

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacy License of)	COMPLAINT
MR. DRUG)	AND
License No. 765)	STATEMENT
Michael C. Topf,)	OF CHARGES
Pharmacist in charge,)	AND
Respondent)	NOTICE OF HEARING

COMES NOW, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 7th day of October, 1991, and files this Complaint and Statement of Charges against Mr. Drug, a pharmacy licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Melba L. Scaglione, Chairperson; Alan M. Shepley, Vice Chairperson; Rollin C. Bridge; Donna J. Flower; Phyllis A. Olson; Marian L. Roberts; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent is licensed to operate a pharmacy at 415 Fourth Street in Sergeant Bluff, Iowa, and holds license number 765.

3. General pharmacy license number 765, issued in the name of Mr. Drug, with Michael C. Topf as pharmacist in charge, was renewed on November 19, 1990, and is current until December 31, 1991.

4. The Board has received Michael C. Topf's medical records from St. Luke's Regional Medical Center in Sioux City, Iowa. These records indicate the following:

a. Michael C. Topf was admitted to St. Luke's Regional Medical Center on July 26, 1991, for detoxification. He was discharged on July 29, 1991.

b. Michael C. Topf was admitted to St. Luke's Gordon Recovery Center in Sioux City, Iowa, on July 29, 1991, for treatment of alcohol and drug dependence. He was discharged on September 12, 1991.

c. Michael C. Topf's medical records dated July 30, 1991, indicate the following: "Laboratory work showed on his [Mr. Topf's] drugs of abuse screen that he is positive for amphetamines and opiates and Benzodiazepines."

5. Michael C. Topf unlawfully diverted schedule III and IV controlled substances from Mr. Drug Pharmacy to his own personal use without or in excess of prescriber authorization. He has excessively used drugs and alcohol on a continuing basis.

6. The Board has received two investigative reports (one dated August 6, 1991, and one dated September 5, 1991) from Pharmacy Investigator Morrell A. Spencer. These reports indicate the following:

a. An audit beginning July 7, 1989, and ending August 29, 1991, revealed the following shortages of schedule III controlled substances from the Mr. Drug Pharmacy in Sergeant Bluff: (1) a shortage of 1,772 tablets of Acetaminophen with Codeine No. 3 and (2) a shortage of 186 Prelu-2 capsules.

b. An audit beginning July 7, 1989, and ending August 29, 1991, revealed the following shortages of schedule IV controlled substances from the Mr. Drug Pharmacy in Sergeant Bluff: (1) a shortage of 1,590 tablets of Propoxyphene N-100; (2) a shortage of 884 tablets of Valium 5mg; (3) a shortage of 170 tablets of Diazepam 5mg; (4) a shortage of 133 tablets of Diazepam 10mg; and (5) a shortage of 1,493 capsules of Phentermine HCl 30mg.

c. An inspection of the Mr. Drug Pharmacy conducted on August 1, 1991, revealed the following:

i. A container of Nembutal Sodium 100mg capsules was found with the bottom of the container cut open and four capsules missing.

ii. The pharmacy failed to obtain the 1990 and 1991 editions of Volumes I and II of the USP DI, a required reference text for all general pharmacies.

iii. The pharmacy was not equipped with a suitable barrier to prevent unauthorized entry into the prescription department.

iv. The pharmacy's computer system contained incomplete prescription refill information and inaccurate product identification (NDC) numbers for generic prescription drug products.

v. Pharmacist in charge Michael C. Topf failed to display his current pharmacist license renewal certificate in the pharmacy.

vi. Copy 3 of DEA form 222 (#880130352) failed to show the date or quantity of drug received.

vii. Supplier invoices for prescription drugs and controlled substances received by the pharmacy failed to show the actual date of receipt and the identity of the receiving individual.

viii. Prescription records maintained by the pharmacy failed to clearly identify the prescription drugs and controlled substances which had been dispensed between July 7, 1989, and August 29, 1991.

