

IN THE MATTER OF	*	BEFORE THE
GERMANTOWN PROFESSIONAL	*	STATE BOARD OF
PHARMACY AND COMPOUNDING	*	PHARMACY
RESPONDENT-PHARMACY	*	CASE NO.: PI-16-223
PERMIT NO.: P06662	*	
* * * * *		

FINAL CONSENT ORDER

The State Board of Pharmacy (“the Board”) charged Germantown Professional Pharmacy and Compounding (“Respondent-Pharmacy”), was charged with violating certain provisions of the Maryland Pharmacy Act, (“the Act”) Md. Code Ann., Health Occ. II (“H. O.”) §§12-101 *et seq.* (2014 Repl. Vol.). The pertinent provisions state:

H.O. §12—409. Suspension and revocations- Grounds

- (a) *In general.* - Subject to the hearing provisions of § 12–411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:
 - (1) Is conducted so as to endanger the public health or safety;
 - (2) Violates any of the standards specified in § 12–403 of this subtitle; or
 - (3) Otherwise is not conducted in accordance with the law.

H.O. §12–403. Required Standards.

- (c) *In general.* - Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:
 - (1) Shall be operated in compliance with the law and with the rules and regulations of the Board;
 - (5) Shall provide complete pharmaceutical service by preparing and dispensing all prescriptions that reasonably may be expected of a pharmacist;
 - (9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12–313 of this title, a registered pharmacy technician under § 12–6B–09 of this title, or a registered pharmacy intern under § 12–6D–11 of this title;

- (11) (i) Shall maintain at all times the minimum professional and technical equipment and sanitary appliances that are necessary in a pharmacy:
 - 1. To prepare and dispense prescriptions properly; and
 - 2. To otherwise operate a pharmacy; and
- (ii) Shall:
 - 1. Be equipped with the minimum equipment and appliances specified by the Board under this section; and
 - 2. Be kept in a clean and orderly manner;
- (12) Shall store all prescription or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board;
- (13) Shall:
 - (i) Make and keep on file for at least 5 years a record of each prescription prepared or dispensed in the pharmacy;
 - (ii) Disclose the records and files maintained of prescriptions for drugs or devices that identify or may be readily associated with the identity of a patient only in accordance with the provisions of Title 4, Subtitle 3 of the Health – General Article; and
 - (iii) Keep additional records as required by the rules and regulations adopted by the Board;
- (19) May not allow an unauthorized individual to represent that the individual is a pharmacist, a registered pharmacy intern, or registered pharmacy technician;
- (21) Shall dispense or dispose of prescription drugs or medical supplies in accordance with Title 15, Subtitle 6 of the Health – General Article[.]

H.O. §12–313. Denials, reprimands, suspensions, and revocations – Grounds.

- (b) Subject to the hearing provisions of § 12–315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a license to any applicant for a pharmacist's license, reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the applicant or licensee.

- (3) Aids an unauthorized individual to practice pharmacy or to represent that the individual is a pharmacist, a registered pharmacy intern, or a registered pharmacy technician;
- (15) Dispenses any drug, device, or diagnostic for which a prescription is required without a written, oral, or electronically transmitted prescription from an authorized prescriber;
- (25) Violates any rule or regulation adopted by the Board[.]

Md. Health General Art. §15-605. Repository.

- (f) A pharmacy may accept prescription drugs and medical supplies taken to the pharmacy for disposal only if the pharmacy is approved by the Board as a repository for this purpose.

Code Md. Regs. tit.10 § 34.07.

01-1 Equipment.

- A. A pharmacy shall have the following equipment to carry out the practice of pharmacy in Maryland:
 - B. A refrigerator, solely for the storage of drugs requiring refrigeration, with a thermometer or a temperature monitoring device [.]
 - C. A freezer, if applicable.

Code Md. Regs. tit.10 § 34.33

.06 Repositories — General Requirements.

