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THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacy License of	:	
	:	
Freeman Pharmacy, License No. 628,	:	COMPLAINT
Kenneth C. Gee, Pharmacist in Charge,:	:	AND
and Joyce Freeman, Pharmacy Owner, :	:	STATEMENT OF CHARGES
Respondent	:	
	:	
	:	

COMES NOW, Norman C. Johnson, Executive Secretary of the Iowa Board of Pharmacy Examiners, on the 19th day of July, 1988, and files this Complaint and Statement of Charges against Freeman Pharmacy, a pharmacy licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Rollin C. Bridge, Chairperson; Melba L. Scaglione, Vice Chairperson; Donna J. Flower; Marian L. Roberts; John F. Rode; Alan M. Shepley; and Gale W. Stapp are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.
2. Respondent is a licensed pharmacy located at 604 Whittier in Whiting, Monona County, Iowa. Respondent holds general pharmacy license number 628. The Iowa Board of Pharmacy Examiners is authorized to take action against a pharmacy license pursuant to 1987 Iowa Code supplement section 155A.15.
3. General pharmacy license number 628, issued in the name of Freeman Pharmacy, with Morton Freeman as pharmacist in charge and pharmacy owner, was renewed on December 29, 1986, for the license period beginning January 1, 1987, and ending December 31, 1987.
4. On January 9, 1987, Morton Freeman passed away. Mr. Freeman's wife, Joyce Freeman, continued to operate Freeman Pharmacy temporarily without a designated pharmacist in charge, by employing several parttime pharmacists until a fulltime pharmacist could be hired.
5. General pharmacy license number 628, issued in the name of Freeman Pharmacy, with Kenneth C. Gee as pharmacist in charge and Joyce Freeman as pharmacy owner, was issued on September 22, 1987, for the license period ending December 31, 1987.
6. General pharmacy license number 628, issued in the name of Freeman Pharmacy, with Kenneth C. Gee as pharmacist in charge and Joyce Freeman as pharmacy owner, was renewed on February 25, 1988, for the license period beginning January 1, 1988, and ending December 31, 1988.

7. An inspection of Freeman Pharmacy was begun on May 20, 1988, and completed on May 24, 1988, by Pharmacy Investigator Morrell A. Spencer.

8. The results of that inspection as reported by Investigator Spencer's inspection report and his investigative report dated May 26, 1988, reveal the following:

a. On May 24, 1988, Kenneth C. Gee repudiated the general pharmacy license renewal application for Freeman Pharmacy which named him as pharmacist in charge for calendar year 1988 and which was signed by him and dated January 15, 1988. In a statement signed by Mr. Gee and received by Investigator Spencer on May 24, 1988, Mr. Gee claimed that his responsibilities as pharmacist in charge of Freeman Pharmacy terminated on December 31, 1987. He further claimed that he agreed to work at Freeman Pharmacy after December 31, 1987, only as a parttime relief pharmacist. In a letter received at the Board office on June 30, 1988, Mr. Gee again stated that he is not and has not been the pharmacist in charge of Freeman Pharmacy during 1988.

b. Freeman Pharmacy employment records indicate that there was no pharmacist on duty during the following days when Freeman Pharmacy was open for business: Tuesday, January 19, 1988; Thursday, January 21, 1988; Saturday, January 30, 1988; Monday, February 8, 1988; Tuesday, February 9, 1988; Wednesday, February 10, 1988; Friday, February 19, 1988; Thursday, March 10, 1988; Thursday, April 28, 1988; Thursday, May 5, 1988; Wednesday, May 11, 1988; and Tuesday, May 17, 1988.

c. On May 24, 1988, Barbara Yudka, the daughter of pharmacy owner Joyce Freeman and the late Morton Freeman, admitted to having engaged in the unauthorized practice of pharmacy in the absence of and without the contemporaneous supervision of a licensed pharmacist. In a statement signed by Ms. Yudka and received by Investigator Spencer on May 24, 1988, Ms. Yudka admitted that she had functioned as a pharmacist by filling prescriptions on days when Freeman Pharmacy was open for business without a licensed pharmacist on duty.

d. Freeman Pharmacy dispensing records indicate that controlled and noncontrolled prescription drugs were dispensed by Barbara Yudka on the following dates: 8 prescriptions on Tuesday, January 19, 1988; 11 prescriptions on Thursday January 21, 1988; 17 prescriptions on Saturday, January 30, 1988; 38 prescriptions on Monday, February 8, 1988; 19 prescriptions on Tuesday, February 9, 1988; 40 prescriptions on Wednesday, February 10, 1988; 24 prescriptions on Friday, February 19, 1988; 12 prescriptions on Thursday, March 10, 1988; 15 prescriptions on Thursday, April 28, 1988; 16 prescriptions on Thursday, May 5, 1988; 17 prescriptions on Wednesday, May 11, 1988; and 13 prescriptions on Tuesday, May 17, 1988. In summary, a total of 230 prescriptions were illegally filled and dispensed by Barbara Yudka between January 19, 1988, and May 17, 1988.

e. Failure by Respondent to maintain a pharmacy reference library as required: the latest edition and supplements to the USP DI, Advice for

the Patient and the USP DI, Drug Information for the Health Care Provider; and a current Iowa Pharmacy Law and Information Manual.

