

**BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA**

Re:)	Case No. 2005-96
Pharmacist License of)	
REX N. MCKEE)	STATEMENT OF CHARGES
License No. 13841,)	
Respondent)	

COMES NOW, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Secretary/Director for the Iowa Board of Pharmacy Examiners and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 147, 155A and 272C (2005).
3. Respondent was originally licensed as a pharmacist in Iowa by examination on March 9, 1971. Effective May 19, 2005, the Board renewed Respondent's pharmacist license number 13841, allowing Respondent to continue to engage in the practice of a pharmacy subject to the laws of the State of Iowa the rules of the Board.
4. Respondent's pharmacist license number 13841 is current and active until June 30, 2007.
5. Respondent is the pharmacist in charge of Nu-Cara Pharmacy #3, 209 East San Marnan, Waterloo, Iowa 50702.

A. CHARGES

COUNT I – VIOLATION OF PHARMACY COMPOUNDING RULES

The Respondent is charged with failure to comply with Board rules for pharmacy compounding in violation of Iowa Code §§ 155A.12(1) (2005), 155A.12(4) (2005), and 657 Iowa Administrative Code §§ 8.30, 20.4(2), 20.5, 20.6(1), 20.8, 20.9, 20.10, 20.11, 20.12, 36.1(4)(j), and 36.1(4)(cc).

COUNT II – LACK OF PROFESSIONAL COMPETENCY

The Respondent is charged with a lack of professional competency in violation of Iowa Code § 155A.15(2)(c) (2005) and 155A.15(2)(h) (2005) and 657 Iowa Administrative Code § 36.1(4)(b).

COUNT III – CONTROLLED SUBSTANCE VIOLATION

The Respondent is charged with destruction of outdated compounded products containing C-III, C-IV and C-V controlled substances in violation of 657 Iowa Administrative Code § 10.18(1).

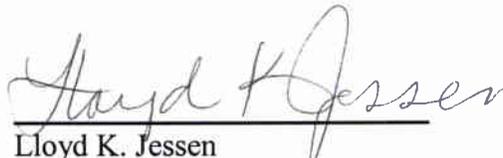
B. CIRCUMSTANCES

On or about June 8, 2005 an inspection and investigation was commenced by the Board, revealing the following:

1. Since approximately December 2000, Respondent and his pharmacy, Nu-Cara Pharmacy #3, has compounded inhalation/nebulizer medications for dispensing to patients, pursuant to prescriptions.
2. The inhalation/nebulizer medications which have been compounded by Respondent and his pharmacy are products consisting primarily of four active ingredients—albuterol, ipratropium, triamcinolone, and morphine—in various combinations.
3. FDA regulations require that inhalation solutions be sterile (21 CFR § 200.51).
4. Preparation of the albuterol—ipratropium—triamcinolone—morphine combination products by Respondent and his pharmacy began with non-sterile ingredients. These products were dispensed in non-sterile containers or vials until approximately July 1, 2005. The products were either not filtered or were inadequately filtered. The final products were not sterilized before they were dispensed to customers. No final products were subjected to proper post-preparation testing for sterility, potency, and pyrogenicity.
5. Respondent and his pharmacy did not have a procedure for ensuring that nebulizer vials contained the proper amount of product.
6. Respondent and his pharmacy did not have a recall procedure for compounded products.
7. Respondent and his pharmacy did not have an acceptable quality assurance program for compounded products.
8. Respondent and his pharmacy did not comply with the Board's administrative rules relating to sterile product compounding.

9. Due to lack of sterility, the inhalation/nebulizer medications prepared by Respondent and his pharmacy were susceptible to microbial growth and contamination. Respondent has demonstrated a lack of professional knowledge and understanding in the area of sterile compounding to such a degree that he has placed patients who have received these products at risk for injury or disease.
10. Respondent and his pharmacy have dispensed a nebulizer solution of albuterol, ipratropium, and triamcinolone which contained subpotent levels of triamcinolone.
11. Respondent and Nu-Cara Pharmacy # 3 have destroyed outdated compounded products containing C-III, C-IV, and C-V controlled substances without proper authority from either the Board or the U.S. Drug Enforcement Administration (DEA).

WHEREFORE, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.



Lloyd K. Jessen
Executive Secretary/Director

On this 13th day of October 2005, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.



Michael J. Seifert, Chairperson
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re:
Pharmacy License of
REX N. McKEE
License No. 13841
Respondent

Case No. 2005-96

STIPULATION AND CONSENT ORDER

Pursuant to Iowa Code §§ 17A.10, 272C.3(2)(f) (2005) and 657 I.A.C. 36.1(2)(k), the Iowa Board of Pharmacy Examiners (hereinafter, "the Board") and Rex N. McKee (hereinafter, "Respondent"), enter into the following Stipulation and Consent Order, settling a licensee disciplinary proceeding currently pending before the Iowa Board of Pharmacy Examiners.

Allegations specified in a Statement of Charges filed against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent was issued a license to practice pharmacy in Iowa on March 9, 1971, after examination, as evidenced by Pharmacist License Number 13841, which is recorded in the permanent records of the Board.
2. The Iowa Pharmacist License issued to and held by Respondent is active and current until June 30, 2007.
3. A Statement of Charges was filed against Respondent on October 13, 2005.
4. Respondent was, at all times material to the Statement of Charges, employed as the pharmacist-in-charge at Nu-Cara Pharmacy #3, 209 East San Marnan, Waterloo, Iowa 50702.
5. The Board has jurisdiction over the parties and jurisdiction over the subject matter of these proceedings.

6. For the purposes of this Stipulation and Consent Order only and without admitting the validity thereof, Respondent does not contest the allegations set forth in the Statement of Charges. Pursuant to 657 I.A.C. § 36.1(2)(k), the parties agree that the Stipulations and Agreements set forth in this Consent Order address and resolve the allegations.

7. As a part of this Stipulation and Consent Order, Respondent agrees that, within sixty (60) days after the date of the Board's approval of this Stipulation and Consent Order, he will submit to the Board, in *typewritten*¹ format, pharmacy policies and procedures regarding (a) compounding of sterile medications, (b) recall of defective products, and (c) destruction of outdated products. Following review and approval by the Board, the Respondent agrees to adhere to these policies and procedures.

8. Should Respondent violate or fail to comply with the terms or conditions of this Stipulation and Consent Order, the Board may initiate action to revoke or suspend Respondent's Iowa license to practice pharmacy or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A and 657 Iowa Administrative Code § 36.1.

9. This Stipulation and Consent Order is the resolution of a contested case. By entering into this Stipulation and Consent Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.

10. This proposed settlement is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be of no force or effect to either the Board or

¹ For the purposes of this order, "typewritten" policies may be generated on computer word-processing equipment.

Respondent. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.

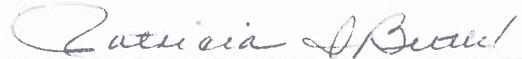
11. The Board's approval of this Stipulation and Consent Order shall constitute a **FINAL ORDER** of the Board in a disciplinary action.

This Stipulation and Consent Order is voluntarily submitted by Respondent to the Board for its consideration on the 23 day of FEBRUARY 2007.



Rex N. McKee, R.Ph.
Respondent

Subscribed and sworn to before me by Rex McKee on this 23 day of FEBRUARY 2007.



NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on the 13 day of March 2007.



_____, Chairperson
Iowa Board of Pharmacy Examiners
400 S.W. Eighth Street, Suite E
Des Moines, Iowa 50309-4688

Copy to:

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