IN THE MATTER OF	*	**BEFORE THE**
CARDINAL HEALTH	*	**MARYLAND**
License Nos.: PW0080/D01333	*	**STATE BOARD**
Respondent-Pharmacy/Distributors	*	**OF PHARMACY**

* * * * * * * * * * * *

ORDER FOR SUMMARY SUSPENSION

Pursuant to Md. State Govt. Code Ann. §10-226 (c) (2004 Repl. Vol.), the State Board of Pharmacy (the "Board") hereby suspends the pharmacy and distributor permits issued to Cardinal Health, Inc., License Nos. PW0080 and D01333, (the "Respondent-Pharmacy"), under the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. §§ 12-101, et seq. (2000 Repl. Vol.). This Order is based on the following investigative findings, which the Board has reason to believe are true:

BACKGROUND

1. At all times relevant, the Respondent-Pharmacy was authorized to operate a pharmacy and distribute prescription drugs in the State of Maryland. The Respondent–Pharmacy was first issued a permit to operate a pharmacy on February 25, 2003, under license number PW0080, and a permit to distribute prescription drugs on February 25, 2003, under license number D01333. The Respondent's permits expire on December 31, 2005.

2. At all times relevant, the Respondent-Pharmacy was operating a pharmacy and distributing prescription drugs at 2003 Greenspring Drive, Timonium, Maryland 21093.

3. The Respondent-Pharmacy produces a radionuclide-tagged cardiac scanning solution ("Cardiolite") for clinics in the State of Maryland. The Respondent-Pharmacy also prepares other radio-labeled products for distribution in Virginia, the District of Columbia, Pennsylvania, Delaware, and New Jersey.

FINDINGS OF FACT

4. On or about December 6, 2004, the Board received a complaint from the Epidemiology and Disease Control Program of the Maryland State Department of Health and Mental Hygiene ("DHMH"). The Maryland State Epidemiologist informed the Board's investigator of a suspected outbreak of Hepatitis C among patients receiving Cardiolite traced to a batch with Lot Number 04289140 prepared by the Respondent-Pharmacy. Hepatitis C is an infectious disease, which can cause death.

5. On or about December 6, 2004, DHMH in collaboration with the Centers for Disease Control and Prevention ("CDC") began an investigation into the reported cluster of Hepatitis C cases.

6. On or about December 6, 2004, the Respondent-Pharmacy voluntarily suspended its preparation and distribution of all radio-labeled parenteral compounds at its Timonium, Maryland location in response to the DHMH investigation.

7. On or about December 10, 2004, the Board's investigator along with officials from the Food and Drug Administration ("FDA"), DHMH Division of Drug Control ("DDC"), and the DHMH Epidemiology and Disease Control Program met with employees of the Respondent-Pharmacy at its Timonium, Maryland location.

8. The manager of the Respondent-Pharmacy explained the various steps involved in the compounding of Cardiolite and the radioactive isotope completed at the Timonium, Maryland location. An employee of the Respondent-Pharmacy demonstrated the Cardiolite preparation process for the Board's investigator and officials of the FDA and DHMH. An employee of the Respondent-Pharmacy explained that the compounding of Cardiolite is completed by a pharmacist, except for the last step of the quality check and volume adjustment, which is completed by a pharmacy technician. The volume adjustment involves the adding of saline solution, which was identified as a possible source of cross contamination by DHMH officials.

9. The Respondent-Pharmacy also prepares a product involving human blood at its Timonium, Maryland location. The product is prepared through a process of placing a container of blood in a centrifuge and separating the plasma, white blood cells, and red blood cells. The process of centrifuge leaves a compacted residue of white blood cells and red blood cells. After the plasma is separated, the compacted mass is agitated with saline solution to separate out the white blood cells. The white blood cells are tagged with a radioisotope and the mixed blood is then injected into a patient. A demonstration of this procedure was also performed by an employee of the Respondent-Pharmacy. The process is known as Tropolone Leukocyte labeling.

10. The production of the human blood product requires strict adherence to aseptic sterile techniques.

11. The investigation of the Respondent-Pharmacy is focusing on the possible cross contamination of Cardiolite and the blood products.

12. On or about December 10, 2004, the Board contracted the services of the Director of Central Admixture Pharmacy Services ("CAPS") to serve as a Board consultant. The Board consultant reviewed the blood product preparation at the Respondent-Pharmacy on or about December 10, 2004, and made the following findings:

a. No standard operating procedure was observed;

b. Labeling occurs at different steps during compounding, and the labeling process was very difficult to follow, which could lead to labeling errors and product mix up;

c. Proper aseptic techniques were not observed during compounding, jewelry (including watches and rings) were observed during the compounding process, and face masks, head bonnets, and scrubs were not worn during the compounding process;

d. No hand washing station was observed near the clean room;

e. Recapping of a syringe was observed during compounding, which can lead to needle sticks;

f. Needles were observed being used during the compounding process even though the Respondent-Pharmacy claimed the process was needle-less;

g. No quality assessment was performed on the end product after the compounding was completed; and

h. No waste disposal process was observed.

