

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

Re:)	
Pharmacy License of)	Case No. 2005-102
LUTZ PHARMACY, PHARMACY)	
SERVICES INC)	STATEMENT OF CHARGES
License No. 40,)	
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 147, 155A and 272C (2005).
3. Effective December 16, 2005, the Board renewed Respondent's general pharmacy license 40 with Eugene M. Lutz as pharmacist in charge, allowing Respondent to engage in the operation of a pharmacy subject to the laws of the State of Iowa and the rules of the Board.
4. General pharmacy license is current and active until December 31, 2006.
5. Respondent is currently operating a general pharmacy at 120 Eighth Street SE, Altoona, Iowa 50009, with Eugene M. Lutz as the pharmacist in charge.

A. CHARGES

COUNT I – VIOLATION OF PHARMACY COMPOUNDING RULES

The Respondent is charged with failure to comply with Board rules for pharmacy compounding in violation of Iowa Code §§ 155A.12(1) (2005), 155A.12(4) (2005), and 657 Iowa Administrative Code 8.30(126,155A), 20.4(2), 20.5(126,155A), 20.6(1), 20.8(126,155A), 20.9(126,155A), 20.10(124,126,155A), 20.11(126), 20.12(124,126,155A), 36.1(4)(j), and 36.1(4)(ac).

COUNT II – LACK OF PROFESSIONAL COMPETENCY

The Respondent is charged with a lack of professional competency in violation of Iowa Code §§ 155A.15(2)(c) (2005) and 155A.15(2)(h) (2005) and 657 Iowa Administrative Code 36.1(4)(b).

COUNT III – ENGAGING IN UNETHICAL CONDUCT

The Respondent is charged with engaging in unethical conduct in violation of Iowa Code § 155A.15(c) (2005) and 657 Iowa Administrative Code 8.11(1) and 36.1(4)(c) by, among other things, placing inaccurate expiration dates on compounds.

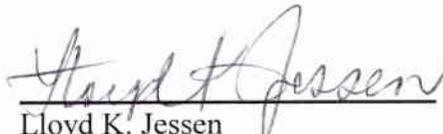
COUNT IV – FAILURE TO MAINTAIN ADEQUATE RECORDS

Respondent is charged with failing to maintain complete and adequate records relating to compounded substances in violation of Iowa Code § 155A.15(2)(i) and 657 Iowa Administrative Code 20.10(3) and 36.1(4)(ac).

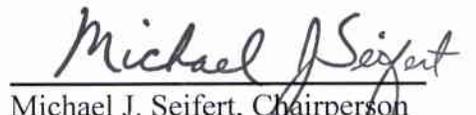
B. CIRCUMSTANCES

Circumstances supporting the above charges are set forth in Attachment A.

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 14th day of March 2006, 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

RECEIVED
JUN 30 2006
IOWA PHARMACY EXAMINERS

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

Re:)	Case No. 2005-102
Pharmacy License of)	
LUTZ PHARMACY,)	STIPULATION
License No. 40,)	AND
Respondent.)	CONSENT ORDER
)	

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2005), the Iowa Board of Pharmacy Examiners (hereinafter, "Board") and Lutz Pharmacy (hereinafter, "Respondent"), enter into this Stipulation and Consent Order settling a pending contested case. The pending contested case is a licensee disciplinary proceeding before the Iowa Board of Pharmacy Examiners based on allegations specified in a Statement of Charges filed March 27, 2006. The Board and Respondent, who hereby agree that the contested case shall be resolved without proceeding to hearing, stipulate to the following:

1. Respondent's license to operate a pharmacy in Iowa was renewed on December 16, 2005, as evidenced by General Pharmacy License Number 40, which is recorded in the permanent records of the Iowa Board of Pharmacy Examiners.
2. General Pharmacy License Number 40, issued to and held by Respondent, is active and current until December 31, 2006.
3. A Statement of Charges and Emergency Order were filed against Respondent on March 27, 2006.
4. The Board has jurisdiction over Respondent and the subject matter herein.

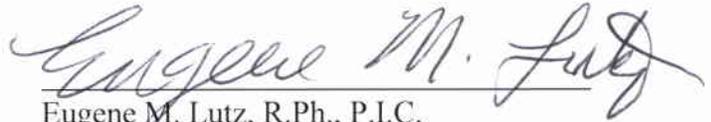
5. Respondent does not admit the allegations set forth in the Statement of Charges and Emergency Order but agrees, for the purpose of this Stipulation and Consent Order, to adhere to certain terms and conditions on its license to operate a pharmacy in the State of Iowa.
6. Upon the date of the Board's approval of this Stipulation and Consent Order, Respondent's license to operate a pharmacy shall be placed on probation for two (2) years. During the probationary period, Respondent shall file written quarterly reports with the Board.
7. Upon the date of the Board's approval of this Stipulation and Consent Order, Respondent agrees to provide to the Board an Assurance of Regulatory Compliance in which Respondent agrees to obey all federal and state laws and regulations related to the practice of pharmacy, including the extemporaneous pharmacy compounding of all sterile and non-sterile products.
8. Respondent agrees to not engage in any sterile compounding until it can demonstrate to the Board that Eugene M. Lutz has successfully completed additional formal training in sterile compounding and that he has adopted and implemented appropriate policies and procedures to ensure that all requirements for sterile compounding have been met. In the event that such a showing is made and Board approval is obtained, this limitation on Respondent's pharmacy license shall be lifted.
9. Respondent agrees to seek, obtain, and document Board approval to compound a temporarily unavailable commercially available product.

10. Respondent agrees to comply with all federal and state laws and regulations related to the handling of any hazardous materials utilized in the pharmacy, the prescription department, or the compounding area and shall take all steps necessary to protect employees and others from exposure to hazardous materials.
11. Respondent shall pay the costs associated with the drug recall which was completed by Board staff on March 17, 2006. Payment in the amount of \$1,150.72 shall be submitted to the Board office within 30 days of the Board's approval of this Stipulation and Consent Order.
12. Respondent agrees to review its policies and procedures annually and to document such review in writing.
13. Respondent shall be subject to pharmacy re-inspection as conducted by compliance officers of the Board.
14. 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 further 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.
15. This Stipulation and Consent Order is the resolution of a contested case. By entering into this Stipulation and Consent Order, the 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.
16. 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.

17. 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 30th day of June 2006.



Eugene M. Lutz, R.Ph., P.I.C.
on behalf of
Lutz Pharmacy,
Respondent

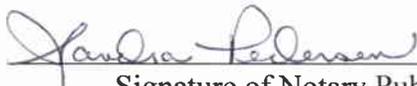
State of Iowa

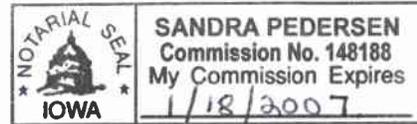
County of Polk

Signed and sworn (or affirmed) before me

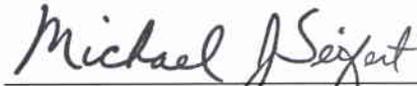
on 6/30/2006
Date

by Eugene M. Lutz
Name(s) of Person(s)


Signature of Notary Public



This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy Examiners on
the 6th day of ^{July}~~June~~ 2006.



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

Bill Wimmer
Wasker, Door, Wimmer & Marcouiller
Three Fountains Office Park—Highland Building
4201 Westown Parkway, Suite 250
West Des Moines, Iowa 50266-6720

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	
Pharmacy License of)	Case No. 2008-63
LUTZ PHARMACY,)	
PHARMACY SERVICES INC)	STATEMENT OF CHARGES
License No. 40,)	
Respondent.)	

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

1. He is the Executive 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 147, 155A and 272C (2007).
3. Effective December 31, 2007, the Board renewed Respondent's general pharmacy license 40 with Eugene M. Lutz as pharmacist in charge, allowing Respondent to engage in the operation of a pharmacy subject to the laws of the State of Iowa the rules of the Board.
4. General pharmacy license 40 is current and active until December 31, 2008.
5. Respondent is currently operating a general pharmacy at 120 Eighth Street SE, Altoona, Iowa 50009, with Eugene M. Lutz as the pharmacist in charge.

A. CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged under Iowa Code § 155A.15(2)(c) (2007) and 657 Iowa Administrative Code § 36.1(4)(b) with a lack of professional competency as demonstrated by willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa as evidenced by Respondent's repeated and extensive violations of standards related to compounding of medications.

COUNT II – VIOLATION OF PHARMACY COMPOUNDING RULES

Respondent is charged under Iowa Code §§ 155A.15(2)(c) (2007), and 657 Iowa Administrative Code §§ 13.13, 13.24, 13.25, 13.27, 13.28, 13.29, 13.31, 13.33 and 36.1(4)(ac), with failure to comply with administrative rules relating to safe compounding of high-risk injectable and intrathecal medications, and other compounded medications purporting to be sterile.

COUNT III – FAILURE TO COMPLY WITH BOARD ORDER

The Respondent is charged under Iowa Code § 272C.3(2)(a) (2007) with a failure to comply with the terms of a Stipulation and Consent Order adopted by the Iowa Board of Pharmacy Examiners on July 6, 2006, which terms required Respondent to, among other things, "obey all federal and state laws and regulations related to the practice of pharmacy, including the extemporaneous pharmacy compounding of all sterile and non-sterile products," and "review its policies and procedures annually and to document such review in writing."

COUNT IV -- FAILURE TO MAINTAIN ADEQUATE RECORDS

Respondent is charged under Iowa Code §§ 155A.15(4)(h) and 155A.23(12) (2007), and 657 Iowa Administrative Code § 36.1(4)(ac), with failing to maintain complete and adequate records relating to compounding of high-risk injectable and intrathecal medications, and other compounded medications purporting to be sterile, as required by administrative rules.

COUNT V – PROVIDING FALSE STATEMENTS

Respondent is charged under Iowa Code §§ 155A.23(13), with failing to provide documentation of product testing which Respondent asserted to have been performed.

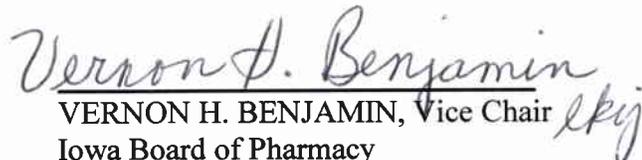
B. CIRCUMSTANCES

Circumstances supporting the above charges are set forth in Attachment A.

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 Director

On this 15th day of July 2008, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.


VERNON H. BENJAMIN, Vice Chair *skj*
Iowa Board of Pharmacy
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

LutzPharmacy-SOC 7-08 version 1

BEFORE THE IOWA BOARD OF PHARMACY

Re:) Case No. 2008-68
Pharmacy License of)
LUTZ PHARMACY,) **EMERGENCY ORDER**
PHARMACY SERVICES INC.)
License No. 40,)
Respondent)

I. JURISDICTION

The Iowa Board of Pharmacy (hereinafter, "Board") has jurisdiction over pharmacy licensees pursuant to Iowa Code Chapters 174, 155A and 272C (2007). Lutz Pharmacy, Pharmacy Services, Inc. (hereinafter, "Respondent"), possesses pharmacy license number 40 issued by the Board. A Statement of Charges was filed against Respondent on July 15, 2008. After receipt and review of the Statement of Charges, and careful review of evidence relating to the Statement of Charges, the Board has adopted the following Findings of Fact, Conclusions of Law and Emergency Order.

II. FINDINGS OF FACT

1. On December 31, 2007, the Board renewed Respondent's license to operate a pharmacy, as evidenced by license number 40 and subject to the laws of the State of Iowa and the rules of the Board.
2. Respondent was, at all material times, operating a pharmacy at 120 Eighth Street Southeast, Altoona, Iowa 50009.
3. On March 14, 2006, the Board issued an Emergency Order to Respondent, which
 - a. Prohibited the preparation and distribution of any and all compounded products required to be sterile.

- b. Required a recall for all compounded intravenous preparations and other products that purported to be sterile but were not prepared in a manner assuring sterilization prior to dispensing.
 - c. Required the surrender of compounded stock solutions and other products which had no guarantee of sterility.
4. On July 6, 2006, the Board approved a Stipulation and Consent Order for Respondent which placed Respondent's license on probation for two years, subject to numerous conditions and restrictions. Respondent also provided a written assurance of regulatory compliance to the Board in which Respondent agreed to obey all federal and state laws and regulations related to the practice of pharmacy, including the compounding of all sterile products.
5. On May 29, 2008, the Board commenced an inspection and investigation of Respondent which revealed the following facts, which the Board hereby finds:
- a. Respondent is compounding intravenous and intrathecal medications, and other compounded medications purporting to be sterile, for dispensing to customers pursuant to prescriptions.
 - b. Preparation of the compounds by Respondent begins with non-sterile ingredients that are mixed in an area that is not aseptic. There is no validation of the sterilization processes employed or appropriate justification of expiration dates assigned. Assigned expiration dates frequently exceeded expiration dates stated on individual components used in the preparation. All aspects of the compounding process have not been performed in environments that have been certified at the appropriate ISO standards.
 - c. Respondent has failed to comply with administrative rules relating to sterile product compounding. Among other things, Respondent does not:
 - (1) Maintain complete and proper compounding records and documentation.
 - (2) Utilize proper aseptic technique.
 - (3) Document lot numbers.
 - (4) Affix complete and accurate labeling.
 - (5) Have all required policies and procedures.
 - (6) Follow established policies and procedures.
 - (7) Conduct adequate testing of products.
 - (8) Utilize appropriate recall procedures.

- d. Cleanrooms, laminar airflow workbenches and barrier isolators have not been certified by an independent contractor as meeting ISO standards. The safety hood used by Respondent was certified for function in July of 2007, but the ISO class was not assessed.
 - e. Microbial sampling of air and pressure differential monitoring has never been conducted, let alone conducted on the weekly basis required where high-risk compounding is performed.
 - f. The buffer area where HEPA filters are intended to be used contains floorboard cracks and removable ceiling tiles which are not impervious and hydrophobic. HEPA filters are not in use.
 - g. Presterilization procedures such as weighing are not performed in an ISO Class 8 environment.
 - h. No media-fill testing is being performed.
 - i. Procedures for cleaning, and established frequencies of cleaning, have not been established.
 - j. A quality assurance program is not in place, involving testing of the sterility of compounds.
 - k. Hot and cold water are not located adjacent to the compounding area.
 - l. The pharmacist assisting Respondent has not received training specific to sterile compounding.
 - m. Due to lack of sterility, intravenous and intrathecal compounds and other compounded medications purporting to be sterile prepared by the Respondent may be contaminated with life-threatening pathogens. Respondent has demonstrated a lack of professional knowledge and understanding in the area of sterile compounding to such a degree that he has placed patients who have received these products at high risk for injury, disease, or death.
 - n. Due to lack of sterility and the failure to comply with the minimum standards for pharmacy compounding, medications prepared by Respondent may be contaminated with dangerous or even life-threatening pathogens.
 - o. Respondent has demonstrated a lack of professional knowledge and understanding in the area of sterile compounding to such a degree that he has placed patients who have received these products at high risk for injury, disease, or death
6. The Board finds that the evidence assembled during the investigation of Respondent supports the July 15, 2008 Statement of Charges against Respondent. The Board also

finds that Respondent has violated the provisions of Iowa Code Chapter 155A and Chapter 657 of the Iowa Administrative Code, particularly 657 Iowa Administrative Code §§ 13.1-13.33, in the manner alleged in the Statement of Charges.

7. The Board finds that Respondent is an immediate danger to the public health, safety and welfare for the following reasons:
 - a. Respondent is preparing, in a *non-sterile* environment, compounds which should only be prepared in a *sterile* environment. Respondent is preparing and dispensing non-sterile injectable and intrathecal medications, and other compounded medications purporting to be sterile.
 - b. Respondent is engaging in an unsafe practice while preparing high risk pharmaceutical compounds. Respondent's practices render the compounded products dangerous for human use as they may be contaminated with life-threatening pathogens.
8. The Board finds that immediate, emergency action must be taken for the reason that if Respondent is allowed to continue to engage in an unrestricted practice of pharmacy compounding, the public health, safety and welfare will be threatened. The public health, safety and welfare will be at risk due to the possibility that compounded products prepared by Respondent – products purporting to be sterile and products which must, by administrative rule, be prepared in a sterile environment – may be contaminated with life-threatening pathogens.
9. The Board finds that the minimum emergency action needed to protect the public health, safety and welfare is as follows:
 - a. Immediate limitation and restriction of Respondent's pharmacy license, prohibiting Respondent from engaging in the practice of sterile compounding, as defined in 657 Iowa Administrative Code § 13.2, including compounding of any and all injectable and intrathecal medications.

