

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

Re: Pharmacist License of)	COMPLAINT
GARVIS G. HOUCK)	AND STATEMENT
License No. 12338)	OF CHARGES
Respondent)	AND
)	NOTICE
)	OF HEARING

COMES NOW, Lloyd K. Jessen, Executive Secretary-Director of the Iowa Board of Pharmacy Examiners, on the 19th day of October, 1992, and files this Complaint and Statement of Charges and Notice of Hearing against Garvis G. Houck, a pharmacist licensed pursuant to Iowa Code chapter 155A, and alleges that:

1. Alan M. Shepley, Chairperson; Marian L. Roberts, Vice Chairperson; Donna J. Flower; Phyllis A. Miller; Phyllis A. Olson; Ronald B. Reiff; and Arlan D. Van Norman are duly appointed, qualified members of the Iowa Board of Pharmacy Examiners.
2. Respondent was issued a license to practice pharmacy in Iowa on August 13, 1957, by examination.
3. Respondent currently resides at 50 Beaumont, Mason City, Iowa 50401.
4. Respondent is currently self-employed as pharmacist in charge and owner of Houck Drug Company, Inc., 8 North 4th Street, Clear Lake, Iowa 50428.
5. Respondent's license to practice pharmacy in Iowa is current until June 30, 1994.

6. The Board has received an investigative report from Pharmacy Investigator Gary D. Ebeling dated December 12, 1990, and other information which alleges the following:

a. On or about October 27, 1990, the Board received a complaint from an Iowa pharmacist (R.Ph."X") who alleged that Respondent had placed an advertisement in a local newspaper which referred to prices of numerous prescription drugs. The pharmacist questioned whether the advertisement was false or misleading.

b. In an interview with Investigator Ebeling on December 18, 1990, Respondent admitted that he had placed an advertisement in the October 16, 1990, issue of the Mason City Shopper for his pharmacy, Houck Drug, located in Clear Lake, Iowa. The "clip 'n save" advertisement referred to drug prices for 12 different brand name prescription drugs and "birth control." The list of drugs in the advertisement began as follows: "Calan SR 240mg - If you now pay more than \$53.98 per hundred, see us." Eleven other brand name drugs and one entry for "birth control" were then listed, followed by a similar statement which referred to a price.

c. The complaining pharmacist (R.Ph."X") alleged that a typical pharmacy's net acquisition cost for #100 Calan SR 240mg was approximately \$95.50. The pharmacist questioned how Respondent could offer or infer to offer 100 tablets of the drug at \$53.98. The pharmacist further alleged that, in this instance, the drug which Respondent was selling at his pharmacy was not the brand name product, Calan SR 240mg.

d. The complaining pharmacist (R.Ph."X") made similar allegations concerning the prices of the other twelve prescription drugs which appeared in the October 16, 1990, advertisement.

e. Investigator Ebeling determined the following: (1) that three of the 13 advertised drugs were actually brand name products; (2) that one of the 13 advertised drugs (birth control) represented two generic products, Nelova 0.5/35 and Nelova 1/35; (3) that eight of the 13 advertised drugs were not commercially-available brand name products but were products that were extemporaneously compounded by Respondent from either bulk chemicals or from higher strength dosages of commercially-available brand name products; and (4) that one of the 13 advertised drugs was a product that was a brand name product but was different from the brand name product which had been advertised.

f. When extemporaneously compounding drug products for prescriptions which called for either Calan SR 240mg or Calan SR 180mg, Respondent utilized a bulk chemical labeled as "Verapamil Hydrochloride BP 80" which he obtained from the Professional Compounding Centers of America, Inc., (PCCA) of Sugar Land, Texas.

g. When extemporaneously compounding drug products for prescriptions which called for Dyazide, Respondent utilized a bulk chemical labeled as "Triamterene USP" and another bulk chemical labeled as "Hydrochlorothiazide USP" which he also obtained from the Professional Compounding Centers of America, Inc., (PCCA) of Sugar Land, Texas.

h. When extemporaneously compounding drug products for prescriptions which called for Corgard 40mg, Respondent claimed that he crushed tablets of Corgard 120mg and added lactose, encapsulating enough of the mixture to constitute 40mg of Corgard per capsule.

i. When extemporaneously compounding drug products for prescriptions which called for Capoten 25mg, Respondent claimed that he crushed tablets of Capoten 100mg and added

lactose, encapsulating enough of the mixture to constitute 25mg of Capoten per capsule.

j. When extemporaneously compounding drug products for prescriptions which called for Tenormin 50mg, Respondent claimed that he crushed tablets of Tenormin 100mg and added lactose, encapsulating enough of the mixture to constitute 50mg of Tenormin per capsule.

k. When extemporaneously compounding drug products for prescriptions which called for Vasotec 5mg, Respondent claimed that he crushed tablets of Vasotec 20mg and added lactose, encapsulating enough of the mixture to constitute 5mg of Vasotec per capsule.

l. When extemporaneously compounding drug products for prescriptions which called for Vasotec 10mg, Respondent claimed that he crushed tablets of Vasotec 20mg and added lactose, encapsulating enough of the mixture to constitute 10mg of Vasotec per capsule.

m. During the months of October and November 1990, Respondent dispensed seven prescriptions of #100 Verapamil SR 240mg each, in the manner described in paragraph (f), above.

n. During the months of October and November 1990, Respondent dispensed 16 prescriptions of #100 Triamterene 50mg / Hydrochlorothiazide 25mg each, in the manner described in paragraph (g), above.

o. During the months of October and November 1990, Respondent dispensed two prescriptions of #100 Capoten 25mg each, in the manner described in paragraph (i), above.

p. Respondent also admitted that he had placed another advertisement in the November 20, 1990, issue of the Mason City

Shopper. This "clip 'n save" advertisement listed drug prices for "alternatives" to 12 different brand name prescription drugs and "birth control" at Respondent's pharmacy, Houck Drug, in Clear Lake, Iowa. The list of drugs in the advertisement began as follows: "Calan SR 240mg - For the alternative, you pay only \$53.98 per hundred." Eleven other brand name drugs and one entry for "birth control" were then listed, followed by a similar statement which listed a price for the alternative.

q. On January 28, 1991, Investigator Ebeling obtained ten of Respondent's compounded Verapamil SR 240mg capsules from Respondent for testing. On May 20, 1992, four of these capsules were submitted to Searle Research and Development in Skokie, Illinois, for analysis. In a Searle project report issued by Searle's physical methodology department dated July 16, 1992, a summary stated, in part, the following:

The material in each capsule consists primarily of a mixture of about 184mg of verapamil hydrochloride with about 147mg amorphous material, probably microcrystalline cellulose or a closely related derivative of cellulose...[A] dissolution study also confirmed the amount of verapamil hydrochloride contained in the capsules.

r. On July 15, 1991, a pharmacist (R.Ph."Y") submitted to the Board a copy of another "clip 'n save" advertisement which had appeared in the Mason City Shopper, presumably during June or July 1991. This "clip 'n save" advertisement listed drug prices for 19 different brand name prescription drugs at Respondent's pharmacy, Houck Drug, in Clear Lake, Iowa. The list of drugs in the advertisement began as follows: "Calan SR 240mg - For the name brand you pay only \$48.98 per sixty." Eighteen other brand name drugs were then listed, followed by a price for the name brand.

s. The complaining pharmacist (R.Ph."Y") alleged that a typical pharmacy's net acquisition cost for #60 Calan SR 240mg was approximately \$57.25. The pharmacist questioned how Respondent could offer 60 tablets of the drug at \$48.98. The

pharmacist further alleged that, in this instance, the drug which Respondent was selling at his pharmacy was not the brand name product, Calan SR 240mg.

t. The complaining pharmacist (R.Ph."Y") made similar allegations concerning the prices of the other eighteen brand name prescription drugs which appeared in the June or July 1991 advertisement. In the opinion of the pharmacist, the prices, as quoted, ranged from \$0.11 to \$19.10 lower than a typical pharmacy's net acquisition cost.

7. Between April and June 1992 the Board received independent investigative information which alleged the following:

a. On April 6, 1992, the Board received a complaint from an Iowa pharmacist (R.Ph."Z") employed at St. Joseph Mercy Hospital in Mason City who alleged that Respondent had sent a handwritten letter to Gary M. Levinson, M.D., of Mason City, seeking Dr. Levinson's approval for the dispensing of Respondent's extemporaneously compounded "Zantac" 150mg capsules to one of Dr. Levinson's female patients (patient "A"). The prescription, as written by Respondent, stated the following:

[name of patient "A"]
Clear Lake
(from Zantac)
Ranitidine 150mg capsules
30
One twice a day

In Respondent's letter dated March 26, 1992, to Dr. Levinson, Respondent stated the following:

Your patient, [patient "A"], of Clear Lake, is interested in our compounded Ranitidine 150mg capsules which I do in my pharmacy lab because of the cost effectiveness.*

Zantac 300mg tablets are crushed and converted into 150mg capsules with Lactose N.F. as the diluent. My lab is equipped with a Feton capsule machine and a Denver Instrument electronic balance sensitive to 10mg.

If it meets with your approval, I will begin compounding the capsules for your patient on her next refill.

Thank you.

Pharmacist Garvis G. Houck

*\$14.00/Hundred less costly

The pharmacist (R.Ph."Z") alleged that Dr. Levinson "ripped up" Respondent's letter; the enclosed prescription; and the stamped, addressed, return envelope. But after doing so, Dr. Levinson turned these items over to the pharmacist (R.Ph."Z") and asked him to contact the Iowa Board of Pharmacy Examiners and report Respondent's activities.

b. On April 15, 1992, the Board received a written complaint, dated April 13, 1992, from Ray Cvjetnicanin, Group Manager, Security Services, Glaxo, Inc., of Research Triangle Park, North Carolina. Mr. Cvjetnicanin's complaint alleged the following:

As previously discussed and for your information, Glaxo became aware of Mr. Garvis Houck's activities on February 25, 1992, as a result of a complaint received [by Glaxo] from employees of...[pharmacy "A"] indicating that Mr. Houck was compounding and selling Zantac in capsule form. It was related to me that on February 14, 1992,...[R.Ph."Y"] presented Mr. Garvis Houck with a prescription for Zantac 150mg tablets [Rx No. RO85221 issued by Dr. John Baker] and Mr. Houck persuaded her to accept 10 clear gelatin capsules containing white powder in lieu of Zantac tablets. [R.Ph."Y"] stated that Mr. Houck advised her that the contents of the capsules were compounded from crushed Zantac 300mg tablets...[Rx label stated "Ranitidine 150mg PCCA #10" and also indicated that 12 Refills were available. "Discount" price was \$10.00]

On March 5, 1992, I travelled to Houck Drug, 8 North Fourth Street, Clear Lake, Iowa 50428 and gave Mr. Houck a prescription for 60 Zantac 150mg tablets with one refill [Rx No. RO85451 issued by Dr. Paul Barber]. I also showed him a March 3, 1992, edition of the Mason City Shopper newspaper containing a Houck Drug advertisement for 60 Zantac 150mg tablets for \$69.98 [the ad stated as follows: "Zantac 150mg - For the name brand you pay only \$69.98 per sixty"]. During my conversation with Mr. Houck he offered to fill my prescription with compounded Zantac tablets made from "larger" crushed Zantac tablets for \$5 less than the

advertised price of \$69.98. He then spent several minutes compounding the capsules and presented me with a bag in which was an amber bottle containing 60 clear gelatin capsules containing white powder. On the bottle label was typed "(from Zantac) ranitidine 150mg PCCA." The prescription cost was \$63.98.

These capsules were tested for content and impurities by the Glaxo Quality Assurance Department. The analysis indicated that the content of the capsules contained active ingredient ranitidine hydrochloride **but in a quantity substantially less than indicated for Zantac 150mg tablets** (emphasis added). The analysis also showed that the contents of the capsules were **not** compounded from Zantac 300mg tablets (emphasis added).

c. On June 29, 1992, the Board received a second letter, dated June 26, 1992, from Ray Cvjetnicanin, Group Manager, Security Services, Glaxo, Inc., of Research Triangle Park, North Carolina. Mr. Cvjetnicanin's letter stated the following:

As previously discussed and for your information, the following is a summary of the analysis performed on the clear gelatin capsules purchased from Mr. Garvis Houck on March 5, 1992, at Houck Drug, 8 North 4th Street, Clear Lake, Iowa. The capsules were evaluated against Glaxo Inc. release requirements for the following:

1. Ranitidine content
2. TLC impurities
3. Identification by HPLC/TLC
4. Appearance

Test results for the impurities and identification of ranitidine by HPLC/TLC are comparable to those of Zantac 150mg. Ranitidine content does **not** conform to Zantac 150mg specifications. The appearance is reported as a white to off-white powder within a clear gelatin capsule. In addition, IR comparison of the capsule content to that of a Zantac 300mg tablet **does not** confirm compounding from Zantac 300mg tablets (emphasis added).

All raw data has been filed by Glaxo Quality Assurance Department and is available if necessary...

8. The Board has also received an investigative report from Pharmacy Chief Investigator James P. Theis dated August 14, 1992, and other information which alleges the following:

a. On August 6, 1992, the Board received a complaint from a male consumer (patient "B") who alleged that "something was wrong" with prescription medication he had obtained from Respondent at Houck Drug in Clear Lake, Iowa.

b. In a telephone interview of patient "B" by Chief Investigator Theis on August 6, 1992, and in a personal interview of patient "B" and his wife by Chief Investigator Theis on August 12, 1992, the following was determined: (1) patient "B" was recovering from brain surgery for removal of a prolactin-secreting adenoma (pituitary tumor); (2) the condition of patient "B" was "life-threatening;" (3) patient "B" had been prescribed the drug Parlodel 2.5mg by C.R. Caughlan, M.D., of Mason City, Iowa; (4) patient "B" had been obtaining Parlodel 2.5mg tablets by prescription from a local pharmacy other than Respondent's pharmacy; and (5) patient "B" then decided to obtain his Parlodel in "compounded" capsule form from Respondent's pharmacy, Houck Drug, in an attempt to save money.

c. In a written statement signed on August 12, 1992, Respondent claims that he "called Dr. Caughlan's office and permission to do the dosage reduction was O.K. with the doctor and his nurse so stated via phone." Respondent then extemporaneously compounded 1.25mg bromocriptine mesylate capsules from 5mg Parlodel capsules. Prescription number RO86387 from Houck Drug (handwritten by Respondent) states the following:

[name of patient "B"]
6-2-92
(from Parlodel 5mg)
Bromocriptine mesylate 1.25mg #120
compounded capsules
Sig: One twice a day
Dr. Caughlan

Prescription number RO86387 was then filled and dispensed by Respondent to patient "B" on June 2, 1992.

d. In a written statement signed by C.R. Caughlan, M.D., of Clear Lake on August 12, 1992, Dr. Caughlan stated the

following: "I did *not* authorize the compounding of Parlodel (bromocriptin) in a capsule form to be administered to [patient "B"] (emphasis added).

e. Respondent also extemporaneously compounded 2.5 mg bromocriptine mesylate capsules from 5mg Parlodel capsules for patient "B". Prescription number RO86796 from Houck Drug (handwritten by Respondent) states the following:

[name of patient "B"]
7-7-92
(from Parlodel)
Bromocriptine mesylate 2.5mg #60
Sig: One am & pm
Dr. Gross
Refill 2 times

Prescription number RO86796 was then filled and dispensed by Respondent to patient "B" on July 7, 1992. Prescription number RO86796 was refilled by Respondent on August 4, 1992. The label on the container given to patient "B" on August 4, 1992, contained the following information:

RO86796 Dr. Gross, Robert O.
[name of patient "B"] 1Rfls 8/4/92 GH
One morning and night
(from Parlodel)
Bromocriptin 2.5mg PCCA

e. In a written statement signed by Robert O. Gross, D.O., of Clear Lake on August 12, 1992, Dr. Gross stated the following: "To the best of my knowledge [patient "B"] did *not* receive a prescription from me for the drug Parlodel" (emphasis added).

f. Information obtained from Charles R. Caughlin, M.D., indicated that patient B's prolactin level had increased from 701 on June 26, 1992, to 766 on August 4, 1992. Patient B's

prolactin level had previously been steadily declining while taking Parlodel **tablets** obtained from another pharmacy.

g. Respondent also extemporaneously compounded cortisone acetate 10mg capsules for patient "B" on June 2, 1992; July 6, 1992; and August 4, 1992. Patient "B" and his wife complained to Chief Investigator Theis on August 12, 1992, that they were unable to differentiate the compounded cortisone acetate 10mg capsules from the compounded bromocriptine mesylate 2.5mg capsules because they looked "just alike." Chief Investigator Theis observed that neither capsule had any external identifying marks.

h. On August 12, 1992, patient "B" gave Chief Investigator Theis four (4) capsules of bromocriptine mesylate 2.5mg capsules obtained from his prescription vial labeled as Rx No. RO86796 and requested that the contents of the capsules be tested. On August 17, 1992, the two (2) capsules were submitted to Sandoz Pharmaceuticals, Physical Distribution Department, East Hanover, New Jersey, for analysis. On September 2, 1992, a letter was received from Diana Wagner, Coordinator of Distribution and Customer Services for Sandoz Pharmaceuticals Corporation. The letter stated, in part, the following:

Our Quality Assurance Department has completed its evaluation on the Parlodel (bromocriptine mesylate) which you recently returned to us for investigation.

The complaint sample was returned to verify that the capsule contained 2.5mg of bromocriptine mesylate. The Parlodel 5mg capsule was reduced to 2.5mg by using lactose as the filler.

Quality Assurance analyzed one of the capsules and found it to contain approximately 47% of the active ingredient in Parlodel 5mg capsules...

i. On September 8, 1992, patient "B" stated to Chief Investigator Theis that he had stopped taking the "compounded" bromocriptine 2.5mg capsules and had gone back to taking Parlodel 2.5mg **tablets** and, after having done so, he had

received a lab report which indicated that his prolactin level had decreased by 300 points.

9. In summary, complaints have been received by the Board between October 1990 and August 1992 from various pharmacists, a drug manufacturer, and a consumer which together or separately allege that Respondent has engaged in unlawful and unethical conduct: (1) by disseminating advertising which is false or misleading and incomplete; (2) by substituting "compounded" drugs for commercially-available strengths of brand name drug products when there is no demonstrated bioavailability for the "compounded" products; (3) by dispensing "compounded" drugs without prescriber authorization; (4) by dispensing misbranded and mislabeled prescription drugs which fail to meet applicable government standards; and (5) by misrepresenting to consumers and a physician that Zantac 150mg capsules were "compounded" from commercially-available Zantac 300mg tablets when, it appears, they were "compounded" from illegal ranitidine powder.

10. Respondent is guilty of violations of 1991 Iowa Code sections 147.55(3), 147.55(7), 155A.12(1), 155A.12(2), 155A.12(3), 155A.23(2), 155A.23(5), 155A.28, 155A.32, 203B.3(1), 203B.3(5), 203B.9(2), 203B.9(3), 203B.10(1), 203B.10(9)(a), 203B.10(9)(b), and 203B.10(9)(c) by virtue of the allegations contained in paragraphs 6, 7, 8, and 9.

1991 Iowa Code section 147.55 provides, in part, the following:

A license to practice a profession shall be revoked or suspended when the licensee is guilty of the following acts or offenses:...

3. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of a profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.

....

7. Use of untruthful or improbable statements in advertisements.

1991 Iowa Code section 155A.12 provides, in part, the following:

...The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:

1. Violated any provision of this chapter or any rules of the board adopted under this chapter.
2. Engaged in unethical conduct as that term is defined by rules of the board.
3. Violated any of the provisions for licensee discipline set forth in section 147.55.

1991 Iowa Code section 155A.23 provides, in part, the following:

A person shall not:...

2. Willfully make a false statement in any prescription, report, or record required by this chapter.

....

5. Affix any false or forged label to a package or receptacle containing prescription drugs.

1991 Iowa Code section 155A.28 provides the following:

The label of any drug or device sold and dispensed on the prescription of a practitioner shall be in compliance with rules adopted by the board.

1991 Iowa Code section 155A.32 provides, in part, the following:

1. If an authorized prescriber prescribes, either in writing or orally, a drug by its brand name or trade

name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and ***demonstrated bioavailability*** as the one prescribed for dispensing and sale to the patient...If the pharmacist exercises drug product selection, the pharmacist shall inform the patient of the savings which the patient will obtain as a result of the drug product selection and pass on to the patient no less than fifty percent of the difference in actual acquisition costs between the drug prescribed and the drug substituted.

2. The pharmacist shall ***not*** exercise the drug selection described in this section if...the following is true:

a. The prescriber specifically indicates that no drug product selection shall be made (emphasis added).

1991 Iowa Code section 203B.3 provides, in part, the following:

The following acts and the causing of the acts within this state are unlawful:

1. The introduction or delivery for introduction into commerce of any drug, device, or cosmetic that is adulterated or misbranded.

....

5. The dissemination of any false advertising.

1991 Iowa Code section 203B.9 provides, in part, the following:

A drug or device is adulterated under any of the following circumstances:...

2. If it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in the official compendium...

3. If it is not subject to subsection 2 and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

1991 Iowa Code section 203B.10 provides, in part, the following:

A drug or device is misbranded under any of the following circumstances:

1. If its labeling is false or misleading in any particular.

....

9. a. If it is a drug and its container is so made, formed, or filled as to be misleading.

b. If it is an imitation of another drug.

c. If it is offered for sale under the name of another drug.

11. Respondent is guilty of violations of 657 Iowa Administrative Code sections 8.5(1), 8.5(8), 8.6, 8.14(1)(g), 8.15(2), 9.1(4)(b)(2), 9.1(4)(c), 9.1(4)(g), 9.1(4)(j), and 9.1(4)(u) by virtue of the allegations contained in paragraphs 6, 7, 8, and 9.

657 Iowa Administrative Code section 8.5 provides, in part, the following:

Unethical conduct or practice. The provisions of this section apply to licensed pharmacists and registered pharmacist-interns.

8.5(1) Misrepresentative deeds. A pharmacist shall not make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

....

8.5(8) Claims of professional superiority. A pharmacist shall not make a claim, assertion, or

inference of professional superiority in the practice of pharmacy which cannot be substantiated, nor claim an unusual, unsubstantiated capacity to supply a drug or professional service to the community.

657 Iowa Administrative Code section 8.6 provides, in part, the following:

Advertising. Prescription drug price and nonprice information may be provided to the public by a pharmacy so long as it is not false or misleading and not in violation of any federal or state laws applicable to the advertisement of such articles generally and if all of the following conditions are met:

1. All charges for services to the consumer must be stated.
2. The effective dates for the prices listed shall be stated...

657 Iowa Administrative Code section 8.14 provides, in part, the following:

Prescription label requirements.

8.14(1) The label affixed to or on the dispensing container of any prescription dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:...

g. Unless otherwise directed by the prescriber, the label shall bear the brand name, or if there is no brand name, the generic name of the drug dispensed, the strength of the drug, and the quantity dispensed. ***Under no circumstances shall the label bear the name of any product other than the one dispensed*** (emphasis added).

657 Iowa Administrative Code section 8.15 provides, in part, the following:

Records. When a pharmacist exercises the drug product selection prerogative pursuant to Iowa Code section 155A.32, the following information shall be noted:...

8.15(2) The name, strength, and either the manufacturer's or distributor's name or the National Drug Code (NDC) of the actual drug product dispensed shall be placed on the file copy of the prescription drug order whether it is issued orally or in writing by the prescriber. This information shall also be indicated on the prescription in those instances where a generically equivalent drug is dispensed from a different manufacturer or distributor than was previously dispensed. This information may be placed upon patient medication records if such records are used to record refill information.

657 Iowa Administrative Code section 9.1(4) provides, in part, the following:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses:...

b. Professional incompetency. Professional incompetency includes but is not limited to:...

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

....

c. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engaging in unethical conduct or practice

harmful to the public. Proof of actual injury need not be established.

....

g. Use of untrue or improbable statements in advertisements.

....

j. Violating a statute or law of this state, another state, or the United States, without regard to its designation as either a felony or misdemeanor, which statute or law relates to the practice of pharmacy.

