

THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacy License of :  
 :  
 : **COMPLAINT**  
 **LONG'S DRUG**, Lic. No. 131, : **AND**  
 Phillip R. Tuetken, Pharmacist : **STATEMENT OF CHARGES**  
 In Charge and Corporate :  
 President, Respondent :

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COMES NOW, Norman C. Johnson, Executive Secretary of the Iowa Board of Pharmacy Examiners, on the 12th day of February, 1988, and files this Complaint and Statement of Charges against Long's Drug, a pharmacy licensed pursuant to Iowa Code Chapter 155A, and alleges that:

1. Rollin C. Bridge, Chairperson; Jerry M. Hartleip, Vice Chairperson; Donna J. Flower; John F. Rode; Melba L. Scaglione; Alan M. Shepley; and Gale W. Stapp are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent is licensed to operate a pharmacy at 419 East First Street in Monticello, Jones County, Iowa, and holds license number 131.

3. General pharmacy license number 131, issued in the name of Long's Drug, with Phillip R. Tuetken as pharmacist in charge and president, was renewed on February 1, 1988, and expires on December 31, 1988.

4. An inspection of Long's Drug was conducted on October 26, 1987, by Pharmacy Investigator E. Ray Shelden.

5. The results of that inspection as revealed by Investigator Shelden's report dated October 29, 1987, reveal the following:

a. On or about October 26, 1987, Respondent allowed a pharmacist to attempt to dispense a prescription drug, Monistat Vaginal Cream, to a patient, A. Mesch, on the verbal order of Dr. Herbert A. Gearhart, D. O., of Hopkinton, Iowa, without reducing the prescription to writing and without labeling the medication.

b. Records kept by Respondent failed to record or include patient addresses on prescriptions for controlled drugs.

c. Records of Respondent failed to identify prescriptions for Schedule III, IV, and V controlled drugs with a red "C" in a filing system where controlled and non-controlled drug prescriptions are filed together.



d. Respondent kept approximately 200 outdated pharmaceuticals in dispensing stock.

e. Failure by Respondent to maintain the prescription department in a sanitary condition.

f. On March 26, 1987, Respondent allowed a pharmacist to use Dexedrine Spansules 10 mg. which had expired on July 31, 1985, to fill prescription number 414462. Respondent allowed the dispensing of sixteen outdated Dexedrine Spansules 10 mg.

g. On April 23, 1987, Respondent allowed a pharmacist to use Dexedrine Spansules 10 mg. which had expired on July 31, 1985, to fill prescription number 415883. Respondent allowed the dispensing of one hundred outdated Dexedrine Spansules 10 mg.

h. On March 25, 1987, Respondent allowed a pharmacist to alter prescription number 414527 for Dilaudid 4 mg., a Schedule II controlled substance. The pharmacist was allowed to change the drug strength from 4 mg. to 3 mg. without explanation, change in directions for use, or documentation of prescriber authorization.

i. Failure by Respondent to account for one DEA order form 222c (#860090402) or to report it as missing.

j. On October 30, 1987, Respondent allowed a pharmacist to create a false prescription for patient Nancy Kraus and dispense 120 Imipramine 50 mg. without prescriber authorization. A pharmacist falsely indicated that Dr. John J. Randolph, M. D., of Monticello, Iowa, had authorized the prescription.

k. On October 30, 1987, Respondent allowed a pharmacist to create a false prescription for patient Ruth Cox and dispense 40 Vapocet tablets, a Schedule III controlled substance, without prescriber authorization. A pharmacist falsely indicated that Dr. Jonathan C. Lindo, M. D., of Monticello, Iowa, had authorized the prescription.

l. On August 17, 1987, Respondent allowed prescription number 421081 to be filled with Milpath 200 mg. tablets which had expired in August 1984. Respondent allowed the dispensing of thirty outdated Milpath 200 mg. tablets.

m. Failure by Respondent to provide accountability for 3.4% (15 capsules) of the pharmacy's stock of Dexedrine 10 mg. Spansules between June 15, 1985, and May 9, 1987.

n. Records kept by Respondent failed to record or include the patient name, patient address, and date of issue on prescription number 421208 for Chloramphenicol Otic.

o. Failure by Respondent to ensure that its pharmacists complied with prescription transfer rules or obtained prescriber authorization for the following three prescriptions originally filled at the Wal-Mart Pharmacy in Anamosa, Iowa: (1) prescription number 416930 for 100 Ogen 0.625 mg.; (2) prescription number 416931 for 40 Provera 10 mg.; and (3) prescription number 422067 for 100 Glucotrol 10 mg.

6. In summary, the findings of Investigator Sheldon indicate that Respondent has allowed pharmacy to be practiced in an illegal, unethical, and unprofessional manner by pharmacists who improperly made out prescriptions, failed to keep proper prescription records, made false prescriptions, sold outdated prescription drugs, altered prescriptions, and failed to properly account for a federal order form for Schedule II controlled substances.

7. Respondent is guilty of violations of former Iowa Code section 155.29(1)(b) and current Iowa Code sections 155A.15(2)(d), 155A.19(1)(g), 155A.23(1)(b), 155A.23(4), 155A.27(1)(a) and (b), 155A.27(2), 155A.28, 155A.34, 204.306, 204.307, 204.308(3), 204.402(1)(a) and (c), and 204.403(1)(d) by virtue of the allegations in paragraph 5, subsections (a), (b), (c), (f), (g), (h), (i), (j), (k), (l), (m), (n), and (o).

Iowa Code section 155A.15(2) provides, in part, the following:

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.

....

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.19 provides, in part, the following:

1. A pharmacy shall report in writing to the board, pursuant to its rules, the following:...

g. Theft or significant loss of any controlled substance on discovery of the theft or loss.

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

"A person shall not:...

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

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:

a. The date of issue.

b. The name and address of the patient for whom, or the owner of the animal for which, the drug is dispensed.

....

2. If oral, the practitioner issuing the prescription shall furnish the same information required for a written prescription, except for the written signature and address of the practitioner. Upon receipt of an oral prescription, the pharmacist shall promptly reduce the oral prescription to a written format by recording the information required in a written prescription.

Iowa Code section 155A.28 provides as follows:

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.

Iowa Code section 155A.34 provides as follows:

A pharmacist may transfer a valid prescription order to another pharmacist pursuant to rules adopted by the board.

Former Iowa Code section 155.29(1)(b) (in effect through June 30, 1987) and current Iowa Code section 155A.23(1)(b) (effective July 1, 1987) provide that a person shall not:

Obtain or attempt to obtain a prescription drug or procure or attempt to procure the administration of a prescription drug by:...

Forgery or alteration of a prescription or of any written order.

Iowa Code section 204.306 provides the following:

Persons registered to manufacture, distribute, dispense, or administer controlled substances under this chapter shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and with such additional rules as may be issued by the board....

Iowa Code section 204.307 provides the following:

Controlled substances in schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.

Iowa Code section 204.308(3) provides the following:

Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in schedule III or IV, which is a prescription drug as determined under Chapter 155A, shall not be dispensed without a written or oral prescription of a practitioner. The prescription may not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner.

Iowa Code section 204.402(1) provides, in part, the following:

It is unlawful for any person:

a. Who is subject to division III to distribute or dispense a controlled substance in violation of section 204.308.

....

c. To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under this chapter.

Iowa Code section 204.403(1) provides, in part, the following:

It is unlawful for any person knowingly or intentionally:...

d. To furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this chapter, or any record required to be kept by this chapter....

8. Respondent is guilty of violations of 21 Code of Federal Regulations sections 1301.76(b), 1304.04(h)(2), 1305.12(b), and 1306.05(a) by virtue of the allegations in paragraph 5, subsections (b), (c), (i), and (m).

21 Code of Federal Regulations section 1301.76(b) provides the following:

The registrant shall notify the Field Division Office of the Administration in his area of the theft or significant loss of any controlled substances upon discovery of such loss or theft. The registrant shall also complete DEA (or BND) Form 106 regarding such loss or theft.

21 Code of Federal Regulations section 1304.04(h) provides, in part, the following:

Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:...

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1-inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances.

21 Code of Federal Regulations section 1305.12(b) provides, in part, the following:

Whenever any used or unused order forms are stolen from or lost (otherwise than in the course of transmission) by any purchaser or supplier, he shall immediately upon discovery of such theft or loss, report the same to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post

Office Box 28083, Central Station, Washington, D. C. 20005, stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers.

21 Code of Federal Regulations section 1306.05(a) provides, in part, the following:

All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and the name, address, and registration number of 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 these regulations.

9. Respondent is guilty of violations of 620 Iowa Administrative Code section 2.2(2) and 657 Iowa Administrative Code sections 6.7(3), 6.7(4), 6.9(1), 6.9(2), 6.9(3), 8.1(3), and 10.10 by virtue of the allegations in paragraph 5, subsections (a), (d), (e), (f), (g), (l), (m), and (o).

620 Iowa Administrative Code section 2.2(2), in effect at all times herein and until January 19, 1988, provided the following:

Storage areas, restrooms, basement and all other areas in the pharmacy shall be kept in a thoroughly clean condition.

657 Iowa Administrative Code section 6.7(3) provides the following:

Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

657 Iowa Administrative Code section 6.7(4) provides the following:

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

657 Iowa Administrative Code section 6.9 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.

(2) The original prescription, whether transmitted orally

or in writing, must be retained by the pharmacy filling the prescription.

(3) A pharmacist may refill a copy of a prescription for drug products other than those classified as controlled substances according to the following procedure:

a. The pharmacist issuing a written or oral copy of a prescription shall cancel the original prescription by recording on its face the date the copy is issued, the name of the pharmacy to whom issued, and the signature of the pharmacist issuing the copy.

b. The written or oral copy issued shall be an exact duplicate of the original prescription except that it shall also include the issuing pharmacy's prescription or serial number, the name of the pharmacy issuing the copy and the number of authorized refills remaining available to the patient.

c. The pharmacist receiving the oral copy of a prescription must exercise reasonable diligence in determining the validity of the copy.

d. The pharmacist receiving the written copy of a prescription must contact the issuing pharmacy to determine the validity of the copy.

e. A prescription meeting all the requirements of 6.9(3)"b" shall be treated by the receiving pharmacy as a new prescription.

f. Copies of nonrefillable prescriptions shall be marked "For Information Purposes Only" and shall not be filled without prescriber authorization.

657 Iowa Administrative Code section 8.1(3) provides the following:

[T]he phrase "fill the prescriptions" shall be deemed to include, but not necessarily be limited to...

[ensuring] adequate label directions as are necessary to assure the patient's understanding of the prescriber's intentions.

657 Iowa Administrative Code section 10.10 provides, in part, the following:

All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a person has provided effective controls against diversion, the board shall use the security requirements set forth in these rules as standards for the physical security controls and operating

procedures necessary to prevent diversion....

The Iowa Board of Pharmacy Examiners finds that paragraphs 7, 8, and 9 constitute grounds for which Respondent's license to operate a pharmacy in Iowa can be suspended or revoked.

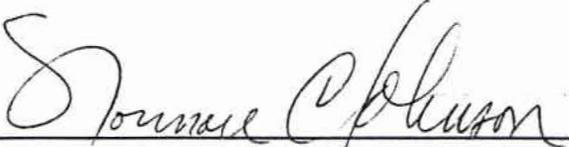
WHEREFORE, the undersigned charges that Respondent Long's Drug has violated former section 155.29(1)(b) of the Code of Iowa 1987; current sections 155A.15(2)(d), 155A.19(1)(g), 155A.23(1)(b), 155A.23(4), 155A.27(1)(a) and (b), 155A.27(2), 155A.28, 155A.34, 204.306, 204.307, 204.308(3), 204.402(1)(a) and (c), and 204.403(1)(d) of the Code of Iowa 1987; sections 1301.76(b), 1304.04(h)(2), 1305.12(b), and 1306.05(a) of 21 Code of Federal Regulations; section 2.2(2) of 620 Iowa Administrative Code; and sections 6.7(3), 6.7(4), 6.9(1), 6.9(2), 6.9(3), 8.1(3), and 10.10 of 657 Iowa Administrative Code.

