

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of:

SAMUEL E. LOWMAN
(License No. 5277)

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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 Samuel E. Lowman (hereinafter "Respondent" or "Lowman") was present. 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 he waives his right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order by his 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 Samuel E. Lowman is, and was at all relevant times referred to herein, the holder of License No. 5277 and the pharmacist-manager of Pharmacy on the Park, Inc., located at 457 North Wendover Road, Charlotte, North Carolina (Permit No. 7593) (“the Pharmacy”). Lowman is, and was 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 of the Pharmacy was conducted on February 18, 2014, Lowman was engaged in the following acts:

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

f. Lowman 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. Lowman 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. Lowman 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. Lowman 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. Lowman maintained misbranded drugs and failed to separate expired drugs in the pharmacy stock; and

k. Lowman 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, Lowman and 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 the Pharmacy holding pharmacy permits in those states, without the Pharmacy holding sterile compounding permits when required, and without Lowman 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, Lowman and the Pharmacy immediately agreed to suspend all sterile compounding. Furthermore, on February 27, 2014, Lowman and the Pharmacy submitted a corrective action plan in which they committed to certain changes, including discontinuing all sterile compounding. The Board has received no evidence that Lowman and the Pharmacy have not followed their 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(a)(6), (7) and (9) 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 his license under North Carolina General Statutes § 90-85.38(a)(6), (7) and (9).

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 license of Respondent Samuel E. Lowman (License No. 5277) is hereby SUSPENDED for a period of ONE (1) YEAR. 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, whether at the Pharmacy on the Park, Inc. (Permit No. 7593) or elsewhere;

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's practices, whether at the Pharmacy on the Park, Inc. (Permit No. 7593) or elsewhere;

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, Respondent shall resign as pharmacist-manager of Pharmacy on the Park, Inc. (Permit No. 7593), 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. Respondent shall not serve as pharmacist-manager of any pharmacy (including but not limited to Pharmacy on the Park, Inc. (Permit No. 7593)) 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. 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);

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

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

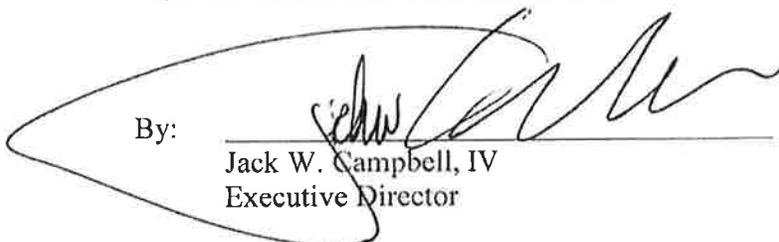
2. If Respondent fails to comply with any terms or conditions of this Consent Order, the stay of Respondent's suspension shall be terminated and Respondent may be subject to additional disciplinary action by the Board.

3. The restrictions in Paragraph 1(a) and (b) shall survive the period during which Respondent's suspension is stayed and shall be permanent restrictions on Respondent's license, 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

Samuel E. Lowman, the holder of license number 5277, has full knowledge that he has the right to a formal hearing, at which he would have the right to be represented at his 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, he certifies that he has read the foregoing Consent Order and that he 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 he 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 he has the right to have counsel of his choice review and advise him with respect to his rights and this Consent Order, and represents that he enters this Consent Order after consultation with his counsel or after knowingly and voluntarily choosing not to consult with counsel.

ACCEPTED AND CONSENTED TO BY:

Samuel E. Lowman Date 10/6/14

SAMUEL E. LOWMAN (License No. 5277)

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:

_____ Date _____

SAMUEL E. LOWMAN (License No. 5277)