....

u. Violating any of the grounds for revocation or suspension of a license listed in Iowa Code sections 147.55, 155A.12 and 155A.15.

The Iowa Board of Pharmacy Examiners finds that paragraphs 10 and 11 constitute grounds for which Respondent's license to practice pharmacy in Iowa can be suspended or revoked.

WHEREFORE, the undersigned charges that Respondent has violated 1991 Iowa Code sections 147.55(3), 147.55(7), 155A.12(1), 155A.12(2), 155A.12(3), 155A.23(2), 155A.23(5), 155A.28, 155A.32, 203B.3(1), 203B.3(5), 203B.9(2), 203B.9(3), 203B.10(1), 203B.10(9)(a), 203B.10(9)(b), and 203B.10(9)(c) and 657 Iowa Administrative Code sections 8.5(1), 8.5(8), 8.6, 8.14(1)(g), 8.15(2), 9.1(4)(b)(2), 9.1(4)(c), 9.1(4)(g), 9.1(4)(j), and 9.1(4)(u).

IT IS HEREBY ORDERED that Garvis G. Houck appear before the Iowa Board of Pharmacy Examiners on Monday, November 23, 1992, at 10:00 a.m., in the second floor conference room, 1209 East Court Avenue, Executive Hills West, Capitol Complex, Des Moines, Iowa.

The undersigned further asks that upon final hearing the Board enter its findings of fact and decision to suspend or revoke the license to practice pharmacy issued to Garvis G. Houck on August 13, 1957, and take whatever additional action that they deem necessary and appropriate.

Respondent may bring counsel to the hearing, may cross-examine any witnesses, and may call witnesses of his own. If Respondent fails to appear and defend, Iowa Code section 17A.12(3) provides that the hearing may proceed and that a decision may be rendered. The failure of Respondent to appear could result in the permanent suspension or revocation of his license.

The hearing will be presided over by the Board which will be assisted by an administrative law judge from the Iowa Department of Inspections and Appeals. The office of the Attorney General is responsible for the public interest in these proceedings. Information regarding the hearing may be obtained from Lynette A. F. Donner, Assistant Attorney General, Hoover Building, Capitol Complex, Des Moines, Iowa 50319 (telephone 515/281-8760). Copies of all filings with the Board should also be served on counsel.

IOWA BOARD OF PHARMACY EXAMINERS

A handwritten signature in cursive script, reading "Lloyd K. Jessen", is written over a horizontal line.

Lloyd K. Jessen
Executive Secretary/Director

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

Re: Pharmacist License of)	NOTICE OF
GARVIS G. HOUCK)	
License No. 12338)	EX PARTE COMMUNICATION

COMES NOW, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 28th day of January, 1993, and declares that:

1. Notice is hereby given of written ex parte communication sent by the Respondent to members of the Iowa Board of Pharmacy Examiners at their place of residence or business on or about January 27, 1993, in violation of Iowa Code section 17A.17(2).

2. On January 27, 1993, Board Member Marian L. Roberts, vice chair, notified the executive secretary/director that she had received, at her home, written communications from the Respondent which had been sent by U. S. priority mail on January 26, 1993.

3. Similar written ex parte communications sent via U. S. priority mail were also received by Board Chair Alan Shepley, and Board Members Phyllis Olson, Arlan Van Norman, Phyllis Miller, Ronald Reiff, and Donna Flower.

4. As provided by Iowa Code section 17A.17(2) and 657 Iowa Administrative Code section 9.21, parties in a contested case shall not communicate, directly or indirectly, in connection with any issue of fact or law in that contested case, with individuals assigned to render a proposed or final decision or to make findings of fact and conclusions of law in that contested case, except upon notice and opportunity for all parties to participate as shall be provided for by agency rules.

5. A formal administrative hearing on this matter is currently set before the Board for February 1, 1993, in Des Moines, Iowa.



Lloyd K. Jessen
Executive Secretary/Director
IOWA BOARD OF PHARMACY EXAMINERS
1209 East Court Avenue
Des Moines, IA 50319
Telephone: 515/281-5944

copy to:
Lynette Donner, A.A.G.
Margaret LaMarche, A.L.J.

BEFORE THE IOWA BOARD OF PHARMACY EXAMINERS

RE: Pharmacist License of)	
)	DIA NO. 92PHB-10
GARVIS G. HOUCK)	
)	
License No. 12338)	FINDINGS OF FACT,
)	CONCLUSIONS OF LAW,
Respondent)	DECISION AND ORDER

TO: GARVIS G. HOUCK

A Complaint and Statement of Charges and Notice of Hearing was filed by Lloyd K. Jessen, Executive Secretary of the Iowa Board of Pharmacy Examiners (Board) on October 19, 1992. The Complaint alleged that the Respondent had violated a number of pharmacy-related statutes and rules. The Complaint and Statement of Charges included the Notice of Hearing, which set the hearing for November 23, 1992. The hearing, which was rescheduled, was held on February 2, 1993, at 10:00 a.m. at the Hotel Fort Des Moines, 10th and Walnut, Des Moines, Iowa. Present were the following members of the Board: Alan M. Shepley, Chairperson; Marian Roberts, Vice Chairperson; Phyllis A. Miller; Phyllis A. Olson; and Arlan D. Van Norman. Lynette Donner, Assistant Attorney General, appeared on behalf of the State. The Respondent, Garvis G. Houck, appeared and was represented by his counsel, Mark Young. Margaret LaMarche, Administrative Law Judge from the Iowa Department of Inspections and Appeals, presided. All of the testimony was recorded by a certified court reporter. The hearing was open to the public. The record was left open to allow the Respondent to submit evidence in response to State's Exhibit K. On February 5, 1993, the record was closed by agreement of the parties. After hearing the testimony and examining the exhibits, the Board convened in closed executive session pursuant to Iowa Code section 21.5(1)(f) (1991) to deliberate. The undersigned administrative law judge was instructed to prepare this Board's Decision and Order.

THE RECORD

The record includes the Complaint and Statement of Charges, the Notice of Ex Parte Communication, the packet of information sent to the Board members, the recorded testimony of the witnesses, and the following exhibits:

State's Exhibits:

- A - Investigative Report 12/20/90 and Attachments (I - XI)
- AA- Drug Samples I, III, V and VI
- B - Materials received April 6, 1992 from S.T., R.Ph.

- C - Letters from Glaxo dated April 13, 1992 and June 29, 1992
- D - Letter from Searle dated July 17, 1992
- E - Complaint report no. C92072 dated August 6, 1992 with attached Investigative Report dated August 14, 1992
- F - Supplemental Investigative Report dated September 8, 1992 with attached Sandoz correspondence
- G - Comparison of Mason City Shopper ads
- H - Resume' - Nita K. Pandit
- I - Presentation materials by Dr. Pandit
- J - Journal Article - "Gastrointestinal absorption II: Formulation factors affecting bioavailability", Blanchard, American Journal of Pharmacy, Sept.-Oct. 1978, pp. 132 - 151
- K - Correspondence January 14, 1993 from Glaxo, January 20, 1993 from Searle

Respondent's Exhibits:

- B - 1992 Ads and attached prescription labels
- G - October 26, 1992 letter from The Shopper
- H - Compounding Quality Control Protocol
- I - Statements from patients
- J - Letters from physicians
- K - R̄ for .075 mg Alprazolam
- L - R̄ specialty preparations (compounded)
- M - R̄ compounded drugs
- O - Letter dated October 29, 1992 from Professional Compounding Centers of America, Inc.
- P - Invoices for purchases of Zantac 300 mg.
- Q - October 27, 1992 Statement of Dick Connor
- T - Phone bill - May, 1992

U - Clear Lake telephone listing

Y - Work Sheets from Bulk Compounding Log

FINDINGS OF FACT

1. Respondent was issued a license to practice pharmacy in Iowa on August 13, 1957, by examination. Respondent's license to practice pharmacy is current until June 30, 1994. (official file)

2. Respondent is currently self-employed as pharmacist in charge and owner of Houck Drug Company, Inc., 8 North 4th Street, Clear Lake, Iowa 50428. (official file; testimony of Respondent)

False or Misleading Advertising

3. On October 27, 1990, the Board received a complaint from an Iowa pharmacist concerning an advertisement which the Respondent had placed in the Mason City Shopper on October 16, 1990. The advertisement listed 12 brand name drugs and "birth control", each followed by the statement, "If you now pay more than \$_____, see us." A specific price was listed for each drug. Effective dates for the prices were not given. The complaining pharmacist alleged that the advertisement was false or misleading because the prices listed were well below the typical net acquisition price for each of the name brand products. The pharmacist alleged that the drug being sold at the listed price was not the brand name drug. (testimony of Gary Ebeling; State's Exhibits A, AI)

4. The Board's investigator, Gary Ebeling, R.Ph., questioned the Respondent about the October 16th ad and determined:

a) Of the 12 name brand drugs listed in the ad, Respondent sold only three for the stated price.

b) For eight of the name brand drugs, Respondent substituted a product that he extemporaneously compounded from either bulk chemicals or from higher strength dosages of commercially available brand name products.

c) For one of the listed drugs Respondent provided a different brand name drug for the price listed in the ad.

(testimony of Ebeling, Respondent; State's Exhibit AI)

5. The Respondent did not intend to mislead the public. In his opinion, the ad did not purport to offer the brand names for the prices given. Investigator Ebeling told Respondent that he felt that the ad could be misleading to the public, and Respondent agreed not to run the ad again. (testimony of Ebeling, Respondent)

6. On November 20, 1990, the Respondent ran another ad in the Mason City Shopper. This ad was similar to the October 16th ad, however, the Respondent changed it to read "For the alternative, you pay only \$_____ per hundred, after the brand name was listed. The Respondent felt that with this change, the ad could not be construed as misleading. Again, the ad did not state the time period the prices would be honored. The Respondent told Ebeling that the prices were good for a month at a time. Mr Ebeling expressed concern about the second ad and Respondent did not run it a second time. (testimony of Ebeling, Respondent; State's Exhibit AX).

7. In July, October and November 1991, and March 1992, the Respondent ran ads in the Mason City Shopper. These ads gave a brand name drug and stated, "For the name brand, you pay only \$_____." A pharmacist complained to the Board that these ads were false or misleading because the typical pharmacy's net acquisition cost for the name brand drugs was higher than the listed price. The Respondent's records indicated that the name brands were provided at the price listed in the ads. Respondent admitted to offering some drugs below his cost in order to retain his customers in a highly competitive market. (testimony of Ebeling, Respondent; State's Exhibit G, State's Exhibit A, p.44; Respondent's Exhibit B)

Compounding

8. The State's expert witness, Nita Pandit, Ph.D., teaches a course on compounding at the College of Pharmacy and Health Sciences, Drake University. Dr. Pandit was previously employed as a scientist for a pharmaceutical company. Dr. Pandit teaches her students how to compound drugs when there is no therapeutically suitable commercial product for the patient. The Food and Drug Administration (FDA), which has jurisdiction over manufacturers but not over compounding pharmacists, has stringent regulations governing the manufacturing process to ensure that the resulting drug and drug product is safe, pure, and effective. A manufacturer seeking FDA approval for a generic drug must demonstrate that their product has the same bioavailability as the FDA-approved name brand drug. This means that the rate and extent of the drug appearing in the bloodstream must be exactly the same for the generic and the name brand drug. (testimony of Nita Pandit, Ph.D., State's Exhibits H, I)

9. Based on her personal experience as a pharmaceutical company scientist, Dr. Pandit testified that formulating a generic with the same bioavailability as the brand name drug is a long and difficult process requiring much trial and error. Using the same drugs with the same concentration is only the starting point. Different excipients (nonactive ingredients) or procedures affect the drug products' bioavailability. As shown in Exhibit I, three different

formulations using the same drug and the same concentration all resulted in different drug profiles. Even after FDA approval is given to a drug product, any change in the formulation or process may cause the FDA to require new bioavailability studies. (testimony of Nita Pandit, Ph.D.; State's Exhibits H, I, J)

10. When compounding is accomplished by crushing tablets and adding excipients (e.g, lactose) to make capsules, many problems can occur:

- a) If the tablets are ground too fine, the drug may dissolve faster than was intended;
- b) Grinding may destroy the coating, which is added to the tablet for stability and gastric protection;
- c) If the tablet is a sustained release product, crushing can cause the patient to get the dosage all at once (dose dumping);
- d) Certain excipients may interact adversely with the drug;
- e) The moisture from the capsule may adversely affect certain drugs;
- f) Removal of a tablet's coating, through crushing, may affect its bioavailability.

(testimony of Nita Pandit, Ph.D.; State's Exhibits H, I, J)

11. Due to the risks associated with a compounded drug product which is not subject to FDA regulation, if a pharmacist has a choice between a commercially available product and a compounded product, then the best interests of the patient requires that the commercially available products be used. The cost of the commercially available product would be higher, because of the rigorous FDA requirements for approval. However, patient safety and well being is the first priority, and a less safe or effective drug should not be chosen solely for economic reasons. (testimony of Nita Pandit, Ph.D.; State's Exhibits H, I, J)

12. If there is no commercially available therapeutically suitable product, in the dose prescribed, then it is appropriate for the pharmacist to compound in order to meet the needs of the physician and the patient. (testimony of Nita Pandit, Ph.D.; State's Exhibits H, I, J)

13. The Respondent was trained in compounding while a student at the University of Iowa Pharmacy School. Respondent did a limited amount of compounding in his practice until two years ago, when he attended training offered by Professional Compounding Centers of America, Inc. (PCCA) of Sugar Land, Texas. Following this

training, the Respondent became enthusiastic about the potential of compounding, and began compounding more frequently in his practice. Respondent utilized the Compounding Quality Control Protocol published by PCCA and a master formula work sheet. Some of the compounding done by the Respondent is for specialty products which are not otherwise commercially available. The remainder of the compounding is to produce drug products that are otherwise commercially available, but at a significantly lower cost. The Respondent has passed considerable cost savings on to his patients, and has economically benefitted himself as well. (testimony of Respondent, Gary Ebeling; State's Exhibit A; Respondent's Exhibits H, K, L, M, Y)

14. When extemporaneously compounding drug products for prescriptions which called for either Calan SR 240 mg or Calan SR 180 mg (both commercially available products), Respondent utilized a bulk chemical labeled as "Verapamil Hydrochloride BP 80" which he obtained from PCCA. During the months of October and November 1990, Respondent dispensed seven prescriptions of #100 Verapamil SR 240 mg each, in this manner. (testimony of Gary Ebeling, Respondent, James Theis, R.Ph.; State's Exhibit A)

15. When extemporaneously compounding drug products for prescriptions which called for Dyazide (a commercially available product) Respondent utilized a bulk chemical labeled as "Triamterene USP" and another bulk chemical labeled as "Hydrochlorothiazide USP" which he also obtained from PCCA. During the months of October and November 1990, Respondent dispensed 16 prescriptions of #100 Triamterene 50 mg/Hydrochlorothiazide 25 mg each, in this manner. (testimony of Gary Ebeling, Respondent, James Theis, R.Ph.; State's Exhibit A)

16. When extemporaneously compounding drug products for prescriptions which called for Corgard 40 mg (a commercially available product), Respondent crushed tablets of Corgard 120 mg and added lactose, encapsulating enough of the mixture to constitute 40 mg of Corgard per capsule. (testimony of Ebeling, Respondent, Theis; State's Exhibit A)

17. When extemporaneously compounding drug products for prescriptions which called for Capoten 25 mg (a commercially available product), Respondent crushed tablets of Capoten 100 mg and added lactose, encapsulating enough of the mixture to constitute 25 mg of Capoten per capsule. During the months of October and November 1990, Respondent dispensed two prescriptions of #100 Capoten 25 mg each, in this manner. (testimony of Ebeling, Respondent, Theis; State's Exhibit A)

18. When extemporaneously compounding drug products for prescriptions which called for Tenormin 50 mg (a commercially available product), Respondent crushed tablets of Tenormin 100 mg and added

lactose, encapsulating enough of the mixture to constitute 50 mg of Tenormin per capsule. (testimony of Ebeling, Respondent, Theis; State's Exhibit A)

19. When extemporaneously compounding drug products for prescriptions which called for Vasotec 5 mg (a commercially available product), Respondent crushed tablets of Vasotec 10 mg and added lactose, attempting to encapsulate enough of the mixture to constitute 5 mg of Vasotec per capsule. For prescriptions which called for Vasotec 10 mg (also a commercially available product), Respondent used the same procedure, crushing tablets of Vasotec 20 mg. (testimony of Ebeling, Respondent, Theis; State's Exhibit A)

Ranitidine capsules

20. On April 6, 1992, the Board received a complaint from an Iowa pharmacist employed at St. Joseph Mercy Hospital in Mason City. The Respondent had sent a handwritten letter to Gary M. Levinson, M.D., of Mason City, seeking Dr. Levinson's approval for the dispensing of Respondent's extemporaneously compounded "Zantac" 150 mg to one of Dr. Levinson's female patients. The prescription, as written by Respondent, stated the following:

[name of patient]
Clear Lake
(from Zantac)
Ranitidine 150 mg capsules
#30
One twice a day.

In Respondent's letter to Dr. Levinson, dated March 26, 1992, Respondent asked Dr. Levinson's approval and explained that Zantac 300 mg tablets are crushed and converted into 150 mg capsules with Lactose N.F. as the diluent. Respondent noted that his lab was equipped with a Fetton capsule machine and a Denver Instrument electronic balance sensitive to 10 mg. Dr. Levinson refused to give his approval. (testimony of James Theis, R.Ph.; Exhibit B)

21. Subsequently the Board received a written complaint from RC, Group Manager, Security Services, Glaxo, Inc., of Research Triangle Park, North Carolina (the manufacturer of Zantac). Apparently both a local pharmacist and RC on separate occasions presented prescriptions to Respondent for Zantac 150 mg tablets and Respondent convinced them each to accept his more economical capsules which were compounded from Zantac 300 mg tablets. On the bottle label was typed "(from Zantac) ranitidine 150 mg PCCA." Respondent charged \$5.00 less than he would have charged for brand name Zantac 150 mg tablets. (testimony of Theis; State's Exhibit C)

22. Glaxo's Quality Assurance Department tested the capsules for content and impurities. They evaluated the capsules against Glaxo,

Inc. release requirements and concluded that the capsules contained the active ingredient ranitidine hydrochloride, but in a quantity substantially less than indicated for Zantac. Comparison of the capsule content did not confirm compounding from Zantac 300 mg tablets. In a letter dated January 14, 1993, Glaxo explained that they concluded the capsules did not contain ground up Zantac 300 mg because of the absence of the yellow dye present in Zantac 300 mg tablets. If the Respondent did not use Zantac tablets, then his only other sources of ranitidine would be illegal. However, the Respondent credibly testified that he only used Zantac 300 mg tablets to make his ranitidine 150 mg capsules. Respondent submitted invoices for the purchase of large quantities of Zantac 300 mg tablets, from McKesson Drug, many more than he would require in his practice. Respondent's Master Formula Work Sheets illustrates his use of the Zantac. Respondent's methods, which include straining the crushed tablets, could account for Glaxo's inability to detect yellow dye in their testing. Moreover, the Board notes that the letters from Glaxo were hearsay evidence, and therefore entitled to less weight than direct evidence. In addition, Glaxo, as the manufacturer of Zantac, had its own interests involved in this issue because Respondent was attempting to compete with its product. A representative of Glaxo, who did not testify, took the capsules from Respondent, arranged for the testing by Glaxo, and then reported their conclusions to the Board. Given all of these circumstances, the Board believed the Respondent, and concludes that he used Zantac 300 mg tablets, not illegally purchased ranitidine, to compound his product. (testimony of Respondent, Theis, Pandit; State's Exhibits C, K; Respondent's Exhibits P, Y)

Dispensing Without Prescriber Authorization

23. On August 6, 1992, Steven Miller complained to the Board concerning a prescription that had been filled by the Respondent. Miller, who had had surgery for a brain tumor, was taking the drug Parlodel. Miller went to the Respondent in late May 1992, in response to one of Respondent's ads. Miller had been taking Parlodel 1.25 mg. since January 1992. Respondent testified that he called Miller's physician, Dr. Caughlan, on May 27, 1992, to seek authorization to compound bromocryptine mesylate 1.25 mg capsules from Parlodel 5 mg. Respondent's phone bill confirms a call to Dr. Caughlan's office on May 27, 1992. According to Respondent, Dr. Caughlan's nurse authorized the prescription. When the Board's investigator interviewed Dr. Caughlan to determine if he had in fact authorized the compounding, they examined Mr. Miller's medical record and found no notation of the authorization. Dr. Caughlan signed a statement for the investigator stating that he did not authorize the prescription. Dr. Caughlan later submitted a statement supporting Respondent which said that the Respondent had done compounding work for several of his patients, and that he never doubted the quality or veracity of his work. (testimony of Theis, Respondent; State's Exhibit E; Respondent's Exhibit J)

24. Miller's prescription for Parlodel was increased from 1.25 to 2.5 mg on July 7, 1992 due to his rising prolactin level. The capsules supplied by Respondent were analyzed by the manufacturer and found to contain the appropriate amounts of bromocriptine mesylate. Based on this record, the Board cannot conclude that the rise in the patient's prolactin level was caused by the Respondent's capsules. (testimony of Theis, Exhibits E, F, J)

25. When the Respondent's customer was interested in his compounded drug product, Respondent would often type a prescription for the compounded product and have the customer take it to his doctor for a signature. If the Respondent had an established relationship with the physician who was familiar with his compounded products, the Respondent would call the physician for authorization. (testimony of Respondent; Exhibit J)

Misbranded or Mislabeled Drugs

26. When Respondent filled the prescription for RC, Group Manager, Security Services, for Glaxo, the bottle was labeled "(from Zantac) ranitidine 150 mg, PCCA." (State's Exhibit C)

27. In addition to the bromocriptine mesylate 2.5 mg capsules which Respondent compounded for Steven Miller, he also compounded cortisone acetate 10 mg capsules for him. However, the capsules had no external markings on them and there was no way to differentiate the two medications after they were taken out of their bottles. (State's Exhibit E)

CONCLUSIONS OF LAW

False or Misleading Advertising

1. 1991 Iowa Code section 147.55 provides, in part, the following:

A license to practice a profession shall be revoked or suspended when the licensee is guilty of the following acts or offenses: . . .

3. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of a profession or engaging in unethical conduct or practice harmful or detrimental to the public. Proof of actual injury need not be established.

7. Use of untruthful or improbable statements in advertisements.

(See also 657 IAC 9.1(4)(g))

2. 1991 Iowa Code section 203B.3 provides, in part, the following:

The following acts and the causing of the acts within this state are unlawful:

• • •

5. The dissemination of any false advertising.
3. 657 IAC 8.6 provides, in part, the following:

Advertising. Prescription drug price and nonprice information may be provided to the public by a pharmacy so long as it is not false or misleading and not in violation of any federal or state laws applicable to the advertisement of such articles generally and if all of the following conditions are met:

1. All charges for services to the consumer must be stated.
2. The effective dates for the prices listed shall be stated . . .

The Respondent's advertisement which was published in the Mason City Shopper on October 16, 1990 was misleading to the public, in violation of 657 IAC 8.6. The average consumer would assume that the Respondent was offering the brand name drug for the price listed. However, the Respondent was not actually selling the brand name drug for the price in the ad.

The advertisement of November 20, 1990 was also misleading. The average consumer would conclude that the "alternative" offered by the Respondent was an FDA approved generic drug. In fact, the alternative was Respondent's own compounded drug product.

The Board believes that the Respondent did not intend to mislead the public by these ads. In terms of the public's perception and understanding, the ads were poorly drafted. The Board notes that the Respondent cooperated with the Board's investigator and did not run the ads again after the investigator expressed his concern. The Respondent did not knowingly make misleading representations.

The ads run by the Respondent in 1991 and 1992 were not misleading, because the Respondent did sell all of the name brands listed for the stated price.

However, all of the ads failed to list the effective dates of the prices listed, in violation of 657 IAC 8.6(2).