IT IS HEREBY ORDERED that Phillip R. Tuetken appear on behalf of Long's Drug before the Iowa Board of Pharmacy Examiners on March 16, 1988, 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 or revoke the license to operate a pharmacy issued to Long's Drug and renewed on February 1, 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.

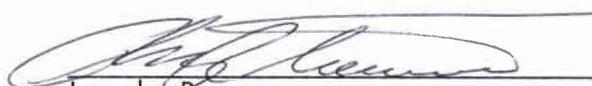
IOWA BOARD OF PHARMACY EXAMINERS

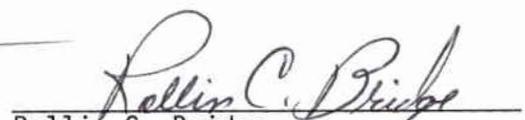
  
Norman C. Johnson  
Executive Secretary



- (2) All outdated drug products will be removed from the pharmacy dispensing area and quarantined until they can be returned or destroyed.
- (3) The pharmacy dispensing area will be maintained in a clean and sanitary condition.
- (4) Written policies and procedures will be established and implemented which shall include, but not be limited to, the following:
  - (a) Maintenance of records and inventories of controlled substances.
  - (b) Compliance with federal regulations on controlled substance order forms.
  - (c) Compliance with state and federal regulations on controlled substance prescriptions.
  - (d) Handling of outdated drug products.
  - (e) Receipt of telephoned prescriptions.
  - (f) Transfer of prescriptions from other pharmacies.
  - (g) Prescription labeling.
  - (h) Access to pharmacy in the absence of a pharmacist.
  - (i) Drug product selection.
  - (j) Maintenance of patient profiles.
  - (k) Housekeeping (cleaning) schedules.
- b. The policies and procedures adopted pursuant to this Order shall be submitted to the Board or its designee for approval within 60 days of the date of this Order.
- c. Pass an inspection, to the Board investigator's satisfaction, within 60 days of this Order.
- d. Upon successful completion of probation, Licensee's license to operate a pharmacy shall be fully restored.

THE ABOVE AND FOREGOING CONSTITUTE THE FULL AND COMPLETE STIPULATION AND AGREEMENT OF THE PARTIES HERETO.

  
Long's Drug  
Phillip R. Tuetken  
Pharmacist-in-Charge

  
Rollin C. Bridge  
Chairman  
Iowa Board of Pharmacy Examiners



THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacy License of :  
: **COMPLAINT**  
**LONG'S DRUG**, Lic. No. 131, : **AND**  
Phillip R. Tuetken, Pharmacist : **STATEMENT OF CHARGES**  
In Charge and Corporate :  
President, Respondent :

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COMES NOW, Norman C. Johnson, Executive Secretary of the Iowa Board of Pharmacy Examiners, on the 9th day of December, 1988, and files this Complaint and Statement of Charges against Long's Drug, 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 licensed to operate a pharmacy at 419 East First Street in Monticello, Jones County, Iowa, and holds license number 131.

3. General pharmacy license number 131, issued in the name of Long's Drug, with Phillip R. Tuetken as pharmacist in charge and president, was renewed on February 1, 1988, and expires on December 31, 1988.

4. In a Complaint and Statement of Charges filed against Respondent on February 12, 1988, Respondent was charged with allowing pharmacy to be practiced in an illegal, unethical, and unprofessional manner by pharmacists who improperly made out prescriptions, failed to keep proper prescription records, made false prescriptions, sold outdated prescription drugs, altered prescriptions, and failed to properly account for a federal order form for Schedule II controlled substances.

5. Pursuant to a Stipulation Agreement, Order, and Consent to Order, Respondent's license to operate a pharmacy was suspended for one year. The suspension was stayed on the provision that certain conditions be met.

6. Paragraph 4 of the Stipulation provided, in part, as follows:

It is the understanding of both the Licensee and the Board that they will enter into an Order and Consent to Order which will provide for the following:

a. Licensee's license to operate a pharmacy is suspended

for a period of one year. Said suspension is stayed provided that the following conditions are met:

....

(4) Written policies and procedures will be established and implemented which shall include, but not be limited to, the following:

- (a) Maintenance of records and inventories of controlled substances.
- (b) Compliance with federal regulations on controlled substance order forms.
- (c) Compliance with state and federal regulations on controlled substance prescriptions.
- (d) Handling of outdated drug products.
- (e) Receipt of telephoned prescriptions.
- (f) Transfer of prescriptions from other pharmacies.
- (g) Prescription labeling.
- (h) Access to pharmacy in the absence of a pharmacist.
- (i) Drug product selection.
- (j) Maintenance of patient profiles.
- (k) Housekeeping (cleaning) schedules.

b. The policies and procedures adopted pursuant to this Order shall be submitted to the Board or its designee for approval within 60 days of the date of this Order.

c. Pass an inspection, to the Board investigator's satisfaction, within 60 days of this Order.

7. An inspection of Long's Drug was conducted on October 18, 1988, by Pharmacy Investigators Morrell A. Spencer and Gary D. Ebeling.

8. The results of that inspection as revealed by Investigator Spencer's report dated October 25, 1988, reveal the following:

a. On October 18, 1988, Investigator Spencer entered Long's Drug at approximately 8:10 a.m. and observed the following: (1) no pharmacist was yet on duty although the pharmacy had been opened for business by a store clerk; (2) a folding door on the right side of the prescription department was held closed only with two hook fasteners; (3) the folding door on the right side of the prescription department was inadequate and ineffectual for preventing unauthorized entry by non-pharmacists into the prescription department during the absence of a pharmacist; and (4) a pharmacist did not arrive at Long's Drug until approximately 9:00 a.m.

b. On October 18, 1988, Investigator Spencer observed Respondent repackaging prescription drugs in the following manner: (1) drugs taken from stock bottles kept at the Long's Drug prescription department were used to refill empty drug stock bottles brought from another pharmacy owned by Respondent, Wyoming Drug, located in Wyoming, Iowa; (2) no

packaging control record was made; and (3) existing labels on the empty drug stock bottles brought from Wyoming Drug were not changed to reflect the new lot numbers and expiration dates of the drugs being placed in those stock bottles.

c. On October 18, 1988, Investigator Spencer observed that Respondent had transferred certain Schedule II controlled substances from Long's Drug to Wyoming Drug without the use of federal order forms (DEA order form 222C). Investigator Spencer found that the Schedule II prescription file at Long's Drug contained the following three Schedule II prescriptions which were numbered, filled, recorded, and dispensed from Wyoming Drug: (1) prescription number 141435 dated August 1, 1988, from J. M. Hoffman, M.D., for #15 Percocet for patient Betty Anderson; (2) prescription number 141927 dated September 1, 1988, from R. M. Hamilton, D.O., for #100 Ritalin 10 mg. for patient Truman Ellefsen; and (3) prescription number 142145 dated September 14, 1988, from T. C. Piekenbrock, M.D., for #60 Ritalin 5 mg. for patient Joey Petersen.

d. On October 18, 1988, Investigator Spencer observed that the prescription information stored in Long's Drug prescription department computer system was incomplete in the following ways: (1) controlled drug prescriptions which were filled and recorded manually at times when the computer system was inoperative were never entered into the system; (2) controlled drug prescriptions for patients with third-party coverage were not entered into the system; and (3) controlled drug prescriptions filled at and dispensed from Wyoming Drug with controlled drugs obtained from Long's Drug were not entered into the system. As a result, the daily computer printouts of controlled substance activity at Long's Drug were also incomplete.

e. On October 18, 1988, Investigator Spencer observed that Respondent began generating daily computer printouts of controlled substance activity at Long's Drug on September 2, 1988. He further observed that most computer printouts generated between September 2, 1988, and October 18, 1988, were not signed by each dispensing pharmacist.

f. On October 18, 1988, Investigator Spencer observed that Respondent had failed to develop and implement written policies and procedures for unit dose dispensing. He further observed the following: (1) Respondent utilizes two unit dose dispensing systems -- an Opus 7-day system and an Artronic Punch Pak 30-day heat-sealed system; (2) Respondent failed to include the lot number and expiration date on all labeling of Artronic unit dose packaging; (3) a "return box" at Long's Drug contained an Artronic unit dose package containing 62 white tablets; these tablets were imprinted "ASPIRIN;" the unit dose package was completely unlabeled; Respondent indicated to Investigator Spencer that this aspirin had been returned from the Cascade Nursing Home; Respondent further indicated that this aspirin would be returned to pharmacy stock at Long's Drug for later redispensing; (4) the same "return box" referred to in (3), above, also contained an Artronic unit dose package containing 29 blue capsules; these capsules were imprinted "4001;" the labeling on this unit dose package included the name and strength of the drug (Cycladate

200 mg.), the directions for use, the patient's name, and the prescriber's name, but did not include the room or bed number of the patient, the name and address of the dispensing pharmacy, the manufacturer's lot number, or the pharmacy's repackaged expiration date; Respondent indicated to Investigator Spencer that these Cycladate 200 mg. capsules had been returned from the Cascade Nursing Home; Respondent further indicated that these capsules would be returned to pharmacy stock at Long's Drug for later redispensing; and (5) the labeling on most of the Opus 7-day unit dose containers did not include the name of the dispensing pharmacy and did not include an expiration date on those containers holding "prn" medications.

g. On October 18, 1988, Investigators Spencer and Ebeling observed Respondent as he filled and dispensed three prescriptions for Pediatric Amoxil Oral Suspension (prescription numbers 502379, 502382, and 502383). For each prescription Respondent reconstituted the Amoxil by adding an unmeasured amount of tap water to each of the bottles. Although measuring devices and deionized water were available in the prescription department, Respondent did not use either.

h. On October 18, 1988, Investigator Spencer requested that Respondent produce the written policies and procedures relating to general pharmacy practice which the Board had ordered Respondent to establish and implement as outlined in paragraph 4, section (a)(4) of the Stipulation agreement incorporated into the Order dated June 30, 1988. Respondent stated to Investigator Spencer that he had failed to revise his written policies and procedures as requested by the Board. Consequently, Respondent did not produce any written policies and procedures when requested by Investigator Spencer.

9. Respondent is guilty of violations of Iowa Code sections 155A.15(2)(c), 155A.15(2)(h), and 204.307 by virtue of the allegations in paragraph 8, subsections (a) through (g).

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 204.307 provides the following:

Controlled substances in schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.

10. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.6, 6.8(1), 6.8(4), 6.8(5), 6.8(6), 8.3(1), 8.3(2), 8.9(3)(a)(2), 8.9(3)(b), 8.9(4)(b), 8.9(6), 8.11(3), 8.11(4), 9.1(4)(b), and 9.1(4)(u) by virtue of the allegations in paragraph 8, subsections (a) through (g).

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 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(1) Controlled substance records shall be maintained in a manner to establish receipt and distribution of all controlled substances;

....

6.8(4) Invoices involving the distribution of Schedule III, IV, or V controlled substances to another pharmacy or practitioner must show the actual date of distribution; the name, strength, and quantity of controlled substances distributed; the name, address, and DEA registration number of the distributing pharmacy and of the practitioner or pharmacy receiving the controlled substances;

6.8(5) Copy 1 of DEA Order Form 222C, furnished by the

pharmacy or practitioner to whom Schedule II controlled substances are distributed, shall be maintained by the distributing pharmacy and shall show the quantity of controlled substances distributed and the actual date of distribution;

6.8(6) Copy 3 of DEA Order Form 222C shall be properly dated, initialed, and filed and shall include all copies of each unaccepted or defective order form and any attached statements or other documents;....

657 Iowa Administrative Code section 8.3 provides the following:

8.3(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 the label.
- e. Initials of the packager.
- f. Initials of the supervising pharmacist.
- g. Quantity per container.
- h. Internal control number or date.

8.3(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 8.9(3) provides, in part, the following:

a. Labeling for single unit or unit dose packaging shall comply with the following:

....

