

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

Re:

Pharmacy License of)	COMPLAINT
BAKER DRUG)	AND STATEMENT
License No. 398)	OF CHARGES
Verlyn Dean Moats,)	AND
Pharmacist in charge,)	NOTICE
Respondent)	OF HEARING

COMES NOW, Lloyd K. Jessen, Executive Secretary-Director of the Iowa Board of Pharmacy Examiners, on the 8th day of March, 1993, and files this Complaint and Statement of Charges and Notice of Hearing against Baker Drug, a pharmacy licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Alan M. Shepley, Chairperson; Marian L. Roberts, Vice Chairperson; Donna J. Flower; Phyllis A. Miller; Phyllis A. Olson; Ronald B. Reiff; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent is licensed to operate a pharmacy at 203 East Main in Knoxville, Marion County, Iowa 50138, and holds license number 398.

3. General pharmacy license number 398, issued in the name of Baker Drug, with Verlyn Dean Moats as pharmacist in charge, was renewed on December 10, 1992, and is current until December 31, 1993.

4. The Board has received an investigative report from Pharmacy Investigator Dennis D. Dobesh dated February 25, 1993, and other investigative information which allege the following:

a. A complaint was received on January 28, 1993, which alleged that Respondent was unlawfully dispensing Mexican drugs to patients.

b. On February 5, 1993, Verlyn Dean Moats admitted, in writing, that he had obtained various drugs in Mexico which he dispensed or caused to be dispensed from his pharmacy, Baker Drug, during 1991 and 1992. The drugs included the following: Zantac 150mg, Zantac 300mg, Naprosyn 250mg, Naprosyn 500mg, Tagamet 400mg, Noroxin 400mg, Seldane-D, Feldene 20mg, and Ceclor 500mg. Respondent further admitted that he had obtained the following total quantities of these drugs: 800 tablets in March 1991; 1,000 tablets in September 1991; 1,500 tablets in March 1992; and 1,200 tablets in December 1992.

c. On February 2, 1993, Board Investigators Dennis D. Dobesh and Gary D. Ebeling seized the following Mexican drugs which were found either on the premises of Baker Drug or inside unit-dose containers which had been filled by pharmacists at Baker Drug and delivered to nursing homes for administration to nursing home residents:

728 tablets of Zantac 150mg
23 tablets of Zantac 300mg
825 tablets of Naprosyn 250mg
538 tablets of Naprosyn 500mg
416 tablets of Tagamet 400mg
69 tablets of Noroxin 400mg
34 tablets of Seldane-D
647 capsules of Feldene 20mg
76 capsules of Ceclor 500mg

d. These drugs were obtained over-the-counter in Mexico. In the United States these drugs are prescription-only. The Mexican Zantac was imprinted as "Azantac" and had a different

appearance from Zantac. Some of the other Mexican drugs obtained by Verlyn Dean Moats also had a different appearance and different imprint from their U.S.-counterparts. None of the Mexican-obtained drugs were authorized by the FDA for use in the United States.

e. Drugs such as the ones purchased by Verlyn Dean Moats in Mexico may not be dispensed by Iowa-licensed pharmacies. Yet, Verlyn Dean Moats dispensed these drugs from his pharmacy, Baker Drug, and/or caused these drugs to be dispensed by other pharmacists employed at Baker Drug.

f. Respondent submitted fraudulent claims to the Iowa Medicaid Program and other third party payer programs for an undetermined number of prescriptions for the following drugs: Zantac 150mg, Zantac 300mg, Naprosyn 250mg, Naprosyn 500mg, Tagamet 400mg, Noroxin 400mg, Seldane-D, Feldene 20mg, and Ceclor 500mg. The claims purported to be for U.S.-priced FDA-approved drugs when, in fact, they were for lower priced Mexican drugs which were not intended or approved for use in the United States. By dispensing lower priced Mexican drugs and submitting Medicaid and other third party payer claims for higher-priced American drugs, Verlyn Dean Moats increased his pharmacy's profits.

g. Verlyn Dean Moats removed the Mexican drugs from their original packaging and repackaged them into stock bottles for storage at his pharmacy, Baker Drug. In most cases, the lot numbers and expiration dates of the individual tablets were not recorded or maintained, nor were they indicated on the label of the stock bottles. It is alleged that tablets of various lot numbers and various expiration dates were mixed together.

h. When these Mexican drugs were dispensed to patients by Verlyn Dean Moats and by other pharmacists at Baker Drug (upon Verlyn Dean Moat's instructions), the prescription vials or containers were labeled with the names of the U.S.-counterparts.

i. A zero-based drug audit beginning January 1, 1991, and ending February 3, 1993, revealed that Respondent failed to provide accountability for the following drugs:

<u>Name & Strength</u>	<u>Shortage in # of tablets</u>	<u>% Shortage</u>
Zantac 300mg	> 251 tablets	40%
Naprosyn 500mg	>1,805 tablets	40%
Tagamet 400mg	>2,407 tablets	32%
Noroxin 400mg	>624 tablets	37%
Seldane-D	>771 tablets	39%

j. An inspection of Baker Drug on February 4, 1993, revealed numerous deficiencies relating to the practice of pharmacy and the distribution of controlled substances. Some of these deficiencies were similar in nature to those included in the previous Complaint and Statement of Charges issued to Verlyn Dean Moats on February 7, 1986.

