IN THE MATTER OF	*	**BEFORE THE**
DAVID DRUGS, INC., d/b/a Kay Cee Drugs	*	**STATE**
	*	**BOARD OF PHARMACY**
PERMIT NO. P00357	*	
Respondent	*	

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FINAL CONSENT ORDER

Based on information received and a subsequent investigation by the State Board of Pharmacy (the "Board") and subject to Md. Health Occ. Code Ann. Tit. 12 (the "Act"), the Board charged David Drugs, Inc., d/b/a Kay Cee Drugs (the "Respondent-Pharmacy"), with violations of the Act. Specifically, the Board charged the Respondent-Pharmacy with violation of the following provisions of §12-409:

> (a) Subject to the hearing provisions of § 12-411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:
>
> > (1) Is conducted so as to endanger the public health or safety;
> >
> > (2) Violates any of the standards specified in § 12-403 of this subtitle.

§12-403:

> (b) Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:
>
> > (1) Shall be operated in compliance with the law and with the rules and regulations of the Board;
> >
> > (2) Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety;

> (9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12-313 of this title;

§ 12-313:

> (b) Subject to the hearing provisions of §12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a license to any applicant, reprimand any licensee, place any licensee on probation; or suspend or revoke a license if the applicant or licensee:
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> > (7) Willfully fails to file or record any report that is required by law;
> >
> > (20) Is professionally, physically, or mentally incompetent;

The Respondent-Pharmacy was given notice of the issues underlying the Board's charges by documents dated February 19, 2001. Accordingly, a Case Resolution Conference was held on April 11, 2001 and was attended by Melvin N. Rubin and W. Irving Lottier, pharmacist members of the Board, Laverne Naesea, Executive Director of the Board, and Paul Ballard, Counsel to the Board. Also in attendance were the Respondent and his attorney, Bruce L. Marcus, and the Administrative Prosecutor, Roberta L. Gill, Assistant Attorney General. At the Case Resolution Conference, Ms. Gill and Mr. Marcus presented to the panel a mutually agreeable proposed Consent Order, which the panel recommended to the full Board that same be accepted by it, in lieu of further proceedings.

Following the Case Resolution Conference, the parties and the Board agreed to resolve the matter by way of settlement. The parties and the Board agreed to the following:

FINDINGS OF FACT

1. At all times relevant herein, the Respondent-Pharmacy was permitted to operate as a pharmacy in the State of Maryland. The Respondent-Pharmacy was first issued a permit on July 1, 1955. The Respondent-Pharmacy was majority-owned and operated by Melvin Chaiet, a dispensing pharmacist, until October, 2000. Thereafter, the stock of the Respondent-Pharmacy was sold to four individuals, one of whom was Stewart Hess, current Vice-President/Treasurer, who worked at the Respondent-Pharmacy as a dispensing pharmacist during the times relevant herein. The Respondent-Pharmacy is located in District Heights, Maryland.

2. On July 21, 2000, in the District Court for Prince George's County, Melvin Chaiet, who at all times relevant hereto was the owner of the Respondent -Pharmacy, but who no longer owns, operate or has any involvement in the management or operation of the Respondent-Pharmacy, pled guilty to and Judge Platt found CHAIET guilty of one count of Conspiracy to Distribute Adulterated Medications, pursuant to Sections 21-216 and 21-256[1] [2]of the Health General Article, Ann. Code of Md. The Settlement Agreement,

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[1]21-216 Adulterated drugs and devices.

> (a) Application for section. For purposes of this subtitle, a drug or device is adulterated if the standards in this section apply.
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> (b) When drug or device is adulterated. A drug or device is adulterated if:
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> > (2) It was produced, prepared, packed, or held under unsanitary conditions that reasonably would be expected to have:
> >
> > > (ii) Caused it to be injurious to health

(c) Additional grounds of drug adulteration. In addition to the grounds specified in subsection (b) of this section, a drug is adulterated if:

(1) Any part of its container is composed of any poisonous or otherwise deleterious substance that reasonably would be expected to have caused the drug to be injurious to health;

(3) The mixing or packing of any substance with the drug has reduced the quality or strength of the drug;

(5) The methods, facilities, or controls used in the manufacture, processing, packing, or holding of the drug do not conform to, or are not administered in conformity to, good practice to assure that the drug:

(i) Meets the requirements of this subtitle as to safety; and
(ii) Has the identity, strength, quality, and purity that it purports to have;

(6) It is purported to be a drug the name of which is recognized in an official compendium and:

(i) The strength of the drug differs from, or the quality or purity of the drug falls below, the standard set in the official compendium; and
(ii) The difference in strength, quality, or purity is not stated plainly on its label; or

21-256. Prohibited acts - General A person may not:

(1) Manufacture or sell any food, drug, device, or cosmetic that is adulterated or misbranded;

(2) Adulterate or misbrand any food, drug, device, or cosmetic;

(3) Make a food, drug, device, or cosmetic become adulterated by altering, mutilating, destroying,

a civil agreement whereby Mr. Chaiet, on behalf of himself and the Respondent-Pharmacy, agreed to pay the State $190,000, was signed by Mr. Chaiet on July 17, 2000, and by the Attorney General's Office on July 20, 2000. The Plea Agreement, Statement of Facts and Criminal Information, were entered into on July 21, 2000.

