

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of:)

TIMOTHY H. CLARK)

(License No. 12114))

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 12, 2016 and, after appropriate notice, was heard on that day by Board Member J. Andrew Bowman at the office of the Board. Respondent Timothy H. Clark (hereinafter "Respondent" or "Clark") was present and represented by counsel, Michael C. Allen. Counsel Clinton R. Pinyan represented the Board. Members of the Board's investigative staff 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 Timothy H. Clark is, and since July 26, 1993 has been, the holder of License No. 12114.

3. At all relevant times, Clark was the Pharmacist-Manager of Health Innovations Pharmacy, Inc. (Permit No. 7705), located at 295 Pinehurst Avenue, Building 2, Southern Pines, North Carolina (the "Pharmacy").

COMPOUNDING AND OTHER PHARMACY MANAGEMENT VIOLATIONS

4. On February 11, 2015, the Board's investigators inspected the Pharmacy. On February 23-27, 2015, investigators from the United States Food and Drug Administration ("FDA") performed related inspections of the Pharmacy. The inspections revealed numerous violations of the Pharmacy Practice Act and its regulations with respect to Clark's and the Pharmacy's compounding practices. These violations are detailed in the Board's Pharmacy Inspection Report, dated February 11, 2015; the Board's Sterile Compounding Pharmacy Inspection Report, also dated February 11, 2015; the FDA's Form 483, dated February 27, 2015; and the FDA Warning Letter, dated July 8, 2016, all of which are incorporated herein by reference.

5. In addition to the compounding violations, the Board's investigators also found other violations, including the fact that the Pharmacy's principal compounding technician had worked at the Pharmacy for a number of years without being registered with the Board. On April 20, 2011, the Board had issued letters warning Clark and the Pharmacy specifically, among other things, about Clark's and the Pharmacy's prior employment of technicians who were not registered with the Board.

6. Clark and the Pharmacy did not dispute the accuracy of any findings in the reports of Board's or the FDA's inspections.

7. As a result of the health and safety concerns, during the Board's February 11, 2015 inspection, Clark and the Pharmacy agreed to stop all compounding until the Pharmacy's compounding facilities and practices could come into compliance with Board requirements. Furthermore, on February 22, 2015, Clark and the Pharmacy recalled all sterile compounded products that had been dispensed in the previous six months.

8. 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.

9. The Pharmacy cooperated with both the recall of the sterile compounded drugs and the Board's investigation. Furthermore, the Pharmacy permanently ceased any sterile compounding. And subsequent inspections on March 24, 2015 and June 10, 2015, revealed no violations in its non-sterile compounding practices.

DIVERSION AND OTHER CONTROLLED SUBSTANCES VIOLATIONS

10. Between May 1, 2013 and August 29, 2015, approximately 131,000 dosage units of schedule II and III controlled substances were diverted from the Pharmacy under Clark's supervision. These controlled substances included about 106,000 dosage units of Oxycodone 15 mg, 20 mg, or 30 mg tablets (a schedule II controlled substance), 20,000 dosage units of hydrocodone/APAP (a schedule II or III controlled substance at various times during this period) in combinations including 7.5 or 10 mg of hydrocodone, 4,400 dosage units of alprazolam in various strengths, 660 dosage units of morphine (a schedule II controlled substance) in various strengths, and 100 dosage units of Adderall 5 mg (a schedule II controlled substance). Some or

all of these controlled substances were diverted by a technician who subsequently was sentenced to five years in the federal penitentiary.

11. During the period when this diversion was occurring, Clark allowed all pharmacists and technicians working at the Pharmacy to access the cabinet where schedule II controlled substances were stored. Clark further performed no inventory control to prevent diversion, other than the Pharmacy's biennial inventories.

12. On March 24, 2015, during the time that this diversion was occurring, Board investigators performed an inspection of the Pharmacy. During this inspection, the Board investigators determined that, on many occasions, the Pharmacy and Clark had dispensed schedule II controlled substances based on prescriptions that did not include the prescribers' DEA number, had changed schedule II controlled substance prescription strengths without approval from the prescribers, and had dispensed schedule II controlled substance prescriptions too early.

13. After the diversion was discovered, the Pharmacy and Clark filed reports with the Board and the DEA that did not promptly, fully and accurately report the extent of the losses.

13. The Board has been presented with no evidence that, following the discovery of the diversion on August 25, 2015, there have been any further diversions from the Pharmacy.

14. On May 18, 2016, the Pharmacy entered into a Memorandum of Agreement with the DEA. Among other things, that Memorandum of Agreement prohibits the Pharmacy from dispensing Schedule II controlled substances for a period of three (3) years.

