

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

Re:) Pharmacist License of) JAMES W. STANGEL) License No. 14826,) Respondent.)	Case No. 2011-109 STATEMENT OF CHARGES
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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 July 1, 1976, the Board issued Respondent, James W. Stangel, by examination, a license to engage in the practice of pharmacy as evidenced by license number 14826, subject to the laws of the State of Iowa and the rules of the Board.
4. Respondent's pharmacist license is current and active until June 30, 2013.
5. Respondent's current address is 1702 16th Street, Onawa, Iowa.
6. At all times relevant to this statement of charges, Respondent was the owner and operator of Stangel Compounding located at 903 Iowa Avenue, Onawa, Iowa.

A. CHARGES

COUNT I – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged pursuant to Iowa Code §§ 155A.12(1) (2011) 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 extensive violations of standards related to compounding of medications.

COUNT II – VIOLATION OF PHARMACY COMPOUNDING RULES

Respondent is charged under Iowa Code §§ 155A.12(1) and 155A.12(4) (2011), and 657 Iowa Administrative Code 13.13, 13.24, 13.25, 13.2, 13.28, 13.29, 13.31, 13.33 and 36.1(4)(ac), with failure to comply with administrative rules relating to the safe compounding of medications purporting to be sterile.

COUNT III – FAILURE TO MAINTAIN ADEQUATE RECORDS

Respondent is charged pursuant to Iowa Code §§ 155A.12(4) and 155A.23(12) (2011), and 657 Iowa Administrative Code 36.1(4)(ac) with failure to comply with Board rules for pharmacy compounding recordkeeping.

COUNT IV – VIOLATION OF CONTROLLED SUBSTANCE LAWS

Respondent is charged pursuant to Iowa Code §§ 124.306, 124.308, 124.401, 124.402 and 155A.15(2)(c) (2011) and 657 Iowa Administrative Code 36.1(4)(j) with failing to comply with controlled substance laws.

B. THE CIRCUMSTANCES

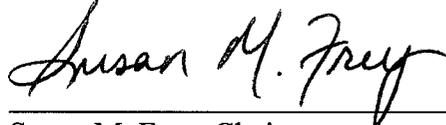
On October 13, 2011, an investigation commenced which revealed the following:

1. Respondent was, at all material times, employed as a pharmacist at Stangel Compounding located at 903 Iowa Avenue, Onawa, Iowa.
2. An inspection report dated October 13, 2011 and an investigative report dated November 3, 2011, allege the following:
 - a. Respondent failed to comply with the minimum standards of the operation of a pharmacy when inspected on October 13, 2011.
 - b. Respondent failed to comply with Board rules pertaining to the compounding of high risk sterile products.
 - c. Respondent engaged in the illegal manufacturing of prescription products.
 - d. Respondent failed to comply with Board rules pertaining to the compounding of warfarin capsules.
 - e. Respondent assigned inappropriate expiration dates to several compounded products.
 - f. Respondent compounded methyltestosterone capsules (Schedule III) without proper prescriber authorization.
 - g. Respondent dispensed compounded methyltestosterone capsules to unauthorized recipients.
 - h. Respondent compounded and dispensed methyltestosterone capsules without a proper prescriber/client/pharmacy relationship.
 - i. Respondent failed to maintain proper records for the compounding and dispensing of methyltestosterone capsules.
3. Since November 3, 2011, Respondent has failed to adequately respond to deficiencies reported by Board compliance officers in their report. Respondent has also failed to take necessary corrective action, including recalls of certain compounded products.

WHEREFORE, the Complainant prays that a hearing be held in this matter and that the Board take such action as it may deem to be appropriate under the law.


Lloyd K. Jessen
Executive Director

On this 19th day of January 2012, the Iowa Board of Pharmacy found probable cause to file this Statement of Charges and to order a hearing in this case.


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
Hoover State Office Building
Des Moines, IA 50319

BEFORE THE IOWA BOARD OF PHARMACY

Re:)	Case No. 2011-109
Pharmacist License of)	
JAMES W. STANGEL)	STIPULATED
License No. 14826)	CITATION AND
Respondent)	WARNING

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), the Iowa Board of Pharmacy (hereinafter, "Board") and James W. Stangel (hereinafter, "Respondent"), enter into the following Stipulated Citation and Warning settling a licensee disciplinary proceeding currently pending before the Board.

