

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

Re:)
Pharmacist License of)
DALENE S. SINNOTT) **STATEMENT OF CHARGES**
License No. 13809)
Respondent)

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

1. He is the Executive Secretary/Director for the Iowa Board of Pharmacy Examiners and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (1999).
3. On November 10, 1970, the Board issued Respondent, Dalene Sinnott, a license to engage in the practice of pharmacy by examination as evidenced by license number 13809, subject to the laws of the State of Iowa and the rules of the Board.
4. License number 13809 is current and active until June 30, 2001.
5. Respondent's current address is 4233 Sunland Court S.E., Cedar Rapids, Iowa 52403.
6. Respondent is currently self-employed as the co-owner and pharmacist in charge of Medicine Shoppe, 1911 First Avenue S.E., Cedar Rapids, Iowa 52402.

COUNT I

The Respondent is charged under Iowa Code § 155A.12(9) (1999) with being convicted of an offense or subjected to a penalty or fine for violation of the Federal Food, Drug and Cosmetic Act.

THE CIRCUMSTANCES

1. On June 10, 1999, the U.S. Attorney for the Northern District of Iowa filed an Information against Respondent alleging two counts of criminal violations related to her misbranding of generic drugs as brand-name drugs.

Dalene Sinnott
Statement of Charges

2. On May 29, 1999, entered into a plea agreement with the U. S. Attorney's Office.
3. On December 17, 1999, the U. S. District Court, Northern District of Iowa, filed its Judgment in a Criminal Case in the case captioned *United States of America v. Dalene S. Sinnott, Case No. 1:99CR00041-001*. The federal court found that Respondent pled guilty to 2 counts of violating 21 U.S.C. Sections 331(K), 333(a)(1) and 18 U.S.C. Section 2, Misbranding Drugs. The Court sentenced Respondent on a one year probation for each of two counts, to run concurrently; and was fined \$4000.

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 10th day of April, 2000, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.


Arlan D. VanNorman, Chairperson
Iowa Board of Pharmacy Examiners
1209 East Court Avenue
Des Moines, Iowa 50319

cc: Shauna Russell Shields
Theresa O'Connell Weeg
Assistant Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

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

Re:)	
Pharmacist License of)	
DALENE S. SINNOTT)	STIPULATION
License No. 13809)	AND
Respondent)	CONSENT ORDER
)	

COME NOW the Iowa Board of Pharmacy Examiners (“the Board”) and Dalene S. Sinnott, R.Ph. (“Respondent”) and, pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (1999), enter into the following Stipulation and Consent Order settling the contested case currently on file.

The licensee disciplinary hearing pending before the Iowa Board of Pharmacy Examiners, on the allegations specified in the Statement of Charges filed against Respondent on April 10, 2000, 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 in Iowa on the 10th day of November, 1970, by examination as evidenced by Pharmacist License Number 13809, which is recorded in the permanent records of the Iowa Board of Pharmacy Examiners.
2. That Iowa Pharmacist License Number 13809, issued to and held by Respondent is active and current until June 30, 2001.

3. Respondent is currently self-employed as the co-owner and pharmacist in charge of Medicine Shoppe, 1911 First Avenue, S.E., Cedar Rapids, Iowa 52403.
4. A Statement of Charges was filed against Respondent on April 10, 2000.
5. That the Iowa Board of Pharmacy Examiners has jurisdiction over the parties and the subject matter herein.
6. This Stipulation and Consent Order is entered into in order to resolve disputed claims and constitutes no admission on the part of the Respondent.
7. Respondent shall pay a civil penalty of \$500.00 within 30 days of the date of approval of this Stipulation and Consent Order by the Board. Respondent shall deliver a check made payable to the Treasurer of the State of Iowa to the Executive Secretary/Director of the Board. The check shall be deposited into the general fund of the State of Iowa.
8. Respondent's license shall be placed on probation with the Iowa Board of Pharmacy Examiners for six (6) months from the date of the Board's approval of this Stipulation and Consent Order, with the following conditions, beginning on the date this Stipulation and Consent Order is accepted by the Board:
 - a. Within sixty (60) days of the date of the Board's approval of this Stipulation and Consent Order, the Respondent shall submit her *typewritten* policies and procedures for dispensing and labeling prescription drugs, including brand name and generic drugs to the Board for its approval. The typewritten policies and procedures shall relate to Respondent's practice of pharmacy in her current work setting. Following review and approval by

the Board, the Respondent agrees to adopt, implement, and adhere to these policies and procedures whenever engaging in the practice of pharmacy.

- b. Within six (6) months of the date of the Board's approval of this Stipulation and Consent Order, the Respondent shall complete continuing pharmacy education (CPE) or other formal, structured education in the area of pharmacy management. The education shall be *not less than* six (6) hours in length and shall be pre-approved by the Board. Documentation of satisfactory completion of the education shall be submitted to the Board. This education is in addition to the thirty (30) hours of continuing pharmacy education required every two years for license renewal.
 - c. During probation, Respondent shall 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.
 - d. During probation, Respondent shall report to the Board or its designee quarterly. Said report shall be in writing. The report shall include the Respondent's place of employment, current address, and any further information deemed necessary by the Board from time to time.
9. The Respondent shall obey all federal and state laws, rules, and regulations substantially related to the practice of pharmacy.
 10. Should 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 and 657 IAC 36.1.

