.O. Box 8366 Madison, WI 53708-8366

Division of Legal Services and Compliance Department of Safety and Professional Services P.O. Box 7190 Madison, WI 53707-7190

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

- 1. Respondent Stroheckers Pharmacy is licensed in the state of Wisconsin as an out of state pharmacy, having license number 620-43, first granted on December 7, 2010 and current through May 31, 2016. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is 2855-A SW Patton Road, Portland, Oregon 97201.
- 2. On November 12, 2015, the Board of Pharmacy of the State of Oregon entered into a Consent Agreement with the Respondent.

- 3. The Consent Agreement incorporates the following allegations:
 - a. On or about December 1, 2014, the Registrant compounded testosterone cypionate lot #T-1201S14 and inadvertently added estradiol valerate to the compound. The pharmacy dispensed the misbranded testosterone cypionate lot #T-1201S14 to 351 patients in 35 states.
 - b. Registrant did not follow procedure when compounding lot #T-1201S14 and in documenting the compounding of lot #T-1201S14. Pharmacist R.H. accidently added an excess of sesame oil while compounding the testosterone and calculated and added the correct amount of what he thought was testosterone cypionate, actually estradiol valerate, needed to maintain the appropriate concentration. There is no documentation of changes to the formula and Pharmacist R.H. stated that he circumvented the system and did not follow procedure.
 - c. Registrant did not follow procedure or take appropriate action after receiving the potency test result for lot #T-1201S14 and identifying that product was not in their customary potency range.
 - d. Registrant did not take appropriate action after becoming aware of the error. The Registrant was alerted to the error on April 6, 2015 by a practitioner and began a recall on April 9, 2015. Patients were not contacted in a timely manner and, in the course of the recall, Registrant did not contact every patient, did not contact every practitioner, and did not ask every patient if they had experienced any adverse events.
- 4. Respondent agreed to the Board of Pharmacy of the State of Oregon Consent Order's terms and conditions as follows:
 - a. Registrant shall pay a civil penalty in the amount of ten thousand dollars (\$10,000), with ten thousand dollars (\$10,000), stayed pending no further similar violation for three years and compliance with the terms of this Order.
 - b. Registrant shall comply with the following terms for three years from the date this Consent Order becomes final:
 - 1. The Registrant shall develop and implement a Quality Assurance Plan acceptable to the Board to correct violations as noted in the Notice. The plan shall address compounding procedures, documentation of compounding, batch lot sizes, ingredient testing of every lot, excursion and recalls. Quality Assurance Plan with a copy of this Order to be submitted within ten days from the date this Consent Order becomes final.
 - 2. The Pharmacist-in-Charge shall directly supervise all compounding practices.

- 3. The Registrant shall provide to the Board a list of all patients, or patient representatives, that have been contacted regarding the recall within thirty (30) days from the date this Order is final.
 - a. If not all patients, or patient representatives, have been contacted, the Registrant shall post a notice of the recall on their website.
- 4. The Registrant must comply with all laws and rules regarding Pharmacy practice.
- c. Failure of the Registrant to comply with all the requirements of this Consent Order constitutes unprofessional conduct and is grounds for revocation or any other form of discipline or sanction authorized by law.
- 5. In resolution of this matter, Respondent consents to the entry of the following Conclusions of Law and Order.

CONCLUSIONS OF LAW

- 1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1), and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).
- 2. By the conduct described in the Findings of Fact, Respondent violated Wis. Admin. Code § Phar 10.03(17), by having a pharmacist license subject to disciplinary action by the licensing authority.
- 3. As a result of the above violations, Respondent is subject to discipline pursuant to Wis. Stat. § 450.10(1)(a)2.

ORDER

- 1. The attached Stipulation is accepted.
- 2. Respondent Stroheckers Pharmacy is REPRIMANDED.
- 3. Within ninety (90) days from the date of this Order, Respondent shall pay a FORFEITURE of \$500.00 and COSTS of this matter in the amount of \$100.00.
- 4. Payment of forfeiture and costs (made payable to the Wisconsin Department of Safety and Professional Services) shall be sent by Respondent to the Department Monitor at the address below:

Department Monitor

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190, Madison, WI 53707-7190
Telephone (608) 267-3817; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov

- 5. Violation of any of the terms of this Order may be construed as conduct imperiling public health, safety and welfare and may result in a summary suspension of Respondent's license. The Board in its discretion may in the alternative impose additional conditions and limitations or other additional discipline for a violation of any of the terms of this Order. In the event Respondent fails to timely submit payment of forfeiture and costs as ordered, Respondent's license (no. 620-43) may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with payment of costs.
 - 6. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

by:

Member of the Board

Date

STATE OF WISCONSIN BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST

STIPULATION

STROHECKERS PHARMACY, RESPONDENT.

0004568

Division of Legal Services and Compliance Case No. 15 PHM 193

Respondent Stroheckers Pharmacy and the Division of Legal Services and Compliance, Department of Safety and Professional Services stipulate as follows:

- 1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Respondent consents to the resolution of this investigation by Stipulation.
- 2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives the following rights:
 - the right to a hearing on the allegations against Respondent, at which time the State has the burden of proving those allegations by a preponderance of the evidence;
 - the right to confront and cross-examine the witnesses against Respondent;
 - the right to call witnesses on Respondent's behalf and to compel their attendance by subpoena;
 - the right to testify on Respondent's own behalf;
 - the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision;
 - · the right to petition for rehearing; and
 - all other applicable rights afforded to Respondent under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and other provisions of state or federal law.
- 3. Respondent is aware of Respondent's right to seek legal representation and has been provided an opportunity to obtain legal counsel before signing this Stipulation.
- 4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining (Board). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.
- 5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division

of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

- 6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.
- 7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.
- 8. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Stroheckers Pharmacy, Respondent

2855-A SW Patton Road Portland, OR 97201

License no. 620-43

Date

1/15/2016

1/20/2016 Date

James E. Polewski, Attorney

Department of Safety and Professional Services

Division of Legal Services and Compliance

P.O. Box 7190

Madison, WI 53707-7190