

BEFORE THE NORTH CAROLINA BOARD OF PHARMACY

In the Matter of:

Larry R. Cloer)
(License No. 6115))

James Mason)
(License No. 4876))

Plaza Pharmacy)
(Permit No. 6457))

CONSENT ORDER

This matter came on for consideration at a prehearing conference (hereinafter "conference") pursuant to 21 N.C.A.C. 46 .2008. This conference was scheduled for May 31, 2006 and was heard on that day at the Board office before Board member Wallace Nelson. Also present at the conference were the following: Holly Price, Board Investigator; Steve Hudson, Director of Investigations and Inspections; Anna Baird Choi, Counsel for the Board; Larry Cloer, RPh. ("Respondent Cloer"); and James Mason, RPh. ("Respondent Mason"). Based upon the record in this proceeding and the statements and materials presented at the conference, the Board makes the following:

FINDINGS OF FACT

1. Respondent Cloer is the holder of license number 6115. At all relevant times, Respondent Cloer was employed as a staff pharmacist at Plaza Pharmacy ("Respondent Pharmacy"), permit number 6457, located at 20 Franklin Plaza Drive, Franklin, North Carolina.
2. Respondent Mason is the holder of license number 4876. At all relevant times, Respondent Mason was employed as the Pharmacist Manager at Respondent Pharmacy and was also the owner of Respondent Pharmacy.

Complaint 375.05

3. On October 12, 2005, the Board received a complaint alleging that Respondent Cloer had dispensed Paxil to his mother ("the patient") without a prescription. The complainant also alleged that Respondent Cloer had previously dispensed Restoril to the patient without a prescription.
4. During an interview with Investigator Price, Respondent Cloer admitted to dispensing Paxil to the patient on several occasions without a prescription.
5. The investigation produced evidence to show that the patient's physician prescribed Restoril to the patient in March and September of 2005. No evidence was produced to show that Respondent Cloer dispensed Restoril without a prescription to the patient.
6. The investigation produced evidence to show that Respondent Cloer dispensed Lanoxin to the patient without a prescription. However, the investigation also produced evidence to show that the patient had previously been prescribed Lanoxin.
7. The investigation produced evidence to show that Respondent Cloer also dispensed samples of Actos, Diltiazem, Naproxen, Aricept, and Glipizide to the patient without a prescription. However, the investigation also produced evidence to show that previously the patient had been prescribed Actos, Aricept, Diltiazem, and Glipizide.
8. On or about December 13, 2005, Investigator Price visited Respondent Pharmacy and observed a technician working at Respondent Pharmacy who was not registered with the Board.
9. On December 13, 2005, Investigator Price requested information to conduct an audit on Restoril (temazepam), a schedule IV controlled substance. The audit revealed a shortage as follows:

Temazepam 15mg	shortage of 145 tablets
Temazepam 30mg	shortage of 968 tablets

Respondent Mason could not explain the reason for the shortage.

10. On February 8, 2006, Investigator Price returned to Respondent Pharmacy, asked Respondent Mason to review the results of her audit, and asked Respondent Mason to provide her with information as to the cause of the shortage. As of May 8, 2006, Investigator Price had not received a response from Respondent Mason.
11. During the Prehearing Conference, Respondent Cloer stated that the shortage of controlled substances may have been due to his failure to run the controlled substances he was dispensing to his mother through Respondent Pharmacy's computer.

Complaint 97.06

12. On February 24, 2006, the Board received a complaint alleging that Respondent Cloer dispensed Ambien on a prescription order for Diovan. Ambien is a schedule IV controlled substance.
13. The patient informed Investigator Price that on January 10, 2006, Respondent Cloer dispensed Ambien on a prescription order for Diovan. The prescription label on the vial indicated that Diovan had been dispensed. The vial shown to Investigator Price was empty.
14. The patient reported that she began taking the medication on January 12, 2006 and noticed that she would fall asleep during the day. The patient reported that she consumed all of the contents of the prescription.
15. On February 12, 2006 and after obtaining a refill of the medication, the patient reported that the tablets in her refill were different from those dispensed on January 10. She

subsequently contacted Respondent Mason and her physician. She was admitted to the hospital overnight and was discharged the next day. There was no evidence of any long-term harm to the patient.

