

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacist License of	}	COMPLAINT
DONALD E. MCKAY	}	AND
License No. 14309	}	STATEMENT
Respondent	}	OF CHARGES
	}	AND
	}	NOTICE OF HEARING

COMES NOW, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 8th day of March, 1993, and files this Complaint and Statement of Charges and Notice of Hearing against Donald E. McKay, a pharmacist licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Alan M. Shepley, Chairperson; Marian L. Roberts, Vice Chairperson; Donna J. Flower; Phyllis A. Miller; Phyllis A. Olson; Ronald B. Reiff; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent was issued a license to practice pharmacy in Iowa on October 21, 1973, by reciprocity.

3. Respondent currently resides at 1613 North Third, Oskaloosa, Iowa 52577.

4. Respondent is currently self-employed as pharmacist in charge and owner of Family Clinic Pharmacy, 1225 C Avenue East, Oskaloosa, Iowa 52577.

5. Respondent's license to practice pharmacy in Iowa is current until June 30, 1993.

6. The board has received investigative reports from Pharmacy Investigator Morrell A. Spencer dated November 2, 1992, and December 3, 1992; investigative reports from Pharmacy Investigator E. Ray Sheldon dated October 30, 1992, and December 3, 1992; and other investigative information which allege the following:

a. A complaint was received on May 18, 1992, which alleged that various controlled substances at Family Clinic Pharmacy were being provided to Respondent's wife, Barbara McKay, without prescriber authorization.

b. On October 29, 1992, Respondent's wife, Barbara McKay, admitted to Pharmacy Investigators Morrell A. Spencer and E. Ray Sheldon that, between 1986 and 1992, she had obtained various

controlled substances from Family Clinic Pharmacy without prescriber authorization.

c. A night break-in occurred at Family Clinic Pharmacy on January 18, 1992. Following that incident, Respondent failed to file a "Report of Theft or Loss of Controlled Substances" with the Board. Respondent also failed to take an inventory of controlled substances remaining following the break-in.

d. A controlled substances accountability audit for the time period beginning January 19, 1992, and ending October 26, 1992, revealed the following:

(1) Significant shortages of the following Schedule II controlled substances: Dexedrine 5mg tablets; Hydromorphone 2mg tablets; Meperidine 50mg tablets; Methylphenidate 5mg, 10mg, and 20mg tablets; Ritalin-SR 20mg tablets; Oxycodone 5mg with Aspirin tablets; Percocet tablets; and Methadone 5mg tablets.

(2) A significant shortage of the following Schedule III controlled substance: Didrex 50mg tablets.

(3) A significant shortage of the following Schedule IV controlled substance: Xanax 2mg tablets.

e. A controlled substances accountability audit for the time period beginning January 19, 1992, and ending October 26, 1992, revealed the following:

(1) Overages of 16 Schedule II controlled substance products;

(2) Overages of 3 Schedule III controlled substance products; and

(3) Overages of 3 Schedule IV controlled substance products.

f. A second controlled substances accountability audit for the time period beginning January 30, 1991, and ending January 19, 1992, also revealed numerous significant shortages and overages of Schedule II controlled substances.

g. Respondent failed to keep accurate records and maintain inventories at Family Clinic Pharmacy in conformance with the record keeping and inventory requirements of federal law and Board rules. Controlled substance records were not readily available. Schedule II controlled substances were illegally transferred to and/or received from other controlled substance registrants. Dispensing records were inaccurate (i.e., recording "Dolophine" when dispensing "Methadone"). The drug or drug quantity indicated on thirteen prescriptions for Schedule II controlled substances differed with the information contained in the pharmacy computer.

h. On October 29, 1992, Pharmacy Investigators Morrell A. Spencer and E. Ray Shelden found prescription drugs, outdated controlled substances, and pharmacy records in an unsecured, basement storage room at Family Clinic Pharmacy.

i. Inspection reports for Family Clinic Pharmacy reveal that Respondent has repeatedly failed to maintain an adequate pharmacy reference library at Family Clinic Pharmacy.

7. Respondent is guilty of violations of 1993 Iowa Code sections 155A.12(1), 155A.12(5), 155A.27, 155A.31, 124.306, 124.307, 124.308, and 124.402(1)(a) by virtue of the allegations in paragraph 6.

1993 Iowa Code section 155A.12 provides, in part, the following:

...The board shall refuse to issue a pharmacist license for failure to meet the requirements of section 155A.8. 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.

...

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

1993 Iowa Code section 155A.27 provides 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.

c. The name, strength, and quantity of the drug, medicine, or device prescribed.

d. The directions for use of the drug, medicine, or device prescribed.

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

f. The federal drug enforcement administration number, if required under chapter 204.

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.

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

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

1993 Iowa Code section 124.306 provides, in part, 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.

1993 Iowa Code section 124.307 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.

1993 Iowa Code section 124.308 provides, in part, the following:

1. Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in schedule II may be dispensed without the written prescription of a practitioner.

2. In emergency situations, as defined by rule of the board, schedule II drugs may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of section 124.306.

3. 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.

1993 Iowa Code section 124.402 provides, in part, the following:

1. It is unlawful for any person:

a. Who is subject to division III to distribute or dispense a controlled substance in violation of section 124.308.

8. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.3, 6.8, 9.1(4)(b)(2), 9.1(4)(b)(4), 9.1(4)(c), 9.1(4)(h), 9.1(4)(j), 9.1(4)(u), 10.10, 10.11, 10.13(1), and 10.13(4) by virtue of the allegations in

paragraph 6.

657 Iowa Administrative Code section 6.3 provides the following:

Reference library. Each pharmacy shall have, as a minimum, the following:

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

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

Controlled substance records shall be maintained in a readily retrievable manner in accordance with federal requirements. Those requirements, in summary, are as follows:

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

....

(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) 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 9.1(4) provides, in part, the following:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses:...

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

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

....

(4) A willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

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

....

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.

...

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.

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

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

prescribed by those regulations.

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

In the case of an emergency situation, as defined by 10.13(5), a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription manually signed by the prescribing individual practitioner);

(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required except for the signature of the prescribing individual practitioner;

....

(4) Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 72-hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the board if the prescribing individual fails to deliver a written prescription. Failure of the pharmacist to do so shall void the authority conferred by this subrule to dispense without a written prescription of a prescribing individual practitioner.

The Iowa Board of Pharmacy Examiners finds that paragraphs 7 and 8 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 1993 Iowa Code sections 155A.12(1), 155A.12(5), 155A.27, 155A.31, 124.306, 124.307, 124.308, and 124.402(1)(a) and 657 Iowa Administrative Code sections 6.3, 6.8, 9.1(4)(b)(2), 9.1(4)(b)(4), 9.1(4)(c), 9.1(4)(h), 9.1(4)(j), 9.1(4)(u), 10.10, 10.11, 10.13(1), and 10.13(4).

