

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

Re:)	Case No. 2005-112
Pharmacist License of)	
RICK L. PAULEY)	STATEMENT OF CHARGES
License No. 18328)	
Respondent.)	

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

1. He is the Executive Secretary/Director for the Iowa Board of Pharmacy Examiners and files this Statement of Charges solely in his official capacity.
2. The Board has jurisdiction in this matter pursuant to Iowa Code Chapters 155A and 272C (2005).
3. On November 3, 1994, the Board issued Respondent, after examination, a license to engage in the practice of pharmacy as evidenced by license number 18328, subject to the laws of the State of Iowa and the rules of the Board.
4. Respondent's pharmacist license is current and active until June 30, 2006.
5. Respondent's current address is 1633 NW 97th Street, Des Moines, Iowa 50325.
6. Respondent was, at all times material, employed as the pharmacist in charge at Five Star Compounding Pharmacy, 9379 Swanson Boulevard, Suite E, Clive, Iowa 50325.

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 I.A.C. 20.2, 20.3(5), and 36.1(4)(j).

COUNT II – LACK OF PROFESSIONAL COMPETENCY

Respondent is charged under Iowa Code §§ 155A.15(2)(c) (2005) 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.

B. CIRCUMSTANCES

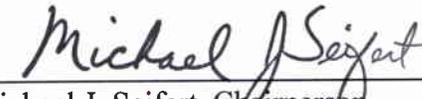
Circumstances supporting the above charges are set forth in Attachment A.

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 17th day of July 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, IA 50319

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BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

IN THE MATTER OF:)	CASE NO: 2005-112
)	DIA NOS. 06PHB026,027
Pharmacist License of)	
RICK L. PAULEY)	
License No. 18328)	
Respondent)	FINDINGS OF FACT, CONCLUSIONS OF LAW,
Pharmacy License of)	DECISION AND ORDER
FIVE STAR COMPOUNDING PHARMACY)	
License No. 1185)	
Respondent)	

On July 17, 2006, the Iowa Board of Pharmacy Examiners (Board) found probable cause to file Statements of Charges against licensed pharmacist Rick L. Pauley (Respondent) and licensed pharmacy Five Star Compounding Pharmacy (Respondent). The Statements of Charges allege that Respondents:

COUNT I: Violated Iowa Code §§155A.12(1), 155A.12(4) (2005) and 657 IAC 20.2, 20.3(5), and 36.1(4)(j), by failing to comply with Board rules for pharmacy compounding.

COUNT II: Violated Iowa Code §155A.15(2)(c) (2005) and 657 IAC 36.1(4)(b), by 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.

Circumstances supporting the charges were set forth in Attachment A to the Statements of Charges.

The consolidated hearing was initially scheduled for October 25, 2006 but was later continued. The hearing was held on January 16, 2007 at 9:00 a.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: Michael J. Seifert, Chairperson; Vernon H. Benjamin; Paul Abramowitz; Leman Olson; Susan Frey; and Barbara O'Roake. The Respondents were self-represented by Rick L. Pauley. Assistant Attorney General Scott Galenbeck represented the state. The hearing was closed 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 and the following exhibits:

- State Exhibit 1: Investigative Report, 1/6/05 (sic)
- State Exhibit 2: Statement of Charges (Rick Pauley), 7/17/06
- State Exhibit 3: Statement of Charges (Five Star Compounding Pharmacy), 7/17/06
- State Exhibit 4: Notice of Hearing (Pauley), 8/14/06 and Certified Mail Return Receipt
- State Exhibit 5: Notice of Hearing (Five Star), 8/14/06 and Certified Mail Return Receipt
- State Exhibit 6: Notice of Hearing (Pauley), 10/26/06, and Certified Mail Return Receipt
- State Exhibit 7: Letter, 10/10/06 (Pauley to Jessen)

FINDINGS OF FACT

1. On November 3, 1994, the Board issued license number 18328 to Rick L. Pauley, 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, Mr. Pauley has been the pharmacist-in-charge at Five Star Compounding Pharmacy, 9379 Swanson Boulevard, Suite E, Clive, Iowa 50325. Five Star Compounding Pharmacy holds general pharmacy license no. 1185.

