

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of:

PHARMACY ON THE PARK, INC.
(Permit No. 7593)

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CONSENT ORDER

THIS MATTER came on to be considered at a prehearing conference (hereinafter, "Conference") before a member of the North Carolina Board of Pharmacy (hereinafter, "Board") pursuant to 21 N.C.A.C. 46 .2008. This Conference was scheduled for September 15, 2014 and, after appropriate notice, was heard on that day by Board Member William A. Mixon at the office the Board. Respondent Pharmacy on the Park, Inc. (hereinafter "Respondent" or "the Pharmacy") was present through its pharmacist-manager, Samuel E. Lowman. Counsel Clinton R. Pinyan represented the Board. Members of the Board's investigative staff and related respondents were also present at the Conference.

Respondent has agreed to waive a formal hearing in the above-referenced matter. Both parties stipulate and agree to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order by its consent. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. The North Carolina Board of Pharmacy is a body duly organized under the laws of North Carolina and is the proper body for this proceeding under the authority granted it in

Chapter 90 of the General Statutes of North Carolina, and the rules and regulations promulgated thereunder.

2. Respondent Pharmacy on the Park, Inc., located at 457 North Wendover Road, Charlotte, North Carolina, is, and was at all relevant times referred to herein, the holder of Pharmacy Permit No. 7593. The Pharmacy and its employees are, and were at all relevant times, subject to the rules and regulations of the North Carolina Board of Pharmacy and the laws of the State of North Carolina.

3. When an inspection was conducted on February 18, 2014, the Pharmacy was engaged in the following acts:

a. The Pharmacy failed to provide sufficient oversight and guidance to employees to exercise their responsibilities to ensure safe and accurate compounding of preparations consistent with the required standard of care;

b. The Pharmacy failed to maintain adequate policies, procedures, references and quality assurance programs to assure the preparation of compounded medication pursuant to practices consistent with the required standard of care;

c. The Pharmacy failed to adequately supervise compounding personnel to assure the safety and integrity of compounding by, among other things, performing and documenting review, assessment and testing of compounding personnel;

d. The Pharmacy failed to maintain facilities and equipment sufficient for the safe and accurate compounding of preparations, and failed to adequately perform and document testing and cleaning of facilities and equipment sufficient for the safe and accurate compounding of preparations;

e. The Pharmacy failed to ensure that personnel used adequate clothing, protective equipment and cleaning processes sufficient for the safe and accurate compounding of preparations;

f. The Pharmacy failed to maintain adequate documentation to assure that preparations were compounded safely and accurately, including but not limited to records of medication errors, testing, sampling, cleaning, validation and storage and counseling and compounding logs;

g. The Pharmacy failed to establish beyond-use dates consistent with the required standard of care, failed to adequately document the standards used for beyond-use dating, failed to adequately record beyond-use dates and lot numbers, and failed to adequately perform and document potency and stability testing;

h. The Pharmacy used compounding and sterilization practices that did not assure the safe and accurate compounding of preparations and that did not comply with the required standard of care;

i. The Pharmacy failed to perform testing and sampling, and failed to maintain documentation of the same, in order to establish compliance with sterility and toxicity standards sufficient to assure the safe and accurate distribution of compounded preparations;

j. The Pharmacy maintained misbranded drugs and failed to separate expired drugs in the pharmacy stock; and

k. The Pharmacy failed to exercise adequate security of controlled substances and failed to maintain the required biennial inventory of controlled substances.

4. Between January 1, 2009 and June 26, 2014, the Pharmacy engaged in dispensing into the states and territories of Alabama, California, Colorado, the District of Columbia, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, New Hampshire, New Jersey, New York, Ohio, South Carolina, Tennessee, Virginia and Wisconsin without holding pharmacy permits in those states, without holding sterile compounding permits when required, and without its pharmacist-manager holding a license in those states in which he was required to do so.