f. Failure by Respondent to equip the prescription department with a suitable barrier to prevent unauthorized entry in the absence of a licensed pharmacist.

g. Failure by Respondent to remove all outdated prescription drugs from dispensing stock and quarantine them until final disposition.

h. Records kept by Respondent failed to record or include prescription serial number and date of dispensing on prescriptions for controlled drugs for nursing home patients.

i. Records kept by Respondent failed to record or include the pharmacist's initials on all prescription refills.

j. Failure by Respondent to display the pharmacist license and renewal certificate of employee pharmacists and the pharmacist in charge.

k. Failure by Respondent to notify the Board of a change of the pharmacist in charge.

l. Failure by Respondent to comply with prepackaging requirements.

m. Failure by Respondent to ensure the development and implementation of written policies and procedures for unit dose dispensing.

n. Records kept by Respondent failed to record or include the actual date of receipt of drugs on all suppliers' invoices for controlled and noncontrolled prescription drugs.

o. Failure by Respondent to take a biennial inventory of all controlled substances (past due since May 1, 1987).

p. Failure by Respondent to take an inventory of all controlled substances upon a change of pharmacy ownership or a change of the pharmacist in charge.

9. In summary, the findings of Investigator Spencer indicate that Respondent has allowed pharmacy to be practiced illegally by an unauthorized individual and by pharmacists who have failed to keep proper prescription records. In addition, Respondent is currently operating a pharmacy without a valid general pharmacy license.

10. Respondent is guilty of violations of 1987 Iowa Code supplement sections 155A.4(1), 155A.7, 155A.10, 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(e), and 155A.15(2)(h) by virtue of the allegations in paragraph 8, subsections (a) through (p).

Iowa Code supplement section 155A.4(1) provides as follows:

A person shall not dispense prescription drugs unless that

person is a licensed pharmacist or is authorized by section 147.107 to dispense or distribute prescription drugs.

Iowa Code supplement section 155A.7 provides as follows:

A person shall not engage in the practice of pharmacy in this state without a license. The license shall be identified as a pharmacist license.

Iowa Code supplement section 155A.10 provides as follows:

A pharmacist shall publicly display the license to practice pharmacy and the license renewal certificate pursuant to rules adopted by the board.

Iowa Code supplement section 155A.15(2) provides, in part, as follows:

The board shall refuse to issue a pharmacy license for failure to meet the requirements of section 155A.13. 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.

d. Delivered without legal authorization prescription drugs or devices to a person....

e. Allowed an employee who is not a licensed pharmacist to practice pharmacy.

....

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

11. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.3(2), 6.3(3), 6.3(5), 6.6, 6.7(4), 6.8, 6.8(8), 6.8(10), 6.9(1), 8.3(2), 8.9(4)(b), and 10.18 by virtue of the allegations in paragraph 8, subsections (e) through (p).

657 Iowa Administrative Code section 6.3 provides, in part, as follows:

Each pharmacy shall have, as a minimum, the following:

...

2. The latest edition and supplements to the USP DI, Advice for the Patient;

3. The latest edition and supplements to the USP DI, Drug Information for the Health Care Provider;

...

5. Current state pharmacy laws.

657 Iowa Administrative Code section 6.6 provides, in part, as follows:

To ensure appropriate control over drugs and chemicals in the prescription department, the department will be equipped with a suitable barrier of sufficient dimensions to prevent anyone from entering at any time the pharmacist is absent from the department....

657 Iowa Administrative Code section 6.7(4) provides as follows:

Outdated drugs shall be removed from dispensing stock and shall be quarantined together until such drugs are disposed of.

657 Iowa Administrative Code section 6.8 provides, in part, as follows:

Every inventory or other record required to be kept under Iowa Code chapter 204, 1987 Iowa Code supplement chapter 155A, or 657--Chapter 6 shall be kept by the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record. Controlled substance records shall be maintained in a readily retrievable manner in accordance with federal requirements. Those requirements, in summary, are as follows:

...

6.8(8) Suppliers' invoices of prescription drugs and controlled substances shall clearly record the actual date of receipt by the pharmacist or other responsible individual;

...

6.8(10) A biennial inventory of controlled substances shall be maintained....

657 Iowa Administrative Code section 6.9(1) provides as follows:

All prescriptions shall be dated and numbered at the time of initial filling and dated and initialed at the time of each refilling.

657 Iowa Administrative Code section 8.3(2) provides as follows:

Each prepackaged container shall bear a label containing the following information:

- a. Name.
- b. Strength.
- c. Internal control number or date.
- d. Expiration date (if any).
- e. Auxiliary labels, as needed.

657 Iowa Administrative Code section 8.9(4)(b) provides as follows:

The following will apply when a unit dose dispensing system is employed:...

b. Established written policies and procedures shall be available in the pharmacy for inspection by the board or its agents which:

(1) Specify the categories of drugs or drug dosage forms which will or will not be dispensed under the particular unit dispensing system employed.

(2) Specify the pharmacy's recall policy for drugs returned upon a particular manufacturer's or FDA recall.

657 Iowa Administrative Code section 10.18 provides as follows:

It shall be the responsibility of the pharmacy owner to take an inventory of all controlled substances whenever there is a change in ownership or a change in pharmacist/manager of any establishment licensed by the board as defined in 1987 Iowa Code supplement section 155A.13(1).

