

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

Re: Pharmacy License of)	COMPLAINT
HOUCK DRUG, INC.)	AND STATEMENT
License No. 793)	OF CHARGES
Garvis G. Houck,)	AND
Pharmacist in charge)	NOTICE
Respondent)	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 Houck Drug Company, Inc., a pharmacy 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 is licensed to operate a pharmacy at 8 North 4th Street in Clear Lake, Cerro Gordo County, Iowa, and holds license number 793.

3. General pharmacy license number 793, issued in the name of Houck Drug Company, Inc., with Garvis G. Houck as pharmacist in charge, was renewed on November 20, 1991, and is current until December 31, 1992.

4. 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.

5. 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...

6. 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.

7. 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.

8. Respondent is guilty of violations of 1991 Iowa Code sections 155A.15(2)(b), 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(f), 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 4, 5, 6, and 7.

1991 Iowa Code section 155A.15 provides, in part, the following:

2...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:...

b. Advertised any prescription drugs or devices in a deceitful, misleading, or fraudulent manner.

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

d. Delivered without legal authorization prescription drugs or devices to a person...

....

f. Delivered mislabeled prescription or nonprescription drugs.

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.

9. 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 4, 5, 6, and 7.

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 8 and 9 constitute grounds for which Respondent's license to operate a pharmacy in Iowa can be suspended or revoked.

WHEREFORE, the undersigned charges that Respondent Houck Drug Company, Inc., has violated 1991 Iowa Code sections 155A.15(2)(b), 155A.15(2)(c), 155A.15(2)(d), 155A.15(2)(f), 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 pursuant to Iowa Code section 17A.12 and 657 Iowa Administrative Code section 1.2, that Garvis G. Houck appear on behalf of Houck Drug Company, Inc., 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, revoke, or not renew the license to operate a pharmacy issued to Houck Drug Company, Inc., on November 20, 1991, 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 its 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 its 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



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: Pharmacy License of)	
Houck Drug, Inc.)	DIA NO. 93PHB-4
)	
License No. 793)	
)	
Garvis G. Houck,)	FINDINGS OF FACT,
Pharmacist in charge,)	CONCLUSIONS OF LAW,
)	DECISION AND ORDER
Respondent)	

TO: HOUCK DRUG

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 hearing on the Complaint and Statement of Charges was consolidated with the identical corresponding Complaint and Statement of Charges filed against the Respondent's pharmacist license. The Findings of Fact and Conclusions of Law, issued to Garvis G. Houck, DIA No. 92PHB-10, are hereby incorporated as though fully set forth.

DECISION AND ORDER

THEREFORE, IT IS THE ORDER of the Iowa Board of Pharmacy Examiners that the Pharmacy License of Houck Drug, Inc., License No. 793, is hereby placed on probation for one year, subject to the same terms and conditions as outlined in the Findings of Fact, Conclusions of Law, Decision and Order issued to Pharmacist Garvis G. Houck.

IT IS FURTHER ORDERED that the Respondent Houck Drug is also liable for the hearing fee and expenses, as specified in the decision issued to Garvis G. Houck.

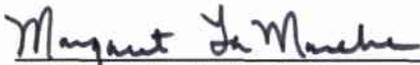
DIA No. 93PHB-4

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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:

Pharmacy License of)	AMENDED
HOUCK DRUG, INC.)	ORDER
License No. 793)	DIA NO. 93PHB-4
<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, Houck Drug, Inc. (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 Garvis G. Houck 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

Iowa Administrative Code section 8.4.

Records and Reports.

Any procedures or other records required to be maintained in compliance with these Good Compounding Practices shall be retained for at least two years from the date of such procedure or record.

All records required to be retained under these Good Compounding Practices, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection.

Records required under these Good Compounding Practices may be retained either as the original records or as true copies, such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records.

Records shall conform with the control and production record requirements contained in 657 Iowa Administrative Code section 8.4.

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Iowa Administrative Code section 8.4.

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