In order to become a repository, a pharmacy:

- A. Shall submit an application to the Board to be designated as a repository [.]

FINDINGS OF FACT

The Board finds that:

- 1. On or about November 18, 2014, the Respondent-Pharmacy was issued a permit to operate as a pharmacy in the State of Maryland.
- 2. The Respondent-Pharmacy permit expires on May 31, 2018.

3. The Respondent-Pharmacy is owned and operated by Pharmacist A¹.

4. Pharmacist A is also the pharmacy manager at the Respondent-Pharmacy.

5. On or about June 22, 2016, the Board received a complaint from Corporation A, a pharmaceutical manufacturer.

6. The complaint alleged that the Respondent-Pharmacy engaged in the inappropriate compounding of the Federal Food and Drug Administration ("FDA") approved, commercially available Enstilar Foam.²

7. The complaint also alleged that the Respondent-Pharmacy dispensed inappropriately compounded Enstilar Foam to a patient in a smaller, clear plastic container that was not the FDA approved 60 grams pressurized aluminum spray can.³

8. On or about July 22, 2016 and August 11, 2016, the Board inspectors conducted inspections of the Respondent-Pharmacy.

9. During the July 22, 2016 inspection, Board inspectors retrieved prescriptions for Enstilar Foam that had been dispensed at the Respondent-Pharmacy. The Board later received additional prescriptions and purchase orders from the Respondent-Pharmacy pursuant to a subpoena.⁴

10. The Respondent-Pharmacy's purchase orders showed that six (6) cans of FDA approved commercially available Enstilar Foam had been purchased by the Respondent-Pharmacy between January 18, 2016 and July 27, 2016.

¹ The names of Pharmacist A and Corporation A referred to in this document have been omitted to protect confidentiality.

² Corporation A manufactures Enstilar until January 18, 2016.

³ Enstilar Foam was not approved by the FDA until October 2015. Enstilar Foam did not become commercially available in Maryland until January 18, 2016.

⁴ Subpoenas were issued to Respondent-Pharmacy requesting that the permit holder of the Respondent-Pharmacy provide invoices for the purchase of Betamethasone Dispropionate and Calcipotriene, for the period between November 14 and July 27, 2016, and the purchase invoices for Enstilar Foam between

11. The Respondent-Pharmacy dispensing logs indicate that Enstilar Foam had been dispensed approximately fifty-seven (57) times between January 18, 2016 and July 22, 2016. The Respondent disputes this reported number of dispensing.

12. Medical providers contacted by Board staff indicated that they did not prescribe the compounding of Enstilar Foam for their patients.

13. The Board investigation revealed that the Respondent-Pharmacy compounded Enstilar Foam, based on the number of times that it was dispensed compared to the number of the FDA commercially available Enstilar Foam that the Respondent-Pharmacy had purchased.

14. During the July 22, 2016 inspection, however, the Pharmacist A told the Board inspectors that Enstilar Foam was not compounded at the Respondent-Pharmacy.

15. During the July 22, 2016 inspection, the Board inspectors found the following:
- A. An unregistered pharmacy technician entering orders and pulling medications.
 - B. No technician registrations posted in the Respondent-Pharmacy.
 - C. Pharmacists were not vaccination certified, but vaccines were found stored in the Respondent-Pharmacy refrigerator.
 - D. A prescription for Zostavax filled for a patient on March 15, 2016 was stored in the Respondent-Pharmacy refrigerator instead of the freezer.
 - E. The refrigerator used for storage of vaccines and medication pick-ups did not have a thermometer.
 - F. Multiple expired compounded medications that were incorrectly labeled were stored in non-sterile compounding room.
 - G. Expired bulk drug products.