Five Star Compounding Pharmacy compounds products for animals and humans. Animal drugs constitute approximately 80% of its business and most prescriptions are shipped out of the pharmacy. Rick Pauley is the only permanent pharmacist/employee working at Five Star Compounding Pharmacy. A relief pharmacist fills in when Mr. Pauley is on vacation. (State Exhibits 1-3; Testimony of Rick Pauley; Jennifer O'Toole)

2. Effective November 5, 2004, the United States Food and Drug Administration (FDA) Center for Veterinary Medicine approved a new animal drug application filed by Animal Health Pharmaceuticals, LLC for Rebalance (sulfadiazine/pyrimethamine), to be used in horses for the treatment of equine protozoal

myeloencephalitis caused by *Sarcocystis neurona*. Notice of the FDA approval was published in the Federal Register on December 2, 2004 and was placed on the FDA website. (Testimony of Jennifer O'Toole; State Exhibit 1)

3. From November 5, 2004 until October 31, 2005, Rick Pauley compounded over 19 lots and 34,000 milliliters of sulfadiazine/pyrimethamine at the Five Star Compounding Pharmacy. (Testimony of Jennifer O'Toole; Rick Pauley; State Exhibit 1)

4. On or about November 21, 2005, Five Star Compounding Pharmacy received a letter from the United States Food and Drug Administration (FDA) Center for Veterinary Medicine. The FDA also sent a copy of the letter to the Board. The FDA attached a copy of the December 2, 2004 Federal Register and notified Five Star Compounding Pharmacy that it should immediately cease the compounding and sales of illegal sulfadiazine/pyrimethamine products. After receiving the letter, Rick Pauley immediately stopped compounding sulfadiazine/pyrimethamine and notified his veterinarian customers that the drug was commercially available. Mr. Pauley credibly testified that he did not know that the FDA had approved the drug until he received this letter. He typically obtains his information about newly approved drugs by checking the FDA website, by attending trade shows, or by talking to veterinarians or other pharmacists. (Testimony of Rick Pauley; Jennifer O'Toole; State Exhibits 1, 7)

5. Two of the Board's compliance officers visited Five Star Compounding Pharmacy on December 15, 2005 and inspected the pharmacy. The compliance officers confirmed that Rick Pauley had been compounding a commercially available drug but that his last preparation of the drug was on October 31, 2005, approximately two weeks before he received the FDA's letter. The compliance officers also conducted an inspection of Five Star Compounding Pharmacy and found numerous violations of Board rules, including but not limited to:

- failure to include allergy information in patient records for humans,
- failure to maintain a log of initials for permanent or temporary employees,
- failure of pharmacist-in-charge to have a name badge,
- failure to keep the refrigerator at a proper temperature,

- failure to keep the pharmacy in an orderly, clean and sanitary condition,
- failure to remove outdated drugs from the pharmacy,
- failure to develop policies and procedures for the delivery and shipment of products,
- failure to update policies and procedures to include quality assurance programs, and
- inability to verify that all compounded products were administered and not resold.

Five Star Compounding and Rick Pauley were sent a report outlining the deficiencies. Mr. Pauley promptly responded to the deficiency report, and the pharmacy was re-inspected on January 9, 2006. Most all of the deficiencies had been corrected at the time of the re-inspection. Mr. Pauley's nametag was on order, and he was still working on the Policies and Procedures for compounding. Most but not all of the outdated drugs had been removed from the pharmacy. (Testimony of Jennifer O'Toole; State Exhibit 1)

CONCLUSIONS OF LAW

COUNT I

Iowa Code §155A.12(2005) 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.

...