7. Respondent is guilty of violations of Iowa Code sections 155A.10, 155A.15(2)(c), 155A.15(2)(d), 155A.23(2), 155A.23(4), 204.308(3), 204.401(1)(c)(6), 204.401(1)(d), 204.402(1)(a), and 204.403(1)(c) by virtue of the allegations in paragraphs 4, 5, and 6.

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.15 provides, in part, the following:

2. The board shall refuse to issue a pharmacy license for failure to meet the requirements of section 155A.13. The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:...

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

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

- (1) A pharmacy licensed by the board.
- (2) A practitioner.
- (3) A person who procures prescription drugs or devices for the purpose of lawful research, teaching, or testing, and not for resale.
- (4) A manufacturer or wholesaler licensed by the board....

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

A person shall not:...

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

chapter.

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

Iowa Code section 204.308 provides, in part, the following:

3. ...[A] controlled substance included in schedule III or IV, which is a prescription drug... shall not be dispensed without a written or oral prescription of a practitioner.

Iowa Code section 204.401 provides, in part, the following:

1. Except as authorized by this chapter, it is unlawful for any person to manufacture, deliver, or possess with the intent to manufacture or deliver, a controlled substance, a counterfeit substance, or a simulated controlled substance, or to act with, enter into a common scheme or design with, or conspire with one or more other persons to manufacture, deliver, or possess with the intent to manufacture or deliver a controlled substance, a counterfeit substance, or a simulated controlled substance.

...
c. Violation of this subsection with respect to the following controlled substances, counterfeit substances, or simulated controlled substances is a class "C" felony, and in addition to the provisions of section 902.9, subsection 3, shall be punished by a fine of not less than one thousand dollars nor more than fifty thousand dollars:...

(6) Any other controlled substance, counterfeit substance, or simulated controlled substance classified in schedule I, II, or III.

d. Violation of this subsection, with respect to any other controlled substances, counterfeit substances, or simulated controlled substances classified in schedule IV or V is an aggravated misdemeanor...

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:...

c. To acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge;...

8. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.3(1), 6.3(2), 6.6, 6.8(1), 6.8(6), 6.8(8), 8.11(8), 9.1(4)(c), 9.1(4)(d), 9.1(4)(h), 9.1(4)(j), 9.1(4)(m), 9.1(4)(u), and 10.10 by virtue of the allegations in paragraphs 4, 5, and 6.

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

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

1. The latest edition and supplements to the USP DI, Advice for the Patient;
2. The latest edition and supplements to the USP DI, Drug Information for the Health Care Provider...

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:

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

....

6. Copy 3 of DEA order form 222 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;

....

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

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

8. Any pharmacy using an automated data processing system must comply with all applicable state and federal laws and regulations.

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:...

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.

d. Habitual intoxication or addiction to the use of drugs. Habitual intoxication or addiction to the use of drugs includes, but is not limited to:

(1) The inability of a pharmacist to practice pharmacy with reasonable skill and safety by reason of the excessive use of alcohol on a continuing basis.

(2) The excessive use of drugs which may impair a pharmacist's ability to practice pharmacy with reasonable skill or safety.

....

h. Distribution of...drugs for other than lawful purposes. The distribution of drugs for other than lawful purposes includes but is not limited to the disposition of drugs in violation of Iowa Code chapters 155A, 203, 203A, and 204.

....

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.

....

m. Inability to practice pharmacy with reasonable skill and safety by reason of mental or physical impairment or chemical abuse.

...

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

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

All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.

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

WHEREFORE, the undersigned charges that Respondent Mr. Drug has violated Iowa Code sections 155A.10, 155A.15(2)(c), 155A.15(2)(d), 155A.23(2), 155A.23(4), 204.308(3), 204.401(1)(c)(6), 204.401(1)(d), 204.402(1)(a), and 204.403(1)(c) and 657 Iowa Administrative Code sections 6.3(1), 6.3(2), 6.6, 6.8(1), 6.8(6), 6.8(8), 8.11(8), 9.1(4)(c), 9.1(4)(d), 9.1(4)(h), 9.1(4)(j), 9.1(4)(m), 9.1(4)(u), and 10.10.