- b. Respondent's pharmacy license should remain restricted until satisfactory evidence of Respondent's ability and intention to resume the unrestricted practice of pharmacy has been provided to the Board.

III. CONCLUSIONS OF LAW

1. Respondent's incompetency, as reflected by its failure to comply with rules for pharmacy compounding in Iowa, has rendered it unable to ensure product integrity and patient safety.
2. The provisions of Iowa Code § 17A.18A (2007) permit the Board of Pharmacy Examiners to take emergency action to protect the health, safety and welfare of the public. A basis for emergency action against Respondent, pursuant to the provisions of the Iowa Code and the Iowa Administrative Code, has been established by the findings of the fact adopted above.

IV. EMERGENCY ORDER

The Board ORDERS as follows:

1. Pursuant to Iowa Code § 17A.18A, Iowa Code chapter 155A (2007) and 657 Iowa Administrative Code § 35.30, the pharmacy license of Respondent is hereby restricted to prohibit any preparation and distribution of compounded products that are required to be sterile, including injectable and intrathecal pharmacy compounds. This restriction is effective immediately upon Respondent's receipt of this Order.
2. Respondent shall issue a recall for all compounded preparations and other products that purport to be sterile or should be sterile, but were not prepared in compliance with the Board's administrative rules on sterile compounding and distributed since the 2006 recall. The recall shall include all compounded preparations dispensed to patients or physicians that were not immediately administered. The recall shall

include all compounded "stock solutions" stored at the pharmacy for use in future intravenous and intrathecal preparations. The recall shall also include written notification to all patients who have received such products and to all practitioners who prescribed the products. The notification shall include the reason for the recall, and shall reference the fact that the recall is being made pursuant to an order of the Board. Respondent shall implement this recall within 72 hours of receipt of this Order and shall report to the Board in writing the names and addresses of all patients and all practitioners who have received the recall notice. This report to the Board shall also be made within 72 hours of receipt of this Order.

3. Respondent shall be notified of this Order as provided in 657 Iowa Administrative Code 35.30(2).
4. A hearing regarding this Emergency Adjudicative Order and the Statement of Charges against Respondent shall be held on July 30, 2008. The hearing shall be held during the morning session beginning at 9:00 a.m. at the office of the Iowa Board of Pharmacy, 400 Southwest Eighth Street, Suite E, Des Moines, Iowa 50309.

DATED this 15th day of July 2008.


VERNON H. BENJAMIN, Vice Chair
Iowa Board of Pharmacy
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

LutzPharm-EmergOr 7-08

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case No. 2008-68
Pharmacy License of)	
LUTZ PHARMACY,)	SUPPLEMENTAL
PHARMACY SERVICES, INC.,)	EMERGENCY ORDER
License No. 40,)	
Respondent.)	

I. JURISDICTION

The Iowa Board of Pharmacy (hereinafter, "Board") has jurisdiction over pharmacy licenses pursuant to Iowa Code Chapters 147, 155A and 272C (2007). Pharmacy Services, Inc., doing business as Lutz Pharmacy (hereinafter, "Respondent") possesses pharmacy license number 40 issued by the Board. A Statement of Charges was filed against Respondent on July 15, 2008, accompanied by an Emergency Order of the same date. After receipt and review of the Statement of Charges, the Emergency Order, a July 29, 2008 report regarding Respondent's compliance with the Emergency Order and careful review of evidence relating to Respondent's compliance with the Emergency Order, the Board has adopted the following Findings of Fact, Conclusions of Law and Supplemental Emergency Order.

II. FINDINGS OF FACT

1. On December 31, 2007, the Board renewed Respondent's license to operate a pharmacy, as evidenced by license number 40, subject to the laws of the State of Iowa and the rules of the Board.
2. Respondent is currently operating a pharmacy at 120 Eighth Street, Altoona, Iowa 50009, with Eugene M. Lutz as the pharmacist in charge.

3. The Emergency Order dated July 15, 2008 was delivered to and served upon Eugene M. Lutz on July 16, 2008. The Emergency Order (which is incorporated herein by this reference) provided, among other things, that Respondent is prohibited from preparing sterile compounds. By the terms of such order, Respondent was further directed to "recall" all sterile, or purportedly sterile, compounds prepared since July of 2006, and to notify both patients and their doctors of the recall.
4. In a letter to the Board dated July 21, 2008, Eugene M. Lutz identified 28 patients who had received compounded products which purported to be sterile, but were not sterile. Lutz' letter identified 28 patients and 3 physicians who had been sent recall notices by Respondent, copies of which notices were supplied to the Board.
5. The July 21, 2008 letter of Eugene M. Lutz did not offer any information to suggest that Respondent had attempted to verify receipt of recall notices by individual patients.
6. Respondent's recall notices did not direct all patients to return unused medications to Respondent. The recall notice sent to physicians did not identify the patients who had received compounded products from Respondent.
7. A subsequent review of Respondent's records revealed that there are 31 patients (rather than 28) who received non-sterile, compounded products from Respondent. Thus, no recall notice has been sent to 3 affected patients and one physician of an affected patient.
8. The Board finds that immediate, emergency action is necessary to ensure that *all* patients who received compounded products from Respondent are fully informed of the recall and to ensure that all possible measures are taken to protect the public health, safety and welfare. The Board also finds that physicians must be notified regarding specific patients who received compounded

products from Respondent, in order to make the recall effort effective.

9. The Board finds that a further, immediate effort to provide notice to patients, and their physicians, is the minimum emergency action needed to protect the public health, safety and welfare.

III. CONCLUSIONS OF LAW

1. The provisions of Iowa Code § 17A.18A (2007) and 657 Iowa Administrative Code § 35.30 permit the Board of Pharmacy Examiners to take emergency action to protect the health, safety and welfare of the public.
2. A basis for emergency action against Respondent, pursuant to the provisions of the Iowa Code and the Iowa Administrative Code, has been established by the findings of the fact adopted above. Specifically, a basis for emergency action exists because Respondent's attempt to give notice to patients using compounds prepared by Respondent has not been adequate to protect the public health, safety and welfare.

IV. SUPPLEMENTAL EMERGENCY ORDER

The Board ORDERS as follows:

1. Pursuant to Iowa Code § 17A.18A, Iowa Code chapter 155A (2007) and 657 Iowa Administrative Code § 35.30, Respondent is hereby directed to re-send notice to *all* patients who have received products compounded by Respondent since July 2006, which products are required to be sterile, that (a) a recall has occurred and (b) any unused portion of the product shall be returned to Respondent. Notification shall occur within 24 hours of Respondent's

receipt of this Order. Notices shall be sent by registered or certified mail, return receipt requested, so that Respondent can verify that notice has been received by patients. In addition, Respondent may personally contact patients to notify patients of the recall and the request that unused medication be returned to the pharmacy. A receipt shall be obtained from patients who are personally contacted regarding the notice of recall.

2. Respondent is further directed to notify the physicians of *all* such patients that (a) a recall has occurred and (b) any unused portion of the product shall be returned to Respondent.

Notification to physicians shall include the name of the affected patient or patients. Notices shall be sent by registered or certified mail, return receipt requested, so that Respondent can verify that notice has been received by physicians.

3. Respondent shall prepare a complete record of the manner in which each patient and each physician was contacted and shall provide a copy of such record to the Board within one week of Respondent's receipt of this Supplemental Emergency Order.

4. Respondent shall be notified of this Order as provided in 657 Iowa Administrative Code 35.30(2).

5. All provisions of the Board's Emergency Order dated July 15, 2008 shall remain in effect, except where such Order conflicts with the contents of this Supplemental Emergency Order.

6. A hearing regarding this Supplemental Emergency Order and the Statement of Charges against Respondent shall be held on Oct. 8, 2008. The hearing will commence at

9:00 a.m. and be held at the office of the Iowa Board of Pharmacy Examiners, 400

Southwest Eighth Street, Suite E, Des Moines, Iowa 50309.

DATED this 6th day of August 2008.