Compounding

4. 1991 Iowa Code section 155A.12 provides, in part, the following:

. . . The board may refuse to issue or renew a license or may impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, and may place a licensee on probation, if the board finds that the applicant or licensee has done any of the following:

1. Violated any provision of this chapter or any rules of the board adopted under this chapter.
2. Engaged in unethical conduct as that term is defined by rules of the board.

5. 1991 Iowa Code section 155A.32 provides, in part, the following:

1. If an authorized prescriber prescribes, either in writing or orally, a drug by its brand name or trade name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and **demonstrated bioavailability** as the one prescribed for dispensing and sale to the patient. . . . If the pharmacist exercises drug product selection, the pharmacist shall inform the patient of the savings which the patient will obtain as a result of the drug product selection and pass on to the patient no less than fifty percent of the difference in actual acquisition costs between the drug prescribed and the drug substituted.

2. The pharmacist shall **not** exercise the drug selection described in this section if . . . the following is true:

- a. The prescriber specifically indicates that no drug product selection shall be made (emphasis added).

6. 1991 Iowa Code section 203B.3 provides, in part, the following:

The following acts and the causing of the acts within this state are unlawful:

1. The introduction or delivery for introduction into commerce of any drug, device, or cosmetic that is adulterated or misbranded.

7. 1991 Iowa Code section 203B.9 provides, in part, the following:

A drug or device is adulterated under any of the following circumstances: . . .

2. If it purports to be or is represented as a drug, the name of which is recognized in an official

compendium, and its strength differs from, or its quality or purity falls below, the standards set forth in the official compendium . . .

3. If it is not subject to subsection 2 and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

8. 657 Iowa Administrative Code section 8.5 provides, in part, the following:

Unethical conduct or practice. The provisions of this section apply to licensed pharmacists and registered pharmacist-interns.

8.5(1) Misrepresentative deeds. A pharmacist shall not make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in pharmacy or in the operation or conduct of a pharmacy.

9. 657 Iowa Administrative Code section 9.1(4) provides, in part, the following:

The board may impose any of the disciplinary sanctions set out in subrule 9.1(2), including civil penalties in an amount not to exceed \$25,000, when the board determines that the licensee or registrant is guilty of the following acts or offenses: . . .

b. Professional incompetency. Professional incompetency includes but is not limited to: . . .

(2) A substantial deviation by a pharmacist from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

c. Knowingly making misleading, deceptive, untrue or fraudulent representations in the practice of pharmacy or engaging in unethical conduct or practice harmful to the public. Proof of actual injury need not be established.

The preponderance of the evidence presented at the hearing established that the Respondent's practice of compounding his own drug products and substituting them for commercially available products that have been prescribed, violates Board statutes and rules and constitutes a substantial deviation from the standards of learning or skill ordinarily possessed and applied by other pharmacists in the state of Iowa acting in the same or similar circumstances.

In addition, the Respondent's actions are misleading both to the average consumer and to physicians, who are generally unaware that the compounded drugs offered by Respondent are not FDA approved and do not have the same demonstrated bioavailability as the commercially available product.

The compounding of specialty products by a pharmacist for drug products that are not commercially available is clearly authorized and desirable. In this case, however, the Respondent was compounding drug products where there was a commercially available FDA approved product. Given the risks associated with non FDA approved drug products, i.e., their safety and effectiveness are unproven, it is incompetent for a pharmacist to dispense them for purely economic reasons, when there is a commercially available product. In essence, the pharmacist who does so is purporting to offer a generic drug, without complying with the requirements of Iowa Code section 155A.32(1) (1991). This is consistent with what is taught to pharmacists who are educated in Iowa.

In addition, although the Respondent explained to the patient and the physician that the product he dispensed was compounded, it is not likely that either the average consumer or the average physician fully understood the risks associated with the compounded products. It is the pharmacist's responsibility to explain to the consumer and the physician that the compounded product is not proven pure, safe, or effective. The Respondent's own testimony indicates that he felt the observations of two professionals, a physician and a pharmacist, of the therapeutic outcome following administration of the compounded product, was equivalent or superior to bioavailability testing. If the Respondent does not understand the risks of his compounded product, he cannot be adequately conveying those risks to the consumer or the physician.

The Respondent's dispensing of compounded drug products when there were commercially available products violated Iowa Code sections 155A.32(1), 203B.3(1), 203B.9(3) (1991), and 657 IAC 8.5(1) and 9.1(4)(b)(2) and (c).

Ramitidine Capsules

10. The preponderance of the evidence failed to establish that the Respondent used illegal ranitidine to compound his Ranitidine 150 mg capsules. The Board found Respondent's testimony that he crushed Zantac 300 mg tablets to be credible.

Dispensing Without Prescriber Authorization

11. The preponderance of the evidence did not establish that the Respondent dispensed his compounded drugs without prescriber authorization. The Board found the Respondent's testimony and documentation concerning prescriber authorization to be credible.

Misbranded or Mislabeled Drugs

12. 1991 Iowa Code section 155A.23 provides, in part, the following:

A person shall not: . . .

2. Willfully make a false statement in any prescription, report, or record required by this chapter.

5. Affix any false or forged label to a package or receptacle containing prescription drugs.

13. 1991 Iowa Code section 155A.28 provides the following:

The label of any drug or device sold and dispensed on the prescription of a practitioner shall be in compliance with rules adopted by the board.

14. 1991 Iowa Code section 203B.10 provides, in part, the following:

A drug or device is misbranded under any of the following circumstances:

1. If its labeling is false or misleading in any particular.

9. a. If it is a drug and its container is so made, formed, or filled as to be misleading.

b. If it is an imitation of another drug.

c. If it is offered for sale under the name of another drug.

15. Iowa Administrative Code section 8.14 provides, in part, the following:

Prescription label requirements.

8.14(1) The label affixed to or on the dispensing container of any prescription dispensed by a pharmacy pursuant to a prescription drug order shall bear the following: . . .

g. Unless otherwise directed by the prescriber, the label shall bear the brand name, or if there is no brand name, the generic name of the drug dispensed, the strength of the drug, and the quantity dispensed. **Under no circumstances shall the label bear the name of any product other than the one dispensed** (emphasis added).

The Respondent violated Iowa Code sections 155A.23(5); 155A.28, 203B.10(1) and (9) (1991) and 657 IAC 8.14(1)(g) when he placed the brand name on a prescription label after the brand name product had been altered.

DECISION AND ORDER

THEREFORE, IT IS THE ORDER of the Iowa Board of Pharmacy Examiners that the Respondent, Garvis G. Houck, License No. 12338, is hereby issued the following citation and warning:

- 1) That the Respondent has violated Iowa Code sections 155A.32(1), 203B.3(1), 203B.9(3) (1991), and 657 IAC 8.5(1), 9.1(b)(2) and (c), and 8.6(2).
- 2) That the Respondent is ordered to CEASE AND DESIST compounding drug products when there is a commercially available drug product.
- 3) That all advertisements by the Respondent shall contain effective dates for any prices listed.

IT IS FURTHER ORDERED, that the License No. 12338, issued to the Respondent, shall be placed on probation for one year, subject to the following terms and conditions:

- 1) Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.
- 2) Respondent shall report to the Board or its designee quarterly. Said report shall be either in person or in writing.
- 3) Respondent shall submit to peer review as deemed necessary by the Board.
- 4) Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board.
- 5) During the period of probation, Respondent shall not supervise any registered intern and shall not perform any of the duties of a preceptor.
- 6) Should Respondent leave Iowa to reside or practice outside this state, Respondent must notify the Board in writing of the dates of departure and return. Periods of residency or practice outside the state shall not apply to reduction of the probationary period.
- 7) Should Respondent violate probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and impose further discipline. If a petition to revoke probation is filed against Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

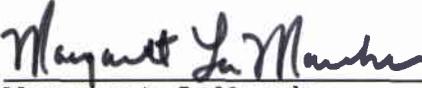
8) Upon successful completion of probation, Respondent's certificate will be fully restored.

Finally, it is ORDERED, pursuant to Iowa Code section 258A.6 and 657 IAC 9.27, that the Respondent shall pay \$75.00 for fees associated with conducting the disciplinary hearing. In addition, the executive secretary of the Board shall bill the Respondent for witness fees and expenses and any transcript costs associated with this disciplinary hearing. The Respondent shall remit for these expenses within thirty (30) days of receipt of the bill.

Dated this 19th day of FEBRUARY, 1993



Alan M. Shepley, Chairperson
Iowa Board of Pharmacy Examiners



Margaret LaMarche
Administrative Law Judge

ML/jmm

Copies to:

Lynette Donner
Mark Young

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

Re:

Pharmacist License of)	AMENDED
GARVIS G. HOUCK)	ORDER
License No. 12338)	DIA NO. 92PHB-10
<u>Respondent</u>		

COMES NOW, Marian L. Roberts, Chairperson of the Iowa Board of Pharmacy Examiners, on the 12th day of October, 1993, and declares that:

1. On September 24, 1993, Garvis G. Houck, R.Ph., (hereafter the Respondent) filed an application with the Iowa Board of Pharmacy Examiners (hereafter the Board), seeking certain amendments to a pharmacy board disciplinary Order issued in the above entitled action on February 19, 1993.

2. On October 12, 1993, the Board considered the Respondent's application and voted to authorize an amendment to the above referenced pharmacy board Order.

THEREFORE IT IS ORDERED that paragraph 2 of the *citation and warning* on page 15 of the above referenced pharmacy board disciplinary Order dated February 19, 1993, is hereby deleted from the Order and is replaced with the following provision:

2) That the Respondent shall follow and adhere to the attached "Good Compounding Practices" guideline (or a successor rule as may be adopted by the Board) whenever engaging in the compounding of drugs and drug products.

Effective this 12th day of October 1993.

IOWA BOARD OF PHARMACY EXAMINERS



Marian L. Roberts, Chairperson

IOWA BOARD OF PHARMACY EXAMINERS
Good Compounding Practices
Guideline
October 12, 1993

The following Good Compounding Practices (GCPs) are meant to apply to compounding of drugs by Iowa-licensed pharmacists and pharmacies.

General Provisions.

The recommendations contained herein are considered to be the minimum current good compounding practices for the preparation of drug products by Iowa-licensed pharmacists and pharmacies for dispensing and/or administration to humans or animals.

Pharmacists engaged in the compounding of drugs shall operate in conformance with applicable Iowa law regulating the practice of pharmacy.

The following definitions from Board rules contained in 657 Iowa Administrative Code chapter 8 apply to these Good Compounding Practices:

657-8.23(155A) Compounding. "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

1. 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, or

2. For the purpose of, or as an incident to, research, teaching, chemical analysis, and not for sale or dispensing.

Compounding also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

657-8.24(155A) Manufacturing. "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 its container. Manufacturing also includes the preparation, promotion, and marketing of commercially available products from bulk compounds for resale by pharmacists, practitioners, or other persons.

In addition, the following definition applies to these Good Compounding Practices:

Component. "Component" means any ingredient intended for use in the compounding of a drug product, including those that may not appear in such product.

Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription, or in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace.

In compounding prescriptions, pharmacists shall receive, store, and use drug substances and drug components that meet official compendia requirements. If these requirements can't be met, and pharmacists document such, pharmacists shall use their professional judgment in the procurement of acceptable alternatives.

Pharmacists may compound drugs in very limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/prescriber relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy as required by Iowa law. The distribution of compounded products without a prescriber/patient/pharmacist relationship is considered manufacturing.

Pharmacists shall not offer compounded drug products to other State-licensed persons or commercial entities for subsequent resale, except in the course of professional practice for a practitioner to administer to an individual patient. Compounding pharmacies/pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services; however, they shall not make a claim, assertion, or inference of professional superiority in the compounding of drug products which cannot be substantiated. All advertisements shall meet the requirements contained in 657 Iowa Administrative Code section 8.6.

Organization and Personnel.

As in the dispensing of all prescriptions, the pharmacist has the responsibility and authority to inspect and approve or reject all components, drug product containers, closures, in-process materials, and labeling, and has the authority to prepare and review all compounding records to assure that no errors have occurred in the compounding process. The pharmacist is also responsible for the proper maintenance, cleanliness, and use of all equipment used in prescription compounding practice.

All pharmacists who engage in compounding of drugs shall be proficient in the art of compounding and shall maintain that proficiency through current awareness and training. Also, every pharmacist who engages in drug compounding must be aware of and familiar with all details of these Good Compounding Practices.

While non-pharmacist personnel may assist in the compounding of drug products, the supervising pharmacist remains responsible for all work performed by the non-pharmacist.

Personnel engaged in the compounding of drug products shall wear clean clothing appropriate to the operation being performed. Protective apparel shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.

Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of the drug compounding operation. Any person shown at any time (either by medical examination or pharmacist determination) to have an apparent illness or open lesions that may adversely affect the safety or quality of a drug product being compounded shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of the product(s) being compounded. All personnel who normally assist the pharmacist in compounding procedures shall be instructed to report to the pharmacist any health conditions that may have an adverse effect on drug products.

Drug Compounding Facilities.

Pharmacies engaging in compounding shall have a specifically designated and adequate area (space) for the orderly placement of equipment and materials to be used to compound medications. The drug compounding area for sterile products shall be separate and distinct from the area used for the compounding or dispensing of non-sterile drug products. The area(s) used for the compounding of drugs shall be maintained in a good state of repair.

Bulk drugs and other materials used in the compounding of drug products must be stored in adequately labeled containers in a clean, dry area or, if required, under proper refrigeration.

Adequate lighting and ventilation shall be provided in all drug compounding areas. Adequate washing facilities, easily accessible to the compounding area(s) of the pharmacy, shall be provided. These facilities shall include, but not be limited to, hot and cold water, soap or detergent, and air-driers or single-source towels.

The area(s) used for the compounding of drug products shall be maintained in a clean and sanitary condition. It shall be free of infestation by insects, rodents, and other vermin. Trash shall be held and disposed of in a timely and sanitary manner. Sewage, trash, and other refuse in and from the pharmacy and immediate drug compounding area(s) shall be disposed of in a safe and sanitary manner.

Sterile Products.

If sterile (aseptic) products are being compounded, the requirements contained in 657 Iowa Administrative Code section 8.12 shall be met.

If radiopharmaceuticals are being compounded, the requirements of 657 Iowa Administrative Code chapter 16 shall be met.

Special Precaution Products.

If drug products with special precautions for contamination, such as penicillin, are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, must be utilized in order to prevent cross-contamination.

Equipment.

Equipment used in the compounding of drug products shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance. Equipment used in the compounding of drug products shall be of suitable composition so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond that desired.

Equipment and utensils used for compounding shall be cleaned and sanitized immediately prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond that desired. In the case of equipment, utensils, and containers/closures used in the compounding of sterile drug products, cleaning, sterilization, and maintenance procedures as set forth in 657 Iowa Administrative Code section 8.12 must be followed.

Equipment and utensils used for compounding drugs must be stored in a manner to protect them from contamination. Immediately prior to the initiation of compounding operations, they must be inspected by the pharmacist and determined to be suitable for use.

Automatic, mechanical, or electronic equipment, or other types of equipment or related systems that will perform a function satisfactorily may be used in the compounding of drug products. If such equipment is used, it shall be routinely inspected, calibrated (if necessary), or checked to ensure proper performance.

Control of Components and Drug Product Containers and Closures.

Components, drug product containers, closures, and bagged or boxed components of drug product containers and closures used in the compounding of drug products shall be handled and stored in a manner to prevent contamination and to permit unhindered cleaning of the work area, (e.g., floors) and inspection.

Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the compounded drug beyond the desired result. Components, drug product containers, and closures for use in the compounding of drug products shall be rotated so that the oldest stock is used first. Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug product. Drug product containers and closures shall be clean and, where indicated by the intended use of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Drug product containers and closures intended for the compounding of sterile products must be handled, sterilized, stored, etc., in keeping with the requirements of 657 Iowa Administrative Code section 8.12. Methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures used in the preparation of sterile pharmaceuticals, if these processes are performed by the pharmacist, or under the pharmacist's supervision, following the requirements of 657 Iowa Administrative Code section 8.12.

Drug Compounding Controls.

There shall be written procedures for the compounding of drug products to assure that the finished products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include a listing of the components (ingredients), their amounts (in weight or volume), the order of component addition, and a description of the compounding process. All equipment and utensils and the container/closure system, relevant to the sterility and stability of the intended use of the drug product, shall be listed. These

written procedures shall be followed in the execution of the drug compounding procedure.

Components for drug product compounding shall be accurately weighed, measured, or subdivided as appropriate. These operations should be checked and rechecked by the compounding pharmacist at each stage of the process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is removed from the original container to another (e.g., a powder is taken from the original container, weighed, placed in a container, and stored in another container) the new container shall be identified with the:

- (a) component name, and
- (b) weight or measure.

To assure the reasonable uniformity and integrity of compounded drug products, written procedures shall be established and followed that describe the tests or examinations to be conducted on the product being compounded (e.g., compounding of capsules). Such control procedures shall be established to monitor the output and to validate the performance of those compounding processes that may be responsible for causing variability in the final drug product. Such control procedures shall include, but are not limited to, the following (where appropriate):

- (a) capsule weight variation;
- (b) adequacy of mixing to assure uniformity and homogeneity;
- (c) clarity, completeness, or pH of solutions.

Appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile shall be established and followed. Such procedures shall include validation of any sterilization process. Accountability for quality control is the responsibility of the compounding pharmacist.

Labeling Control of Excess Products.

In the case where a quantity of a compounded drug product in excess of that to be initially dispensed in accordance with the general provisions described above is prepared, the excess product shall be labeled or documentation referenced with the complete list of ingredients (components), the preparation date, and the assigned expiration date based upon professional judgment, appropriate testing, or published data. It shall also be stored and accounted for under conditions dictated by its composition and stability characteristics (e.g., in a clean, dry place on a shelf or in the refrigerator) to ensure its strength, quality, and purity.

At the completion of the drug finishing operation, the product shall be examined for correct labeling. Labeling shall conform with the label information requirements contained in 657

RECEIVED

JUL 3 1 2002

IOWA PHARMACY EXAMINERS

B. MICHAEL DUNN
Attorney at Law
23 Third Street N.W.
Mason City, Iowa 50401

Phone (641) 423-1433

e-mail: bmichaeldunn@yahoo.com

RECEIVED

JUL - 8 2002

IOWA PHARMACY EXAMINERS

Fax (641) 423-1436

July 3, 2002

Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite, E
Des Moines, IA 50309-4688

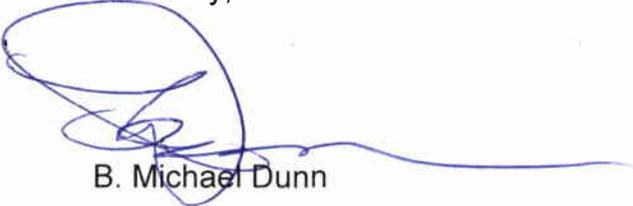
Re: Statement of Charges
Garvis G. Houck, Case No. 2002-12338
Houck Drug Co., Inc. Case No. 2002-793

Sirs:

Enclosed find the Answers of the above named respondents to the respective Statement of Charges.

Please return the extra copy of each Answer with your filing stamp affixed in the self addressed postage paid envelope enclosed.

Sincerely,



B. Michael Dunn

BMD:jh

Enclosures

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

IN THE MATTER OF:)	CASE NO. 2002-793
)	
HOUCK DRUG CO., INC.)	ANSWER
)	
Respondent)	

COMES NOW respondent, Houck Drug Co., Inc, and for response to the respective counts of the Statement of Charges filed herein states:

COUNT I

It denies said allegations.

COUNT II

It denies said allegations.

WHEREFORE, respondent prays said Statement of Charges be dismissed.

Dated on this 3rd day of July, 2002.

**B. Michael Dunn ISBA#000001342
Attorney at Law
23 Third Street N.W.
Mason City, Iowa 50401
Phone (641) 423-1433 Fax (641) 423-1436
ATTORNEY FOR RESPONDENT**

Original filed, copy to:

Shauna Russell Shields
Assistant Attorney General
Hoover State Office Building
Des Moines, IA 50419

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon all parties to the above cause to each of the attorneys of record herein at their respective addresses disclosed on the

pleadings, on July 3, 2002 19__

By: U.S. Mail Fax
 Hand Delivered UPS
 Federal Express Other

Signature:

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

IN THE MATTER OF:)	CASE NO. 2002-12338
GARVIS G. HOUCK,)	
)	MOTION TO DISMISS
Respondent.)	

COMES NOW the Respondent and moves the Iowa Board of Pharmacy Examiners to dismiss the pending Complaint and Statement of Charges for the following reasons:

1. The pending Complaint and Statement of Charges has, as its main focus, a claim that the Respondent and Respondent's pharmacy prepared a mixture of nonprescription medications in the form of a bottle of nose drops for a customer without having had the said product prepared in response to a prescription written by an authorized "prescriber".

2. The position of the Iowa Board of Pharmacy Examiners is that pharmacists are not permitted to mix, make, compound, or prepare any combination of products for sale to the public unless that compound is mixed, compounded or made at the order of and with the participation of a prescriber such as a licensed physician or other licensed professional as designated by the Code of Iowa.

3. The Iowa Code has not vested the Iowa Board of Pharmacy Examiners with the authority to prohibit a licensed pharmacist from preparing a non-prescription product for sale to the public in situations where other non-pharmacist members of the public can prepare equivalent substances for sale to the public without restriction.

4. The action of the Board in prohibiting pharmacists from "compounding" non-prescription products for sale to the public is an "ultra vires" action by said Board.

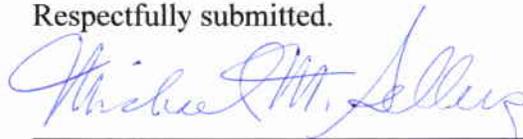
5. The other matters set forth in the Complaint and Statement of Charges, other than “compounding”, involve minor infractions that are not normally pursued for disciplinary purposes.

6. There is no reasonable basis for the Board to pursue disciplinary action in this case even if the Board believes that it has statutory authority to pursue this disciplinary procedure. The complainant is a nonresident of the State whose complaint is subject to substantial issues of credibility and rationality.

7. The Board, its staff, and the Iowa Attorney General’s office have expended enormous resources over a period of over two years in pursuing a clearly minor alleged infraction of the Board’s Administrative Rules. For all of the reasons set forth in this motion the Board should, by telephone conference call, dismiss this disciplinary proceeding.

WHEREFORE, Respondent requests that the Board schedule a telephone conference call meeting for the purpose of considering this motion to dismiss this disciplinary proceeding and respondent does request that said telephone conference call meeting be scheduled within two weeks of the date of the filing of the State’s resistance to this motion to dismiss and that the Respondent and counsel for Respondent be given an opportunity to participate in the telephone conference call hearing on this motion to dismiss.

Respectfully submitted.



Michael M. Sellers, Attorney-at-Law (PK0004971)
One Corporate Place
1501 - 42nd Street, Suite 380
West Des Moines, Iowa 50266-1005
Telephone: (515) 221-0111
Telefax: (515) 221-2702

ATTORNEY FOR RESPONDENT

ORIGINAL FILED.

Copy to:

Scott M. Galenbeck
Iowa Assistant Attorney General
Iowa Department of Justice
Hoover Building, Second Floor
1305 East Walnut Street
Des Moines, Iowa 50319

Lloyd Jessen
Executive Director
Pharmacy Board
River Point Business Park
400 S.W. Eighth Street, Suite E
Des Moines, Iowa 50309-4688

B. Michael Dunn
23 Third Street N.W.
Mason City, Iowa 50401

Garvis G. Houck

PROOF OF SERVICE

The undersigned certifies that the foregoing instrument was served upon all parties to the above cause to each of the attorneys of record herein at their respective addresses disclosed on the pleadings on August 10, 2004.

By: U.S. Mail FAX
 Hand Delivered Overnight Courier
 Federal Express Other.

