

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

In the Matter of the Complaint	:	
and Statement of Charges Against	:	COMPLAINT AND
KENNETH E. VANDER LINDEN,	:	
Pharmacist,	:	STATEMENT OF CHARGES
Respondent	:	

COMES NOW, Norman C. Johnson, Executive Secretary of the Iowa Board of Pharmacy Examiners, on the 5th day of August 1986, and files this Complaint and Statement of Charges against Kenneth E. Vander Linden, a pharmacist licensed pursuant to Iowa Code Chapter 155, and alleges that:

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

2. Respondent is a resident of Pella, Iowa, and was issued license number 12278 on October 4, 1956.

3. Respondent's license to practice pharmacy is current until June 30, 1987.

4. Respondent is the pharmacist-manager/president of Vander Linden Drug Store, Inc., 826 Main Street, Pella, Iowa.

5. Audits of the records of Vander Linden Drug Store, Inc., were conducted on June 19, 1985, by Holger Christensen, James Reardon, Morrell Spencer, and Charles Vandenburg, who are duly authorized agents of the Iowa Board of Pharmacy Examiners.

6. Four separate audits were conducted.

7. Audit I comprised 15 Schedule II drug dosage forms and covered the time period May 1, 1985, through June 19, 1985.

8. Audit II comprised 55 Schedule II drug dosage forms and covered the time period May 1, 1983, through June 19, 1985.

9. Audit III comprised 30 Schedule III, IV and V drug dosage forms and covered the time period May 1, 1985, through June 19, 1985.

10. Audit IV comprised Schedule V exempt codeine-containing cough preparations and covered the time period of May 1, 1983, through June 19, 1985.

11. The results of Audit I revealed the following:

- a. Shortages of 20 doses of Dexedrine 5mg tablets, a 5.45% difference.
- b. Overages of 24 doses of Percocet-5 tablets, a 10.71% difference.
- c. Overages of 20 doses of Ritalin SR 20mg tablets, a 14.29% difference.
- d. Overages of 14 doses of Tylox capsules, a 10.29% difference.

12. The results of Audit II revealed the following:

- a. Shortages of 31 doses of Demerol 50mg tablets, an 18.45% difference.
- b. Shortages of 100 doses of Dilaudid 4mg tablets, a 3.79% difference.
- c. Shortages of 28 doses of Morphine Sulfate 15mg tablets, a 21.87% difference.
- d. Shortages of 8 doses of Opium and Belladonna Suppositories, a 61.5% difference.
- e. Shortages of 151 doses of Ritalin 5mg tablets, a 5.85% difference.
- f. Shortages of 110 doses of Seconal 50mg capsules, a 14.18% difference.
- g. Shortages of 97 doses of Tuinal 200mg capsules, a 49.48% difference.
- h. Shortages of 186 Tylox capsules, a 10.22% difference.
- i. Shortages of 303 Quaalude 300mg tablets, an 11% difference.
- j. Overages of 60 doses of Amytal 65mg capsules, a 16.95% difference.
- k. Overages of 30 doses of Demerol with APAP tablets, a 30% difference.
- l. Overages of 100 doses of Dolophine 5mg tablets, a 19.6% difference.
- m. Overages of 29 doses of Tuinal 100mg capsules, a 23.58% difference.

13. The results of Audit III revealed the following:

- a. Shortages of 540cc of Ambenyl syrup, a 75% difference.
- b. Shortages of 1320cc of Robitussin AC, a 46% difference.
- c. Shortages of 720cc of Guiatuss A.C., a 15% difference.
- d. Shortages of 3300cc of Iophen C Liquid, a 69% difference.
- e. Shortages of 690cc of Tylenol with Codeine Elixir, a 47% difference.
- f. Shortages of 128 doses of Valium 5mg tablets, a 9% difference.
- g. Shortages of 560 doses of Valium 10mg tablets, a 50% difference.
- h. Shortages of 692 doses of Acetaminophen with Codeine 30mg tablets, a 14% difference.
- i. Shortages of 223 doses of APC with Codeine 60mg tablets, a 64% difference.
- j. Shortages of 270cc of Tussend Expectorant, a 32% difference.
- k. Shortages of 960cc of Nucofed Expectorant, a 50% difference.
- l. Shortages of 90cc of Tussionex Suspension, a 9% difference.
- m. Overages of 240cc of Bromanyl C.S. Expectorant, a 33% difference.
- n. Overages of 480cc of Detussin Liquid, a 100% difference.
- o. Overages of 1590cc of Novahistine DH Liquid, a 633% difference.
- p. Overages of 240cc of Dihistine D Liquid, a 33% difference.
- q. Overages of 480cc of Triacin C Expectorant, a 100% difference.
- r. Overages of 680cc of Triaminic Expectorant DH, a 100% difference.
- s. Overages of 4200cc of Tussi-organidin Liquid, a 97% difference.
- t. Overages of 8640cc of Terpin Hydrate with Codeine Elixir, a 54% difference.
- u. Overages of 102 doses of Acetaminophen with Codeine 60mg tablets, a 10% difference.
- v. Overages of 386 doses of Aspirin with Codeine 30mg tablets, a 110% difference.