LEMAN OLSON, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

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

William J. Wimer
4201 Westown Parkway
West Des Moines, IA 50266

LutzPh-SuppEmergOr 8-08.doc

BEFORE THE IOWA BOARD OF PHARMACY

IN THE MATTER OF:) CASE NO: 2008-63
) DIA NOS. 09PHB019,020
Pharmacist License of)
EUGENE M. LUTZ)
License No. 13243) FINDINGS OF FACT,
) CONCLUSIONS OF LAW,
Pharmacy License of) DECISION AND ORDER
LUTZ PHARMACY,)
PHARMACY SERVICES, INC.)
License No. 40)
Respondents)

On July 15, 2008, the Iowa Board of Pharmacy (Board) found probable cause to file Statements of Charges against pharmacist Eugene M. Lutz (Respondent) and Lutz Pharmacy, Pharmacy Services Inc. (Respondent). The Statements of Charges charged both Respondents as follows:

- Count I: Lack of Professional Competency
- Count II: Violation of Pharmacy Compounding Rules
- Count III: Failure to Comply With Board Order
- Count IV: Failure to Maintain Adequate Records
- Count V: Providing False Statements

Circumstances supporting the charges were set forth in Attachment A to the Statements of Charges. In addition, the Board issued an Emergency Order to Respondent Lutz Pharmacy, Pharmacy Services, Inc. (Lutz Pharmacy), immediately prohibiting it from preparing and distributing any compounded products that are required to be sterile, including injectable and intrathecal pharmacy compounds. The Emergency Order also required Lutz Pharmacy to issue a recall for all compounded preparations and other products that purport to be sterile or should be sterile, but were not prepared in compliance with the Board's administrative rules. Lutz Pharmacy was required to implement its recall within 72 hours and to report the names and addresses of all patients and practitioners who received the recall notice.

On August 6, 2008, the Board issued a Supplemental Emergency Order against the Lutz Pharmacy requiring it to re-send the recall notice and to require the return of any unused portion of the recalled product.

The consolidated hearing was held on July 22, 2009 at 1:00 p.m. in the Board Conference Room, 400 SW 8th Street, Des Moines, Iowa. The following members of the Board served as presiding officers for the hearing: Vernon H. Benjamin, Chairperson; Susan Frey; DeeAnn Wedemeyer Oleson; Edward L. Maier; Mark Anliker, and Ann Diehl. Assistant Attorney General Scott Galenbeck represented the state. Respondents were represented by attorney Fred L. Dorr. The hearing was open to the public at Respondents' election, in accordance with Iowa Code §272C.6(1). Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing and was later instructed to prepare the Board's written Decision and Order for their review, in conformance with their deliberations.

THE RECORD

The record includes the testimony of the witnesses, State Exhibits 1-22 and Respondent Exhibits A-N (See the Exhibit Indexes for description of the exhibits; a number of the exhibits are duplicates)

FINDINGS OF FACT

1. On September 7, 1966, the Board issued license number 13243 to Eugene M. Lutz, thereby authorizing him to engage in the practice of pharmacy in the state of Iowa, subject to the laws of the state and the rules of the Board. The pharmacist license is current and active. At all times material to the Statements of Charges, Eugene Lutz has been the pharmacist-in-charge at Lutz Pharmacy, Pharmacy Services Inc., 120 Eighth Street SE in Altoona, Iowa.

Lutz Pharmacy, Pharmacy Services, Inc. (hereinafter "Lutz Pharmacy") holds pharmacy license no. 40. Lutz Pharmacy is engaged in the compounding of injectable and intrathecal medications, and other compounded medications purporting to be sterile. The compounded medications are dispensed to patients, pursuant to prescriptions. (Testimony of Eugene Lutz; State Exhibits 12-14)

2. Respondents have a history of discipline by the Board.

a. On March 14, 2006, the Board filed Statements of Charges against both Respondents charging them with violating pharmacy compounding rules, professional incompetency, engaging in unethical conduct, and failure to maintain adequate records. The Board also issued an Emergency Order to Lutz Pharmacy prohibiting it from preparing or distributing all compounded products that are required to be sterile and requiring it to issue a recall. (State Exhibits 1-6; Testimony of Jean Rhodes)

On June 30, 2006, Respondents agreed to Stipulations and Consent Orders, which placed the pharmacist and pharmacy licenses on probation for a period of two years, subject to conditions. Respondents further agreed that they would not engage in any sterile compounding until they could demonstrate to the Board that Eugene Lutz had successfully completed additional formal training in sterile compounding and until after appropriate policies and procedures had been adopted and implemented. The Board approved the Stipulations and Consent Orders on July 6, 2008. (State Exhibits 7, 8, 12)

b. On March 7, 2008, the Board sent Eugene Lutz a Letter of Education concerning a medication dispensing error that resulted in a patient receiving medications that had not prescribed for her. (State Exhibits 9-11)

3. In 2006, Eugene Lutz applied for accreditation for Lutz Pharmacy through the Pharmacy Compounding Accreditation Board (PCAB). PCAB is a private association that has been in existence for five years and that follows its own standards, which are similar to the U.S. Pharmacopeia Guidelines. PCAB provides accreditation to compounding pharmacies on a voluntary basis. It is not affiliated with any state licensing board.

A pharmacy that is interested in pursuing accreditation through PCAB submits an application along with its written policies and procedures. PCAB sends out a surveyor, who is an independent contractor, to conduct an on-site survey and issue a report. If approved, the pharmacy pays PCAB an annual fee based on pharmacy volume. Each year the pharmacy must fill out a self analysis and report any changes in its volume or its policies and procedures. Over 200 pharmacies are currently in the accreditation process. Eleven pharmacies have either been denied accreditation or have withdrawn their applications. (Testimony of Tom Murry; Eugene Lutz)

4. In May 2007, Lutz Pharmacy completed construction of a new compounding room on pharmacy's east side. (Testimony of Eugene Lutz) A PCAB surveyor visited Lutz Pharmacy on May 10 and 11, 2007. The surveyor, who was a pharmacy technician, issued an initial report recommending that the pharmacy wait until they are better prepared for accreditation. The report noted that there were no standardized operating procedures, written or otherwise, and that there were no cleaning or maintenance logs for the lab or lab equipment. However, the same surveyor also issued a revised report, which recommended preliminary accreditation when eight listed compliance measures had been met. In the revised report, the surveyor states "During the survey I saw no evidence of outcome monitoring, complaint reporting procedures, quality control documents, and methodologies for formulation and compounding preparations, or product procurement procedures." (State Exhibit 20, p. 3) (State Exhibits 19, 20, 22)

5. Effective July 11, 2007, the Board adopted new rules governing sterile compounding.¹

6. One of the Board's Compliance Officers, Dennis Dobesh, inspected Lutz Pharmacy on May 29, 2008. At that time, the pharmacy remained on probation under the prior Stipulation and Consent Order. Respondents were conducting high risk² compounding of injectable and intrathecal³ medications made from non-sterile powders. Eugene Lutz estimated that he prepared approximately 10 intrathecal prescriptions a month. (State Exhibit 12)

Mr. Dobesh issued an Inspection Report on May 29, 2008, which noted 15 items of deficiency for Lutz Pharmacy, including 7 deficiencies specifically related to compounding procedures within the pharmacy. (State Exhibit 12, Attachment A)

7. On May 31, 2008, Eugene Lutz submitted a written Report of Deficiency Corrections in response to Dennis Dobesh's initial findings. Mr. Lutz admitted some of the deficiencies and denied others. On some items, Mr. Lutz stated that

¹ 657 IAC chapter 13.

² "High-risk preparation" means a sterile preparation that is compounded from non-sterile ingredients. See 657 IAC 13.2.

³ "Intrathecal" means within the spinal space. Intrathecal pumps are typically programmed to infuse over 21-90 days. (State Exhibit 12, p. 2)

the inspector did not ask for evidence (of compliance) during the inspection. With respect to sterility testing of high-risk preparations, Mr. Lutz wrote:

As indicated in the comments, we are having compounded preparations tested on a regular basis to indicate several parameters: sterility when made, @14 days and 28 days-concentration of active ingredients when made and @14 days and 28 days (which allows us to establish appropriate expiration dates to assure stability). We test a sample of each type of preparation at least once annually (and more frequently if problems were to be found.) So far we have tested each of the types of sterile products we make routinely and have had verification of sterility, appropriate active ingredient percentage and stability for every sample tested in the last 8 months.