(2) Doses packaged by the pharmacy shall be properly labeled according to subrule 8.3(2) if used beyond a 24-hour period.

b. Labeling for unit of issue packages shall contain the

following information:

(1) Name, strength, and expiration date of drug when the packages are utilized for floor stock in an institutional setting.

(2) Name and room or bed number of patient, name of prescribing practitioner, name and strength of drug, directions for use, and name and address of the dispensing pharmacy, when the packages are utilized for patients in an institutional setting. Room or bed number, the name of prescribing practitioner, and the name and address of the dispensing pharmacy is not required if this information appears on a medication administration record used by the institution.

657 Iowa Administrative Code section 8.9(4) provides, in part, the following:

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 8.9(6) provides the following:

Drugs dispensed in single unit, unit dose, or unit of issue packaging in compliance with board subrules 8.9(1) to 8.9(5) may be returned to the pharmacy stock and reissued provided that:

a. The expiration dating information is retrievable and identifiable.

b. Drugs returned from unit of issue packaging are kept separate according to manufacturer's lot number and the pharmacy's repackaged expiration date unless the pharmacy's recall policy states that all lots of a drug will be returned upon recall. In this instance, drugs returned to stock shall be kept separate according to the pharmacy's repackaged expiration date as determined in board subrule 8.9(5).

c. The drugs were stored under proper storage conditions.

d. The drugs are returned to the pharmacy in the original packaging as when dispensed.

e. The pharmacy includes in their written policies and procedures the manner in which they will record or identify controlled substances returned.

657 Iowa Administrative Code section 8.11(3) provides the following:

Documentation of the correctness of controlled substance prescription refill 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 refill 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 refill information. This printout shall be verified, dated, and signed by each dispensing pharmacist. This printout of the day's controlled substance prescription refill information shall be provided to the pharmacy using an automated data processing system within seventy-two hours of the date on which the refill was dispensed.

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

657 Iowa Administrative Code section 8.11(4) provides the following:

An auxiliary record keeping system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason. The auxiliary system shall ensure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When the automated data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated data processing system as soon as possible. Auxiliary records may be destroyed after entry into the system. This subrule does not require that a permanent dual recordkeeping system be maintained.

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.

....

u. Violating any of the grounds for revocation or suspension of a license listed in Iowa Code sections 147.55, and 1987 Iowa Code supplement sections 155A.12 and 155A.15.

11. Respondent is guilty of violating paragraph 4, sections (a)(4), (b), and (c), of the Stipulation agreement incorporated into the Order dated June 30, 1988, by virtue of the allegation in paragraph 8, subsection (h).

The Iowa Board of Pharmacy Examiners finds that paragraphs 9, 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 Long's Drug has violated paragraph 4, sections (a)(4), (b), and (c) of the Stipulation agreement incorporated into the Order dated June 30, 1988; sections 155A.15(2)(c), 155A.15(2)(h), and 204.307 of the Code of Iowa 1987; and sections 6.6, 6.8(1), 6.8(4), 6.8(5), 6.8(6), 8.3(1), 8.3(2), 8.9(3)(a)(2), 8.9(3)(b), 8.9(4)(b), 8.9(6), 8.11(3), 8.11(4), 9.1(4)(b), and 9.1(4)(u) of 657 Iowa Administrative Code.

IT IS HEREBY ORDERED that Phillip R. Tuetken appear on behalf of Long's Drug before the Iowa Board of Pharmacy Examiners on January 10, 1989, at 2:00 p.m. in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to suspend or revoke the license to operate a pharmacy issued to Long's Drug and renewed on February 1, 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

  
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Norman C. Johnson  
Executive Secretary

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacy License of	)	
	)	DIA NO. 89DPB-8
LONG'S DRUG	)	
License No. 131	)	
Phillip R. Tuetken,	)	FINDINGS OF FACT,
Pharmacist in Charge	)	CONCLUSIONS OF LAW
and Corporate President,	)	AND DECISION
Respondent	)	

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To: Long's Drug, Phillip R. Tuetken, Pharmacist in Charge and President:

A Complaint and Statement of Charges for the above case was filed by Norman C. Johnson, Executive Secretary of the Iowa Board of Pharmacy Examiners (hereinafter the Board), on December 9, 1988.

The hearing for this case was consolidated with the hearing for Phillip R. Tuetken, DIA No. 89DPB-7. However, two separate decisions will be issued. The hearing was held on July 11, 1989 beginning at 2:00 p.m. The hearing was held in the conference room, Iowa Board of Pharmacy Examiners, Executive Hills West, Des Moines, Iowa. Present were the Board, members of the Board staff, and a court reporter. Pharmacy Board member Alan M. Shepley disqualified himself and did not participate in the hearing or decision in this case. Appearing for the State was Thomas D. McGrane, Assistant Attorney General. The Respondent, Long's Drug, Phillip R. Tuetken, pharmacist in charge and president, was represented by attorney Bob Shimanek. The undersigned administrative law judge from the Iowa Department of Inspections and Appeals presided. At the request of Mr. Tuetken, the hearing was closed to the public pursuant to Iowa Code section 258A.6(1) (1989).

After hearing the testimony and examining the exhibits, the Board convened in closed executive session pursuant to Iowa Code section 21.5(1)(f) (1989) 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 State's Exhibits 1, 1A, 1B, 1C, 2, 3, 4 and 5, and Respondent's Exhibits 1 through 5.

## FINDINGS OF FACT

1. Phillip R. Tuetken holds Iowa pharmacist license number 12514. Phillip R. Tuetken is the pharmacist-in-charge and president of Long's Drug, which holds pharmacy license number 131. Long's Drug is located in Monticello, Iowa. Phillip R. Tuetken's pharmacist license remains on probation pursuant to a stipulation entered into in June of 1988. The pharmacy license of Long's Drug, license number 131, was suspended for a period of one year and as of June 30, 1989, is no longer under suspension.
2. On June 30, 1988 Phillip R. Tuetken and the Iowa Board of Pharmacy Examiners entered into a Stipulation and Consent Order. Pursuant to the Stipulation and Consent Order, Mr. Tuetken's license was placed on probation for a period of 18 months. Also on June 30, 1988, Long's Drug, with Mr. Tuetken as pharmacist-in-charge and president, entered into a Stipulation and Consent Order with the Board. This Stipulation and Consent Order addressed a number of violations of Iowa pharmacy law which were to be corrected.
3. On October 18, 1988, Board investigator Morrell Spencer went to Long's Drug in Monticello Iowa. Board investigator Gary Ebling accompanied Mr. Spencer on this inspection. As a result of this inspection Mr. Spencer and Mr. Ebling prepared an inspection form and an investigative report regarding Long's Drug. This inspection led to the filing of the current Complaint and Statement of Charges in this case.
4. As of October 18, 1988, Mr. Tuetken and Long's Drug were not in compliance with a number of Iowa Code sections and Pharmacy Board rules.
5. After the Board inspection in October of 1988, Mr. Tuetken made a number of corrections in the procedures followed in Long's Drug. Mr. Tuetken requested that a Board investigator return to Long's Drug to conduct an inspection prior to this hearing. As a result of that request, the Board investigator returned to Long's Drug and conducted a further inspection on the Friday before the hearing.
6. Mr. Tuetken has corrected the violations which led to both the original Complaint and Statements of Charges. Once the Board has made Mr. Tuetken aware of the problems in his pharmacy, the Board is convinced that this pharmacist has changed his pharmacy practices to come into compliance with Iowa law. The Board does note that it is the pharmacist's responsibility to stay current in Iowa law and rules related to the practice of pharmacy. The Board is convinced that as of the date of the hearing, Long's Drug is essentially in compliance with Board rules and pharmacy law.
7. The Board's duty to the public has been carried out in this case. The pharmacist in the related case has done his duty as a

licensed pharmacist in the State of Iowa to correct the problems which existed in his pharmacy.

89. In order to ensure that compliance with Iowa law and Pharmacy Board rules continue, another inspection of Long's Drug is necessary prior to the ending of Mr. Tuetken's probation, which is December 30, 1989.

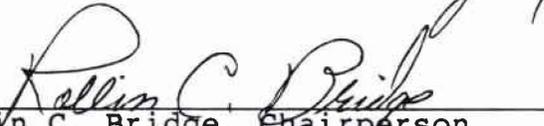
CONCLUSIONS OF LAW

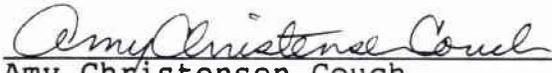
As of July 11, 1989, Long's Drug, license number 131, was not in violation of any of the Iowa Code sections or Board rules as charged in the Complaint and Statement of Charges filed December 9, 1988.

DECISION AND ORDER

IT IS THEREFORE THE ORDER of the Iowa Board of Pharmacy Examiners that no additional disciplinary action will be imposed against Long's Drug, license number 131. The Board staff is directed to conduct an unannounced inspection of Long's Drug in Monticello, Iowa prior to December 30, 1989.

Dated this 18<sup>th</sup> day of July, 1989.

  
\_\_\_\_\_  
Rollin C. Bridge, Chairperson  
Iowa Board of Pharmacy Examiners

  
\_\_\_\_\_  
Amy Christensen Couch  
Administrative Law Judge

ACC/jmm

THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacist License of :  
 :  
 **PHILLIP R. TUEIKEN** : **COMPLAINT**  
 : **AND**  
 Lic. No. 12514 : **STATEMENT OF CHARGES**  
 Respondent :  
 :

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COMES NOW, Norman C. Johnson, Executive Secretary of the Iowa Board of Pharmacy Examiners, on the 12th day of February, 1988, and files this Complaint and Statement of Charges against Phillip R. Tuetken, a pharmacist licensed pursuant to Iowa Code Chapter 155A, and alleges that:

1. Rollin C. Bridge, Chairperson; Jerry M. Hartleip, Vice Chairperson; Donna J. Flower; John F. Rode; Melba L. Scaglione; Alan M. Shepley; and Gale W. Stapp are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent was issued a license to practice pharmacy in Iowa on July 1, 1959, by examination.

3. Respondent is self-employed as the owner/pharmacist/manager of Long's Drug located at 419 East First Street in Monticello, Iowa.

4. Respondent currently resides at R. F. D. #3, Monticello, Iowa.

5. Respondent's license to practice pharmacy in Iowa is current until June 30, 1989.

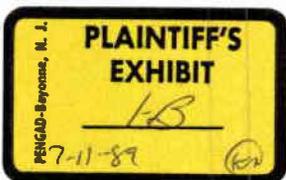
6. An inspection of Long's Drug was conducted on October 26, 1987, by Pharmacy Investigator E. Ray Sheldon.

7. The results of that inspection as revealed by Investigator Sheldon's report dated October 29, 1987, reveal the following:

a. On or about October 26, 1987, Respondent attempted to dispense a prescription drug, Monistat Vaginal Cream, to a patient, A. Mesch, on the verbal order of Dr. Herbert A. Gearhart, D. O., of Hopkinton, Iowa, without reducing the prescription to writing and without labeling the medication.

b. Failure by Respondent to record patient addresses on prescriptions for controlled drugs. Upon reviewing 60 controlled drug prescriptions, Investigator Sheldon found that 20 of those prescriptions lacked the address of the patient.

c. Failure by Respondent to identify prescriptions for



Schedule III, IV, and V controlled drugs with a red "C" in a filing system where controlled and non-controlled drug prescriptions are filed together. Upon reviewing 30 prescriptions for Schedule III, IV, or V controlled drugs, Investigator Shelden found that 10 of those prescriptions lacked an identifying, red "C."

d. Failure by Respondent to remove approximately 200 outdated pharmaceuticals from dispensing stock.

e. Failure by Respondent to maintain the prescription department in a sanitary condition. Investigator Shelden observed that the prescription department was dusty, dirty, and cluttered.

f. On March 26, 1987, Respondent used Dexedrine Spansules 10 mg. which had expired on July 31, 1985, to fill prescription number 414462. Respondent dispensed sixteen outdated Dexedrine Spansules 10 mg.

g. On April 23, 1987, Respondent used Dexedrine Spansules 10 mg. which had expired on July 31, 1985, to fill prescription number 415883. Respondent dispensed one hundred outdated Dexedrine Spansules 10 mg.

h. On March 25, 1987, Respondent altered prescription number 414527 for Dilaudid 4 mg., a Schedule II controlled substance. Respondent changed the drug strength from 4 mg. to 3 mg. without explanation, change in directions for use, or documentation of prescriber authorization.

i. Failure by Respondent to account for one DEA order form 222c (#860090402) or to report it as missing.

j. On October 30, 1987, Respondent created a false prescription for patient Nancy Kraus and dispensed 120 Imipramine 50 mg. without prescriber authorization. Respondent falsely indicated that Dr. John J. Randolph, M. D., of Monticello, Iowa, had authorized the prescription.

k. On October 30, 1987, Respondent created a false prescription for patient Ruth Cox and dispensed 40 Vapocet tablets, a Schedule III controlled substance, without prescriber authorization. Respondent falsely indicated that Dr. Jonathan C. Lindo, M. D., of Monticello, Iowa, had authorized the prescription.

