

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacist License of GARY L. LEVINE License No. 16727 Respondent	} } } } } }	COMPLAINT AND STATEMENT OF CHARGES AND NOTICE OF HEARING
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COMES NOW, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 20th day of October, 1993, and files this Complaint and Statement of Charges and Notice of Hearing against Gary L. Levine, a pharmacist licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Marian L. Roberts, Chairperson; Phyllis A. Olson, Vice Chairperson; Phyllis A. Miller; Mary Pat Mitchell; Matthew C. Osterhaus; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.

2. Respondent was issued a license to practice pharmacy in Iowa on July 18, 1986, by reciprocity.

3. Respondent currently resides at 6000 Cottage Drive, Des Moines, Iowa 50311.

4. Respondent is currently employed as the pharmacist in charge of Phar-Mor Pharmacy #212, 10101 "B" University Avenue, Clive, Iowa 50325. He has been the pharmacist in charge of Phar-Mor Pharmacy # 212 since April 27, 1993. The pharmacy license of Phar-Mor Pharmacy # 212 has been on probation with the Board since May 14, 1993.

5. Respondent's license to practice pharmacy in Iowa is current until June 30, 1994.

6. On September 14, 1993; October 12, 1993; and October 20, 1993, the Board received and reviewed information which alleges the following:

a. Since the beginning of Phar-Mor Pharmacy #212's probation, the Board has received six complaints against Phar-Mor Pharmacy # 212 directly from consumers. The dates of occurrence of the complaints are as follows: May 7, 1993; May 11, 1993; June 14, 1993; July 2, 1993; July 6, 1993; and October 17, 1993. Five of the six complaints involved one or more dispensing errors.

b. During the months of May, June, and July 1993, Phar-Mor Pharmacy # 212 failed to comply with subparagraph 4 of the Board's Disciplinary Order dated

May 14, 1993, by failing to report to the Board any dispensing errors brought to Respondent's attention by consumers within thirty (30) days of such occurrence.

c. Pharmacists employed by Phar-Mor Pharmacy # 212 committed nine additional dispensing errors which occurred on the following dates: August 18, 1993; September 2, 1993 (2 errors); September 3, 1993; September 7, 1993; September 8, 1993; September 9, 1993; September 17, 1993; and October 4, 1993. Respondent notified the Board of these incidents (consumer complaints) on October 7, 1993. All nine incidents involved one or more dispensing errors. Respondent Gary L. Levine was directly responsible for one of these dispensing errors.

d. All fourteen dispensing errors reviewed by the Board could have been prevented if adequate prospective drug use review and patient counseling had been provided by the pharmacists employed by Phar-Mor Pharmacy # 212.

e. An inspection of Phar-Mor Pharmacy # 212's controlled substance records on October 19, 1993, by Board Investigator Dennis D. Dobesh revealed the following:

(1) No patient addresses were recorded on 19 schedule II controlled substance prescriptions filled between August 5, 1993, and September 20, 1993.

(2) Prescription number N2200778 for patient "E.B." for #60 Ritalin 5mg, a Schedule II controlled substance, was dispensed on September 25, 1993, without a written prescription of a practitioner. No written prescription had been obtained as of October 19, 1993.

(3) Prescription number N2200816 for patient "J.C." for #30 Demerol 100mg, a Schedule II controlled substance, was dispensed on October 8, 1993, without a written prescription of a practitioner. No written prescription had been obtained as of October 19, 1993.

(4) Phar-Mor Pharmacy # 212's Schedule II Inventory Record for August 1993 reveals the following significant shortages of Schedule II controlled substances:

40 tablets of Percodan  
150 tablets of Ritalin 10mg  
83 tablets of Methylphenidate-SR 20mg

(5) Phar-Mor Pharmacy # 212's Schedule II Inventory Record for September 1993 reveals the following significant shortages of Schedule II controlled substances:

- 72 tablets of Oxycodone/APAP
- 44 tablets of Methylphenidate 10mg
- 60 tablets of Ritalin 20mg
- 20 capsules of Dexedrine 10mg

f. Phar-Mor Pharmacy # 212 has failed to obey all federal and state laws and regulations substantially related to the practice of pharmacy. Respondent Gary L. Levine has failed to keep and maintain records as required by the controlled substances Act. Respondent Gary L. Levine has also failed to establish effective controls against diversion of prescription drugs.

g. The staffing and procedures of Phar-Mor Pharmacy # 212's prescription department are inadequate to protect the public health and safety.

h. Respondent, as pharmacist in charge of Phar-Mor Pharmacy # 212, has the authority and responsibility for the pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

7. Respondent is guilty of violating Iowa Code sections 155A.12(1), 155A.12(5), 124.308(1), 124.402(1)(a), and 124.402(1)(c) by virtue of the allegations in paragraph 6 above.

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.

...

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

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

6. To qualify for a pharmacy license, the applicant shall submit to the board a license fee as determined by the board and a completed application on a form prescribed by the board that shall include the following information and be given under oath:...

e. The name of the pharmacist in charge, who has the authority and responsibility for the pharmacy's compliance with laws and rules pertaining to the

practice of pharmacy.

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.

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 204.308;

....

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

8. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.1, 8.5(4), 8.18, 8.19, 8.20, 9.1(4)(i), 9.1(4)(j), and 9.1(4)(u) by virtue of the allegations in paragraph 6 above.

657 Iowa Administrative Code section 6.1 provides, in part, the following:

General requirements. A general pharmacy is a location where prescription drugs are compounded, dispensed, or sold by a pharmacist and where prescription drug orders are received or processed in accordance with pharmacy laws. Pharmacists shall be responsible for any delegated act performed by supportive personnel under their supervision.

657 Iowa Administrative Code section 8.5(4) provides the following:

Nonconformance with law. A pharmacist shall not knowingly serve in a pharmacy which is not operated in conformance with law, or which engages in any practice which if engaged in by a pharmacist would be unethical conduct.

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

Pharmaceutical care -- patient records.

8.18(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist

to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for making a reasonable effort to obtain, record, and maintain the following information:

- a. Full name of the patient for whom the drug is intended;
- b. Address and telephone number of the patient;
- c. Patient's age or date of birth;
- d. Patient's gender;
- e. Significant patient information including a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and
- f. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

8.18(2) The pharmacist shall be responsible for making a reasonable effort to obtain from the patient or the patient's caregiver, and shall be responsible for recording, any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

657 Iowa Administrative Code section 8.19 provides the following:

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

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

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

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

Pharmaceutical care -- patient counseling.

8.20(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

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

8.20(2) When the patient or the patient's caregiver is present, counseling shall be in person.

8.20(3) When the patient or patient's caregiver is not present, the pharmacist shall counsel the patient or patient's caregiver either by initiating telephone discussion or by sending with the medication or device legible written notice including all of the following:

- a. Patient-specific information satisfying all elements identified in subrule 8.20(1) and including the statement: "If any of this information is unclear or contrary to the instructions of the prescriber, contact the pharmacist at (insert toll-free telephone number)."

- b. A statement of the patient's right to request consultation; and

- c. A toll-free telephone number at which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

8.20(4) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, and video programs.

....

8.20(6) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient or

caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

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:...

i. ...violating a lawful order of the board in a disciplinary hearing...

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

....

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

The Iowa Board of Pharmacy Examiners finds that paragraphs 7 and 8 allege grounds for which Respondent's license to practice pharmacy in Iowa can be disciplined.

**WHEREFORE**, the undersigned charges that Respondent Gary L. Levine has violated Iowa Code sections 155A.12(1), 155A.12(5), 124.308(1), 124.402(1)(a), and 124.402(1)(c) and 657 Iowa Administrative Code sections 6.1, 8.5(4), 8.18, 8.19, 8.20, 9.1(4)(i), 9.1(4)(j), and 9.1(4)(u).

**IT IS HEREBY ORDERED**, pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2(1), that Gary L. Levine appear before the Iowa Board of Pharmacy Examiners on Tuesday, November 23, 1993, at 9:00 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 discipline the license to practice pharmacy issued to Gary L. Levine on July 18, 1986, 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 Theresa O'Connell Weeg, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319 (telephone 515/281-6858). Copies of all filings with the Board should also be served on counsel.

IOWA BOARD OF PHARMACY EXAMINERS

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

Lloyd K. Jessen  
Executive Secretary/Director

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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RE: Pharmacist License of	)	FINDINGS OF FACT,
	)	CONCLUSIONS OF LAW,
GARY L. LEVINE	)	DECISION AND ORDER
License No. 16727	)	
	)	DIA NO. 93PHB-10
Respondent	)	

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TO: GARY L. LEVINE

On October 20, 1993, the Executive Secretary/Director of the Iowa Board of Pharmacy Examiners (Board) filed a Complaint and Statement of Charges and Notice of Hearing against Gary L. Levine (Respondent), a licensed pharmacist, alleging that the Respondent had violated a number of pharmacy related statutes and rules.