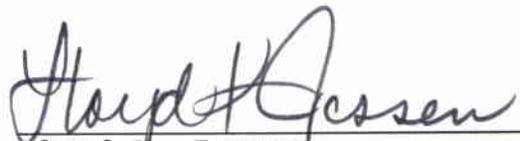
IT IS HEREBY ORDERED that Donald E. McKay appear before the Iowa Board of Pharmacy Examiners on Wednesday, April 7, 1993, at 10:00 a.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to suspend or revoke the license to practice pharmacy issued to Donald E. McKay on October 21, 1973, 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. 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 his 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 R. Jessen
Executive Secretary/Director

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacist License of)	STIPULATION
DONALD E. MCKAY)	AND
License No. 14309)	INFORMAL
Respondent)	SETTLEMENT

COMES NOW the Iowa Board of Pharmacy Examiners (the Board) and Donald E. McKay (Respondent) and, pursuant to Iowa Code sections 17A.10 and 258A.3(4), enter into the following Stipulation of the contested case currently on file:

1. Respondent was issued a license to practice pharmacy in Iowa on October 21, 1973, by reciprocity.

2. Respondent's license is current until June 30, 1993.

3. Respondent's current address is 1613 North Third, Oskaloosa, Iowa 52577.

4. A Complaint and Statement of Charges and Notice of Hearing was filed against Respondent on March 8, 1993.

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

6. Respondent does not contest the allegations set forth in the complaint. The Respondent agrees that the Board may treat the allegations as true for the purpose of this Informal Settlement only and it is expressly understood that the Respondent is not affirmatively admitting to the

allegations.

7. Respondent's license is suspended for a period of six months from the date of approval of this Stipulation and Informal Settlement. Said suspension is stayed.

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

a. Inform the Board in writing within ten (10) days of any change of home address, place of employment, home telephone number, or work telephone number.

b. Pay all required fees for renewal of his pharmacist license to prevent the license from lapsing during the period of probation.

c. Obey all federal and state laws, rules, and regulations substantially related to the practice of pharmacy and all federal and state criminal laws.

d. Not supervise any registered intern and shall not perform any of the duties of a preceptor.

e. Submit a written report to the Board once every six months, beginning 30 days after the date of approval of this Stipulation and Informal Settlement, stating truthfully whether or not he has complied with all terms and conditions of his probation.

f. Provide evidence of efforts to maintain skill and knowledge as a pharmacist through continuing education

(CE) as directed by the Board.

g. Notify all present and prospective employers of the resolution of this case and the terms, conditions, and restrictions imposed on Respondent by this document. Within fifteen (15) days of Respondent undertaking new employment, Respondent shall cause his employer to report to the Board in writing acknowledging the employer has read this document.

9. Within 30 days of approval of this Stipulation and Informal Settlement, Respondent shall remit a civil penalty in the amount of \$5,000 made payable to the Iowa Board of Pharmacy Examiners to be deposited to the General Fund of the state of Iowa.

10. Should Respondent practice outside of this state, Respondent shall notify the Board in writing of the dates of such practice. Periods of practice outside of this State shall not apply to reduction of the probationary period.

11. Should Respondent violate probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the stayed suspension. 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.

12. Upon successful completion of probation, Respondent's certificate will be fully restored.

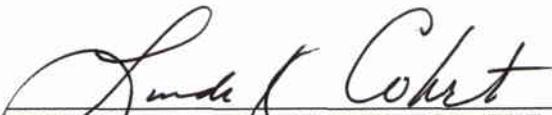
13. Stipulation and Informal Settlement is subject to approval of the Board. If the Board approves this Stipulation and Informal Settlement, it becomes the final disposition of this matter. If the Board fails to approve this Stipulation and Informal Settlement, it shall be of no force or effect to either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

14. This Informal Settlement is voluntarily submitted by the Respondent to the Board for its consideration on the 9 day of April, 1993.



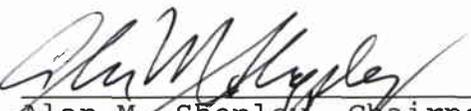
Donald E. McKay
Respondent

Signed and sworn to before me this 9th day of April, 1993.



NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

15. This Informal Settlement is accepted by the Iowa Board of Pharmacy Examiners on the 9th day of April, 1993.



Alan M. Shepley, Chairperson
Iowa Board of Pharmacy Examiners

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

Re:)	PETITION
Pharmacist License of)	TO REVOKE
DONALD E. MCKAY)	PROBATION
License No. 14309)	AND
Respondent)	NOTICE
)	OF HEARING

COMES NOW, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 24th day of October, 1994, and files this Petition to Revoke Probation and Notice of Hearing against Donald E. McKay, a pharmacist licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Marian L. Roberts, Chairperson; Phyllis A. Olson, Vice Chairperson; Jay J. Cayner; Phyllis A. Miller; Mary Pat Mitchell; Matthew C. Osterhaus; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.
2. Respondent was issued a license to practice pharmacy in Iowa on October 21, 1973, by reciprocity.
3. Respondent currently resides at 2678 248th Street, Oskaloosa, Iowa 52577.
4. Respondent is currently self-employed as the owner and pharmacist in charge of Family Clinic Pharmacy, 1225 C Avenue East, Oskaloosa, Iowa 52577.
5. Respondent's license to practice pharmacy in Iowa is current until June 30, 1995.
6. In February 1987 Respondent was investigated by the Board for mishandling of the drug Duradyne DHC® (Hydrocodone bitartrate 5mg/Acetaminophen 500mg). Respondent had purchased 58,000 tablets of Duradyne DHC® from Forest Pharmaceuticals, Inc., under the name of an Oskaloosa physician in order to obtain a

special price. Although the Duradyne DHC® was dispensed by Respondent's pharmacy, the Family Clinic Pharmacy, it was never legally transferred by invoice from the Oskaloosa physician to the Family Clinic Pharmacy. An accountability audit for the time period beginning June 30, 1984, and ending February 25, 1987, which included the purchase of the 58,000 tablets from Forest Pharmaceuticals, Inc., revealed an overage of 1,464 Duradyne DHC® tablets at the Family Clinic Pharmacy. The Respondent did not receive formal discipline from the Board for these violations.

7. On July 13, 1990, the Board received a complaint from the Iowa Department of Inspections and Appeals, Health Facilities Division, which alleged that Respondent had failed to provide adequate pharmacy consultant services at two health care facilities in Oskaloosa between November 1, 1989, and July 9, 1990.

a. On November 17, 1989, a health facility surveyor inspected the Mahaska Manor and observed that Respondent had failed to review the drug regimen of each resident. The surveyor also noted that Respondent did not report any irregularities to the doctor on any records reviewed, even though the surveyor found reportable problems involving six residents.

b. On April 12, 1990, a health facility surveyor inspected the Siesta Park and observed that the inspection of drug storage and condition reports had not been completed by Respondent every three months during 1989. The surveyor also observed that discontinued medications had not been properly disposed of for at least six residents.

c. On May 3, 1990, a health facility surveyor inspected the Mahaska Manor and observed that Respondent had failed to provide monthly drug usage counts, had failed to check for patient diagnosis for the use of one or more drugs, and had failed to check for duplication of patient medications. It was also observed that the Respondent's drug regimen reviews were not available at the facility on four of four survey days.

d. The Respondent did not receive formal discipline from the Board for these violations.