8. In summary, the findings of Investigator Shelden indicate that Respondent has acted in an illegal, unethical, and unprofessional manner by improperly making out prescriptions, failing to keep proper prescription records, making false prescriptions, selling outdated prescription drugs, altering prescriptions, and failing to properly account for a federal order form for Schedule II controlled substances.

9. Respondent is guilty of violations of former Iowa Code section 155.29(1)(b) and current Iowa Code sections 147.55(3), 155A.12(4), 155A.23(1)(b), 155A.23(4), 155A.27(1)(b), 155A.27(2), 155A.28, 204.307, 204.308(3), 204.402(1)(a), and 204.403(1)(d) by virtue of the allegations in paragraph 7, subsections (a), (b), (c), (f), (g), (h), (i), (j), and (k).

Iowa Code section 147.55(3) provides the following:

A license to practice a profession shall be revoked or suspended when the licensee is guilty of any of the following acts or offenses:...

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

Iowa code section 155A.12 provides, in part, the following:

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:

1. Violated any provision of this chapter or any rules of the board adopted under this chapter.

....

3. Violated any of the provisions for licensee discipline set forth in section 147.55.

4. Failed to keep and maintain records required by this chapter or failed to keep and maintain complete and accurate records of purchases and disposal of drugs listed in the controlled substances Act.

5. Violated any provision of the controlled substances Act or rules relating to that Act.

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

"A person shall not:...

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

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:...

b. The name and address of the patient for whom, or the owner of the animal for which, the drug is dispensed.

....

2. If oral, the practitioner issuing the prescription shall furnish the same information required for a written prescription, except for the written signature and address of the practitioner. Upon receipt of an oral prescription, the pharmacist shall promptly reduce the oral prescription to a written format by recording the information required in a written prescription.

Iowa Code section 155A.28 provides as follows:

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.

Former Iowa Code section 155.29(1)(b) (in effect through June 30, 1987) and current Iowa Code section 155A.23(1)(b) (effective July 1, 1987) provide that a person shall not:

Obtain or attempt to obtain a prescription drug or procure or attempt to procure the administration of a prescription drug by:...

Forgery or alteration of a prescription or of any written order.

Iowa Code section 204.307 provides the following:

Controlled substances in schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.

Iowa Code section 204.308(3) provides the following:

Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in schedule III or IV, which is a prescription drug as

determined under Chapter 155A, shall not be dispensed without a written or oral prescription of a practitioner. The prescription may not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner.

Iowa Code section 204.402(1) provides, in part, the following:

It is unlawful for any person:

a. Who is subject to division III to distribute or dispense a controlled substance in violation of section 204.308....

Iowa Code section 204.403(1) provides, in part, the following:

It is unlawful for any person knowingly or intentionally:...

d. To furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this chapter, or any record required to be kept by this chapter....

10. Respondent is guilty of violations of 21 Code of Federal Regulations sections 1304.04(h)(2), 1305.12(b), and 1306.05(a) by virtue of the allegations in paragraph 7, subsections (b), (c), and (i).

21 Code of Federal Regulations section 1304.04(h) provides, in part, the following:

Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:...

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1-inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances.

21 Code of Federal Regulations section 1305.12(b) provides, in part, the

following:

Whenever any used or unused order forms are stolen from or lost (otherwise than in the course of transmission) by any purchaser or supplier, he shall immediately upon discovery of such theft or loss, report the same to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, D. C. 20005, stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers.

21 Code of Federal Regulations section 1306.05(a) provides, in part, the following:

All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and the name, address, and registration number of 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 these regulations.

11. Respondent is guilty of violations of 620 Iowa Administrative Code section 2.2(2) and 657 Iowa Administrative Code sections 6.7(3), 6.7(4), 6.9(1), 6.9(2), 8.1(3), 9.1(4)(b)(3), and 9.1(4)(c) by virtue of the allegations in paragraph 7, subsections (a), (d), (e), (f), and (g).

620 Iowa Administrative Code section 2.2(2), in effect at all times herein and until January 19, 1988, provided the following:

Storage areas, restrooms, basement and all other areas in the pharmacy shall be kept in a thoroughly clean condition.

657 Iowa Administrative Code section 6.7(3) provides the following:

Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

657 Iowa Administrative Code section 6.7(4) provides the following:

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

657 Iowa Administrative Code section 6.9 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.

(2) The original prescription, whether transmitted orally or in writing, must be retained by the pharmacy filling the prescription.

657 Iowa Administrative Code section 8.1(3) provides the following:

...the phrase "fill the prescriptions" shall be deemed to include, but not necessarily be limited to,...

[ensuring] adequate label directions as are necessary to assure the patient's understanding of the prescriber's intentions.

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)...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:...

(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.

....

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.

The Iowa Board of Pharmacy Examiners finds that paragraphs 9, 10, and 11 constitute grounds for which Respondent's license to practice pharmacy in Iowa can be suspended or revoked.

WHEREFORE, the undersigned charges that Respondent has violated

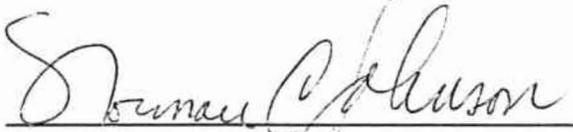
former section 155.29(1)(b) of the Code of Iowa 1987; current sections 147.55(3), 155A.12(4), 155A.23(1)(b), 155A.23(4), 155A.27(1)(b), 155A.27(2), 155A.28, 204.307, 204.308(3), 204.402(1)(a), and 204.403(1)(d) of the Code of Iowa 1987; sections 1304.04(h)(2), 1305.12(b), and 1306.05(a) of 21 Code of Federal Regulations; section 2.2(2) of 620 Iowa Administrative Code; and sections 6.7(3), 6.7(4), 6.9(1), 6.9(2), 8.1(3), 9.1(4)(b)(3), and 9.1(4)(c) of 657 Iowa Administrative Code.

IT IS HEREBY ORDERED that Phillip R. Tuetken appear before the Iowa Board of Pharmacy Examiners on March 16, 1988, 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 or revoke the license to practice pharmacy issued to Phillip R. Tuetken on July 1, 1959, 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 his own. The failure of Respondent to appear could result in the permanent suspension or revocation of his license. Information regarding the hearing may be obtained from Thomas D. McGrane, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319.

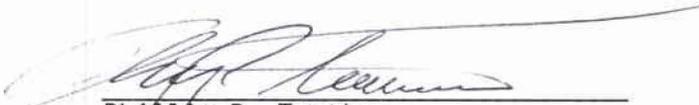
IOWA BOARD OF PHARMACY EXAMINERS

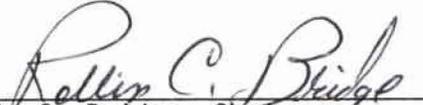
  
Norman C. Johnson  
Executive Secretary



- (2) Should Licensee fail the examination, he shall be allowed to repeat the examination at its next regularly scheduled administration in Iowa.
  - (3) If Licensee fails the examination on the second attempt, the suspension will take effect and remain in effect until such time as he successfully passes such examination.
- b. Licensee is placed on probation for a period of 18 months from the date of this Order.
  - c. During the period of probation Licensee shall:
    - (1) Obey all federal and state laws substantially related to the practice of pharmacy.
    - (2) Report to the Board or its designee quarterly. Said reports shall be in writing. Should the final report not be made as directed, the period of probation shall be extended until such time as the final report is made.
    - (3) Provide evidence of continuing education in compliance with Board rules.
    - (4) Not supervise a registered pharmacist intern, nor perform the duties of a preceptor.
  - d. Should licensee leave Iowa to reside or practice outside this state, he must notify the Board in writing of the dates of departure and return. Periods of residency or practice outside the state shall not apply to reduction of the probationary period.
  - e. Within 15 days of Licensee undertaking new employment, he shall cause his employer to report to the Board in writing acknowledging that the employer has read the decision in this case, including the terms, conditions and restrictions imposed on Licensee.
  - f. Should Licensee violate probation in any respect, the Board, after giving him notice and an opportunity to be heard, may revoke probation and carry out the suspension order which was stayed. If a petition to revoke probation is filed against Licensee during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.
  - g. Upon successful completion of probation, Licensee's license to practice pharmacy will be fully restored.

THE ABOVE AND FOREGOING CONSTITUTE THE FULL AND COMPLETE STIPULATION AND AGREEMENT OF THE PARTIES HERETO.

  
Phillip R. Tuetken  
Licensee

  
Rollin C. Bridge, Chairman  
Iowa Board of Pharmacy Examiners

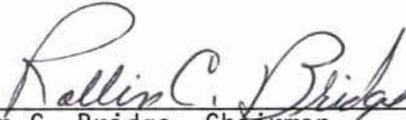
BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

In the Matter of Pharmacist :  
: ORDER AND CONSENT TO ORDER  
PHILLIP R. TUETKEN :

The Iowa Board of Pharmacy Examiners, having been advised of the allegations and charges against Phillip R. Tuetken, which could cause action to be taken against his license, and Licensee, having entered into a Stipulation representing their mutual informed consent as to waiver of provisions found in Sections 17A.12 and 17A.18, Code of Iowa 1987, in regards to notice and hearing, the parties to this action agree to an informal settlement of the matter, namely that the license of Phillip R. Tuetken be disciplined according to the conditions attached hereto.

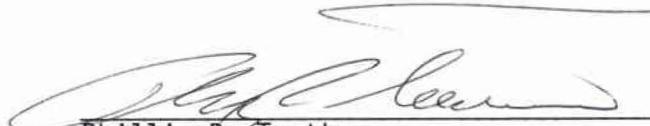
ORDER

IT IS THEREFORE ORDERED, subject to Phillip R. Tuetken's consent to be contained in this Order, that the license of Phillip R. Tuetken to practice pharmacy in Iowa be disciplined according to the conditions outlined in the Stipulation attached hereto and made part of this Order.

  
\_\_\_\_\_  
Rollin C. Bridge, Chairman  
Iowa Board of Pharmacy Examiners  
Date May 28, 1988

CONSENT TO ORDER

I, Phillip R. Tuetken, hereby consent to the Order set forth above, waive my right to a hearing in this matter, and thereby specifically waive a right to confrontation, cross-examination of witnesses, production of evidence, making of a record and judicial review.

  
\_\_\_\_\_  
Phillip R. Tuetken  
Date 6-30-88

THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacist License of	:	COMPLAINT
	:	AND
PHILLIP R. TUETKEN	:	STATEMENT OF CHARGES
License No. 12514	:	AND
Respondent	:	PETITION TO REVOKE PROBATION

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COMES NOW, Norman C. Johnson, Executive Secretary of the Iowa Board of Pharmacy Examiners, on the 9th day of December, 1988, and files this Complaint and Statement of Charges and Petition to Revoke Probation against Phillip R. Tuetken, a pharmacist 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 was issued a license to practice pharmacy in Iowa on July 1, 1959, by examination.