(State Exhibit 12, Attachment B, p. 5; Respondent Exhibit C, p. 4)

Jean Rhodes contacted DynaLabs, where Respondents had the sterility testing conducted, but was only able to confirm that Respondents performed sterility testing on three products. Respondents produced 41 different intrathecal compounds and a total of 203 prescriptions classified as high-risk preparations. Respondents were later asked to produce documentation of their sterility testing as well as documentation to support their claim that if products tested sterile at 14 days out there was no need to conduct further testing before placing these products in intrathecal pumps that would be used for 90 days. Respondent never produced further documentation of sterility testing for the Board. (Testimony of Jean Rhodes; State Exhibits 12, 16)

8. On June 9 and June 11, 2008, Compliance Officer Jean Rhodes returned to Lutz Pharmacy with Dennis Dobesh to review and clarify the pharmacy records. On June 26, 2008, Rhodes and Dobesh issued an inspection report which documented fourteen areas of non-compliance for sterile compounding. These included six items that were environmental concerns, six items that were sterility concerns, three items that were technique concerns, and eight items that were procedure concerns. (State Exhibit 12, pp. 3-8). The inspection report included citations to the applicable sterile compounding rules. The documented violations included:

- Cleanrooms, laminar airflow workbenches, and barrier isolators had not been certified by an independent contractor as meeting ISO Standards. This was required every six months. 657 IAC 13.29(1). On July 16, 2007, only the safety hood was certified for function, but the ISO class was not assessed (State Exhibit 12, Attachment D) ;
- Microbial sampling of air and pressure differential monitoring had never been conducted. Sampling was required on a weekly basis when high-risk compounding was performed. 657 IAC 13.29(2) ENV Services had not record of performing particle counts for Lutz Pharmacy in their hood, buffer area, or anteroom (State Exhibit 12, Attachment C);
- The buffer area where HEPA filters are intended to be used contained floorboard cracks and removable ceiling tiles which are not impervious or hydrophobic, as required by 657 IAC 13.27(2). There was no HEPA filter for the buffer area;
- Presterilization procedures, such as weighing, were not performed in an ISO Class I environment, as required by 657 13.24(1);
- The anteroom was not maintained at ISO Class 8, as required by 657 IAC 13.27(4);
- No media-fill testing was being performed. 657 IAC 13.25(1) and (3) required media-fill testing annually for low-risk and semi-annually for high-risk sterile compounding;
- There were no established procedures for cleaning and cleaning frequency for each compounding area, as required by 657 IAC 13.28;
- There was no quality assurance program for sampling for sterility testing, as required by 657 IAC 13.13(1);
- High risk injectables/intrathecal were given a 30 day expiration date without sterility testing, as required by 657 IAC 13.13(1)(e). In the absence of the preparation passing a sterility test, the storage periods may not exceed 24 hours at controlled room temperature; 3 days at a cold temperature; or 45 days for a solid-frozen state. The pharmacy had only sent 3 high-risk compounded intrathecal samples out for sterility and potency testing in a two year period when more than 200 doses were compounded;
- The expiration dates assigned to compounded products frequently exceeded the expiration dates on the individual components used in the preparation;
- Hot and cold running water was not convenient to the compounding area, as required by 657 IAC 13.28(1)(b). Staff was required to walk down a

long hallway⁴ and through doors after washing hands to reach the compounding area;

- The pharmacist assisting Eugene Lutz (Brad Kline) had not been trained specific to sterile compounding, as required by 657 IAC 13.3(3);

(Testimony of Jean Rhodes; State Exhibit 12)

9. Respondents continued to pursue PCAB accreditation. On July 8, 2008, PCAB surveyor Michael W. Anneken, RPh conducted a follow-up survey at the Lutz Pharmacy. His July 11, 2008 report noted that Eugene Lutz had made some progress toward meeting the PCAB standards, but significant issues still needed to be corrected. In particular, Mr. Anneken noted that Lutz Pharmacy's sterile compounding facilities do not meet current USP 797 guidelines and a that a powder/fume containment system is needed. In addition, he noted that the pharmacy needs a program of potency testing for non-sterile compounds, that the sterility testing program needs to be more robust and consistent, and that BUDs (Beyond Use Dates) need to be supported with documented evidence or brought into line with USP guidelines. Eugene Lutz has responded to this report, and the next step is for PCAB to determine if the response is adequate. However, since one of PCAB's standards is regulatory compliance, PCAB is waiting for the outcome of the Board's hearing before going forward on the accreditation application. (Testimony of Michael W. Anneken; Tom Murry; State Exhibit 21)

10. On July 15, 2008, the Board issued its Statements of Charges against Eugene Lutz and Lutz Pharmacy. (State Exhibits 13, 14). The Board also issued its Emergency Order against Lutz Pharmacy, finding that the pharmacy posed an immediate danger to the public health, safety and welfare for the following reasons:

- a. Respondent is preparing, in a *non-sterile* environment, compounds which should only be prepared in a *sterile* environment. Respondent is preparing and dispensing non-sterile injectable and intrathecal medications, and other compounded medications purporting to be sterile.

⁴ It is approximately 15-20 feet from the doorway of the compounding room to the anteroom/cleanroom. (Testimony of Eugene Lutz; Respondent Exhibit K, p. 5)

b. Respondent is engaging in an unsafe practice while preparing high risk pharmaceutical compounds. Respondent's practices render the compounded products dangerous for human use as they may be contaminated with life-threatening pathogens.

The Board determined that the minimum emergency action necessary to protect the public was the immediate restriction of the Lutz Pharmacy license from engaging in sterile compounding, as defined by 657 IAC 13.2, and to continue the restriction until receiving satisfactory evidence of the pharmacy's ability and intention to resume the unrestricted practice.

In addition, the Board ordered Lutz Pharmacy to issue a recall within 72 hours for all compounded preparations and other products it had distributed since the 2006 recall that purported to be sterile or that should be sterile. The recall was required to include 1) all compounded preparations dispensed to patients or physicians that were not immediately administered; and 2) all compounded "stock solutions" stored at the pharmacy for use in future intravenous and intrathecal preparations. The recall was also required to include written notification to all patients who have received such products and to all practitioners who prescribed the products and the reason for the recall. Lutz Pharmacy was required to report, in writing, all names and addresses of patients and practitioners receiving the notice. (State Exhibit 16)

11. On July 21, 2008, Eugene Lutz signed a statement that he sent a recall letter to all prescribers and all patients who received compounded products "purporting to be sterile" from July 1, 2006 through July 18, 2008. 28 patients and 3 physicians were listed. The Board's Compliance Officer later identified 3 additional patients and 1 physician who did not receive recall notices. (State Exhibit 16)

On August 6, 2008, the Board issued a Supplemental Emergency Order requiring Lutz Pharmacy to re-send the recall notice to all patients by registered or certified mail, return receipt requested, and to notify them that any unused portion of the product shall be returned to the pharmacy. Lutz Pharmacy was further required to notify physicians of all patients that the recall had occurred and that all unused portions of the product must be returned to Lutz Pharmacy. (State Exhibit 17)

12. On October 2, 2008, Compliance Officers Jennifer Tiffany and Jennifer O'Toole conducted a follow-up inspection at Lutz Pharmacy at Respondents' request. Ms. Tiffany is a pharmacist who had three years of experience in a compounding pharmacy prior to joining the Board's staff and who continues to practice as a relief pharmacist at a compounding pharmacy. Ms. Tiffany and Ms. O'Toole spent an entire day at the pharmacy, and Ms. Tiffany returned to the pharmacy for several hours on October 3 and October 8, 2009 to gather additional information.