Signature Cindy Jo Berry

STATE OF IOWA
BEFORE THE IOWA BOARD OF PHARMACY EXAMINERS

In the Matter of	:	CASE NO. 2002-12338
	:	
GARVIS G. HOUCK,	:	REPLY TO THE STATE'S
License No. 12338,	:	RESISTANCE TO RESPONDENT'S
	:	MOTION TO DISMISS
Respondent.	:	

COMES NOW Respondent Garvis G. Houck (hereinafter "Respondent") and, in reply to the State's resistance to Respondent's motion to dismiss, states to the Iowa Board of Pharmacy Examiners (hereinafter "the Board") that:

REPEATED REQUEST FOR ORAL HEARING

1. In Respondent's motion to dismiss, Respondent stated, in his concluding paragraph:

, Respondent requests that the Board schedule a telephone conference call meeting ... and that the Respondent and counsel for Respondent be given an opportunity to participate in the telephone conference call hearing on this motion to dismiss.

2. The motion to dismiss included a specific request for an oral hearing, as set forth above, to enable Respondent and/or counsel for Respondent to be available to answer questions by members of the Board or to be able to make a presentation of Respondent's position, as set forth in the motion to dismiss.

3. Respondent, therefore, herein repeats his prior request for an oral hearing and agrees that Respondent's presentation to the Board will be limited to no more than ten minutes, not including time utilized to respond to questions from the Board or the Board's counsel.

4. Respondent anticipates that the Board would also give an equivalent allocation of time to the counsel for the State to respond to Respondent's motion to dismiss and, lastly, that a short time period be permitted for a response to the State's resistance to the motion to dismiss. It

is anticipated that the actual time required for oral presentation will be shorter than requested in this reply.

5. Counsel for the State did not resist Respondent's request for an opportunity to make an oral presentation or to be able to respond to questions from Board members.

REQUEST FOR RECUSAL

6. Respondent requests that Lemman Olson (hereinafter "Mr. Olson") recuse himself from participation in any aspect of this matter, as Mr. Olson is a duly appointed full member of the Board and also a pharmacist who is licensed to practice in the same community as Respondent. Respondent feels that Mr. Olson should not participate in these proceedings and would appreciate his recusal.

REPLY TO THE RESISTANCE TO THE MOTION TO DISMISS

7. The State recited, in paragraph no. 1 of its resistance, that "... Respondent does not appear to question the broad authority of the Iowa Board of Pharmacy Examiners" The resistance quoted part of Iowa Code Section 155A.2, but left out the more significant last half of that empowerment sentence. The full sentence states:

1. It is the purpose of this chapter to promote, preserve, and protect the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized.

8. The importance of this paragraph is that the terms in the paragraph are defined by the same statute; and those definitions control the interpretation of the language of the authorizing statute.

a. "Pharmacy" means a location where **prescription drugs** (emphasis added) are compounded, dispensed, or sold by a pharmacist and where **prescription drug orders** (emphasis added) are received or processed in

accordance with the pharmacy laws. Iowa Code Section 155A.3(24), Code of Iowa 2003 as amended.

b. "Pharmacy license" means a license issued to a pharmacy or other place where **prescription drugs or devices** (emphasis added) are dispensed to the general public **pursuant to a prescription drug order** (emphasis added). Iowa Code Section 155A.3(25), Code of Iowa 2003 as amended.

c. "Practice of pharmacy" is a dynamic patient-oriented health service profession that applies to a scientific body of knowledge to improve and promote patient health by means of appropriate drug use and related drug therapy. Iowa Code Section 155A.3(27), Code of Iowa 2003 as amended.

d. "Pharmacist" means a person licensed by the board to practice pharmacy. Iowa Code Section 155A.3(21), Code of Iowa 2003 as amended.

e. "Distribute" means the delivery of a **prescription drug or device** (emphasis added). Iowa Code Section 155A.3(12), Code of Iowa 2003 as amended.

f. "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be **ordered or prescribed** (emphasis added) by a practitioner. Iowa Code Section 155A.3(10), Code of Iowa 2003 as amended.

g. "Dispense" means to deliver a **prescription drug** (emphasis added) or **controlled substance** (emphasis added) to an ultimate user or research subject by or pursuant to the lawful **prescription drug order** (emphasis added) or medication order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. Iowa Code Section 155A.3(11), Code of Iowa 2003 as amended.

h. "Practitioner" means a physician, dentist, podiatric physician, veterinarian, or other person licensed or registered to distribute or dispense a prescription drug or device in the course of professional practice in this state or a person licensed by another state in a health field in which, under Iowa law, licensees in this state **may legally prescribe drugs** (emphasis added). Iowa Code Section 155A.3(28), Code of Iowa 2003 as amended.

i. "Prescription drug" means any of the following:

a. A substance for which federal or state law requires a **prescription** (emphasis added) before it may be legally dispensed to the public.

b. A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(1) Caution: Federal law prohibits dispensing **without a prescription** (emphasis added).

(2) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

c. A drug or device that is required by any applicable federal or state law or regulation to be dispensed **on prescription only** (emphasis only), or is restricted to use by a practitioner only.

Iowa Code Section 155A.3(30), Code of Iowa 2003 as amended.

9. These definitions relate directly to the specific statutory language set forth in Iowa Code Section 155A.2, which is the legislative authorization that empowers the Board to regulate the practice of pharmacy in this State.

10. Counsel for the State goes on, in paragraph no. 1 of the resistance, to discuss the authority for the adoption of administrative rules. That authority is set forth in Iowa Code Section 147.76, Code of Iowa 2003 as amended, which states: “The examining boards for the various professions shall adopt all necessary and proper rules **to implement and interpret this chapter** (emphasis added)” There is no argument that the Board has full power and authority to adopt rules for the implementation of **its authority as vested** in the Board by Chapter 155A.2(1). State agencies are **strictly limited** to operate within the parameters of the legislative authority vested in those agencies by published statutory authority. This means that agencies may not do things that are not specifically authorized by the Legislature. Agencies are not permitted, under federal or state law, to create areas of authority or power, unless those areas of authority or power are within, and confined by, the language of the empowering statutes. Definitions set forth in Chapter 155 of the Iowa Code give the Board broad-based authority to operate within the areas assigned to it; but that same language also strictly confines the operation of the Board to only the powers vested in it.

11. The Board **has not been authorized** by the Iowa Legislature to be able to prohibit a licensed pharmacist from compounding and selling non-prescription drugs or devices as defined by the specific paragraphs of the definitional portion of Iowa Code Section 155A.3.

12. Counsel for the State did not cite any claimed authority that broadens the authority of the Board beyond the empowering statute and the limiting definitions set forth herein.

13. Counsel for the State correctly stated, in paragraph no. 3, on page 2 of his resistance, that **Respondent states** that the Board does **not** have the authority to limit and prohibit pharmacists from compounding products that are not prescription drugs or devices pursuant to a prescription. Counsel for the State states that: "... Respondent appears to object to the provisions of 657 IAC 20.2" This is **not** an accurate portrayal. Respondent is **not** objecting to the provisions of Iowa Code Sections 20.2, 20.3(1), and 20.3(3), but, rather, is telling the Board that it **does not have the authority** to prohibit the compounding practices listed in its own Administrative Rules.

14. Counsel for the State states, at paragraph no. 4 on page 2 of his resistance, that:

..., Respondent is questioning whether possession of a license to practice pharmacy can be conditioned on achievement ..., performance of tasks ..., avoidance of behaviors ..., compliance with professional standards ... and general professional competence.

He further states that: "Respondent cites no authority that such conditions of licensure are *ultra vires*."

15. Counsel for the State has misunderstood the fundamental thrust of the motion to dismiss. Respondent is not, **in any way**, questioning or disrespecting the full authority of the Board to condition possession of a license to practice pharmacy on achievement, performance, behaviors, compliance with professional standards, and the requirement of general professional competence. No authority is necessary with respect to this matter because the Board obviously

has full authority to require all of these areas of demonstrated compliance and competence in order for a person to be qualified to be granted a license to practice pharmacy as defined in the statute. There is no question that extraordinary education, fund of knowledge, achievements, reliable performance, avoidance of inappropriate behaviors or unethical conduct, compliance with professional standards, and general professional competence are all fundamental necessary requirements to protect the public health, safety, and welfare in the Board's effective regulation of the practice of pharmacy in this State, as defined by the statute. None of those areas of action by the Board are *ultra vires* and are not claimed to be so.

16. The same statement applies to paragraph no. 5, on page 2 of the resistance. Respondent has no argument with, and supports, the Board's requirements that the practice of pharmacy, as defined by the Iowa Code, is, and should be, conditioned on all of the successful maintenance of the standards and requirements set forth by counsel for the State in paragraph no. 5.

17. Paragraph nos. 6 and 7, on pages 2 and 3 of the resistance, claim that the issuance of a license to a pharmacist constitutes "... the imprimatur of the State of Iowa, by a licensee of this Board." Counsel for the States goes on to state that: "The public - the purchasers of the compound - would have no reasonable expectation that the non-pharmacist was regulated by the State of Iowa and compliant with professional pharmacist standards." Counsel for the State goes on to state that the "... pharmacist license on the wall ..." advises the public that "... the State's imprimatur attaches and the public will anticipate that Respondent has met all relevant standards for the conduct of a pharmacist."

18. Counsel for the State has misunderstood the fundamental thrust of Respondent's position regarding the breadth of the authority placed with the Board by statutory provisions.

Respondent agrees that licenses for a pharmacy and a pharmacist do place the imprimatur of the State of Iowa upon that facility and do hold forth to the public that the prescription drugs and devices, as defined by the statute and by the law, are, in fact, being dispensed and distributed by persons regulated by, and who have met, the high exacting standards published by the Board in the practice of the dispensation of those materials and products. Just because the pharmacy and the pharmacist are properly licensed and regulated in the dispensation of prescription drugs and devices does not, in any way, place the imprimatur of the State as a necessary requirement upon the sale of other non-prescription drugs and devices or products in the same building by the same owners as retail products, any more than the placement of a pharmacy in a Hy-Vee food store places the imprimatur of the State as some sort of authorization or protective device on the sale of food products by that store or meat by its butcher. In point of fact, the Board should limit the meaning of a license to practice pharmacy or the licensing of a pharmacy only to the portion of that business that relates directly to the matters set forth in the statute, so that the Board is not taking on the responsibility of purporting to manage and control, or be responsible for, any of the other products or things that might be sold, manufactured, or distributed in that location, even if by the same persons when they are acting in capacities other than as a licensee.

19. In paragraph no. 8, on page 3 of the resistance, counsel for the State suggests that Respondent can do what he wishes to compound substances by surrendering his license. Again, counsel misses the mark. Respondent has been a successful and respected licensee in the geographical area of the State where he has practiced pharmacy for decades. He has advanced the interests of the profession of pharmacy and has advanced the stature of the profession. His objection, with respect to the Board's complaint regarding his compounding of one bottle of nose drops, is squarely based upon a reasonable and sound straightforward interpretation of clear,

unambiguous, statutory language that prohibits the Board from pursuing this disciplinary action. Respondent's motion to dismiss has been filed to enable the Board to stop this procedure, to limit the risk that this procedure might limit the Board's operations in ways that could be even more restrictive than the limited matters that apply just to this disciplinary procedure. With respect to that concern, the Board is advised by this reply to the State's resistance to Respondent's motion to dismiss that Respondent does preserve, in this pleading, the right to appeal the issue of all the Board's actions that appear to be attempts for the enforcement of regulatory authority over pharmacists as it appears in the Iowa Administrative Rules, to the extent that those extensions of authority **exceed the limits and boundaries set forth in the statutory empowerment provisions** of the Iowa Code as related to the authority granted to the Board.

WHEREFORE, Respondent requests a hearing on the motion to dismiss and that this disciplinary proceeding be dismissed, in its entirety.

Respectfully submitted,



Michael M. Sellers, Attorney-at-Law (PK0004971)
Sellers Law Office
One Corporate Place
1501 - 42nd Street, Suite 380
West Des Moines, Iowa 50266-1005
Telephone: (515) 221-0111
Telefax: (515) 221-2702
E-mail: sellers@sellersoffice.com

ATTORNEY FOR RESPONDENT

ORIGINAL FILED

Copy to:

Scott M. Galenbeck, Iowa Assistant Attorney General
Iowa Department of Justice
Hoover State Office Building, Second Floor
1305 East Walnut Street
Des Moines, Iowa 50319

**VIA TELEFAX (281-7551)
and U.S. MAIL**

Lloyd Jessen, Executive Director
Iowa Board of Pharmacy Examiners
River Point Business Park
400 S.W. Eighth Street, Suite E
Des Moines, Iowa 50309-4688

**VIA TELEFAX (281-4609)
and U.S. MAIL**

B. Michael Dunn, Attorney-at-Law
23 Third Street N.W., Suite 200
Mason City, Iowa 50401

VIA U.S. MAIL

Garvis G. Houck
Houck Drug Company
8 North Fourth Street
Clear Lake, Iowa 50428

VIA U.S. MAIL

reply

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing instrument was served upon all parties to the above cause to each of the attorneys of record herein at their respective addresses disclosed on the pleadings on 9-9 2004

By: U.S. Mail FAX *as indicated*
 Hand Delivered Overnight Courier
 Certified Mail Other:

Signature *Patricia E. Blair*

IN THE IOWA DISTRICT COURT IN AND FOR CERRO GORDO COUNTY

GARVIS G. HOUCK,

Petitioner,

v.

IOWA BOARD OF PHARMACY
EXAMINERS,

Respondent.

NO. CVCV061964

Iowa Board of Pharmacy Examiners Case
No. 2002-12338

**PETITIONER'S AFFIDAVIT IN
SUPPORT OF HIS RESISTANCE TO
RESPONDENT'S MOTION TO
DISMISS AND IN SUPPORT OF HIS
BRIEF IN SUPPORT OF HIS
RESISTANCE**

STATE OF IOWA

:

ss.

COUNTY OF POLK

:

I, Garvis G. Houck, Petitioner in the above-captioned case, hereby state to the Court that:

1. I am a pharmacist licensed by Respondent Iowa Board of Pharmacy Examiners (hereinafter "the Board"); and my pharmacy, known as Houck Drug Company, is a pharmacy licensed by the Board.

2. I am the person who is the subject of the disciplinary proceeding pending before the Board which is the subject of this appeal.

3. My current pending matter with the Board arose as a result of my preparation of a small amount of nose drops for a customer who was complaining of a chronic burning sensation in her nasal passages. She was dissatisfied with the product and registered a complaint with the Board. She pursued that complaint against me, claiming that I did not have the authority to compound the nose drops, which was a product that contained no prescription or legend drugs or any other product that is controlled by administrative regulations administered and enforced by the Federal Food and Drug Administration or by any other known governmental agency.

4. I have never denied, and do not deny, that I prepared the mixture of nose drops which is the subject of these proceedings.

5. I worked with my attorney to bring to the attention of the Board, through my motion to dismiss, the specific claim that the Board does not have any basis for any authority from the Iowa Legislature to restrict or prohibit my compounding of materials at my pharmacy that do not contain legend drugs, or prescription drugs, or controlled substances. My attorney and the attorney for the Board appeared at a full-Board hearing and presented their arguments; however, the Board, after that full-Board hearing, decided to continue to claim that it has the authority from the Iowa Legislature to prohibit me from compounding products that do not contain any legend, or prescription, or controlled substances, even though I know of no other segment of the population that has any similar restrictions placed upon it.

6. Licensed pharmacists and pharmacies are the one group of Iowa residents who have extensive, established, direct, educational, professional, experiential backgrounds to be best suited to determine what pharmacy-generated products (PGPs) can, and should, be prepared for use by the general public, to deal with situations that arise that in their view or opinion do not require intervention by a physician or other health licensee.

7. I have reviewed every part of the petition for judicial review of the Board's decision to continue with its claim that it has a right to prohibit my preparation of pharmacy-generated products that do not include prescription, legend, or controlled substances, the Board's motion to dismiss the petition, the Board's brief in support of its motion to dismiss, the resistance to the Board's motion to dismiss, and the brief in support of the resistance; and I hereby state to the Court that all of the facts and arguments set forth in the petition for judicial review, in my resistance to the Board's motion to dismiss, as filed in this Court, and my brief in support of the

resistance to the Board's motion to dismiss. All of the fact statements and arguments therein are true and correct to the best of my knowledge and belief.

8. I am requesting judicial intervention on behalf of myself and my pharmacy, as well as on behalf of other licensed pharmacists and pharmacies in Iowa who are unfairly restricted in their daily business and operations, particularly with respect to the operation of the typical, current, retail pharmacy business, in meeting the needs of Iowa's citizens for the preparation of products that do not require medical intervention or prescriptions. We request that the Court determine that this Administrative Rule exceeds the boundaries of the authority vested in the Board; and we request that the Court set aside this Administrative Rule, so that licensed pharmacists and pharmacies can enjoy the same rights that that rest of the population of the State of Iowa have, with respect to the preparation of such non-prescription, non-legend, and non-controlled substances.

FURTHER, Affiant saith not.



Garvis G. Houck
Houck Drug Company
8 North Fourth Street
Clear Lake, Iowa 50428
Telephone: (641) 357-8621

PETITIONER

The above-named Garvis G. Houck did, after having been duly sworn upon oath by me, state that he is one and the same person who did execute the above and foregoing affidavit; and I did, as a Notary Public in and for the State of Iowa, confirm his identity, either from my own personal knowledge or by appropriate methods of verification. Said Garvis G. Houck also did state, while under oath, that his execution of the above and foregoing affidavit was his voluntary act and deed and did further state that he understood the contents of the various paragraphs of said affidavit; he did further state that the facts and statements set forth therein are true and

correct to the best of his knowledge and belief. This affidavit was sworn to before me and executed by said Garvis G. Houck on this 16th day of March, 2005.



Patricia A. Wilson

Notary Public in and for the State of Iowa

ORIGINAL FILED

Copy to:

The Honorable Jon Stuart Scoles
Judge, Second Judicial District of Iowa
Cerro Gordo County Courthouse
220 North Washington Avenue
Mason City, Iowa 50401

VIA U.S. MAIL

Iowa Assistant Attorney General Scott M. Galenbeck
Iowa Department of Justice
Hoover State Office Building, Second Floor
1305 East Walnut Street
Des Moines, Iowa 50319

**VIA TELEFAX (281-7551)
and U.S. MAIL**

Lloyd Jessen, Executive Director
Iowa Board of Pharmacy Examiners
River Point Business Park
400 S.W. Eighth Street, Suite E
Des Moines, Iowa 50309-4688

**VIA TELEFAX (281-4609)
and U.S. MAIL**

nff2

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing instrument has been served upon all parties to the above cause to each of the persons listed of record herein at their respective addresses disclosed on the pleadings on 3-16 2005.

- By: U.S. Mail
- Hand Delivered
- Certified Mail
- FAX *as indicated*
- Overnight Courier
- Other: *Wilson*

Signature *Patricia A. Wilson*

IN THE IOWA DISTRICT COURT IN AND FOR CERRO GORDO COUNTY

GARVIS G. HOUCK,	:	NO. CVCV061964
	:	Iowa Board of Pharmacy Examiners Case
Petitioner,	:	No. 2002-12338
	:	
v.	:	
	:	
IOWA BOARD OF PHARMACY	:	PETITIONER'S RESISTANCE TO
EXAMINERS,	:	RESPONDENT'S MOTION TO
	:	DISMISS
Respondent.	:	

COMES NOW Petitioner Garvis G. Houck (hereinafter "Petitioner") and, for his resistance to the motion to dismiss filed herein by Respondent Iowa Board of Pharmacy Examiners (hereinafter "Respondent"), hereby states to the Court that:

RECEIVED
MAR 11 2005

IOWA PHARMACY EXAMINERS

1. Petitioner admits that Respondent has the authority to enforce licensing standards, that Petitioner is a licensed Iowa pharmacist, that Respondent commenced disciplinary proceedings against Petitioner, and that Petitioner served a motion to dismiss in said disciplinary proceedings, contending that Respondent lacked authority to pursue discipline relating to restrictions by Respondent on compounding practices.
2. Petitioner denies that a final action by Respondent has not occurred and denies Respondent's claim that Petitioner has not exhausted administrative remedies.
3. This is not an interlocutory appeal from a preliminary action by Respondent as it pertains to the issues of jurisdiction and lack of statutory authority as brought before Respondent in Petitioner's motion to dismiss.
4. There was a full hearing, with arguments, before Respondent regarding the specific issue of the lack of Respondent's authority to discipline a pharmacist for compounding non-prescription pharmacy-generated products (hereinafter "PGPs").
5. Respondent ruled that it has the statutory authority to enforce its Administrative Rule prohibiting the compounding of non-prescription PGPs, in direct contravention of Iowa statutes,

case law, and a United States Supreme Court opinion that has defined the terms and conditions relating to this specific topic and issue.

6. If Respondent is permitted to prosecute a disciplinary claim in the absence of clear authority to do so, a final order imposing discipline would be a public record, pursuant to Iowa Code Section 272C.6(4), and would be published throughout the State, irreparably harming Petitioner's reputation and business and furthering Respondent's restrictions on the practice and conduct of retail pharmacy business, throughout the State, by all licensed retail pharmacists.

7. Subsequent appeals could not repair the damage done by such a published disciplinary order.

8. Respondent has already issued its final decision on the legal and jurisdictional issues presented to it. It would be futile and a waste of administrative and judicial resources to argue these issues twice. There is no dispute that the non-prescription nose drops were prepared by Petitioner. Respondent has stated that it deems that preparation to be illegal and unauthorized and, therefore, subject to discipline. There is no chance of a reversal or dismissal by Respondent.

9. Respondent was advised that if the jurisdictional motion to dismiss was overruled by Respondent this issue would be appealed immediately to District Court.

10. The only reason for Respondent's present motion to dismiss is to increase the cost to Petitioner of not conforming to Respondent's edicts. The Court should consider sanctions against the State for the filing of this motion to dismiss.

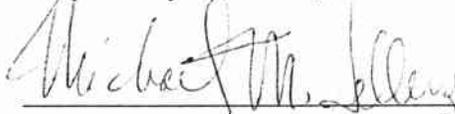
11. There is no question that Iowa law requires exhaustion of administrative remedies before a 17A judicial review is proper. It was the reason for the full disclosure and complete briefing of the jurisdictional issue before Respondent in a formal hearing. The exceptions to the exhaustion requirement are also applicable and one fully briefed for the Court, if the Court finds this appeal to be interlocutory.

12. In this case, the fact issue is undisputed; and the legal issues of jurisdiction and authority have been ruled upon for all necessary administrative purposes.

13. Petitioner has stated a proper basis for a 17A administrative appeal and also demonstrated that irreparable injury is imminent if an additional, futile, disciplinary procedure is required.

WHEREFORE, Petitioner prays that Respondent's motion to dismiss be overruled.

Respectfully submitted,



Michael M. Sellers, Attorney-at-Law (PK0004971)
Sellers Law Office
One Corporate Place
1501 - 42nd Street, Suite 380
West Des Moines, Iowa 50266-1005
Telephone: (515) 221-0111
Telefax: (515) 221-2702
E-mail: sellers@sellersoffice.com

ATTORNEY FOR PETITIONER

ORIGINAL FILED

Copy to:

The Honorable Jon Stuart Scoles
Judge, Second Judicial District of Iowa
Cerro Gordo County Courthouse
220 North Washington Avenue
Mason City, Iowa 50401

VIA U.S. MAIL

Iowa Assistant Attorney General Scott M. Galenbeck
Iowa Department of Justice
Hoover State Office Building, Second Floor
1305 East Walnut Street
Des Moines, Iowa 50319

HAND DELIVERED

Lloyd Jessen, Executive Director
Iowa Board of Pharmacy Examiners
River Point Business Park
400 S.W. Eighth Street, Suite E
Des Moines, Iowa 50309-4688

HAND DELIVERED

resistmtdismiss

CERTIFICATE OF SERVICE
The undersigned certifies that the foregoing instrument was served upon all parties to the above cause to each of the addresses of record herein at their respective addresses disclosed on the pleadings on 2-11-05 05.

