

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

Re: Wholesale Drug License of	}	COMPLAINT AND
JAMES PHILLIPS COMPANY	}	STATEMENT OF CHARGES
License No. 5212	}	AND
Respondent	}	NOTICE OF HEARING

COMES NOW, Lloyd K. Jessen, Executive Secretary/Director of the Iowa Board of Pharmacy Examiners, on the 8th day of October, 1992, and files this Complaint and Statement of Charge and Notice of Hearing against James Phillips Company, a drug wholesaler licensed pursuant to 1991 Iowa Code Supplement section 155A.17, 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 conduct wholesale drug business in Iowa from its facility located at 4155 Berkshire Lane, Plymouth, Minnesota 55446, and holds license number 5212.

3. Wholesale Drug license number 5212 was renewed on December 10, 1991, and is current until December 31, 1992.

4. The Board has received an investigative report from Investigator E. Ray Shelden which alleges the following:

a. A complaint was received from pharmacist Joseph L. Cunningham of Waukon, Iowa, which alleged that Respondent had distributed an unspecified number of vials of Engerix-B (Hepatitis) vaccine, a prescription drug, directly to numerous nursing homes in Iowa via drop-shipments, in violation of state and federal law governing the distribution of prescription drugs.

b. In a telephonic interview conducted by Investigator Shelden on March 27, 1992, Jim Pfau, a distribution manager for the SmithKline Beecham Company (manufacturer of Engerix-B vaccine), stated that

Respondent, through its agent Pamela Wedow, had shipped a "large quantity" of hepatitis vaccine to the ABCM Corporation of Hampton, Iowa, for direct distribution to ABCM's 33 nursing homes in Iowa.

c. The "large quantity" of hepatitis vaccine shipped by Respondent to ABCM's nursing homes in Iowa was estimated by Investigator Shelden to be 990 vials. Investigator Shelden ascertained that the contract between Respondent and the ABCM Corporation called for three separate shipments, totaling 2,970 vials of vaccine. He further concluded that the contract prevented legal distribution of the vaccine through either a licensed pharmacy or a licensed physician.

d. Investigator Shelden observed that the receiving, storage, and re-distribution of Engerix-B (Hepatitis) vaccine, a prescription drug, was performed at ABCM Corporation in Hampton, Iowa, and at ABCM's various nursing homes, by persons who were not licensed to perform these activities and that these activities occurred at facilities which had no legal authority to independently obtain or acquire bulk supplies of prescription drugs such as Engerix-B (Hepatitis) vaccine directly from a wholesale distributor such as Respondent.

e. Investigator Shelden concluded that Engerix-B (Hepatitis) vaccine was delivered by Respondent to the above-mentioned sites in Iowa without legal authorization to do so.

5. Respondent is guilty of violations of 1991 Iowa Code sections 155A.3(34) and 155A.15(2)(d) by virtue of the allegations in paragraph 4, above.

1991 Iowa Code section 155A.3 provides, in part, the following:

34. "Wholesaler" means a person operating or maintaining, either within or outside this state, a...wholesale business...in which prescription drugs, medicinal chemicals, medicines, or poisons are sold, manufactured, compounded, dispensed, stocked, exposed, or offered for sale *at wholesale* in this state (emphasis added).

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:...

d. Delivered without legal authorization prescription drugs or devices to a person other than one of the following:

- (1) A pharmacy licensed by the board.
- (2) A practitioner.

(3) A person who procures prescription drugs or devices for the purpose of lawful research, teaching, or testing, and not for resale.

(4) A manufacturer or wholesaler licensed by the board.

1991 Iowa Code Supplement section 155A.17 provides, in part, the following:

2. The board shall establish standards for drug wholesaler licensure and may deny, suspend, or revoke a drug wholesale license for failure to meet the standards or for violation of the laws of this state, another state, or the United States relating to prescription drugs or controlled substances, or for a violation of this chapter, chapter 203B, 204, 204A, 204B, or 205, or a rule of the board.

3. The board shall adopt rules pursuant to chapter 17A on matters pertaining to the issuance of a wholesale drug license. The rules shall provide for conditions of licensure, compliance standards, licensure fees, disciplinary action, and other relevant matters.

1991 Iowa Code section 155A.18 provides the following:

The board shall impose penalties as allowed under section 258A.3. In addition, civil penalties not to exceed twenty-five thousand dollars, may be imposed.