Jennifer Tiffany reviewed the sterile compounding facility and procedures at Lutz Pharmacy and submitted a Memorandum on October 16, 2008 outlining the following findings:

- Many of the pharmacy's policies and procedures were still generic and were not representative of the activities actually occurring at the pharmacy. The policy and procedure on "Environmental Testing-Air Sampling" was marked as a "Revision" even though the pharmacy has only started air sampling in July 2008. The same policy and procedure provided that testing paddles will be incubated at "room temperature" for 96 hours or at "elevated temperature 48 hours. However, the instructions supplied with the Enviro Test kit state that the paddles must be incubated at an elevated temperature. It was not appropriate to provide the option of incubating them at room temperature.
- Eugene Lutz continued to mistakenly believe that "skip-lot testing" is an acceptable practice for assigning beyond-use dates for single use sterile products. However, unless the sterility of each single use sterile product is verified every time that Mr. Lutz makes a high-risk preparation, he cannot assign his own beyond-use date to each product. See 657 IAC 13.13(1)(e);
- The pharmacy had the following policies and procedures: "Cleaning Procedures-Sterile (Ante-Clean)" and "Laminar Airflow Hood/Workbench Cleaning." There was a cleaning maintenance log on the wall outside the sterile compounding anteroom and a tacky mat inside the anteroom door.
- An electronic scale and printer had been purchased and were kept on the counter in the anteroom. The scale internally calibrates.
- The pharmacy had a policy and procedure entitled "Compounding Laboratory Apparel-Sterile" and all items listed were available for use in the anteroom;

- The pharmacy had a new policy and procedure entitled "Media Fill for High Risk Compounding."
- The pharmacy's sterile compounding worksheets had a box at the bottom that says "sterility checked." The box was checked on all of the worksheets for the high-risk intrathecal. However, it appeared that this meant that the product was run through a 0.22 micron filter. Although this is an appropriate method of terminal sterilization, it does not prove that the final preparation is indeed sterile.
- Eugene Lutz no longer entered an expiration date for syringes and sterile needles into the compounding computer database at the recommendation of PCAB. However, there were two boxes of syringes with expiration dates.
- Eugene Lutz had taken the aseptic compounding class through Professional Compounding Centers of America (PCCA) as his documented training;
- Although the compounding worksheets for high risk sterile preparations do not list the initials of the person completing each step, Mr. Lutz reported that a pharmacist performs all phases of the compounding;
- The compound log sheets and the prescription processing are done through two different software programs and there is no electronic link permitting the pharmacy to link a lot number for a sterile compounded product to the prescription number that it was dispensed under.
- HEPA filters, a positive pressure system, including pressure gauges, and non-porous ceiling tiles were installed at the pharmacy in late July 2008. Eugene Lutz told Ms. Tiffany that they were installed on July 29 and July 30, 2008, however the pharmacy documented that it started monitoring the pressure gauges on July 25, 2008;
- There were still openings and crevices in portions of the ceiling in the anteroom and cleanroom;
- The biologic safety cabinet where high risk sterile compounds were prepared was not certified to ISO Class 5 from July 11, 2007 until August 1, 2008. This was required to be done every six months. 567 IAC 13.27(1);
- The pharmacy's policy and procedures on "Laminar Airflow Hood-ANTE-Room ISO Class Certification" states that its purpose is to ensure that the Clean Room and Ante Room are certified to ISO 5 and ISO 8 environments, respectively. However, the Clean Room must be certified to ISO Class 7, not ISO Class 5.

Jennifer Tiffany's last visit to the pharmacy was on October 8, 2008. At the time of hearing, she did not know what improvements had been made to the pharmacy since that time. (Testimony of Jennifer Tiffany; State Exhibit 18)

13. Brad Kline has worked as a pharmacist for Lutz Pharmacy since July 2006. He has cooperated with the Board's investigation and has met privately with the Board's investigators. Mr. Kline reported that Eugene Lutz trained him in sterile compounding by demonstration. (Testimony of Brad Kline)

14. Eugene Lutz and Lutz Pharmacy have been compounding sterile products for nearly twenty years. They have not performed any sterile compounding since the Board issued its Emergency Order on July 15, 2008. Mr. Lutz has now complied with the Supplemental Emergency Order with respect to the recall. Mr. Lutz testified that the three additional patients and additional physician were inadvertently omitted from the first recall. Mr. Lutz does not dispute that there were deficiencies from the sterile compounding rules at the pharmacy at the time that he Statement of Charges and Emergency Orders were issued. He believes that he has now corrected all deficiencies and is willing to work with the Board to ensure that the deficiencies are corrected so that he can resume sterile compounding. (Testimony of Eugene Lutz; Respondent Exhibit K)

CONCLUSIONS OF LAW

Count I – Lack of Professional Competency

Iowa Code §155A.12(1)(2007) provides, in relevant part, that the Board may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a pharmacist license, or place a license on probation if the Board finds that a licensee has:

1. Violated any provision of this chapter or any rules of the Board adopted under this chapter.

Iowa Code §155A.15(2)(c)(2005) provides, in relevant part, that the Board may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, or place a pharmacy license on probation if the Board finds that a licensee has:

...

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

657 IAC 36.1(4)(b) provides that the Board may impose any of the disciplinary sanctions set out in subrule 36.1(2) when it determines that a licensee is guilty of professional incompetency. Professional incompetency includes but is not limited to a willful or repeated departure from, or the failure to conform to, the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa.

Effective July 11, 2007, the Board adopted new rules establishing standards and procedures for the preparation, labeling and distribution of sterile compounds. 657 IAC chapter 13. The preponderance of the evidence established that both Eugene Lutz and Lutz Pharmacy, Pharmacy Services Inc. repeatedly departed from and failed to conform to those rules, which constitute the minimal standard or acceptable and prevailing practice of pharmacy in the state of Iowa for sterile compounding. Respondent Eugene Lutz has violated Iowa Code section 155A.12(1)(2007) and 657 IAC 36.1(4)(b). Respondent Lutz Pharmacy, Pharmacy Services Inc. has violated Iowa Code section 155A.15(2)(c)(2007) and 657 IAC 36.1(4)(b).

Count II: Violation of Pharmacy Compounding Rules

The preponderance of the evidence established that both Eugene Lutz and Lutz Pharmacy, Pharmacy Services Inc. failed to comply with administrative rules relating to safe compounding of high-risk injectable and intrathecal medications and other compounded medications purporting to be sterile. The Board adopted new regulations on sterile compounding, effective July 11, 2007. The June 2008 inspection of Respondents' pharmacy documented numerous serious violations of these rules, as set out in the Findings of Fact. The preponderance of the evidence in the record supported the findings that these violations existed at the pharmacy at the time that the Statements of Charges and Emergency Orders were issued. Respondents have not attempted to dispute the majority of the violations.

Count III: Failure to Comply With Board Order

The preponderance of the evidence established that both Eugene Lutz and Lutz Pharmacy, Pharmacy Services Inc. violated Iowa Code section 272C.3(2)(a)(2007) by their failure to comply with the Stipulations And Consent Orders approved by the Board on July 6, 2006, which required them to obey all federal and state laws and regulations related to the practice of pharmacy, including the extemporaneous pharmacy compounding of all sterile and non-sterile products, and to review policies and procedures annually. As fully documented in the June 2008 inspection report, Respondents' sterile compounding facility and procedures were not in compliance with the sterile compounding regulations adopted effective July 11, 2007.

Count IV: Failure To Maintain Adequate Records

The Board is authorized to discipline pharmacists and pharmacies for failure to keep and maintain records required by Iowa Code chapter 155A or rules of the Board. Iowa Code sections 155A.12(4); 155A.23(12); 657 IAC 36.1(4)(ac). The preponderance of the evidence in this record established that Respondents have not maintained complete and proper compounding records as required by 657 IAC chapter 13. Respondents failed to affix complete and accurate labeling to compounded products, and failed to maintain written justification of the chosen beyond-use date, in violation of 657 IAC 13.13(1). Respondents failed to document training for sterile compounding, in violation of 657 IAC 13.3(3).

Respondents also failed to have all required policies and procedures documented, including specific cleaning procedures and frequencies for each compounding area, as well as a written plan for evaluation of airborne microorganisms, equipment calibration, and an appropriate cleansing and garbing procedure, in violation of 657 IAC 13.28. Respondents failed to have a Quality Assurance program for sampling for sterility testing, visual inspection of preparations, routine disinfection and air quality testing, training of personnel and media-fill testing, and methods for establishing beyond-use dates, in violation of 657 IAC 13.31(1). Respondents did not have current policies and procedures for the storage and delivery of sterile preparations to ensure product quality and packaging integrity until the preparation is administered, in violation of 657 IAC 13.33. Respondents failed to maintain appropriate production records for each drug product compounded for an individual patient, including an internal control or prescription number, in violation of 657 IAC

20.10(3). Respondents were not recording lot numbers on the prescription labels.