5. Respondent is guilty of violations of 1993 Iowa Code sections 126.3(1), 126.10(1), 126.10(9)(a), 126.10(9)(b), 126.10(9)(c), 155A.15(2)(c), 155A.15(2)(f), and 155A.15(2)(h) by virtue of the allegations contained in paragraph 4.

1993 Iowa Code section 155A.15 provides, in part, the following:

2...The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:...

c. Violated any provision of this chapter or any rule adopted under this chapter or that any owner or employee of the pharmacy has violated any provision of this chapter or any rule adopted under this chapter.

....

f. Delivered mislabeled prescription or nonprescription drugs.

....

h. Failed to keep and maintain records as required by this chapter, the controlled substances Act, or rules adopted under the controlled substances Act.

1993 Iowa Code section 126.3 (formerly 1991 Iowa Code section 203B.3) provides, in part, the following:

The following acts and the causing of the acts within this state are unlawful:

1. The introduction or delivery for introduction into commerce of any drug, device, or cosmetic that is adulterated or misbranded.

1993 Iowa Code section 126.10 (formerly 1991 Iowa Code section 203B.10) provides, in part, the following:

A drug or device is misbranded under any of the following circumstances:

1. If its labeling is false or misleading in any particular.

....

9. a. If it is a drug and its container is so made, formed, or filled as to be misleading.

b. If it is an imitation of another drug.

c. If it is offered for sale under the name of another drug.

6. Respondent is guilty of violations of 657 Iowa Administrative Code sections 8.5(1), 8.14(1)(g), 9.1(4)(b)(2), 9.1(4)(b)(4), 9.1(4)(c), 9.1(4)(j), 9.1(4)(t) and 9.1(4)(u) by virtue of the allegations contained in paragraph 4.

657 Iowa Administrative Code section 8.5 provides, in part, the following:

Unethical conduct or practice. The provisions of this section apply to licensed pharmacists and registered pharmacist-interns.

8.5(1) Misrepresentative deeds. A pharmacist shall not make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

657 Iowa Administrative Code section 8.14 provides, in part, the following:

Prescription label requirements.

8.14(1) The label affixed to or on the dispensing container of any prescription dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:...

g. Unless otherwise directed by the prescriber, the label shall bear the brand name, or if there is no brand name, the generic name of the drug dispensed, the strength of the drug, and the quantity dispensed. ***Under no circumstances shall the label bear the name of any product other than the one dispensed*** (emphasis added).

657 Iowa Administrative Code section 9.1(4) provides, in part, the following:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses:...

b. Professional incompetency. Professional incompetency includes but is not limited to:...

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

....

(4) A willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

c. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engaging in unethical conduct or practice harmful to the public. Proof of actual injury need not be established.

....

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy.

....

t. Obtaining any fee by fraud or misrepresentation.

u. Violating any of the grounds for revocation or suspension of a license listed in Iowa Code sections 147.55, 155A.12 and 155A.15.

The Iowa Board of Pharmacy Examiners finds that paragraphs 5 and 6 constitute grounds for which Respondent's license to operate a pharmacy in Iowa can be suspended or revoked.

WHEREFORE, the undersigned charges that Respondent has violated 1993 Iowa Code sections 126.3(1), 126.10(1), 126.10(9)(a), 126.10(9)(b), 126.10(9)(c), 155A.15(2)(c), 155A.15(2)(f), and 155A.15(2)(h) and 657 Iowa Administrative Code sections 8.5(1), 8.14(1)(g), 9.1(4)(b)(2), 9.1(4)(b)(4), 9.1(4)(c), 9.1(4)(j), 9.1(4)(t), and 9.1(4)(u).

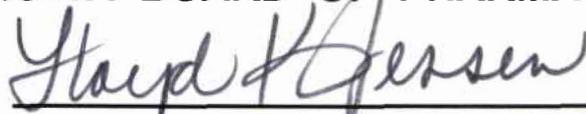
IT IS HEREBY ORDERED pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2, that Verlyn Dean Moats appear on behalf of Baker Drug before the Iowa Board of Pharmacy Examiners on Wednesday, April 7, 1993, at 2:00 p.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to suspend, revoke, or not renew the license to operate a pharmacy issued to Baker Drug on December 10, 1992, and take whatever additional action that they deem necessary and appropriate.

