IN THE MATTER OF	*	**BEFORE THE**
CENTRAL ADMIXTURE PHARMACY	*	**MARYLAND**
SERVICES, INC.	*	**STATE BOARD**
Permit Nos.: PW0184/D01075	*	**OF PHARMACY**
Respondent-Pharmacy/Distributors	*	

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ORDER FOR SUMMARY SUSPENSION

The State Board of Pharmacy (the "Board") hereby **SUMMARILY SUSPENDS** the pharmacy and distributor permits issued to Central Admixture Pharmacy Services Inc. (hereinafter "CAPS"), Permit Nos. PW0184 and D01075. The Board takes such action pursuant to its authority under Md. State Gov't Code Ann. § 10-226(c)(2)(i) (2004 Repl. Vol.), concluding that the public health, safety, or welfare imperatively requires emergency action.

BACKGROUND

Based on information received by, and made known to the Board, and the investigatory information obtained by, received by and made known to and available to the Board and the Office of the Attorney General, including the instances described below, the Board has reason to believe that the following facts are true:[1]

1. At all times relevant hereto, CAPS[2] was authorized to operate a pharmacy and distribute prescription drugs in the State of Maryland. CAPS was first issued a

[1] The statements regarding the Respondent's conduct are intended to provide the Respondent with notice of the basis of the suspension and likely charges. They are not intended as, and do not necessarily represent a completed description of the evidence, either documentary or testimonial, to be offered against the Respondent in this matter.

[2] CAPS operates multiple pharmacies across the United States. All references to CAPS in this order are to its Lanham, Maryland facilities unless otherwise noted.

permit to operate a pharmacy on March 25, 1999, under permit number PW0184, and a permit to distribute prescription drugs on March 26, 1999, under permit number D01075.

2. At all times relevant, CAPS was operating a pharmacy and distributing prescription and nonprescription drugs at 9730 Martin Luther King Jr. Highway, Unit C, Lanham, Maryland 20706.

3. CAPS admixes, dispenses and delivers labeled, patient specific and anticipatory Intravenous ("IV") prescriptions to patients and hospitals in the District of Columbia, Delaware, Virginia, and Maryland. Among the many products CAPS produces are an array of cardioplegia solutions ("Cardioplegia") that are administered to patients during heart-by-pass surgery to stop the beating heart.

FINDINGS OF FACT

4. On or about September 12, 2005, the Board received a complaint concerning a series of cases involving "systemic inflammatory response syndrome" (SIRS) that had taken place in open-heart surgery patients at Mary Washington Hospital in Virginia.

5. The Board's investigator was informed that the patients suffering from SIRS had received Cardioplegia during open-heart surgery that was compounded by CAPS. Approximately five patients at Mary Washington Hospital exhibited SIRS symptoms following open-heart surgery. Of those five patients, three patients died at the hospital and two remain in critical condition.

6. On or about September 12, 2005, the Food and Drug Administration ("FDA") Baltimore District Office began an investigation into the reported cluster of SIRS cases at Mary Washington Hospital. The FDA also concurrently inspected CAPS'

facility in Lanham, Maryland and discovered significant Good Manufacturing Product violations, specifically stating that there was no assurance of sterility of any of the products manufactured by CAPS.

7. On or about September 16, 2005, the FDA contacted the Board to inform it that following its preliminary investigation the FDA had: (1) stopped shipment of all products manufactured at CAPS' Lanham, Maryland facility; (2) required CAPS to notify customers of all products to quarantine and/or hold all product(s) until further notice; and (3) required CAPS to issue a press release concerning the situation.

8. On or about September 16, 2005, CAPS issued an "Urgent Drug Recall" notification to its customers for all injectable products manufactured at the Lanham, Maryland facility. Additionally, CAPS, at the Board's request, voluntarily ceased distributing and dispensing all prescription products from the Lanham, Maryland facility.

9. On or about September 16, 2005, the FDA received lab results from its New York Regional Laboratory (NRL). Preliminary test results of some intact Cardioplegia samples collected from Mary Washington Hospital exhibited the presence of bacteria, raising further sterility concerns about CAPS' products.

10. On or about September 19, 2005, the FDA reviewed records at the CAPS facility documenting that the hood CAPS uses for the manufacture of Cardioplegia was found positive for bacterial growth last year during the firm's environmental testing.

11. On or about September 20, 2005, the FDA received a report from Sinai Hospital, Baltimore, Maryland concerning a patient who was administered Cardioplegia compounded by CAPS on September 11, 2005, post-operatively. On or about September 14, 2005, the patient developed "sepsis with pseudomonas."

12. The Cardioplegia administered to patients at Mary Washington Hospital consists of three solutions.[3] Each patient receives one bag of each solution during surgery. Solutions One and Two have different levels of potassium and are used during surgery. Solution three is a warmed solution that is used at the end of surgery. Upon testing, Mary Washington Hospital found gram negative bacteria in an intact IV bag of solution Two.[4] Furthermore, testing by the FDA's North Regional Laboratory detected the presence of bacteria in intact IV bags of Cardioplegia from both Mary Washington Hospital and Sinai Hospital.

13. The production of Cardioplegia and other patient specific and anticipatory IV drug products requires the strict adherence to aseptic sterile techniques.

14. On or about October 12, 2005, the FDA issued a list of Inspectional Observations to CAPS, finding CAPS failed to meet the standards required by United States Pharmacopeia (USP), Chapter 797. The FDA reviewed product preparation and processing at CAPS on or about September 13, 14, 15, 19, 20, and October 5, 11, 12, 2005, and made the following observations:

a. Information received during the inspection indicates that the firm has not designated any staff member or multiple staff members at this location to be part of a Quality Control Unit (QCU);

b. Sterility testing is not performed for infusion products produced by the firm with twenty-four (24) to thirty (30) day expiration dates (for example, Dialysate, Oxytocin, Magnesium) produced by the firm;

c. Infusion/Injectable products are not always labeled as sterile;

d. Employees did not follow proper gowning procedures;

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[3] The Cardioplegia at Mary Washington Hospital was manufactured per the hospital's instructions. The pertinent date codes at this time consist of Cardioplegia manufactured by CAPS on August 11, 2005 and August 30, 2005.