5. These findings are more specifically described in the following documents that were attached to the Notice of Prehearing Conference, which are incorporated herein by reference, and which describe the nature of the Pharmacy's actions:

- a. A Board Pharmacy Inspection Report dated February 18, 2014; and
- b. A Board Compounding Pharmacy Inspection Report dated February 18, 2014.

6. The Board has received no evidence of any contamination in the Pharmacy's sterile compounded products or injury to any patient. No patient or prescriber has complained to the Board or otherwise reported any issues with any of the Pharmacy's sterile compounded products.

7. Upon notice by the Board during the February 18, 2014 inspection, the Pharmacy immediately agreed to suspend all sterile compounding. Furthermore, on February 27, 2014, the Pharmacy submitted a corrective action plan in which it committed to certain changes, including discontinuing all sterile compounding. The Board has received no evidence that the Pharmacy has not followed its corrective action plan.

CONCLUSIONS OF LAW

1. All parties are properly before the Board, and the Board has jurisdiction over Respondent and the subject matter of this proceeding.

2. Respondent's conduct, as set out in the findings of fact and conclusions of law above, constitutes grounds for discipline pursuant to North Carolina General Statutes § 90-85.38(b) because Respondent's acts were in violation of North Carolina General Statutes §§ 90-85.15A(b), 90-85.26(b), 90-85.29, 90-85.40(b) and (f), 90-85.47, 106-122, 106-133, 106-134 and 106-134.1; 21 NCAC 46 .1601(a), 46 .1804(a), 46 .1810, 46 .2501, 46 .2502(a), (g) and (k), 46 .2504, 46 .2803, 46 .2804, 46 .2805, 46 .2806 and 46 .2808; 21 U.S.C. §§ 331, 351(a), (b) and (c) and 352(f); 21 C.F.R. §§ 201.17, 201.18, 211.28, 211.42, 211.113, 211.165, 211.166, 211.167, 1301.75 and 1304.11; Ala. Code § 34-23-31; Ala. Admin. Code r. 680-X-2-.07; Cal. Bus. & Prof. Code §§ 4112, 4120 and 4127.2; Colo. Rev. Stat. § 12-42.5-130; D.C. Mun. Regs. tit. 22, § B1903; Fla. Stat. ch. 465.0156; Fla. Admin. Code Ann. r. 64B16-28.100; Ga. Code Ann. § 26-4-114.1; 225 Ill. Comp. Stat. § 85/16a; Ind. Code § 25-26-17-3; Ky. Rev. Stat. Ann. § 315.0351; 201 Ky. Admin. Regs. 2:205; La. Rev. Stat. Ann. § 37:1232; La. Admin. Code tit. 46, LII.2301; Md. Code Ann. Health Occ. §§ 12-403, 12-4A-02; Mich. Comp. Laws § 333.17748; Minn. Stat. § 151.19; Minn. R. 6800.0300 and 6800.0350; Miss. Code Ann. § 73-21-106; Miss. Reg. 50-018-301; Mo. Rev. Stat. § 338.220; 20 Mo. Code Regs. Ann. §§ 2220-2.010, 2220-2.020 and 2220-2.025; N.H. Rev. Stat. Ann. § 318:37; N.H. Code Admin. R. Ann. Ph., Chapter 900; N.J. Stat. Ann. § 45:14-73, N.J. Admin. Code tit. 13, §§ 39-4.20 and 39-11.3; N.Y. Educ. Law § 6808-b; N.Y. Comp. Codes R. & Regs., tit. 8, § 63.8; Ohio Rev. Code Ann. §§ 4729.54 and 4729.55; Ohio Admin. Code § 4729-10-02; S.C. Code Ann. §§ 40-43-83 and 40-43-86; Tenn. Code Ann. § 63-10-210; Tenn. Comp. R. & Regs.

1140-01-.08; Va. Code Ann. §§ 54.1-3434.1 and 54.1-3434.2; Wis. Stat. § 450.065; and Wis. Admin. Code Phar. 6.01.

3. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on its permit under North Carolina General Statutes § 90-85.38(b).