4. Failed to keep and maintain records required by this chapter...

657 IAC 20.2 provides the following relevant definitions:

"*Compounding*" means preparing, mixing, assembling, packaging, and labeling a drug or device for an identified individual patient as a result of a practitioner's prescription drug order or initiative based on the prescriber/patient/pharmacist relationship in the course of professional practice...All compounding, regardless of type of product, is to be done pursuant to a prescription...

...
"Manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substances or labeling or relabeling of the drug's or device's container. Manufacturing also includes the promotion, marketing, or preparation from bulk drug substances of commercially available products for resale by pharmacists, practitioners, or other persons.

657 IAC 20.3(5)"b" prohibits pharmacists from compounding, regularly or in inordinate amounts, drugs that are essentially copies of commercially available drug product except as provided in subrule 20.3(1).

The preponderance of the evidence established that from November 5, 2004 until October 31, 2005, Rick Pauley, while working as the pharmacist in charge for Five Star Compounding Pharmacy, compounded over 19 lots and 34,000 milliliters of sulfadiazine/pyrimethamine, when that product had been approved by the FDA and was commercially available. Rick Pauley and Five Star Compounding Pharmacy have violated Iowa Code §§155A.12(1)(2005), 155A.15(2)(c) and 657 IAC 20.2 and 20.3(5). The record does not support a finding that Respondents were preparing the drug for resale by veterinarians.

Based on this record, the Board believes that Rick Pauley ceased compounding sulfadiazine/pyrimethamine as soon as he became aware of the FDA's action approving the new animal drug application. Lack of actual knowledge is not a defense to the violation; it was Mr. Pauley's responsibility to consult readily available sources to obtain current information about FDA approved drugs. Nevertheless, the Board considered Mr. Pauley's lack of actual knowledge in making its determination that the violation can be adequately addressed by the issuance of a Citation and Warning. The Board also considered Mr. Pauley's cooperation with the Board's compliance officers and with the Board's investigation.

COUNT II

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.

The state failed to establish that Five Star Compounding Pharmacy and/or Rick Pauley are professionally incompetent, in violation of Iowa Code §155A.15(2)(c)(2005) and 657 IAC 36.1(4)(b). The Board's compliance officers identified numerous areas of noncompliance with Board rules within the pharmacy at the time of their December 15, 2005 inspection. However, Mr. Pauley, who works alone, credibly testified that he cleans up and washes the preparation surfaces before preparing drug products. Mr. Pauley satisfactorily explained the temperature of his refrigerator but admitted that he should have been more diligent in cleaning drawers and cupboards and in removing outdated drugs. Rick Pauley was fully cooperative and had corrected most of the deficiencies when the pharmacy was revisited approximately three weeks later. Based on this record, the Board was unable to conclude that Respondents' failure to conform to minimal standards in the pharmacy was willful or repeated or warrants a finding of professional incompetency.

Order

IT IS THEREFORE ORDERED that Respondent Rick Pauley, License No. 18328, and Respondent Five Star Compounding Pharmacy, License No. 1185, are both hereby CITED for their violation of Iowa Code §§155A.12(1), 155A.15(2)(c)(2005) and 657 IAC 20.2 and 20.3(5) [Count I].

IT IS FURTHER ORDERED that Respondent Rick Pauley, License No. 18328, and Respondent Five Star Compounding Pharmacy, License No. 1185, are hereby WARNED that any future violations may result in more severe disciplinary sanctions.

IT IS FURTHER ORDERED that within thirty (30) days of this final Decision and Order, Respondents shall provide the Board with a complete copy of the pharmacy's written Policies and Procedures, including but not limited to the Policies and Procedures addressing compounding and removal of outdated drugs.

IT IS FURTHER ORDERED that Count II is DISMISSED as to both Respondents.

IT IS FURTHER ORDERED, pursuant to Iowa Code §272C.6 and 657 IAC 36.18(2), that Respondents Rick Pauley and Five Star Compounding Pharmacy 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 13th day of March, 2007.



Michael Seifert, Chairperson
Iowa Board of Pharmacy Examiners

cc: Scott Galenbeck, Assistant Attorney General

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.