16. Respondent Mason informed Investigator Price that he did not complete an incident report because he was not able to confirm whether the error actually occurred. Respondent Mason also informed Investigator Price that the patient had previously been prescribed Ambien.
17. During her investigation, Investigator Price obtained daily dispensing records from Respondent Pharmacy. The investigation produced evidence to show that on the dates listed below, Respondent Cloer dispensed prescriptions at the following rates:

<u>Date</u>	<u>New rx</u>	<u>Refill rx</u>	<u>Total rx dispensed</u>
1/5/06	221	210	431
1/12/06	212	174	386
1/19/06	218	166	384
1/26/06	219	195	414

Respondent Pharmacy has subsequently hired additional pharmacy staff to reduce the number of prescriptions filled per pharmacist per day.

18. On March 22, 2006, Investigator Price identified three technicians employed at Respondent Pharmacy who were not registered with the Board.
19. Respondent Mason informed Investigator Price that at times, Respondent Pharmacy would exceed the statutory technician-to-pharmacist ratio.

Based on the above findings, the Board concludes as a matter of law:

CONCLUSIONS OF LAW

1. Respondent Cloer admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on his license under G.S. 90-85.38.
2. Respondent Mason admits that the conduct in this matter constitutes sufficient grounds for disciplinary action on his license under G.S. 90-85.38.
3. Respondent Pharmacy admits that the conduct in this matter constitutes grounds for disciplinary action on its permit under G.S. 90-85.38.
4. Respondent Cloer violated the following statutes and rules when he dispensed medications without a prescription and dispensed Ambien on a prescription order for Diovan:
 - a. G.S. 90-85.38(a)(6), (7), and (9);
 - b. G.S. 90-85.40;
 - c. G.S. 90-106;
 - d. G.S. 90-108;
 - e. G.S. 106-134.1;
 - f. 21 N.C.A.C. 46 .1805;
 - g. 21 U.S.C. 331, 352, 353, 824 and 829; and
 - h. 21 C.F.R. 1306.21.
5. Respondent Mason violated the following statutes and rules when he allowed a pharmacist to dispense medications without a prescription, failed to register pharmacy technicians, allowed pharmacy staff to exceed the technician-to-pharmacist ratio, allowed pharmacists to dispense at an excessive rate, failed to document a misfill error, failed to implement a system of inventory recordkeeping to allow him to detect a shortage of

controlled substances, and failed to provide requested information to the Board's

Investigator:

- a. G.S. 90-85.15A;
 - b. G.S. 90-85.38(a)(6), (7), and (9);
 - c. G.S. 90-85.40;
 - d. G.S. 90-85.47;
 - e. G.S. 90-106;
 - f. G.S. 90-108;
 - g. G.S. 106-134.1;
 - h. 21 N.C.A.C. 46 .1804;
 - i. 21 N.C.A.C. 46 .1805;
 - j. 21 N.C.A.C. 46 .1811;
 - k. 21 N.C.A.C. 46 .2502;
 - l. 21 U.S.C. 331, 352, 353, 824 and 829; and
 - m. 21 C.F.R. 1306.21.
6. Respondent Pharmacy violated the following statutes and rules when it allowed a pharmacist to dispense medications without a prescription, failed to register pharmacy technicians, allowed pharmacy staff to exceed the technician-to-pharmacist ratio, allowed pharmacists to dispense at an excessive rate, failed to document a misfill error, failed to implement a system of inventory recordkeeping to allow the pharmacy to detect a shortage of controlled substances, and failed to provide requested information to the Board's Investigator:
- a. G.S. 90-85.15A;

- b. G.S. 90-85.38(a)(6), (7), and (9);
- c. G.S. 90-85.40;
- d. G.S. 90-85.47;
- e. G.S. 90-106;
- f. G.S. 90-108;
- g. G.S. 106-134.1;
- h. 21 N.C.A.C. 46 .1804;
- i. 21 N.C.A.C. 46 .1805;
- j. 21 N.C.A.C. 46 .1811;
- k. 21 N.C.A.C. 46 .2502;
- l. 21 U.S.C. 331, 352, 353, 824 and 829; and
- m. 21 C.F.R. 1306.21.