DEVICE AND MEDICAL EQUIPMENT VIOLATIONS

15. On June 10, 2015, the Board's investigators inspected the device and medical equipment ("DME") operations at Health Innovations, managed by Clark. The inspection

revealed a number of violations of the Pharmacy Practice Act and its regulations, including failing to keep the DME operations in clean, orderly and sanitary conditions, and failure to keep a number of records required for DME operations.

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(a1), (b) and (c), 90-85.25(b), 90-85.28, 90-85.29, 90-85.38(a)(6), (7) and (9) and (b), 90-85.40(b) and (f), 90-106, 90-108, 106-122; 106-133, 106-134, 106-134.1, 106-135, and 106-140.1; 21 N.C.A.C. 46 .1601(a), 46 .1801, 46 .1802, 46 .1804(a) and (c), 46 .1805, 46 .1809, 46 .1810, 46 .2501, 46 .2502(a), (d), (e) and (k), 46 .2601(b), 46 .2604, 46 .2606, 46 .2607, 46 .2611, and 46 .2801; 21 U.S.C. §§ 331, 351, 352, 353, 353a, 355, 827, 829 and 842; 21 C.F.R. §§ 201.17, 201.18, 211.25, 211.28, 211.42, 211.46, 211.48, 211.56, 211.58, 211.63, 211.65, 211.67, 211.80, 211.84, 211.87, 211.100, 211.103, 211.110, 211.113, 211.122, 211.130, 211.134, 211.137, 211.142, 211.150, 211.160, 211.165, 211.166, 211.167, 211.170, 211.180, 211.182, 211.184, 211.186, 211.188, 211.192, 211.194, 211.196, 1301.71, 1301.76, 1304.21, 1306.05, 1306.12 and 1306.22.

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).

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 TIMOTHY H. CLARK (License No. 12114) is hereby PERMANENTLY SUSPENDED. That suspension shall be served as follows:

a. Active Suspension. Thirty (30) days of the suspension must be served as an active suspension, which suspension shall be served on thirty (30) consecutive days, beginning on Monday, October 31, 2016 at 12:01 a.m., and running through Wednesday, November 30, 2016, at 11:59 p.m.

Clark shall surrender his original wall license, wallet card, and annual renewal to the Executive Director before the commencement of the period of active suspension.

During the 30-day active suspension period, Clark shall not be involved in the practice of pharmacy in North Carolina in any capacity, and shall not enter into any pharmacy in the State of North Carolina, except as a patient with a valid prescription, and for the limited purposes of filling that prescription.

b. Stayed Suspension. The remainder of the permanent suspension shall be stayed INDEFINITELY, upon the following conditions:

- i. Respondent Clark shall violate no laws governing the practice of pharmacy or the distribution of drugs, medical devices or medical equipment; and
- ii. Respondent Clark shall violate no rules or regulations of the Board.

2. The license of Respondent Clark is further restricted in that he consents that he shall not hereinafter serve as pharmacist-manager of any pharmacy, and it is so ordered.

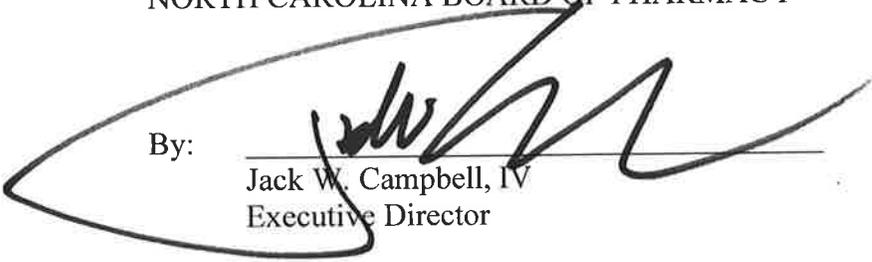
Respondent Clark further consents that this restriction shall be permanent, and he will never request that this restriction be lifted or modified.

3. Respondent Clark shall cooperate with the Board, its attorneys, investigators and other representatives in any investigation regarding compliance with the provisions of this Consent Order.

4. If Respondent Clark fails to comply with any terms or conditions of this Order, the period of stay described above shall be lifted and the Board shall activate the permanent suspension of his license.

This the 18th day of October, 2016.

NORTH CAROLINA BOARD OF PHARMACY

By: 

Jack W. Campbell, IV
Executive Director

Timothy H. Clark, the holder of license number 12114, 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:

Timothy H. Clark Date 10.14.16

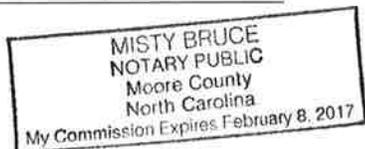
TIMOTHY H. CLARK (License No. 12114)

STATE OF NC

Moore 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: Timothy H. Clark.

Date: 10-14-16



Misty Bruce
Notary Public

My commission expires: 2-8-17

REJECTED BY:

_____ Date _____

TIMOTHY H. CLARK (License No. 12114)