

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

Re:)	COMPLAINT
Pharmacy License of)	AND STATEMENT
TREYNOR CON DRUG)	OF CHARGES
License No. 570)	AND
Ronald J. Schulz,)	NOTICE
Pharmacist in charge,)	OF HEARING
Respondent)	

COMES NOW, Lloyd K. Jessen, Executive Secretary-Director of the Iowa Board of Pharmacy Examiners, on the 3rd day of June, 1993, and files this Complaint and Statement of Charges and Notice of Hearing against Treynor Con Drug, a pharmacy licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Marian L. Roberts, Chairperson; Phyllis A. Olson, Vice Chairperson; Phyllis A. Miller; Mary Pat Mitchell; Matthew C. Osterhaus; 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 8 East Main Street, Treynor, Iowa 51575, and holds license number 570.

3. General pharmacy license number 570, issued in the name of Treynor Con Drug, with Ronald J. Schulz as pharmacist in charge, was renewed on December 21, 1992, and is current until December 31, 1993.

4. The Board has received an investigative report from Pharmacy Investigator Morrell A. Spencer dated February 8, 1993, and other investigative information which allege the following:

a. A complaint was received on January 26, 1993, from "D.R." who alleged that pharmacist Ronald J. Schulz had misfilled prescriptions for her two children: "A.R.," age 21 months, and "J.R.," age 5 years. Although the drug "Vantin" had been prescribed for the children on January 15, 1993, Mr. Schulz initially dispensed the drug "Ventolin." When this dispensing error was brought to his attention, Mr. Schulz then dispensed the drug "Suprax" which he intentionally mislabeled as "Vantin." In addition, when dispensing the Suprax which was falsely labeled as Vantin, Mr. Schulz: (1) dispensed the Suprax in the same bottle which had contained the Ventolin Syrup; (2) failed to provide a complete and correct prescription label (label was *missing* one patient name, the dosage instruction for one patient, a "keep refrigerated" auxiliary label, and the correct dispensing date); (3) failed to obtain the date of birth for both patients as required for patient records; (4) initially failed to provide patient counseling and later provided false information and improper patient counseling; and (5) failed to dispense the medication in a child-resistant container.

b. Ronald J. Schulz gave a false statement to Board Investigator Morrell A. Spencer on February 1, 1993, when he stated that he had dispensed the drug "Vantin" to "J.R." and "A.R." on January 15, 1993. Laboratory testing has confirmed that the prescription container in question contained the drug "Suprax" and not "Vantin."

c. Numerous and repeated pharmacy violations have been documented in four pharmacy inspection reports for Treynor Con Drug dated April 6, 1989; June 26, 1991; November 17, 1992, and February 2, 1993. Included in these reports are the following deficiencies: (1) failure to maintain current library references; (2) no thermometer in refrigerator; (3) pharmacy license not posted; (4) failure to remove numerous outdated prescription drugs from the active dispensing area of the pharmacy; (5) failure to provide lot numbers and expiration dates for repackaged prescription drugs; (6) failure to maintain accurate computerized prescription records resulting in incorrect prescription fill and refill dates; (7) failure to file an application for pharmacy license following a change in the pharmacist in charge of Treynor Con Drug; (8) failure to meet prescription label requirements; (9) failure to properly complete DEA "222" order forms; and (10) failure to routinely prepare and sign a daily computer printout of controlled substance activity.

5. Respondent is guilty of violations of 1993 Iowa Code sections 155A.13(11), 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(f), 155A.15(2)(h), 155A.23(2), 155A.23(5), 155A.28, 155A.31, 155A.32, and 155A.35 by virtue of the allegations contained in paragraph 4.

1993 Iowa Code section 155A.13 provides, in part, the following:

11. The license of the pharmacy shall be displayed.

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.

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

....

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 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.

....

5. Affix any false or forged label to a package or receptacle containing prescription drugs.

1993 Iowa Code section 155A.28 provides the following:

The label of any drug or device sold and dispensed on the prescription of a practitioner shall be in compliance with rules adopted by the board.

1993 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.