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

1. Respondent was issued a license to practice pharmacy in Iowa on July 1, 1976, following examination, as evidenced by Pharmacist License Number 14826 which is recorded in the permanent records of the Board.
2. The Iowa pharmacist license issued to and held by Respondent is active and current until June 30, 2013.
3. Respondent was, at all times material to the Statement of Charges, the owner and operator of Stangel Compounding, 903 Iowa Avenue, Onawa, Iowa.
4. A Statement of Charges was filed against Respondent by the Board on January 19, 2012.
5. The Board has jurisdiction over Respondent and jurisdiction over the subject matter of these proceedings.

6. Respondent denies the allegations contained in the Statement of Charges, but in the interest of settlement has chosen not to contest the allegations.

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

7. Upon the Board's approval of this Stipulated Citation and Warning, Respondent shall be obligated to do the following:

a. Within ninety (90) days after the date of the Board's approval of this Stipulated Citation and Warning, Respondent shall complete not less than two (2) hours of formal, structured continuing pharmacy education ("CPE") which shall be pre-approved by the Board. The CPE shall be focused on the proper handling and dispensing of controlled substances. Upon completion of the 2 hours of CPE, documentation of satisfactory completion shall be promptly submitted to the Board. This CPE shall be in addition to – not in lieu of – the thirty (30) hours of continuing pharmacy education required every two years for license renewal.

b. Within sixty (60) days after the date of the Board's approval of this Stipulated Citation and Warning, Respondent shall submit to the Board *typewritten*¹ pharmacist policies and procedures regarding (a) sterile compounding and (b) the secure and appropriate handling and dispensing of controlled substances. Following review and approval by the Board, Respondent agrees to adopt, implement, and adhere to these policies and procedures whenever employed as a pharmacist in charge and whenever

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

engaging in the practice of pharmacy in a pharmacy which has no conflicting policies and procedures.

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

d. Should the Board request such an appearance within ninety (90) days of the Board's approval of this Stipulated Citation and Warning, Respondent agrees to appear informally before the Board for the purpose of reviewing his performance as a pharmacist. Respondent shall be given reasonable notice of the date, time, and place for the appearance.

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

8. Upon the Board's approval of this Stipulated Citation and Warning, Respondent shall be assessed a civil penalty in the amount of \$1500. This civil penalty shall be paid promptly after the Board's approval of this Stipulated Citation and Warning, made payable to the Treasurer of Iowa and mailed to the executive director of the Board. All civil penalty payments shall be deposited into the State of Iowa general fund.

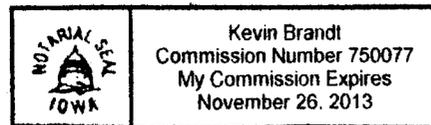
9. Should Respondent violate or fail to comply with any of the terms and conditions of this Stipulated Citation and Warning, the Board may initiate action to revoke or suspend Respondent's Iowa pharmacist license or impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011)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

10. 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.
11. The State's legal counsel may present this Stipulated Citation and Warning to the Board.
12. This Stipulated Citation and Warning is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be of no force or effect to either the Board or Respondent. If the Board approves this Stipulated Citation and Warning, it shall be the full and final resolution of this matter.
13. The Board's approval of this Stipulated Citation and Warning shall constitute a FINAL ORDER of the Board.

This Stipulated Citation and Warning is voluntarily submitted by Respondent to the Board for its consideration on the 19th day of JUNE 2012.


JAMES W. STANGEL, R.Ph.
Respondent

Subscribed and sworn to before me by James W. Stangel on this 19 day of June 2012.



NOTARY PUBLIC IN AND FOR
THE STATE OF IOWA

This Stipulated Citation and Warning is accepted by the Iowa Board of Pharmacy on the

26th day of June 2012.


SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy
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Des Moines, Iowa 50309-4688

cc: Theresa Weeg
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