8. Respondent was disciplined by the Board in 1993. That disciplinary action involved the following:

a. On March 8, 1993, the Board issued a Complaint and Statement of Charges and Notice of Hearing to Respondent. Paragraph six of the Complaint and Statement of Charges included the following allegations:

(a) A complaint was received on May 18, 1992, which alleged that various controlled substances at Family Clinic Pharmacy were being

provided to Respondent's wife, Barbara McKay, without prescriber authorization.

(b) On October 29, 1992, Respondent's wife, Barbara McKay, admitted to Pharmacy Investigators Morrell A. Spencer and E. Ray Sheldon that, between 1986 and 1992, she had obtained various controlled substances from Family Clinic Pharmacy without prescriber authorization.

(c) A night break-in occurred at Family Clinic Pharmacy on January 18, 1992. Following that incident, Respondent failed to file a "Report of Theft or Loss of Controlled Substances" with the Board. Respondent also failed to take an inventory of controlled substances remaining following the break-in.

(d) A controlled substances accountability audit for the time period beginning January 19, 1992, [the day *after* the theft or loss] and ending October 26, 1992, revealed the following:

(1) Significant shortages of the following Schedule II controlled substances: Dexedrine 5mg tablets; Hydromorphone 2mg tablets; Meperidine 50mg tablets; Methylphenidate 5mg, 10mg, and 20mg tablets; Ritalin-SR 20mg tablets; Oxycodone 5mg with Aspirin tablets; Percocet tablets; and Methadone 5mg tablets.

(2) A significant shortage of the following Schedule III controlled substance: Didrex 50mg tablets.

(3) A significant shortage of the following Schedule IV controlled substance: Xanax 2mg tablets.

(e) A controlled substances accountability audit for the time period beginning January 19, 1992, and ending October 26, 1992, revealed the following:

- (1) Overages of 16 Schedule II controlled substance products;
- (2) Overages of 3 Schedule III controlled substance products; and
- (3) Overages of 3 Schedule IV controlled substance products.

(f) A second controlled substances accountability audit for the time period beginning January 30, 1991, and ending January 19, 1992, also revealed numerous significant shortages and overages of Schedule II controlled substances.

(g) Respondent failed to keep accurate records and maintain inventories at Family Clinic Pharmacy in conformance with the record keeping and inventory requirements of federal law and Board rules. Controlled substance records were not readily available. Schedule II controlled substances were illegally transferred to and/or received from other controlled substance registrants. Dispensing records were inaccurate

(i.e., recording "Dolophine" when dispensing "Methadone"). The drug or drug quantity indicated on thirteen prescriptions for Schedule II controlled substances differed with the information contained in the pharmacy computer.

(h) On October 29, 1992, Pharmacy Investigators Morrell A. Spencer and E. Ray Shelden found prescription drugs, outdated controlled substances, and pharmacy records in an unsecured, basement storage room at Family Clinic Pharmacy.

(i) Inspection reports for Family Clinic Pharmacy reveal that Respondent has repeatedly failed to maintain an adequate pharmacy reference library at Family Clinic Pharmacy.

b. According to a report filed by Respondent with the Board on October 6, 1992, the theft or loss of controlled substances at Family Clinic Pharmacy that occurred on January 18, 1992, included the following quantities of 36 Schedule II controlled substances:

- #250 Dexedrine 5mg tablets
- #295 Amytal 30mg tablets
- #140 Codeine Sulfate 30mg tablets
- #20 Demerol 50mg tablets
- #2 Demerol 50mg/ml 50ml*
- #1 Demerol 100mg/ml 20ml*
- #200 Dilaudid 2mg tablets
- #350 Dolophine 5mg tablets
- #190 Dolophine 10mg tablets
- #325 Hydromorphone 10mg tablets
- #240 Levo-Dromoran 2mg tablets
- #200 Meperidine 50mg tablets
- #400 Methylphenidate 20mg SR tablets
- #950 Methylphenidate 10mg tablets
- #120 Methylphenidate 20mg tablets
- #90 Morphine Sulfate 15mg tablets
- #1 Morphine Sulfate 15mg/ml 20ml
- #5 Morphine Sulfate (Lilly) 15mg/ml 20ml
- #200 Morphine Sulfate (Lilly) 30mg tablets
- #200 Nembutal 50mg capsules
- #100 Nembutal 100mg capsules
- #700 Roxanol 5/325 tablets

#300 Roxicet 5/325 tablets
#50 Percocet tablets
#30 Percodan tablets
#25 Ritalin 5mg tablets
#70 Ritalin 10mg tablets
#20 Ritalin 20mg tablets
#10 Ritalin 20mg SR tablets
#100 Tuinal 200mg capsules
#120 Tylox capsules
#200 Oxycodone/APAP tablets*
#144 Pentobarbital 100mg capsules*
#300 Codeine Phosphate 60mg tablets
#150 Codeine Sulfate 60mg tablets
#450 Methylphenidate 5mg tablets

*Some or all of these drugs were later located by Board Investigators Morrell A. Spencer and E. Ray Shelden at the Family Clinic Pharmacy on October 26, 1992.

c. In an earlier report filed by Respondent with the Oskaloosa Police Department on January 21, 1992, Respondent reported that the following quantities of 30 Schedule II controlled substances had been stolen on January 18, 1992:

#300 Dexedrine 5mg tablets*
#400 Amytal 30mg tablets*
#250 Codeine Sulfate 30mg tablets*
#74 Demerol 50mg tablets*
#100 Dilaudid 2mg tablets*
#150 Dilaudid 4mg tablets**
#300 Dolophine 5mg tablets*
#200 Meperidine 50mg tablets
#250 Methylphenidate 20mg SR tablets*
#1,200 Methylphenidate 10mg tablets*
#200 Nembutal 50mg capsules
#150 Nembutal 100mg capsules*
#25 Percodan tablets*
#60 Ritalin 5mg tablets*
#100 Ritalin 10mg tablets*
#300 Ritalin 20mg SR tablets*
#750 Oxycodone APAP tablets**

#60 Tylox capsules*
#350 Oxycodone/APAP capsules***
#200 Codeine Sulfate 60mg tablets*
#300 Methylphenidate 5mg tablets*
#100 MS Contin 30mg**
#75 MS Contin 15mg**
#200 MS Contin 60mg**
#250 Hydromorphone 2mg**
#150 Hydromorphone 4mg**
#176 Dolophine 10mg**
#250 Oxycodone ASA**
#300 Codeine Phosphate 60mg**
#150 Tuinal 100mg**

Respondent's report to the police did not include several other Schedule II controlled substances (including injectable drugs) which Respondent later reported to the Board as having been stolen. Respondent's report to the Board did not include several Schedule II controlled substances which were earlier reported to the police as having been stolen. Only *two* of the missing drugs were reported to both the police and the Board in the same quantity.