IT IS HEREBY ORDERED, pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2, that Michael C. Topf appear on behalf of Mr. Drug before the Iowa Board of Pharmacy Examiners on Friday, November 22, 1991, at 10:00 a.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

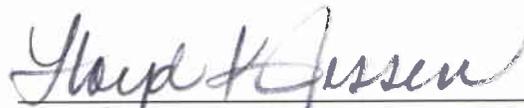
The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to suspend, revoke, or not renew the license to operate a pharmacy issued to Mr. Drug on November 19, 1990, and take whatever additional action that they deem necessary and appropriate.

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

The hearing will be presided over by the Board which will be assisted by an administrative law judge from the Iowa Department of Inspections and Appeals. The office of the Attorney General is responsible for the public interest in these proceedings.

Information regarding the hearing may be obtained from Lynette A. F. Donner, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319 (telephone 515/281-8760). Copies of all filings with the Board should also be served on counsel.

IOWA BOARD OF PHARMACY EXAMINERS



Lloyd K. Jessen
Executive Secretary/Director

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

Re:)	Case No. 2000-765
Pharmacy License of)	
MR. DRUG)	STATEMENT OF CHARGES
License No. 765)	
Respondent)	

COMES NOW, the Complainant, Lloyd K. Jessen, and states:

1. He is the Executive Secretary/Director for the Iowa Board of Pharmacy Examiners and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (1999).
3. On December 1, 1999, the Board renewed Respondent general pharmacy license number 765 with Michael C. Topf as pharmacist in charge, allowing Respondent to engage in the operation of pharmacy subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license number 765 is current until December 31, 2000.
5. Respondent is currently operating a general pharmacy at 415 Fourth Street, Sergeant Bluff, Iowa 51054 with Michael C. Topf as the pharmacist in charge.

COUNT I

The Respondent is charged under Iowa Code § 155A.15(2) 155A.27, 155A.32(3) (1999) and 657 Iowa Administrative Code §§ 6.2(1)(i) & (k), 6.8, 8.4(3), 8.15(2) & 36.1(4) and 21 CFR 1304.11 & 1306.22(b)(3) with inadequate record keeping for controlled substances.

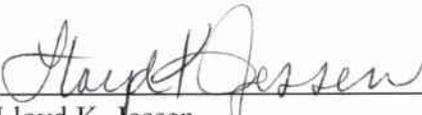
COUNT II

The Respondent is charged under Iowa Code §§ 124.308(3), 124.402(1)(a), 124.403 (1)(c), 155A.15(2)(c), 155A.15(2)(d), and 155A.15(2)(h) (1999) and 657 Iowa Administrative Code §§ 6.8, 36.1(4)(u) with failing to provide accountability for certain controlled substances.

THE CIRCUMSTANCES

1. An accountability audit of Schedule II controlled substances at Respondent's pharmacy for the time period between May 1, 1997 and April 30, 1999 revealed multiple shortages of Schedule II controlled drugs.
2. An accountability audit of Schedule II controlled substances at Respondent's pharmacy for the time period between May 1, 1999 and November 4, 1999 revealed additional shortages of Schedule II controlled drugs.
3. An accountability audit of Schedule III and IV controlled substances at Respondent's pharmacy for the time period between May 1, 1999 and November 4, 1999 revealed multiple shortages and overages of Schedule III and IV controlled drugs.
4. The accountability audits of controlled substances referred to in Paragraph 1-3, above, also revealed numerous discrepancies in Respondent's record-keeping for controlled substances.

WHEREFORE, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.



Lloyd K. Jessen
Executive Secretary/Director

On this 7th day of February, 2000, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.



Arlan D. VanNorman, Chairperson
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Shauna Russell Shields
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa 50319