The hearing on the Complaint and Statement of Charges was held on November 23, 1993, in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Des Moines, Iowa. The following members of the Board were present: Marian L. Roberts, Chairperson; Phyllis A. Olson, Vice Chairperson; Phyllis A. Miller; Mary Pat Mitchell; Matthew C. Osterhaus and Arlan D. Van Norman. The Respondent appeared and was represented by counsel, James Gritzner. The state was represented by Theresa Weeg, Assistant Attorney General. The hearing was recorded by a certified court reporter. Margaret LaMarche, Administrative Law Judge from the Iowa Department of Inspections and Appeals, presided.

The parties agreed to include in this record the recording of four informal interviews of Gary Roseman, Nick Bluel, Ken Blythe, and Dennis Harker, which were conducted by the Board immediately preceding the hearing. The attorneys were present for the interviews but did not participate.

The parties were allowed to submit closing arguments in written form. On December 2, 1993, the Board convened in closed executive session, by telephone conference call, pursuant to Iowa Code section 272C.6(1), to deliberate its decision. The Administrative Law Judge was directed to prepare the Board's Findings of Fact, Conclusions of Law, Decision and Order.

THE RECORD

The record includes the Complaint and Statement of Charges and Notice of Hearing, Respondent's Motion for Continuance, November 2, 1993 letter notifying Respondent that the continuance motion had been denied, testimony of the witnesses, and the following exhibits:

- Exhibit 1: Complaint and Statement of Charges, Phar-Mor Pharmacy, March 22, 1993
- Exhibit 2: Order, May 14, 1993
- Exhibit 3: Petition to Revoke Probation, Phar-Mor Pharmacy, October 20, 1993
- Exhibit 4: Complaint and Statement of Charges, Gary Levine, October 20, 1993
- Exhibit 5: Phar-Mor Pharmacy, monthly report, May 30, 1993
- Exhibit 6: Phar-Mor Pharmacy, monthly report, July 3, 1993
- Exhibit 7: Phar-Mor Pharmacy, monthly report, August 2, 1993
- Exhibit 8: Phar-Mor Pharmacy, monthly report, August 31, 1993
- Exhibit 9: Phar-Mor Pharmacy, monthly report, September 29, 1993
- 9-A. Incident report, 8/18/93 (DG)
  - 9-B. Incident report, 9/2/93 (JC)
  - 9-C. Incident report, 9/2/93 (ND)
  - 9-D. Incident report, 9/3/93 (AA)
  - 9-E. Incident report, 9/7/93 (NM)\*
  - 9-F. Incident report, 9/8/93 (EM)
  - 9-G. Incident report, 9/9/93 (KH)\*
  - 9-H. Incident report, 9/17/93 (KH)
  - 9-I. Incident report, 10/4/93 (BC)\*
- \* "Date RX dispensed" is unclear from reporting form; date information is derived from other information on that form.
- Exhibit 10: Phar-Mor Pharmacy, monthly report, November 1, 1993
- 10-A. Incident report, 10/17/93 (BS)
  - 10-B. Incident report, 10/18/93 (JM)
- Exhibit 11: Complaint report re: Incident on 5/7/93 (GV and S. Humphrey, M.D.)
- Exhibit 12: Complaint reports re: VP:
- 12-A. Complaint report re: incident on 5/11/93 (VP)

- 12-B. Complaint report re: incident on 4/21/93 (VP)
- Exhibit 13: Complaint report re: incident on 6/14/93 (KK)
- Exhibit 14: Complaint report re: incident on 7/6/93 (SG)
- Exhibit 15: Complaint report dated 8/9/93 re: incident (BS)
- Exhibit 16: Letter from L. Jessen to G. Levine, 8/25/93
- Exhibit 17: Investigative report of D. Dobesh, 10/19/93
  - 17-A. Letter and attachments from MS, 10/17/93
  - 17-B. Statement of N. Blue1, 10/19/93
  - 17-C. Prescription No. N2200856 for BS, 10/17/93
  - 17-D. Prescription No. N2200857 for BS, 10/17/93
  - 17-E. Prescription No. N2200778 for EB, 9/25/93
  - 17-F. Prescription No. N2200816 for JC, 10/18/93
  - 17-G. List of Schedule II prescriptions without addresses
  - 17-H. Phar-Mor Schedule II inventory record for August 1993
  - 17-I. Phar-Mor Schedule II inventory record for September 1993.
- Exhibit 18: IBPE memo re: Phar-Mor C-II filling discrepancies, 4/21/93-10/26/93 (L. Pearson)
- Exhibit 19: 102 Schedule II prescriptions with no addresses (\* not included in Board exhibit folders \*)
- Exhibit 20: 2 Schedule II prescriptions for JC and EB with no doctor's signature
- Exhibit 21: 5 "on-hold" prescriptions (GO 4/27/93 and 6/30/93, TM 8/25/93, LP 9/27/93, and A 9/28/93)
- Exhibit 22: Prescription for GM, 6/11/93
- Exhibit 23: Prescription for JC, 9/2/93
- Exhibit 24: IBPE General Pharmacy Inspection Report for Phar-Mor, 10/26/93
- Exhibit 25: Computation Table

- Exhibit 26: Phar-Mor Schedule II monthly inventories for 5/93-9/93
- Exhibit 27: Complaint report re: incident on 11/3/93 (AB)
- Exhibit 28: Complaint report re: incident on 11/11/93 (RC)
- Exhibit 29: Letter from J. Rovers to L. Jessen, 11/11/93
- Exhibit 30: Letter from L. Jessen to J. Rovers, 11/16/93
- Exhibit 31: Graphs, May to October 1993, total pharmacist hours v. new prescriptions and total prescriptions  
(\* not included in Board exhibit folders \*)
- Exhibit 32: Graphs, May to October 1993, total pharmacy staff hours v. new prescriptions  
(\* not included in Board exhibit folders \*)
- Respondent's Exhibit A: Affidavit of Randell Kavalier, D.O.
- Respondent's Exhibit B: Affidavit of John P. Clark D.O.
- Respondent's Exhibit C: Copy of prescription refill form for Ritalin and prescription for Demerol
- Respondent's Exhibit D: Factbase: Phar-Mor #212
- Respondent's Exhibit E: Future of #212, Des Moines

#### FINDINGS OF FACT

1. Gary Levine was issued a license to practice pharmacy in Iowa on July 18, 1986, by reciprocity. His license is current until June 30, 1994. (Board file)
2. Gary Levine is currently employed as the pharmacist in charge of Phar-Mor Pharmacy #212, 10101 "B" University Avenue, Clive, Iowa 50325. He has been the pharmacist in charge of Phar-Mor Pharmacy #212 since April 27, 1993. (testimony of Gary Levine; Board file)
3. On March 22, 1993, the Executive Secretary/Director for the Board filed Complaint and Statement of Charges against the pharmacy license of Phar-Mor Pharmacy #212 alleging that the pharmacy had violated a number of pharmacy related statutes and rules. (Exhibit 1)
4. Following a hearing, the Board issued its Findings of Fact, Conclusions of Law, Decision and Order on May 14, 1993. The Board found that the pharmacy had failed to promptly report pharmacist

staffing changes to the Board, in violation of Iowa Code section 155A.15(2)(c) (1991) and 657 IAC 3.4 and 3.4(7). In addition, the Board found that the pharmacy had allowed severe understaffing and adverse working conditions in the pharmacy, which resulted in the inability of staff pharmacists to comply with the mandates of 657 IAC 8.18, 8.19, and 8.20, and caused dispensing errors (Exhibit 2).

5. The Board ordered that pharmacy license 436, issued to Phar-Mor Pharmacy #212, be suspended for a period of ninety (90) days. However, the suspension was stayed and the pharmacy was placed on probation for a period of three years, subject to certain terms and conditions. The terms and conditions included the payment of a \$25,000.00 civil penalty and the following probationary terms, in relevant part:

. . .

2. The Respondent must submit monthly written reports to the Board stating truthfully whether or not all terms and conditions of probation have been complied with and whether or not pharmacists employed by the Respondent are maintaining and reviewing patient records and providing patient counseling as required by Board rules. The reports shall include:

a. The weekly work schedule for all pharmacy staff (pharmacists and supportive personnel), and the total number of hours worked by each registered pharmacist and each pharmacy assistant each day.

b. The total number of new and refilled prescriptions filled each day.

The monthly reports shall be submitted during the first year of probation and thereafter, as directed by the Board.

3. The Respondent must immediately notify the Board if (later modified to "when") the level of staffing falls below 175 pharmacist hours per week.

4. The Respondent shall report any judgment or settlement of a malpractice claim or action and any dispensing errors brought to their attention by consumers within thirty (30) days of such occurrence.

5. The Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.

6. No pharmacist employed by the Respondent and practicing at the Clive location (store #212) shall supervise any registered intern or perform any of the duties of a preceptor.