1993 Iowa Code section 155A.32 provides the following:

1. If an authorized prescriber prescribes, either in writing or orally, a drug by its brand or trade name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and demonstrated bioavailability as the one prescribed for dispensing and sale to the patient. If the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A, the pharmacist shall exercise professional judgment by selecting a drug product with the same generic name and demonstrated bioavailability as the one prescribed for dispensing and sale. If the pharmacist exercises drug product selection, the pharmacist shall inform the patient of the savings which the patient will obtain as a result of the drug product selection and pass on the patient no less than fifty percent of the difference in actual acquisition costs between the drug prescribed and the drug substituted.

2. The pharmacist shall not exercise the drug product selection described in this section if either of the following is true:

a. The prescriber specifically indicates that no drug product selection shall be made.

b. The person presenting the prescription indicates that only the specific drug product prescribed should be dispensed. However, this paragraph does not apply if the cost of the prescription or any part of it will be paid by expenditure of public funds authorized under chapter 249A.

3. If selection of a generically equivalent product is made under this section, the pharmacist making the selection shall note that fact and the name of the manufacturer of the selected drug on the prescription presented by the patient or the patient's representative.

1993 Iowa Code section 155A.35 provides the following:

A licensed pharmacy shall maintain patient medication records in accordance with rules adopted by the Board.

6. Respondent is guilty of violations of 657 Iowa Administrative Code sections 3.4(6), 6.3(1), 6.3(2), 6.3(5), 6.4(3), 6.7(2), 6.7(4), 6.8, 6.8(8), 8.2(1), 8.3, 8.5(1), 8.11(3), 8.14(1)(c), 8.14(1)(e), 8.14(1)(f), 8.14(1)(g), 8.14(1)(h), 8.15, 8.18(1)(c), 8.18(2), 8.19, 8.20(1), 8.20(2), 9.1(4)(b), 9.1(4)(c), 9.1(4)(j), 9.1(4)(r), 9.1(4)(s), and 9.1(4)(u) by virtue of the allegations contained in paragraph 4.

657 Iowa Administrative Code section 3.4 provides, in part, the following:

6. Change of pharmacist in charge. When the pharmacist in charge position becomes vacant, a newly completed application shall be filed with the board within 90 days of the vacancy indicating the name of the new pharmacist in charge and the old license returned to the board office. A fee of \$100 will be charged for issuance of a new license.

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

Reference library. 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;
-
5. The latest edition and supplements to Approved Drug Products With Therapeutic Equivalence Evaluations or USP DI, Volume III.

657 Iowa Administrative Code section 6.4 provides, in part, the following:

Prescription department equipment. Each pharmacy shall have, as a minimum, the following:...

3. Suitable refrigeration unit. The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration;

657 Iowa Administrative Code section 6.7 provides, in part, the following:

Procurement and storage of drugs. The pharmacist in charge shall be responsible for the procurement and storage of all drugs.

....

2. All drugs shall be stored at the proper temperatures, as defined by the USP/NF.

....

4. 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, the following:

Records. 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.

....

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

657 Iowa Administrative Code section 8.2 provides, in part, the following:

1. 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 provides, in part, the following:

Prepackaging.

1. Control record. Pharmacies may prepackage and label drugs in convenient quantities for subsequent prescription labeling and dispensing. Such drugs shall be prepackaged by or under the direct supervision of a pharmacist. The supervising pharmacist shall prepare and maintain a packaging control record containing the following information:

- a. Date.
- b. Identification of drug.
 - (1) Name.
 - (2) Dosage form.
 - (3) Manufacturer.
 - (4) Manufacturer's lot number.
 - (5) Strength.
 - (6) Expiration date (if any).
- c. Container specification.
- d. Copy of a sample label.
- e. Initials of the packager.
- f. Initials of the supervising pharmacist.
- g. Quantity per container.
- h. Internal control number or date.

2. Label information. 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 8.5 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 8.11 provides, in part, the following:

Automated patient record systems. 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:

....

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.

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

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:...

c. The name of the patient, or if such drug is prescribed for an animal, the species of the animal and the name of its owner;

....

e. The date the prescription is dispensed;

f. The directions or instructions for use, including precautions to be observed;

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.

h. The initials of the dispensing pharmacist.