The Iowa Board of Pharmacy Examiners finds that paragraphs 10 and 11 constitute grounds for which Respondent's license to operate a pharmacy in Iowa can be suspended or revoked.

WHEREFORE, the undersigned charges that Respondent Freeman Pharmacy has violated 1987 Iowa Code supplement sections 155A.4(1), 155A.7, 155A.10, 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(e), and 155A.15(2)(h), as well as sections 6.3(2), 6.3(3), 6.3(5), 6.6, 6.7(4), 6.8, 6.8(8), 6.8(10), 6.9(1), 8.3(2), 8.9(4)(b), and 10.18 of 657 Iowa Administrative Code.

IT IS HEREBY ORDERED that Kenneth C. Gee and Joyce Freeman appear on behalf of Freeman Pharmacy before the Iowa Board of Pharmacy Examiners on August 23, 1988, at 2:00 p.m. in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to suspend or revoke the license to operate a pharmacy issued to Freeman Pharmacy and renewed on February 25, 1988, 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. The failure of Respondent to appear could result in the permanent suspension or revocation of its license. Information regarding the hearing may be obtained from Thomas D. McGrane, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319.

IOWA BOARD OF PHARMACY EXAMINERS


Norman C. Johnson
Executive Secretary

THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacy License of)
Freeman Pharmacy, License No. 628)
Kenneth C. Gee, Pharmacist in Charge,) FINDINGS OF FACT,
and Joyce Freeman, Pharmacy Owner,) CONCLUSIONS OF LAW,
Respondent) AND DECISION

TO: Freeman Pharmacy, Joyce Freeman, Owner:

A Complaint and Statement of Charges was filed by Norman C. Johnson, Executive Secretary of the Iowa Board of Pharmacy Examiners (hereinafter the Board), on the 19th day of July, 1988 alleging that:

1. The Freeman Pharmacy, License No. 628, was operated without a licensed pharmacist in charge from January 9, 1987 through September 22, 1987; and from December 31, 1987 through May 24, 1988.

2. On twelve days in 1988, there was no pharmacist on duty when Freeman Pharmacy was open for business.

3. Barbara Yudka, the daughter of owner Joyce Freeman, engaged in the unauthorized practice of pharmacy in the absence of and without the contemporaneous supervision of a licensed pharmacist at Freeman Pharmacy during 1988. She dispensed 230 controlled and noncontrolled drug prescriptions during 1988.

4. The Respondent pharmacy failed to maintain the required reference library, failed to equip the prescription department with a suitable barrier, failed to remove outdated prescription drugs, failed to keep required records, failed to display the required licenses, failed to notify the Board of a change of the pharmacist in charge, failed to comply with prepackaging requirements, failed to develop and implement written policies and procedures for unit dose dispensing, failed to keep required records, and failed to take required inventories.

5. The Respondent allowed pharmacy to be practiced illegally by an unauthorized individual and by pharmacists who have failed to keep proper prescription records, and the Respondent is currently operating a pharmacy without a valid general pharmacy license.

6. The Respondent is guilty of violations of Iowa Code sections 155A.4(1), 155A.7, 155A.10, 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(e), and 155A.15(2)(h) (Supp. 1987) and 657 Iowa Administrative Code sections 6.3(2), 6.3(3), 6.3(5), 6.6, 6.7(4), 6.8, 6.8(8), 6.8(10), 6.9(1), 8.3(2), 8.9(4)(b), and 10.18.

The hearing on the above Complaint and Statement of Charges was held on August 23, 1988 at 2:00 p.m. in the conference room, Iowa Board of Pharmacy Examiners, Executive Hills West, Des Moines, Iowa 50319. Present were the Board and members of the Board staff. Appearing for the State was Thomas D. McGrane, Assistant Attorney General. Appearing for the Respondent was Gavin Nevans, attorney. Also present for the Respondent pharmacy was Joyce Freeman, owner. Kenneth Gee, pharmacist, was also present. The undersigned Administrative Law Judge from the Iowa Department of Inspections and Appeals presided. At the request of the Respondent, the hearing was closed to the public pursuant to Iowa Code section 258A.6(1) (1987).

At the hearing, the parties stipulated that the violations charged in the Statement of Charges occurred. After hearing the testimony and examining the exhibits, the Board convened in closed executive session pursuant to Iowa Code section 21.5(1)(f)(1987) to deliberate. The undersigned Administrative law Judge was instructed to prepare this Board's Decision and Order.

THE RECORD

The evidentiary record in this case includes the Complaint and Statement of Charges, the recorded testimony of the witnesses and statements of attorneys, and State's Exhibits 1 - 11 (except there is no Exhibit 3) and Freeman Exhibit A.

FINDINGS OF FACT

1. The parties stipulated that the violations contained in the Complaint and Statement of Charges occurred. A copy of the Complaint and Statement of Charges is attached and is incorporated herein by reference as if fully set forth.