Based on the foregoing, and with the consent of the parties, IT IS THEREFORE,
ORDERED, as follows:

1. Respondent Cloer, License No. 6115, is disciplined as follows:
 - a. Respondent Cloer is hereby reprimanded.
 - b. Respondent Cloer shall cooperate with the Board, its attorneys, investigators, and other representatives in any investigation of his practice and compliance with the provisions of this Consent Order.
 - c. Respondent Cloer shall violate no laws governing the practice of pharmacy or the distribution of drugs.
 - d. Respondent Cloer shall violate no rules and regulations of the Board.
 - e. If Respondent Cloer fails to comply with any terms or conditions of this Consent

Order, Respondent Cloer may be subject to additional disciplinary action by the Board.

2. Respondent Mason, License No. 4876, is disciplined as follows:

a. Respondent Mason's license is hereby suspended for five (5) business days. This suspension is stayed for three (3) years, subject to the conditions set forth in below.

b. Respondent Mason shall successfully complete the jurisprudence portion of the Board's licensure examination within six (6) months of the date this Order is approved by the Board.

c. If Respondent Mason is the Pharmacist Manager for Respondent Pharmacy as of the date this Order is approved by the Board, Respondent Mason shall implement a system of accountability of controlled substances and shall submit written documentation of this system to the Board's Executive Director within ninety (90) days of the Board's approval of this Order. The system shall include but is not limited to matters regarding recordkeeping, inventory, and security.

d. If Respondent Mason is the Pharmacist Manager for Respondent Pharmacy as of the date this Order is approved by the Board and if staffing needs require Respondent Pharmacy to exceed the technician-to-pharmacist ratio, Respondent Mason shall request prior approval pursuant to G.S. 90-85.15A(c).

e. Respondent Mason shall cooperate with the Board, its attorneys, investigators, and other representatives in any investigation of his practice and compliance with the provisions of this Consent Order.

f. Respondent Mason shall violate no laws governing the practice of pharmacy or the distribution of drugs.

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

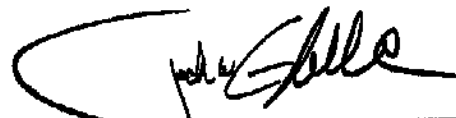
- h. If Respondent Mason fails to comply with any terms or conditions of this Consent Order, Respondent Mason may be subject to additional disciplinary action by the Board.
3. Respondent Pharmacy, permit no. 6457, is disciplined as follows:
- a. Respondent Pharmacy's permit is hereby suspended for five (5) business days. This suspension is stayed for three (3) years, subject to the conditions set forth below.
 - b. Respondent Pharmacy's Pharmacist Manager shall successfully complete the jurisprudence portion of the Board's licensure examination within six (6) months of the date this Order is approved by the Board.
 - c. Respondent Pharmacy's Pharmacist Manager shall implement a system of accountability of controlled substances and shall submit written documentation of this system to the Board's Executive Director within ninety (90) days of the Board's approval of this Order. The system shall include but is not limited to matters regarding recordkeeping, inventory, and security.
 - d. If staffing needs require Respondent Pharmacy to exceed the technician-to-pharmacist ratio, Respondent Pharmacy shall request prior approval pursuant to G.S. 90-85.15A(c).
 - e. Respondent Pharmacy shall cooperate with the Board, its attorneys, investigators, and other representatives in any investigation of its practice and compliance with the provisions of this Consent Order.
 - f. Respondent Pharmacy shall violate no laws governing the practice of pharmacy or the distribution of drugs.
 - g. Respondent Pharmacy shall violate no rules and regulations of the Board.
 - h. If Respondent Pharmacy fails to comply with any terms or conditions of this

Consent Order, Respondent Pharmacy may be subject to additional disciplinary action by the Board.