657 Iowa Administrative Code section 8.15 provides the following:

Records. When a pharmacist exercises the drug product selection prerogative pursuant to Iowa Code section 155A.32, the following information shall be noted:

1. Dispensing instructions by the prescriber or prescriber's agent shall be noted on the file copy of a prescription drug order which is orally communicated to the pharmacist.

2. The name, strength, and either the manufacturer's or distributor's name or the National Drug Code (NDC) of the actual drug product dispensed shall be placed on the file copy of the prescription drug order whether it is issued orally or in writing by the prescriber. This information shall also be indicated on the prescription in those instances where a generically equivalent drug is dispensed from a different manufacturer or distributor than was previously dispensed. This information may be placed upon patient medication records if such records are used to record refill information.

657 Iowa Administrative Code section 8.18 provides, in part, the following:

Pharmaceutical care -- patient records.

1. A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for making a reasonable effort to obtain, record, and maintain the following information:...

c. Patient's age or date of birth.

2. The pharmacist shall be responsible for making a reasonable effort to obtain for the patient or the patient's caregiver, and shall be responsible for recording any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

657 Iowa Administrative Code section 8.19 provides the following:

Pharmaceutical care -- prospective drug review. A pharmacist shall review the patient record and each prescription drug order presented for initial dispensing or refilling for purposes of promoting therapeutic appropriateness by identifying:

1. Overutilization or underutilization;
2. Therapeutic duplication;

3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions;
7. Clinical abuse/misuse.

Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the prescriber. The review and assessment of patient records shall not be delegated to staff assistants other than pharmacist interns.

657 Iowa Administrative Code section 8.20 provides, in part, the following:

Pharmaceutical care -- patient counseling.

1. Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

- a. The name and description of the drug;
- b. The dosage form, dose, route of administration, and duration of drug therapy;
- c. Intended use of the drug, if known, and expected action;
- d. Special directions and precautions for preparation, administration, and use by the patient;

- e. Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
 - f. Techniques for self-monitoring drug therapy;
 - g. Proper storage;
 - h. Prescription refill information;
 - i. Action to be taken in the event of a missed dose;
 - j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.
2. When the patient or the patient's caregiver is present, counseling shall be in person.

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:

(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.

....

r. Willful or repeated malpractice.

s. Willful or gross negligence.

....

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 155A.13(11), 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(f), 155A.15(2)(h), 155A.23(2), 155A.23(5), 155A.28, 155A.31, 155A.32, and 155A.35 and 657 Iowa Administrative Code sections 3.4(6), 6.3(1), 6.3(2), 6.3(5), 6.4(3), 6.7(2), 6.7(4), 6.8, 6.8(8), 8.2(1), 8.3, 8.5(1), 8.11(3), 8.14(1)(c), 8.14(1)(e), 8.14(1)(f), 8.14(1)(g), 8.14(1)(h), 8.15, 8.18(1)(c), 8.18(2), 8.19, 8.20(1), 8.20(2), 9.1(4)(b), 9.1(4)(c), 9.1(4)(j), 9.1(4)(r), 9.1(4)(s), 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 Ronald J. Schulz appear on behalf of Treynor Con Drug before the Iowa Board of Pharmacy Examiners on Tuesday, July 13, 1993, 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 suspend, revoke, or not renew the license to operate a pharmacy issued to Treynor Con Drug on December 21, 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

A handwritten signature in cursive script, reading "Lloyd K. Jessen", written over a horizontal line.

Lloyd K. Jessen
Executive Secretary/Director

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re:)	
Pharmacy License of)	DIA NO.: 93PHB-8
TREYNOR CON DRUG)	
License No. 570)	
Ronald J. Schulz,)	
Pharmacist in Charge,)	FINDINGS OF FACT,
)	CONCLUSIONS OF LAW,
Respondent)	DECISION AND ORDER