3. Respondent is self-employed as the owner/pharmacist-in-charge of Long's Drug located at 419 East First Street in Monticello, Iowa.

4. Respondent currently resides at R.F.D. #3, Monticello, Iowa.

5. Respondent's license to practice pharmacy in Iowa is current until June 30, 1989.

6. In a complaint and statement of charges filed against Respondent on February 12, 1988, Respondent was charged with acting in an illegal, unethical, and unprofessional manner by improperly making out prescriptions, failing to keep proper prescription records, making false prescriptions, selling outdated prescription drugs, altering prescriptions, and failing to properly account for a federal order form for Schedule II controlled substances.

7. Pursuant to a stipulation agreement, order, and consent to order, Respondent's license to practice pharmacy in Iowa was suspended for one year. The suspension was stayed on the provision that certain conditions be met. Respondent was placed on probation for 18 months, from June 30, 1988, to December 30, 1989.

8. Paragraph 4 of the stipulation provided, in part, as follows:

It is the understanding of both the Licensee and the Board that they will enter into an Order and Consent to Order which will provide for the following:

a. Licensee's license to practice pharmacy is suspended for a period of one year. Said suspension is stayed provided that the following conditions are met:

....  
b. Licensee is placed on probation for a period of 18 months from the date of this Order.

c. During the period of probation Licensee shall:

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

....  
f. Should Licensee violate probation in any respect, the Board, after giving him notice and an opportunity to be heard, may revoke probation and carry out the suspension order which was stayed. If a petition to revoke probation is filed against Licensee during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

9. An inspection of Long's Drug was conducted on October 18, 1988, by Pharmacy Investigators Morrell A. Spencer and Gary D. Ebeling.

10. The results of that inspection as revealed by Investigator Spencer's report dated October 25, 1988, reveal the following:

a. On October 18, 1988, Investigator Spencer entered Long's Drug at approximately 8:10 a.m. and observed the following: (1) no pharmacist was yet on duty although the pharmacy had been opened for business by a store clerk; (2) a folding door on the right side of the prescription department was held closed only with two hook fasteners; (3) the folding door on the right side of the prescription department was inadequate and ineffectual for preventing unauthorized entry by non-pharmacists into the prescription department during the absence of a pharmacist; and (4) a pharmacist did not arrive at Long's Drug until approximately 9:00 o'clock a.m.

b. On October 18, 1988, Investigator Spencer observed Respondent repackaging prescription drugs in the following manner: (1) drugs taken from stock bottles kept at the Long's Drug prescription department were used to refill empty drug stock bottles brought from another pharmacy owned by Respondent, Wyoming Drug, located in Wyoming, Iowa; (2) no packaging control record was made; and (3) existing labels on the empty drug stock bottles brought from Wyoming Drug were not changed to reflect the new lot numbers and expiration dates of the drugs being placed in those stock bottles.

c. On October 18, 1988, Investigator Spencer observed that Respondent had transferred certain Schedule-II controlled substances

from Long's Drug to Wyoming Drug without the use of federal order forms (DEA order form 222c). Investigator Spencer found that the Schedule-II prescription file at Long's Drug contained the following three Schedule-II prescriptions which were numbered, filled, recorded, and dispensed from Wyoming Drug: (1) prescription number 141435 dated 8-1-88 from J. M. Hoffman, M.D., for #15 Percocet for patient Betty Anderson; (2) prescription number 141927 dated 9-1-88 from R. M. Hamilton, D.O., for #100 Ritalin 10mg for patient Truman Ellefsen; and (3) prescription number 142145 dated 9-14-88 from T. C. Piekenbrock, M.D., for #60 Ritalin 5mg for patient Joey Petersen.

d. On October 18, 1988, Investigator Spencer observed that the prescription information stored in Long's Drug prescription department computer system was incomplete in the following ways: (1) controlled drug prescriptions which were filled and recorded manually at times when the computer system was inoperative were never entered into the system; (2) controlled drug prescriptions for patients with third-party coverage were not entered into the system; and (3) controlled drug prescriptions filled at and dispensed from Wyoming Drug with controlled drugs obtained from Long's Drug were not entered into the system. As a result, the daily computer printouts of controlled substance activity at Long's Drug were also incomplete.

e. On October 18, 1988, Investigator Spencer observed that Respondent began generating daily computer printouts of controlled substance activity at Long's Drug on September 2, 1988. He further observed that most computer printouts generated between September 2, 1988, and October 18, 1988, were not signed by each dispensing pharmacist.

f. On October 18, 1988, Investigator Spencer observed that Respondent had failed to develop and implement written policies and procedures for unit dose dispensing. He further observed the following: (1) Respondent utilizes two unit dose dispensing systems -- an Opus 7-day system and an Artromick Punch Pak 30-day heat-sealed system; (2) Respondent failed to include the lot number and expiration date on all labeling of Artromick unit dose packaging; (3) a "return box" at Long's Drug contained an Artromick unit dose package containing 62 white tablets; these tablets were imprinted "ASPIRIN"; the unit dose package was completely unlabeled; Respondent indicated to Investigator Spencer that this aspirin had been returned from the Cascade Nursing Home; Respondent further indicated that this aspirin would be returned to pharmacy stock at Long's Drug for later redispensing; (4) the same "return box" referred to in (3), above, also contained an Artromick unit dose package containing 29 blue capsules; these capsules were imprinted "4001"; the labeling on this unit dose package included the name and strength of the drug (Cycladate 200mg), the directions for use, the patient's name, and the prescriber's name, but did not include the room or bed number of the patient, the name and address of the dispensing pharmacy, the manufacturer's lot number, or the pharmacy's repackaged expiration date; Respondent indicated

to Investigator Spencer that these Cycladate 200mg capsules had been returned from the Cascade Nursing Home; Respondent further indicated that these capsules would be returned to pharmacy stock at Long's Drug for later redispensing; and (5) the labeling on most of the Opus 7-day unit dose containers did not include the name of the dispensing pharmacy and did not include an expiration date on those containers holding "prn" medications.

g. On October 18, 1988, Investigators Spencer and Ebeling observed Respondent as he filled and dispensed three prescriptions for Pediatric Amoxil Oral Suspension (prescription numbers 502379, 502382, and 502383). For each prescription Respondent reconstituted the Amoxil by adding an unmeasured amount of tap water to each of the bottles. Although measuring devices and deionized water were available in the prescription department, Respondent did not use either.

11. An inspection of Wyoming Drug located in Wyoming, Iowa, was conducted on October 18, 1988, by Pharmacy Investigator E. Ray Shelden.

12. The results of that inspection as revealed by Investigator Shelden's report dated October 24, 1988, reveal the following:

a. On October 18, 1988, Investigator Shelden observed that Respondent had failed to publicly display the renewal certificate for his pharmacist license posted at Wyoming Drug. Respondent routinely engages in the practice of pharmacy at Wyoming Drug on a limited basis.

13. Respondent is guilty of violations of Iowa Code sections 155A.10, 155A.12(1), 155A.12(4), 155A.12(5), and 204.307 by virtue of the allegations in paragraph 10, subsections (a) through (g) and paragraph 12, subsection (a).

Iowa Code section 155A.10 provides the following:

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

Iowa Code section 155A.12 provides, in part, the following:

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:

1. Violated any provision of this chapter or any rules of the board adopted under this chapter.

....

4. Failed to keep and maintain records required by this chapter or failed to keep and maintain complete and accurate records of purchases and disposal of drugs listed in the controlled substances Act.

5. Violated any provision of the controlled substances Act or rules relating to that Act.

Iowa Code section 204.307 provides the following:

Controlled substances in schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms shall be deemed compliance with this section.

14. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.6, 6.8(1), 6.8(4), 6.8(5), 6.8(6), 8.3(1), 8.3(2), 8.9(3)(a)(2), 8.9(3)(b), 8.9(4)(b), 8.9(6), 8.11(3), 8.11(4), 9.1(4)(b), and 9.1(4)(u) by virtue of the allegations in paragraph 10, subsections (a) through (g) and paragraph 12, subsection (a).

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 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(1) Controlled substance records shall be maintained in a manner to establish receipt and distribution of all controlled substances;

....

6.8(4) Invoices involving the distribution of Schedule III, IV, or V controlled substances to another pharmacy or practitioner must show the actual date of distribution; the name, strength, and quantity of controlled substances distributed; the name, address, and DEA registration number of the distributing pharmacy and of the practitioner or pharmacy receiving the controlled substances;

6.8(5) Copy 1 of DEA Order Form 222C, furnished by the pharmacy or practitioner to whom Schedule II controlled substances are distributed, shall be maintained by the distributing pharmacy and shall show the quantity of controlled substances distributed and the actual date of distribution;

6.8(6) Copy 3 of DEA Order Form 222C shall be properly dated, initialed, and filed and shall include all copies of each unaccepted or defective order form and any attached statements or other documents;....

657 Iowa Administrative Code section 8.3 provides the following:

8.3(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 the label.
- e. Initials of the packager.
- f. Initials of the supervising pharmacist.
- g. Quantity per container.
- h. Internal control number or date.

8.3(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 8.9(3) provides, in part, the following:

a. Labeling for single unit or unit dose packaging shall comply with the following:

....

(2) Doses packaged by the pharmacy shall be properly labeled according to subrule 8.3(2) if used beyond a 24-hour period.

b. Labeling for unit of issue packages shall contain the following information:

(1) Name, strength, and expiration date of drug when the packages are utilized for floor stock in an institutional setting.

(2) Name and room or bed number of patient, name of prescribing practitioner, name and strength of drug, directions for use, and name and address of the dispensing pharmacy, when the packages are utilized for patients in an institutional setting. Room or bed number, the name of prescribing practitioner, and the name and address of the dispensing pharmacy is not required if this information appears on a medication administration record used by the institution.

657 Iowa Administrative Code section 8.9(4) provides, in part, the following:

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 8.9(6) provides the following:

Drugs dispensed in single unit, unit dose, or unit of issue packaging in compliance with board subrules 8.9(1) to 8.9(5) may be returned to the pharmacy stock and reissued provided that:

a. The expiration dating information is retrievable and identifiable.

b. Drugs returned from unit of issue packaging are kept separate according to manufacturer's lot number and the pharmacy's repackaged expiration date unless the pharmacy's recall policy states that all lots of a drug will be returned upon recall. In this instance, drugs returned to stock shall be kept separate according to the pharmacy's repackaged expiration date as determined in board subrule 8.9(5).

c. The drugs were stored under proper storage conditions.

d. The drugs are returned to the pharmacy in the original packaging as when dispensed.

e. The pharmacy includes in their written policies and procedures the manner in which they will record or identify controlled substances returned.

657 Iowa Administrative Code section 8.11(3) provides the following:

Documentation of the correctness of controlled substance prescription refill 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 refill 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 refill information. This printout shall be verified, dated, and signed by each dispensing pharmacist. This printout of the day's controlled substance prescription refill information shall be provided to the pharmacy using an automated data processing system within seventy-two hours of the date on which the refill was dispensed.

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

657 Iowa Administrative Code section 8.11(4) provides the following:

8.11(4) An auxiliary record keeping system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason. The auxiliary system shall ensure that all refills are authorized by the original prescription and that the maximum number of refills is not exceeded. When the automated data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated data processing system as soon as possible. Auxiliary records may be destroyed after entry into the system. This subrule does not require that a permanent dual recordkeeping system be maintained.

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.

....

u. Violating any of the grounds for revocation or suspension of a license listed in Iowa Code sections 147.55, and 1987 Iowa Code supplement sections 155A.12 and 155A.15.

15. Respondent is guilty of violating paragraph 4, section (c)(1), of the stipulation agreement incorporated into the order dated June 30, 1988, by virtue of the allegations in paragraph 10, subsections (a) through (g) and paragraph 12, subsection (a).