- w. Overages of 300 doses of Aspirin with Codeine 60mg tablets, a 300% difference.
- x. Overages of 10 doses of APC with Codeine 30mg tablets, a 9% difference.
- y. Overages of 90cc of Novahistine Expectorant, a 9% difference.

14. Respondent sold four ounce (120cc) bottles of Schedule V cough preparations with full knowledge that prior sales of those cough preparations had been made within a 48-hour period. Reference Investigative Report of June 9, 1986, Exhibit 4.

15. Respondent sold four-ounce (120cc) bottles of Schedule V cough preparations with full knowledge that the purchases were not for medical purposes. Reference Investigative Report of June 9, 1986, Exhibits 4, 5, 6 and 7.

16. Respondent is guilty of violations of Iowa Code Sections 155.13(3) and (8); 155.30; 204.306; 204.308(3) and (4); 204.402(1)"a" by virtue of the allegations in paragraphs 11, 12, 13, 14 and 15.

Section 155.13(3) and (8) read as follows:

"...The board shall have the authority to deny, suspend or revoke a license in any case where it finds that there has been a substantial failure to comply with the provisions of this chapter or the regulations promulgated hereunder, or the violation thereof, and in addition, the board shall have the power to deny, suspend or revoke a license, when the applicant or licensee, or any employee, providing the offense is committed on licensed premises or is in the conduct of the business licensed, is guilty of any of the following facts or offenses:...

(3) Distributing on the premises of...drugs for any other than lawful purposes.

(8) Violations of the provisions of this chapter."

Section 155.30 reads as follows:

"...Any person who violates a provision of Section 155.29 or who sells, gives away or administers to another person any prescription drug shall be guilty of a public offense..."

Section 204.306 reads as follows:

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

Federal regulations in this regard can be found in Code of Federal Regulations (CFR) Title 21. Pertinent parts of those regulations are 1304.03, 1304.04, and 1304.11.

Part 1304.03 reads, in part, as follows:

"Persons required to keep records and file reports.

(a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section...."

Part 1304.04 reads, in part, as follows:

"Maintenance of records and inventories.

(a) Every inventory and other records required to be kept under this Part shall be kept by the registrant and be available, for at least 2 years from the date of such inventory or records, for inspection and copying by authorized employees of the Administration...."

Part 1304.11 reads, in part, as follows:

"General requirements for inventories.

(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken...."

Section 204.308(3) and (4) read as follows:

"(3) Except when dispensed directly by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in Schedule III or IV, which is a prescription drug as determined under Section 155.3, subsections 9 and 10, 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 from the date thereof or be refilled more than five times, unless renewed by the practitioner.

(4) A controlled substance included in Schedule V shall not be distributed or dispensed other than for a medical purpose."

Section 204.402(1)"a" reads as follows:

"It is unlawful for any person:

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

17. Respondent is guilty of a violation of Board Rule §620--10.1(4) "h," "j" and u."

Rule 10.1(4) reads as follows:

"The board may impose any of the disciplinary sanctions set out in subrule 10.1(2), including civil penalties in an amount not to exceed \$1000.00, when the board determines that the licensee or registrant is guilty of the following acts of offenses:

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

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 section...155.13 of The Code."

18. Paragraphs 16 and 17 constitute grounds for which Respondent's license to practice pharmacy can be suspended or revoked.

WHEREFORE, the undersigned charges that Kenneth E. Vander Linden has violated Section 155.13(3); 155.13(8); 155.30; 204.306; 204.308(3); 204.308(4) and 204.402(1)"a" of the Code of Iowa, and Board Rule §620--10.1(4) "h," "j" and "u" of the Iowa Administrative Code.