* These quantities are significantly *different* from the quantities which were later reported by Respondent to the Board.

** These shortages were *never* reported to the Board by Respondent.

*** Some of these drugs were later located by Board Investigators Morrell A. Spencer and E. Ray Shelden at the Family Clinic Pharmacy on October 26, 1992.

d. An investigative report prepared by Pharmacy Investigator E. Ray Shelden on October 30, 1992, contains, in part, the following observations:

(1) The break-in of Family Clinic Pharmacy [on January 18, 1992] appears to have been "staged."

(a) The outer door appeared to have screw driver marks around the exterior of the lock, but the hardware attached to the door frame did not appear to have been broken enough to allow the door to open.

(b) The hole punched through the wall of the pharmacy was located under a desk...the only area of the pharmacy which did not have shelving covering the wall area. This area was approximately 3 feet x 3

feet. The person entering the pharmacy had to know exactly where to make the hole.

(c) The top drawer that was locked sustained very little damage. The two other drawers involved were not locked. (The top drawer lock was not repaired.)

(2) The person who took the narcotics also took the DEA order forms 222, but apparently did not take the Meperidine Tubex's 50 mg/ml and 100mg/ml. These items were not listed on any loss report.

(3) Some of the items listed on the loss report received by the Board of Pharmacy (10-6-92) were located by Mr. Spencer and myself, and destroyed on 10-26-92...

...

(e) Dispensing by prescriptions did not match dispensing by computer print-outs. Mr. McKay stated that the discrepancies were because prescriptions for dispensing had been sent to the physician for signature, and had not been returned.

Investigator Shelden also noted on page five of his report dated October 30, 1992, that on October 29, 1992, Mrs. Barbara McKay stated that her son might have taken some Tylenol with Codeine from the Family Clinic Pharmacy on one occasion.

e. No disciplinary hearing for Respondent was held. Rather, on April 9, 1993, Respondent and the Board reached an informal settlement of the allegations contained in the Complaint and Statement of Charges issued on March 8, 1993. The Stipulation and Informal Settlement suspended Respondent's license to practice pharmacy for a period of six (6) months. The suspension was stayed, however, and Respondent's license was placed on probation for a period of five (5) years beginning April 9, 1993, and ending April 9, 1998. Respondent also agreed to pay a civil penalty in the amount of \$5,000.

f. The Stipulation and Informal Settlement also provided, in part, that during the probationary period the Respondent shall:

(8)(c) Obey all federal and state laws, rules, and regulations substantially related to the practice of pharmacy and all federal and state criminal laws.

g. In addition, the Stipulation and Informal Settlement provided the following:

(11) Should Respondent violate probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the stayed suspension. 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. On or about October 6, 1993, Respondent received a letter from the Iowa Department of Justice which contained, in part, the following allegation:

...[I]t appears to us that your pharmacy engaged in a pricing practice relating to senior citizen discounts which constituted an unfair or deceptive practice under the Iowa Consumer Fraud Act. The objectionable practice consisted of offering a senior citizen discount but then charging seniors the same price as non-seniors were charged for items which would appear to be covered by the discount.

On October 18, 1993, the Respondent signed an "Assurance of Voluntary Compliance" which provides, in part, the following:

...Family Clinic Pharmacy has advertised or represented a senior citizen's discount program to consumers aged 55 or over by telephone directory advertisements. For certain prescriptions, Respondents charged consumers who would otherwise qualify for the senior discount the same price as non-seniors. Respondents did not clearly and conspicuously disclose to senior consumers that they were charged the same prices as non-seniors for these prescriptions.

The Attorney General has concluded that Respondents' practice of offering senior prescription discounts, but failing to charge lesser prices to seniors for some prescriptions without disclosing this limitation, may be deceptive and may constitute the failure to disclose a material fact with intent that others rely on the omission, in violation of the Iowa Consumer Fraud Act, Iowa Code § 714.16. The Attorney General acknowledges that Respondents deny any violation of the Consumer Fraud Act or any other law, and that the execution of this Assurance by the Respondents does not constitute an admission of wrongdoing or liability.

Wherefore, the parties agree as follows:

1. Upon signing this Assurance, Family Clinic Pharmacy, or any other pharmacy owned or operated by Don McKay will either:

a. for all merchandise, offer consumers covered by any senior discount a final purchase price which is less, by whatever percentage or amount of discount is advertised, than the price for consumers not covered by the senior discount; or,

b. clearly and conspicuously disclose any and all limitations on senior discounts in all instances in which Respondents advertise senior discounts, including, but not limited to, the fact that for certain prescriptions consumers who qualify for a senior citizen's discount are charged the same prescription purchase prices as those who do not qualify for the discount, or that discounts are not available for prescriptions involving third party reimbursement, if applicable; or,

c. cease advertising and representing senior discounts.

"Advertising" a discount includes all manner of disseminating the information, including statements by Respondents or their agents to prospective customers.

2. Any violation of this Assurance shall be a violation of the Iowa Consumer Fraud Act, Iowa Code § 714.16.

...

4. Respondents must abide by the terms of this Assurance and acknowledge receipt of a copy of it. In addition, Don McKay agrees to provide copies of this Assurance as soon as reasonably possible to all current and future employees and successors and assigns of Family Clinic Pharmacy.

10. On October 18, 1994, the Board issued a Complaint and Statement of Charges to Respondent based upon the following: (1) the allegations made by the Iowa Attorney General's office on October 6, 1993, and (2) the findings and terms of the "Assurance of Voluntary Compliance" signed by Respondent on October 18, 1993.

11. The Board has received additional, new investigative information relating to Respondent. On April 8, 1994, the Board received an investigative report from Pharmacy Investigator Dennis D. Dobesh. That report alleged the following:

a. On March 22, 1994, and March 25, 1994, the Board office received telephone calls from "John Doe" who alleged that Respondent was having an affair with "John Doe's" wife, "Jane Doe." "John Doe" also alleged that Respondent had been stalking his wife, "Jane Doe."

b. During an interview with Investigator Dobesh on March 29, 1994, Respondent stated the following:

(1) "John and Jane Doe" met one another when "John" was selling drugs (including cocaine) to "Jane."

(2) Respondent admitted that he had a sexual relationship with "Jane Doe" "for a few months."

(3) Respondent admitted that "some Roxicet" (a Schedule II controlled substance) was stolen from the Family Clinic Pharmacy on a Friday night. Respondent stated that "it was just a few tablets...and I wasn't that concerned about it." Respondent stated that he later telephoned "John Doe's" house and told the person who answered the telephone "You tell...["John Doe"] I know he took it." This theft or loss of a controlled substance was not reported to the Board.

(4) In regard to the missing Roxicet, Respondent made the following additional statements: "Well, we did an audit, and my account is over on Roxicet. My account right now is over, and I don't know how we lost -- how it got messed up, but I'm not going to pull the stuff out and try to make the numbers come out right. I'm not going to do that. My account -- you know, it used to get messed up because we were doing 16, you know. We were always short because they would call in an order and we wouldn't have the scripts. So what we do now is make them call in -- you know, when they call in an order, we take a hundred and we set that aside. So somehow we just lost the handle on some Roxicet, you know, and somehow we're over. So now I don't have any proof."