3. The Statement of Facts sets forth the following information:

A. In March, 1997, the Medicaid Fraud Control Unit (MFCU) of the Attorney General's Office received a referral from the Department of Health and Mental Hygiene (DHMH) regarding the Respondent-Pharmacy's billing practices for disposable medical supplies. Specifically, DHMH was concerned that the Respondent-Pharmacy overbilled it for diapers.

B. Subsequently, Mr. Chaiet conducted an audit and determined that the Respondent-Pharmacy had overbilled Medicaid $210, 000 for diapers over a period of several years. During its investigation regarding the diapers, MFCU obtained information regarding prescriptions paid for by Medicaid being returned to the Respondent-Pharmacy, but not being credited to Medicaid.

C. Accordingly, Medicaid applied for and obtained a search and seizure warrant for the Respondent-Pharmacy's premises, which warrant was executed on July 8,

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obliterating, or removing any part of its labeling while the food, drug, device, or cosmetic is held for sale;

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1999. The search team found dozens of bags and boxes of returned prescriptions on the Respondent-Pharmacy's floor and under the cabinets: over 3000 returned prescriptions in various forms, returned multi-pill bubble packs, brown bottles containing several different medications with labels from bubble packs attached thereto, and manufacturers' bottles labeled to contain 100 pills that actually contained more than 100 pills were found.

D. The investigation disclosed that, as part of its business, the Respondent-Pharmacy SOLD prescriptions in the form of multi-pill bubble packs[3]. The Respondent-Pharmacy sold many of these packs to nursing home patients, whose prescriptions were often changed due to doctors' orders, patient relocation or patient demise. As a result, many of these bubble packs went unused. Because pills issued in multi-pill packs come in contact with other medications, multi-pill pack bubbles cannot be resold once returned to the pharmacy.

E. Beginning in 1984 and continuing until July 8, 1999, the Respondent-Pharmacy took returned multi-pack bubble packs, punched out the pills and placed all the pills from that pack into empty brown pharmacy bottles, transferring the label from the bubble pack cards to the brown bottles. Thereafter, Mr. Chaiet and several other pharmacists, at Mr. Chaiet's direction, removed the multiple types of pills from the brown bottles and placed them with other like pills on the Respondent-Pharmacy's stock shelves for resale. Mr. Chaiet usually performed these activities on Sundays, when the Respondent-Pharmacy was closed to the public.

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[3] Bubble pack prescriptions are issued on pieces of cardboard that contain individual plastic bubbles wherein daily doses of medications are placed, allowing patients to easily identify the medications they need to take each day. Bubbles can contain one pill or multiple pills.

F. As a result of this recycling of pills, there were times when an individual manufacturer's bottle contained different colored pills of the same medication or different medications than described on the manufacturer's label. In so doing, the Respondent-Pharmacy failed to assure that the lot numbers and expiration dates on the recycled medications were recorded and tracked.

4. As a result of the sale of adulterated medications, as set forth above, the Respondent-Pharmacy placed public safety in jeopardy by failing to guarantee that the drugs had the strength, quality and purity purported by the manufacturer, as prescribed by the patients' health providers, and required under Maryland law.

5. On behalf of himself only (and not the Respondent-Pharmacy), Mr. Chaiet entered into a Plea Agreement with the Attorney General's Office, wherein he agreed to enter a plea of guilty to the One Count Information charging him with a conspiracy to violate Maryland Health General Article, Sections 21-216 and 256, be sentenced to one year of imprisonment, with all but six months suspended, serving the six months as home confinement, followed by three years' supervised probation. On behalf of himself and the Respondent-Pharmacy on July 20, 2000, Mr. Chaiet entered into a Civil Settlement whereby they agreed to pay $190, 000 to the State. On that same day, Judge Platt adopted the Plea Agreement in finding Mr. Chaiet guilty and fining him, as outlined in the Agreement.

6. The gravamen of the above actions is that the Respondent-Pharmacy failed to credit Medicaid for returned drugs that Medicaid had paid for. In addition, the Respondent-Pharmacy endangered public health and safety by the manner in which the drugs were repackaged and/or sold.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, the Board finds that Respondent-Pharmacy violated §§ §12-409 (1) and (2), §§ 12-403 (b) (1), (2) and (9), and § 12-313 (7).