By: U.S. Mail FAX
 Hand Delivered Overnight Courier
 Certified Mail Other

Signature Michael M. Sellers

IN THE IOWA DISTRICT COURT IN AND FOR CERRO GORDO COUNTY

GARVIS G. HOUCK,	:	NO. CVCV061964
	:	Iowa Board of Pharmacy Examiners Case
Petitioner,	:	No. 2002-12338
	:	
v.	:	
	:	
IOWA BOARD OF PHARMACY	:	PETITIONER'S BRIEF IN SUPPORT
EXAMINERS,	:	OF HIS RESISTANCE TO
	:	RESPONDENT'S MOTION TO
Respondent.	:	DISMISS

THIS CASE INVOLVES AN ADMINISTRATIVE RULE OF RESPONDENT IOWA BOARD OF PHARMACY EXAMINERS (HEREINAFTER "RESPONDENT") THAT PROHIBITS LICENSED PHARMACISTS FROM COMPOUNDING NON-PRESCRIPTION PRODUCTS OF ANY KIND UNLESS IT IS IN RESPONSE TO A PRESCRIPTION FROM AN AUTHORIZED SOURCE. THE ADMINISTRATIVE RULE IS VOID, BECAUSE RESPONDENT HAS NOT HAD, AND DOES NOT HAVE, THE AUTHORITY TO ISSUE OR ENFORCE THIS PROHIBITION. THIS BRIEF EXPLAINS WHY THIS CASE IS CLEARLY A PROPER SUBJECT FOR DISTRICT COURT REVIEW AT THIS STAGE; AND THAT POSITION IS BACKED BY IOWA SUPREME COURT AUTHORITY. THIS BRIEF ALSO EXPLAINS THE ORIGINAL SOURCE OF THE RESTRICTION THAT IS CONTAINED IN THE ADMINISTRATIVE RULES OF RESPONDENT THAT STARTED WITH AMENDMENTS TO THE FEDERAL FOOD AND DRUG ADMINISTRATION'S EMPOWERMENT LEGISLATION, WHICH WAS LATER STRICKEN BY A UNITED STATES SUPREME COURT CASE IN 2002. THIS BRIEF ALSO EXPLAINS EXACTLY HOW THE LANGUAGE IN THE ADMINISTRATIVE RULE THAT

RESPONDENT IS TRYING TO ENFORCE LIES COMPLETELY OUTSIDE THE DEFINITIONS AND STATUTORY AUTHORITY VESTED IN RESPONDENT AND ALSO EXPLAINS, WITH SPECIFIC AUTHORITY, HOW RESPONDENT'S ACTION, IN PROMULGATING AND ENFORCING THIS RULE, IS NOT PERMITTED AND IS, IN FACT, PROHIBITED BY SPECIFIC IOWA STATUTES. THIS BRIEF SUPPORTS EACH ARGUMENT WITH CLEAR AUTHORITY AND ALSO DETAILS THE STEPS THAT WERE TAKEN TO BRING THESE ISSUES SQUARELY BEFORE RESPONDENT. RESPONDENT HAS ENUNCIATED ITS LEGAL POSITION ON THESE ISSUES IN ITS ORDER, WHICH IS NOW THE LAW OF THE CASE. THIS BRIEF SHOWS HOW THIS CASE WAS PURSUED PROCEDURALLY, SO THAT IT WOULD BE A PROPER SUBJECT FOR DISTRICT COURT AND IOWA SUPREME COURT EXAMINATION AND DETERMINATION.

BACKGROUND

1. In the petition for judicial review filed by Petitioner Garvis G. Houck (hereinafter "Petitioner"), a pharmacist, the compounding of the one-ounce bottle of non-prescription nose drops was admitted.

2. Respondent accused Petitioner of "manufacturing" a non-prescription product, in violation of its Administrative Rule prohibiting such activity.

THIS IS A CHAPTER 17A ADMINISTRATIVE APPEAL

3. Contrary to the position of Respondent in its motion to dismiss and its brief in support of that motion to dismiss, this is an appeal from final agency action, because the issues that are the subject of this appeal have been finally decided by Respondent. The motion to dismiss that was filed by Petitioner with Respondent was intended to create a record of

Respondent's official position regarding the issues of (1) the subject matter jurisdiction, (2) statutory interpretation of Iowa Code Chapter 155, (3) *ultra vires* action by Respondent in the promulgation of Chapter 20 of section 657 of the Iowa Administrative Code, (4) *ultra vires* action by Respondent in its enforcement of 657 IAC 20, (5) the interpretation and enforcement of "manufacturing" definitions and prohibitions in 657 IAC 20, and (6) the constitutionality of Respondent's infringement on the rights of pharmacists to conduct their proper business pursuits.

4. Respondent's "argument" that it could somehow render this appeal MOOT makes no sense. On all of the issues, Respondent has announced its position in a ruling that is now the law of the case. Respondent would have to reverse its own ruling, based on the same arguments it heard before. The cases cited by Respondent, especially Salisbury Laboratories v. Iowa Department of Environmental Quality, 287 N.W.2d 830, involved an actual application for direct District Court intervention to prevent an action by the Department. It did not involve presentation to, and ruling by, the Department over disciplinary actions already commenced by it, where the substantive issues presented were already adjudicated by the Department, as has occurred in this case.

5. In this case, Respondent argues that it could find Petitioner violated the compounding restriction, but then impose no discipline, rendering the case moot. That opportunity has already been rejected by Respondent, after argument and consideration by Respondent's full board after a formal hearing. If Respondent had any inclination to find Petitioner violated the restriction, but then chose to impose no discipline, it could have done so with its ruling on Petitioner's motion to dismiss before Respondent.

6. There has never been any dispute over the fact of the compounding of the one-ounce bottle of nose drops. When Respondent ruled on the issue, its ruling could have simply stated its intent not to impose discipline; and Respondent could have dismissed the case.

7. As will be demonstrated by a more detailed analysis of the Salsbury opinion, the unique posture of this specific case meets all of the necessary tests for an appeal from a final action by an administrative agency, or, in the alternative, a proper appeal from a preliminary, or pre-final, agency adjudication, or a proper challenge to the jurisdiction or authority of an agency to act in the specific case before the District Court, where the lack of statutory authority to act is alleged.

“SALSBURY” ANALYSIS

8. In Salsbury, at page 833, the Iowa Supreme Court referred to Richards v. Iowa State Commerce Commission, 270 N.W.2d 616 (Iowa 1978), stating: “In Richards We also held: (A) party seeking judicial review of intermediate agency action under s 17A.19(1) must show ... (1) adequate administrative remedies have been exhausted And (2) review of the final agency action would not provide an adequate remedy. Id. at 619-20”

9. This case fits on all fours with this two-part Richards test as restated and reconfirmed in Salsbury. Here, Petitioner’s motion to dismiss presented all the relevant challenges and arguments regarding the lack of statutory authority for Respondent to promulgate or enforce its Administrative Rule. It was argued by the Iowa Attorney General’s Office and by Petitioner; and the issues were decided and became the law of the case. Any further procedures would be repetitive rubber-stamping actions. The appeal issues would be the same. Neither party would gain or lose from a repeat hearing with the same facts and legal issues. Valuable resources would be wasted.

10. In Salsbury, the petition in District Court was for an injunction, or for declaratory relief, or for *certiorari*. The Iowa Supreme Court construed the appeal as an appeal under section 17A.19 in order to determine whether the appeal should be permitted. Id., at page 835. Furthermore, at page 836, the Iowa Supreme Court supplemented Salsbury's petition with judicial notice to add the department ORDER that was the subject of Salsbury's complaint. This enabled the Iowa Supreme Court to consider the allegation of facial invalidity of the departmental order. The Iowa Supreme Court stated:

Salsbury alleges the enabling statutes, because they fail to provide notice and hearing prior to issuance of an executive order which can deprive Salsbury of property interests, are violative of due process and are an unconstitutional delegation of legislative power. U.S.Const. amend. XIV; Iowa Const. art. I, s 9, art. III, s 1.

11. Here, the Salsbury opinion is instructive in the very situation presented by the case at bar; and the Iowa Supreme Court's discussion, at page 836, is directly relevant to this case:

Salsbury refers to this situation as "a time-honored exception to the exhaustion doctrine." We approved this "emerging rule" in *Matters v. City of Ames*, 219 N.W.2d 718, 719-20 (Iowa 1974), a pre-IAPA case. Division IA of this opinion holds judicial review of agency action has been codified in Iowa. If there is such an exception today, it must be found in section 17A.19.

Section 17A.19(1) provides the only authority for reviewing agency action which is not final:

A preliminary, procedural or intermediate agency action is immediately reviewable if all adequate administrative remedies have been exhausted and review of the final agency action would not provide an adequate remedy.

This test was set out in *Richards*, from which we quoted earlier. Salsbury's petition must demonstrate the contested case proceeding is not an adequate remedy. Salsbury must also show delaying judicial review until after the agency proceeding is inadequate.

[6] 1. We are satisfied that where an attack is made on the validity of an agency's enabling statute, an administrative remedy ordinarily is inadequate for purposes of section 17a.19(1) and the first prong of *Richards*.

[7] The doctrine of exhaustion of administrative remedies has never been thought to be absolute. Accord, *Matters*, 219 N.W.2d at 719 (“Exhaustion is not required before every court challenge.”). See also 3 K. Davis, *Administrative Law* s 20.01 (1958); 5 B. Mezines, J. Stein & J. Gruff, *Administrative Law* s 49.02 (1978); B. Schwartz, *Administrative Law* s 173, at 499 (1976). If the agency is incapable of granting the relief sought during the subsequent administrative proceedings, a fruitless pursuit of these remedies is not required. *Matters*, 219 N.W.2d at 719; 3 K. Davis, *Supra*, at s 20.07; 5 B. Mezines at al., *Supra*, at s 49.02(1); B. Schwartz, *Supra*, at 499-500.

[8] Agencies cannot decide issues of statutory validity. *Califano v. Sanders*, 430 U.S. 99, 109, 97 S.Ct. 980, 986, 51 L.Ed.2d 192, 201 (1977); *Public Utilities Commission v. United States*, 355 U.S. 534, 539, 78 S.Ct. 446, 450, 2 L.Ed.2d 470, 475 (1958); *Matters*, 219 N.W.2d at 719; 3 K. Davis, *Supra*, at 74; B. Schwartz, *Supra*, at s 178. If the constitutional issue does not need to be examined in a particular factual context, the administrative remedy is “inadequate” for purposes of section 17A.19(1).

Thus in *W.E.B. DuBois Clubs of America v. Clark*, 389 U.S. 309, 88 S.Ct. 450, 19 L.Ed.2d 546 (1967), the United States Supreme Court declined to decide “important and difficult constitutional issues ... devoid of factual context” when it was undetermined whether the law was applicable to those seeking early judicial review. 389 U.S. at 312, 88 S.Ct. at 452, 19 L. Ed.2d at 549. In *Mathews v. Eldridge*, 424 U.S. 319, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976), exhaustion was not required where the constitutional *837 issue, the right to notice and hearing in advance of termination of social security benefits, was “entirely collateral to (Eldridge’s) substantive claim of entitlement.” 424 U.S. at 330, 96 S.Ct. at 900, 47 L.Ed.2d at 31.

Salsbury alleges these statutes, which allegedly permit the issuance of executive orders without prior notice or hearing, are unconstitutional. Courts can decide that issue without the benefit of factual adjudications entrusted to DEQ. As in *Mathews v. Eldridge*, this issue is collateral to the factual issues surrounding the merits of DEQ’s order. Salsbury’s allegations, taken as true, present a situation in which the contested case proceeding is not an adequate administrative remedy.

[9][10] 2. Under section 17A.19(1), however, an inadequate administrative remedy still must be exhausted if judicial review from the final agency action is adequate. This test is not so easily met. Unless it is the only issue raised, the facial constitutional challenge, even though collateral, may be mooted by a favorable agency adjudication of fact or law. See *Aircraft & Diesel Equipment Corp. v. Hirsch*, 331 U.S. 752, 772, 67 S.Ct. 1493, 1503, 91 L.Ed.2d 1796, 1808 (1947). Avoidance of constitutional issues except when necessary for proper disposition of controversy is a bulwark of America jurisprudence. See, e.g., *Motor Club of Iowa v. Department of Transportation*, 251 N.W.2d 510, 519 (Iowa 1977).

12. The Iowa Supreme Court concluded, because Salsbury had not exhausted its administrative remedies and not even pled irreparable injury, if the intermediate agency action were not appealed, that it had not justified the need for intermediate appellate review. **Here**, the Iowa Supreme Court's analysis that places a challenge to the agency's authority as a primary basis for finding that an administrative remedy ordinarily is inadequate (see section [6] of the opinion at page 836) clearly fits the facts of this case, even without the fact that further procedures at the agency level would be futile for this Petitioner.

13. Respondent's position, in its continued insistence on enforcing its compounding restrictions, has created, and creates, an ongoing restriction on the availability of compounding services by Iowa pharmacists to the public; and this restriction directly violates the public interest of the citizens of this State by administratively depriving the public of these services. Every day that these restrictions are permitted to continue increases the loss to the public and exacerbates the irreparable harm being done, not just to Petitioner but to all pharmacists and to the public.

14. Attached hereto and made a part hereof as though fully set forth herein are (1) Exhibit A, which is a copy of the Salsbury opinion, (2) Exhibit B, the motion to dismiss filed with Respondent by Petitioner, (3) Exhibit C, the resistance to Petitioner's motion to dismiss filed by the Iowa Attorney General's Office in opposition to Petitioner's motion to dismiss, and (4) Exhibit D, Petitioner's reply to the resistance filed by the Iowa Attorney General's Office.

THE LIMITS OF RESPONDENT'S AUTHORITY WERE DEMONSTRATED

15. In Petitioner's reply to Respondent's resistance to his motion to dismiss, at page 2, the actual word-for-word recitation of the statutory empowerment provisions were set out for Respondent's review. This was done because, in Iowa, the same Assistant Attorney General

who is assigned to PROSECUTE disciplinary cases before Respondent also acts as GENERAL COUNSEL to Respondent. Therefore, a licensee must explain the legal basis of a legal controversy to Respondent. That was done in the brief submitted to Respondent here as follows:

7. The State recited, in paragraph no. 1 of its resistance, that "... Respondent does not appear to question the broad authority of the Iowa Board of Pharmacy Examiners" The resistance quoted part of Iowa Code Section 155A.2, but left out (emphasis added) the more significant last half of that empowerment sentence. The full sentence states:

1. It is the purpose of this chapter to promote, preserve, and protect the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized.

8. The importance of this paragraph is that the terms in the paragraph are defined by the same statute; and those definitions control the interpretation of the language of the authorizing statute.

a. "Pharmacy" means a location where **prescription drugs** (emphasis added) are compounded, dispensed, or sold by a pharmacist and where **prescription drug orders** (emphasis added) are received or processed in accordance with the pharmacy laws. Iowa Code Section 155A.3(24), Code of Iowa 2003 as amended.

b. "Pharmacy license" means a license issued to a pharmacy or other place where **prescription drugs or devices** (emphasis added) are dispensed to the general public **pursuant to a prescription drug order** (emphasis added). Iowa Code Section 155A.3(25), Code of Iowa 2003 as amended.

c. "Practice of pharmacy" is a dynamic patient-oriented health service profession that applies to a scientific body of knowledge to improve and promote patient health by means of appropriate drug use and related drug therapy. Iowa Code Section 155A.3(27), Code of Iowa 2003 as amended.

d. "Pharmacist" means a person licensed by the board to practice pharmacy. Iowa Code Section 155A.3(21), Code of Iowa 2003 as amended.

e. "Distribute" means the delivery of a **prescription drug or device** (emphasis added). Iowa Code Section 155A.3(12), Code of Iowa 2003 as amended.

f. "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be **ordered or prescribed** (emphasis added) by a practitioner. Iowa Code Section 155A.3(10), Code of Iowa 2003 as amended.

g. "Dispense" means to deliver a **prescription drug** (emphasis added) or **controlled substance** (emphasis added) to an ultimate user or research subject by or pursuant to the lawful **prescription drug order** (emphasis added) or medication order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. Iowa Code Section 155A.3(11), Code of Iowa 2003 as amended.

h. "Practitioner" means a physician, dentist, podiatric physician, veterinarian, or other person licensed or registered to distribute or dispense a prescription drug or device in the course of professional practice in this state or a person licensed by another state in a health field in which, under Iowa law, licensees in this state **may legally prescribe drugs** (emphasis added). Iowa Code Section 155A.3(28), Code of Iowa 2003 as amended.

i. "Prescription drug" means any of the following:

a. A substance for which federal or state law requires a **prescription** (emphasis added) before it may be legally dispensed to the public.

b. A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(1) Caution: Federal law prohibits dispensing **without a prescription** (emphasis added).

(2) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

c. A drug or device that is required by any applicable federal or state law or regulation to be dispensed **on prescription only** (emphasis only), or is restricted to use by a practitioner only.

Iowa Code Section 155A.3(30), Code of Iowa 2003 as amended.

9. These definitions relate directly to the specific statutory language set forth in Iowa Code Section 155A.2, which is the legislative authorization that empowers the Board to regulate the practice of pharmacy in this State.

10. Counsel for the State goes on, in paragraph no. 1 of the resistance, to discuss the authority for the adoption of administrative rules. That authority is set forth in Iowa Code Section 147.76, Code of Iowa 2003 as amended, which states: “The examining boards for the various professions shall adopt all necessary and proper rules **to implement and interpret this chapter** (emphasis added)” There is no argument that the Board has full power and authority to adopt rules for the implementation of **its authority as vested** in the Board by Chapter 155A.2(1). State agencies are **strictly limited** to operate within the parameters of the legislative authority vested in those agencies by published statutory authority. This means that agencies may not do things that are not specifically authorized by the Legislature. Agencies are not permitted, under federal or state law, to create areas of authority or power, unless those areas of authority or power are within, and confined by, the language of the empowering statutes. Definitions set forth in Chapter 155 of the Iowa Code give the Board broad-based authority to operate within the areas assigned to it; but that same language also strictly confines the operation of the Board to only the powers vested in it.

11. The Board **has not been authorized** by the Iowa Legislature to be able to prohibit a licensed pharmacist from compounding and selling non-prescription drugs or devices as defined by the specific paragraphs of the definitional portion of Iowa Code Section 155A.3.

12. Counsel for the State did not cite any claimed authority that broadens the authority of the Board beyond the empowering statute and the limiting definitions set forth herein.

13. Counsel for the State correctly stated, in paragraph no. 3, on page 2 of his resistance, that **Respondent states** that the Board does **not** have the authority to limit and prohibit pharmacists from compounding products that are not prescription drugs or devices pursuant to a prescription. Counsel for the State states that: “... Respondent appears to object to the provisions of 657 IAC 20.2” This is **not** an accurate portrayal. Respondent is **not** objecting to the provisions of Iowa Code Sections 20.2, 20.3(1), and 20.3(3), but, rather, is telling the Board that it **does not have the authority** to prohibit the compounding practices listed in its own Administrative Rules.

Section 17A.23 of the Iowa Code prohibits an agency from expanding the authority granted to the agency by the Legislature. There are no exceptions to this parameter. Section 17A.23 states: **“An agency shall have only that authority or discretion delegated to or conferred upon the agency by law and shall not expand or enlarge its authority or discretion beyond the powers delegated to or conferred upon the agency (emphasis added).”**

RESPONDENT'S COMPLAINT

16. The section of the Iowa Administrative Rules which is the foundation for Respondent's enforcement action in this case is attached hereto and made a part hereof as though fully set forth herein as Exhibit E; but section 20.2 also is set forth herein in full, because the “compounding” and “manufacturing” sections related directly to this case:

657 - 20.2(124,126,155A) Definitions.

For the purposes of this chapter, the following definitions apply: **“Bulk drug substance”** means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug. the term does not include intermediates used in the synthesis of such substances.

“Component” means any ingredient, other than a bulk drug substance, intended for use in the compounding of a drug product, including those ingredients that may not be identifiable in the final product.

“Compounding (emphasis added)” 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 or for the purpose of, or incident to, research, teaching, or chemical analysis, and not for sale or dispensing. **All compounding, regardless of the type of product, is to be done pursuant to a prescription. Compounding also includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription or in anticipation of prescription drug orders based on routine (emphasis added),** regularly observed prescribing patterns pursuant to subrule 20.3(3). Compounding does not include mixing or reconstructing a drug according to the product's labeling or to the manufacturer's directions.

“FDA” means the Food and Drug Administration of the U.S. Department of Health and Human Services.

“Manufacturing (emphasis added)” 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.

17. As can be seen from the Administrative Rule, any product that is made up of anything by a pharmacist has to have an official prescription from an authorized prescriber. If someone comes in who is allergic to most sunburn products and asks the pharmacist to mix up a non-allergenic sunburn lotion, the pharmacist must describe the appropriate product and then send the customer to a doctor to have the prescription for this non-prescription product signed by the prescriber and brought back to the pharmacist, so that the product can be made.

Commercially manufactured products are made for the needs of the majority of the population and, by their very nature, are not tailored to the special needs of individuals. This is not an issue of drug approval and testing procedures. This is an issue over dandruff shampoos, dry skin creams, anti-itching formulas, vitamins, and an endless list of daily product needs that do not involve prescription drugs or controlled substances.

18. This entire area of controversy started years ago, when major drug manufacturers procured restrictions, through the Federal Food and Drug Administration, to try to limit local manufacturing of competitive products that might be done to try to circumvent the costly FDA approval process. This same national effort led to a detailed discussion of the issue of advertising by pharmacists nationwide and also led to a detailed and directly relevant discussion of the need to PROTECT the availability of compounding services at the local level, especially when a specific product is prepared for a specific customer, like one ounce of nose drops at a specific customer's request.

19. A complete copy of the 2002 United States Supreme Court case of Thompson v. Western States Medical Center, 535 U.S. 357, is attached hereto as Exhibit F and made a part hereof as though fully set forth herein. Thompson unequivocally establishes the conceptual framework of the constitutional bases for prohibiting restrictions on compounding by local pharmacists. Thompson describes the controversy over the “manufacturing” fears of major drug companies and the FDA. That controversy and the 1997 Drug Reform Act were the genesis of the definitions in Chapter 20 of the Iowa Administrative Code and also the genesis of the anti-manufacturing controversy that led directly to the attack on Petitioner. Even though those national restriction attempts were stricken by the United States Supreme Court, the left-over State restrictions are still being pursued, but on a wholesale broader basis involving compounding of all products by local pharmacists, not just prescription medications that were the target of the original, stricken, federal act.

20. The Food and Drug Administration Modernization Act of 1992 (FDAMA), 21 U.S.C. 353a(c), was the genesis for the re-assertion of restrictions at the state level, by pharmacy boards, to attempt to prohibit local manufacturing of legend or prescription drugs by pharmacists. The following excerpts demonstrate the rationale of the United States Supreme Court in striking such restrictions as unconstitutional restrictions on free speech. Exactly the same rationale is even more applicable to the compounding of products that have nothing to do with mixing prescription products for customers.

“THOMPSON” EXCERPTS

21. Tommy G. Thompson, Secretary of Health and Human Services, et al., v. Western States Medical Center et al., 535 U.S. 357, 122 S.Ct. 1497, beginning at page 357, states:

Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to an individual

patient's needs. The Food and Drug Administration Modernization Act of 1997 (FDAMA) exempts "compounded drugs" from the Food and Drug Administration's (FDA) standard drug approval requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA), so long as the providers of the compounded drugs abide by several restrictions, including that the prescription be "unsolicited," 21 U.S.C. § 353a(a), and that the providers "not advertise or promote the compounding of any particular drug, class of drug, or type of drug." § 353a(c).

Held: The FDAMA's prohibitions on soliciting prescriptions for, and advertising, compounded drugs amount to unconstitutional restrictions on commercial speech. Pp. 1503-1509.

(a)

(b) Because pharmacists do not make enough money from ****1499** small-scale compounding to make safety and efficacy testing of their compounded drugs economically feasible, however, it would not make sense to require compounded drugs created to meet the unique needs of individual patients to undergo the entire new drug approval process. The Government therefore needs to be able to draw a line between small-scale compounding and large-scale drug manufacturing.