The Iowa Board of Pharmacy Examiners finds that paragraphs 13, 14, and 15 constitute grounds for which Respondent's probation can be revoked and for which his license to practice pharmacy in Iowa can be suspended or revoked.

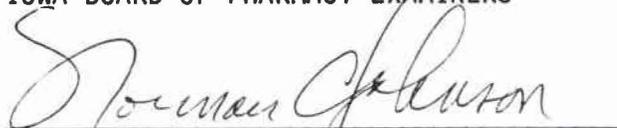
WHEREFORE, the undersigned charges that Respondent has violated paragraph 4, section (c)(1), of the stipulation agreement incorporated into the order dated June 30, 1988; sections 155A.10, 155A.12(1), 155A.12(4), 155A.12(5), and 204.307 of the Code of Iowa 1987; and sections 6.6, 6.8(1), 6.8(4), 6.8(5), 6.8(6), 8.3(1), 8.3(2), 8.9(3)(a)(2), 8.9(3)(b), 8.9(4)(b), 8.9(6), 8.11(3), 8.11(4), 9.1(4)(b), and 9.1(4)(u) of 657 Iowa Administrative Code.

IT IS HEREBY ORDERED that Phillip R. Tuetken appear before the Iowa Board of Pharmacy Examiners on January 10, 1989, 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 or revoke the license to practice pharmacy issued to Phillip R. Tuetken on July 1, 1959, 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 his own. The failure of Respondent to appear could result in the permanent suspension or revocation of his 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

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacist License of	)	DIA NO. 89DPB-7
	)	
PHILLIP R. TUETKEN	)	FINDINGS OF FACT,
License No. 12514	)	CONCLUSIONS OF LAW
Respondent	)	AND DECISION

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To: Phillip R. Tuetken

A Complaint and Statement of Charges and Petition to Revoke Probation for the above case was filed by Norman C. Johnson, Executive Secretary of the Iowa Board of Pharmacy Examiners (hereinafter the Board), on December 9, 1988.

The hearing for this case was consolidated with the hearing for Long's Drug, DIA No. 89DPB-8. However, two separate decisions will be issued. The hearing was held on July 11, 1989 beginning at 2:00 p.m. The hearing was held in the conference room, Iowa Board of Pharmacy Examiners, Executive Hills West, Des Moines, Iowa. Present were the Board, members of the Board staff, and a court reporter. Pharmacy Board member Alan M. Shepley disqualified himself and did not participate in the hearing or decision in this case. Appearing for the State was Thomas D. McGrane, Assistant Attorney General. The Respondent, Phillip R. Tuetken, was represented by attorney Bob Shimanek. 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) (1989).

After hearing the testimony and examining the exhibits, the Board convened in closed executive session pursuant to Iowa Code section 21.5(1)(f) (1989) 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 and Petition to Revoke Probation, the recorded testimony of the witnesses, and State's Exhibits 1, 1A, 1B, 1C, 2, 3, 4 and 5, and Respondent's Exhibits 1 through 5.

FINDINGS OF FACT

1. Phillip R. Tuetken holds Iowa pharmacist license number 12514. Phillip R. Tuetken is the pharmacist-in-charge and president of Long's Drug, which holds pharmacy license number 131. Long's Drug is located in Monticello, Iowa. Phillip R. Tuetken's pharmacist license remains on probation pursuant to a

stipulation entered into in June of 1988. The pharmacy license of Long's Drug, license number 131, was suspended for a period of one year and as of June 30, 1989, is no longer under suspension.

2. On June 30, 1988, the Respondent, Phillip R. Tuetken, and the Iowa Board of Pharmacy Examiners entered into a Stipulation and Consent Order. Pursuant to the Stipulation and Consent Order, the Respondent's license was placed on probation for a period of 18 months. Also on June 30, 1988, Long's Drug, with the Respondent as pharmacist-in-charge and president, entered into a Stipulation and Consent Order with the Board. This Stipulation and Consent Order addressed a number of violations of Iowa pharmacy law which were to be corrected.

3. On October 18, 1988, Board investigator Morrell Spencer went to Long's Drug in Monticello Iowa. Board investigator Gary Ebling accompanied Mr. Spencer on this inspection. As a result of this inspection Mr. Spencer and Mr. Ebling prepared an inspection form and an investigative report regarding Long's Drug. This inspection led to the filing of the current Complaint and Statement of Charges in this case.

4. As of October 18, 1988, the Respondent and his pharmacy were not in compliance with a number of Iowa Code sections and Pharmacy Board rules.

5. After the Board inspection in October of 1988, the Respondent made a number of corrections in the procedures followed in Long's Drug. The Respondent requested that a Board investigator return to Long's Drug to conduct an inspection prior to this hearing. As a result of that request, the Board investigator returned to Long's Drug and conducted a further inspection on the Friday before the hearing.

6. The Respondent has corrected the violations which led to both the original Complaint and Statements of Charges. Once the Board has made the Respondent aware of the problems in his pharmacy, the Board is convinced that this pharmacist has changed his pharmacy practices to come into compliance with Iowa law. The Board does note that it is the pharmacist's responsibility to stay current in Iowa law and rules related to the practice of pharmacy. The Board is convinced that as of the date of the hearing the Respondent and his pharmacy are essentially in compliance with Board rules and pharmacy law.

7. The Board's duty to the public has been carried out in this case. The pharmacist in this case has done his duty as a licensed pharmacist in the State of Iowa to correct the problems which existed in his pharmacy.

8. The Respondent's probation remains in effect until December 30, 1989. No purpose would be served by revoking probation or by extending the period of probation longer than that date.

9. In order to ensure that compliance with Iowa law and Pharmacy Board rules continue, another inspection of Long's Drug is necessary prior to the ending of probation.

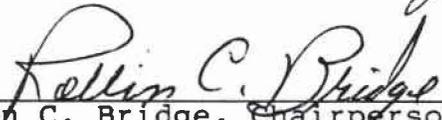
#### CONCLUSIONS OF LAW

As of July 11, 1989, the Respondent, Phillip R. Tuetken, was not in violation of any of the Iowa Code sections or Board rules as charged in the Complaint and Statement of Charges and Petition to Revoke Probation filed December 9, 1988.

#### DECISION AND ORDER

IT IS THEREFORE THE ORDER of the Iowa Board of Pharmacy Examiners that Respondent's pharmacy license number 12514 will remain on probation until December 30, 1989. The Board staff is directed to conduct an unannounced inspection of Long's Drug in Monticello, Iowa prior to December 30, 1989. IT IS THE FURTHER ORDER of the Board that no additional disciplinary action will be imposed.

Dated this *18<sup>th</sup>* day of *July*, 1989.

  
\_\_\_\_\_  
Rollin C. Bridge, Chairperson  
Iowa Board of Pharmacy Examiners

  
\_\_\_\_\_  
Amy Christensen Couch  
Administrative Law Judge

ACC/jmm

**BEFORE THE IOWA BOARD OF PHARMACY**

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Re:	)	Case Nos. 2013-45 & 2013-91
Pharmacist License of	)	
<b>PHILLIP TUETKEN</b>	)	<b>STATEMENT OF CHARGES</b>
License No. 12514,	)	<b>&amp; NOTICE OF HEARING</b>
Respondent.	)	

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**COMES NOW** the Iowa Board of Pharmacy (Board) and files this Notice of Hearing and Statement of Charges pursuant to Iowa Code sections 17A.12(2) and 17A.18(3) (2013). Respondent was issued Iowa license 12514. Respondent's license is currently active.

**A. TIME, PLACE, AND NATURE OF HEARING**

Hearing. A disciplinary contested case hearing shall be held on April 29, 2014, before the Iowa Board of Pharmacy. The hearing shall be held during the morning session, beginning at 9:00 a.m. and shall be located in the Board conference room located at 400 S.W. 8<sup>th</sup> Street, Des Moines, Iowa.

Presiding Officer. The Board shall serve as presiding officer, but the Board may request an Administrative Law Judge from the Department of Inspections and Appeals make initial rulings on prehearing matters, and be present to assist and advise the board at hearing.

Hearing Procedures. The procedural rules governing the conduct of the hearing are found at 657 Iowa Administrative Code rule 35.19. At hearing you will be allowed the opportunity to respond to the charges against you, to produce evidence on your behalf, cross-examine witnesses, and examine any documents introduced at hearing. You may appear personally or be represented by counsel at your own expense. The hearing may be open to the public or closed to the public at your discretion.

Prosecution. The office of the Attorney General is responsible for representing the public interest (the State) in this proceeding. Pleadings shall be filed with the Board and copies should be provided to counsel for the State at the following address.

Meghan Gavin  
Assistant Attorney General  
Iowa Attorney General's Office  
2<sup>nd</sup> Floor Hoover State Office Building  
Des Moines, Iowa 50319.

Ms. Gavin can also be reached by phone at (515)281-6736 or e-mail at [Meghan.Gavin@iowa.gov](mailto:Meghan.Gavin@iowa.gov).

Communications. You may contact the Board office (515)281-5944 with questions regarding this notice and other matters relating to these disciplinary proceedings. However, you

may NOT contact individual members of the Board to discuss these proceedings by phone, letter, facsimile, email, or in person. Board members can only receive information about the case when all parties have notice and an opportunity to participate, such as at the hearing or in pleadings you file with the Board office and serve upon all parties in the case. You may also direct questions relating to settlement of these proceedings to Assistance Attorney General Meghan Gavin at (515)281-6736.

## **B. LEGAL AUTHORITY AND JURISDICTION**

Jurisdiction. The Board has jurisdiction over this matter pursuant to Iowa Code chapters 17A, 147, 155A, and 272C.

Legal Authority. If any of the allegations against you are founded, the Board has authority to take disciplinary action against you under Iowa Code chapters 17A, 147, 155A, and 272C and 657 Iowa Administrative Code chapter 36.

Default. If you fail to appear at the hearing, the Board may enter a default decision or proceed with the hearing and render a decision in your absence, in accordance with Iowa Code section 17A.12(3) and 657 Iowa Administrative Code rule 35.21.

## **C. CHARGES**

### **Count I**

#### **UNETHICAL BEHAVIOR OR PRACTICE HARMFUL OR DETRIMENTAL TO THE PUBLIC**

Respondent is charged with engaging in unethical behavior or practice harmful or detrimental to the public in violation of Iowa Code section 155A.12(2) and 657 Iowa Administrative Code rule 36.1(4)(c).

### **Count II**

#### **FAILURE TO MAINTAIN A CQI PROGRAM**

Respondent is charged with failing to maintain a continuous quality improvement program in violation of Iowa Code section 155A.12(1) and 657 Iowa Administrative Code rules 8.3(1), 8.26, and 36.1(4)(u).

### **Count III**

#### **FAILURE TO VERIFY PRESCRIPTION**

Respondent is charged with failing to verify a prescription in violation of Iowa Code section 155A.12(1) and 657 Iowa Administrative Code rule 8.3(1), 8.3(3), and 36.1(4)(u).

### **Count IV**

#### **VIOLATING THE DUTIES OF A PHARMACIST-IN-CHARGE**

Respondent is charged with violating the duties of a pharmacist-in-charge in violation of Iowa Code section 155A.12(1) and 657 Iowa Administrative Code rules 6.2, 8.3(1), 8.26(2), and 36.1(4)(u).

## **D. FACTUAL CIRCUMSTANCES**

### ***Case 2013-45***

1. On May 14, 2013 the Board opened a complaint against Wyoming Drug and the Respondent. The complaint alleged the Respondent filled numerous forged prescriptions for Hydromorphone 8mg.
2. On December 10, 2012, the Respondent received a drug alert from Finley Hospital Pain Clinic advising of forged prescriptions for Hydromorphone 8mg listing Dr. Tim Miller as the prescriber.
3. The Respondent continued to fill prescriptions for Hydromorphone 8mg following the alert, without consulting the prescriber.
4. Several of the forged prescriptions were "signed" by Dr. Miller. In addition to the alert, Dr. Miller had previously informed the Respondent that he did not prescribe Hydromorphone 8mg.