7. Should the pharmacy violate probation in any respect, the Board, after giving the pharmacy notice and an opportunity to be heard, may revoke probation and impose the license suspension or further discipline. If a petition to revoke probation is filed against the pharmacy 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. (Exhibit 2)
6. On October 20, 1993, the Board filed a Petition to revoke Probation against the pharmacy license of Phar-Mor #212 and a Compliant and Statement of Charges against the pharmacist license of Gary Levine. (Exhibits 3, 4)
7. In the monthly reports filed by Gary Levine and Phar-Mor from May through October, 1993, there were only three weeks where pharmacist staffing was 175 hours or more. While the probation terms did not mandate 175 pharmacist hours each week, there is no doubt that 175 hours was the suggested staffing goal. Often, the pharmacist hours were significantly less than 175 hours. (testimony of Lindy Pearson; Exhibits 5 - 10)
8. The monthly reports filed by Gary Levine and Phar-Mor in May, June, and July listed no dispensing errors. On August 25, 1993, the Board's Executive Director sent a letter of warning to Gary Levine as pharmacist in charge of Phar-Mor. The letter informed Phar-Mor that the Board had received five consumer complaints since April 28, 1993, four of which involved dispensing errors at Phar-Mor. None of these dispensing errors were reported to the Board by Phar-Mor. Phar-Mor was reminded that it was required to report errors brought to its attention by consumers within thirty days of their occurrence. The letter further stated,  
  
Due to the number of dispensing errors which have occurred in a brief period of time, the committee is very concerned that the staffing and procedures of the prescription department are inadequate to protect the public health and safety. Furthermore, they regard these incidents as a violation of the terms and conditions of probation as set forth in the Board's Decision and Order.  
  
The pharmacy was warned that continued failure to report dispensing errors or another complaint regarding lack of counseling or a serious dispensing error would result in formal charges. (testimony of Denny Dobesh; Exhibits 5 - 8, 16)
9. Gary Levine admitted that he failed to report dispensing errors to the Board in May, June, and July. As pharmacist in charge, it was his duty to make records of all errors and report them to the Board. The Board still does not know what errors may have occurred during these months, with the exceptions of those

directly reported by consumers to the Board. Of these consumer complaints, two stand out as the most serious:

a. On May 7, 1993, customer GV took two prescriptions to Phar-Mor to be filled, one was for Tylenol #3, a pain medication, the other was for Naprosyn, a muscle relaxant. The pharmacist erroneously gave the customer Tylenol #3 in both bottles. This incident occurred before the Board's order of May 14, 1993 was issued. Nevertheless, it should have been reported in June. Levine admitted that he knew about this error and should have reported it.

b. On June 14, 1993, customer KK received a prescription for ear drops with erroneous instructions to apply to the toes. Levine admitted that this error should have been reported. (testimony of Holger Christensen; Exhibits 11 - 15).

10. After receiving the Board's letter of warning in August, Gary Levine did begin reporting consumer complaints and dispensing errors. One complaint was reported in August, nine dispensing errors were reported in September, and two were reported in October. In addition, two complaints were received in November, which have not yet been investigated by the Board. The errors included wrong drugs, wrong strength, and incorrect labeling (wrong patient name, erroneous directions). At the times these errors occurred, pharmacist staffing was generally significantly below the 175 hours per week suggested by the Board. Phar-Mor has fired one full-time pharmacist who was responsible for many of the dispensing errors and has removed a part-time pharmacist from its schedule. (testimony of Denny Dobesh, Lindy Pearson, Gary Levine; Exhibits 8 - 10, 31-32)

11. During a general pharmacy inspection, Board investigators found evidence of two more misfilled prescriptions that had not been previously reported. (testimony of Lindy Pearson; Exhibits 22, 23)

12. Phar-Mor Pharmacy #212 has numerous deficiencies in its handling of Schedule II controlled substances and inventories. Over 100 prescriptions for Schedule II controlled substances did not contain written addresses of the patient. Schedule II controlled drugs were dispensed on two occasions for which the pharmacy could not produce a written prescription signed by the physician. The pharmacy produced affidavits from the physicians at the hearing which stated they had authorized or executed prescriptions to the patients and a copy of one prescription. However, the pharmacy failed to demonstrate that the written prescription was ever presented to the pharmacy. (testimony of Denny Dobesh, Lindy Pearson; Exhibits 17, 17-E, 17-F, 17-G, 19, 20; Exhibits A, B)

13. The actual physical count of Schedule II controlled substances from May 2, 1993, to October 27, 1993, at Phar-Mor #212 demonstrates numerous shortages and overages of Schedule II drugs. Most of the shortages involved stimulants. Gary Levine could not adequately document or explain these discrepancies. It is not possible to conclude whether these discrepancies are due to paper errors or diversion. In October, the pharmacy instituted a perpetual inventory system for Schedule II controlled substances. (testimony of Denny Dobesh, Lindy Pearson, Gary Levine; Exhibit 25)

14. Phar-Mor Pharmacy #212 was inspected in October 1993. The inspection report cited numerous deficiencies. The Board agrees with Phar-Mor that only six of the drugs on the shelves were outdated. The Board is concerned about the following deficiencies:

a. New prescriptions are improperly entered on the computer with the date dispensed as the date of entry, rather than the date written. In one case, this caused the prescription to be extended eleven months beyond its expiration date.

b. The pharmacy failed to have a current law manual.

c. Genders and phone numbers were missing on patient records.

(testimony of Gary Ebeling; Exhibit 24)

15. None of the pharmacists employed at Phar-Mor and interviewed by the Board could recall having read the pharmacy's Policy and Procedure Manual. (testimony of Gary Roseman, Nick Bluel, Ken Blythe, Dennis Harker)

16. Robert McCurdy, Vice President of Pharmacy Operations for Phar-Mor, testified that Phar-Mor is willing to do whatever is necessary to resolve the problems at store #212, regardless of cost. The pharmacy operating hours have been reduced by five hours. McCurdy testified that he has re-emphasized the pharmaceutical care regulations to the pharmacists at store #212 because he was not satisfied that they were being performed consistently. Phar-Mor has hired John Rovers, an Assistant Clinical Professor of Pharmacy at Drake University, as a consultant to provide on-site supervision at Phar-Mor #212. Rovers reports directly to McCurdy. (testimony of Robert McCurdy)

17. Robert McCurdy concedes that Gary Levine lacks a sense of management and testified that Phar-Mor would help Levine develop to become a better manager. When McCurdy visited the store, he was not convinced that the right number of pharmacy employees were scheduled for the right time. McCurdy has become more proactive in scheduling at store #212. In the opinion of McCurdy, 168 pharmacist hours should be ample to staff the pharmacy for seventy-five

(75) hours of operation and the filling of approximately 2,400 prescriptions. (testimony of Robert McCurdy)

18. John Rovers has been on site at Phar-Mor #212 all but two days since November 1, 1993, observing the operations of the pharmacy and auditing record keeping. He reviews the perpetual inventory daily. Specifically, Rovers is monitoring staff compliance with drug utilization review, prospective drug review, and patient counseling. (testimony of John Rovers)

#### CONCLUSIONS OF LAW

1. Iowa Code section 155A.12 (1993) provides in relevant part:

. . . 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 the Act.

2. Iowa Code section 155A.13 (1993) provides in relevant part:

6. To qualify for a pharmacy license, the applicant shall submit to the board a license fee as determined by the board and a completed application on a form prescribed by the board that shall include the following information and be given under oath: . . .

e. The name of the pharmacist in charge, who has the authority and responsibility for the pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

3. Iowa Code section 155A.15 (1993) provides in relevant part;

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.



which if engaged in by a pharmacist would be unethical conduct.

9. 657 IAC 8.18 provides in relevant part:

Pharmaceutical care -- patient records.

8.18(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for making a reasonable effort to obtain, record, and maintain the following information:

- a. Full name of the patient for whom the drug is intended;
- b. Address and telephone number of the patient;
- c. Patient's age or date of birth;
- d. Patient's gender;
- e. Significant patient information including a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and
- f. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

8.18(2) The pharmacist shall be responsible for making a reasonable effort to obtain from the patient or the patient's caregiver, and shall be responsible for recording, any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

657 Iowa Administrative Code section 8.19 provides the following:

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

1. Overutilization or underutilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;

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

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

10. 657 Iowa Administrative Code section 8.20 provides in relevant part:

Pharmaceutical care -- patient counseling.

8.20(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

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

8.20(2) When the patient or the patient's caregiver is present, counseling shall be in person.

8.20(3) When the patient or patient's caregiver is not present, the pharmacist shall counsel the patient or patient's caregiver either by initiating telephone discussion or by sending with the medication or device legible written notice including all of the following:

- a. Patient-specific information satisfying all elements identified in subrule 8.20(1) and including the

statement: "If any of this information is unclear or contrary to the instructions of the prescriber, contact the pharmacist at (insert toll-free telephone number)."

b. A statement of the patient's right to request consultation; and

c. A toll-free telephone number at which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

8.20(4) Alternative forms of patient information shall be used to supplement patient counseling when appropriate. Examples include written information leaflets, pictogram labels, and video programs. . . .

8.20(6) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

11. 657 Iowa Administrative Code section 9.1(4) provides in relevant part:

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: . . .

i. . . . violating a lawful order of the board in a disciplinary hearing . . .

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.