6. Respondent is guilty of violations of 657 Iowa Administrative Code sections 17.1 and 17.14 by virtue of the allegations in paragraph 4, above.

657 Iowa Administrative Code section 17.1 provides, in part, the following:

"Wholesale distribution" means distribution of prescription drugs to persons *other than a consumer or patient*...(emphasis added)

"Wholesale distributor" means anyone engaged in wholesale distribution of prescription drugs...

657 Iowa Administrative Code section 17.14 provides, in part, the following:

Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

657 Iowa Administrative Code section 17.16 provides the following:

Pursuant to 657--Chapter 9, the board may deny, suspend, or revoke a wholesale drug license for any violation of Iowa Code chapters 155A, 203B, 204, 204A, 204B, and 205, or a rule of the board promulgated thereunder.

The Iowa Board of Pharmacy Examiners finds that paragraphs 5 and 6 constitute grounds for which Respondent's license to conduct wholesale drug business in Iowa can be suspended or revoked.

WHEREFORE, the undersigned charges that Respondent James Phillips Company has violated 1991 Iowa Code sections 155A.3(34) and 155A.15(2)(d) and 657 Iowa Administrative Code sections 17.1 and 17.14.

IT IS HEREBY ORDERED, pursuant to 1991 Iowa Code section 17A.12, 1991 Iowa Code Supplement section 155A.17(2), and 657 Iowa Administrative Code section 17.16, that Respondent appear before the Iowa Board of Pharmacy Examiners on Tuesday, November 17, 1992, at 9:30 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 wholesale drug license issued to James Phillips Company on December 10, 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

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: Wholesale	}	
Drug License of	}	STIPULATION
JAMES PHILLIPS COMPANY	}	AND
License No. 5212	}	INFORMAL
Respondent	}	SETTLEMENT
	}	

COMES NOW the Iowa Board of Pharmacy Examiners (the Board) and James Phillips Company (Respondent) and, pursuant to Iowa Code sections 17A.10 and 258A.3(4), enter into the following Stipulation of the contested case currently on file:

1. Respondent is licensed to conduct wholesale drug business in Iowa from its facility at 4155 Berkshire Lane, Plymouth, Minnesota 55446, and holds license number 5212.

2. Respondent's license to conduct wholesale drug business in Iowa was renewed on December 10, 1991.

3. Respondent's license is current until December 31, 1992.

4. A Complaint and Statement of Charges and Notice of Hearing was filed against Respondent on October 8, 1992.

5. The Board has jurisdiction of the parties and the subject matter.

6. Respondent does not admit the allegations of the Complaint and Statement of Charges, and entry into this Stipulation and Informal Settlement does not constitute any admission. Submission of this Stipulation and Informal

Settlement is only for the purpose of resolution of the Complaint and Statement of Charges.

7. Respondent shall remit a \$1,000.00 civil penalty to the Board office within thirty (30) days of acceptance of this Stipulation and Informal Settlement by the Board.

8. Respondent has taken substantial remedial action by modifying its order processing system to require the state license number of the individual or firm seeking to make a purchase of a prescription drug. In addition to this, Respondent shall submit a written report to the Board within thirty (30) days of acceptance of this Stipulation and Informal Settlement by the Board which includes the following:

a. Further modification of Respondent's order processing system to categorize the type of state license held by a prospective purchaser.

b. Further modification of Respondent's order processing system or procedure to assure that the particular state license of the purchaser authorizes that individual or firm to obtain and possess prescription drugs within that state.

9. Stipulation and Informal Settlement is subject to approval of the Board. If the Board approves this Stipulation and Informal Settlement, it becomes the final disposition of this matter. If the Board fails to approve this Stipulation and Informal Settlement, it shall be of no force or effect to either party.

10. This Informal Settlement is voluntarily submitted by the Respondent to the Board for its consideration on the 17 day of November, 1992.


Timothy R. Gentz
President and CEO
James Phillips Company
Respondent

Signed and sworn to before me this 17th day of November 1992, 1992.


NOTARY PUBLIC IN AND FOR THE
STATE OF IOWA

11. This Informal Settlement is accepted by the Iowa Board of Pharmacy Examiners on the 12th day of JANUARY, 1993.


Alan M. Shepley, Chairperson
Iowa Board of Pharmacy Examiners