This the 26 day of September, 2006.

NORTH CAROLINA BOARD OF PHARMACY

By:



Jack W. Campbell, IV
Executive Director

Larry Cloer, the holder of License #6115, has full knowledge that he has the right to a hearing and to be represented by counsel in this matter. He freely, knowingly, and voluntarily waives such right by entering into this Consent Order on behalf of License #6115. 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 out 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.

Larry Cloer, License #6115, accepts Board member Wallace Nelson's proposal in this matter.

CONSENTED TO BY: Larry R. Cloer 8/22/06
Larry Cloer Date
License No. 6115

State of NORTH CAROLINA
MACON County

I, Gwynnoodla McConnell, a Notary Public for the above-named County and State, do hereby certify that Larry Cloer personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witnessed my hand and official seal

This the 22nd day of August, 2006, by Larry Cloer.

Gwynnoodla S. McConnell
Notary Public

Gwynnoodla S. McConnell
Typed or Printed Notary Name

My Commission Expires Nov. 9, 2008

Larry Cloer, License No. 6115, does not accept the proposed Consent Order in this matter.

By: _____ Date _____
Larry Cloer
License No. 6115

James Mason, the holder of License #4876, has full knowledge that he has the right to a hearing and to be represented by counsel in this matter. He freely, knowingly, and voluntarily waives such right by entering into this Consent Order on behalf of License #4876. 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 out 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.

James Mason, License #4876, accepts Board member Wallace Nelson's proposal in this matter.

CONSENTED TO BY: James Mason _____ 8/22/06
James Mason Date
License No. 4876

State of North Carolina

Macon County

I, Gwyndola McConnell, a Notary Public for the above-named County and State, do hereby certify that James Mason personally appeared before me this day and acknowledged the due execution of the foregoing instrument.

Witnessed my hand and official seal

This the 22nd day of August, 2006, by James Mason.

Gwyndola S. McConnell
Notary Public

Gwyndola S. McConnell
Typed or Printed Notary Name

My Commission Expires Nov. 9, 2008

James Mason, License No. 4876, does not accept the proposed Consent Order in this matter.

By: _____ Date _____
James Mason
License No. 4876

I, _____, (name), the undersigned, am _____ (title) for the holder of permit no. 6457 and am authorized to sign this Consent Order. I have full knowledge that the permit holder has the right to a hearing and to be represented by counsel in this matter. I freely, knowingly, and voluntarily waive such right by entering into this Consent Order on behalf of permit no. 6457. I understand and agree that by entering into this Consent Order, I certify that I have read the foregoing Consent Order and that the permit holder voluntarily consents to the terms and conditions set out therein and relinquishes any right to judicial review of Board actions which may be taken concerning this matter. I further understand that should the permit holder violate the terms and conditions of this Consent Order, the Board may take additional disciplinary action. I understand and agree that this Consent Order will not become effective unless and until approved by the Board.

James C. Mason on behalf of permit no. 6457, **accepts** Board member Wallace Nelson's proposal in this matter.

CONSENTED TO BY: James C. Mason 8/22/06
Name: _____ Date
Title OWNER

State of NORTH CAROLINA
MACON County

I, Gwendola M. Connell, the undersigned Notary Public of the County and State aforesaid, certify that James Carter Mason personally appeared before me this day, acknowledging to me that he voluntarily signed the foregoing document for the purposes therein expressed. I have received satisfactory evidence of the principal's identity in the form of DRIVERS LICENCE.

Witness my hand and Notarial stamp or seal

This the 22nd day of August, 2006, by _____

Gwendola S. M. Connell
Notary Public

Gwendola S. M. Connell My Commission Expires Nov. 9, 2008
Typed or Printed Notary Name

_____, _____ on behalf of permit no. 6457, **does not accept** the proposed Consent Order in this matter.

By: _____
Name: _____ Date
Title: _____