ORDER

Based on the foregoing Findings of Fact, Conclusions of Law and agreement of the parties, it is this 18 day of APRIL, 2001, by a majority of a quorum of the Board,

ORDERED that the Respondent-Pharmacy be **REPRIMANDED**; and be it further

ORDERED that the Respondent-Pharmacy shall be placed on one year's Probation during which an agent of the Board shall conduct at least one random inspection of the pharmacy to determine if the practices detailed herein have ceased and that the pharmacy is being operated in accordance with the laws and regulations pertaining to pharmacy. That agent shall provide a report to the Board of its findings.

ORDERED that the Consent Order is effective as of the date of its signing by the Board; and be it

ORDERED that should the Board receive a report that the Respondent-Pharmacy's practice is a threat to the public health, welfare and safety, the Board may take immediate action against the Respondent-Pharmacy, including suspension or revocation, providing notice and an opportunity to be heard are provided to the Respondent-Pharmacy in a reasonable time thereafter. Should the Board receive in good faith information that the Respondent-Pharmacy has substantially violated the Act or if the Respondent-Pharmacy violates any conditions of this Order or of Probation, after providing the Respondent-Pharmacy with notice and an opportunity for a hearing, the Board may take further disciplinary action against the Respondent-Pharmacy, including suspension or revocation. The burden of proof for any action brought against the Respondent-Pharmacy as a result of a breach of the conditions of the Order or of Probation shall be on the Respondent-Pharmacy to demonstrate compliance with the Order or conditions.

ORDERED that one year from the effective date of the Order, the Respondent-Pharmacy may petition the Board in writing to remove the conditions of Probation. If the Respondent-Pharmacy has complied with the Act and the Order, the Board shall remove the conditions of Probation. If the Respondent-Pharmacy has not complied with the Act or the Conditions of Probation, the Board may extend the Probation and place on the Respondent-Pharmacy any additional conditions that it deems necessary. If the Respondent-Pharmacy fails to petition for a removal of the conditions of Probation, the conditions shall continue in effect:

ORDERED that for purposes of public disclosure, as permitted by §10-617(h) State Government Article, Annotated Code of Maryland, this document consists of the contents

of the foregoing Findings of Fact, Conclusions of Law and Order and may be reported to any health practitioner data bank the Board is obligated to report to .

Stanton Ades, P.D., President
State Board of Pharmacy

CONSENT OF DAVID DRUGS, INC., d/b/a/ KAY CEE DRUGS

I, Stewart Hess, Vice President/Treasurer, on behalf of David Drugs, Inc., d/b/a Kay Cee Drugs, by affixing my signature hereto, acknowledge that:

1. The Respondent-Pharmacy is represented by an attorney, Bruce L. Marcus, and has been advised by him of the legal implication of signing this Consent Order.

2. I, on behalf of the Respondent-Pharmacy, am aware that without my consent, the Respondent-Pharmacy's permit to operate as a pharmacy in this State cannot be limited except pursuant to the provisions of § 12-411 of the Act and §10-201, et seq., of the Administrative Procedure Act (APA), Md. State Gov't Code Ann. (1999 Repl. Vol.);

3. I, on behalf of the Respondent-Pharmacy, am aware that the Respondent-Pharmacy, is entitled to a formal evidentiary hearing before the Board.

By this Consent Order, I, on behalf of the Respondent-Pharmacy, hereby consent without admission to the foregoing Findings of Fact, Conclusions of Law and Order provided the Board adopts the foregoing Consent Order in its entirety. By doing so, I, on behalf of the Respondent-Pharmacy, waive our right to a formal hearing as set forth in § 12-411 of the Act and §10-201, et seq., of the APA, and any right to appeal as set forth in § 412 of the Act and §10-201, et seq., of the APA. I, on behalf of the Respondent-

Pharmacy, acknowledge that failure to abide by the conditions set forth in this Order and following proper procedures, may suffer disciplinary action, possibly including revocation, against the Respondent-Pharmacy's permit to operate as a pharmacy in the State of Maryland.

4/10/01
Date

P.D VP/Treasurer
Stewart Hess, P.D., Vice President/Treasurer
David Drugs, Inc., d/b/a/ Kay Cee Drugs

STATE OF MARYLAND

CITY/COUNTY OF Prince George's :

I HEREBY CERTIFY that on this 10th day of April, 2001, a Notary Public of the State of Maryland and (City/County), Calvert, personally appeared Stewart Hess, P.D., Vice President/Treasurer of David Drugs, Inc., d/b/a/ Kay Cee Drugs, Permit No. 00357, and made oath in due form of law that signing the foregoing Consent Order was his voluntary act and deed, and the statements made herein are true and correct.

AS WITNESSETH my hand and notarial seal.

Donna H. Rummel
Notary Public DONNA H. RUMMEL

My Commission Expires: 03/01/2005

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