2. Selma Mills, a licensed pharmacist, has agreed to become the pharmacist in charge of the Freeman Pharmacy. She is aware of this action and the prior violations and plans to bring the Respondent pharmacy into compliance with Board statutes and rules. Ms. Mills will also be the pharmacist in charge of her own pharmacy in Anthon, Iowa. She will be available between one and one-half and two and one-half days per week to be at the Respondent pharmacy. (Freeman Exhibit A; Attorney Nevans' professional statement)

CONCLUSIONS OF LAW

The Respondent stipulated that it violated 1987 Iowa Code Supplement sections 155A.4(1), 155A.7, 155A.10, 155A.15(2)(c), 155A(2)(d), 155A.15(2)(e), 155A.15(2)(h), and 657 Iowa Administrative Code sections 6.3(2), 6.3(3), 6.3(5), 6.6, 6.7(4), 6.8, 6.8(8), 6.8(10), 6.9(1), 8.3(2), 8.9(4)(b), and 10.18.

DECISION AND ORDER

The Respondent admitted guilt of the charged violations. The dispensing of 230 prescriptions without a licensed pharmacist is an extremely serious offense which endangered the public health. The other violations must also be corrected to protect the public health.

It is therefore the ORDER of the Iowa Board of Pharmacy Examiners that license number 628 issued to the Freeman Pharmacy is hereby suspended for a period of one year, effective upon receipt by Joyce Freeman of this Decision and Order. It is the further ORDER of the Board that this suspension is stayed and the Respondent is placed on probation for a period of five years subject to the following terms and conditions:

(1) The only persons who may have access to and be in the prescription department of the Respondent Freeman Pharmacy at any time are employees of the Freeman Pharmacy who are also licensed pharmacists.

(2) The Respondent will equip the prescription department with a suitable barrier which will prevent access to the prescription department to anyone not having a key. The only persons who may have a key to the prescription department of the Respondent pharmacy are employees who are licensed pharmacists. Joyce Freeman, owner, and her daughter, Barbara Yudka, may not have a key. This barrier will be examined by an investigator from the Iowa Board of Pharmacy Examiners within ten (10) days of the issuance of this Order. The investigator must approve the barrier before the Respondent's prescription department may be open for business.

(3) Within thirty (30) days of the receipt of this Order, the Respondent, by its owner and the pharmacist in charge, must submit a policies and procedures manual regarding the prescription area, prescription services, who will be in charge of taking required inventories and ordering prescription drugs, who has control of keys to the prescription department, security of the prescription department, and store management.

(4) When the prescription department is open, there must always be a licensed pharmacist present. No persons other than a licensed pharmacist may sell prescriptions. The barrier to the prescription department must remain locked when there is not a licensed pharmacist on duty.

(5) A daily log must be kept of who is working in the pharmacy. This log must include the names of all licensed pharmacists, the date and hours worked, and be signed by the licensed pharmacist who is working on each date he or she works. This log must be available for inspection at the pharmacy at any time by the Board or its representative or investigator.

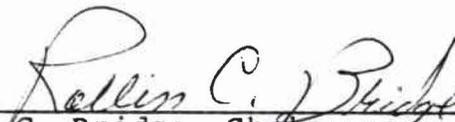
(6) The pharmacist in charge must submit a semiannual report to the Board detailing employee schedules, which employees are licensed pharmacists, hours the prescription department is open, and hours the entire pharmacy is open.

(7) The Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.

(8) Should Respondent violate probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which was stayed. If a petition to revoke probation is filed against Respondent 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.

It is the further ORDER of the Iowa Board of Pharmacy Examiners that the Respondent Joyce Freeman is fined the amount of five thousand dollars (\$5,000.00) to be paid to the Board within thirty (30) days of the receipt of this Order.

Dated this 2ND day of September, 1988.



Rollin C. Bridge, Chairperson
Iowa Board of Pharmacy Examiners



Amy Christensen Couch
Administrative Law Judge
Department of Inspections and Appeals
Lucas State Office Building
Des Moines, Iowa 50319

ACC/jmm

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacy License of	}	COMPLAINT
FREEMAN PHARMACY	}	AND
License No. 628	}	STATEMENT
Joseph G. Schwartz	}	OF CHARGES,
Pharmacist in charge,	}	PETITION TO REVOKE
Joyce Freeman	}	PROBATION
Pharmacy Owner,	}	AND
Respondent	}	NOTICE OF HEARING

COMES NOW, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 30th day of January, 1992, and files this Complaint and Statement of Charges and Petition to Revoke Probation against Freeman Pharmacy, a pharmacy licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Melba L. Scaglione, Chairperson; Alan M. Shepley, Vice Chairperson; Rollin C. Bridge; Donna J. Flower; Phyllis A. Olson; Marian L. Roberts; 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 604 Whittier in Whiting, Iowa, and holds license number 628.

3. General pharmacy license number 628, issued in the name of Freeman Pharmacy, with Joseph G. Schwartz as pharmacist in charge, was renewed on January 6, 1992, and is current until December 31, 1992.

4. In a complaint and statement of charges filed against Respondent on July 19, 1988, Respondent was charged with various violations of the Iowa Code and the Iowa Administrative Code relating to the operation of a pharmacy.

5. Following the issuance of a Board decision and order dated September 2, 1988, Respondent's license to operate a pharmacy in Iowa was suspended for one year. The suspension was stayed, however, and Respondent's license was placed on probation for a period of five years, from September 2, 1988, to September 1, 1993.

6. The decision and order of the Board dated September 2, 1988, also provided, in part, the following:

Respondent is placed on probation for a period of five years subject to the following terms and conditions:...