IT IS HEREBY ORDERED that Kenneth E. Vander Linden appear before the Iowa Board of Pharmacy Examiners on September 9, 1986 at 10:00 a.m. in the second floor conference room, 1209 East Court, Executive Hill West, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its Findings of Fact and Decision to suspend or revoke the license to practice pharmacy issued to Kenneth E. Vander Linden on October 4, 1956, or take whatever additional steps they deem necessary.

IOWA BOARD OF PHARMACY EXAMINERS


Norman C. Johnson
Executive Secretary

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

In the Matter of the Complaint and :
Statement of Charges Against : **DECISION AND ORDER**
Kenneth E. Vander Linden, :
Pharmacist, :
Respondent. :

TO: Kenneth E. Vander Linden, Pharmacist:

A Complaint and Statement of Charges was filed by the Executive Secretary of the Iowa Board of Pharmacy Examiners on August 5, 1986, alleging that:

1. The respondent, Kenneth E. Vander Linden, was issued license to practice pharmacy number 12278, which is current until June 30, 1987.

2. The respondent was the pharmacist-manager and president of Vander Linden Drug Store, Inc. Four audits of the records of Vander Linden Drug Store, Inc., were conducted on June 19, 1985, by agents of the Iowa Board of Pharmacy Examiners. The audits covered different schedules of drugs and different time periods. Each of the first three audits showed certain shortages and overages of doses of drugs which were listed in detail in the complaint.

3. The respondent sold four-ounce bottles of Schedule V cough preparations with full knowledge that prior sales of those preparations had been made within the previous 48 hours, and that the purchases were not for legitimate medical purposes.

4. The respondent failed to keep adequate records of the receipt and disposition of controlled substances.

The Complaint and Statement of Charges alleged violations of Iowa Code Sections 155.13(3) and (8), 155.30, 204.306, 204.308(3) and (4), 204.402(1)a(1985), and 620 Iowa Administrative Code §8.13(9) and §10.1(4)h, j, and u.

A joint hearing on the above Complaint and Statement of Charges, and on the Complaints and Statements of Charges against Thomas Vander Linden and Vander Linden Drug Store, Inc., was held on October 15, 1986, at 9:00 a.m. in the second floor conference room, 1209 East Court, Executive Hill West, Des Moines, Iowa. Present were the Board and its counsel, Thomas D. McGrane, Assistant Attorney General. The respondent appeared and was represented by Bert Bandstra, attorney at law. Present also were Thomas B. Vander Linden, pharmacist, and members of the Vander Linden family. Also present were members of the staff of the Board and a court reporter. The undersigned Administrative Hearing Officer for the State of Iowa presided. At the request of the Vander Lindens, the hearing was closed to the public pursuant to Iowa Code 258A.6(1985).

Board member Gale W. Stapp declined to participate in the hearing, deliberations, or decision because of a conflict of interest.

After hearing the testimony and examining the exhibits, the Board convened in closed executive session pursuant to Iowa Code §21.5(1)f, to deliberate. The Board then went into open session, and the Vander Lindens were present when the Board took its final action. The Administrative Hearing Officer was instructed to prepare this Board's Decision and Order.

THE RECORD

The evidentiary record in this case includes the Complaint and Statement of Charges, the recorded testimony of witnesses, the Investigative Report dated June 9, 1986, prepared by Holger A. Christensen, except for Exhibits 10 and 11 on pages 14 and 15, which were struck, and the following exhibits:

- Exhibit 1. Computation Table for Audit I.
- Exhibit 2. Computation Table for Audit II.
- Exhibit 3. Computation Table for Audit III.
- Exhibit 4. Sales of four-ounce bottles of C-5 substances by name of customer (information obtained from exempt narcotic registers of Vander Linden Drug Store, Inc.).
- Exhibit 5. Copy of a letter dated May 17, 1985, from the Iowa Board of Pharmacy Examiners to all pharmacist/managers in Marion and Mahaska counties.
- Exhibit 6. Sam Allen's patient profile and prescription.
- Exhibit 7. Mike and Mary Schreiner's patient profile and prescriptions.
- Exhibit 8. Kelly Clark's patient profile and prescriptions.
- Exhibit 9. Dave Bender's patient profile and prescriptions.
- Unnumbered Exhibit. Four red books: Exempt Narcotic Registers from Vander Linden Drug Store.

FINDINGS OF FACT

1. The respondent, Kenneth E. Vander Linden, is a practicing pharmacist licensed under the State of Iowa and issued pharmacist's license number 12278. (Official file; testimony of Mr. Kenneth E. Vander Linden.)