To: TREYNOR CON DRUG

A Complaint and Statement of Charges and Notice of Hearing was filed by Lloyd K. Jessen, Executive Secretary of the Iowa Board of Pharmacy Examiners (Board) on June 3, 1993. The Complaint alleged that the Respondent had violated a number of pharmacy-related statutes and rules. The Complaint and Statement of Charges included the Notice of Hearing, which set the hearing for July 13, 1993. The hearing, which was rescheduled, was held on September 14, 1993, at 10:10 a.m. at Executive Hills West, 1209 East Court Avenue, Des Moines, Iowa. The following members of the Board were present: Marian Roberts, Chairperson; Phyllis A. Olson, Vice Chairperson; Phyllis A. Miller, Arlan D. Van Norman, Matthew C. Osterhaus, and Mary Pat Mitchell. Lynnette Donner, Assistant Attorney General, appeared on behalf of the State. The Respondent, Ronald J. Schulz, did not appear nor was he represented by counsel. Margaret LaMarche, Administrative Law Judge from the Iowa Department of Inspections and Appeals, presided. All of the testimony was recorded by a certified court reporter. The hearing was open to the public. After hearing the testimony and examining the exhibits, the Board convened in closed executive session pursuant to Iowa Code section 21.5(1)(f)(1993) to deliberate. The undersigned administrative law judge was instructed to prepare this Board's Decision and Order.

THE RECORD

The record includes the Complaint and Statement of Charges and Notice of Hearing, the notice rescheduling the hearing with attached return receipt card, and the following exhibits:

Exhibit A: Investigative Report dated February 8, 1993, with attachments.

- 1) Complaint report and letter by Diane Rath
- 2) Statement by Shirley Koehler
- 3) Prescription R055529, 30, and 31
- 4) Patient profiles
- 5) Patient Information Record
- 6) Prescription Log, Original

- 7) Prescription Log, Corrected
 - 8) Notes, receipts re: rx R055529, 30 and 31
 - 9) Schulz Statement 1 Feb. 93
 - 10) Schulz Statement 2 Feb. 93
 - 11) Whitmire invoice for Vantin purchase 18 Jan. 93
 - 12) Inspection reports, Treynor Con Drug, 2 Feb. 93, and 17 Nov. 92
 - 13) Inspection reports, Con Drug (Council Bluffs) 2 Feb. 93, and 18 Nov. 92
- Exhibit B: Label, custody receipt, description re: Prescription R055530
- Exhibit C: Correspondence with Upjohn Company dated Feb. 5, 1993 (agreement to test) and March 5, 1993 (results) re: testing of substance in R055530
- Exhibit D: Inspection Report, Treynor Con Drug, June 26, 1991
- Exhibit E: Inspection Report, Treynor Con Drug, April 6, 1989
- Exhibit F: Prior discipline: Preliminary Notice of Hearing dated March 26, 1984, and Stipulation, Order, and Consent finalized April 14, 1984
- Exhibit G: Lederle Laboratories letter dated June 1, 1993

FINDINGS OF FACT

1. Respondent was issued a license to practice pharmacy in Iowa on April 24, 1963, by examination. Respondent's license to practice pharmacy was current until June 30, 1993. (Board file)
2. Respondent is currently self-employed as pharmacist in charge and owner of Treynor Con Drug, 8 East Main Street, Treynor, Iowa 51575. Respondent holds pharmacy license number 570 to operate this pharmacy. (Board file)
3. On January 15, 1993, a physician prescribed the drug "Vantin" for two children, "AR", age 21 months, and "JR", age 5 years. The Respondent dispensed the drug "Ventolin" by mistake. The bottles did not have child safety caps. The grandmother of AR and JR knew that the physician had prescribed an antibiotic and Ventolin was not an antibiotic. She called the physician, who alerted the Respondent to his error. The grandmother returned the two bottles of Ventolin to Treynor Con Drug. The Respondent poured out the contents of one of the bottles, and poured another drug into the

same bottle. The Respondent crossed out "Ventolin" with a pen and wrote "Vantin." (testimony of Morrell Spencer; Exhibits A, B)

4. The Respondent told the patients' grandmother that he did not have enough Vantin for two bottles, but would have the second bottle on January 18, 1993. The label of the bottle he gave to the grandmother had AR's name and dosage typed on it. The Respondent wrote a dosage for JR on the label as well, but JR's name did not appear anywhere on the label. The bottle did not bear a "refrigerate" label, although Vantin must be refrigerated. (testimony of Morrell Spencer; Exhibit A)