Respondent may bring counsel to the hearing, may cross-examine any witnesses, and may call witnesses of its own. If Respondent fails to appear and defend, Iowa Code section 17A.12(3) provides that the hearing may proceed and that a decision may be rendered. The failure of Respondent to appear could result in the permanent suspension or revocation of its license.

The hearing will be presided over by the Board which will be assisted by an administrative law judge from the Iowa Department of Inspections and Appeals. The office of the Attorney General is responsible for the public interest in these proceedings. Information regarding the hearing may be obtained from Lynette A. F. Donner, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319 (telephone 515/281-8760). Copies of all filings with the Board should also be served on counsel.

IOWA BOARD OF PHARMACY EXAMINERS



Lloyd K. Jessen, Executive Secretary/Director

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacy License of BAKER DRUG License No. 398 Verlyn Dean Moats, Pharmacist in charge, Respondent	} } } } } }	STIPULATION AND INFORMAL SETTLEMENT
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COMES NOW the Iowa Board of Pharmacy Examiners (the Board) and Baker Drug (Respondent) and, pursuant to Iowa Code sections 17A.10 and 258A.3(4), enter into the following Stipulation of the contested case currently on file:

1. Respondent is licensed to operate as a pharmacy at 203 East Main, Knoxville, Marion County, Iowa 50138, and holds license number 398.

2. Respondent's license is current until December 31, 1993.

3. A Complaint and Statement of Charges and Notice of Hearing was filed against Respondent on March 8, 1993.

4. The Board has jurisdiction of the parties and the subject matter.

5. Respondent does not contest the allegations set forth in the complaint. The Respondent agrees that the Board may treat the allegations as true for the purpose of this Informal Settlement only and it is expressly understood that the Respondent is not affirmatively admitting to the

allegations.

6. Respondent's license is placed on indefinite probation from the date of approval of this Stipulation and Informal Settlement. Upon change of ownership, a petition for modification or dissolution of probation may be filed. During the probationary period the Respondent shall obey all federal and state laws, rules, and regulations substantially related to the practice of pharmacy and all federal and state criminal laws.

7. The owner, Verlyn Dean Moats, cannot be employed as a pharmacy assistant and cannot engage in any type of active management associated with the pharmaceutical aspect of the Pharmacy. This condition precludes Mr. Moats from acting as office manager wherein he would generate prescription drug billings. Mr. Moats shall not be permitted to enter the prescription department.

8. Within 30 days of approval of this Stipulation and Informal Settlement, Respondent shall remit a civil penalty in the amount of \$10,000 made payable to the Iowa Board of Pharmacy Examiners to be deposited in the General Fund of the state of Iowa.

9. Should Respondent violate probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation. If a petition to revoke probation is filed against Licensee during probation, the Board shall have continuing jurisdiction until the matter is

final, and the period of probation shall be extended until the matter is final.

10. Stipulation and Informal Settlement is subject to approval of the Board. If the Board approves this Stipulation and Informal Settlement, it becomes the final disposition of this matter. If the Board fails to approve this Stipulation and Informal Settlement, it shall be of no force or effect to either party.

11. This Informal Settlement is voluntarily submitted by the Respondent to the Board for its consideration on the 9 day of April, 1993.


BAKER DRUG
Verlyn Dean Moats,
Pharmacist in charge,
Respondent

Signed and sworn to before me this 9th day of April, 1993.




NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

12. This Informal Settlement is accepted by the Iowa Board of Pharmacy Examiners on the 9th day of April, 1993.


Alan M. Shepley, Chairperson
Iowa Board of Pharmacy Examiners

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

Re:)	
Pharmacy License of)	AMENDED
BAKER DRUG)	STIPULATION
License No. 398)	AND
Lisa A. Crossett,)	INFORMAL
Pharmacist in charge,)	SETTLEMENT
Respondent)	

COMES NOW, Marian L. Roberts, Chairperson of the Iowa Board of Pharmacy Examiners, on the 19th day of April, 1994, and declares that:

1. On April 6, 1994, Lisa A. Crossett, R.Ph., on behalf of Baker Drug (hereafter the Respondent) filed an application with the Iowa Board of Pharmacy Examiners (hereafter the Board), seeking termination of Baker Drug's probationary status in Iowa.

2. On April 19, 1994, the Board considered the Respondent's application and voted to reduce Baker Drug's probation from "indefinite duration" to a date ending the 30th day of June, 1994.

THEREFORE IT IS AGREED that Baker Drug's probation shall be terminated on the 30th day of June, 1994. Further, the conditions of probation expire with the ending of the probation.

DATED this 19th day of April, 1994.

IOWA BOARD OF PHARMACY EXAMINERS



Marian L. Roberts, Chairperson