12. The preponderance of the evidence established that the Respondent, Gary Levine, failed to carry out the duties of the pharmacist-in-charge of Phar-Mor #212, when he failed to report dispensing errors to the Board in the monthly reports filed for May, June, and July 1993. As pharmacist-in-charge, the Respondent was responsible for filing the monthly reports required by the Board's Order of May 14, 1993. The Respondent has violated 155A.13(6)(e) and 657 IAC 9.1(4)(i).

13. The preponderance of the evidence established that Gary Levine violated 657 IAC 8.18, 8.19 and 8.20. Most of the numerous errors

reviewed by the Board could have been prevented if adequate prospective drug use review and patient counseling had been provided by the pharmacists employed by Phar-Mor #212. The inadequate number of pharmacist hours at times of high prescription volume when errors occurred also supports the conclusion that prospective drug use review and patient counseling was inadequate or omitted. In addition the patient record systems were inadequate because some lacked patient genders, phone numbers, and dates of birth.

14. The preponderance of the evidence established that Gary Levine violated Iowa Code sections 155A.15(c)(h) and (i), 124.308 and 124.402 (1993) and 657 IAC 9.1(4)(j) when he failed to ensure that pharmacists recorded patient addresses on Schedule II controlled substance prescriptions, when Schedule II controlled substances were dispensed without a written prescription of the practitioner, and when he failed to provide sufficient safeguards and effective controls against diversion of prescription drugs. The physical count of Schedule II controlled drugs at the pharmacy establishes significant shortages which have not been accounted for by the pharmacy.

15. The preponderance of the evidence has established that Gary Levine has failed to obey all federal and state laws and regulations substantially related to the practice of pharmacy, in violation of paragraph 5 of the Board's Order and Iowa Code section 272C.3 (1993) and 657 IAC 9.1(4)(i).

#### DECISION AND ORDER

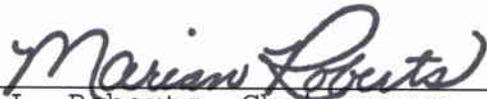
IT IS HEREBY ORDERED, that pharmacist license number 16727, issued to Gary L. Levine (Respondent), is suspended for a period of thirty (30) days. However, the suspension is stayed and Respondent is placed on probation for a period of two (2) years upon the following terms and conditions:

1. Within thirty (30) days of the date of this Order, Respondent shall pay a civil penalty of \$2,500.00 by delivering a check made payable to the Treasurer of Iowa to the Executive Secretary of the Board. The check shall be deposited into the general fund.

2. Respondent shall take and successfully pass the Iowa Drug Law Exam (IDLE) with a score of 75 percent, and the Federal Drug Law Exam (FDLE) with a score of 75, within one year of the effective date of this order. Respondent may take the exams a maximum of three (3) times each in the one-year period. Failure to pass IDLE or FDLE within the one-year period will be grounds to revoke probation and carry out the stayed suspension.

3. Within six months of the effective date of this order, the Respondent shall complete a six-hour continuing education course in counseling and a formal management training course, each course to be pre-approved by the Board. Documentation of completion shall be submitted to the Board. These courses are in addition to the thirty (30) hours of continuing education required for license renewal.
4. The Respondent shall report to the Board or its designee, in writing, on a quarterly basis. The report shall include the Respondent's place of employment current address, and any further information specifically requested by the Board.
5. The Respondent shall not supervise any registered intern and shall not perform any of the duties of a preceptor.
6. If the Respondent changes employment, he shall promptly notify his new employer of the terms of his probation.
7. The Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.
8. Should the Respondent violate probation in any respect, the Board, after giving the pharmacy notice and an opportunity to be heard, may revoke probation and impose the license suspension or further discipline. 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.
9. Upon successful completion of probation, the pharmacist license will be fully restored.

Dated this 9th day of December, 1993.



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Marian L. Roberts, Chairperson  
Iowa Board of Pharmacy Examiners

ML/jmm

cc: Theresa Weeg  
James Gritzner

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

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Re: Pharmacist License of	}	<b>PETITION TO</b>
<b>GARY L. LEVINE</b>	}	<b>REVOKE</b>
License No. 16727	}	<b>PROBATION</b>
Respondent	}	<b>AND</b>
	}	<b>NOTICE OF HEARING</b>
	}	

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**COMES NOW**, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 6th day of March, 1995, and files this Petition to Revoke Probation and Notice of Hearing against Gary L. Levine, 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 July 18, 1986, by reciprocity.

3. Respondent currently resides at 6000 Cottage Drive, Des Moines, Iowa 50311.

4. Respondent is currently employed as the pharmacist in charge of Phar-Mor Pharmacy #212, 10101 "B" University Avenue, Clive, Iowa 50325. He has been the pharmacist in charge of Phar-Mor Pharmacy # 212 since April 27, 1993. The pharmacy license of Phar-Mor Pharmacy # 212 has been on probation with the Board since May 14, 1993.

5. Respondent's license to practice pharmacy in Iowa is current until June 30, 1996.

6. A Complaint and Statement of Charges and Notice of Hearing was filed against Respondent on October 20, 1993. The Complaint alleged that Respondent had violated a number of pharmacy related statutes and rules. An administrative hearing was held on November 23, 1993, in Des Moines, Iowa.

7. On December 9, 1993, the Board issued its "Findings of Fact, Conclusions of Law, Decision and Order." The Board found Respondent guilty of the following: (1) failing to carry out the duties of the pharmacist in charge by failing to report to the Board several dispensing errors which occurred at Phar-Mor Pharmacy #212, as required by a Board disciplinary order issued to Phar-Mor on May 14, 1993; (2) failing to comply with Board rules pertaining to patient records, prospective drug use review, and patient counseling; (3) failing to keep complete and accurate controlled substance records; (4) failing to provide

accountability for certain Schedule II controlled substances; and (5) failing to obey all federal and state laws and regulations substantially related to the practice of pharmacy. The Board's Order suspended Respondent's pharmacist license for 30 days. The suspension was stayed, however, and Mr. Levine was placed on probation with conditions for two years beginning December 9, 1993. In addition, Mr. Levine was ordered to do the following: (1) to take and pass the Iowa Drug Law Examination (IDLE) and the Federal Drug Law Examination (FDLE); (2) to complete a six-hour continuing education course in patient counseling; (3) to complete a formal pharmacy management training course; and (4) to pay a civil penalty of \$2,500.

In a related disciplinary action, the Board required Phar-Mor Pharmacy #212 to maintain an average staffing ratio of seven (7) pharmacist hours (R.Ph. licensed in Iowa) per every 100 prescriptions filled.

8. The Board's Findings of Fact dated December 9, 1993, included the following:

13. The actual physical count of Schedule II controlled substances from May 2, 1993, to October 27, 1993, at Phar-Mor #212 demonstrates numerous shortages and overages of Schedule II drugs. Most of the shortages involved stimulants. Gary Levine could not adequately document or explain these discrepancies...

9. The Board's Conclusions of Law dated December 9, 1993, included the following:

13. The preponderance of the evidence established that Gary Levine violated 657 IAC 8.18, 8.19, and 8.20. Most of the numerous errors reviewed by the Board could have been prevented if adequate prospective drug use review and patient counseling had been provided by the pharmacists employed by Phar-Mor #212. The inadequate number of pharmacist hours at times of high prescription volume when errors occurred also supports the conclusion that prospective drug use review and patient counseling was inadequate or omitted. In addition the patient record systems were inadequate because some lacked patient genders, phone numbers, and dates of birth.

14. The preponderance of the evidence established that Gary Levine violated Iowa Code section...155A.15(2)(i)...when he failed to provide sufficient safeguards and effective controls against diversion of prescription drugs.

10. The Board's Order dated December 9, 1993, provided, in part, that during the probationary period the Respondent must do the following:

7. The Respondent shall obey all federal and state laws and regulations substantially related to the

practice of pharmacy.

...  
8. Should the Respondent violate probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and impose the license suspension or further discipline. 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.

Another Board Order dated December 9, 1993, provided, in part, that during the probationary period of Phar-Mor Pharmacy #212, the pharmacy must do the following:

2. ...[S]ubmit monthly written reports to the Board stating truthfully whether or not all terms and conditions of probation have been complied with and whether or not pharmacists employed by the Respondent are maintaining and reviewing patient records and providing patient counseling as required by Board rules...

3. Phar-Mor Pharmacy #212 is required to maintain an average staffing ratio of seven (7) pharmacist hours (R.Ph. licensed in Iowa) per every 100 prescriptions filled, to be calculated on a weekly basis. If the pharmacy discovers that it has failed to meet this mandatory minimum staffing ratio for a particular week, it must report this information to the Board no later than 9:00 a.m. on the following Monday and take immediate action to prevent such future occurrences. The Board, in its discretion, may take further disciplinary action for any violation of this minimum staffing requirement...

4. Phar-Mor Pharmacy #212 shall submit its Policies and Procedures Manual to the Board, for its approval, before January 5, 1994. The manual must specifically address issues of patient records, dispensing accuracy, incident report procedures, prospective drug review, patient counseling, and procedures for Schedule II controlled substance prescriptions.

