# COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF STATE BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania Bureau of Professional and Occupational Affairs

vs.

Case Nos.

23-54-010874 23-54-014562

Boothwyn Pharmacy, LLC t/d/b/a Boothwyn Pharmacy and Wayne Charles Sartorio, R.Ph. Respondents

# CONSENT AGREEMENT AND ORDER

## **PARTIES**

The Commonwealth of Pennsylvania, Department of State, Bureau of Professional and Occupational Affairs ("Commonwealth") and Boothwyn Pharmacy, LLC t/d/b/a Boothwyn Pharmacy and Wayne Charles Sartorio, R.Ph. ("Respondents") stipulate as follows in settlement of the above-captioned case.

#### **APPLICABLE LAW**

1. This matter is before the State Board of Pharmacy ("Board") pursuant to the Pharmacy Act, act of September 27, 1961, P.L. 1700, ("Act"), as amended, 63 P.S. §§ 390-1 to 390-13; and/or 63 Pa.C.S. Chapter 31 ("Chapter 31").

#### LICENSURE STATUS

- 2. At all relevant and material times, Respondent Boothwyn Pharmacy held the following permit to operate as a pharmacy in the Commonwealth of Pennsylvania: permit no. PP410228L, which was originally issued on September 29, 1977, and which is currently set to expire on August 31, 2025.
- 3. At all relevant and material times, Respondent Wayne Sartorio held the following license to practice as a pharmacist in the Commonwealth of Pennsylvania: license no. RP044686R,

which was originally issued on December 10, 1998, and which is currently set to expire on September 30, 2024.

#### **ALLEGED FACTS**

- 4. Respondents neither admit nor deny the following alleged facts asserted by the Commonwealth, and the Commonwealth avers it could prove the following alleged facts if the matters were taken to a hearing:
  - a. Absent additional Board action, Boothwyn Pharmacy's permit may be continually reactivated or reinstated upon the filing of the required documentation and payment of the applicable fees.
  - b. Absent additional Board action, Wayne Sartorio's license may be continually reactivated or reinstated upon the filing of the required documentation and payment of the applicable fees.
  - c. Boothwyn Pharmacy's address is: 221 Gale Lane, Kennett Square, PA
     19348.
    - d. Wayne Sartorio's address is: 102 Jasper Ct, Eagleville, PA 19403.
  - e. At all times pertinent to these Stipulated Facts, Wayne Sartorio was the pharmacist manager of Boothwyn Pharmacy.
  - f. On or about August 9<sup>th</sup>, 10<sup>th</sup>, and 14<sup>th</sup>, 2023, the Department of State's Bureau of Enforcement and Investigation conducted a three (3) day inspection of Boothwyn Pharmacy.
  - g. On or about August 9<sup>th</sup>, 10<sup>th</sup>, and 14<sup>th</sup>, 2023, the following discrepancies existed in Boothwyn Pharmacy:
    - (1) The following expired medications were observed in active drug stock: Flavor Beef-Ade Powder

Spray-Dried expired 02/19/2023, Doxepin HCL USP expired 04/30/2023, Capsule Coni-Snap #1 Green/Yellow expired 07/2023, Pink/Powder #3 Blue Capsules expired 06/22/2023, Capsule Coni-Snap #1 Blue/Powder expired 07/2023, Capsule Coni-Snap #1 Pink/Yellow expired 04/2022, Omeprazole USP (Non-Micronized) Powder expired 04/12/2023, Mineral Oil USP (Heavy) expired 12/2022, Corn Starch NF expired 06/22/2023, Methocel E4M 1% Solution expired 07/22/2023.

- (2) An employee pharmacy technician was compounding a non-sterile hazardous drug in the non-sterile clean room while a different non-sterile compound was mixing on the counter. This employee pharmacy technician, while handling hazardous drugs, repeatedly went to the shelves and handled other medication/compounding bottles without changing his gloves. This employee pharmacy technician inserted his upper torso into the hood while cleaning the hood.
- (3) There were uncapped bottles and bottles with measuring syringes still attached on the shelves in the non-sterile compounding clean room.
- h. On or about September 20, 2023, Respondent passed a re-inspection conducted by the Department of State's Bureau of Enforcement and Investigation.

## **AUTHORITY OF THE BOARD**

5. The Board is authorized to suspend or revoke, or otherwise restrict Respondents' permit and license under section 5(a) and/or (b) & (8) of the Act, 63 P.S. §§ 390-5(a) and/or (b) & 390-8; impose a civil penalty upon Respondents under sections 5(a) and/or (b) & (8) of the Act, 63 P.S. §§ 390-5(a) and/or (b) & 390-8; or impose a civil penalty under section 63 Pa.C.S. § 3108(b)(4); and/or impose the costs of investigation under 63 Pa.C.S. § 3108(b)(5).

## **PROPOSED ORDER**

6. The parties, intending to be legally bound, consent to the issuance of the following Order in settlement of this matter:

#### a. VIOLATIONS:

- (1) Boothwyn Pharmacy violated Section 5(b)(2), 63
  P.S. § 390-5(b)(2), by and through violating Board regulation 49 Pa. Code § 27.601, in that Boothwyn Pharmacy failed to be in accordance with the current version of the USP chapters governing compounding, as evidenced by the employee pharmacy technician's failure to ensure proper sanitization in his compounding methods and evidenced by the existence of uncapped bottles or bottles with measuring syringes still attached on shelves in the non-sterile compounding clean room;
- (2) Wayne Sartorio violated Board regulation 49 Pa.

  Code § 27.14(b), in that Wayne Sartorio, as the pharmacist manager, failed to ensure there were no expired medications in Boothwyn Pharmacy's active drug stock.

