

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacy License of) PALMER DRUG) License No. 544) Clifford W. Hart,) Pharmacist in charge,) Respondent)	COMPLAINT AND STATEMENT OF CHARGES AND NOTICE OF HEARING
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COMES NOW, Lloyd K. Jessen, Executive Secretary of the Iowa Board of Pharmacy Examiners, on the 5th day of September, 1991, and files this Complaint and Statement of Charges against Palmer Drug, 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 2600 Dodge Street in Dubuque, Iowa, and holds license number 544.

3. General pharmacy license number 544, issued in the name of Palmer Drug, with Clifford W. Hart as pharmacist in charge, was renewed on December 20, 1990, and is current until December 31, 1991. Clifford W. Hart has been the pharmacist in charge of Palmer Drug since 1983. Prior to 1983 the pharmacist in charge of Palmer Drug was Richard E. Palmer.

4. On January 28, 1991, a consumer complaint was received at the Board office which alleged that pharmacists employed at Palmer Drug had repeatedly dispensed two prescription medications, chlorpromazine 50mg (Thorazine 50mg) and doxepin hydrochloride 50mg (Sinequan 50mg), to a female patient without prescriber authorization between 1972 and 1986. It was further alleged that Richard H. Lee, M.D., had issued the original prescriptions for both medications but had not authorized continuous refills. The complaint was referred to Pharmacy Investigator E. Ray Shelden for investigation.

5. On April 3, 1991, the Board received a written statement and a copy of a patient medical record from Richard H. Lee, M.D. Dr. Lee stated that he had first seen the patient around 1971. The patient medical record indicated that Dr. Lee did not see the patient between 1976 and 1986. The patient

medical record also indicated that Dr. Lee did not authorize prescriptions for the patient for chlorpromazine 50mg (Thorazine 50mg) or doxepin hydrochloride 50mg (Sinequan 50mg) between approximately 1976 and September 19, 1986.

6. On April 11, 1991, the Board received an investigative report from Pharmacy Investigator E. Ray Shelden which indicates that pharmacists employed at Palmer Drug dispensed the prescription drugs chlorpromazine 50mg (Thorazine 50mg) and doxepin hydrochloride 50mg (Sinequan 50mg) in the following manner and during the following time period:

a. The patient alleges that on April 3, 1972, Richard H. Lee, M.D., issued her a prescription for chlorpromazine 50mg (Thorazine 50mg). The patient also alleges that on April 17, 1972, Richard H. Lee, M.D., issued her a prescription for doxepin hydrochloride 50mg (Sinequan 50mg). The patient states that after seeing Dr. Lee in April 1972 she did not see him again until 1986.

b. The patient alleges that the prescriptions for chlorpromazine 50mg (Thorazine 50mg) and doxepin hydrochloride 50mg (Sinequan 50mg) were repeatedly and continuously refilled by pharmacists employed at Palmer Drug from 1972 to 1986 without authorization from Richard H. Lee, M.D., or any other authorized prescriber.

c. Evidence produced by the patient indicates that pharmacists employed at Palmer Drug dispensed either doxepin hydrochloride 50mg (Sinequan 50mg) or chlorpromazine 50mg (Thorazine 50mg) on sixteen occasions in 1981, seventeen occasions in 1982, and ten occasions in 1984. The records purport that all of the prescriptions were issued by Richard H. Lee, M.D.

d. Prescription number 657154 obtained from Palmer Drug indicates that a prescription for 100 capsules of doxepin hydrochloride 50mg (Sinequan 50mg) was filled and dispensed to the patient on July 24, 1986. In addition, prescription number 657156 obtained from Palmer Drug indicates that a prescription for 120 tablets of chlorpromazine 50mg (Thorazine 50mg) was filled and dispensed to the patient on July 24, 1986. Pharmacy records from Palmer Drug indicate that prescription numbers 657154 and 657156 were purportedly issued by Richard H. Lee, M.D.

7. Respondent is guilty of violations of Iowa Code sections 155A.15(2)(c), 155A.15(2)(d), 155A.23(2), 155A.23(4), and 155A.29 by virtue of the allegations in paragraphs 4, 5, and 6.

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.

d. Delivered without legal authorization prescription drugs or devices to a person other than one of the following:

(1) A pharmacy licensed by the board.

(2) A practitioner.

(3) A person who procures prescription drugs or devices for the purpose of lawful research, teaching, or testing, and not for resale.

