

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of: )

ASHLEA CAUSEY )

(License No. 18841) )

**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 January 5, 2016 and, after appropriate notice, was heard on that day by Board Member Robert A. Graves at the office of the Board. Respondent Ashlea Causey (hereinafter "Respondent" or "Causey") was present and represented by counsel, K. Brooke Ottesen. 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 Ashlea Causey, is, and was at all relevant times referred to herein, the holder of License No. 18841. At all relevant times up to December 3, 2015, Causey was the pharmacist-manager of Bryan Drugs, Inc. (Permit No. 3938), located at 421 Main Street, Tarboro, North Carolina (the "Pharmacy"). Causey 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. Between March 20 and April 17, 2015, on six (6) occasions, the Pharmacy engaged in wholesale shipments into the states of Mississippi, New Jersey, Texas and Virginia, without having the required non-resident permits. In addition, the Pharmacy shipped some of these drugs in opened, partial packages, which was not permitted by some or all of these states. The Pharmacy made these shipments by using services provided by MatchRx to pair interested buying and selling pharmacies for overstocked prescription drugs. Similar services are provided by other companies, including RxCherryPick, RxTrade and ExchangeMeds. In using the MatchRx service, the Pharmacy relied upon representations that the Pharmacy could lawfully ship to other states using the service. The Pharmacy's representatives acknowledged that they should have researched permitting requirements in other states before shipping there, rather than relying upon MatchRx's representations. Although the Board finds that it was not reasonable for the Pharmacy to rely on the representations of a third-party with a profit motive to cause the Pharmacy to use the service, rather than researching legal requirements on its own, the Board finds that the Pharmacy acted in good faith in its reliance.

4. Causey testified that she had further objected to the Pharmacy's shipment of the drugs through MatchRx, unless Pharmacy employees first confirmed with this Board that the shipments were lawful. Causey testified that, when shipments began, she assumed that the Board had been contacted to provide assurances of lawfulness. However, the Board had not been contacted, and – as the pharmacist-manager responsible for assuring compliance with the laws – Causey was personally responsible for ensuring the Pharmacy's compliance with the laws.

5. On April 27, 2015, the Arizona Board of Pharmacy sent a cease and desist letter to another location owned by Bryan Drugs, Inc., requesting that the sister pharmacy cease shipments into Arizona without a permit. The Arizona Board of Pharmacy sent similar letters to a number of other North Carolina pharmacies. The states into which the Pharmacy had shipped (Mississippi, New Jersey, Texas and Virginia) had similar permitting requirements with which the Pharmacy had not complied. Upon the sister pharmacy's receipt of this letter, the Pharmacy immediately stopped using the MatchRx service, and Causey fully cooperated with the Board's investigation of MatchRx shipments.

6. Although Causey cooperated completely with the Board's investigation of the Pharmacy's shipments through MatchRx, the Board is unable to accurately find the full scope of shipments made to other states because MatchRx refused to cooperate fully with the Board's investigation.

7. When an inspection was conducted on August 19, 2015, the Board investigator found a number of violations of the North Carolina Pharmacy Practice Act and its regulations by the Pharmacy, under the management and supervision of Causey:

- a. The Pharmacy maintained in the dispensing stock several drugs that had expired as early as 2011;

- b. The Pharmacy lacked adequate written policies and procedures for the destruction or disposal of adulterated, misbranded, expired and unwanted drugs;
- c. The Pharmacy failed to keep separate prescription files for Schedule II medications;
- d. The Pharmacy failed to obtain and review certificates of analysis for all bulk APIs used for compounding;
- e. The Pharmacy failed to segregate hazardous bulk components for compounding;
- f. The Pharmacy applied beyond-use dates to compounding products that failed to comply with USP <795> and <797> standards, without appropriately securing valid stability information supporting the beyond-use dates and without documenting the circumstances for extending those beyond-use dates, and further set a number of inappropriate and unlawful beyond-use dates for compounded products;
- g. The Pharmacy maintained inadequate and inconsistent master formulation records for compounding products;
- h. The Pharmacy maintained inadequate and unlawful compounding logs and records in a number of respects;
- i. The Pharmacy failed to adequately document the results of quality control procedures;
- j. The Pharmacy failed to have the powder containment hood certified or tested on an appropriate schedule;
- k. The Pharmacy failed to have hood prefilters checked and replaced regularly;
- l. The Pharmacy failed to make available appropriate protective attire for compounding;
- m. The Pharmacy failed to document that adequate temperature and humidity monitors were maintained;
- n. The Pharmacy failed to document adequate training of personnel in a number of required areas;

- o. The Pharmacy failed to calibrate scales, balances and other equipment for measurement annually;
- p. The Pharmacy failed to adequately assess finished preparations in a number of respect, to document the same, and to set policies and procedures for doing so; and
- q. The Pharmacy failed to provide adequate labels for compounded drugs.