13. The blood product preparation and Cardiolite production was also reviewed by the DHMH DDC at the Respondent-Pharmacy on or about December 10, 2004. DDC made the following findings:

a. The pharmacist performing the demonstration was observed recapping syringes during compounding, which can increase the risk of needle sticks and lead to confusion over used syringes;

b. It was unclear what the pharmacist performing the demonstration did with the waste and if unused material under the hood was considered waste;

c. The pharmacist performing the demonstration did not have all the materials necessary and had to leave the room several times to obtain them;

d. The pharmacist did not use masks or gowns;

e. No materials to be used in case of spills were observed;

f. No hand washing facilities were near the worksite;

g. If the cardiolite was heated as demonstrated, contamination would occur in the verification and dilution process or when the cardiolite was divided into individual doses;

h. The equipment used to verify the radioactivity of the cardiolite was not cleaned after each use;

i. The room in which the blood product had been compounded had a refrigerator. The presence of a refrigerator could have lead to more traffic in the area[1]; and

j. An employee of the Respondent-Pharmacy indicated that blood products from more than one patient are processed at the same time under the same hood, which could lead to confusion.

14. On or about December 13, 2004, the Board received a written complaint from the Maryland State Epidemiologist. The complaint alleges the possibility of contamination of Cardiolite produced by the Respondent-Pharmacy based on epidemiological evidence leading to multiple lab confirmed cases of acute viral Hepatitis C.

1 The refrigerator has since been removed from this area.

15. Specifically, the complaint alleged that eleven patients had been identified with acute Hepatitis C virus infection. All of the patients had undergone a cardiac imaging study on October 15, 2004, using a radionuclide-tagged cardiac scanning solution, Tc99m-labeled Cardiolite. All of the patients received the same lot of Tc99m labeled Cardiolite, which was prepared at the Respondent-Pharmacy.

16. The above actions constitute violations of the Maryland Pharmacy Act, Md. Health Occ. Code Ann. §§ 12-101 *et seq.* (2000 Repl. Vol.). Specifically, the Board finds that the Respondent-Pharmacy violated § 12-409 of the Act, which states:

> (a) *In general.* -- * * *, 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; or
>
> (3) Otherwise is not conducted in accordance with the law.

17. The above actions also constitute violations of COMAR 10.34.19, which states in relevant part:

> **.04 General Requirements**
>
> F. The pharmacy shall provide protection for its products, environment, and personnel involved in the handling of antineoplastics and other sterile parenterals by using the proper equipment and having a procedure manual for those agents.

CONCLUSIONS OF LAW

Based on the foregoing, the Board finds that the public health, safety or welfare imperatively requires emergency action, pursuant to Md. St. Gov't. Code Ann. § 10-226(c)(2) (2004 Repl. Vol.).

ORDER

Based on the foregoing, it is therefore, by a majority vote of a quorum of the State Board of Pharmacy, by authority granted to the Board by Md. St. Govt. Code Ann. ə 10-226(c)(2) (2004 Repl. Vol.), hereby:

ORDERED that the licenses held by the Respondent-Pharmacy to operate a pharmacy and distribute prescription drugs in the State of Maryland, License Nos. PW0080/D01333, are hereby **SUMMARILY SUSPENDED;** and be it further

ORDERED, that a Show Cause Hearing shall be scheduled for Wednesday January 19, 2005, at 1:30 p.m. at the Board's offices, 4201 Patterson Avenue, Baltimore, Maryland 21215, at which the Respondent-Pharmacy will be given an opportunity to be heard as to whether the Summary Suspension should be lifted/terminated, regarding the Respondent-Pharmacy's fitness to operate a pharmacy and distribute prescription drugs and the danger to the public; and be it further

ORDERED, that the Respondent shall immediately turn over to the Board its wall certificate and wallet-sized license to operate a pharmacy and distribute prescription drugs issued by the Board; and be it further

ORDERED, that this document constitutes a final Order of the Board and is therefore a public document for purposes of public disclosure, as required by Md. State Gov't Code Ann. § 10-617(h) (2004 Repl. Vol.).

Jan. 11, 2005
Date

LaVerne G. Naesea, Executive Director
Maryland Board of Pharmacy

NOTICE OF HEARING

A Show Cause hearing to determine whether the Summary Suspension shall be lifted/terminated will be held before the Board at 4201 Patterson Avenue, Baltimore, 21215 on **Wednesday January 19, 2005, at 1:30 p.m.**