5. On Monday, January 18, 1993, the father of AR and JR stopped at the pharmacy, but the Respondent did not have the second bottle of Vantin. The Respondent said he would have it the next day. The next day the father stopped at the pharmacy again. The Respondent asked how the children were doing and if they were better. When the father said he thought so, the Respondent replied "If they are better, maybe we'll just want to skip the second bottle of Vantin." The Respondent said he had it if the father wanted it. The Respondent told the father that the Vantin sells for \$69.95 but he would sell it for \$59.95. The father felt the Respondent really did not want to sell it, so he said he would check with his wife. (testimony of Morrell Spencer, Exhibit A)

6. Later that day the children's mother called K-Mart and Walgreen's pharmacies and found out that Vantin came in a "factory" bottle and there would be no need to pour it into a used bottle. After some discussion, it became apparent that the drug in the bottle was not Vantin. The doctor was called the next day and he telephoned a new prescription for Vantin to another pharmacy. When the two medications were compared, it was clear that they were not the same. Their smell, taste, and consistency were different. (testimony of Morrell Spencer; Exhibit A)

7. The Board's investigator obtained the bottle of medication, dispensed by the Respondent and labeled "Vantin," from the mother. He submitted the bottle to the Upjohn Company, the manufacturer of Vantin, for chemical analysis. The Upjohn Company did not detect the active ingredient in Vantin to be present in the sample which was submitted. (testimony of Morrell Spencer; Exhibits B, C)

8. The Board's investigator examined the purchasing records of the Respondent with his sole supplier, Whitmire Distributing Corporation, Omaha, Nebraska. According to these records, the Respondent had not purchased Vantin prior to January 18, 1993. (testimony of Morrell Spencer; Exhibit A)

9. The Board's investigator submitted a sample of the medication dispensed by Respondent and labeled "Vantin" to Lederle Laboratories, the manufacturer of Suprax. Suprax, which is another

antibiotic, had been previously prescribed for the children. Lederle confirmed that the chemical composition of the medication was consistent with Suprax suspension. (testimony of Morrell Spencer; Exhibit G)

10. Suprax and Vantin are chemically different. It is not legal to substitute Suprax for Vantin in Iowa. (testimony of Morrell Spencer)

11. The Respondent did not clear his computer and print a prescription log each day. As a result his computer would often bear the same date for several days in a row. For example, the prescription label at issue in this case bore a date of 1/13/93, although the prescription was actually written and dispensed on 1/15/93. The Respondent's failure to clear his computer daily was poor management and caused many of his store records to be misdated. (testimony of Morrell Spencer, Exhibits A, B)

12. Numerous and repeated pharmacy violations have been documented in four pharmacy inspection reports for Treynor Con Drug dated April 6, 1989, June 26, 1991, November 17, 1992, and February 2, 1993, including:

- a) failure to maintain current library references (Exhibits A, D)
- b) no thermometer in the refrigerator (Exhibit A)
- c) pharmacy license not posted (Exhibits A, E)
- d) Failure to remove numerous outdated prescription drugs from the active dispensing area of the pharmacy (Exhibits A, E)
- e) failure to provide lot numbers and expiration dates for repackaged prescription drugs (Exhibit A)
- f) failure to maintain accurate computerized prescription records resulting in incorrect prescription fill and refill dates (Exhibit A)
- g) failure to file an application for pharmacy license following a change in the pharmacist in charge of Treynor Con Drug. Charles Hudek, the pharmacist in charge, left Treynor Con Drug on August 16, 1992, and this had not been reported as of November 17, 1992. (Exhibit A)
- h. failure to meet prescription label requirements (Exhibits A, E)
- i. failure to properly complete DEA "222" order forms (Exhibits A, E)
- j. failure to routinely prepare and sign a daily computer printout of controlled substance activity (Exhibit A)

(testimony of Morrell Spencer)

13. On April 4, 1984, the Respondent and the Board entered into a Consent Order which provided that the Respondent repay fees that he obtained in error from the Iowa Medical Assistance program. The

Respondent was to repay \$546.77 to the State of Iowa for overpayments made to the licensee by the Iowa Department of Social (Human) Services during the period from January 1, 1983, to November 15, 1983. (Exhibit F)

14. The Complaint and Statement of Charges and Notice of Hearing was served on the Respondent by certified mail, return receipt requested, more than 30 days prior to the hearing. The Respondent did not appear for the hearing. (Board file, proof of service)

CONCLUSIONS OF LAW

1. 657 IAC 9.5 provides that a notice of hearing involving revocation or suspension of a license shall be served, by personal service or certified mail, return receipt requested, no less than 30 days before the time set for hearing.