(4) A manufacturer or wholesaler licensed by the board....

Iowa Code section 155A.23 provides, in part, the following:

A person shall not:...

2. Willfully make a false statement in any prescription, report, or record required by this chapter.

....

4. Make or utter any false or forged prescription or written order.

Iowa Code section 155A.29 provides the following:

1. Except as specified in subsection 2, a prescription for any prescription drug or device which is not a controlled substance shall not be filled or refilled more than eighteen months after the date on which the prescription was issued and a prescription which is authorized to be refilled shall not be refilled more than eleven times.

2. A pharmacist may exercise professional judgment by refilling a prescription without prescriber authorization if all of the following are true:

a. The pharmacist is unable to contact the prescriber after reasonable effort.

b. Failure to refill the prescription might result in an interruption of therapeutic regimen or create patient suffering.

c. The pharmacist informs the patient or the patient's representative at the time of dispensing, and the practitioner at the earliest convenience that prescriber reauthorization is required.

3. Prescriptions may be refilled once pursuant to subsection 2 for a period of time reasonably necessary for the pharmacist to secure prescriber authorization.

8. Respondent is guilty of violations of 657 Iowa Administrative Code sections 9.1(4)(b), 9.1(4)(c), 9.1(4)(j), and 9.1(4)(u) by virtue of the allegations in paragraphs 4, 5, and 6.

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:...

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

(1) A substantial lack of knowledge or ability to discharge professional obligations within the scope of the pharmacist's practice.

(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.

(3) A failure by a pharmacist to exercise in a substantial respect that degree of care which is ordinarily exercised by the average pharmacist in the state of Iowa acting under 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.

....

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 7 and 8 constitute grounds for which Respondent's license to operate a pharmacy in Iowa can be suspended or revoked.

WHEREFORE, the undersigned charges that Respondent Palmer Drug has violated Iowa Code sections 155A.15(2)(c), 155A.15(2)(d), 155A.23(2), 155A.23(4), and 155A.29 and 657 Iowa Administrative Code sections 9.1(4)(b), 9.1(4)(c), 9.1(4)(j), 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 Clifford W. Hart appear on behalf of Palmer Drug before the Iowa Board of Pharmacy Examiners on Tuesday, November 19, 1991, at 1:00 p.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

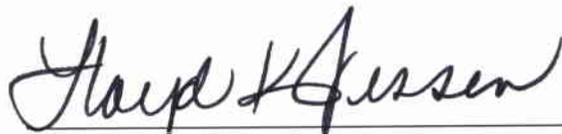
The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to suspend, revoke, or not renew the license to operate a pharmacy issued to Palmer Drug on December 20, 1990, and take whatever additional action that they deem necessary and appropriate.

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

Board approval written policies and procedures for information to be included for prescription refill verification, which shall include the name of the person authorizing refills, and the date and time of the authorization.

7. On or before March 1, 1992, Respondent shall pay a civil penalty in the amount of \$5000 by delivering a check made payable to the Treasurer of Iowa to the Executive Secretary of the Board. The check shall be deposited into the general fund.

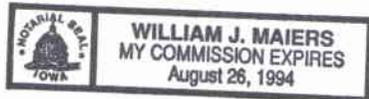
8. This Stipulation and Informal Settlement is subject to approval of the Board. If the Board approves this Stipulation and Informal Settlement, it becomes the final disposition of this matter. If the Board fails to approve this Stipulation and Informal Settlement, it shall be of no force or effect to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

9. This Informal Settlement is voluntarily submitted by the Respondent to the Board for its consideration on the 6 day of JANUARY, 1992.

Palmer Drug
by Clifford W. Hart
PALMER DRUG
By Clifford W. Hart,
Pharmacist in charge,
Respondent

Signed and sworn to before me this 6 day of JANUARY, 1992.

William J. Maiers
NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA



Approved as to form:

William J. Maiers

WILLIAM J. MAIERS
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ATTORNEY FOR RESPONDENT

Lynette A. F. Donner

LYNETTE A. F. DONNER
Assistant Attorney General
Iowa Department of Justice
Second Floor, Hoover Bldg.
Des Moines, Iowa 50319

ATTORNEY FOR THE
PUBLIC INTEREST

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

Melba L. Scaglione

MELBA L. SCAGLIONE, Chairperson
Iowa Board of Pharmacy Examiners