CONCLUSIONS REGARDING DISCIPLINE

Based upon the foregoing Findings of Fact and Conclusions of Law, and with the consent of the Respondent, IT IS THEREFORE ORDERED that:

1. The permit of Respondent Pharmacy on the Park, Inc. (Permit No. 7593) is hereby SUSPENDED for a period of FIVE (5) YEARS. The suspension is stayed for a period of FIVE (5) YEARS from the date that this Order is accepted by the Board, upon the following conditions:

a. Respondent shall not prepare or dispense any sterile compounded drugs preparations;

b. Respondent shall not prepare or dispense any non-sterile compounded drug preparations until approved in the sole discretion of the Executive Director, following one or more inspections of Respondent;

c. Respondent shall not ship, mail or deliver in any manner any drug, device or medical equipment into any other jurisdiction without obtaining all required permits, registration and licenses;

d. Within 15 days after this Consent Order is accepted by the Board, Samuel E. Lowman (License No. 5277) shall resign as pharmacist-manager of Pharmacy on the Park, Inc., and a replacement pharmacist-manager shall sign the permit indicating his or

her service as pharmacist-manager, and that permit shall be received in the office of the Board. Samuel E. Lowman shall not serve as pharmacist-manager for a period of ONE (1) YEAR from the time that the permit of Pharmacy on the Park, Inc. is received in the office of the Board indicating the replacement pharmacist-manager;

e. For so long as Samuel E. Lowman (License No. 5277) is an owner, officer, director or employee of Respondent, he shall remain in compliance with the terms of his Consent Order accepted contemporaneously hereto;

f. Respondent shall violate no laws governing the practice of pharmacy or the distribution of drugs (including, but not limited to, laws of the State of North Carolina and all other jurisdictions);

g. Respondent shall violate no rules or regulations of the Board; and

h. Respondent shall cooperate with the Board, its attorneys, investigators, and other representatives in any investigation or inspection.

2. If Respondent fails to comply with any terms or conditions of this Consent Order, the stay of Respondent's suspension shall be terminated and Respondent may be subject to additional disciplinary action by the Board.

3. The restrictions in Paragraph 1(a), (b) and (c) shall survive the period during which Respondent's suspension is stayed and shall be permanent restrictions on Respondent's permit, unless and until lifted by future order of the Board.

This the 21st day of October, 2014.

NORTH CAROLINA BOARD OF PHARMACY

By: 

Jack W. Campbell, IV
Executive Director

Pharmacy on the Park, Inc., the holder of permit number 7593, has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. The undersigned freely, knowingly and voluntarily waives such right by entering into this Consent Order.

The undersigned understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions which may be taken concerning this matter.

The undersigned further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional disciplinary action.

The undersigned understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

The undersigned understands that it has the right to have counsel of its choice review and advise it with respect to its rights and this Consent Order, and represents that it enters this Consent Order after consultation with its counsel or after knowingly and voluntarily choosing not to consult with counsel. The undersigned certifies that its agent executing this Consent Order is duly authorized to accept the Consent Order on behalf of Stewart Pharmaceuticals, Inc. and to bind the permit holder.

ACCEPTED AND CONSENTED TO BY:

PHARMACY ON THE PARK, INC. (Permit No. 7593)

Sam E Lowman Date 10/2/14

By: Samuel E Lowman

Title: Pharmacist - Manager
OWNER

STATE OF North Carolina

Mecklenburg COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the following person personally appeared before me this day and acknowledged the due execution of the foregoing document: Samuel E. Lowman.

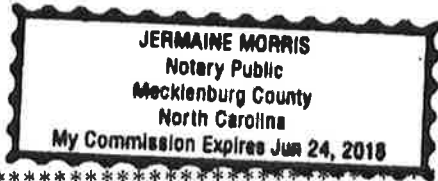
Date: 10/06/2014

Jermaine Morris

Notary Public

Jermaine Morris

My commission expires: 06/24/2018



REJECTED BY:

PHARMACY ON THE PARK, INC. (Permit No. 7593)

_____ Date _____

By: _____

Title: _____