657 IAC 9.13 provides that if a Respondent, upon whom a proper notice of hearing has been served, fails to appear either in person or by counsel at the hearing, the Board may proceed with the conduct of the hearing and the Respondent shall be bound by the results of such hearing to the same extent as if the Respondent were present.

The Respondent was properly served with the notice of hearing but failed to appear. He is bound by this decision of the Board.

2. Iowa Code section 155A.15 (1993) 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.

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

. . .
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.

Iowa Code section 155A.23 (1993) 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.

5. Affix any false or forged label to a package or receptacle containing prescription drugs.

Iowa Code section 155A.28 (1993) provides the following:

The label of any drug or device sold and dispensed on the prescription of a practitioner shall be in compliance with rules adopted by the Board.

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:

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:

c. The name of the patient, or if such drug is prescribed for an animal, the species of the animal and the name of its owner;

e. The date the prescription is dispensed;

f. The directions or instructions for use, including precautions to be observed;

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.

h. The initials of the dispensing pharmacist.

657 Iowa Administrative Code section 8.20 provides, in part, the following:

Pharmaceutical care -- patient counseling.

1. Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

- a. The name and description of the drug;
- b. The dosage form, dose, route of administration, and duration of drug therapy;
- c. Intended use of the drug, if known, and expected action;
- d. Special directions and precautions for preparation, administration, and use by the patient;
- e. Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- f. Techniques for self-monitoring drug therapy;
- g. Proper storage;
- h. Prescription refill information;
- i. Action to be taken in the event of a missed dose;
- j. Pharmacist comments relevant to the individual's drug therapy including any other information peculiar to the specific patient or drug.

2. When the patient or the patient's caregiver is present, counseling shall be in person.

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.

(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.

The preponderance of the evidence established that the Respondent violated Iowa Code sections 155A.15(2)(d), (f), 155A.23, 155A.28 and 657 IAC 8.5, 8.14(1)(c), (e), (f) and (g), and 9.1(4)(b)(2), (3), and (4), and 9.1(c) when he purposefully dispensed the antibiotic "Suprax" while filling a prescription for "Vantin" and when he failed to provide the correct drug name, one of the patient's names, the correct date, and a "refrigerate" auxiliary label on the label of the prescription bottle.

The laboratory reports, visual observation of the liquid medication, and the absence of any inventory records for the purchase of Vantin, prior to January 18, 1993, all established that the Respondent intentionally dispensed Suprax to these patients. The "Suprax" was chemically different from "Vantin" and could not be legally substituted for the Vantin. The Respondent did not have legal authorization to deliver "Suprax" to the patient and therefore violated Iowa Code section 155A.15(d). In addition, the Respondent falsely labeled the "Suprax" as "Vantin" in violation of Iowa Code sections 155A.15(f), 155A.23, 155A.28 and 657 IAC 8.14(1)(g). The prescription label did not bear one patient's name, the correct date, or a required auxiliary label, in violation of Iowa Code section 155A.15(f), 155A.28 and 657 IAC 8.14(1)(c), (e) and (f).

The actions of the Respondent concerning this prescription constitute unethical conduct, in violation of 657 IAC 8.5. The substitution of the Suprax, without the knowledge of the prescribing physician or the patient, was a deceitful practice or transaction in pharmacy and in the operation or conduct of a pharmacy.

The Respondent violated 657 IAC 8.20(1)(b) when he provided improper counseling to a patients' caregiver by telling the caregiver that it was unnecessary to complete the course of antibiotic treatment if the patients were improving.

The Respondent's deceitful substitution of "Suprax" for "Vantin," his improper and incorrect labeling of the prescription bottle, and his improper counseling of the patient constitute professional incompetency, in violation of 657 IAC 9.1(4)(b)(2), (3), (4) and 9.1(4)(c). The Respondent's actions demonstrated a gross disregard for the health and welfare of the patients and were a substantial deviation 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. In addition, the Respondent failed to exercise that degree of care ordinarily exercised by the average pharmacist and failed to conform to the minimal standards or acceptable and prevailing practice of pharmacy in Iowa. The Respondent knowingly made deceptive and untrue representations in the practice of pharmacy, in violation of 657 IAC 9.1(4)(c).