(2) The Respondent will equip the prescription department with a suitable barrier which will prevent access to the prescription department to anyone not having a key. The only persons who may have a key to the prescription department of the Respondent pharmacy are employees who are licensed pharmacists. Joyce Freeman, owner, and her daughter, Barbara Yudka, may not have a key. This barrier will be examined by an Investigator from the Iowa Board of Pharmacy Examiners within ten (10) days of the issuance of this Order. The investigator must approve the barrier before the Respondent's prescription department may be open for business.

(3) Within thirty (30) days of the receipt of this Order, the Respondent, by its owner and the pharmacist in charge, must submit a policies and procedures manual regarding the prescription area, prescription services, who will be in charge of taking required inventories and ordering prescription drugs, who has control of keys to the prescription department, security of the prescription department, and store management.

....

(5) A daily log must be kept of who is working in the pharmacy. This log must include the names of all licensed pharmacists, the date and hours worked, and be signed by the licensed pharmacist who is working on each date he or she works. This log must be available for inspection at any time by the Board or its representative or investigator.

(6) The pharmacist in charge must submit a semiannual report to the Board detailing employee schedules, which employees are licensed pharmacists, hours the prescription department is open, and hours the entire pharmacy is open.

(7) The Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.

(8) Should Respondent violate probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which was stayed. If a petition to revoke probation is filed against Respondent 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.

7. An inspection of Respondent Freeman Pharmacy was conducted by Pharmacy Investigator Morrell A. Spencer on January 7, 1992. The results of that inspection as reported by Investigator Spencer's inspection report reveal the following:

a. Failure by Respondent to maintain a current pharmacy library as required: (1) the latest edition and supplements to the USP DI Volume IA and IB, Drug Information for the Health Care Provider; (2) the latest edition and supplements to the USP DI Volume II, Advice for the Patient; and (3) the latest edition and supplements to the Approved Drug Products With Therapeutic Equivalence Evaluations or USP DI Volume III.

b. Failure by Respondent to maintain the prescription department with a suitable barrier to prevent unauthorized entry in the absence of a licensed pharmacist.

c. Failure by Respondent to post the telephone number of a poison control center in the pharmacy.

d. Failure by Respondent to display the license of the pharmacy.

e. Failure by Respondent to ensure the development and implementation of written policies and procedures for unit dose dispensing.

f. Failure by Respondent to record the complete address of the purchaser when dispensing Schedule V controlled substances without a prescription.

g. Failure by Respondent to provide a printout of each day's controlled substance prescription activity which has been verified, dated, and signed by each dispensing pharmacist.

h. Failure by Respondent to obtain the prescriber's signature on the following Schedule II prescriptions: prescription number 1534 dated October 15, 1991; prescription number 1630 dated October 25, 1991; prescription number 1632 dated October 26, 1991; prescription number 1724 dated November 7, 1991; prescription number 1732 dated November 20, 1991; prescription number 1739 dated December 4, 1991; prescription number 1793 dated December 17, 1991; prescription number 1794 dated December 23, 1991; prescription number 1795 dated December 23, 1991; and prescription number 1799 dated December 30, 1991.

i. Failure by Respondent to maintain a biennial inventory of all controlled substances (May 1, 1991, biennial inventory missing).

j. Failure by Respondent to maintain, review, and update the policy and procedure manual for the prescription department.

k. Failure by Respondent to maintain a daily log which identifies the pharmacist(s) who worked in the prescription department and which includes the date and hours worked by each pharmacist.

l. Failure by Respondent to submit a semiannual report to the Board detailing employee schedules, which employees are licensed pharmacists, hours the prescription department is open, and hours the entire pharmacy is open.

8. An inspection of Respondent Freeman Pharmacy was also conducted by Pharmacy Investigator Morrell A. Spencer on January 17, 1991. The results of that inspection as reported by Investigator Spencer's inspection report reveal the following:

a. Failure by Respondent to maintain a current pharmacy library as required: (1) the latest edition and supplements to the USP DI Volume IA and IB, Drug Information for the Health Care Provider and (2) the latest edition and supplements to the USP DI Volume II, Advice for the Patient.

b. Failure by Respondent to maintain the prescription department with a suitable barrier to prevent unauthorized entry in the absence of a licensed pharmacist.

c. Failure by Respondent to display the current license of the pharmacy.

d. Failure by Respondent to ensure the development and implementation of written policies and procedures for unit dose dispensing.

e. Failure by Respondent to obtain the prescriber's signature on the following Schedule II prescriptions: prescription number 160542 dated September 7, 1990; prescription number 160645 dated September 19, 1990; prescription number 160694 dated September 24, 1990; prescription number 160844 dated October 5, 1990; prescription number 160880 dated October 9, 1990; prescription number 160950 dated October 16, 1990; prescription number 161025 dated October 24, 1990; prescription number 161032 dated October 24, 1990; prescription number 161202 dated November 5, 1990; prescription number 161245 dated November 8, 1990; prescription number 161425 dated November 27, 1990; prescription number 161510 dated November 30, 1990; prescription number 161665 dated December 12, 1990; prescription number 161664 dated December 12, 1990; prescription number 161702 dated December 17, 1990; prescription number 161720 dated December 19, 1990; prescription number 161743

dated December 20, 1990; prescription number 161933 dated January 4, 1991; and prescription number 162069 dated January 16, 1991.