### ***Case 2013-91***

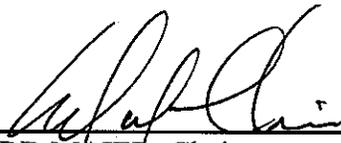
1. On May 10, 2013 a complaint was filed against Wyoming Drug and the Respondent. The complaint alleged several dispensing errors.
2. Numerous errors were made in regarding patient C.W.'s medications, including C.W.'s insulin prescription was issued in his granddaughter's name, a Warafarin prescription was filled without request, and one of C.W.'s wife prescriptions was incorrectly filled with a medication not covered by her insurance.
3. None of the errors were recorded in a Continuous Quality Improvement Program.

## **E. SETTLEMENT**

This matter may be resolved by settlement agreement. The procedural rules governing the Board's settlement process are found at 657 Iowa Administrative Code rule 36.3. If you are interested in pursuing settlement of this matter, please contact Assistant Attorney General Meghan Gavin.

## **F. PROBABLE CAUSE FINDING**

On this the 12th day of March, 2014, the Iowa Board of Pharmacy found probable cause to file this Notice of Hearing and Statement of Charges.



EDWARD MAIER, Chairperson  
Iowa Board of Pharmacy  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Meghan Gavin  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, Iowa

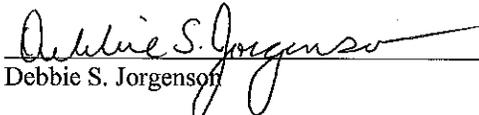
PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon Respondent to the above cause by:

- |  |   |
|--|---|
| <input type="checkbox"/> personal service                                    | <input type="checkbox"/> first class mail |
| <input checked="" type="checkbox"/> certified mail, return receipt requested | <input type="checkbox"/> facsimile        |
| Article Number <u>9171999991703239255028</u>                                 | <input type="checkbox"/> other _____      |

on the 13th day of March, 2014.

I declare that the statements above are true to the best of my information, knowledge and belief.

  
Debbie S. Jorgenson

BEFORE THE IOWA BOARD OF PHARMACY

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IN THE MATTER OF:	)	
	)	
Pharmacist License of	)	Docket Nos. 2013-45 & 2013-91
<b>PHILLIP TUETKEN</b>	)	DIA No. 14PHB010
License No. 12514	)	
	)	
Pharmacy License of	)	
<b>WYOMING DRUG</b>	)	
License No. 390	)	
	)	
Respondents.	)	<b>FINDINGS OF FACT,</b>
	)	<b>CONCLUSIONS OF LAW,</b>
	)	<b>DECISION, AND ORDER</b>

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**STATEMENT OF THE CASE**

On March 12, 2014, the Iowa Board of Pharmacy (Board) found probable cause to file a Statement of Charges & Notice of Hearing against Respondents Phillip Tuetken and Wyoming Drug. The Statement of Charges alleges that Respondents Tuetken and Wyoming Drug: 1) engaged in unethical behavior or practice harmful or detrimental to the public; 2) failed to maintain a CQI program; and 3) failed to verify a prescription. Additionally, the Statement of Charges alleges that Respondent Tuetken violated the duties of a pharmacist-in-charge.

The hearing was held on June 30, 2014. The following members of the Board presided at the hearing: Edward Maier, Chairperson; James Miller; LaDonna Gratias; Susan Frey; Judith Trumpy; and Edward McKenna. Respondents appeared and were represented by attorney Nick Strittmatter. Assistant attorney general Meghan Gavin represented the State. The hearing was closed to the public at the election of Respondents, pursuant to Iowa Code section 272C.6(1). The hearing was recorded by a certified court reporter. Administrative Law Judge Laura Lockard assisted the Board in conducting the hearing and was instructed to prepare the Board's written decision in accordance with its deliberations.

**THE RECORD**

The record includes the Notice of Hearing and Statement of Charges with regard to both Respondents. The record also includes hearing testimony of Curt Gerhold and Phillip Tuetken. The State introduced Exhibits 1 through 17, which were admitted as evidence. Respondents introduced Exhibit A, which was admitted as evidence.

## FINDINGS OF FACT

Respondent Wyoming Drug holds Iowa pharmacy license number 390, which is currently active. Respondent Phillip Tuetken holds Iowa pharmacist license number 12514, which is currently active. At all times relevant to this action, Tuetken was employed at Wyoming Drug in Wyoming, Iowa as pharmacist-in-charge. Tuetken has been a licensed pharmacist since approximately 1959. He has worked at Wyoming Drug for the last four to five years and works approximately 35 to 40 hours per week.

### Complaint 1: Forged Hydromorphone Prescriptions

In mid-December 2012, Amy Moet, a relief pharmacist who works one to two days per month at Wyoming Drug, alerted the Board that Wyoming Drug had been filling forged prescriptions for hydromorphone 8 mg tablets. Curt Gerhold, a compliance officer for the Iowa Board of Pharmacy, was assigned to investigate the matter. Gerhold interviewed Moet, who informed him that she had a prescription come in from Dr. Tim Miller for hydromorphone 8 mg that looked suspicious. Moet called Finley Pain Clinic, where Dr. Miller practices, on December 6, 2012 to inquire whether the prescription was valid. Moet was informed by the clinic that Dr. Miller does not write prescriptions for hydromorphone. After receiving this information, Moet went through all of the hydromorphone prescriptions that Wyoming Drug had filled recently that were purportedly written by Dr. Miller. Moet checked with Dr. Miller's office and determined that all of these prescriptions were forged. (Exh. 5; Gerhold testimony).

As a result of Moet's call, Finley Pain Clinic generated a drug alert form to be sent to all pharmacies in the area. Additionally, the clinic filed a report with the Jones County Sheriff's Department on December 17, 2012. (Exh. 6, 7).

Gerhold visited Wyoming Drug on or about December 18, 2012 and spoke with Tuetken about the forged hydromorphone prescriptions. Tuetken was aware of the issue of the forged prescriptions because he had been visited by a representative of the sheriff's office that day or the prior day, who had taken copies of records related to six months of hydromorphone prescriptions filled by Wyoming Drug. Gerhold advised Tuetken that all of the hydromorphone prescriptions that had been filled in the last six months by Wyoming Drug were forged. Gerhold wrote down for Tuetken the list of 13 names that Moet had generated of individuals who had filled forged hydromorphone prescriptions at Wyoming Drug. Tuetken indicated that he would not fill hydromorphone prescriptions for members of the family in question without contacting the prescribing physician to verify the legitimacy of the prescription. (Gerhold testimony; Exh. 5).

On March 1, 2013, Moet sent Gerhold an e-mail indicating that prescriptions for hydromorphone 8 mg were still being filled at Wyoming Drug. On March 20, 2013, Gerhold visited Wyoming Drug to obtain copies of the hydromorphone prescriptions that had been filled. At that time, Gerhold asked Tuetken if any of the individuals on the list of 13 that Gerhold had provided Tuetken in December had tried to fill additional hydromorphone prescriptions. Tuetken responded that he did not know. Upon review, Gerhold discovered that six individuals had filled forged prescriptions for

hydromorphone subsequent to his December 18, 2012 visit to the pharmacy; all of those individuals were on the list that Gerhold provided to Tuetken during that visit. The pharmacy dispensed a total of 720 tablets of hydromorphone 8 mg between January and March 2013, after Gerhold's initial visit with Tuetken. (Exh. 5; Gerhold testimony).

Prior to Tuetken's initial discussion with Gerhold in December 2012, Tuetken had filled two prescriptions for morphine and a morphine derivative for a single patient, F.B., very close in time. Tuetken filled a prescription for 120 pills of morphine on November 29, 2012, then another prescription for 120 pills of hydromorphone 8 mg on December 4, 2012. According to Gerhold, a single patient filling these two prescriptions so close in time should raise a red flag for a pharmacist. Pharmacies maintain patient profiles, and it should be relatively easy for a pharmacist to access a particular patient's prescription history. (Exh. 10, Gerhold testimony).

Tuetken could not say definitively at hearing whether the computer system that Wyoming Drug uses has an auto alert that alerts a pharmacist to a drug interaction (for example, duplicate therapy). Tuetken testified that he did not recall filling a second prescription for F.B. for morphine just six days prior to the hydromorphone prescription she presented. He acknowledged that he should have recalled this, but did not. Tuetken then filled another prescription for F.B. for hydromorphone 8 mg dated March 8, 2013, after he had already been informed that the previous prescriptions she filled were forged. (Exh. 10; Gerhold, Tuetken testimony).

At hearing, Tuetken testified that he did not know why he did not call Dr. Miller's office when he received additional prescriptions for hydromorphone 8 mg after Gerhold's December visit. Tuetken acknowledged that he should have done so and that hydromorphone is not a prescription that is commonly filled at Wyoming Drug. (Tuetken testimony).

### Complaint 2: Errors Filling Legitimate Prescriptions

In May 2013, the Board received a second complaint regarding Wyoming Drug and Tuetken from UnityPoint Clinic Family Medicine in Clarence, Iowa. Mary Coon, an RN at UnityPoint Clinic Family Medicine, reported to the Board that a patient of the clinic, C.W., as well as his wife, reported several medication errors by Wyoming Drug and Tuetken. (Exh. 13, pp. 47-48).

First, C.W. had his insulin prescription filled by Tuetken at Wyoming Drug and it was erroneously filled in the name of C.W.'s granddaughter, who has the same last name but a different first name. The family returned the insulin to the pharmacy and the error was corrected. (Exh. 13, p. 48).

Second, C.W.'s wife called in in May 2013 and asked for a refill on some of his medications after a stay at a nursing facility. When C.W.'s wife picked up the medications, she noticed that Tuetken had filled a prescription for warfarin, which C.W. had not been taking for years. The last warfarin prescription on file for C.W. was written

on October 17, 2011. The prescription provided for a 60-day supply and four refills. (Exh. 14, 15).

On May 28, 2013, Gerhold met with Tuetken to discuss the prescription errors that had been reported. There was no incident report available for either of the errors. At hearing, Tuetken testified that he did not have any recollection of the situation where C.W.'s medication was mislabeled with his granddaughter's name. (Exh. 14; Tuetken testimony).

With regard to the warfarin incident, Tuetken testified that C.W.'s wife called the pharmacy and asked him to fill C.W.'s maintenance prescriptions. According to Tuetken, he was unable to get ahold of C.W.'s wife by telephone, therefore assumed that C.W. needed warfarin because it was past time for the prescription to be filled. Tuetken recalled that C.W. had been on warfarin previously. (Tuetken testimony).

When asked at hearing about whether Wyoming Drug has a continuous quality improvement (CQI) program in place, Tuetken testified that he keeps track of errors at the pharmacy mentally. (Tuetken testimony).

Tuetken was unable to describe with specificity at hearing the computer system that Wyoming Drug uses to track and verify prescriptions. Tuetken testified that if he fills a prescription himself at the pharmacy and there is no pharmacy tech on site he is the person who does all of the required steps, including data entry, filling the prescription, and verifying the prescription. Tuetken testified that the computer system does not allow him to compare the finished bottle with the original prescription at the same time. Tuetken testified that all he can review when he is verifying the prescription after it has been filled is what he manually entered into the computer system, not the original prescription that the patient presented. (Tuetken testimony).

With regard to the labeling error for C.W.'s insulin prescription, Tuetken testified that there is a way for the computer system to have caught the name difference in the final verification process. He did not specify why that did not occur in that particular case. (Tuetken testimony).

With regard to the pharmacy's policies and procedures, Tuetken testified that these are done at a "central place." He testified that he does not develop policies and procedures for the pharmacy. (Tuetken testimony).