(5) Respondent also admitted the following: "She ["Jane Doe"] would always secretly meet with me, you know, for a while... I know one time we [Respondent and "Jane Doe"] went to a store together -- I don't want to tell bad things about her, but she'll take DHC [dihydrocodeine] once in a while. It might be one of the reasons that she ["Jane Doe"] stays around because he ["John Doe"] gets 120 a month and he only needs one or two a day." ["John Doe" regularly gets prescriptions filled by Respondent at the Family Clinic Pharmacy for Hydrocodone/APAP/5/500.]

c. During an interview with Investigator Dobesh on March 29, 1994, a pharmacist who works for Respondent at the Family Clinic Pharmacy stated the following: "If Don McKay is guilty of anything, it's exercising really bad judgment at a time when he was vulnerable; and at some point in time for a brief time, becoming involved with...["John Doe's"] wife."

d. During an interview with Investigator Dobesh on March 28, 1994, a pharmacy assistant who works for Respondent at the Family Clinic Pharmacy stated the following: "[John Doe]" is unemployed...he stands around in the pharmacy [Family Clinic Pharmacy], which has been a very uncomfortable situation for all of us."

e. On April 14, 1994, the Board received a "Report of Theft or Loss of Controlled Substance" from Respondent dated April 12, 1994. The report indicated that on April 4, 1994, a pint bottle containing about 2 ounces of Promethazine VC with Codeine cough syrup (manufactured by Goldline), a Schedule V controlled substance, had been taken from the Family Clinic Pharmacy. On the report, the Respondent indicated the "type of theft or loss" as an "armed robbery" followed by a question (?) mark.

12. The Board has received other new investigative information relating to the Respondent. On October 18-19, 1994, Pharmacy Investigator Lindy A. Pearson and other Board representatives conducted a survey and audit of Respondent's pharmacy, the Family Clinic Pharmacy. Investigator Pearson's report alleges the following:

a. On or about October 5, 1994, the Board office received a telephone call from "John Doe" who alleged that Respondent was providing drugs, including Lortabs®, to "John Doe's" wife, "Jane Doe," in exchange for sexual favors. "John Doe" further alleged that, if audited, Respondent's pharmacy would be unable to accurately account for Lortab® brandname products and generics. "John Doe" also alleged that "Jane Doe" was selling some of these drugs on the street.

b. Upon surveying the Family Clinic Pharmacy on October 18, 1994, the prescription department was observed by Investigator Pearson and other Board representatives to be very disorderly and unsanitary. The shelves and counters were cluttered and disorganized. The walls and floor were dirty and unkempt.

c. Respondent's Pharmacy, the Family Clinic Pharmacy, failed to take a biennial inventory of all controlled substances when it was due on May 1, 1993. The biennial inventory was not taken until July 23, 1993. The taking of the inventory should not vary more than four (4) days from the biennial inventory date. A registrant who wishes to change the biennial inventory date must notify the DEA in advance of the date on which the inventory is to be taken. The DEA was not notified of this change.

d. An inventory taken at Family Clinic Pharmacy on October 18, 1994, revealed the following drugs on hand:

Lortab® 5/500:	222
Hydrocodone bitartrate 5mg/ Acetaminophen 500mg (Watson):	1,026
Lortab® 7.5/500:	233
Hydrocodone bitartrate 7.5mg/ Acetaminophen 500mg (Watson):	560
Hydrocodone bitartrate 7.5mg/ Acetaminophen 500mg (Geneva):	30

e. A controlled substance accountability audit for the time period beginning July 23, 1993, and ending October 18, 1994, based on prescription hardcopies and including all authorized refills indicated on the hardcopies, revealed the following:

Lortab® 5/500 Tablets:	+ 189
Hydrocodone bitartrate 5mg/ Acetaminophen 500mg:	(-)5,554
Lortab® 7.5/500 Tablets:	+ 132
Hydrocodone bitartrate 7.5mg/ Acetaminophen 500mg:	+ 2,040

f. A controlled substance accountability audit for the time period beginning July 23, 1993, and ending October 18, 1994, based on computer-generated printouts prepared by Respondent on October 18, 1994, revealed the following:

Lortab® 5/500 Tablets:	+ 177
Hydrocodone bitartrate 5mg/ Acetaminophen 500mg:	+ 298
Lortab® 7.5/500 Tablets:	+ 1,667
Hydrocodone bitartrate 7.5mg/ Acetaminophen 500mg:	+ 2,372

g. The audit based on prescription hardcopies indicates both a significant shortage and a significant overage of Lortab® brandname products and generics. Lortab® brandname products and generics are Schedule III controlled substances.

h. The audit based on computer-generated printouts indicates a significant overage of Lortab® brandname products and generics. Lortab® brandname products and generics are Schedule III controlled substances.

i. Respondent has failed to provide accurate accountability for Lortab® brandname products and generics received by and dispensed from his pharmacy, the Family Clinic Pharmacy, during the time period beginning July 23, 1993, and ending

October 18, 1994. Once again, dispensing by prescriptions does not match dispensing by computer printouts, as observed during the Board's 1992 investigation of Respondent.

j. On October 19, 1994, Respondent's wife, Barbara McKay, asked to talk with Pharmacy Investigator Pearson and other representatives of the Board. At that time, Mrs. McKay stated that her husband, the Respondent, had been having a sexual relationship with "Jane Doe." She indicated that she had seen her husband, the Respondent, and "Jane Doe" meet in the Family Clinic Pharmacy from time to time. She stated that she was worried that "Jane Doe" may have obtained drugs, including controlled substances, from Respondent's pharmacy, the Family Clinic Pharmacy. She stated that her husband, the Respondent, was very distraught over the situation.

k. On October 19, 1994, Mahaska County law enforcement officers executed a search warrant at a residence located in Oskaloosa, Iowa. "Jane Doe" was living at the residence at the time the search warrant was executed. The search of the residence produced, in part, the following evidence:

(1) An empty stock bottle labeled Lortab® 7.5mg tablets #100, NDC # 50474-907-01, Lot # 940313C, Expiration Date 3-97, with a pharmacy sticker from the drug wholesaler, AmeriSource Corporation, which included the number "04546270818." On October 21, 1994, Scott Dallow of the AmeriSource Corporation traced the number "04546270818" to an invoice which indicates that this bottle of Lortab® 7.5mg was shipped from AmeriSource Corporation to Respondent's pharmacy, the Family Clinic Pharmacy, on August 18, 1994. This stock bottle was found in a purse which contained other items that identified the purse as belonging to "Jane Doe." Hydrocodone Bitartrate/APAP 5/500 is a Schedule III controlled substance.