9. In summary, the findings of Pharmacy Investigator Morrell A. Spencer indicate that the Respondent has failed to comply with the terms and conditions of probation as outlined in the Board's decision and order dated September 2, 1988, and has failed to comply with federal and state laws and regulations related to the practice of pharmacy.

10. Respondent is guilty of violations of Iowa Code sections 155A.13(11), 155A.15(2)(c), 155A.15(2)(h), 155A.27(1)(e), 155A.31, 204.306, and 204.308(1) by virtue of the allegations in paragraphs 7 and 8.

Iowa Code section 155A.13 provides, in part, the following:

11. The license of the pharmacy shall be displayed.

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

2. The board shall refuse to issue a pharmacy license for failure to meet the requirements of section 155A.13. 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.

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

Iowa Code section 155A.27 provides, in part, the following:

Each prescription drug order issued or filled in this state:

1. If written, shall contain:...

e. The name, address, and signature of the practitioner issuing the prescription.

Iowa Code section 155A.31 provides the following:

A licensed pharmacy in this state shall maintain a reference library pursuant to rules of the board.

11. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.3(1), 6.3(2), 6.3(3), 6.3(5), 6.6, 6.8(3), 6.8(10), 8.9(4)(b), 8.11(3)(b), 9.1(4)(i), 9.1(4)(j), 9.1(4)(u), 10.11, 10.11(3), and 10.13(13)(e) by virtue of the allegations in paragraphs 7 and 8.

657 Iowa Administrative Code section 6.3 provides, in part, the following:

Each pharmacy shall have, as a minimum, the following:

1. The latest edition and supplements to the USP DI, Advice for the Patient;
2. The latest edition and supplements to the USP DI, Drug Information for the Health Care Provider;
3. Current toxicology reference text or telephone number of a poison control center;
-
5. The latest edition and supplements to Approved Drug Products With Therapeutic Equivalence Evaluations or USP DI, Volume III.

657 Iowa Administrative Code section 6.6 provides, in part, the following:

To ensure appropriate control over drugs and chemicals in the prescription department, the department will be equipped with a suitable barrier of sufficient dimensions to prevent anyone from entering at any time the pharmacist is absent from the department.

657 Iowa Administrative Code section 6.8 provides, in part, the following:

Every inventory or other record required to be kept under Iowa Code chapters 204 and 155A or 657--Chapter 6 shall be kept by the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record. Controlled substance records shall be maintained in a readily retrievable manner in accordance with federal requirements. Those requirements, in summary, are as follows:...

6.8(3) A Schedule V nonprescription registry book shall be maintained in accordance with subrule 10.13(13).

....
6.8(10) A biennial inventory of controlled substances shall be maintained.

657 Iowa Administrative Code section 8.9 provides, in part, the following:

8.9(4) General procedures. The following will apply when a unit dose dispensing system is employed:...

b. Established written policies and procedures shall be available in the pharmacy for inspection by the board or its agents which:

(1) Specify the categories of drugs or drug dosage forms which will or will not be dispensed under the particular unit dispensing system employed.

(2) Specify the pharmacy's recall policy for drugs returned upon a particular manufacturer's or FDA recall.

657 Iowa Administrative Code section 8.11 provides, in part, the following:

An automated data processing system may be used as an alternative method for the storage and retrieval of prescription information subject to the following conditions:...

8.11(3) Documentation of the correctness of controlled substance prescription information entered into an automated data processing system shall be provided by the individual pharmacist who makes use of such a system. In documenting this information, the pharmacy shall have the option to either:

a. Maintain a bound log book, or separate file, of daily statements which have been signed by each dispensing pharmacist and which state that the information entered into the system that day has been reviewed and is correct as shown; or

b. Provide a printout of each day's controlled substance prescription activity. This printout shall be verified, dated, and signed by each dispensing pharmacist. This printout of the day's controlled substance prescription information shall be provided to the pharmacy using an automated data processing system within 72 hours of the date on which the prescription was dispensed.

This documentation shall be maintained by the pharmacy for two years from the date of last dispensing.

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

4. 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:...

i. Willful or repeated violations of the provisions of Iowa Code chapter 147. Willful or repeated violations of this Act include but are not limited to a pharmacist intentionally or repeatedly violating a lawful rule or regulations promulgated by the board of pharmacy examiners or the state department of health or violating a lawful order of the board in a disciplinary hearing or violating the provisions of Title VII (Public Health) or Title VIII (Practice Acts), Code of Iowa, as amended.

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.

....

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.

657 Iowa Administrative Code section 10.11 provides, in part, the following:

Manner of issuance of prescriptions. All prescriptions for controlled substances shall be dated as of, and manually signed on, the day when issued and shall bear the full name and address and registration number of the practitioner. A practitioner must manually sign a prescription in the same manner the practitioner would sign a check or legal document. Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by those regulations.

....

10.11(3) Identifying prescribers in institutions. All prescriptions issued by individual practitioners (M.D., D.O., et al) practicing in institutions (hospitals or hospital emergency rooms) or other health care systems that do not use prescriber identified prescription forms shall have the name of the individual practitioner typed or hand-printed on it, as well as the usual signature of the physician and their federal registration number.

