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

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CONSENT ORDER

Based on information received and a subsequent investigation by the State Board of Pharmacy (the "Board"), and subject to the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. (H.O.) §§ 12-101, et seq., (2005 Repl. Vol.), the Board issued an Order for Summary Suspension dated November 15, 2005, which summarily suspended the pharmacy and distributor permits issued to Central Admixture Pharmacy Service Inc., (the "Respondent-Pharmacy"). Specifically, the Board found that the public health, safety or welfare imperatively required emergency action, pursuant to Md. St. Gov't Code Ann. § 10-226(c)(2) (2004 Repl. Vol.). The Board also had cause to believe that the Respondent-Pharmacy had violated the following provisions of H.O. § 12-409:

> (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.

The Board also had cause to believe that the Respondent-Pharmacy violated H.O. § 12-403, which provides:

§ 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.

Additionally, the Board also had cause to believe that the Respondent-Pharmacy 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.

The Respondent-Pharmacy was given notice of the Order for Summary Suspension by letter dated November 16, 2005.

The parties and the Board agreed to resolve the matter by way of settlement. As a result of negotiations, the Respondent-Pharmacy agreed to enter into this Consent Order, consisting of Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. At all relevant times, the Respondent-Pharmacy[1] 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 March 25, 1999, under permit number PW0184, and a permit to distribute prescription drugs on March 26, 1999, under permit number D01075.

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

2. At all relevant times, the Respondent-Pharmacy was operating a pharmacy and distributing prescription drugs at 9730 Martin Luther King Jr. Highway, Lanham, Maryland 20706.

3. The Respondent-Pharmacy 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 the Respondent-Pharmacy produces are an array of cardioplegia solutions ("Cardioplegia") that are administered to patients during heart by-pass surgery to stop the beating heart.

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. The Board's investigator was informed that the patients suffering from SIRS had received Cardioplegia during open-heart surgery that was compounded by the Respondent-Pharmacy. The Board makes no finding of fact as to any direct relationship between CAPS' Cardioplegia and any patient injury at Mary Washington Hospital.

5. On or about September 12, 2005, the Food and Drug Administration's ("FDA") Baltimore District Office began an investigation into the reported cluster of SIRS cases at Mary Washington Hospital. The FDA also concurrently inspected the Respondent-Pharmacy's facility in Lanham, Maryland and discovered significant Good Manufacturing Product violations, specifically stating that there was no assurance of sterility of any of the Respondent-Pharmacy's manufactured products.

6. 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 the Respondent-Pharmacy's Lanham, Maryland facility; (2) required the Respondent-Pharmacy to notify customers of all products to quarantine and/or hold all product(s) until further notice; and (3) required the Respondent-Pharmacy to issue a press release concerning the situation.

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

8. 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.

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

10. On or about September 20, 2005, the FDA received a report from Sinai Hospital in Baltimore, Maryland concerning a patient who was administered Cardioplegia compounded by the Respondent-Pharmacy on September 11, 2005, post-

operatively. The Board makes no finding of fact concerning any direct relationship between any patient injury at Sinai Hospital and CAPS' Cardioplegia.

11. The Cardioplegia administered to patients at Mary Washington Hospital consists of three solutions.[2] Each patient received 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 bacteria in an intact IV bag of solution Two.[3] 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.

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

13. On or about October 12, 2005, the FDA issued a list of Inspectional Observations to the Respondent-Pharmacy, finding the Respondent-Pharmacy failed to meet the standards required by United States Pharmacopeia ("USP"), Chapter 797. The FDA reviewed product preparation and processing at the Respondent-Pharmacy 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);

[2] 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 the Respondent-Pharmacy on August 11, 2005 and August 30, 2005.

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

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;

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.

14. Additionally, information provided by the FDA and the Respondent-Pharmacy demonstrated that recent environmental testing performed at the Respondent-Pharmacy's 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.

15. Based on the above investigative facts, the Board contracted the services of an independent expert in compounding/infusion pharmacy (hereinafter "Board Expert") to conduct a review of the investigative findings of the Respondent-Pharmacy's practices. The practices affected the production of Cardioplegia and the patient specific and other anticipatory IV drug products produced by the Respondent-Pharmacy at its Lanham facility. Furthermore, the practices and information raised sterility concerns about Respondent-Pharmacy's facility and its drug products.