- b. CIVIL PENALTY: Respondents shall pay a joint and severable civil penalty of two thousand dollars (\$2,000.00).
  - c. Payment of the civil penalty is subject to the following terms:
  - (1) The full civil penalty shall be tendered to the prosecution division of the Department of State with the executed consent agreement;
  - (2) The civil penalty shall be paid by certified check, cashier's check, attorney's check, or money order issued by a usual, customary, and reputable issuer (e.g. U.S. Postal Money Order, Western Union Money Order, etc.);
  - (3) Payment shall be valid for a period of at least 180 days and shall be made payable to the "Commonwealth of Pennsylvania"; and
  - (4) Respondents agree that payment shall only be made by one of the methods indicated and shall not be made by uncertified personal or corporate check.
- d. This Order constitutes disciplinary action by the Board. This Order will be reported to other licensing authorities and any applicable national licensing databank as a disciplinary action by the Board.
- e. This case shall be deemed settled and discontinued upon the Board issuing an order adopting this Consent Agreement.

#### ADMISSIBILITY OF CONSENT AGREEMENT IN FUTURE PROCEEDINGS

7. Respondents agree that this Consent Agreement and Order may be admitted into evidence, without objection, in any proceeding before the Department of State.

## ACKNOWLEDGMENT OF NOTICE AND WAIVER OF HEARING

8. Respondents acknowledge receipt of an Order to Show Cause in this matter. Respondents knowingly and voluntarily waive the right to an administrative hearing in this matter and the following rights related to that hearing: to be represented by counsel; to present witnesses and testimony in defense or in mitigation of any sanction that may be imposed for a violation; to cross-examine witnesses and to challenge evidence presented by the Commonwealth; to present legal arguments by means of a brief; and to take an appeal from any adverse final decision.

# **ACKNOWLEDGMENT OF RIGHT TO ATTORNEY**

9. Respondents acknowledge the right to consult with and be represented by private legal counsel of Respondents' choosing and at Respondents' expense when reviewing, considering and accepting the terms of this Consent Agreement. Respondents have had an opportunity to discuss the contents of this Consent Agreement with Attorney Joseph McHale.

# **WAIVER OF CLAIMS**

10. Should the Board vote not to adopt the Order proposed in this Consent Agreement, the presentation and consideration of this Consent Agreement shall not prejudice the Board or any of its members from further participation in the adjudication of this matter. Respondents expressly waive the right to raise any claims or issues, including any and all constitutional claims or issues, which may arise or have arisen during the review, presentation and deliberation of this Consent Agreement. These claims or issues include, but are not limited to, bias, the commingling of prosecutorial and adjudicative functions by the Board or its counsel, and the Board, in its discretion, recommending a different sanction based upon the facts set forth in the Consent Agreement. If a hearing is subsequently held, neither this Consent Agreement nor the proposed terms of settlement may be admitted into evidence and any facts, averments, and allegations

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contained in the Consent Agreement must be proven at a hearing unless otherwise separately stipulated.

# LIMITS ON MODIFICATION OF ORDER

11. Respondents agree not to seek modification of the Order adopting and implementing this Consent Agreement without first obtaining the express written permission from the prosecution division. Any modification is at the sole discretion of the Board.

# AGREEMENT NOT BINDING UNTIL APPROVED

12. This Consent Agreement is between the Commonwealth and the Respondents. The Office of General Counsel has approved this Consent Agreement as to form and legality. The disciplinary provisions of this Consent Agreement do not take effect unless and until the Board issues an order adopting this Consent Agreement.

#### **ENTIRE AGREEMENT**

13. This Consent Agreement contains the entire agreement between the parties. There are no other terms, obligations, covenants, representations, statements, or conditions, oral or otherwise, of any kind whatsoever concerning this agreement.

#### AGREEMENT DOES NOT PREVENT FUTURE DISCIPLINE

14. Nothing in this Order shall preclude the prosecution division of the Department of State from filing charges, or the Board from imposing disciplinary or corrective measures, for violations or facts not contained in this Consent Agreement.

# **VERIFICATION OF FACTS AND STATEMENTS**

15. Respondents verify that the facts and statements set forth in this Consent Agreement are true and correct to the best of Respondents' knowledge, information and belief. Respondents

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understand that statements in this Consent Agreement are made subject to the criminal penalties of 18 Pa.C.S.A. §4904 relating to unsworn falsification to authorities.

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Glenn P. Masser

**Prosecuting Attorney** 

**DATED: 12/1/2023** 

Wayne Charles Sartorio, R.Ph.

11/1/23

Boothwyn Pharmacy, LLC t/d/b/a Boothwyn Pharmacy

Respondents

DATED:

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# **ORDER**

AND NOW, this 19th day of December 2023, the STATE BOARD OF PHARMACY ("Board") approves and adopts the foregoing Consent Agreement and incorporates the terms of paragraph 6, which shall constitute the Board's Order and is now issued in resolution of this matter.

This Order shall take effect immediately.

<b>BUREAU OF PROFESSIONAL AND</b>
OCCUPATIONAL AFFAIRS

anon of Clargett

Arion R. Claggett Acting Commissioner

For the Commonwealth:

For the Respondents:

Date of mailing:

BY ORDER:

STATE BOARD OF PHARMACY

Theresa M. Talbott, R.Ph.

Chairperson

Glenn P. Masser, Esquire 2601 North Third Street

P.O. Box 69521

Harrisburg, PA 17106-9521

Stradley Ronon Stevens & Young, LLP

Attn: Joseph McHale, Esquire 30 Valley Stream Parkway Malvern, PA 19355-1481

December 27, 2023