...  
e. ...Respondent shall cause any new pharmacy employee, including a temporary, part-time, or full-time pharmacy employee, to report to the Board in writing acknowledging that the employee has read the Board's Order.

11. On March 23, 1994, the Board issued a letter of warning to Phar-Mor. The letter advised Respondent that "continued dispensing errors...which indicate a lack of adequate pharmacist staffing or a lack of effective patient counseling, may result in further formal disciplinary action."

12. On April 1, 1994, the Board received a written response from Robert W. McCurdy of Phar-Mor Inc., who stated that he did not believe that the dispensing errors were related to scheduling. He indicated that he believed the pharmacy had a pharmacist "quality" problem. He further indicated that pharmacist personnel would be changed.

13. On May 11, 1994, the Board required Respondent to appear at an informal conference on June 9, 1994, to discuss the dispensing errors which had occurred at Phar-Mor Pharmacy #212 since November 23, 1993. Following the informal conference, Respondent submitted a letter dated June 15, 1994, to the Board for its consideration. The letter stated that "we have reviewed the prescription operating procedures of our pharmacy and will make or have made the following changes or additions in order that dispensing accuracy be the number one priority."

14. In a letter dated June 16, 1994, the Board responded to Respondent's letter of June 15 and stated the following:

...The Board has reviewed the proposed changes which you have outlined in your letter and has agreed, at this time, to allow the probationary period of the pharmacy to continue.

....

...[I]t is also our understanding that your pharmacy will increase the pharmacist staffing of the prescription department from approximately 140-145 hours per week to 160-168 hours per week and that you are currently striving to hire an additional pharmacist to alleviate the problems associated with staffing.

The Board will continue to monitor the activities of your pharmacy very closely in order to determine if these changes will enable the pharmacy to function in a manner that protects the public health and safety.

15. A review of the weekly prescription volume and pharmacist staffing at Phar-Mor Pharmacy #212 between June 19, 1994, and January 28, 1995, indicates that dispensing errors have occurred on high prescription volume days and that pharmacist staffing has not reached a consistent level of 160-168 hours per week.

16. A series of 52 documented dispensing errors has occurred at Phar-Mor Pharmacy #212. These errors have included wrong drug (24 times); wrong strength of drug (18 times); wrong quantity of drug (2 times); incorrect drug substitution (2 times); and incorrect labeling, including wrong patient name, wrong doctor name, or wrong directions for use (6 times).

a. During 1993 a total of 22 dispensing errors occurred at Phar-Mor Pharmacy #212 on the following dates:

- (1) February 8, 1993 -- wrong drug
- (2) April 12, 1993 -- wrong strength
- (3) May 7, 1993 -- wrong drug
- (4) May 11, 1993 -- wrong quantity of drug
- (5) June 14, 1993 -- wrong directions for use
- (6) July 6, 1993 -- wrong drug
- (7) August 18, 1993 -- wrong quantity of drug
- (8) September 2, 1993 **(two Rx errors)** --  
one wrong strength and one wrong drug
- (9) September 3, 1993 -- wrong strength
- (10) September 7, 1993 -- wrong drug
- (11) September 8, 1993 -- wrong strength
- (12) September 9, 1993 -- wrong drug
- (13) September 17, 1993 -- wrong strength
- (14) October 1, 1993 -- wrong drug
- (15) October 4, 1993 -- wrong directions for use
- (16) October 17, 1993 -- wrong patient name
- (17) October 18, 1993 -- wrong patient name
- (18) November 3, 1993 -- wrong drug
- (19) December 20, 1993 -- wrong drug
- (20) December 30, 1993 -- wrong strength
- (21) December 31, 1993 -- wrong strength

b. During 1994 a total of 28 dispensing errors occurred at Phar-Mor Pharmacy #212 on the following dates:

- (1) January 6, 1994 **(two Rx errors)** --  
one wrong drug and one wrong doctor name
- (2) January 26, 1994 -- wrong drug
- (3) January 29, 1994 **(two Rx errors)** --  
both wrong drugs
- (4) January 30, 1994 -- wrong drug
- (5) January 31, 1994 -- wrong strength
- (6) February 1, 1994 -- wrong strength
- (7) February 4, 1994 -- wrong strength
- (8) February 21, 1994 -- wrong drug
- (9) March 1, 1994 -- wrong drug
- (10) March 2, 1994 -- wrong strength
- (11) March 3, 1994 -- wrong strength
- (12) April 12, 1994 -- wrong strength
- (13) April 25, 1994 **(three Rx errors)** --  
one wrong drug, one wrong strength, and  
one substituted drug
- (14) May 2, 1994 -- wrong drug
- (15) May 27, 1994 **(two Rx errors)** --  
both wrong drugs
- (16) June 1, 1994 -- wrong strength
- (17) July 21, 1994 -- wrong directions
- (18) August 16, 1994 -- wrong strength
- (19) August 24, 1994 -- wrong drug
- (20) September 2, 1994 -- wrong strength
- (21) November 9, 1994 -- substituted drug
- (22) November 30, 1994 -- incomplete drug
- (23) December 2, 1994 -- wrong drug

c. During January 1995 a total of two dispensing errors occurred at Phar-Mor Pharmacy #212 on the following dates:

- (1) January 10, 1995 -- wrong strength
- (2) January 12, 1995 -- wrong drug

d. Most, if not all, of these 52 dispensing errors which have occurred between February 8, 1993, and January 12, 1995, could have been prevented if adequate prospective drug use review and patient counseling had been provided by the pharmacists employed by Respondent.

e. Respondent failed to report to the Board a dispensing error which is alleged to have occurred on July 21, 1994. The consumer who reported the dispensing error to the Board has indicated, in writing, that she confronted a male pharmacist at Phar-Mor #212 on July 21, 1994, regarding the error. Respondent reported no errors or incident reports for the month of July 1994.

f. Respondent also failed to report to the Board a dispensing error which is alleged to have occurred on January 6, 1994. The consumer reported the error to the Board by telephone on January 14, 1994.

g. The Board also received another complaint directly from a different consumer on January 14, 1994. That complaint alleged that a male pharmacist at Phar-Mor #212 had failed to provide the consumer with information that she needed.

17. A review of Respondent's hardcopy prescription records from June 1, 1994, to December 27, 1994, has revealed various inconsistencies, ambiguous notations, and a lack of pertinent information on some hardcopy prescriptions.

18. On February 8, 1995, the Board received a complaint from "Jane Doe", a former employee of Phar-Mor #212 (Complaint No. 95010). "Jane Doe" alleged that irregularities were occurring within the prescription department of Phar-Mor #212. The irregularities included misconduct by employees of the prescription department. "Jane Doe" also alleged that the drug "Lortab" was being diverted from the pharmacy by an employee of the prescription department. "Jane Doe" further alleged that she had contacted an assistant store manager at Phar-Mor #212 to report the problems, but that no action was taken. Soon after "Jane Doe" reported the problems to a Phar-Mor company "employee complaint telephone hotline," she was discharged from her employment at Phar-Mor #212. "Jane Doe" has also alleged that Respondent failed to allow her to read the entire Board disciplinary order dated December 9, 1993, when she began working

in the prescription department, as required by subparagraph (4)(e) of the Board Order.

19. Respondent has repeatedly been unable to provide accountability for all controlled substances purchased.

a. Respondent's Schedule II Inventory Record for August 1993 revealed a shortage of 273 tablets of Schedule II controlled substances, including Percodan, Ritalin 10mg, and Methylphenidate-SR 20mg.

b. Respondent's Schedule II Inventory Record for September 1993 revealed a shortage of 196 tablets of Schedule II controlled substances, including Oxycodone/APAP, Methylphenidate 10mg, Ritalin 20mg, and Dexedrine 10mg.

c. Two selective accountability audits of Respondent's Schedule III, IV, and V controlled substances were conducted by the Board in February 1995 following receipt of Complaint No. 95010 from "Jane Doe" on February 8, 1995. The audit period for ten Schedule III hydrocodone products was approximately nine months, from May 1, 1994, to February 9, 1995. The audit period for various other Schedule III, IV, and V controlled substances was nearly ten months, from May 1, 1994, to February 22, 1995. These audits revealed the following significant shortages and overages of controlled substances:

(1) A shortage of 13,277 tablets or capsules as follows:

<u>Qty</u>	<u>Name &amp; Strength of Drug</u>
1,024	Lorcet 10/650
495	Lortab 7.5/500
3,224	Hydrocodone/APAP 7.5/500
3,828	Hydrocodone/APAP 7.5/750
38	Vicodin 5
1,344	Vicodin ES 7.5/750
58	Phentermine 37.5
584	Alprazolam 1
229	Xanax 1
42	Xanax 0.5
527	Xanax 0.25
22	Lorazepam 0.5
73	Valium 10
1,733	Diazepam 10
16	Diazepam 2
40	Ativan 1

(2) A shortage of 5,415ml of oral liquids as follows:

<u>Qty</u>	<u>Name &amp; Strength of Drug</u>
5,192ml	Promethazine with Codeine Liquid
223ml	Tussionex Suspension

(3) An overage of 1,887 tablets or capsules as follows:

<u>Qty</u>	<u>Name &amp; Strength of Drug</u>
82	Lortab 2.5/500
75	Hydrocodone/APAP 5/500
29	Ionamin 15
52	Ionamin 30
29	Diethylpropion 75
653	Propoxyphene/NAP/APAP 100
53	Alprazolam 2
112	Alprazolam 0.5
133	Alprazolam 0.25
33	Valium 5
17	Valium 2
23	Diazepam 5
69	Ativan 0.5
527	Lorazepam 1

(4) An overage of 257ml of liquids as follows:

<u>Qty</u>	<u>Name &amp; Strength of Drug</u>
245ml	Codclear-DH Syrup
12ml	Testosterone Enanthate Injection 200mg

20. A review of selected patient medication profiles at Phar-Mor #212 has revealed that Phar-Mor's pharmacists have failed to conduct effective prospective drug use review (DUR) as required by Board rules. Certain patients appear to have received excessive amounts of certain controlled substances. Phar-Mor pharmacists have failed to take appropriate steps to avoid or resolve over-utilization and clinical abuse or misuse of these drugs.