- H. Excessive stock of compounded medications (including ointments and capsules) that were not being used as anticipatory compounding, including ointments and capsules compounded for patients prescriptions. The labels on the prescription had the patient name crossed out. Several ointments did not have sufficient closures.
- I. Unlabeled and illegibly labeled compounded medications.
- J. The pharmacy was acting as repository and was accepting several patient medications for disposal but was not registered to act as a repository.
- K. The compounding area of the Respondent-Pharmacy was disorganized with poor segregation of different compounded preparations. For example, two baskets filled with unlabeled tubes next to one another containing different strengths of Tretinoin
- L. An expired box of Oral Transmucosal Fentanyl Citrate was stored outside the controlled substance cabinet in an unlocked cabinet alongside miscellaneous storage.
- M. A bottle of simple syrup without an expiration date or other information was stored in a deer park water bottle, beside compounding ingredients.
- N. No compounding logs.
- O. Expired eye drop products in the over the counter area.
- P. A bottle labeled with prescription information found on shelf with compounded medication contained the kidney stones of the managing pharmacist.
- Q. A bottle containing an unknown powder with a patient prescription labeled for Viagra tablets was stored with the compounding stock.
- R. A bottle of an herbal sleep aid contained an assortment of unknown partially broken tablets.

16. During the August 11, 2016 inspection, the inspectors observed and found the following:

- A. The Zostavax that was found in the refrigerator during the July 22, 2016 was moved to the freezer and not disposed.

17. The Board inspectors found no evidence that the pharmacists or other personnel at the Respondent-Pharmacy were, in fact, administering vaccinations.

18. State records reflect that the pharmacy technician who was not registered at the time of the July 11, 2017 inspection had successfully registered prior to the subsequent August 11, 2017 inspection.

19. The Respondent-Pharmacy's conduct, as described above, is a violation of H.O. § 12-403(c)(1), (5), (9), (11), (12), (13), (19), and (21); § 12-409 (a) (1), (2), and (3); § 12-313(b) (3), (15), and (25); 409 and Code Md. Tit § 10.34.22.03A (1)(a) and (b), and (2).

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Respondent-Pharmacy violated H.O. § 12-403(c)(1), (5), (9), (11), (12), (13), (19), and (21); § 12-409 (a) (1), (2), and (3); § 12-313(b) (3), (15), and (25); 409 and Code Md. Tit § 10.34.22.03A (1)(a) and (b), and (2).

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 7th day of December 2017, by a majority of the quorum of the Board, hereby

ORDERED that the permit of Respondent-Pharmacy shall be placed on **PROBATION** for a period of **TWO (2) YEARS** subject to the following conditions:

ORDERED that Respondent-Pharmacy shall pay a fine in the amount of ten thousand dollars (\$10,000), payable to the Maryland Board of Pharmacy, no later than 60 (sixty) days from the date that this Order is signed by the Board; and it is further

ORDERED that Board staff shall be allowed entry into Respondent-Pharmacy during pharmacy hours of operation for any purpose that the Board deems appropriate, and it is further

ORDERED that the Respondent-Pharmacy shall comply the Board's requests for all documents within twenty-four (24) hours the request, and it is further

ORDERED that the Respondent-Pharmacy shall get accreditation in non-sterile compounding within six (6) months of the date of this Order

ORDERED that the Respondent-Pharmacy shall operate in accordance with the Maryland Pharmacy Act and all applicable laws and regulations; and it is further

ORDERED that at the end of the Respondent-Pharmacy's probationary period, the Respondent-Pharmacy may file a written petition to the Board for termination of the probationary status and the removal of any conditions or restrictions that resulted from this disciplinary action, if Respondent-Pharmacy has fulfilled all the terms and conditions set forth herein, is not in violation of this Order, and there are no outstanding complaints against the Respondent-Pharmacy the Board at its discretion may approve the Respondent-Pharmacy's petition; and it is further

ORDERED that if the Respondent-Pharmacy fails to make any such petition, then the probationary period status may continue indefinitely, subject to the conditions set forth in this Order; and it is further