(c) Even if the Government had argued (as does the dissent) that the FDAMA's speech-related restrictions were motivated by a fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway, that fear would fail to justify the restrictions. This ***359** concern rests on the questionable assumption that doctors would prescribe unnecessary medications and amounts to a fear that people would make bad decisions if given truthful information, a notion that the Court rejected as a justification for an advertising ban in, *e.g.*, *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770, 96 S.Ct. 1817, 48 L.Ed.2d 346. Pp. 1507-1508.

(d) If the Government's failure to justify its decision to regulate speech were not enough to convince the Court that the FDAMA's advertising provisions were unconstitutional, the amount of beneficial speech prohibited by the FDAMA would be. Forbidding the advertisement of compounded drugs would prevent pharmacists with no interest in mass-producing medications, but who serve clienteles with special medical needs, from telling the doctors treating those clients about the alternative drugs available through compounding. For example, a pharmacist serving a children's hospital where many patients are unable to swallow pills would be prevented from telling the children's doctors about a new development in compounding that allowed a drug that was previously available only in pill form to be administered another way. **The fact that the FDAMA would prohibit such seemingly useful speech even though doing so does not**

appear to directly further any asserted governmental objective confirms that the prohibition is unconstitutional (emphasis added). Pp. 1508-1509.

238 F.3d 1090, affirmed.

22. In Iowa, department stores mix up all kinds of skin and facial creams and products for customers. Nutrition stores make up an endless variety of food supplements. Natural food stores make up mixtures of specialty food products. Restaurants create endless varieties of food combinations and items. Salons sell an endless variety of “special” formulas for skin, hair, nails, and makeup. Only pharmacists are prohibited from any of these activities, even though they are the only group of highly educated professionally trained people who are knowledgeable in these very areas of product effect on human beings. Furthermore, a licensed pharmacist is often the intervenor who spots a condition that requires emergency or medical treatment and directs customers to seek appropriate medical attention. The public should be encouraged, instead of prohibited, from seeking advice and remedies from a licensed pharmacist.

23. The compounding prohibition requiring a prescription for making non-prescription products is not authorized by law. The compounding restriction requiring a prescription for non-prescription products is illogical and also detrimental to the best interests of the public. The actions of Respondent in the enforcement of the compounding restriction is an *ultra vires* exercise of administrative power.

SECTION 17A.19(10) PROVISIONS

24. The following specific sub-sections of section 17A.19 of the 2005 Code of Iowa are applicable to the actions of Respondent in this administrative appeal:

25. Section 17A.19(10) of the 2005 Code of Iowa provides that:

The court may affirm the agency action or remand to the agency for further proceedings. The court **shall** (emphasis added) reverse, modify, or grant other appropriate relief from agency action, equitable or legal and including declaratory

relief, if it determines that substantial rights of the persons seeking judicial relief have been prejudiced because the agency action is **any of the following** (emphasis added):

a. Unconstitutional on its face or as applied or is based upon a provision of law that is unconstitutional on its face or as applied.

26. Attached hereto as Exhibit G and made a part hereof as though fully set forth herein is a copy of ABC Disposal Systems, Inc., v. Department of Natural Resources, 681 N.W.2d 596 (Iowa 2004). In that recent case, the Iowa Supreme Court discussed the general rules of statutory interpretation as they are applied to the authority of legislative enactments that empowers state agencies to operate in given areas. The Iowa Supreme Court said:

[4][5][6][7] In interpreting a statute, our goal is to determine the legislature's intent when it enacted the statute. *State v. Tague*, 676 N.W.2d 197, 201 (Iowa 2004). "We do not speculate as to the probable legislative intent apart from the words used in the statute." *State v. Adams*, 554 N.W.2d 686, 689 (Iowa 1996); accord *State v. Welton*, 300 N.W.2d 157, 160 (Iowa 1981) (stating, "when a statute is plain and its meaning is clear, courts are not permitted to search for meaning beyond its expressed terms"). If the statute's language is clear and unambiguous, we apply a plain and rational meaning consistent with the subject matter of the statute. *City of Waukee v. City Dev. Bd.*, 590 N.W.2d 712, 717 (Iowa 1999). ABC Disposal at page 603.

27. In the ABC Disposal case, the Iowa Supreme Court found that the agency had clear statutory authority to promulgate the Administrative Rule in question, based on its statutory mandate.

28. The Iowa Supreme Court further discussed 17A.19(10)(a), stating that:

[11][12] *Standard of Review*. Iowa Code section 17A.19(10)(a) allows us to grant relief from agency action if the action is "[u]nconstitutional on its face or as applied or is based upon a provision of the law that is unconstitutional on its face or *605 as applied." Iowa Code § 17A.19(10)(a). Under the doctrine of separation of powers, the judiciary is required to determine the constitutionality of legislation and rules enacted by the other branches of government. *Luse v. Wray*, 254 N.W.2d 324, 327 (Iowa 1977). We will not give any deference to the view of the agency with respect to the constitutionality of a statute or administrative rule, because it is exclusively up to the judiciary to determine the constitutionality of legislation and rules enacted by the other branches of the government. Iowa Code

§ 17A.19(11)(b). When a party raises constitutional issues in an agency proceeding, our review is de novo. *Rosen v. Bd. of Med. Exam'rs*, 539 N.W.2d 345, 348 (Iowa 1995). ABC Disposal at page 605.

29. Iowa Code section 17A.19(10)(b) provides that the District Court shall take corrective action if the agency action is “beyond the authority (emphasis added) delegated to the agency by a provision of law or in violation of any provision of law.”

30. In the case before the District Court, Respondent cannot present any rational interpretation of its enabling statute that gives it the authority to restrict pharmacists from compounding non-prescription materials and products into non-prescription pharmacy-generated products (PGPs). Its exercise of these powers represents an *ultra vires* exercise of power and an unconstitutional taking of the property rights and interests of Petitioner without due process of law. It deprives the public of the right to procure individual tailored products from knowledgeable licensed professionals.

31. Iowa Code section 17A.19(10)(c) provides that the District Court shall take corrective action if the action by Respondent was “Based on an erroneous interpretation of a provision of law whose interpretation has not clearly been vested by a provision of law in the discretion of the agency.”

32. In this case, Respondent has not cited to the District Court any specific statutory or common law authority clearly vesting in Respondent the discretion or the authority to act as it has with respect to its alleged restriction of compounding by pharmacists and pharmacies.

33. Iowa Code section 17A.19(10)(d) further provides that the District Court shall take corrective action, with respect to an action by Respondent, if Respondent’s action was “Based upon a procedure or decision-making process prohibited by law or was taken without following the prescribed procedure or decision-making process.” The actions by Respondent in dealing

with Petitioner's issues involve decision-making processes prohibited by law, particularly in that Respondent may only do what it is specifically authorized to do by law; and, where its actions are *ultra vires*, any such action outside the specific statutory mandate is action prohibited by law. The burden to prove it has authority to act is on Respondent, not Petitioner. See section 17A.19(23), the 2005 Code of Iowa as amended.

34. Iowa Code section 17A.19(10)(i) further provides that the District Court shall take corrective action if Respondent's actions were "The product of reasoning that is so illogical as to render it wholly irrational."

35. This is a situation where the actions and reasoning of Respondent are illogical. Those actions should, therefore, be deemed by the District Court to be wholly irrational. For these reasons, the actions of Respondent should be set aside; and Respondent should be ordered to cease and desist from enforcing its prohibition of compounding by pharmacists. See Auen Supra.

36. Iowa Code section 17A.19(10)(j) further provides that the District Court shall modify Respondent's action or intervene when a decision of Respondent is "The product of a decision-making process in which the agency did not consider a relevant and important matter relating to the propriety or desirability of the action in question that a rational decision maker in similar circumstances would have considered prior to taking that action."

37. Here, if Respondent had been rational and reasonable, it would not have pursued these actions at all, not only because there was no legislative or case law authority for its pursuit but primarily because these activities constituted a pointless and extensive waste of Respondent's and taxpayers' resources. These prohibitions are directly contrary to the rights and interests of not just of licensees but, more importantly, of the citizens of the State. See Thompson opinion.

38. Iowa Code section 17A.19(10)(k) furthermore provides that the District Court shall intervene and modify Respondent's action when that action was "Not required by law and its negative impact on the private rights affected is so grossly disproportionate to the benefits accruing to the public interest from that action that it must necessarily be deemed to lack any foundation in rational agency policy."

39. This statement, as set forth in Iowa Code section 17A.19(10)(k), is the best description of the nature and negative impact of these actions of Respondent that are brought to the attention of this Court. There is no rational explanation as to why these procedures are being followed, when there can be such a devastating negative impact on the private rights of Petitioner in his practice of his profession. Compounding is what a licensed pharmacist is educated to do in the average five or six years of collegiate and graduate education required to obtain a license.

40. Iowa Code section 17A.19(10)(l) further provides that the District Court shall intervene to reverse or modify Respondent's action if that action was "Based upon an irrational, illogical, or wholly unjustifiable interpretation of a provision of law whose interpretation has clearly been vested by a provision of law in the discretion of the agency." Here, Petitioner argues that even if the District Court were convinced that somehow Respondent had the statutory authority to take the actions that it has taken in the past, nevertheless, the activities that are negative to the interests of Petitioner are based upon an irrational, illogical, and wholly unjustifiable interpretation of those provisions of law and that authority.

41. Iowa Code section 17A.19(10)(n) further provides that the District Court shall intervene to reverse or modify Respondent's action if that action was "Otherwise unreasonable, arbitrary, capricious, or an abuse of discretion." Here, Petitioner does claim that these actions of Respondent qualify under the usual definition of each of the four terms set forth in this sub-

section and that District Court intervention is not only appropriate but necessary to terminate the ongoing harm to Petitioner created by Respondent's inappropriate and unjustifiable actions.

"LUNDY" ANALYSIS

42. Attached hereto as Exhibit H and made a part hereof as though fully set forth herein is a copy of Lundy v. Iowa Department of Human Services, which is an Iowa Supreme Court opinion found at 376 N.W.2d 893 (Iowa 1985).

43. This appeal to the District Court is an appeal from Respondent's rulemaking action, which is specifically treated, in detail, in the Lundy opinion. The facts and allegations of this case are the same as the Lundy case. In Lundy, the petitioner in District Court sought review of the promulgation of the respondent's rule that petitioner claimed was outside and beyond the authority of the respondent to promulgate and enforce. In Lundy, the Iowa Supreme Court ruled that upon meeting specific conditions the petitioner could challenge the rulemaking authority of the respondent department directly, in District Court, without being required to exhaust other administrative remedies.

44. In Lundy, the petitioner was a food stamp recipient who was challenging an Administrative Rule that required participation in a work registration and job search program to seek employment through the Iowa Department of Job Services in order to maintain eligibility for the specific food stamp program. The petitioner alleged that the respondent failed to comply with specific procedural requirements in the implementation of the rule. In this case, Petitioner challenges Respondent's legislative authority to adopt and implement the subject rule at all.

45. In Lundy, the Iowa Supreme Court ruled that the petitioner could seek judicial review of the rulemaking authority of respondent, if he could demonstrate that he was "... a person aggrieved or adversely affected by agency action," where the final action of the

respondent challenged is rulemaking. The Iowa Supreme Court ruled that a statement in the petition to District Court, claiming that the petitioner was adversely affected by the implementation and enforcement of the rule, had to be taken as true; and, therefore, the petitioner was deemed to be aggrieved or adversely affected by the enforcement of the rule.

46. The Iowa Supreme Court further required that the petitioner must demonstrate "... a specific, personal and legal interest in the subject matter and a special and injurious effect on such interest." See City of Des Moines v. Public Employment Relations Board, 275 N.W.2d 753 at 759 (Iowa 1979). In Lundy, the Iowa Supreme Court concluded that: "Obviously petitioner's allegations showed he had an interest in the agency action that distinguished him from members of the community at large."

47. Here, Petitioner has demonstrated an obvious interest in the implementation of the invalid rule, because he is currently the subject of a disciplinary action by Respondent with respect to its allegations that Petitioner and his pharmacy violated Respondent's rule prohibiting the compounding of non-legend and non-prescription products without a prescription from an authorized prescriber.

48. In Lundy, the Iowa Supreme Court further specifically identified the petitioner's direct interest by stating: "Moreover, the fact he is subject to the **allegedly invalid rules** (emphasis added) demonstrates the requisite injurious effect." Lundy at page 895.

49. The Iowa Supreme Court went on to state: "We note that a person or party challenging agency rulemaking procedures under section 17A.4 is not required to show personal prejudice. See Iowa Bankers Association v. Iowa Credit Union Department, 335 N.W.2d 439, 447 (Iowa 1983)."

50. In the Lundy case, the District Court dismissed the petition upon the respondents' motion to dismiss; and the Iowa Supreme Court "held" that the District Court ruling could not be upheld on the ground that the petitioner was not a person aggrieved or adversely affected by the respondent' final action.

51. In Lundy, the Iowa Supreme Court stated, at page 895, that: "Failure of an agency to comply substantially with the procedural requirements of section 17A.4 makes the resulting rule invalid."

APPLICABILITY OF SECTION 17A.3

52. Section 17A.3(c) of the 2005 Iowa Code as amended provides that: "c. As soon as feasible and to the extent practicable, adopt rules, in addition to those otherwise required by this chapter, embodying appropriate standards, principles, and procedural safeguards that the agency will apply to the law it administers."

53. This paragraph is part of the mandate in 17A.3 which was introduced with the language that: "1. In addition to other requirements imposed by Constitution or statute, each agency shall:" This section of 17A.3 limits the authority of all governmental agencies to promulgate Administrative Rules **limited** to the law that each agency administers. See also section 17A.23 of the 2005 Iowa Code as amended. To the extent that an agency attempts to promulgate or administer a rule that is not consistent with the law that it administers that authorizes the agency to exist or to act, those rules are ineffective, unconstitutional, and void.

54. Likewise, in section 17A.3(1)(d), the 2005 Iowa Code provides that the agency shall: "Make available for public inspection all rules, and make available for public inspection and index by subject, all other written statements of law or policy, or interpretations formulated, adopted, or used by the agency in the discharge of its functions." This section of 17A.3 is

mandatory and authorizes and requires the agency to make available for public inspection all of its rules, policies, and written statements of law, including all interpretations “in the discharge of its functions.” The agency is not permitted, and is not authorized anywhere, to promulgate, maintain, or enforce any rules, statements of law or policy, interpretations, or other actions, unless they are in the discharge of its functions as specifically defined by statute.

55. The Lundy opinion is directly applicable to the provisions of 17A.3; and, as was the case in Lundy with respect to the ethical procedures required for the formulation and adoption of rules, judicial review is available for a determination of whether or not an agency has the authority to have promulgated or to enforce a rule that is claimed to be outside its statutory mandate.

“IES UTILITIES” CASE

56. These concepts are further delineated in the case of IES Utilities, Inc., v. Iowa Department of Revenue and Finance, 545 N.W.2d 536, which was an Iowa Supreme Court case that discussed Lundy and its applicability to the standard of scope-of-review issues involving agency action that is brought directly to the District Court for resolution. In IES, the Iowa Supreme Court held that the utility was not excused from exhausting its administrative remedies; however, the discussion regarding Lundy, Salsbury, and other relevant cases is instructive, regarding situations where the right to judicial review could be available. A copy of IES is attached hereto as Exhibit I and made a part hereof as though fully set forth herein for the District Court’s convenience.

**APPLICABILITY OF IOWA CODE SECTION 17A.23 AND THE APPLICABILITY OF
THE CASE OF “AUEN V. ALCOHOLIC BEVERAGES DIVISION OF THE IOWA
DEPARTMENT OF COMMERCE”**

57. Iowa Code section 17A.23 states: “**An agency shall have only that authority or discretion delegated to or conferred upon the agency by law and shall not expand or enlarge its authority or discretion beyond the powers delegated to or conferred upon the agency (emphasis added).**”

58. In Auen, the Iowa Supreme Court dealt specifically with an appeal to the District Court that was a direct appeal from a promulgation of a rule by the agency, in which case the District Court sustained the agency’s motion to dismiss. The District Court’s ruling was reversed by the Iowa Supreme Court; and the Iowa Supreme Court found that the rule that had been promulgated by the agency exceeded its legislative authority, pursuant to its statutory mandate, and invalidated the rule. A copy of the Auen opinion is attached hereto at Exhibit J and made a part hereof as though fully set forth herein for the District Court’s convenience.

59. Under “Standard of Review,” at page 589 of the Auen opinion, the Iowa Supreme Court stated:

The Iowa Administrative Procedure Act, Iowa Code chapter 17A, governs the standards under which we review the district court’s decisions on judicial review of agency action. Locate.Plus.Com, Inc., v. Iowa Dep’t of Transp., 650 N.W.2d 609, 612 (Iowa 2002). “The agency decision itself is reviewed under the standards set forth in section 17A.19(10).” Mosher v. Dep’t of Inspections & Appeals, 671 N.W.2d 501, 508 (Iowa 2003). If the agency action affects the substantial rights of the person seeking judicial review and the agency’s conduct meets one of the enumerated provisions contained in Iowa Code section 17A.19(10), the court shall reverse, modify, or grant other appropriate relief from the agency’s action. Iowa Code § 17A.19(10).

We must apply the standards set forth in section 17A.19(10) and determine whether our application of those standards produce the same result as reached by the district court. Mosher, 671 N.W.2d at 508. The first standard upon which the Wholesalers challenge the agency action is on the ground that the promulgation of the amended rule by the ABD was beyond the authority delegated to the agency by any provision of law. Iowa Code § 17A.19(10)(b).

60. The Auen opinion also pointed out that the appellants pled, in the alternative, that the agency had violated sub-section c and sub-section l of sub-section 10 of 17A.19, stating that even if the rule did not go beyond the authority delegated to the agency the agency had erroneously interpreted the law and that the Legislature had not clearly vested the interpretation of the statute at issue with the agency. In Auen, the Iowa Supreme Court stated, at the bottom of page 589 and the top of page 590, that: “If the legislature has *590 not clearly vested the interpretation of the statute at issue with the agency, we are free to substitute our judgment de novo for the agency’s interpretation and determine if the interpretation is erroneous. Iowa Code § 17.19(10)(c); ...” The Iowa Supreme Court further stated, on page 590, that: “If, however, the legislature has clearly vested the interpretation of the statute at issue with the agency, we will only reverse the agency’s interpretation if it is ‘based upon an irrational, illogical, or wholly unjustifiable’ interpretation of the statute at issue. Iowa Code § 17A.19(10)(l).”

61. In Auen, the Iowa Supreme Court concluded that the agency’s interpretation of the statute at issue was illogical and exercised its authority in reversing the decision of the District Court, which upheld the Administrative Rule but also stated, at page 593:

Accordingly, we reverse the decision of the district court upholding the ABD’s exercise of its rulemaking power, declare the amended rule **null and void** (emphasis added), and remand the case to the district court, which must then return the case to the ABD for rule-making proceedings in compliance with the provisions of the Iowa Administrative Procedure Act.

It should be noted that the opinion of the Iowa Supreme Court in Auen, which was written by Justice Wiggins, had no dissent.

62. Just as was done by the Iowa Supreme Court in Auen, the District Court has full authority to not only reverse the action of Respondent herein but to declare that the rule, which exceeded statutory authority, is null and void.

CONCLUSION

63. This brief and argument has described, for the District Court, the careful procedural mechanism that was employed to be sure that Respondent's full board had a complete and adequate opportunity to be advised with respect to the fact that its Administrative Rule that it is pursuing in this disciplinary case is completely outside the area of power and authority vested in Respondent by the Legislature. That procedure was utilized to give Respondent an opportunity to reverse its enforcement position and to discontinue its *ultra vires* activity, which it refused to do by issuing an order making it clear that Respondent is enforcing, and will continue to enforce, its improper Administrative Rule prohibiting the compounding of non-prescription products. That order is now the law of this disciplinary case. Specific approved procedures were employed to bring this matter directly to the attention of Respondent's full board, so that it would have an opportunity to review the lack of statutory authority that had been brought to its attention and to empower Respondent with an opportunity to cease and desist from its enforcement of this Administrative Rule, which it had no power or authority to enact and which it has no power or authority to enforce, neither with respect to this individual pharmacist and pharmacy nor with respect to all pharmacists and pharmacies licensed in Iowa

64. This brief and argument has detailed, for the District Court, substantial statutory and case law authority proving that Respondent, and all agencies of government within the State of Iowa, is prohibited from promulgating rules or taking enforcement action that is outside and beyond the scope of specific authority vested in it by the Legislature. This brief and argument has clearly delineated the specific levels of authority and power vested by the Legislature in Respondent and demonstrates that the Administrative Rule which is the subject of this

proceeding exceeds, and is outside and beyond, any reasonable interpretation of the scope of authority vested in Respondent by its legislative mandate.

65. There are no fact issues to be determined, with respect to the enforcement by Respondent of its restriction prohibiting pharmacists from compounding non-prescription products. This matter is ripe for a proper legal view and determination by the District Court and by the Iowa Supreme Court. This is a matter of first impression; and the enforcement of the subject rule impacts negatively on the operation of the businesses of retail pharmacies throughout the State of Iowa and negatively impacts the right to carry on business of every licensed pharmacist and pharmacy within the State.

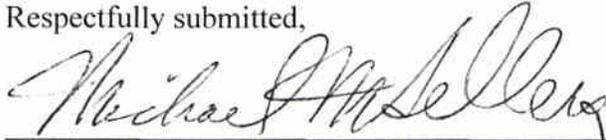
66. This Administrative Rule imposes a prohibition upon pharmacists and pharmacies that does not exist and does not impair any other person or any other group within Iowa, neither is any other person nor any other group in Iowa impaired or restricted by any other rules, regulations, statutes, or case law arising from any other agency or authority that is in any way similar to the broad-based restriction imposed by this Administrative Rule by Respondent.

67. The District Court should resolve this matter immediately, for the benefit of Petitioner as well as for the benefit all pharmacists and pharmacies licensed to do business in Iowa.

68. Petitioner requests that the District Court protect his interests and the interests of all pharmacists and pharmacies similarly situated by overruling Respondent's motion to dismiss and

setting this matter for immediate hearing, so that the District Court can rule on the merits of this controversy and resolve this dispute.