21. Respondent failed to take a complete and accurate biennial inventory of all controlled substances on May 1, 1994. This failure to take a complete and accurate inventory has contributed to Respondent's inability to provide accountability for all controlled substances purchased by Phar-Mor #212.

22. Respondent failed to maintain in the pharmacy a complete set of purchase invoices for controlled substances purchased by Phar-Mor #212 since May 1, 1994. This failure to maintain invoices has also contributed to Respondent's inability

to provide accountability for all controlled substances purchased by Phar-Mor #212.

23. Respondent, as pharmacist in charge of Phar-Mor Pharmacy #212, has the authority and responsibility for the pharmacy's compliance with laws and rules pertaining to the practice of pharmacy. Respondent also has the responsibility for the pharmacy's compliance with the Board's disciplinary order dated December 9, 1993.

24. Respondent has again failed to obey all federal and state laws and regulations substantially related to the practice of pharmacy. Respondent has again failed to keep and maintain records as required by law and Board rules. Respondent has again failed to establish effective controls against loss or diversion of controlled substances.

25. The staffing and procedures of Respondent's prescription department are still inadequate to protect the public health and safety.

26. Respondent is guilty of violating the terms of his probation by violating paragraph 7 of the Board's Order by virtue of the information contained in paragraphs 11 through 25 of this Petition to Revoke Probation.

27. Respondent is guilty of violating Iowa Code sections 155A.12(1), 155A.12(5), 124.308(1), 124.402(1)(a), and 124.402(1)(c) by virtue of the allegations in paragraphs 11 through 25 above.

1995 Iowa Code section 124.308 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. 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.

1995 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 204.308;  
....  
c. To refuse or fail to make, keep or furnish any record, notification, order form, statement, invoice or information required under this chapter;

1995 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.

...

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

1995 Iowa Code section 155A.13 provides, in part, the following:

6. To qualify for a pharmacy license, the applicant shall submit to the board a license fee as determined by the board and a completed application on a form prescribed by the board that shall include the following information and be given under oath:...

e. The name of the pharmacist in charge, who has the authority and responsibility for the pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

28. Respondent is guilty of violations of 657 Iowa Administrative Code sections 6.1, 8.5(4), 8.18, 8.19, 8.20, 9.1(4)(i), 9.1(4)(j), and 9.1(4)(u) by virtue of the allegations in paragraphs 11 through 25 above.

657 Iowa Administrative Code section 6.1 provides, in part, the following:

General requirements. A general pharmacy is a location where prescription drugs are compounded, dispensed, or sold by a pharmacist and where prescription drug orders are received or processed in accordance with pharmacy laws. Pharmacists shall be responsible for any delegated act performed by supportive personnel under their supervision.

657 Iowa Administrative Code section 8.5(4) provides the following:

Nonconformance with law. A pharmacist shall not knowingly serve in a pharmacy which is not operated in conformance with law, or which engages in any practice which if engaged in by a pharmacist would be unethical conduct.

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

Pharmaceutical care -- patient records.

8.18(1) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed. The patient

record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The pharmacist shall be responsible for making a reasonable effort to obtain, record, and maintain the following information:

- a. Full name of the patient for whom the drug is intended;
- b. Address and telephone number of the patient;
- c. Patient's age or date of birth;
- d. Patient's gender;
- e. Significant patient information including a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and
- f. Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

8.18(2) The pharmacist shall be responsible for making a reasonable effort to obtain from the patient or the patient's caregiver, and shall be responsible for recording, any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

657 Iowa Administrative Code section 8.19 provides the following:

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

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

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

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

Pharmaceutical care -- patient counseling.

8.20(1) Upon receipt of a new prescription drug order and following a review of the patient's record, a pharmacist shall counsel each patient or patient's caregiver. The counseling shall be on matters which, in the pharmacist's professional judgment, will enhance or optimize drug therapy. Appropriate elements of patient counseling may include:

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

8.20(2) If in the pharmacist's professional judgment oral counseling is not practicable, the pharmacist may use alternative forms of patient information. Alternative forms of patient information may include written information leaflets, pictogram labels, video programs, or information generated by electronic data processing equipment. When used in place of oral counseling, alternative forms of patient information shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy by toll-free telephone or collect call. A combination of oral counseling and alternative forms of counseling is encouraged.

8.20(3) Patient counseling, as described above, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drugs.

8.20(4) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation. A patient or caregiver's refusal of consultation shall be documented by the pharmacist. The absence of any record of a refusal of the pharmacist's attempt to counsel shall be presumed to signify that the offer was accepted and that counseling was provided.

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:...

i. ...violating a lawful order of the board in a disciplinary hearing...

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

....

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

The Iowa Board of Pharmacy Examiners finds that paragraphs 26, 27, and 28 allege grounds for which Respondent's probation may be revoked and his license to practice pharmacy in Iowa can be disciplined.

**WHEREFORE**, the undersigned charges that Respondent Gary L. Levine has violated 1995 Iowa Code sections 155A.12(1), 155A.12(5), 124.308(3), 124.402(1)(a), and 124.402(1)(c) and 657 Iowa Administrative Code sections 6.1, 8.5(4), 8.18, 8.19, 8.20, 9.1(4)(i), 9.1(4)(j), and 9.1(4)(u).

**IT IS HEREBY ORDERED**, pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2(1), that Gary L. Levine appear before the Iowa Board of Pharmacy Examiners on Wednesday, April 5, 1995, at 9:00 a.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

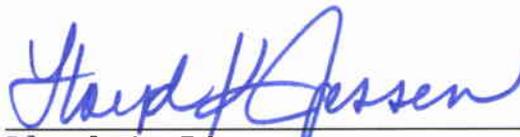
The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to revoke Respondent's probation and to impose the thirty (30) day suspension which was stayed on December 9, 1993, and take whatever additional action that they deem necessary and appropriate.

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 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



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Lloyd K. Jessen  
Executive Secretary/Director

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

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Re: Pharmacist License of  
**GARY L. LEVINE**  
License No. 16727  
Respondent

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**STIPULATION  
AND  
CONSENT ORDER**

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On this 10th day of July, 1995, the Iowa Board of Pharmacy Examiners and Gary L. Levine, R.Ph., 6000 Cottage Drive, Des Moines, 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 March 6, 1995, shall be resolved without proceeding to hearing, as the parties have agreed to the following Stipulation and Consent Order:

1. That Respondent was issued a license to practice pharmacy on the 18th day of July, 1986, as evidenced by License Number 16727, which is recorded in the permanent records of the Iowa Board of Pharmacy Examiners.
2. That Iowa Pharmacist License Number 16727 issued to and currently held by Respondent is current and active until June 30, 1996.
3. That Iowa Pharmacist License Number 16727 was placed on probation with conditions for two (2) years beginning on December 9, 1993.
4. That a Petition to Revoke Probation and Notice of Hearing was filed against Respondent on March 6, 1995.

5. That the Iowa Board of Pharmacy Examiners has jurisdiction over the parties and the subject matter herein.

6. Respondent does not admit to the truth of any of the allegations set forth in the Petition to Revoke Probation. This Stipulation and Consent Order is executed as a compromise settlement of disputed claims.

### SECTION I

THEREFORE, IT IS HEREBY ORDERED that Respondent shall pay a civil penalty of \$6,500.00. Five thousand dollars is due and payable within 30 days of the date of approval of this Stipulation and Consent Order by the Board. The remaining \$1,500 shall be due and payable within 90 days of the date of approval of this Stipulation and Consent Order by the Board. Respondent shall deliver checks made payable to the Treasurer of the State of Iowa to the Executive Secretary/Director of the Board. The checks shall be deposited into the general fund of the State of Iowa.

### SECTION II

Upon approval of this Stipulation and Consent Order by the Board, Respondent's license to practice pharmacy shall be placed on probation for three (3) years. During the probationary period the Respondent shall not serve as the pharmacist in charge of any pharmacy, shall not supervise any registered intern, and shall not perform any of the duties of a preceptor. In addition, during the probationary period the Respondent shall:

1. 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.