657 Iowa Administrative Code section 10.13 provides, in part, the following:

10.13(13) Dispensing without prescription. A controlled substance listed in Schedule V which is not a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:...

e. A bound record book for dispensing of controlled substances (other than by prescription) is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase and the name or initials of the pharmacist who dispensed the substance to the purchaser.

12. Respondent is guilty of violating the terms and conditions of probation contained in paragraphs 2, 3, 5, 6, and 7 of the Board decision and order dated September 2, 1988, by virtue of the information contained in paragraphs 7 and 8 of this Complaint and Statement of Charges.

The Iowa Board of Pharmacy Examiners finds that paragraphs 10, 11, and 12 constitute grounds for which Respondent's probation can be revoked and for which its license to operate a pharmacy in Iowa can be suspended or revoked.

WHEREFORE, the undersigned charges that Respondent Freeman Pharmacy has violated Iowa Code sections 155A.13(11), 155A.15(2)(c), 155A.15(2)(h), 155A.27(1)(e), 155A.31, 204.306, and 204.308(1) and 657 Iowa Administrative Code sections 6.3(1), 6.3(2), 6.3(3), 6.3(5), 6.6, 6.8(3), 6.8(10), 8.9(4)(b), 8.11(3)(b), 9.1(4)(i), 9.1(4)(j), 9.1(4)(u), 10.11, 10.11(3), and 10.13(13)(e).

IT IS HEREBY ORDERED, pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2, that Joyce Freeman and Joseph G. Schwartz appear on behalf of Freeman Pharmacy before the Iowa Board of Pharmacy Examiners on Monday, March 2, 1992, at 10:00 a.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 revoke Respondent's probation and to suspend, revoke, or not renew the license to operate a pharmacy issued to Freeman Pharmacy on January 6, 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	}	
FREEMAN PHARMACY	}	STIPULATION
License No. 628	}	AND
Joseph G. Schwartz	}	INFORMAL
Pharmacist in charge,	}	SETTLEMENT
Joyce Freeman	}	
Pharmacy Owner,	}	
Respondents	}	

COMES NOW the Iowa Board of Pharmacy Examiners (the Board) and Freeman Pharmacy (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 a pharmacy at 604 Whittier in Whiting, Iowa, and holds license number 628.

2. Respondent's license to operate a pharmacy in Iowa was renewed on January 6, 1992.

3. Respondent's license is current until December 31, 1992.

4. A Complaint and Statement of Charges, Petition to Revoke Probation, and Notice of Hearing was filed against Respondent on January 30, 1992.

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

6. Respondent does not contest the allegations set forth in the complaint and agrees that the Board may treat the allegations as true. The Respondent understands that there is no admission on his part of the truth of the

allegations, but merely an agreement that the Board may treat the allegations as true for the purpose of this Informal Settlement.

7. Respondent shall remit a \$1,000.00 civil penalty to the Board office within thirty (30) days of the effective date of this Stipulation and Informal Settlement.

8. Respondent's license is placed on probation for a period of five (5) years from the approval of this Stipulation and Informal Settlement. During the probationary period the Respondent shall:

(a) Equip the prescription department with lockable doors which will prevent access to the prescription department to anyone not having a key. The only persons who may have a key to the prescription department of the Respondent pharmacy are employees who are licensed pharmacists. Joyce Freeman, owner, and her daughter, Barbara Freeman, may not have a key.

(b) Submit a policies and procedures manual regarding the prescription area, prescription services (specifically including but not limited to Schedule II prescriptions issued for nursing home patients), who will be in charge of taking required inventories and ordering prescription drugs, who has control of keys to the prescription department, security of the prescription department, and store management.

(c) Keep a daily log of who is working in the pharmacy. This log must include the names of all licensed pharmacists, the date and hours worked, and be signed by the licensed pharmacist who is working on each date he or she works. This

log must be available for inspection at any time by the Board or its representative or investigator.

(d) Submit a semiannual report to the Board detailing employee schedules, which employees are licensed pharmacists, hours the prescription department is open, and hours the entire pharmacy is open.

(e) Complete a quarterly self-inspection for one year beginning April 1, 1992, on forms provided by the Board. Such self-inspection shall be conducted by the pharmacist in charge and shall, upon completion, be submitted to the Board office. Self-inspection reports shall be due no later than April 15, 1992; July 15, 1992; October 15, 1992; and January 15, 1993.

(f) Obey all federal and state laws and regulations substantially related to the practice of pharmacy.

9. Within 90 days from the approval of this Stipulation and Informal Settlement, the Board shall conduct a complete inspection to verify compliance with the terms of this Stipulation and Informal Settlement.

10. Should Respondent violate probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which was stayed. If a petition to revoke probation is filed against Respondent 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.

11. 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.

12. This Informal Settlement is voluntarily submitted by the Respondent to the Board for its consideration on the 4TH day of March, 1992.

Joseph G. Schwartz
Joseph G. Schwartz
Pharmacist in charge
Freeman Pharmacy
Respondent

13. This Informal Settlement is voluntarily submitted by the Respondent to the Board for its consideration on the 4TH day of March, 1992.