[4] This testing was performed on or about September 11, 2005.

e. Sterile parenteral products made by the firm are not always kept at appropriate temperatures during shipping;

f. CAPS has not sent out one sample from each of the environmental monitoring tests for speciation each quarter;

g. No specific instructions are provided for the location of weekly surface touch plate monitoring;

h. Positive and negative controls are not run concurrently with each microbiological environmental monitoring test;

i. Production areas (Class 100 hoods) have not been qualified under dynamic conditions to assure that unidirectional airflow sweeps any potential contamination away from the product;

j. CAPS Standard Operating Procedures (SOP) fails to address the frequency of calibration of the thermometers used to monitor the temperature in CAPS' refrigerators, freezers, production rooms and incubators where components and products are stored. Likewise, there is no documentation demonstrating that the thermometers were properly calibrated;

k. Documentation of the calibration of several of the balances used in the production of parenteral drug products indicated that the balances were found by the contractor to be out of calibration. There is no documentation indicating that the out-of-specification results were investigated to determine if there was an effect on the product. Likewise, CAPS' SOP fails to provide corrective action for out-of-specification results;

l. Employees routinely involved in the production of parenteral drug products made by CAPS lacked intial and/or annual aseptic and gowning training and/or there was inadequate documentation reflecting that such training had occurred;

m. The Director of Pharmacy is not performing or documenting a monthly review of environmental logs;

n. Required cleaning log sheets are not always completed and the monthly review of the cleaning log sheets is not always conducted; and

o. CAPS uses unapproved forms and/or fails to document the lot numbers of all the components brought into the production room each day.

p. While CAPS has a manual of SOPs in place concerning Quality Control, Gowning Requirements, Environmental Monitoring, Training Policy,

Room Cleaning and Documentation, TPN and Cardioplegia Compounding Procedure, it fails to follow the requirements of the same.

15. Additionally, information provided by the FDA and CAPS demonstrates that recent environmental testing performed at the CAPS' facility showed the presence of bacteria in a water container used for cleaning, additive port tube holders, and spray bottles filled with sterile water. Likewise, sterility testing demonstrated similar bacteria in its drug products.

16. The Board obtained the services of an independent expert in compounding/infusion pharmacy (hereinafter "Board Expert") to conduct a review of CAPS' practices. The practices as delineated in paragraph 14, supra, affect the production of Cardioplegia and the patient specific and other anticipatory IV drug products produced by CAPS at its Lanham facility. Furthermore, the practices and information as discussed in paragraphs 14 and 15, supra, raise sterility concerns about CAPS' facility and its drug products.

17. Based on a review of the documents relating to the FDA's inspection and observations as well as the documents turned over to the Board by CAPS, CAPS is not operating within the standards required of an aseptic facility suitable for the compounding of patient specific and anticipatory IV drug products. Accordingly, CAPS' operation of a pharmacy poses a risk to the public health, safety, or welfare imperatively requiring emergency action.

18. Based on the above investigative facts, the Board also has cause to believe that CAPS violated Md. Health Occ. Code Ann. § 12-409, which provides:

> (a) In general. – 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; or

(3) Otherwise is not conducted in accordance with the law.

§ 12-403 Required Standards

(b) In general. – 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.

19. Additionally, based on the above investigative facts, the Board also has cause to believe that CAPS violated Code Md. Regs. tit. 10, § 34.19.03, which states in relevant part:

.03 **Pharmacy Environment**

In addition to all statutes, laws, and regulations applicable to all pharmacies operating under permits issued by the Board of Pharmacy, a pharmacy engaged in the compounding and dispensing of sterile parenteral/enteral prescription preparations within a pharmacy shall maintain an environment for this practice which is set apart, and is designed and equipped to provide controlled aseptic conditions.

CONCLUSIONS OF LAW

Accordingly, the Board concludes that the public health, safety or welfare imperatively requires emergency action in this case, pursuant to Md. State Gov't Code Ann. § 10-226(c)(2)(i) (2004 Repl. Vol.).

ORDER

Based on the foregoing, it is this 15th day of November 2005, by a majority vote of a quorum of the Board, hereby:

ORDERED that pursuant to the authority vested by Md. State Gov't Code Ann., § 10-226(c)(2) the permits held by the Respondent-Pharmacy to operate a pharmacy and distribute prescription drugs, Nos. PW0184/D01075, are hereby **SUMMARILY SUSPENDED;** and be it further

ORDERED, that a post-deprivation show cause hearing in accordance with Code Md. Regs. tit. 10, § 34.01.12.F (2) on the summary suspension shall be scheduled for **Wednesday, December 7, 2005, at 1:30 p.m.** at the Board's offices, 4201 Patterson Avenue, Baltimore, Maryland 21215; and be it further

ORDERED, that the Respondent-Pharmacy shall immediately turn over to the Board its permits to operate a pharmacy and distribute prescription drugs issued by the Board; and be it further

ORDERED, that this document constitutes a 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.).

John H. Balch, President
Maryland Board of Pharmacy

NOTICE OF HEARING

A Show Cause hearing to determine whether the Summary Suspension shall be lifted will be held before the Board at 4201 Patterson Avenue, Baltimore, 21215 on **Wednesday, December 7, 2005, at 1:30 p.m.**