(2) A stock bottle labeled Hydrocodone Bitartrate/APAP 5/500 tablets #500, NDC # 0781-1606-05, Lot # 34944E4, Expiration Date 5-96, Geneva Generic, with a pharmacy sticker from the drug wholesaler, AmeriSource Corporation, which included the number "04727710831." On October 21, 1994, Scott Dallow of the AmeriSource Corporation traced the number "04727710831" to an invoice which indicates that this bottle of Hydrocodone Bitartrate/APAP 5/500 tablets was shipped from AmeriSource Corporation to Respondent's pharmacy, the Family Clinic Pharmacy, on August 31, 1994. This stock bottle contained 13 tablets of Hydrocodone Bitartrate with Acetaminophen 5mg/500mg manufactured by a different company, Watson Laboratories, Inc., bearing the marking "Watson 349." This stock bottle was found under the bed in the downstairs

bedroom of the residence. Hydrocodone Bitartrate/APAP 5/500 is a Schedule III controlled substance.

(3) Two empty stock bottles that once contained Lortab® 7.5mg tablets #100, which were found in a drawer in the kitchen of the residence. The manufacturer's labels had been removed from the bottles, but the imprint on the bottom of the plastic bottles identified them as Lortab® 7.5mg #100 bottles.

(4) One 4 oz. amber prescription bottle containing Calcidrine® Syrup which had been dispensed by Respondent's pharmacy, Family Clinic Pharmacy, to a male patient, "A.A.," on December 24, 1993. The label on the bottle identified the prescription as number 4011919 from the Family Clinic Pharmacy. This bottle was found in the bathroom medicine cabinet of the residence. Calcidrine® Syrup is a Schedule V controlled substance.

(5) Six tablets of Hydrocodone Bitartrate with Acetaminophen 5mg/500mg manufactured by Watson Laboratories, Inc., bearing the marking "Watson 349" were found in the front pocket of blue jeans which "Jane Doe" was wearing at the time Mahaska County law enforcement officers arrived at the residence on October 19, 1994.

1. In summary, Respondent has again failed to provide effective controls and procedures to guard against theft and diversion of controlled substances at his pharmacy, the Family Clinic Pharmacy. Respondent has intentionally, inadvertently, or negligently provided controlled substances to "Jane Doe" during and/or after an ongoing sexual relationship with her. In addition, Respondent has failed to obey all federal and state laws, rules, and regulations substantially related to the practice of pharmacy by failing to provide accurate accountability for controlled substances received by and dispensed from his pharmacy, the Family Clinic Pharmacy, between July 23, 1993, and October 18, 1994; by failing to report a theft or loss of Roxicet; by failing to take a biennial inventory of controlled substances when due; and by continuing to fill prescriptions for large quantities of Hydrocodone/APAP for "John Doe" when he knew or should have known that some of the Hydrocodone/APAP was being abused by "Jane Doe."

13. Respondent is guilty of violating subparagraph 8(c) of the Stipulation and Informal Settlement dated April 9, 1993, by virtue of the information contained in paragraphs 11 and 12 of this Petition to Revoke Probation.

14. Respondent is guilty of violations of 1993 Iowa Code sections 124.308(3), 124.401(1)(c)(6), 124.402(1)(a), 147.55(2), 147.55(3), 147.55(8), 155A.12(1), 155A.12(2), 155A.12(3), 155A.12(4), 155A.12(5), 155A.23(2), 155A.23(4), 272C.10(2), 272C.10(3), and 272C.10(8) by virtue of the allegations contained in paragraphs 6, 7, 8, 9, 10, 11, and 12.

1993 Iowa Code section 124.308 provides, in part, the following:

3. 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.

1993 Iowa Code section 124.401 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.

1993 Iowa Code section 124.402 provides, in part, the following:

1. It is unlawful for any person:

o

a. Who is subject to division III to distribute or dispense a controlled substance in violation of section 124.308.

1993 Iowa Code section 147.55 provides, in part, 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:...

2. Professional incompetency.

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.

...

8. Willful or repeated violations of the provisions of this Act.

1993 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.

2. Engaged in unethical conduct as that term is defined by rules of the board.

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.

1993 Iowa Code section 155A.23 provides, in part, the following:

A person shall not:...

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

...

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

1993 Iowa Code section 272C.10 provides, in part, the following:

A licensing board established after January 1, 1978, and pursuant to the provisions of this chapter shall by rule include provisions for the revocation or suspension of a license which shall include but is not limited to the following:...

2. Professional incompetency.

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

...

8. Willful or repeated violations of the provisions of this chapter.

15. Respondent is guilty of violations of 657 Iowa Administrative Code sections 8.5(1), 9.1(4)(b)(2), 9.1(4)(b)(3), 9.1(4)(b)(4), 9.1(4)(c), 9.1(4)(i), 9.1(4)(j), 9.1(4)(u), and 10.10 by virtue of the allegations contained in paragraphs 6, 7, 8, 9, 10, 11, and 12.

657 Iowa Administrative Code section 8.5 provides, in part, the following:

Unethical conduct or practice. The provisions of this section apply to licensed pharmacists and registered pharmacist-interns.

8.5(1) Misrepresentative deeds. A pharmacist shall not make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

657 Iowa Administrative Code section 9.1(4) provides, in part, the following:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses:...

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

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

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

(4) A willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

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

....

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

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy.

....

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

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

Security requirements generally. 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 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 disciplined.

WHEREFORE, the undersigned charges that Respondent has violated subparagraph 8(c) of the Stipulation and Informal Settlement dated April 9, 1993; 1993 Iowa Code sections 124.308(3), 124.401(1)(c)(6), 124.402(1)(a), 147.55(2), 147.55(3), 147.55(8), 155A.12(1), 155A.12(2), 155A.12(3), 155A.12(4), 155A.12(5), 155A.23(2), 155A.23(4), 272C.10(2), 272C.10(3), and 272C.10(8); and 657 Iowa Administrative Code sections 8.5(1), 9.1(4)(b)(2), 9.1(4)(b)(3), 9.1(4)(b)(4), 9.1(4)(c), 9.1(4)(i), 9.1(4)(j), 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 Donald E. McKay appear before the Iowa Board of Pharmacy Examiners on Tuesday, November 29, 1994, 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 his license to practice pharmacy issued on October 21, 1973, 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. If Respondent fails to appear and defend, Iowa Code section 17A.12(3) provides that the hearing may proceed and that a decision, including disciplinary action, may be rendered.

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 representation of the public interest in these proceedings. Information regarding the hearing may be obtained from Linny C. Emrich, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319 (telephone 515/281-3658). 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: Pharmacist License of
DONALD E. MCKAY
License No. 14309
Respondent

}
}
}
}
}
}

**STIPULATION
AND
CONSENT ORDER**

On this 25th day of November, 1994, the Iowa Board of Pharmacy Examiners and Donald E. McKay of 2678 248th Street, Oskaloosa, Iowa, each hereby agree with the other and stipulate as follows:

The licensee disciplinary hearing pending before the Iowa Board of Pharmacy Examiners, on the allegations specified in the Petition to Revoke Probation and Notice of Hearing filed against Respondent on October 24, 1994, shall be resolved without proceeding to hearing on November 29, 1994, as the parties have agreed to the following Stipulation and Consent Order:

1. That Respondent was issued a license to practice pharmacy in Iowa on the 21st day of October, 1973, by reciprocity as evidenced by Pharmacist License Number 14309, which is recorded in the permanent records of the Iowa Board of Pharmacy Examiners.
2. That Iowa Pharmacist License Number 14309 issued to Respondent is active and current until June 30, 1995.
3. That the Iowa Board of Pharmacy Examiners has jurisdiction over the parties and the subject matter herein.