Respectfully submitted,



Michael M. Sellers, Attorney-at-Law (PK0004971)
Sellers Law Office
One Corporate Place
1501 - 42nd Street, Suite 380
West Des Moines, Iowa 50266-1005
Telephone: (515) 221-0111
Telefax: (515) 221-2702
E-mail: sellers@sellersoffice.com

ATTORNEY FOR PETITIONER

ORIGINAL TO:

The Honorable Jon Stuart Scoles
Judge, Second Judicial District of Iowa
Cerro Gordo County Courthouse
220 North Washington Avenue
Mason City, Iowa 50401

VIA U.S. MAIL

Copy to:

Iowa Assistant Attorney General Scott M. Galenbeck
Iowa Department of Justice
Hoover State Office Building, Second Floor
1305 East Walnut Street
Des Moines, Iowa 50319

HAND DELIVERED

Lloyd Jessen, Executive Director
Iowa Board of Pharmacy Examiners
River Point Business Park
400 S.W. Eighth Street, Suite E
Des Moines, Iowa 50309-4688

HAND DELIVERED

brfresistmotdissmiss

CERTIFICATE OF SERVICE
 The undersigned certifies that the foregoing instrument was served on all parties to the above cause to each of the attorneys of record herein at their respective addresses disclosed on the pleadings on 3-11 2005

By: U.S. Mail FAX *as indicated*
 Hand Delivered Overnight Courier
 Certified Mail Other

Signature: *Patricia D. Baird*

ORIGINAL FILED

Copy to:

The Honorable Jon Stuart Scoles
Judge, Second Judicial District of Iowa
Cerro Gordo County Courthouse
220 North Washington Avenue
Mason City, Iowa 50401

VIA U.S. MAIL

Iowa Assistant Attorney General Scott M. Galenbeck
Iowa Department of Justice
Hoover State Office Building, Second Floor
1305 East Walnut Street
Des Moines, Iowa 50319

HAND DELIVERED

Lloyd Jessen, Executive Director
Iowa Board of Pharmacy Examiners
River Point Business Park
400 S.W. Eighth Street, Suite E
Des Moines, Iowa 50309-4688

HAND DELIVERED

motamendpet

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing instrument was served upon all parties to the above cause to each of the attorneys of record herein at their respective addresses disclosed on the pleadings on 3-11 2005

Sy: U.S. Mail FAX *as indicated*
 Hand Delivered Overnight Courier
 Certified Mail Other:

Signature *Patricia L. ...*

RECEIVED

MAR 4 2005

IOWA PHARMACY EXAMINERS

IN THE IOWA DISTRICT COURT IN AND FOR CERRO GORDO COUNTY

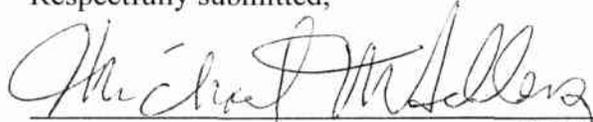
GARVIS G. HOUCK,	:	NO. CVCV061964
	:	Iowa Board of Pharmacy Examiners Case
Petitioner,	:	No. 2002-12338
	:	
v.	:	
	:	
IOWA BOARD OF PHARMACY EXAMINERS,	:	PETITIONER'S APPLICATION FOR AN EXTENSION OF TIME IN WHICH TO FILE A RESISTANCE TO RESPONDENT'S MOTION TO DISMISS
	:	
Respondent.	:	

COMES NOW Petitioner Garvis G. Houck (hereinafter "Petitioner") and, for his application for an extension of time in which to file a resistance to the motion to dismiss filed herein by Respondent Iowa Board of Pharmacy Examiners (hereinafter "Respondent"), hereby states to the Court that:

1. Respondent filed a motion to dismiss the above-captioned matter on February 23, 2005.
2. Petitioner would have until March 5, 2005, in which to resist said motion to dismiss.
3. Petitioner hereby requests a one-week extension of time, until March 12, 2005, for the filing of his resistance to said motion to dismiss, due to a heavy concurrent litigation schedule.
4. Iowa Assistant Attorney General Scott M. Galenbeck, counsel for Respondent, has advised counsel for Petitioner that he will not object to the Court's granting of this requested one-week extension of time.

WHEREFORE, Petitioner requests that the Court grant a one-week extension of time, until March 12, 2005, for the filing of his resistance to Respondent's motion to dismiss.

Respectfully submitted,



Michael M. Sellers, Attorney-at-Law (PK0004971)
Sellers Law Office
One Corporate Place
1501 - 42nd Street, Suite 380
West Des Moines, Iowa 50266-1005
Telephone: (515) 221-0111
Telefax: (515) 221-2702
E-mail: sellers@sellersoffice.com

ATTORNEY FOR PETITIONER

ORIGINAL FILED

Copy to:

Iowa Assistant Attorney General Scott M. Galenbeck
Iowa Department of Justice
Hoover State Office Building, Second Floor
1305 East Walnut Street
Des Moines, Iowa 50319

Lloyd Jessen, Executive Director
Iowa Board of Pharmacy Examiners
River Point Business Park
400 S.W. Eighth Street, Suite E
Des Moines, Iowa 50309-4688

appextentime

CERTIFICATE OF SERVICE
The undersigned certifies that the foregoing instrument was
served in all parties to the above cause to each of the other
parties herein at their respective addresses disclosed on the
pledging on 3-3-05 20 05

By: U.S. Mail FAX
 Hand Delivered Overnight Courier
 Certified Mail Other: _____

Signature: Michael M. Sellers

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

Case No. 2002-12338

**RESISTANCE TO
MOTION TO DISMISS**

Re:
Pharmacist License of
GARVIS G. HOUCK
License No. 12338
Respondent

Complainant, Lloyd K. Jessen, resists Respondent's Motion to Dismiss on the following

basis:

1. Although Respondent does not appear to question the broad authority of the Iowa Board of Pharmacy Examiners (hereinafter referred to as the "Board") or the authority of the Board to adopt administrative rules, a brief review of those powers may be useful. The Board is created by Iowa Code section 147.12(13) (2003) and generally empowered by that statute to regulate the licensure of pharmacists and the practice of pharmacy. See Iowa Code section 155A.2 (2003) ("It is the purpose of this chapter to promote, preserve, and protect the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others . . ."). Specific authority for adoption of administrative rules by the Board is found at Iowa Code section 147.76 (2003) ("The examining boards for the various professions shall adopt all necessary and proper rules to implement and interpret this chapter and chapters 147A through 158 . . .").
2. Respondent's Motion to Dismiss does not raise issues regarding whether rules have been adopted in a procedurally correct manner, or designate a specific rule to which he objects. Instead, Respondent questions whether chapter 20 ("Pharmacy Compounding Practices")

of the Board's administrative rules are beyond the scope of the Board's rulemaking authority.

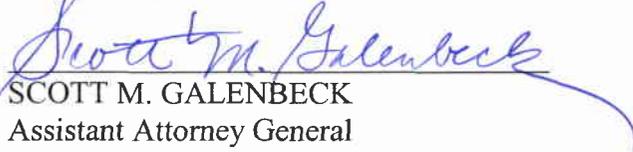
3. More specifically, Respondent appears to object to the provisions of 657 IAC 20.2, 20.3(1) and 20.3(3) which consistently limit compounding – by pharmacists – to preparation of drugs or devices pursuant to a prescription. Respondent asserts that, as a pharmacist licensee, he should be able to prepare “equivalent” compounds to those prepared by non-licensees.
4. At the most basic level, Respondent is questioning whether possession of a license to practice pharmacy can be conditioned on achievement (e.g., award of an educational degree), performance of tasks (e.g., continuing education, records keeping, counseling), avoidance of behaviors (e.g., drug and alcohol dependence, crimes), compliance with professional standards (e.g., ethical conduct, prevailing practices, federal and state law and rules) and general professional competence. Respondent cites no authority that such conditions of licensure are *ultra vires*.
5. As noted above, the statutory language of Iowa Code chapters 147 and 155A make apparent the Iowa legislature's intention to condition pharmacist licensure on achievement, avoidance of behaviors, compliance with professional standards and general competence – plus payment of fees.
6. While it is certainly possible that a non-pharmacist might prepare – and sell – a compound purporting to have healing qualities (e.g., multiple vitamins), such a compound would not be prepared and sold under the imprimatur of the State of Iowa, by a licensee of this Board. The public – the purchasers of the compound – would have no

reasonable expectation that the non-pharmacist was regulated by the State of Iowa and compliant with professional pharmacist standards.

7. However, if Respondent prepares such a compound – in his pharmacy, with his pharmacist license on the wall – the State’s imprimatur attaches and the public will anticipate that Respondent has met all relevant standards for the conduct of a pharmacist. Under such a circumstance of licensure, Respondent simply may not do what unlicensed individuals may do.
8. If Respondent disagrees with this Board’s administrative rules, and wishes to compound substances outside of the physician/patient/pharmacist triad, he may (a) surrender his license, (b) petition this Board for changes to the administrative rules or (c) approach the general assembly with specific legislation. However, disagreement with content of the Board rules which regulate the practice of pharmacy – or the contention that infractions of rules are “minor” – does not form a basis for dismissal of disciplinary charges which allege violation of those rules.

WHEREFORE, the complainant requests that Respondent’s Motion to Dismiss be denied.

Respectfully submitted,



SCOTT M. GALENBECK
Assistant Attorney General
Administrative Law Division
Hoover Building, 2nd Fl.
Des Moines, IA 50319
Tele: (515) 281-7262
FAX: (515) 281-7551
scott.galenbeck@ag.state.ia.us

Copies to:

Michael Sellers
One Corporate Place
1501 42nd Street, Suite 380
West Des Moines, IA 50266-1005

Houck resistance.doc

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing instrument was served upon each of the attorneys of record of all parties in the above-entitled cause by enclosing the same in an envelope addressed to each such attorney at his respective address as disclosed by the pleadings of record herein, with postage fully paid, and by depositing said envelope in a United States Post Office depository in Des Moines, Iowa, on the 3rd day

of September, 2004.

R. Dales

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

RE:) CASE NO. 2002-12338
) DIA NO: 04PHB012
Pharmacist License of:)
GARVIS G. HOUCK) ORDER DENYING MOTION
License No. 12338) TO DISMISS
Respondent)

Procedural Background

On June 18, 2002, the Iowa Board of Pharmacy Examiners (Board) found probable cause to file a Statement of Charges against Garvis G. Houck (Respondent), a registered pharmacist. The Statement of Charges alleged that the Respondent violated Iowa Code section 155A.12(2001) and 657 IAC 36.1(4)(i) by intentionally or repeatedly violating Board rules including but not limited to rules 6.2(1)(a)(legal operation of a pharmacy) and 6.8 (controlled substance records). [Count I] The Statement of Charges further alleged that the Respondent violated Iowa Code section 155A.12 (2001) and 657 IAC 36.1(4)"i" by unlawfully manufacturing and dispensing a compounded drug without prescriber authorization, in violation of 657 IAC 20.2. [Count II]

On or about August 10, 2004, the Respondent filed a Motion to Dismiss the pending Statement of Charges and requested oral argument. The state filed a Resistance on or about September 3, 2004, and the Respondent filed a Reply on September 10, 2003. The Board heard oral arguments on the Motion to Dismiss on October 6, 2004 at approximately 3:40 p.m., in the conference room, 400 SW 8th Street, Des Moines, Iowa. The following members of the Board presided at the motion hearing: Michael J. Seifert, Chairperson; Katherine A. Linder; Vernon H. Benjamin; and Kathleen Halloran. The Respondent was represented by attorney Michael Sellers. The state was represented by Scott Galenbeck, Assistant Attorney General. The oral arguments were recorded by a certified court reporter. Administrative Law Judge Margaret LaMarche assisted the Board and was instructed to prepare the Board's Ruling, in conformance with their deliberations.

Discussion

The Respondent asserts that the Board does not have statutory authority to prohibit a licensed pharmacist from compounding a non-prescription product for sale to the public without an authorizing prescription because other non-pharmacist members of the public can prepare equivalent substances for sale to the public without restriction. The Respondent further asserts that the Board's rules prohibiting such conduct are "ultra vires."

The Iowa Board of Pharmacy Examiners was created, pursuant to Iowa Code section 147.13, and has been empowered by statute with general authority to adopt all necessary and proper rules to implement and interpret Iowa Code chapters 147 and 155A. Iowa Code section 147.76. The declared purpose of Iowa Code chapter 155A is to promote, preserve, and protect the public health, safety and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized. Iowa Code section 155A.2.

Pursuant to its statutory authority and the rulemaking procedures outlined in Iowa Code chapter 17A, the Board has promulgated 657 IAC chapter 20, entitled Pharmacy Compounding Practices. This chapter was initially promulgated effective November 29, 1995 and has been subsequently amended. The Respondent has been charged under 657 IAC 20.2, 20.3(1), and 20.3(3), which limits compounding by licensed pharmacists to the preparation of drugs or devices pursuant to a prescription. The Respondent contends that 657 IAC chapter 20 is invalid and cannot be enforced because the Board does not have the requisite statutory authority to regulate a licensed pharmacist's compounding or preparation of non-prescription products for sale to the public.

The Board has reviewed the relevant statutes and rules and has fully considered the arguments made by both parties. The Board is confident that it had statutory authority to promulgate 657 IAC chapter 20, which regulates the compounding of drug products by Iowa licensed pharmacists and pharmacies, and that it is authorized to enforce its provisions.

Order

IT IS THEREFORE ORDERED that the Motion to Dismiss filed by Respondent Garvis Houck is hereby DENIED.

Dated this 15th day of Dec. , 2004.



Michael Seifert, Chairperson
Iowa Board of Pharmacy Examiners

cc: Scott Galenbeck, Assistant Attorney General
Michael Sellers, Attorney for Respondent

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

IN THE MATTER OF:)	CASE NO. 2002-12338
)	
GARVIS G. HOUCK)	ORDER GRANTING MOTION
)	FOR CONTINUANCE
RESPONDENT)	

On February 1, 2005, the Respondent, by and through Attorney Michael M. Sellers, filed a Request for Continuance of Contested Case Hearing on the Statement of Charges filed against the Respondent, Garvis G. Houck. The Respondent has provided sufficient justification for its motion for continuance.

IT IS HEREBY ORDERED that the hearing on the Statement of Charges filed against the respondent is hereby continued indefinitely.

Respondent's current address is 50 Beaumont, Mason City, IA 50401.

Dated this 3rd day of February, 2005.



Lloyd K. Jessen
Executive Secretary/Director

cc: Scott Galenbeck
Assistant Attorney General
Iowa Attorney General's Office
2nd Floor, Hoover State Office Building
Des Moines, IA 50319

Michael M. Sellers
1501 42nd Street, Suite 380
West Des Moines, IA 50266-1005

BEFORE THE IOWA BOARD OF PHARMACY EXAMINERS

In the Matter of	:	CASE NO. 2002-12338
	:	
GARVIS G. HOUCK,	:	REQUEST FOR CONTINUANCE OF
	:	CONTESTED CASE HEARING
Respondent.	:	

COMES NOW Respondent Garvis G. Houck (hereinafter “Respondent”) in the above-captioned matter and states to the Iowa Board of Pharmacy Examiners (hereinafter “Board”) that:

1. The Board issued an order on December 15, 2004, denying Respondent’s motion to dismiss.
2. The motion to dismiss was with respect to Count II, which was an accusation of unlawfully manufacturing and dispensing a compounded drug without prescription or authorization to do so.
3. The maintenance of controlled substance records initially identified in Count I was earlier resolved when the requested records were located and copies furnished to the investigator.
4. It is believed that the portions of the complaint and statement of charges relating to Count I would not have been pursued as an official complaint and statement of charges but for the allegations set forth in Count II, which was the allegation connected with a complaint made to the Board that originated the investigation.
5. Respondent has filed an interlocutory request for appeal with the Iowa District Court in and for Cerro Gordo County with respect to the Board’s ruling in dismissing Respondent’s motion to dismiss, in order to obtain a Court determination with respect to the interpretation of

Iowa Administrative Code Section 20.2. The Board and the Iowa Attorney General's Office have been so notified of said filing.

6. Because Respondent claims that the Board does not have jurisdiction to pursue enforcement of Count II, it would be in the best interests of judicial economy, the Board, and the public to procure a Court determination of the Board's interpretation of Iowa Administrative Code Section 20.2 prior to pursuing a contested case proceeding when the Board's jurisdiction is the legal issue presented.

7. A ruling by the Court with respect to Respondent's appeal of the ruling on the motion to dismiss will assist the Board and Respondent in determining how or whether a defense to the accusation in Count II will be required.

8. Respondent requests that the hearing previously scheduled for February 15, 2005, be continued, pending further order of the Board.

9. Respondent does separately request the consent of the Board to the pursuit of an interlocutory appeal of the legal interpretation of Iowa Administrative Code Section 20.2 and related sections of the Iowa Code for the purpose of determining the jurisdictional questions raised by Respondent's petition as filed in the District Court.

WHEREFORE, Respondent requests that the Board (1) continue this contested case proceeding pending further order of the Board and (2) separately consent to a determination by the District Court with respect to the jurisdictional issues raised by Respondent's petition as filed in the Iowa District Court in and for Cerro Gordo County relating to the judicial interpretation of

both Iowa Code and Iowa Administrative Code sections that relate to the issues presented by
Count II of the complaint and statement of charges.

Respectfully submitted,



Michael M. Sellers, Attorney-at-Law (PK0004971)
Sellers Law Office
One Corporate Place
1501 - 42nd Street, Suite 380
West Des Moines, Iowa 50266-1005
Telephone: (515) 221-0111
Telefax: (515) 221-2702
E-mail: sellers@sellersoffice.com

ATTORNEY FOR RESPONDENT

ORIGINAL FILED

Copy to:

Iowa Assistant Attorney General Scott M. Galenbeck
Iowa Department of Justice
Hoover State Office Building, Second Floor
1305 East Walnut Street
Des Moines, Iowa 50319

**VIA TELEFAX (281-7551)
and U.S. MAIL**

Lloyd Jessen, Executive Director
Iowa Board of Pharmacy Examiners
River Point Business Park
400 S.W. Eighth Street, Suite E
Des Moines, Iowa 50309-4688

**VIA TELEFAX (281-4609)
and U.S. MAIL**

Garvis G. Houck
Houck Drug Company
8 North Fourth Street
Clear Lake, Iowa 50428

VIA U.S. MAIL

motcon

CERTIFICATE OF SERVICE
This instrument certifies that the foregoing instrument was served upon all parties to the above cause to each of the attorneys of record herein at their respective addresses disclosed on the pleadings on 2-1, 2005.

Sys: U.S. Mail FAX *as indicated*
 Hand Delivered Overnight Courier
 Certified Mail Other

Signature Patricia J. Quinn

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

Re:)	Case No. 2002-12338
Pharmacist License of)	
GARVIS G. HOUCK)	RESISTANCE TO
License No. 12338)	REQUEST FOR CONSENT TO
Respondent)	TO INTERLOCUTORY APPEAL
)	

Complainant, Lloyd K. Jessen, resists Respondent Garvis Houck's request for consent to an interlocutory appeal, as contained in "Respondent's Request for Continuance of Contested Case Hearing," served February 1, 2005. Complainant's resistance is based upon the following:

1. This Board's contested case disciplinary proceeding against Respondent Garvis G. Houck was recently postponed at the request of Respondent. See "Request for Continuance of Contested Case Hearing" served February 1, 2005.

2. In his "Request for Continuance of Contested Case Hearing," Respondent notes that he has filed a petition, in Cerro Gordo County District Court, seeking interlocutory appeal of this Board's denial of his "Motion to Dismiss" regarding the second of two charges (Count II) contained in a "Statement of Charges" filed against Respondent on June 18, 2002. This Board denied Respondent's "Motion to Dismiss" on December 15, 2004 and subsequently set a hearing date for all charges against Respondent.

3. Respondent's District Court petition was filed January 24, 2005. As Respondent's "Request for Continuance of Contested Case Hearing" explains, the Cerro Gordo County District Court petition seeks review of the jurisdiction of this Board to consider Count II (dispensing a compounded drug without prescriber authorization) of the Statement of Charges filed against Respondent, but does not seek review of anything related to Count I (failure to maintain records

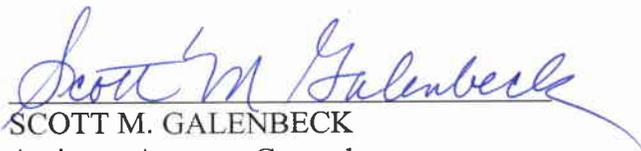
a part of the case (Count II; dispensing a compounded drug without prescriber authorization) which would proceed in Cerro Gordo County District Court while the balance of the case proceeds before the Board.

9. The more practical manner in which this case should proceed is to complete the contested case proceedings now pending before the Board. Once such proceedings are complete, and all administrative remedies exhausted, Respondent may appropriately seek judicial review. Until that time, judicial review is premature.

10. The Board should *not* consent to proceedings which evade the established administrative process – and inappropriately seek judicial review – when the Board has not completed the Board's quasi-judicial function with regard to either Count I or Count II.

WHEREFORE, Complainant requests that Respondent's request for consent to an interlocutory appeal be denied.

Respectfully submitted,



SCOTT M. GALENBECK
Assistant Attorney General
Administrative Law Division
Hoover Building, 2nd Fl.
Des Moines, IA 50319
Tele: (515) 281-7262
FAX: (515) 281-7551
scott.galenbeck@ag.state.ia.us

Copies to:

Michael Sellers
One Corporate Place
1501 42nd Street, Suite 380
West Des Moines, IA 50266-1005

Houck resistance 2.doc

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing instrument was served upon each of the attorneys of record of all parties in the above-entitled cause by enclosing the same in an envelope addressed to each such attorney at his respective address as disclosed by the pleadings of record herein, with postage fully paid, and by depositing said envelope in a United States Post Office depository in Des Moines, Iowa, on the 15th

of February, 2025.

Scott M Galenbeck

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

Re:

Pharmacist License of
GARVIS G. HOUCK
License No. 12338
Respondent

)
)
)
)
)

Case No. 2002-12338

STATEMENT OF CHARGES

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 (2001).
3. On August 13, 1957, the Board issued the Respondent, Garvis G. Houck, a license to engage in the practice of pharmacy by examination as evidenced by license number 12338, subject to the laws of the State of Iowa and the rules of the Board.
4. License number 12338 is current and active until June 30, 2002.
5. The Board filed a Statement of Charges against the Respondent's license to practice pharmacy on October 19, 1992. That case went to hearing and the Board issued its Findings of Facts, Conclusions of Law, Decision and Order on February 19, 1993. The Board issued an Amended Order on October 12, 1993.
6. Upon information and belief, the Respondent's current address is 50 Beaumont, Mason City, Iowa 50401.
7. The Respondent is self-employed as the pharmacist in charge at Houck Drug Co, Inc. and has been so employed during all times relevant to this statement of charges.

COUNT I

The Respondent is charged under Iowa Code § 155A.12 (2001) and 657 Iowa Administrative Code §§ 36.1(4)(i) with intentional or repeated violation of Board rules including but not limited to rules 6.2(1)(a) (legal operation of pharmacy) and 6.8 (controlled substance

records).

COUNT II

The Respondent is charged under Iowa Code § 155A.12 (2001) and 657 Iowa Administrative Code §§ 36.1(4)(i) with unlawful manufacturing and dispensing a compounded drug without prescriber authorization in violation of 657 Iowa Administrative Code § 20.2.

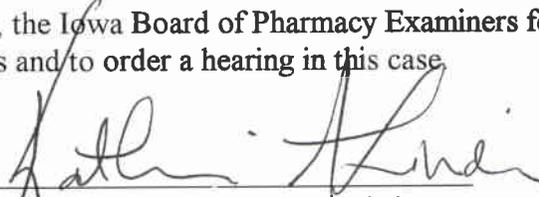
THE CIRCUMSTANCES

1. On or about March 13, 2002, the Board received a complaint about a drug that the Respondent compounded for a patient.
2. Upon investigation, the Board investigator learned that the Respondent compounded a nasal suspension using non-legend drugs for the patient without prescriber authorization.
3. While investigating the complaint referred to in paragraph 1, a Board investigator conducted a follow up review of deficiencies that had been noted in the last inspection of the Respondent's pharmacy, which was conducted on October 24, 2000.
4. The review of the inspection deficiencies revealed that numerous violations of the Board's rules continue to exist in the pharmacy where the Respondent serves as pharmacist in charge. The continuing violations included failure to maintain all required copies of DEA form 222, failure to maintain all required information on DEA form 222, failure to maintain log for permanent and non-permanent pharmacists, failure to include initials of dispensing pharmacists on schedule V drug dispensing log.

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 18 day of June, 2002, the Iowa Board of Pharmacy Examiners found probable cause to file this Statement of Charges and to order a hearing in this case.



Katherine A. "KAP" Linder, Chairperson
Iowa Board of Pharmacy Examiners
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

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

BEFORE THE BOARD OF PHARMACY EXAMINERS
OF THE STATE OF IOWA

RE:) CASE NOS: 2002-12338
) 2002-793
Pharmacist License of:) DIA NO. 04PHB012
GARVIS G. HOUCK)
License No. 12338)
Respondent)
) FINDINGS OF FACT,
and:) CONCLUSIONS OF LAW,
) DECISION AND ORDER
Pharmacy License of)
HOUCK DRUG CO. INC.)
License No. 793)
Respondent)

On June 18, 2002, the Iowa Board of Pharmacy Examiners (Board) found probable cause to file Statements of Charges against Garvis G. Houck (Respondent), a registered pharmacist, and against Houck Drug Co. Inc. (Respondent), a licensed pharmacy. Both Statements of Charges¹ alleged that the Respondent:

COUNT I: Violated Iowa Code section 155A.12(2001) and 657 IAC 36.1(4)(i) by intentionally or repeatedly violating Board rules including but not limited to rules 6.2(1)(a)²(legal operation of a pharmacy) and 6.8 (controlled substance records).