Joyce Freeman
Joyce Freeman
Pharmacy Owner
Freeman Pharmacy
Respondent

14. This Informal Settlement is accepted by the Iowa Board of Pharmacy Examiners on the 4th day of March, 1992.

Melba L. Scaglione
MELBA L. SCAGLIONE, Chairperson
Iowa Board of Pharmacy Examiners

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

Re:)
Pharmacy License of)
FREEMAN PHARMACY) **STATEMENT OF CHARGES**
License No. 628)
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 155A and 272C (1997).
3. On December 18, 1996, Freeman Pharmacy, Inc., the Respondent, was issued a renewal of general pharmacy license number 628 by the Board to engage in the operation of pharmacy, subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 628 is current until December 31, 1997.
5. Respondent currently operates a general pharmacy at 604 Whittier, Whiting, Iowa 51063.
6. John L. Zortman has been the pharmacist in charge of Freeman Pharmacy, Inc., since March 15, 1996.
7. Respondent's license to operate a pharmacy was previously disciplined by the Board in 1988 and 1992.

In the 1988 disciplinary action, Respondent's pharmacy license was placed on probation with conditions for five years, from September 2, 1988, to September 2, 1993. In addition, Respondent paid a civil penalty of \$5,000.00.

In the 1992 disciplinary action, Respondent and the Board reached an informal settlement on March 4, 1992, in which Respondent's pharmacy license was placed on probation with conditions for five years, from March 4, 1992, to March 4, 1997. In addition, Respondent paid a civil penalty of \$1,000.00.

COUNT I

The Respondent is charged with failure to comply with the requirements for prescription drug orders filled in Iowa in violation of 1997 Iowa Code §§ 155A.15(2)(c) and 155A.27.

COUNT II

The Respondent is charged with failing to keep and maintain records required by Iowa Code chapter 155A and complete and accurate records of purchases and disposal of drugs listed in the controlled substances Act in violation of 1997 Iowa Code § 155A.15(2)(h).

COUNT III

The Respondent is charged with failure to provide accurate accountability for controlled substances in violation of 1997 Iowa Code § 155A.15(2)(h).

COUNT IV

The Respondent is charged with failure to ensure that a pharmacist adequately supervises delegated acts performed by supportive personnel in violation of 1997 Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code Section 6.1.

COUNT V

The Respondent is charged with failure to maintain controlled substance records in a manner to establish receipt and distribution of all controlled substances in violation of 1997 Iowa Code § 155A.15(2)(h) and 657 Iowa Administrative Code Section 6.8(1).

COUNT VI

The Respondent is charged with failure to distinguish controlled substances from non-controlled substances in pharmacy records in which controlled substances and non-controlled substances are listed together in violation of 1997 Iowa Code § 155A.15(2)(h) and 657 Iowa Administrative Code Section 6.8(7).

COUNT VII

The Respondent is charged with failure to maintain a complete and accurate biennial inventory of controlled substances in violation of 1997 Iowa Code § 155A.15(2)(h) and 657 Iowa Administrative Code Section 6.8(10).

COUNT VIII

The Respondent is charged with engaging in unethical conduct, misrepresentative deeds, and misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy in violation of 1997 Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code Sections 8.5(1) and 9.1(4)(c).

COUNT IX

The Respondent is charged with obtaining a fee by fraud or misrepresentation in violation of 1997 Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code Section 9.1(4)(t).

COUNT X

The Respondent is charged with failure to take an inventory of all controlled substances upon a change of pharmacist in charge of the pharmacy in violation of 1997 Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code Section 10.18.

COUNT XI

The Respondent is charged with failure to maintain the required pharmacy reference library in violation of 1997 Iowa Code § 155A.15(2)(c) and 657 Iowa Administrative Code Section 6.3.

THE CIRCUMSTANCES

1. On April 22, 1997, the Board received a complaint against Respondent alleging unlawful practices at Freeman Pharmacy. A subsequent investigation and audit by Board investigators and U.S. Postal Inspectors confirmed various violations of Iowa law and administrative rules including, but not limited to, the following:

a. Lack of complete information on prescription drug orders processed at Freeman Pharmacy.

b. Lack of complete and accurate records of purchases, dispensing, disposal, and other distribution of prescription drugs, including controlled substances, from Freeman Pharmacy.

c. Inability to accurately account for prescription drugs, including controlled substances, purchased by and dispensed from Freeman Pharmacy.

d. Inadequate and ineffective supervision and control of non-pharmacist employees of Freeman Pharmacy by the pharmacist in charge.

e. Failing to take complete and accurate inventories of controlled substances as required by state and federal law.

f. Obtaining Medicaid fees by fraud or misrepresentation as a result of overbilling for prescription drugs, including controlled substances, allegedly dispensed to Medicaid recipients by Freeman Pharmacy.

2. A general pharmacy inspection of Freeman Pharmacy was conducted on April 29, 1997. The inspection revealed the following deficiencies:

a. Failure to have the current edition of the USP/DI Volume III.

b. Failure to have the current edition of the *Iowa Pharmacy Law and Information Manual*.

c. Failure to take a complete and accurate inventory of controlled substances on March 15, 1996, when there was a change of the pharmacist in charge at Freeman Pharmacy.

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 10th day of September, 1997, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.


Phyllis A. Olson, Chairperson
Iowa Board of Pharmacy Examiners
1209 East Court Avenue
Des Moines, Iowa 50319

cc: Linny Emrich
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319