8. Causey testified that, during the relevant time period, she was unable to enter the compounding room in order to personally monitor its conditions because of certain medical conditions. However, although being able to personally enter the compounding room undoubtedly would have made supervision easier, Causey could have supervised and ensured the Pharmacy's compliance with compounding and documentation standards without personally entering the compounding room, and – as pharmacist-manager – she was required to do so.

9. The Board has received no evidence of any contamination in the Pharmacy's 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 compounded products.

10. After the inspection, Causey cooperated with the Board's efforts to ensure compliance with all applicable laws governing compounding and documentation. This cooperation includes voluntarily stopping all compounding, other than simple, non-sterile compounding.

11. As substantial mitigating factors in this case, the Board has considered Causey's cooperation with the investigation, her immediate compliance with its obligations not to ship without wholesale permits (once she was alerted to those requirements), and her efforts to promptly remedy compounding and documentation deficiencies. Further, Causey has resigned from her position as pharmacist-manager of the Pharmacy, and she testified that she did so

because she recognized the weighty responsibility involved in serving as the pharmacist-manager of a pharmacy and recognized that she could not supervise this Pharmacy to her satisfaction, in light of certain aspects particular to this Pharmacy. The Board has considered Causey's actions to recognize the responsibility of a pharmacist-manager as another substantial mitigating factor in determining the appropriate disposition of this matter.

### **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 21 N.C.A.C. 46 .2502(k), .2801 and .3001, 21 U.S.C. § 353(e); 21 C.F.R., Part 205 and 1304.04; Miss. Code Ann. § 73-21-105; Miss. Code R. § 30-030-3001; N.J. Stat. Ann. § 24:6B-1; N.J. Admin. Code §§ 8:21-3A.4, 8:21-3A.5 and 8:21-3A.12; Tex. Health & Safety Code §§ 431.402, 431.406; 25 Tex. Admin. Code § 229.424; Va. Code Ann. § 54.1-3435.01; and 18 Va. Admin. Code § 110--50-110.

3. Respondent admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on her 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 the license of Respondent Ashlea Causey (License No. 18841) is hereby REPRIMANDED.

This the 16<sup>th</sup> day of February, 2016.

NORTH CAROLINA BOARD OF PHARMACY

By:



Jack W. Campbell, IV  
Executive Director

Ashlea Causey, the holder of license number 18841, has full knowledge that she has the right to a formal hearing, at which she would have the right to be represented at her expense by counsel, in this matter. The undersigned freely, knowingly and voluntarily waives such right by entering into this Consent Order.

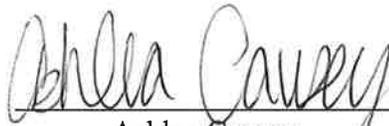
The undersigned understands and agrees that by entering into this Consent Order, she certifies that she has read the foregoing Consent Order and that she voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions which may be taken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

The undersigned further understands that should she 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 she has the right to have counsel of her choice review and advise her with respect to her rights and this Consent Order, and represents that she enters this Consent Order after consultation with her counsel or after knowingly and voluntarily choosing not to consult with counsel.

CONSENTED TO BY:

  
\_\_\_\_\_  
Ashlea Causey  
(License No. 18841)

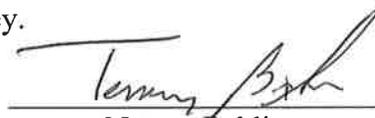
Date 1/25/16

NORTH CAROLINA

EDGE COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the following person(s) personally appeared before me this day, and each acknowledged the due execution of the foregoing document: Ashlea Causey.

Date: 1.25.16

  
\_\_\_\_\_  
Notary Public

My commission expires: 9.25.16

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OBJECTED TO BY: \_\_\_\_\_ Date \_\_\_\_\_  
Ashlea Causey  
(License No. 18841)