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 party. 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.

14. This Stipulation and Consent Order is voluntarily submitted by Respondent to the Board for its consideration on the 11 day of September, 2000.


Dalene S. Sinnott, R.Ph.
Respondent

Subscribed and sworn to before me by Dalene S. Sinnott on this 11 day of September, 2000.


NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

15. This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on the 12th day of Sept, 2000.



MATTHEW C. OSTERHAUS, Chairperson
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

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

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

Re:)	Case No. 2001-13809
Pharmacist License of)	
DALENE S. SINNOTT)	STATEMENT OF CHARGES
License No. 13809)	
Respondent)	

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

1. He is the Executive Secretary/Director for the Iowa Board of Pharmacy Examiners and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (1999) & (2001).
3. On November 10, 1970, the Board issued Respondent, Dalene S. Sinnott, a license to engage in the practice of pharmacy by examination as evidenced by license number 13809, subject to the laws of the State of Iowa and the rules of the Board.
4. License number 13809 is current and active until June 30, 2001.
5. Respondent's current address is 4233 Sunland Court S.E., Cedar Rapids, Iowa 52403.
6. Respondent is currently self-employed as the co-owner and pharmacist in charge of Medicine Shoppe, 1911 First Avenue, S.E., Cedar Rapids, Iowa 52403.

COUNT I

The Respondent is charged under Iowa Code §§155A.12(1), (4), & (5) (1999) and 124.306 and 657 Iowa Administrative Code §§ 6.2(1)(i) & (k), 6.8, & 36.1(4)(j) & (u) and 21 CFR 1304.4, 1304.11, 1304.22 1305.9(e), 1305.13, 1306.32 & 1306.22(b)(3) with inadequate record keeping, including but not limited to, failure to conduct and maintain controlled substance inventories for two years, failure to maintain controlled substance records in a manner to establish receipt and distribution, and failure to properly date, initial and file DEA form 222; and failure to place initials and dates on controlled substances invoices.

COUNT II

The Respondent is charged under Iowa Code §§ 124.308(3), 124.402(1)(a), 124.403 (1)(c), 155A.12(1), (4), & (5), and 155A.15(2)(h) (1999) and 657 Iowa Administrative Code §§ 6.2(i) & (k), 6.8, 36.1(4)(u) with failing to provide accountability for certain controlled substances.

COUNT III

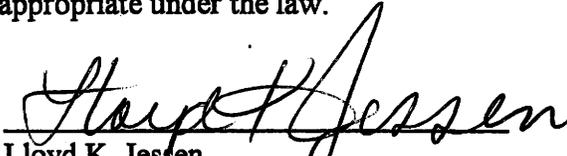
The Respondent is charged under Iowa Code § 155A.12(1), (4), & (5) (1999), 124.302 and 657 Iowa Administrative Code §§ 10.2, 36.1(4)(j) and (u) with dispensing controlled substances without a current and effective controlled substance registration.

THE CIRCUMSTANCES

1. On or about August 31, 2000, the Board received a complaint that the Respondent's pharmacy where she serves as pharmacist in charge had failed to renew its federal DEA registration.
2. A review of the Board's records revealed that the Respondent's pharmacy's controlled substance registration with the Board expired on January 31, 1998.
3. As of August 31, 2000, the Respondent's pharmacy had failed to renew the registration even after a Board investigator reminded one of its agents of the requirement to maintain its controlled substance registration with the Board.
4. An investigation and controlled substance audit at the Respondent's pharmacy revealed that the pharmacy was dispensing controlled substances between January 31, 1998 and August 31, 2000.
5. The investigation and controlled substance audit at the Respondent's pharmacy revealed multiple deficiencies in the pharmacy's record keeping as it relates to controlled substances. The deficiencies included, but were not limited to:
 - a. failure to maintain records of Schedule II controlled substances separately from other records;
 - b. failure to initial DEA form 222 for controlled substances;
 - c. failure to maintain controlled substance records in a manner to establish receipt and distribution of all controlled substances;

- d. failure to record the date of receipt and responsible person on suppliers' invoices;
6. The investigation and controlled substance audit revealed numerous apparent overages and shortages of controlled substances at the Respondent's pharmacy.

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 17 day of April, 2001, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.


Matthew C. Osterhaus, Chairperson
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

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

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

Re:)	Case No: 2001-13809
Pharmacist License of)	
DALENE S. SINNOTT)	STIPULATION
License No. 13809)	AND
Respondent)	CONSENT ORDER
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COME NOW the Iowa Board of Pharmacy Examiners (“the Board”) and Dalene S. Sinnott, R.Ph. (“Respondent”) and, pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2001), enter into the following Stipulation and Consent Order settling the contested case currently on file.