2. The respondent, Kenneth E. Vander Linden, was the pharmacist-manager and president of Vander Linden Drug Store, Inc., license number 304, prior to and during the investigation conducted by employees of the Board of Pharmacy Examiners. (Official file; testimony of Mr. Kenneth E. Vander Linden.)

3. On June 19, 1985, Board Investigators Holger Christensen, James Reardon, Morrell Spencer, and Charles Vandenburg conducted four audits of certain records of Vander Linden Drug Store, Inc., and began an investigation of the records of the drug store. (Testimony of Mr. Christensen.)

4. Audit I was of fifteen Schedule II drugs from May 1, 1985, to June 19, 1985. (Exhibit 1; testimony of Mr. Christensen.) Audit II was of 55 Schedule II drugs from May 1, 1983, to June 19, 1985. (Exhibit 2; testimony of Mr. Christensen.) Audit III was of 30 Schedule III, IV and V drugs from May 1, 1985, to June 19, 1985. (Exhibit 3; testimony of Mr. Christensen.) Audit IV was of Schedule V exempt codeine-containing cough preparations from May 1, 1983, to June 19, 1985. (Testimony of Mr. Christensen.)

5. Investigator Christensen prepared a report of the investigation, including the four audits, which was conducted by the four Board investigators. This report was dated June 9, 1986. (Investigative report; testimony of Mr. Christensen.)

6. The results of the audits were detailed in the investigative report. Audits I through III showed numerous shortages and overages of the drugs audited. The respondent failed to maintain adequate records of controlled substances on hand in the pharmacy. The records were inaccurate and/or incomplete. The records show there was a significant lack of attention paid to the details of required recordkeeping. (Investigative report; Exhibits 1, 2, and 3; testimony of Mr. Christensen, Mr. Johnson, Mr. Kenneth E. Vander Linden, and Mr. Thomas Vander Linden.)

7. The results of Audit IV and testimony of the witnesses show indiscriminate dispensing of Schedule V codeine-containing cough preparations. From May 1, 1983, to June 19, 1985, Vander Linden Drug Store, Inc., through its employed pharmacists, including Mr. Kenneth E. Vander Linden, sold 2571 four-ounce bottles of Schedule V cough preparations; 1629 of those bottles were sold to five persons. Forty-three sales were made when prior sales of those preparations had been made to the same person within the previous 48 hours. The respondent, Mr. Kenneth E. Vander Linden, made 476 of those sales to five persons. The respondent, Mr. Kenneth E. Vander Linden, made 22 sales of Schedule V cough preparations when prior sales of those preparations had been made to the same person within the previous 48 hours. The frequency and amounts of purchases show that many were for other than legitimate medical purposes. (Investigative report; Exhibit 4; Exempt Narcotic Register; testimony of Mr. Christensen and Mr. Kenneth E. Vander Linden.)

8. Mr. Kenneth E. Vander Linden testified that he was not concerned about the large amount of Schedule V cough syrup purchased by a few individuals, because he grew up in a community where terpin hydrate was frequently used by many people in Pella. He testified it was all people had in the old days, and it was viewed as a panacea. He believed that so long as people adhered to the purchase limit of no more than four ounces per 48 hours there would be no abuse, and that amount could be for a legitimate medical purpose. This testimony reveals a total lack of knowledge and understanding regarding the potential problems associated with this type of drug. It also reveals a disregard or ignorance of the law regarding this type of drug. (Testimony of Mr. Kenneth E. Vander Linden.)

9. On May 20, 1985, a letter regarding abuse of Schedule V controlled substances and sales by pharmacists was sent from the Iowa Board of Pharmacy Examiners to all pharmacists in Mahaska and Marion counties, including Vander Linden Drug Store, Inc. (Exhibit 5; testimony of Mr. Christensen, Mr. Kenneth E. Vander Linden.) After the letter was received, the pharmacy and Mr. Kenneth E. Vander Linden continued to sell Schedule V controlled substances to the same individuals, although at less frequent intervals. (Investigative report, testimony of Mr. Christensen, Mr. Kenneth E. Vander Linden.)

10. The evidence showed that the respondent refilled some prescriptions for controlled substances so frequently that it was obvious the patients were exceeding the prescribed dosage requirements. (Investigative report; Exhibits 6, 7, 8, 9; testimony of Mr. Christensen.) In most of these instances, these were the same people who were excessive users of Schedule V codeine-containing cough preparations, so particular care should have been taken with these people. (id.)