2. Provide evidence of efforts to maintain skill and knowledge as a pharmacist through continuing pharmacy education (CPE) as directed by the Board.

3. Obey all federal and state laws, rules, and regulations substantially related to the practice of pharmacy and the distribution of controlled substances.

4. 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 thirty (30) days after approval of this Stipulation and Consent Order by the Board, and 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.

### SECTION III

1. Should Respondent leave Iowa to reside or practice in another state, he shall notify the Board in writing fourteen (14) days prior to his departure and within fourteen (14) days of his return. Periods of residency or practice outside the State of Iowa shall not apply to reduction of the probationary period.

2. Respondent may apply for modification of the provision prohibiting Respondent from serving as a pharmacist in charge after one year of probation has been successfully completed.

3. Respondent shall fully and promptly comply with all 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).

4. Should Respondent violate probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and

impose additional disciplinary sanctions, including the revocation of Respondent's license to practice pharmacy. If a petition to revoke probation is filed against 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.

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

6. This Stipulation and Consent Order 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.

7. This Stipulation and Consent Order is voluntarily submitted by Respondent to the Board for its consideration on the 10<sup>th</sup> day of July, 1995.

  
GARY L. LEVINE, R.Ph.  
Respondent

Subscribed and Sworn to before me on this 10<sup>th</sup> day of July, 1995.

  
NOTARY PUBLIC IN AND FOR THE  
STATE OF IOWA

6. This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on the 11<sup>th</sup> day of July, 1995.



PHYLLIS A. OLSON, Vice Chairperson  
Iowa Board of Pharmacy Examiners  
Executive Hills West  
1209 East Court Avenue  
Des Moines, Iowa 50319

cc: Linny Emrich  
Assistant Attorney General  
Office of the Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

David L. Brown  
Attorney For Respondent  
Eighth Floor, Fleming Building  
218 Sixth Avenue  
Des Moines, Iowa 50309

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

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Re: Pharmacist License of  
**GARY L. LEVINE**  
License No. 16727  
Respondent

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**ORDER**

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**COMES NOW**, Phyllis A. Olson, Chairperson of the Iowa Board of Pharmacy Examiners, on the 10th day of June, 1997, and declares that:

1. On December 9, 1993, Respondent's pharmacist license number 16727 was placed on probation with conditions for two (2) years.
2. On March 6, 1995, a Petition to Revoke Probation was filed against Respondent. On July 11, 1995, Respondent's pharmacist license number 16727 was placed on probation with conditions for three (3) years.
3. On June 10, 1997, the Respondent appeared in person before the Board at an informal conference to request modification of his disciplinary order. At the conclusion of the conference, the Board agreed to modify the terms of Respondent's Stipulation and Consent Order dated July 11, 1995, by terminating Respondent's probationary status on July 11, 1997.

**WHEREFORE**, it is hereby ordered that the probationary period of pharmacist license number 16727 issued to Respondent and the terms, restrictions, and conditions of Respondent's probation shall end on July 11, 1997, and that as of July 11, 1997, Respondent's pharmacist certificate is fully restored.



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**PHYLLIS A. OLSON**, 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**

Re:	)	Case No. 2005-89
Pharmacist License of	)	
<b>GARY LEVINE</b>	)	<b>STATEMENT OF CHARGES</b>
License No. 16727	)	
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 (2005).
3. On July 18, 1986, the Board issued Respondent, Gary Levine, by reciprocity, a license to engage in the practice of pharmacy as evidenced by license number 16727, subject to the laws of the State of Iowa and the rules of the Board.
4. Respondent's pharmacist license is current and active until June 30, 2006.
5. Respondent's current address is 850 Cummins Parkway, Des Moines, Iowa 50312.
6. Respondent is employed as the pharmacist in charge at the Hy-Vee Care, 3998 N.W. Urbandale Drive, Urbandale, Iowa 50322.

**A. CHARGES**

**COUNT I – DEPARTURE FROM PROFESSIONAL STANDARDS**

Respondent is charged under Iowa Code § 155A.12 (2005) and 657 Iowa Administrative Code § 6.14 and 36.1(4) with a lack of professional competency, including repeated departure from, or failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the State of Iowa.

**COUNT II – FAILURE TO MAINTAIN RECORDS AND CONTROL OVER DRUGS**

Respondent is charged with failing to maintain complete and adequate records of purchases and disposal of drugs listed in the Controlled Substances Act in violation of Iowa Code § 155A.12

(4) (2005) and 657 Iowa Administrative Code § 36.1(4)(cc), and with failing to maintain accurate control over and accountability for drugs, including controlled substances, in violation of Iowa Code §§ 124.308(3), 124.402(1)(a), 155A.12(5) and 657 Iowa Administrative Code §§ 6.2, 6.7 and 36.1(4)(u).

#### COUNT III – ILLEGAL DISTRIBUTION OF DRUGS

Respondent is charged with distribution of drugs for other than lawful purposes in violation of Iowa Code § 155A.12(1) (2005) and 657 Iowa Administrative Code § 36.1(4)(h), specifically, distribution of prescription medications in the absence of a prescription.

#### COUNT IV– FAILURE TO ACT AS PHARMACIST IN CHARGE

The Respondent is charged with failing to perform the duties of a pharmacist in charge in violation of Iowa Code §§ 155A.12(1) (2005) and 657 Iowa Administrative Code § 6.2.

#### COUNT V – PROCURING PERSONS TO PERFORM AS TECHNICIANS

Respondent is charged with knowingly aiding, assisting and procuring non-technicians to perform the functions of a pharmacy technician in violation of Iowa Code § 155A.12(1) (2005) and 657 Iowa Administrative Code § 36.1(4)(l).

#### COUNT VI – EMPLOYMENT OF UNREGISTERED TECHNICIANS

Respondent is charged with employment of unregistered technicians in violation of Iowa Code § 155A.12(1) (2005) and 657 Iowa Administrative Code § 36.1(4)(aa).

#### COUNT VII – FAILURE TO TRAIN TECHNICIANS

Respondent is charged with failure to develop and implement policies for training and utilization of technicians in violation of Iowa Code § 155A.12(1) (2005) and 657 Iowa Administrative Code § 3.17.

#### COUNT VIII – ENGAGING IN UNETHICAL CONDUCT

The Respondent is charged with engaging in unethical conduct in violation of Iowa Code § 155A.12(2) (2005) and 657 Iowa Administrative Code §§ 8.11(5) and 36.1(4)(c) by, among other things, offering free medication administration forms to long-term healthcare facilities.

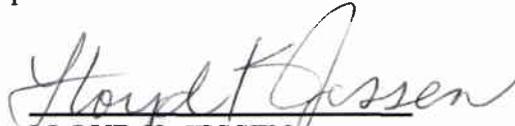
### **B. CIRCUMSTANCES**

On or about September 28, 2005 an investigation was commenced, which revealed the following:

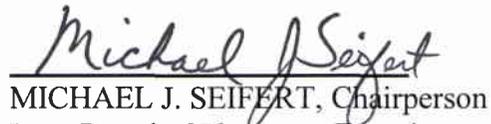
1. Respondent is the pharmacist-in-charge at Hy-Vee Care, a pharmacy specializing in service to long-term healthcare facilities. Hy-Vee Care employs 7 pharmacists and had over 60 employees acting as pharmacy technicians.
2. As of September 29, 2005, 39 of the 69 acting technicians employed at Hy-Vee Care were not registered with the Board. As of October 27, 2005, 10 of the 62 acting technicians employed at Hy-Vee Care were not registered with the Board. Individuals employed by Hy-Vee Care and acting as technicians have worked as long as 24 months without registering with the Board.
3. An audit of schedule II controlled substances revealed numerous, substantial shortages including shortages of Fentanyl patches (-585 units), Methylin solution (-565 ml), morphine 15mg ER (-1238 units), Roxanol solution (-599 ml). The audit disclosed that, as to 86 medications stocked by Hy-Vee Care, supplies of 20 (23%) were significantly short – while supplies of 31 (36%) were significantly ‘long.’
4. An inspection of Hy-Vee Care revealed the following deficiencies:
  - a. Hy-Vee Care had no program of technician training
  - b. technician utilization policies and procedures – specific to the nature of pharmacy service provided by Hy-Vee Care – were not maintained
  - c. Hy-Vee Care had operated an uncertified sterile compounding hood for a year
  - d. Hy-Vee Care had no policies and procedures relating to delivery of prescription drugs and devices
  - e. outdated drugs were observed on dispensing shelves and in the controlled substance storage room
  - f. Hy-Vee Care maintained an incomplete controlled substance inventory
  - g. pharmacy technicians were not wearing identification badges
  - h. no permanent log of the employee work hours was maintained
  - i. NDC and manufacturer information on medication labels did not match the medication dispensed
  - j. Hy-Vee Care had no policies relating to unit dosing systems
  - k. Hy-Vee Care had no policies regarding sterile compounding
  - l. documentation of pharmacist review of medications being dispensed was incomplete
  - m. prescription documentation forms – relating to emergency supplies of Schedule 2 medications – failure to seek authorization for dispensing for periods in excess of any emergency
  - n. Hy-Vee Care is providing incomplete information on "DEA form 222" forms
  - o. technicians are compounding medications without adequate pharmacist supervision
  - p. Hy-Vee Care has not calibrated and inspected automated equipment
  - q. bulk compounding records are incomplete
  - r. Hy-Vee Care is not affixing a unique identification number for each med pak dispensed
  - s. Hy-Vee Care does not maintain policies and procedures for effecting a drug recall