ORDERED that if the Board determines that the terms or conditions of this Order have not been successfully completed, the Board may modify the terms and conditions of Respondent-Pharmacy's probation, upon notice to the Respondent-Pharmacy; and it is further

ORDERED that if the Respondent-Pharmacy violates any of the terms of this Order, the Board, after notice and a show cause hearing, and a determination of violation, may impose any other disciplinary sanctions it deems appropriate, said violation being proved by a preponderance of evidence; and it is further

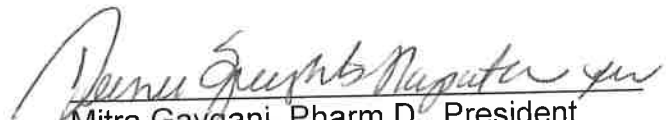
ORDERED that Respondent-Pharmacy shall be responsible for all costs incurred under this Order; and it is further

ORDERED that for purposes of public disclosure and as permitted by Md. General Provisions §§ 4-101 *et seq.* (2014), this document consists of the contents of the foregoing Findings of Fact, Conclusions of Law, and Order, and is reportable to any entity to whom the Board is obligated to report; and it is further

ORDERED that the effective date of this Order is the date that it is signed by the Board; and it is further

ORDERED that this Order is final and a public document pursuant to Md. General Provisions §§ 4-104 *et seq.* (2014).

12-7-17
Date


Mitra Gavvani, Pharm.D., President
State Board of Pharmacy

**CONSENT OF GERMANTOWN PHARMACY
AND COMPOUNDING HOSSEIN ZAMANI, OWNER**

I, Hossein Zamani, owner of Germantown Pharmacy and Compounding ("Germantown Pharmacy"), by affixing my signature hereto, acknowledge that:

1. Germantown Pharmacy is represented by Joel Schwartz, Esquire and Courtney Schaefer.

2. I am aware that Germantown Pharmacy entitled to a formal evidentiary hearing before the Board, pursuant to Md. Code Ann., Health Occ. II § 12-315 (2014 Repl. Vol.) and Md. Code Ann., State Govt. II §§ 10-201 *et seq.* (2014 Repl. Vol.).

3. I, Hossein Zamani, owner for Germantown Pharmacy acknowledge the validity and enforceability of this Consent Order as if entered after a formal evidentiary hearing in which Germantown Pharmacy would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections provided by law. As owner of Germantown Pharmacy, I am waiving those procedural and substantive protections.

4. I, as owner voluntarily enter into and consent to the foregoing findings of fact, conclusions of law, and order and agree to abide by the terms and conditions set forth in this Consent Order, as a resolution of the Board's case, based on the findings set forth herein.

5. I, as owner waive Germantown Pharmacy right to contest the findings of fact and conclusions of law, and I waive Germantown Pharmacy's right to a full

evidentiary hearing, and any right to appeal this Consent Order as set forth in Md. Code Ann., Health Occ. II § 12-315 (2014 Rep. Vol.) and Md. Code Ann., State Govt II §§ 10-201 *et seq.* (2014 Rep. Vol.).

6. I as owner acknowledge that by failing to abide by the terms and conditions set forth in this Consent Order, and, following proper procedures, Germantown Pharmacy may be subject to disciplinary action.

7. I as owner this consent order, without reservation, as my voluntary act and deed. I acknowledge that I fully understand and comprehend the language, meaning, and terms of this Consent Order.

12/05/2017

Date

Hossein Zamani

Hossein Zamani, Pharm.D, Owner
Germantown Professional Pharmacy
and Compounding

STATE OF Maryland

CITY/COUNTY OF Montgomery

I hereby certify that on this 5th day of December, 2017, before me, a Notary Public for the State of Maryland and the City/County aforesaid, personally appeared and made an oath in due form of law that the foregoing Final Consent Order was a voluntary act and deed.

AS WITNESS my hand and Notarial Seal.

Michelle L. Moore
Notary Public

My Commission Expires: 7/20/2019