4. A Petition to Revoke Probation and Notice of Hearing was filed against Respondent on October 24, 1994.

5. Respondent does not contest the allegations set forth in the complaint. The Respondent agrees that the Board may treat the allegations as true solely for the purpose of this Stipulation and Consent Order subject to the clarification provided by Respondent in the document filed herein captioned "Admissions of Respondent and Proposed Disposition of Charges."

SECTION I

THEREFORE, IT IS HEREBY ORDERED that Iowa Pharmacist License Number 14309 issued to Respondent is indefinitely suspended beginning on December 1, 1994. In addition, within sixty (60) days of December 1, 1994, the Respondent shall pay a civil penalty of \$8,000.00 by delivering a check made payable to the Treasurer of the State of Iowa to the Executive Secretary/Director of the Board. The check shall be deposited into the general fund.

SECTION II

1. During the term of the license suspension, Respondent agrees to the following restrictions, limitations, and conditions:

a. Respondent shall not be physically present in the Family Clinic Pharmacy located at 1225 C Avenue East in Oskaloosa, Iowa, at any time.

b. Respondent shall not be directly or indirectly involved in the current, active management of any aspect of the Family Clinic Pharmacy located at 1225 C Avenue East in Oskaloosa, Iowa.

c. Respondent shall not function or serve as a pharmacy technician, pharmacy assistant, or pharmacy clerk at the Family Clinic Pharmacy located at 1225 C Avenue East in Oskaloosa, Iowa, or in any other pharmacy.

d. Respondent shall not represent himself to be a pharmacist nor in any way cause other persons to view him as a pharmacist.

e. Respondent shall not provide drug or medical information to the public or to other health professionals and shall not provide any other cognitive service related to or involving the practice of pharmacy.

2. Respondent may petition the Board for reinstatement of his license after July 1, 1997. To achieve reinstatement, Respondent must meet the eligibility requirements contained in 657 Iowa Administrative Code § 9.23.

SECTION III

1. Respondent shall fully and promptly comply with this and all other Orders of the Board and the statutes and rules regulating the practice of pharmacy in Iowa. Any violation of the terms of this Order is grounds for further disciplinary action, upon notice and opportunity for hearing, for failure to comply with an Order of the Board, in accordance with Iowa Code section 272C.3(2)(a).

2. This proposed settlement is subject to approval of a majority of the full Board. If the Board approves this Stipulation and Consent Order, it becomes the final disposition of this matter. If the Board fails to approve this Stipulation and Consent Order, it shall be of no force or effect to either party.

3. This Stipulation and Consent Order is voluntarily submitted by Respondent to the Board for its consideration on the 24 day of November, 1994.

Donald McKay

DONALD E. MCKAY, R.Ph.
Respondent

Subscribed and Sworn to before me on this 25 day of November, 1994.

J. de C. Cohet

NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

4. This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on the 16 day of November, 1994.

Marian L. Roberts

MARIAN L. ROBERTS, Chairperson
Iowa Board of Pharmacy Examiners
Executive Hills West
1209 East Court Avenue
Des Moines, Iowa 50319

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

IN THE MATTER OF THE REQUEST)	DIA NO: 97PHB-006
FOR REINSTATEMENT OF:)	
)
DONALD E. MCKAY)	FINDINGS OF FACT,
License No. 14309)	CONCLUSIONS OF LAW,
RESPONDENT)	DECISION AND ORDER

TO: DONALD E. MCKAY

On November 25, 1994, the Iowa Board of Pharmacy Examiners (Board) and Donald E. McKay (Respondent) entered into a Stipulation and Consent Order which indefinitely suspended the Respondent's license to practice pharmacy, effective December 1, 1994. The Respondent filed a request for reinstatement, and a formal hearing was scheduled for October 14, 1997.

On October 14, 1997, a hearing was held before the Board. The following Board members were present: Phyllis A. Olson, R.Ph., Chairperson; Katherine A. Linder, R.Ph.; Phyllis A. Miller, R.Ph.; Matthew C. Osterhaus, R.Ph.; Arlan D. Van Norman, R.Ph.; and Mary Pat Mitchell, Public Member. The Respondent appeared and was represented by William Olsen. Linny Emrich, Assistant Attorney General, appeared for the state of Iowa. Margaret LaMarche, Administrative Law Judge from the Iowa Department of Inspections and Appeals, presided. The hearing was open to the public, pursuant to Iowa Code Section 272C.6(1) (1997).

After hearing the testimony and examining the exhibits, the Board convened in closed executive session, pursuant to Iowa Code section 21.5(1)(f), to deliberate its decision. The administrative law judge was instructed to prepare the Board's Findings of Fact, Conclusions of Law, Decision and Order, in conformance with the Board's deliberations.

THE RECORD

The record includes the Notice of Hearing; Complaint and Statement of Charges, filed March 8, 1993; Stipulation and Informal Settlement, accepted April 9, 1993; Petition to Revoke Probation and Notice of Hearing, filed October 24, 1994; Stipulation and Consent Order, dated November 25, 1994; the testimony of the witnesses; and the following exhibits:

Respondent Exhibit A:	Security Policy of Family Clinic Pharmacy
Respondent Exhibit B:	Proposed Pharmacist Staffing of Family Clinic Pharmacy

Respondent Exhibit C: Barbara McKay, Work History

Respondent Exhibit D: Barbara McKay, Treatment Center History

Respondent Exhibit E: Continuing Education records; letters of reference

FINDINGS OF FACT

1. Respondent was issued a license to practice pharmacy in Iowa on October 21, 1973, by reciprocity. The Respondent was self-employed as pharmacist in charge and owner of Family Clinic Pharmacy in Oskaloosa, Iowa. On March 8, 1993, the Board filed a Complaint and Statement of Charges against the Respondent alleging numerous violations of the Board's statutes and rules relating to his accountability for controlled substances. The Board and the Respondent entered into a Stipulation and Informal Settlement of the Complaint and Statement of Charges which placed the Respondent's license on probation for five years, subject to terms and conditions. (Complaint and Statement of Charges, 3/8/93; Stipulation and Informal Settlement; 4/9/93)

2. On October 24, 1994, the Board filed a Petition To Revoke Probation and Notice of Hearing which alleged additional violations of the statutes and rules governing controlled substances. On November 25, 1994, the Respondent entered into a Stipulation and Consent Order. Pursuant to the terms of the Stipulation and Consent Order, the Respondent's pharmacy license was indefinitely suspended, effective December 1, 1994. In addition the Respondent was required to pay a civil penalty of \$8,000.00. The Respondent agreed that he would not be physically present in the Family Clinic Pharmacy and would not be directly or indirectly involved in its management. The Stipulation and Consent Order further provided that the Respondent could petition the Board for reinstatement of his license after July 1, 1997. (Petition to Revoke Probation and Notice of Hearing, 10/24/94; Stipulation and Consent Order, 11/25/94)