## **CONCLUSIONS OF LAW**

### **Count I: Unethical Behavior or Practice Harmful or Detrimental to the Public**

The Board is authorized to impose a disciplinary sanction on a licensee when the licensee knowingly makes misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engages in unethical conduct or practice harmful or

detrimental to the public. It is not necessary that there be proof of actual injury for a violation to be found.<sup>1</sup>

The undisputed evidence in this case demonstrates that Tuetken, the pharmacist-in-charge at Wyoming Drug, continued filling forged prescriptions for hydromorphone even after being warned by both a compliance officer from the Board and the sheriff's office that all of the prescriptions that the pharmacy had filled in the six months prior to December 2012 for hydromorphone were forged. Tuetken acknowledged that hydromorphone was not commonly filled at Wyoming Drug, yet despite this fact he nevertheless dispensed 720 more pills from prescriptions forged with Dr. Miller's name over the course of three months after being informed of the forgeries.

While Tuetken repeatedly emphasized at hearing his belief that Wyoming Drug did not receive a copy of the drug alert that was issued by Dr. Miller's office after they discovered the forgeries, the Board does not believe that whether or not Wyoming Drug received the drug alert mitigates Tuetken's conduct. The drug alert would have added nothing to what Tuetken had already been personally informed by the Board's compliance officer and the sheriff's office. It is difficult to imagine that the drug alert would have changed Tuetken's conduct in a way that those notifications did not.

While that conduct alone would have been enough to find a violation under this count, the evidence also demonstrates that Tuetken committed at least one labeling error and filled at least one expired prescription during the relevant time period. In his testimony at hearing, Tuetken exhibited a shocking lack of familiarity with the computer system that Wyoming Drug utilizes and was unable to describe in any detail safeguards that have been put in place to prevent errors of the sort that he committed.

Tuetken was acting as pharmacist-in-charge at Wyoming Drug during the time period in question and there is no evidence that the pharmacy had in place any safeguards to prevent the sort of large-scale dispensing of schedule II narcotics based on forged prescriptions that occurred there. The pharmacy was aware of the high likelihood of forgery and took no steps to prevent filling forged prescriptions.

Dispensing large quantities of schedule II narcotics without a valid prescription is harmful and detrimental to the public. The preponderance of the evidence demonstrates that Respondent Tuetken and Respondent Wyoming Drug committed a violation of 657 Iowa Administrative Code 36.1(4)(c).

#### Count II: Failure to Maintain a CQI Program

The Board's regulations provide that the pharmacy and the pharmacist-in-charge share responsibility for ensuring that all operations of the pharmacy are in compliance with federal and state laws, rules, and regulations relating to pharmacy operations and the practice of pharmacy.<sup>2</sup> All licensed pharmacies in Iowa are required to implement or

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<sup>1</sup> Iowa Code § 155A.12(2) (2013); 657 Iowa Administrative Code 36.1(4)(c).

<sup>2</sup> 657 IAC 8.3(1).

participate in a continuous quality improvement (CQI) program.<sup>3</sup> The pharmacist in charge is responsible for ensuring that the pharmacy utilizes a CQI program consistent with the requirements of 657 Iowa Administrative Code 8.26.<sup>4</sup>

The CQI program is intended to be an ongoing, systematic program of standards and procedures to detect, identify, evaluate, and prevent medication errors, thereby improving medication therapy and the quality of patient care.<sup>5</sup>

A pharmacy is required to develop, implement, and adhere to written policies and procedures for operation and management of the CQI program. The policies and procedures must address a process to identify and document reportable program events. A reportable program event is a preventable medication error that results in the incorrect dispensing of a prescribed drug, including an incorrect drug dispensed, incorrect labeling, or a drug received by the wrong patient.<sup>6</sup>

The preponderance of the evidence demonstrates in this case that Respondent Tuetken and Respondent Wyoming Drug violated Iowa Code section 155A.12(1) and 657 Iowa Administrative Code 8.26, and 36.1(4)(u) by failing to have a CQI program compliant with the Board's requirements. In response to questioning on this issue at hearing, Tuetken could not identify any CQI program. Tuetken stated that he keeps tracks of errors mentally; there is no evidence that Wyoming Drug keeps any written record of reportable events, as required by the Board's regulations. No written incident report was available for either the incorrect labeling of C.W.'s insulin with his granddaughter's name or for the incorrect dispensing of warfarin to C.W. after the prescription had expired.

Count III: Failure to Verify Prescription

Pursuant to the Board's regulations, the pharmacist must provide and document the final verification for accuracy, validity, completeness, and appropriateness of a patient's prescription or medication order prior to the delivery of the medication to the patient or to the patient's representative.<sup>7</sup> The pharmacy and pharmacist-in-charge share responsibility for making sure that procedures are in place to ensure such verification is occurring.<sup>8</sup>

The evidence here demonstrates that in more than one instance Tuetken failed to verify a prescription that resulted in an error that left the pharmacy. Tuetken improperly labeled C.W.'s insulin with his granddaughter's name and then refilled C.W.'s expired prescription for warfarin. Tuetken's explanation at hearing of the pharmacy's system for verification was nearly incomprehensible. Under these circumstances, Respondent

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<sup>3</sup> 657 IAC 8.26.

<sup>4</sup> 657 IAC 8.26(2).

<sup>5</sup> 657 IAC 8.26.

<sup>6</sup> 657 IAC 8.26(1), (3).

<sup>7</sup> 657 IAC 8.3(3).

<sup>8</sup> 657 IAC 8.3(1).

Tuetken and Respondent Wyoming drug committed a violation of 657 Iowa Administrative Code 8.3(3) and 36.1(4)(u).

Count IV: Violating the Duties of a Pharmacist-in-Charge

This charge relates only to Tuetken. Under the Board's regulations, a pharmacist-in-charge is required to, among other things: 1) ensure that the pharmacy utilizes an ongoing, systematic program for achieving performance improvement and ensuring the quality of pharmaceutical services; and 2) ensure the legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, and regulations governing the practice of pharmacy.<sup>9</sup>

As discussed above, with regard to Count II, Tuetken failed to ensure that Wyoming Drug utilized an ongoing, systematic CQI program. Tuetken did not document either of the reportable events that were discovered during the Board's investigation. Tuetken appeared to have no knowledge of the Board's requirement for a CQI program utilizing written documentation of reportable events; instead, he testified that he keeps track of errors mentally. The preponderance of the evidence establishes a violation of 657 Iowa Administrative Code 6.2(2) and 6.2(15).

Sanction

The Board may consider a number of factors in determining the nature and severity of the disciplinary sanction to be imposed when a violation is established, including the relative seriousness of the violation as it relates to assuring a high standard of professional care; the facts of the violation; any extenuating circumstances; whether remedial action has been taken; and any other factors that reflect upon the competency, ethical standards, and professional conduct of the licensee.<sup>10</sup>

The Board has extremely serious concerns about Tuetken's ability to safely practice pharmacy. As discussed above, Tuetken ignored the warnings of the Board's compliance officer and the sheriff's office regarding forged prescriptions coming into the pharmacy purporting to be from Dr. Miller. The warnings were not speculative; the pharmacy had already filled a number of the forged prescriptions prior to December 2012. Despite the warnings, Tuetken dispensed 720 more pills on the basis of forged prescriptions in the three months following the warnings. Not only that, Tuetken appears to lack insight into the magnitude of the violation and his role in creating it; at hearing, Tuetken repeatedly emphasized his belief that Wyoming Drug had not received the drug alert from Finley Pain Clinic. Regardless of whether or not the official drug alert had been received, Tuetken had been alerted by both the Board and the sheriff's office that he had filled forged prescriptions. There should have been no additional information needed for Tuetken to take swift, corrective action. None was taken.

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<sup>9</sup> 657 IAC 6.2(2), (15).

<sup>10</sup> 657 IAC 36.1(3).

As discussed above, Tuetken did not demonstrate a comprehensive understanding at hearing of either the need to verify a filled prescription against the prescription that comes into the pharmacy, nor any systems in place at Wyoming Drug to do so. Tuetken's lack of care in this regard resulted in at least two prescription errors that left the pharmacy without being caught. No record was made of those errors by the pharmacy, even after the pharmacy was alerted. The errors were only reported to the Board when the individual who received the prescriptions notified his health care provider, who made the report. Without evidence that there are any systems in place to prevent these types of errors from happening, it is impossible to know how many other such errors may be occurring on a regular basis at this pharmacy.

The Board likewise has serious concerns about Wyoming Drug's compliance with the laws and regulations applicable to the practice of pharmacy. Tuetken has been the pharmacist-in-charge for several years and it does not appear that any action has been taken regarding the systemic errors that have been occurring over his tenure.

Finally, despite the severity of the violations, there is no evidence that, to date, either Wyoming Drug or Tuetken have taken any steps to address the problems have been identified by the Board.

### **DECISION AND ORDER**

IT IS THEREFORE ORDERED that Respondent Phillip Tuetken's license shall be suspended indefinitely effective upon issuance of this order. Pursuant to 657 Iowa Administrative Code 36.13(1), no application for reinstatement shall be made until at least one year has elapsed from the date of this order.

IT IS FURTHER ORDERED that Respondent Phillip Tuetken shall have no involvement in the ownership, management, direction, or control of any business engaged in the practice of pharmacy during the time that his license is suspended.

IT IS FURTHER ORDERED that Respondent Phillip Tuetken shall pay a civil penalty in the amount of \$3,500. The civil penalty payment shall be made by check, payable to the Treasurer of Iowa, and mailed to the executive director of the Board within 30 days of the issuance of this Decision and Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

IT IS FURTHER ORDERED that Respondent Wyoming Drug's license shall be placed on probation for a period of two years.

IT IS FURTHER ORDERED that Respondent Wyoming Drug shall, within 30 days of the date this Order is issued, designate a new pharmacist in charge for Wyoming Drug by submitting a new license application which indicates a change of PIC, along with the required fee of \$135, to the Board office.

IT IS FURTHER ORDERED that, as a condition of probation, Respondent Wyoming Drug shall require that its pharmacist-in-charge sign up for and effectively utilize the Iowa Prescription Monitoring Program (PMP).

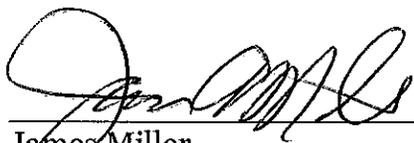
IT IS FURTHER ORDERED that, as a condition of probation, Respondent Wyoming Drug shall file sworn quarterly reports to the Board. The reports shall be filed no later than the 5<sup>th</sup> day of March, June, September, and December of each year. The quarterly reports shall describe Respondent Wyoming Drug's compliance with the terms of this order, including the requirement that the pharmacist-in-charge sign up for and utilize the PMP. Additionally, the quarterly reports shall describe Respondent's implementation of its written CQI program.

IT IS FURTHER ORDERED that Respondent Wyoming Drug shall, within 30 days of the date this order is issued, submit to the Board for its approval a copy of policies and procedures unique to Wyoming Drug, including a Continuous Quality Improvement program. Once the policies and procedures are approved by the Board, Respondent Wyoming Drug shall implement and follow the policies and procedures.

IT IS FURTHER ORDERED that Respondent Wyoming Drug shall pay a civil penalty in the amount of \$3,500. The civil penalty payment shall be made by check, payable to the Treasurer of Iowa, and mailed to the executive director of the Board within 30 days of the issuance of this Decision and Order. All civil penalty payments shall be deposited into the State of Iowa general fund.

IT IS FURTHER ORDERED pursuant to Iowa Code section 272C.6 and 657 Iowa Administrative Code 36.18(2), that Respondent Wyoming Drug and Respondent Phillip Tuetken shall pay \$75 for fees associated with conducting the disciplinary hearing. In addition, the executive secretary/director of the Board may bill Respondent for any witness fees and expenses or transcript costs associated with this disciplinary hearing. Respondent shall remit for these expenses within 30 days of receipt of the bill.

Dated this 26<sup>th</sup> day of August, 2014

  
\_\_\_\_\_  
James Miller  
Vice-Chairperson, Iowa Board of Pharmacy

cc: Meghan Gavin, Assistant Attorney General  
Nick Strittmatter, Attorney for Respondent

*Any aggrieved or adversely affected party may seek judicial review of this decision and order of the Board, pursuant to Iowa Code section 17A.19.*