3. Iowa Code section 155A.13 (1993) provides, in part, the following:

11. The license of the pharmacy shall be displayed.

Iowa Code section 155A.31 (1993) provides the following:

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

Iowa Code section 155A.35 (1993) provides the following:

A licensed pharmacy shall maintain patient medication records in accordance with rules adopted by the Board.

657 Iowa Administrative Code section 3.4 provides, in part, the following:

6. Change of pharmacist in charge. When the pharmacist in charge position becomes vacant, a newly completed application shall be filed with the board within 90 days of the vacancy indicating the name of the new pharmacist in charge and the old license returned to the board office. A fee of \$100 will be charged for issuance of a new license.

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

Reference library. 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;

5. The latest edition and supplements to Approved Drug Products with Therapeutic Equivalence Evaluations or USP DI, Volume III.

657 Iowa Administrative Code section 6.4 provides, in part, the following:

Prescription department equipment. Each pharmacy shall have, as a minimum, the following:

3. Suitable refrigeration unit. The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration;

657 Iowa Administrative Code section 6.7 provides, in part, the following:

Procurement and storage of drugs. The pharmacist in charge shall be responsible for the procurement and storage of all drugs.

2. All drugs shall be stored at the proper temperatures, as defined by the USP/NF.

4. 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, the following:

Records. 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.

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

657 Iowa Administrative Code section 8.2 provides, in part, the following:

1. 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 provides, in part, the following:

Prepackaging.

1. Control record. Pharmacies may prepackage and label drugs in convenient quantities for subsequent prescription labeling and dispensing. Such drugs shall be prepackaged by or under the direct supervision of a pharmacist. The supervising pharmacist shall prepare and maintain a packaging control record containing the following information:

- (4) Manufacturer's lot number.
- (6) Expiration date (if any).

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

Automated patient record systems. 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:

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.

The preponderance of the evidence established that the Respondent has repeatedly violated Iowa Code section 155A.13 by his failure to post his pharmacy license. The Respondent has repeatedly violated Iowa Code section 155A.31 and 657 IAC 6.3 by his failure to maintain a reference library as required by the rules of the Board. The Respondent has violated Iowa Code section 155A.35 and 657 IAC 8.2(1), 8.11 and 8.18 when he failed to maintain accurate computerized prescription records resulting in incorrect prescription fill and refill dates. The Respondent violated 651 IAC 3.4 when he failed to notify the Board of change in the pharmacist-in-charge at Treynor Con Drug. The Respondent violated 657 IAC 6.4(3) and

6.7(2) when he failed to have a thermometer in his refrigerator. The Respondent violated 657 IAC 6.7 when he repeatedly failed to remove numerous outdated prescription drugs from the active dispensing area of the pharmacy. The Respondent violated Iowa Code section 155A.15(2)(h) and 657 IAC 6.8 and 8.11 when he failed to properly complete DEA "222" order forms and to routinely prepare and sign a daily computer printout of controlled substance activity. The Respondent violated 657 IAC 8.3 when he failed to provide lot numbers and expiration dates for repackaged prescription drugs.

DECISION AND ORDER

THEREFORE, IT IS THE ORDER of the Iowa Board of Pharmacy Examiners that the pharmacy license of TREYNOR CON DRUG, License No. 570, is hereby REVOKED.

Finally, it is ORDERED, pursuant to Iowa Code section 272C.6 and 657 IAC 9.27, that the Respondent shall pay \$75.00 for fees associated with conducting the disciplinary hearing. In addition, the executive secretary of the Board shall bill the Respondent for witness fees and expenses and any transcript costs associated with the disciplinary hearing. The Respondent shall remit for these expenses within thirty (30) days of receipt of the bill.

Dated this 12 day of October, 1993.



Marian L. Roberts, Chairperson
Iowa Board of Pharmacy Examiners

ML/jmm

Copy to: Lynnette Donner