COUNT II: Violated Iowa Code section 155A.12 (2001) and 657 IAC 36.1(4)"i" by unlawfully manufacturing and dispensing a compounded drug without prescriber authorization, in violation of 657 IAC 20.2.

On August 10, 2004, the Respondent filed a Motion to Dismiss the pending Statement of Charges. The state filed a Resistance on or about September 3, 2004, and the Respondent filed a Reply on

¹ The parties stipulated that the hearing would address the Statement of Charges filed against Respondent's *pharmacist* license and the parallel Statement of Charges filed against the Respondent's *pharmacy* license, even though the Notice of Hearing caption referred only to the pharmacist license.

² This is a typographical error. At the time relevant to the Statements of Charges, the subsection relating to legal operation of the pharmacy was found at 657 IAC 6.2(1), subsection "k", not subsection "a." See 657 IAC 6.2, published 10/8/97, effective 11/12/97.

September 10, 2004. After oral arguments, the Board issued an Order Denying Motion To Dismiss on December 15, 2004.

The hearing on the Statements of Charges was held on July 12, 2005 at 2:00 p.m. at the Board's offices in Des Moines, Iowa. The following members of the Board presided: Michael J. Seifert, Chairperson; Katherine A. Linder; Vernon H. Benjamin; Paul Abramowitz, Barbara O'Roake, and Kathleen Halloran. Attorney Michael Sellers represented the Respondent. Assistant Attorney General Scott Galenbeck represented the state. The hearing was closed to the public at the election of the Respondent, in accordance with Iowa Code section 272C.6(1). Administrative Law Judge Margaret LaMarche assisted the Board in conducting the hearing and was instructed to prepare the Board's written Decision and Order, in conformance with their deliberations.

THE RECORD

The record includes the Statements of Charges filed against Respondents Garvis Houck and Houck Drug Co. on June 18, 2002; Notice of Hearing; Motion to Dismiss, Resistance, and Reply; Order Denying Motion to Dismiss; Notice of Hearing and revised Notice of Hearing; the testimony of the witnesses, and the following exhibits:

- State Exhibit A: Statement of Charges against Garvis Houck, 6/18/02
- State Exhibit B: Investigative Report, 4/25/02
- State Exhibit C: Pharmacy Inspection Report, 10/24/00
- State Exhibit D: Statement of Charges against Houck Drug Co., Inc., 6/18/02
- State Exhibit E: Findings of Fact, Conclusions of Law, Decision and Order, issued 2/19/93
- State Exhibit F: Amended Order, issued 10/12/93

- Respondent Exhibit 1: Relevant Portions of Respondent's Brief Resisting State's Motion to Dismiss in District Court
- Respondent Exhibit 2: 657 IAC chapter 20 (current)
 - 2A: 657 IAC chapter 20 (in effect at time of Board's investigation and Statement of Charges)
- Respondent Exhibit 3: Oklahoma provisions
- Respondent Exhibit 4: P.G.P. Generated Products
- Respondent Exhibit 5: Prescription records and pharmacy logs

Respondent Exhibit 6: 21 CFR §1305.13
Respondent Exhibit 7: Mayo Clinic publication re: patent
for sinus infection treatment,
©2003 Mayo Press.
Respondent Exhibit 8: Curriculum Vitae, Diane Johnson
Respondent Exhibit 9: excluded (oral offer of proof
made)
Respondent Exhibit 10: Bottle of nose drops

FINDINGS OF FACT

1. On August 13, 1957, Respondent Garvis Houck was issued license number 12338 to engage in the practice of pharmacy, subject to the laws of the state of Iowa and the rules of the Board. The Respondent owns and operates Houck Drug Co. Inc., which has been issued License No. 793 to operate a pharmacy at 8 North Fourth Street in Clear Lake, Iowa. Both licenses are current and active.

The Respondent is the pharmacist in charge and the only permanent pharmacist working at the Clear Lake pharmacy. The Respondent's daughter is also a licensed pharmacist and is the pharmacist in charge of Houck Drug in Mason City. The Respondent's daughter occasionally fills in for her father as a relief pharmacist at the Clear Lake pharmacy. (State Exhibits A, D; Testimony of Respondent; Jacqueline Devine)

2. A consumer filed a telephone complaint with the Board on March 13, 2002. The consumer reported that while visiting in Clear Lake, she stopped at Houck Drug Co. because she was experiencing nasal burning from chemicals used in her home.³ The Respondent told the consumer that he could mix up something to treat her symptoms. The consumer returned to the pharmacy later that day to pick up a bottle of nose drops prepared by the Respondent.

The consumer later provided the bottle of nose drops to the Board. It is a standard one-ounce amber dropper bottle with a label bearing the name and address of "Houck Drug, Prescription Pharmacy." The bottle is labeled "Antiviral Nose Drops 30 ML." The label also contains the following instructions for use: "3-4 drops in each nostril every 4-6 hours." The bottle has a list

³ The Respondent had a different recollection of the consumer's complaint. The Respondent recalled that the consumer reported suffering from a chronic sinus condition that had been diagnosed at Mayo Clinic. (Testimony of Respondent) The exact reason for the nose drops is immaterial to the Board's decision.

of ingredients, an expiration date of 3-22-02, and an indication that the bottle should be refrigerated. The label does not include a prescription number or the name of a prescriber. The consumer produced a receipt dated 2-21-02 showing that she paid \$50.88 for the nose drops. (Testimony of Jacqueline Devine; State Exhibit B; Respondent Exhibit 10)

When the consumer picked up the nose drops, she also asked the Respondent's advice about using St. John's Wort for depression. The Respondent suggested that he could order something better for her, and she agreed. The consumer used the nose drops just one time and found that they burned her nose for about two hours.⁴ The consumer returned to the Respondent's pharmacy 3-4 weeks later to pick up the product (Inositol) that the Respondent recommended for depression. She was surprised that the Respondent required her to purchase four bottles. When she returned home, the consumer noticed that the Respondent's directions for use exceeded the directions printed on the manufacturer's label. The consumer contacted the Federal Drug Administration (FDA) with her concerns, and they referred her to the Iowa Board of Pharmacy Examiners. (Testimony of Jacqueline Devine; State Exhibit B)

3. The Respondent received compounding training in 1991 at Professional Compounding Centers of America (PCCA) and has had additional compounding training through seminars and audio recordings. The Respondent uses this training to prepare compounded drugs pursuant to a prescription, but he also compounds non-legend drugs⁵ for consumers without a prescriber's order. The Respondent admits that he compounded the nasal drops for the consumer in this case without a prescriber's authorization. According to the Respondent, the nasal drops included the following ingredients:

- Deoxy-D-Glucose(2), which is classified as a nutritional supplement with antiviral properties;
- Dyclonine, which is the anesthetic used in Sucrets;
- Miconazole, an antifungal; and
- Methocel, a form of methylcellulose used as a suspending agent.

The Respondent put these four ingredients and sodium chloride in distilled water to make the nose drops preparation. The four

⁴ When the consumer spoke to the Board's investigator on April 12, 2002, she reported that she was still experiencing some nasal burning.

⁵ "Non-legend" drugs are those that do not require a prescription.

ingredients are all individually available over-the-counter, without a prescription. When the Board's investigator visited the Respondent's pharmacy, she found all of the ingredients as dry powders or crystals stored in the pharmacy.

The Respondent derived the nose drops formula from his personal, prior experience. He also claimed to have relied on a publication discussing Mayo Clinic's recent patent for a new treatment for chronic rhinosinusitis, which delivers antifungal drugs directly into the nose. However, the article cited by the Respondent was published in 2003, which is after the Respondent compounded the nose drops for the consumer. (Testimony of Jacqueline Devine; Respondent; State Exhibit B; Respondent's Exhibits 7, 10)

4. Board inspector/investigator Jacqueline Devine previously inspected the Respondent's Clear Lake pharmacy on October 24, 2000. Devine noted numerous deficiencies in her inspection report, including but not limited to:

- numerous chemicals past their expiration date in the compounding area;
- failure to correctly document DEA form 222;
- failure to record actual date of receipt on drug invoices;
- failure to maintain a log of all permanent and non-permanent pharmacists;
- failure to record the name or initials of the pharmacist who dispensed Schedule V medications to the purchaser;
- failure to complete the required biennial inventory of controlled drugs that was due within four days of August 29, 2000.

In her October 24, 2000 inspection report summary, Devine instructed the Respondent to take the controlled drug biennial inventory "now, then resume the normal schedule." Devine reminded the Respondent that compounding of products must have a valid prescriber/patient/pharmacist relationship and compounding without a prescriber's order is considered manufacturing. (Testimony of Jacqueline Devine; State Exhibit C)

5. After she investigated the consumer's complaint concerning the compounded nose drops, Devine conducted a follow-up inspection of the Respondent's pharmacy on April 17, 2002. Devine observed several deficiencies that had been noted in her October 2000 inspection but still had not been corrected:

- There were still outdated chemicals in the pharmacy that were past their "use by" date or their "expiration" date;
- The third copy of DEA form 222 was still not being properly documented with quantity, date received, and the initials of the person receiving the drugs;
- The Respondent produced a biennial controlled drug inventory dated 8-29-00, which was the inventory that was missing at the time of the last inspection. When the inspector questioned the inventory's date, the Respondent explained that after the October 2000 inspection, he went through his prescriptions and invoices and figured out what inventory he would have had on hand on 8-29-00. He then backdated the inventory to 8-29-00. This inventory was inadequate because it was not dated on the date it was actually taken, was not signed, did not have an indication as to open or close of business, and did not separate the Schedule II drugs from the other drugs.
- There were still no logs for permanent or non-permanent pharmacists. In addition, the Schedule V log book had some entries that were not initialed by the pharmacist who dispensed the medication.
- The Respondent had been previously reminded that he need a prescriber's order for compounded drugs but had compounded nose drops without a prescriber order. The Respondent claimed that he thought that the prescriber order requirement only applied if the drugs being compounded were legend drugs, i.e. required by law to have a prescription, but not to over the counter drugs;
- The production records kept in the pharmacy still did not have the initials of the compounding pharmacist.

Devine attempted to conduct a controlled drug mini-audit, but the Respondent was missing several of the required DEA 222 forms. When Devine returned to the pharmacy the following day, the Respondent had found all but two and parts of a third missing DEA-222 form. However, all forms are supposed to be available at the time of the inspection. (Testimony of Jacqueline Devine; State Exhibit B)

CONCLUSIONS OF LAW

I. Board's Authority to Promulgate 657 IAC chapter 20.

The Respondent reasserts the arguments previously made in his Motion to Dismiss, i.e. that the Board does not have statutory authority to prohibit a licensed pharmacist from compounding

non-prescription drug products for sale to the public. The Respondent argues that 657 IAC chapter 20 is "ultra vires" or beyond the Board's statutory authority. The Respondent does not allege any procedural irregularities in the promulgation of chapter 20. The Board remains convinced that it was authorized by statute to promulgate 657 IAC chapter 20 and that the Respondent's criticisms concerning the wisdom of the rules should have been presented as public comment at the time the rules were proposed and published.

The Iowa Board of Pharmacy Examiners was created, pursuant to Iowa Code section 147.13, and has been empowered by statute with general authority to adopt all necessary and proper rules to implement and interpret Iowa Code chapters 147 and 155A. Iowa Code section 147.76. In addition, the legislature has vested the Board with authority to promulgate rules interpreting, implementing and enforcing the Iowa Drug, Device, and Cosmetic Act. Iowa Code sections 126.2(3); 126.10(8); 126.11(2); 126.17. The declared purpose of Iowa Code chapter 155A is to promote, preserve, and protect the public health, safety and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized. Iowa Code section 155A.2. (emphasis supplied)

Pursuant to its statutory authority under Iowa Code chapters 124, 126, and 155A and the rulemaking procedures outlined in Iowa Code chapter 17A, the Board has promulgated 657 IAC chapter 20, entitled Pharmacy Compounding Practices. This chapter was initially promulgated effective November 29, 1995 and has been subsequently amended. The Respondent contends that 657 IAC chapter 20 is invalid and cannot be enforced because the Board does not have the requisite statutory authority to regulate a licensed pharmacist's compounding of non-prescription drug products for sale to the public.

The Board is convinced that 657 IAC chapter 20 is a necessary and proper exercise of its statutory authority to regulate the practice of pharmacy to protect to the public health, safety, and welfare. By holding a professional license, a licensee accept numerous professional and ethical responsibilities and restrictions that might not apply to the general public. This is necessary and appropriate because licensed professionals hold themselves out to the public as persons with special education and expertise who are worthy of public trust and confidence. The issuance of a professional license is essentially the

state's endorsement that the individual has met the stringent requirements for issuance of a professional license and that the person's practice is regulated by the state.

A licensed pharmacist's preparation and distribution of a compounded drug product to a consumer without prescriber authorization raises significant public health, safety, and welfare concerns. For example, consumers are likely to place far greater trust and confidence in compounded drug products prepared and recommended by a licensed pharmacist than they would if an unlicensed person prepares similar products. Compounded drug products have not been proven safe and effective through the FDA approval process. In addition, pharmacists are not authorized to diagnose and treat patients, and the Board has a responsibility to ensure that pharmacists do not misrepresent or exceed their permissible scope of practice. For these reasons, the Board is confident that it has statutory authority to promulgate and enforce 657 IAC chapter 20, which regulates the compounding of drug products by Iowa licensed pharmacists.

II. Compounding Without A Prescriber's Authorization

Count II charged Respondent Garvis Houck and Respondent Houck Drug Co. Inc. with unlawful manufacturing and dispensing of a compounded drug without prescriber authorization, in violation of Iowa Code section 155A.12(2001) and 657 IAC 36.1(4)(i) and 20.2.

Iowa Code section 155A.12(1)(2001) authorizes the board to impose a fine, issue a reprimand, or revoke, restrict, cancel, or suspend a license, or place a license on probation, if the board finds that the licensee has violated any provision of Iowa Code chapter 155A or any rules of the Board adopted under Iowa Code chapter 155A.

657 IAC 36.1(4)(i) provides, in relevant part, that the board may impose any of the disciplinary sanctions set out in subrule 36.1(2) when the board determines that the licensee is guilty of willful or repeated violations of a lawful rule or regulation promulgated by the board of pharmacy examiners.

657 IAC 20.1⁶ provides the purpose and scope of chapter 20:

⁶ The citation is to the administrative code in effect at the time of the violation. See Respondent Exhibit 2A.

The requirements of this chapter apply to compounding of drugs by Iowa-licensed pharmacists and pharmacies and are minimum good compounding practices for the preparation of drug products for dispensing to humans or animals...

657 IAC 20.2 provides the following relevant definitions:

"Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:

1. 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,

...
"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 its container. Manufacturing also includes the preparation, promotion, and marketing of commercially available products from bulk compounds for resale by pharmacists, practitioners, and other persons.

657 IAC 20.3(3) clearly provides that there must be a triad relationship: prescriber/patient/pharmacist, before the pharmacist may provide a compounded drug to a patient:

20.3(3) Prescriber/patient/pharmacist relationship. A prescription for a compounded drug shall either be unsolicited or marked with a notation by the pharmacist, and approved by the physician that the compounded drug is necessary. Pharmacists may compound drugs in very limited quantities prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/prescriber relationship provided that they maintain the prescriptions on file for all such products compounded at the pharmacy as required by Iowa law...The sale or other distribution of compounded products to other pharmacies or to prescribers without a prescriber/patient/pharmacist

relationship is considered manufacturing. However, compounded products may be provided to a prescriber for the prescriber's use in treatment of the prescriber's patients.

The Respondent admits compounding nose drops for sale to a consumer without prescriber authorization. The facts establish a clear violation of 657 IAC 20.2. The Respondent was previously ordered by this Board to comply with the Board's "Good Compounding Practices" guideline (or a successor rule as may be adopted by the Board) whenever engaging in the compounding of drugs and drug products. (State Exhibit F) At the time of the October 2000 inspection of the Respondent's pharmacy, the Respondent was reminded that compounding must be done as a result of a practitioner's prescription drug order and must have a valid prescriber/patient/pharmacist relationship. The Respondent was also reminded that compounding of preparations for sale to a customer, without a prescriber order, is considered manufacturing. (State Exhibit C) Given the Respondent's past history of discipline/reminders concerning this issue, the Board can only conclude that his violation of the rule was intentional or willful.

III. Intentional or Repeated Violation of Board Rules, Including But Not Limited To Rules Regarding Legal Pharmacy Operation and Controlled Substance Records

Count I charged the Respondent with intentional or repeated violations of the Board's rules, including but not limited to rules relating to legal operation of the pharmacy and controlled substance records. 657 IAC section 6.2(1)⁷ provides in relevant part:

657-6.2(155A) Personnel

6.2(1) Pharmacist in charge. Each pharmacy shall have one pharmacist in charge who is responsible for, at a minimum, the following:

...

k. Legal operation of the pharmacy, including meeting all inspection and other requirements of state and federal laws, rules, or regulations governing the practice of pharmacy.

⁷ All rule references are to those rules in effect at the time of the April 17, 2002 inspection.

The preponderance of the evidence established that on April 17, 2002, the Respondent operated his Clear Lake pharmacy in a manner that violated several Board rules. The evidence further established that similar deficiencies were observed and pointed out to the Respondent during an October 2000 inspection, but the Respondent failed to make the necessary improvements. The Respondent has repeatedly violated 657 IAC 6.2(1) and 6.8.

657 IAC chapter 6 provides, in relevant part:

657-6.7 Procurement and storage of drugs. The pharmacist in charge shall have the responsibility for procurement and storage of drugs.

...

6.7(3) Out-of-date drugs or devices.

...

b. Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined until such drugs or devices are disposed of properly.

...

657-6.8(155A) Records. Every inventory or other record required to be kept under Iowa Code chapters 124 and 155A or 657-Chapter 6 shall be kept at the licensed location of the pharmacy and be available for inspection and copying by the board or its representative for at least two years from the date of the inventory or record except as otherwise required in this rule. Controlled substances records shall be maintained in a readily retrievable manner in accordance with federal requirements. Those requirements, in summary, are as follows:

...

6.8(6) Copy 3 of DEA Order Form 222 shall be properly dated, initialed, and filed and shall include all copies of each unaccepted or defective order form and any attached statements or other documents.

...

6.8(8) Suppliers' invoices of prescription drugs and controlled substances shall clearly record the actual date of receipt by the pharmacist or other responsible individual.

When the Board's investigator visited the Respondent's pharmacy on April 17, 2002, he did not have all of the required copies of DEA Order Form 222 maintained in a readily retrievable manner. Although the Respondent produced most of the required forms by the following day, he was still missing at least two of the

required DEA forms. The same deficiency was noted at the time of the prior inspection in October 2000.

657 IAC section 8.4 provides, in relevant part:

657-8.4(155A) Pharmacist identification and notification.

...

8.4(3) Identification codes. A permanent log of the initials or identification codes which will identify each dispensing pharmacist by name shall be maintained and available for inspection and copying by the board and its representative. The initials or identification code shall be unique to ensure that each pharmacist can be identified. Identical initials or identification codes shall not be used.

8.4(4) Nonpermanent employee pharmacists. The pharmacy shall maintain a log of all licensed pharmacists who have worked at that pharmacy and who are not regularly employed at that pharmacy. Such log shall be available for inspection and copying by the board or its representative.

When the Board's investigator visited the Respondent's pharmacy on April 17, 2002, the Respondent did not have the permanent or non-permanent logs of licensed pharmacists required by 657 IAC 8.4. The same deficiency was noted at the time of the prior inspection in October 2000. The Respondent believes that the Board should ignore this violation since he and his daughter are the only permanent and non-permanent pharmacists who work in the Respondent pharmacy. However, the Board rule is not restricted to pharmacies with multiple pharmacists. The Respondent was not sanctioned for violating this rule in 2000 but was advised to maintain the required logs. He failed to comply.

657 IAC section 10.13 provides, in relevant part:

657-10.13(124) Controlled substances-requirement of prescription, emergency prescriptions, and partial fills...

10.13(13) Dispensing without prescription. A controlled substance listed in Schedule V which is not a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

e. A bound record book for dispensing of controlled substances (other than by prescription) is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase and the name or initials of the pharmacist who dispensed the substance to the purchaser.

When the Board's investigator visited the Respondent's pharmacy on April 17, 2002, he had initialed most, but not all of the prescriptions listed in the Schedule 5 log. The same deficiency was noted at the time of the prior inspection in October 2000.

At the prior inspection in October 2000, the Respondent was advised to immediately conduct the overdue biennial controlled substances inventory required by 21 CFR 1304.11 and then to return to his previous schedule, which required an inventory every two years within four days of August 29th. Instead of taking a current inventory and contemporaneously dating it in October 2000, the Respondent attempted to reconstruct the inventory he should have taken on August 29, 2000 and then backdated the inventory. This did not satisfy the inventory requirements because it was inaccurate and could be misleading.

The Board concedes that it is unlikely that the record keeping violations cited in this Order would have resulted in a formal disciplinary proceeding if they were isolated. However, these same record keeping deficiencies were pointed out to the Respondent by the Board's inspector two years earlier. Although compliance with the rules was a simple matter, the Respondent has exhibited a pattern of choosing which rules to follow and which rules to ignore.

Order

IT IS THEREFORE ORDERED that pharmacist license no. 12338, issued to Garvis Houck, and pharmacy license no. 793, issued to Houck Drug Co. Inc., are hereby placed on probation for a period of three (3) years, subject to the following terms and conditions:

- 1) Within thirty (30) days, the Respondent shall submit, for Board approval, written policies and procedures for the handling of outdated drugs, for controlled drug record keeping and logs, and for compounding. Once approved, the

Respondent shall abide by the written policies and procedures.

2) The Respondent shall file quarterly written reports with the Board by September 5th, December 5th, March 5th, and June 5th of each year of probation and shall appear before the Board if requested.

3) During the period of probation, the Respondent shall not supervise any registered intern and shall not perform any of the duties of a preceptor.

4) The Respondent shall notify the Board of any change in address or employment within ten (10) days.

5) The Respondent shall obey all federal and state laws and regulations substantially related to the practice of pharmacy.

6) Should Respondent leave Iowa to reside or practice outside this state, Respondent must notify the Board in writing of the dates of departure and return. Periods of residency or practice outside the state shall not apply to reduction of the probationary period.

7) Should Respondent violate probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and impose further discipline. If a petition to revoke probation is filed against Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

8) Upon successful completion of probation, Respondent's pharmacist license and pharmacy license will be fully restored.

IT IS FURTHER ORDERED that the Respondent shall not engage in any compounding of any kind except compounding that has been authorized by a prescriber and based on the prescriber/patient/pharmacist relationship in the course of professional practice. In the event the administrative rules are changed in the future, Respondent shall be permitted to engage in compounding only to the extent specifically authorized by agency rule.

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

Dated this 4th day of August, 2005.



Michael Seifert, Chairperson
Iowa Board of Pharmacy Examiners

cc: Scott Galenbeck, Assistant Attorney General
Michael Sellers, Attorney for Respondent

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 BOARD OF PHARMACY STATE OF IOWA

**IN THE MATTER OF THE STIPULATION AND CONSENT ORDER AGAINST
GARVIS HOUCK, R.Ph., RESPONDENT
2002-12338**

TERMINATION ORDER

DATE: August 26, 2008

1. On August 4, 2005, the Iowa Board of Pharmacy adopted the Findings of Fact, Conclusions of Law, Decision and Order placing the license to practice pharmacy, number 12338 issued to Garvis G. Houck on August 13, 1957, on probation for a period of three years under certain terms and conditions.

2. Respondent has successfully completed the probation as directed.

3. The Board directed that the probation placed upon the Respondent's license to practice pharmacy should be terminated.

IT IS HEREBY ORDERED:

That the probation placed upon the Respondent's license to practice pharmacy is terminated, and the license is returned to its full privileges free and clear of all restrictions.

IOWA BOARD OF PHARAMCY



Leman E. Olson, Board Chairperson
400 SW 8th Street, Suite E
Des Moines, Iowa 50309-4688