- t. Hy-Vee Care does not maintain policies and procedures for packaging and dispensing to residents of a long-term healthcare facility
- u. 62 of 184 "DEA form 222" forms maintained by Hy-Vee Care did not have invoices
- v. faxed partial fill orders for Schedule II controlled substances did not contain information indicating the medication was dispensed to an LTCF (Long Term Care Facility) patient
- w. records of partial fills were not maintained on the prescription or medication order
- x. Hy-Vee Care dispensed partial fills of Schedule II medications to long term care patients more than 60 days after the date of the prescription
- y. Hy-Vee Care dispensed medications in the absence of a signed prescription
- z. Hy-Vee Care failed to maintain documentation of the NDC or the manufacturer information relating specific medication dispensed
- aa. Hy-Vee Care personnel were unable to retrieve requested information from the computer system
- bb. compounded products lack adequate ingredient identification
- cc. Hy-Vee Care maintained incomplete records regarding the formulae used in compounding products
- dd. Hy-Vee Care did not maintain batch records relating to compounded products

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 28 day of November, 2005, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.

  
MICHAEL J. SEIFERT, Chairperson  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck  
Assistant Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

BEFORE THE BOARD OF PHARMACY EXAMINERS  
OF THE STATE OF IOWA

RECEIVED  
JAN 31 2007  
IOWA PHARMACY EXAMINERS

Re: ) Case No. 2005-89  
Pharmacist License of )  
GARY LEVINE ) STIPULATION  
License No. 16727 ) AND  
Respondent ) CONSENT ORDER  
)

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2005), the Iowa Board of Pharmacy Examiners (hereinafter, "the Board") and Gary Levine (hereinafter, "Respondent"), enter into the following Stipulation and Consent Order settling a licensee disciplinary proceeding currently pending before the Iowa Board of Pharmacy Examiners.

Allegations specified in a Statement of Charges filed against Respondent shall be resolved without proceeding to hearing, as the Board and Respondent stipulate as follows:

1. Respondent was issued a license to practice pharmacy in Iowa on July 18, 1986, by reciprocity, as evidenced by Pharmacist License Number 16727, which is recorded in the permanent records of the Board.
2. The Iowa Pharmacist License issued to and held by Respondent is active and current until June 30, 2007.
3. The Board has jurisdiction over the parties and jurisdiction over the subject matter of these proceedings.
4. A Statement of Charges was filed against Respondent on November 28, 2006.
5. Respondent was, at all times material to the Statement of Charges, employed as the pharmacist in charge at Hy-Vee Care, 3998 N.W. Urbandale Drive, Urbandale, IA 50322.
6. Respondent does not contest the allegations set forth in the Statement of Charges

and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline described herein.

7. On the date of the Board's approval of this Stipulation and Consent Order, Respondent's license shall be placed on probation. The period of probation shall be three (3) years. Respondent's period of probation shall begin on the date of this order and continue for three years or until Respondent has been employed as a pharmacist in Iowa for three years subsequent to commencement of probation. Only those time periods during which Respondent is employed as a pharmacist in Iowa shall count toward satisfaction of the probation requirement. After two years of Respondent's probationary period has been completed, Respondent may petition the Board for early termination of probation.

8. Probation is granted under the following conditions, which Respondent agrees to follow:

a. Within three (3) months after the date of the Board's approval of this Stipulation and Consent Order, Respondent shall complete continuing pharmacy education ("CPE") or other formal, structured education regarding (i) techniques for prevention of medication errors and (ii) continuous quality improvement. The CPE shall be not less than fourteen (14) hours in length, shall include not less than twelve hours relating to prevention of medication errors and shall be pre-approved by the Board. Documentation of satisfactory completion of the education shall be promptly submitted to the Board. This CPE shall be in addition to – not in lieu of – the thirty (30) hours of continuing pharmacy education required every two years for license renewal.

- b. Within sixty (60) days after the date of the Board's approval of this Stipulation and Consent Order, Respondent will submit to the Board *typewritten*<sup>1</sup> pharmacy policies and procedures for his personal use. The policies and procedures must cover: (1) preventing, detecting and handling medication dispensing errors, (2) performance of the duties of a consultant pharmacist, including performance of drug regimen reviews at nursing homes, and (3) supervision of pharmacy technicians. Following review and approval by the Board, Respondent agrees to adopt, implement, and adhere to these policies and procedures in his current employment setting and whenever engaging in the practice of pharmacy – unless specific policies and procedures adopted by his employer prevent such adherence.
- c. Respondent shall inform the Board, in writing, of any change of home address, place of employment, home telephone number, or work telephone number, within ten (10) days of such a change.
- d. During probation, Respondent shall report to the Board or its designee quarterly, in writing. The report shall include Respondent's place of employment, current address, *Respondent's most recent efforts to implement the provisions of this Stipulation and Consent Order, by date*, and any further information deemed necessary by the Board from time to time.
- e. Respondent shall not serve as a preceptor, as a pharmacist in charge or own a controlling interest in a pharmacy.
- f. Respondent shall notify all present employers and prospective employers

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<sup>1</sup> For the purposes of this order, "*typewritten*" policies may be generated on computer word-processing equipment.

(no later than at the time of an employment interview), including any pharmacist-in-charge, of the resolution of this case and the terms, conditions, and restrictions imposed on Respondent by this Stipulation and Consent Order.

g. Within thirty (30) days after approval of this Stipulation and Consent Order by the Board, and within fifteen (15) days of undertaking new employment as a pharmacist, Respondent shall cause his present pharmacy employer, and any pharmacist-in-charge he works under, to report to the Board in writing acknowledging that the employer and the pharmacist-in-charge have read this document and understand it.

h. Respondent shall appear informally before the Board, upon the request of the Board, for the purpose of reviewing his performance as a pharmacist during his probationary period. Respondent shall be given reasonable notice of the date, time, and place for the appearances.

i. Respondent shall obey all federal and state laws, rules, and regulations substantially related to the practice of pharmacy.

9. Upon the Board's approval of this Stipulation and Consent Order, Respondent shall be assessed a civil penalty in the amount of \$2500, payable within six (6) months of the date of Board approval of this Stipulation and Consent Order. This civil penalty payment shall be made payable to the Treasurer of Iowa and mailed to the executive director of the Board. All civil penalty payments shall be deposited into the State of Iowa general fund.

10. Should the Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate action to revoke

or suspend the Respondent's Iowa pharmacist license or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2005) and 657 IAC 36.

11. This Stipulation and Consent Order is the resolution of a contested case. By entering into this Stipulation and Consent Order, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.

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

13. The Board's approval of this Stipulation and Consent Order shall constitute a FINAL ORDER of the Board in a disciplinary action.

This Stipulation and Consent Order is voluntarily submitted by Respondent to the Board for its consideration on the 29 day of December 2006.



Gary Levine, R.Ph.  
Respondent

Subscribed and sworn to before me by Gary Levine on this 29 day of December 2006.



NOTARY PUBLIC IN AND FOR  
THE STATE OF IOWA

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on the 13 day of March 2007.



MICHAEL J. SEIFERT, Chairperson  
Iowa Board of Pharmacy Examiners  
400 SW Eighth Street, Suite E  
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck  
Assistant Attorney General  
Office of the Attorney General  
Hoover State Office Building  
Des Moines, Iowa 50319

David Brown  
218 Sixth Avenue, 8<sup>th</sup> Floor  
Des Moines, IA 50309

Levine settlement.doc

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

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**IN THE MATTER OF THE STIPULATION AND CONSENT ORDER AGAINST  
GARY LEVINE, R.Ph., RESPONDENT**

**2005-89**

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**TERMINATION ORDER**

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**DATE: March 13, 2010**

1. On March 13, 2007, a Stipulation and Consent Order was issued by the Iowa Board of Pharmacy placing the license to practice pharmacy, number 16727 issued to Gary Levine on July 18, 1986, on probation for a period of three years under certain terms and conditions.

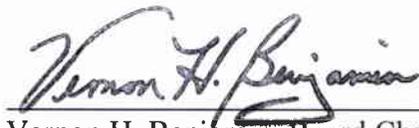
2. Respondent has successfully completed the probation as directed.

3. The Board directed that the probation placed upon the Respondent's license to practice pharmacy should be terminated.

**IT IS HEREBY ORDERED:**

That the probation placed upon the Respondent's license to practice pharmacy is terminated, and the license is returned to its full privileges free and clear of all restrictions.

**IOWA BOARD OF PHARMACY**



Vernon H. Benjamin, Board Chairperson  
400 SW 8<sup>th</sup> Street, Suite E  
Des Moines, Iowa 50309-4688