11. The respondent, as manager of the pharmacy and its employee pharmacists, had a responsibility for the actions of those employee pharmacists. The employee pharmacists refilled prescriptions for controlled substances more times than allowed, or refilled prescriptions for more than the amount of medication prescribed. There was nothing written in the pharmacy records to indicate that authorization was obtained from the prescribing doctors, and new prescriptions were not written when required. (Investigative report; Exhibits 6, 7, 8 and 9; testimony of Mr. Christensen, Mr. Kenneth E. Vander Linden, and Mr. Thomas Vander Linden.)

12. The respondent, Kenneth E. Vander Linden, does not know the rules and regulations regarding proper handling of emergency prescriptions. (Testimony of Mr. Kenneth E. Vander Linden.)

CONCLUSIONS OF LAW, DECISION, AND ORDER

Substantial evidence was presented to show violations of Iowa Code Sections 155.13(3) and (8); 155.30; 204.306; 204.308(3) and (4); 204.402(1)a; and 620 Iowa Administrative Code Sections 8.13(9) and (15)b; and 10.1(4)h, j, and u. The respondent, Kenneth E. Vander Linden, is therefore found to have violated the above Code sections and rules.

It is therefore the ORDER of the Iowa Board of Pharmacy Examiners that the respondent's license to practice pharmacy, license number 12278, is hereby suspended for a period of two (2) years beginning on the date of receipt of this Order. It is the further ORDER of the Board that this suspension will be stayed except for a period of 30 days beginning 31 days after the date of receipt of this Order. The suspension is stayed on the condition that the pharmacist-manager of the pharmacy prepare and submit for Board approval a manual of policies and procedures relating to dispensing and recordkeeping of controlled substances in the pharmacy. These policies and procedures will include but will not

be limited to the following: (a) proper handling of emergency C-2 prescriptions; (b) proper handling of over-the-counter exempt C-5 sales when allowed; (c) proper filling and refilling and documentation of all prescriptions; (d) a policy to ensure accurate controlled substance inventory, (e) a policy relating to return of outdated and/or controlled substances. Along with this manual, the pharmacist-manager will submit signed affidavits of all pharmacist employees, including Mr. Kenneth E. Vander Linden, stating that they have read and will comply with the policies and procedures contained in the manual. Any pharmacist employees hired in the future must sign such an affidavit, and such will be submitted to the Board. The proposed manual and affidavits must be submitted to the Board for its approval within 45 days of the receipt of this Order.

It is the further ORDER of the Board that Mr. Kenneth E. Vander Linden is placed on probation for a period of five years beginning on the date of the receipt of this Order. The period of probation will run concurrently with the suspension.

It is the further ORDER of the Board that the following are the terms and conditions of Mr. Kenneth E. Vander Linden's probation:

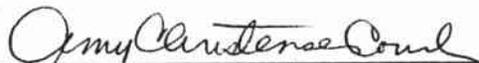
- (a) Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.
- (b) Respondent shall submit monthly written reports to the Board or its designee showing his residence and employment. Should the final probation report not be made as directed, the period of probation shall be extended until such time as the final report is made.
- (c) Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board.
- (d) Respondent shall notify all present and prospective employers of the decision in this case and the terms, conditions and restriction imposed on respondent by said decision. Within 30 days of the effective date of this decision, and within 15 days of respondent undertaking new employment, respondent shall cause his employer to report to the Board in writing acknowledging the employer has read the decision in this case.
- (e) Respondent shall not supervise any registered intern and shall not perform any of the duties of a preceptor.
- (f) Should respondent leave Iowa to reside or practice outside this state, respondent must notify the Board in writing of the dates of departure and return. Periods of residency or practice outside the state shall not apply to reduction of the probationary period.

(g) Should respondent violate probation in any respect, the Board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which was stayed. 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.

(h) Upon successful completion of probation, respondent's license will be fully restored.

Mr. Kenneth E. Vander Linden was the pharmacist-manager and owner at the time the above violations occurred. As such, he had more responsibility to ensure that proper procedures were being implemented and followed. It is therefore the further ORDER of the Board that the respondent is fined \$1000 for violation of 620 Iowa Administrative Code Sections 10.1 (4)h, j, and u. The fine is to be paid within 45 days of the receipt of this Order.

This Decision and Order was prepared by me at the direction of the Iowa Board of Pharmacy Examiners on the 29th day of October, 1986.



Amy Christensen Couch
Iowa Administrative Hearing Officer