The licensee disciplinary hearing pending before the Iowa Board of Pharmacy Examiners, on the allegations specified in the Statement of Charges filed against the Respondent on April 17, 2001, shall be resolved without proceeding to hearing, as the parties have agreed to the following Stipulation and Consent Order:

1. That the Respondent was issued a license to practice pharmacy in Iowa on November 10, 1970, by examination as evidenced by Pharmacist License Number 13809, which is recorded in the permanent records of the Iowa Board of Pharmacy Examiners.
2. That Iowa Pharmacist License Number 13809, issued to and held by Respondent is active and current until June 30, 2003.

3. Respondent is not currently employed as a pharmacist.
4. A Statement of Charges was filed against Respondent on April 17, 2001.
5. That the Iowa Board of Pharmacy Examiners has jurisdiction over the parties and the subject matter herein.
6. This Stipulation and Consent Order is entered into in order to resolve disputed claims and constitutes no admission on the part of the Respondent.
7. Upon the date of the Board's approval of this Stipulation and Consent Order, Respondent's license to practice pharmacy shall be placed on probation for two (2) years with the following conditions, beginning on the date this Stipulation and Consent Order is accepted by the Board:
 - a. Within sixty (60) days of the date of approval of this Stipulation and Consent Order by the Board, the Respondent will provide her *typewritten* policies and procedures for the following: (a) controlled substance record keeping and (b) ensuring that she is in compliance with all applicable controlled substances laws and regulations. The typewritten policies and procedures shall relate to Respondent's practice of pharmacy in her current work setting. Following review and approval by the Board, the Respondent agrees to adopt, implement, and adhere to these policies and procedures whenever engaging in the practice of pharmacy.
 - b. Within six (6) months of the date of approval of this Stipulation and Consent Order by the Board, the Respondent shall complete the following continuing pharmacy education (CPE) courses: (1) DEA Handling

Requirements for Community Pharmacies (1.0 hours) -- ACPE #406-999-00-038-H03, (2) DEA Dispensing Requirements for Community Pharmacies (1.0 hours) -- ACPE #406-999-00-039-H03, and (3) DEA Reporting, Enforcement and Audits (1.0 hours) -- ACPE #406-999-00-040-H03. Each of these CPE courses is provided by *Community Pharmacist* and may be obtained by writing the CE Editor of the *Community Pharmacist*, 5285 West Louisiana Ave., Lakewood, Colorado 80232-5976 or from the July/August 2000 edition of *Community Pharmacist*. Documentation of satisfactory completion of the education shall be submitted to the Board. This education is in addition to the thirty (30) hours of continuing pharmacy education required every two years for license renewal.

- c. The Respondent shall not serve as the pharmacist in charge of any pharmacy.
- d. The Respondent shall not have an ownership interest in a pharmacy licensed in the State of Iowa.
- e. The Respondent shall not perform the duties of a pharmacy preceptor.
- f. The Respondent shall notify all present employers and prospective employers (no later than at the time of an interview), including the pharmacist-in-charge, 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 undertaking new employment as a pharmacist, Respondent shall cause her pharmacy employer and the pharmacist-in-charge that she 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.

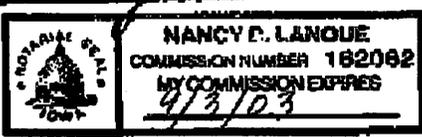
- g. During probation, Respondent shall inform the Board in writing within ten (10) days of any change of home address, place of employment, home telephone number, or work telephone number.
- h. The Respondent shall file written, sworn quarterly reports with the Board attesting her compliance with all the terms and conditions of this Stipulation and Consent Order. The reports shall be filed not later than June 5, 2002, September 5, 2002, and December 5, 2002. The quarterly reports shall include the Respondent's place of employment, current home address, home telephone number, or work telephone number, and any further information deemed necessary by the Board from time to time.
- i. Respondent shall appear informally before the Board as upon the request of the Board, for the purpose of reviewing her performance as a pharmacist during her probationary period. Respondent shall be given reasonable notice of the date, time, and place for the appearances. Any such appearance shall be subject to the waiver provisions of 657 Iowa Administrative Code § 35.9.

8. The Respondent shall obey all federal and state laws, rules, and regulations substantially related to the practice of pharmacy.
9. 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 and 657 IAC 36.1.
10. 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.
11. 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 party. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.
12. The Board's approval of this Stipulation and Consent Order shall constitute a **FINAL ORDER** of the Board in a disciplinary action.

13. This Stipulation and Consent Order is voluntarily submitted by the Respondent to the Board for its consideration on the 4 day of January, 2002

Dalene S. Sinnott
Dalene S. Sinnott, R.Ph.
Respondent

Subscribed and sworn to before me by Dalene S. Sinnott on this 4th day of January, 2002



Nancy D. Lanoue
NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

14. This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on the 24 day of Jan., 2002.

Matthew C. Osterhaus
MATTHEW C. OSTERHAUS, Chairperson
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

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