Count V: Providing False Statements

Iowa Code section 155A.23(13) prohibits licensees from providing the Board or any of its representatives or any state or federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the scope of this chapter, chapter 124, or the rules of the Board. In his May 31, 2008 deficiency correction response, Eugene Lutz claimed that Lutz Pharmacy performed sterility testing of compounded products on a regular basis but in fact Lutz Pharmacy was only performing potency (skip-lot) testing, not sterility testing. Although Eugene Lutz was compounding 41 different intrathecal preparations and 203 high-risk prescription products, he only produced verification of sterility testing on three products. Eugene Lutz and Lutz Pharmacy violated Iowa Code section 155A.23(13) by making false statements to Board representatives concerning his sterility testing.

DECISION AND ORDER

IT IS THEREFORE ORDERED that License Number 13243, issued to Respondent Eugene Lutz, and License Number 40, issued to Respondent Lutz Pharmacy, Pharmacy Services Inc., shall immediately be placed on probation for a period of five (5) years, subject to the following terms and conditions:

1. Respondents shall not resume sterile compounding until authorized by the Board. In order to obtain authorization to resume sterile compounding, Respondents must establish to the Board's satisfaction that they are in full compliance with 657 IAC chapter 13, that they have corrected all deficiencies cited by the Board's Compliance Officers, and that they have adopted and implemented appropriate policies and procedures to ensure that all requirements for sterile compounding have been met. The required corrections must include, but are not limited to:

a. Revision of all written policies and procedures to be Iowa and Lutz Pharmacy specific;

b. Installation of a sink with hot and cold running water for hand sanitizing in the anteroom OR replacement or modification of the doors to the anteroom and clean room to permit staff to enter without using their hands to open the doors. However, if Respondents choose to replace/modify the doorways as an interim measure they will still be required to install the sink in the anteroom no later than December 31, 2010, as required by 657 IAC 13.27(4), (5) and 13.28(1)(b); and

c. Repairs (or replacement) of the ceiling and baseboards in the buffer/cleanroom area to ensure that all cracks and crevices are sealed.

The pharmacy will be re-inspected upon Respondents' request. Upon receipt and approval of an inspection report verifying full compliance with all provisions of 657 IAC chapter 13, the Board will authorize Respondents to resume sterile compounding.

2. Respondent Lutz Pharmacy, Pharmacy Services Inc. shall be subject to periodic random inspections to verify compliance.

3. Respondents shall file written, sworn quarterly reports with the Board attesting to their compliance with all the terms and conditions of probation. The reports shall be filed no later than March 5, June 5, September 5 and December 5 of each year of Respondents' probation. The quarterly reports shall provide information concerning:

a. The total number of prescriptions compounded that quarter with a breakdown of the number of low-risk, medium-risk, and high-risk compounded products;

b. Documentation of sterility testing, hood testing, and air sampling;

c. Documentation that staff pharmacists have all received training in sterile compounding prior to engaging in any sterile compounding; and

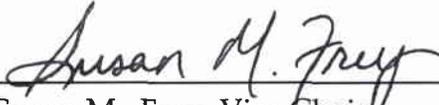
d. Any further information deemed necessary by the Board

from time to time.

4. Respondent Eugene Lutz shall not supervise any registered pharmacist-intern and shall not perform any of the duties of a pharmacy preceptor.
5. Respondents shall comply with all federal and state laws and regulations related to the practice of pharmacy, including but not limited to the laws and regulations pertaining to sterile compounding.
6. Should Respondents violate or fail to comply with any of the terms and conditions of probation, the Board may initiate action to revoke or further discipline Respondents' pharmacist and pharmacy licenses, pursuant to Iowa Code chapters 272C, 155A (2009) and 657 IAC chapter 36.

IT IS FURTHER ORDERED, pursuant to Iowa Code §272C.6 and 657 IAC 36.18(2), that Respondents Eugene Lutz and Lutz Pharmacy, Pharmacy Services Inc. shall pay \$75.00 for fees associated with conducting the disciplinary hearing. In addition, the executive secretary/director of the Board shall bill Respondents for any witness fees and expenses or transcript costs associated with this disciplinary hearing. Respondents shall remit for these expenses within thirty (30) days of receipt of the bill.

Dated this 17th day of *August*, 2009.



Susan M. Frey, Vice Chair
Iowa Board of Pharmacy

cc: Scott Galenbeck, Assistant Attorney General
Fred L. Dorr, Respondents' Attorney

Any aggrieved or adversely affected party may seek judicial review of this decision and order of the board, pursuant to Iowa Code section 17A.19.

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	
Pharmacy License of)	Case No. 2010-31
LUTZ PHARMACY)	
License No. 40,)	STATEMENT OF CHARGES
Respondent.)	

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

1. He is the Executive Director for the Iowa Board of Pharmacy 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 (2009).
3. On December 17, 2009, the Board renewed general pharmacy license number 40 for Lutz Pharmacy (hereinafter, "Respondent"), allowing Respondent to engage in the operation of a pharmacy subject to the laws of the State of Iowa and the rules of the Board. Lutz Pharmacy was placed in a probationary status by order of the Board dated August 17, 2009.
4. General pharmacy license number 40 is current until December 31, 2010.
5. Respondent operates a general pharmacy at 120 8th Street Southeast, Altoona, Iowa, 50009 with Eugene M. Lutz as the pharmacist in charge.

A. CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged under Iowa Code § 155A.15(2)(c) (2009) and 657 Iowa Administrative Code § 36.1(4)(b) with a lack of professional competency as demonstrated by willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa as evidenced by Respondent's failure to timely file quarterly reports as required by a Board order.

COUNT II – FAILURE TO COMPLY WITH BOARD ORDER

Respondent is charged under Iowa Code § 272C.3(2)(a) (2009) with a failure to comply with terms found in the Findings of Fact, Conclusions of Law, Decision and Order adopted by the Iowa Board of Pharmacy on August 17, 2009, which terms required

Respondent to, among other things, file quarterly reports no later than the 5th day of March, June, September and December.

B. CIRCUMSTANCES

On or about March 30, 2010, an investigation was commenced which revealed the following:

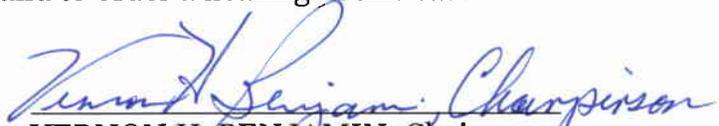
1. Respondent was, at all material times, operating a general pharmacy located at 120 8th Street Southeast, Altoona, Iowa 50009, with Eugene M. Lutz as the pharmacist in charge.
2. Respondent failed to timely file quarterly reports as required by the Findings of Fact, Conclusions of Law, Decision and Order adopted by the Iowa Board of Pharmacy on August 17, 2009.
3. Quarterly reports for the following dates were untimely filed: September 2009, December 2009, and March 2010.
4. After being notified of the filing deficiency, Respondent filed the September 2009, December 2009, and March 2010 reports on March 18, 2010.

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 Director

On this 28 day of Sept. 2010, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.



VERNON H. BENJAMIN, Chairperson
Iowa Board of Pharmacy
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

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OCT 28 2010

BEFORE THE IOWA BOARD OF PHARMACY IOWA BOARD OF PHARMACY

Re:)	Case No. 2010-31
Pharmacy License of)	
LUTZ PHARMACY)	STIPULATION
License No. 40,)	AND
Respondent.)	CONSENT ORDER

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2009), the Iowa Board of Pharmacy (hereinafter, "Board") and Lutz Pharmacy (hereinafter, "Respondent"), enter into this Stipulation and Consent Order settling a pending contested case. The pending contested case is a licensee disciplinary proceeding before the Iowa Board of Pharmacy based on allegations specified in a Statement of charges filed September 28, 2010. The Board and Respondent, who hereby agree that the contested case shall be resolved without proceeding to hearing, stipulate to the following:

1. Respondent's license to operate a pharmacy in Iowa was renewed on December 17, 2009, as evidenced by General Pharmacy License Number 40, which is recorded in the permanent records of the Iowa Board of Pharmacy.
2. General Pharmacy License Number 40, issued to and held by Respondent, is active and current until December 31, 2010.
3. A Statement of Charges was filed against Respondent on September 28, 2010.
4. The Board has jurisdiction over Respondent and the subject matter herein.
5. Respondent does not admit the allegations set forth in the Statement of Charges but agrees, for the purpose of this Stipulation and Consent Order, to adhere to certain terms and conditions on its license to operate a pharmacy in the State of Iowa.