3. Some of the Respondent's prior violations were related to his wife's drug addiction and diversion of drugs from his pharmacy. Barb McKay is currently in recovery from her drug and alcohol addictions. She has maintained her sobriety for two years and is employed full time. The Respondent has been attending Al Anon and has obtained a sponsor. (Testimony of Barb McKay; Respondent; David Dixon; Shirley Ewald)

4. The Respondent has paid the \$8,000.00 civil penalty imposed by the Board and has abided by the terms of the Stipulation and Consent Order. He placed Family Clinic Pharmacy in trust and named his oldest son as the trustee. He hired a pharmacist to serve as

the pharmacist in charge. During his suspension, the Respondent has been employed as a car salesman and has volunteered for Hospice. He has participated in counselling once or twice a month. The Respondent has completed between 110 and 120 hours of continuing education. (Testimony of Respondent; Respondent Exhibit E)

5. The Respondent concedes that if he is reinstated, his practice of pharmacy would need to be supervised for a period of time. His pharmacy is open 48 to 50 hours a week. The Respondent proposes that he begin working approximately 30-32 hours per week, with approximately 20 of those hours supervised by the pharmacist in charge. The Respondent submitted documents entitled "Proposed Pharmacist Staffing of Family Clinic Pharmacy" and "Security Policy of Family Clinic Pharmacy." (Testimony of Respondent; Respondent Exhibits A, B)

CONCLUSIONS OF LAW

657 Iowa Administrative Code 9.23 provides, in relevant part:

657-9.23 (17A, 124B, 147, 155A, 272C) Reinstatement. Any person whose license to practice pharmacy...has been revoked...must meet the following eligibility requirements:

1. Must have satisfied all the terms of the order of revocation or suspension or court proceedings as they apply to that revocation or suspension. If the order of revocation or suspension did not establish terms or conditions upon which reinstatement might occur,...an initial application for reinstatement may not be made until one year has elapsed from the date of the board's order...

2. A person whose license to practice pharmacy was revoked must successfully pass NAPLEX or an equivalent examination as determined by NABP, the Federal Drug Law Examination (FDLE), and the Iowa Drug Law Examination.

3. All proceedings for reinstatement shall be initiated by the respondent who shall file with the board an application for reinstatement of the license...Such application shall be docketed in the original case in which the license... was revoked...All proceedings upon petition for reinstatement, including all matters preliminary and ancillary thereto, shall be subject to the same rules of procedure as other cases before the board. The board and the respondent may informally settle the issue of reinstatement. The respondent may

choose to have an informal settlement conference before the board...

4. An application for reinstatement shall allege facts which, if established, will be sufficient to enable the board to determine that the basis for the revocation... no longer exists and that it will be in the public interest for the license... to be reinstated. The burden of proof to establish such facts shall be on the respondent.

5. An order for reinstatement shall be based upon a decision which incorporates findings of fact and conclusions of law and must be based upon the affirmative vote of a quorum of the board. This order shall be available to the public as provided in 657-Chapter 14.

Based on the testimony and evidence presented at the hearing, the Board concludes that the Respondent appears ready to resume the practice of pharmacy, subject to certain terms and conditions. The Board concludes that with safeguards in place, it will be in the public interest to reinstate the Respondent's license to practice pharmacy. In reaching this decision, the Board has concluded that it will be necessary for the Respondent's practice of pharmacy to be closely supervised for the first year.

DECISION AND ORDER

The Board is satisfied that the basis for the revocation has been sufficiently addressed by the Respondent, and it is in the public interest that his license be reinstated, provided that the Respondent successfully completes the requirements outlined in this order.

IT IS THEREFORE ORDERED that prior to the reinstatement of the Respondent's license to practice pharmacy in the state of Iowa:

1) The Respondent must successfully pass the Federal Drug Law Examination (FDLE) with a score of 75 and the Iowa Drug Law Examination (IDLE) with a score of 75 percent. If there has been a change in the Board's rules before the Respondent is ready to take these examinations, he must successfully complete whatever exams are then currently required by the Board for reinstatement.

2) The Respondent must provide proof of completion of six (6) hours of continuing pharmacy education in patient counselling. All hours of continuing pharmacy education must be approved by the American Council on Pharmaceutical Education (ACPE) and must be pre-approved by the Board.

When the Respondent successfully passes all required licensing exams, and submits verification of six (6) hours of continuing pharmacy education in patient counselling, his license will be reinstated. The Respondent's license will immediately be placed on probation for a period of five (5) years, subject to the following terms and conditions:

- 1) For the first year of his probation, the Respondent shall only work under the direct supervision of another pharmacist. He may not work in any pharmacy unless a second pharmacist is physically present.
- 2) The Respondent shall not manage, administer, or be the pharmacist-in-charge of any pharmacy.
- 3) The Respondent shall not supervise any registered intern and shall not perform any of the duties of a preceptor.
- 4) The Respondent shall report to the Board or its designee quarterly. The report shall be in writing. The Respondent shall report any significant changes in his family situation or relationships. The report shall also include the Respondent's place of employment, current address, and any other information deemed necessary by the Board from time to time.
- 5) The Respondent shall continue to attend Al Anon on a twice weekly basis. The Respondent must submit written verification of his attendance with his quarterly reports.
- 6) The Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy and the distribution of controlled substances. The Respondent shall obey all federal and state criminal laws.
- 7) Every pharmacy which employs the Respondent must complete monthly physical inventories of all controlled substances. The Respondent shall submit verified inventory reports and accountings, signed and verified by the pharmacist in charge or another pharmacist, every six months.
- 8) The Respondent shall notify all present and prospective pharmacy employers and fellow employees of the decision in this case and the terms, conditions and restrictions imposed upon the Respondent by this decision. Within fifteen (15) days of Respondent undertaking employment as a pharmacist, Respondent shall cause his pharmacy employer and/or fellow employees to report to the Board in writing acknowledging that they have read this Order of the Board and understand it.

9) The Respondent shall implement the Proposed Security Policy for the Family Clinic Pharmacy, which he submitted as Exhibit A. Any changes to this policy must be pre-approved by the Board.

10) Should Respondent violate probation in any respect, the Board, after giving the Respondent notice and an opportunity to be heard, may revoke probation and take additional disciplinary action. If a petition to revoke probation is filed against the Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

11) Upon successful completion of probation, the Respondent's license will be fully restored.

Dated this 12th day of November, 1997.



Phyllis A. Olson
Chairperson
Iowa Board of Pharmacy Examiners

cc: Linny Emrich
David Olsen

Judicial review of the board's action may be sought in accordance with the terms of the Iowa administrative procedure Act (Iowa Code chapter 17A), from the date of the board's decision.