6. Respondent shall pay a civil penalty in the amount of \$250 within thirty (30) days of the Board's approval of this Stipulation and Consent Order.
7. All other terms of the August 19, 2009 Findings of Fact, Conclusions of Law, Decision and Order shall remain in effect.
8. 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 further suspend the Respondent's Iowa pharmacy license, or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2009), and 657 IAC 36.
9. This Stipulation and Consent Order is the resolution of a contested case. By entering into this Stipulation and Consent Order, the 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.
10. 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.
11. 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 26th day of October 2010.

Eugene M. Lutz, R.Ph., P.I.C.
Eugene M. Lutz, R.Ph., P.I.C.
on behalf of
Lutz Pharmacy, Respondent

State of Iowa

County of POLK

Signed and sworn (or affirmed) before me
on 10/26/10

Date

by Eugene M. Lutz
Name(s) of Person(s)



Joann Fry

Signature of Notary Public

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on the
3rd day of November 2010.

Vernon H. Benjamin, Chairperson
VERNON H. BENJAMIN, Chairperson
Iowa Board of Pharmacy
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

Lutz Pharmacy
Attn: Eugene M. Lutz, R.Ph.
120 Eighth Street SE
Altoona, IA 50009

BEFORE THE IOWA BOARD OF PHARMACY

Re)
Pharmacy License of) Case no. 2011-1
LUTZ PHARMACY)
License No. 40) **STATEMENT OF CHARGES**
Respondent.)

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

1. He is the Executive Director for the Iowa Board of Pharmacy 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 (2011).
3. On December 1, 2010, the Board renewed general pharmacy license number 40 for Lutz Pharmacy (hereinafter, "Respondent"), allowing Respondent to engage in the operation of a pharmacy subject to the laws of the State of Iowa and the rules of the Board. Lutz Pharmacy was placed in a probationary status by order of the Board dated August 17, 2009.
4. General pharmacy license number 40 is current until December 31, 2011.
5. Respondent operates a general pharmacy at 120 8th Street Southeast, Altoona, Iowa, 50009 with Eugene M. Lutz as the pharmacist in charge.

A. CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged under Iowa Code § 155A.15(2)(c) (2011) and 657 Iowa Administrative Code § 36.1(4)(b) with lack of professional competency as demonstrated by Respondent's (a) substantial deviation from the standards of learning and skill ordinarily possessed and applied by other Iowa pharmacies, (b) failure to exercise in a substantial respect that degree of care which is ordinarily exercised by an Iowa pharmacy and (c) willful and repeated departures from, and a failure to conform to, the minimal standard and acceptable and prevailing practice of pharmacy in the state of Iowa, as evidenced by Respondent's failure to maintain adequate controls over controlled substances.

COUNT II – FAILURE TO MAINTAIN ADEQUATE CONTROLS

Respondent is charged under Iowa Code §§ 124.306, 124.402(1) and 155A.15(2)(i) (2011), and 657 Iowa Administrative Code § 6.7, with failing to maintain adequate control over and accountability for controlled substances.

B. CIRCUMSTANCES

On or about January 3, 2011, an investigation was commenced which revealed the following:

1. At all times material, Respondent operated a general pharmacy at 120 8th Street Southeast, Altoona, Iowa, 50009 with Eugene M. Lutz as the pharmacist in charge.

2. Another pharmacist employed by Respondent was arrested by police on January 3, 2011. During a related search of her vehicle, over 100 tablets were found loose in the pharmacist's purse. The recovered drugs and their quantities were as follows:

Hydrocodone/APAP 7.5/500mg	68
Hydrocodone/APAP 10/325mg	4
Hydrocodone/APAP 10/500mg	21
Lorazepam 2mg	5
Diazepam 10mg	13
Zolpidem 10mg	2

3. All of the drugs in the pharmacist's possession at the time of her arrest were of the same generic brand that Respondent has in its dispensing stock.

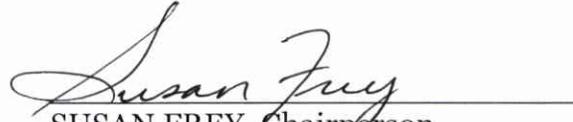
4. On the following day, January 4, 2011, the same pharmacist-employee entered Respondent sometime after the pharmacy closed and left her key to the door, along with a note. After it was discovered that the pharmacist had made an after-hours entry into Respondent, a pharmacy audit was performed. The audit covered the same six drugs the pharmacist had in her possession when she was arrested on January 3, 2011. The audit revealed the following inventory shortages:

Hydrocodone/APAP 10/500mg	-516
Zolpidem 10mg	-66
Diazepam 10mg	-49
Lorazepam 2mg	-931.5

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 Director

On this 13th day of Sept. 2011, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.


SUSAN FREY, Chairperson
Iowa Board of Pharmacy
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

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BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case No. 2011-1
Pharmacy License of)	
LUTZ PHARMACY)	STIPULATED
License No. 40)	CITATION
Respondent)	AND WARNING

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), and 657 I.A.C. § 36.1(2) (j), the Iowa Board of Pharmacy (hereinafter, “the Board”) and Lutz Pharmacy (hereinafter, “Respondent”), enter into the following Stipulated Citation and Warning, settling a licensee disciplinary proceeding currently pending before the Board.

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 operates a general pharmacy at 120 8th Street Southeast, Altoona, Iowa 50009, with Eugene M. Lutz as the pharmacist in charge.
2. Pharmacy license number 1327 is active and current through December 31, 2012.
3. A Statement of Charges was filed against Respondent on September 13, 2011.
4. The Board has jurisdiction over Respondent and jurisdiction over the subject matter of these proceedings.
5. For the purposes of this Stipulated Citation and Warning, Respondent does not contest the allegations set forth in the Statement of Charges.

Respondent accepts, pursuant to 657 I.A.C. § 36.1(2)(j), this citation and warning

for failure maintain adequate controls over controlled substances.

6. Beginning not later than thirty (30) days after the Board's approval of this Stipulated Citation and Warning, and continuing for the duration of Respondent's license, Respondent shall maintain a perpetual inventory of all products containing hydrocodone.

7. Within thirty (30) days of the Board's approval of this Stipulated Citation and Warning, Respondent shall submit, for the Board's approval, policies and procedures relating to security and accountability for controlled substances. Respondent agrees to adopt, implement, and adhere to these policies and procedures upon Board approval.

8. Should the Respondent violate or fail to comply with any of the terms or conditions of this Stipulated Citation and Warning, the Board may initiate action to revoke or suspend Respondent's Iowa pharmacy license or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011), and 657 IAC § 36.

9. This Stipulated Citation and Warning is the resolution of a contested case. By entering into this Stipulated Citation and Warning, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulated Citation and Warning.

10. The State's legal counsel may present this Stipulated Citation and Warning to the Board.

11. This proposed settlement is subject to approval by a majority of the full Board. If the Board fails to approve this Stipulated Citation and Warning, it shall

be of no force or effect to either the Board or Respondent. If the Board approves this Stipulated Citation and Warning, it shall be the full and final resolution of this matter.

12. The Board's approval of this Stipulated Citation and Warning shall constitute a **FINAL ORDER** of the Board in a disciplinary action.

This Stipulated Citation and Warning is voluntarily submitted by Respondent to the Board for its consideration on the 5th day of March 2012.

LUTZ PHARMACY,
Respondent

By Eugene M. Lutz

Subscribed and sworn to before me by Eugene M. Lutz, who has stated to me that she is the pharmacist in charge at Lutz Pharmacy and is authorized to sign this Stipulation and Consent Order on behalf of Lutz Pharmacy, on this 5th day of March 2012.



Joann Fry

NOTARY PUBLIC IN AND FOR
THE STATE OF IOWA

This Stipulated Citation and Warning is accepted by the Iowa Board of Pharmacy on this 7th day of March 2012.

Susan M. Frey

SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy
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