16. 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 the Respondent-Pharmacy, the Board concluded that the Respondent-Pharmacy was not operating within the standards required of an aseptic facility suitable for the compounding of patient specific and anticipatory IV drug products. The Board concluded that the Respondent-

Pharmacy's operation of a pharmacy posed a risk to the public health, safety, or welfare imperatively requiring emergency action and summarily suspended the Respondent-Pharmacy's pharmacy permits.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, the Board finds that Respondent-Pharmacy violated Md. Health Occ. Code Ann. § 12-409(a)(1) – (3), § 12-403(b)(1) and (2), and COMAR 10.34.19.03.

ORDER

Based on the foregoing Findings of Fact, Conclusions of Law and agreement of the parties, it is this 10th day of January, 2006 by a majority of a quorum of the Board,

ORDERED that the suspension shall be continued and the Respondent-Pharmacy shall remain closed and all operations related to the operation of a pharmacy and distribution of prescription drugs in the State of Maryland shall remain discontinued; and it is further

ORDERED that the Respondent-Pharmacy may be reinstated, such reinstatement to be conditioned upon completion of the following terms and conditions, and upon the filing of a petition for reinstatement:

1. The Respondent-Pharmacy shall implement a corrective action plan, which includes (a) revisions to the Respondent-Pharmacy's procedures and quality assurance plan and (b) adequate safeguards for the Respondent-Pharmacy to reopen without posing a threat to the safety and health of the public;

2. The Board will review the Respondent-Pharmacy's corrective action plan and operations to determine if the Respondent-Pharmacy has an adequate corrective action plan and has implemented the corrective action plan to the Board's satisfaction;

3. If the Board determines that the corrective plan or its implementation is not adequate, it will promptly notify the Respondent-Pharmacy to enable it to revise or amend the corrective action plan as appropriate; and

4. The Respondent-Pharmacy may petition the Board for reinstatement. If the Board is satisfied that the Respondent-Pharmacy has demonstrated to the Board a sufficient corrective action plan is in place and has been adequately implemented in its Lanham facility, the Board will, in accordance with the terms and conditions of this Consent Order, reinstate the Respondent-Pharmacy and approve the Respondent-Pharmacy to reopen; and it is further

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

ORDERED that the Respondent-Pharmacy shall comply with all laws governing the operation of a pharmacy and the distribution of prescription drugs; and it is further

ORDERED that the Respondent-Pharmacy shall be responsible for all costs incurred under this Consent Order; and it is further

ORDERED that for purposes of public disclosure, as permitted by Md. State Gov't Code Ann. § 10-617(h) (2004 Repl. vol.), this document consists of the contents of the foregoing Findings of Fact, Conclusions of Law and Order and that the Board may disclose the contents of this Consent Order to any mandatory reporting data bank(s) that it is required to.

JAN 1 0 2006

~~John H. Baleh~~ Jeanne Furman
~~President~~ Secretary
Maryland State Board of Pharmacy

CONSENT OF CENTRAL ADMIXTURE PHARMACY SERVICES, INC.

I, Thomas J Wilverding a duly authorized representative of the Respondent-Pharmacy and on behalf of same, affixing my signature hereto, acknowledge that:

I am represented by my attorney, Constance H. Baker, Venable LLP, and have consulted with counsel before entering this Consent Order. By this Consent and for the purpose of resolving the issues raised by the Board, I agree and accept to be bound by the foregoing Consent Order and its conditions.

I acknowledge the validity of this Consent Order as if entered into after the conclusion of a formal evidentiary hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf, and to all other substantive and procedural protections provided by the law. I agree to forego my opportunity to challenge these allegations. I acknowledge the legal authority and jurisdiction of the Board to initiate these proceedings and to issue and enforce this Consent Order.

By entering into this Consent Order, I acknowledge that the failure to abide by the conditions set forth in this Consent Order and following proper procedures, the Respondent-Pharmacy may suffer disciplinary action, possibly including revocation, against its permit to operate a pharmacy and distribute prescription drugs in the State of Maryland.

I sign this Consent Order after having an opportunity to consult with counsel, voluntarily and without reservation, and I fully understand and comprehend the language, meaning and terms of the Consent Order.

12/27/05
Date

Central Admixture Pharmacy Services, Inc.

STATE OF MARYLAND)
) to wit:
CITY OF)

I HEREBY CERTIFY that, on this 27 day of December, 2005 before me, the subscriber, a Notary Public of the State and City aforesaid, personally appeared Thomas Wilvereding, and he/she acknowledged the foregoing to be his act and deed.

AS WITNESS my hand and Notarial Seal.

Angela L Warn
Notary Public

My Commission Expires: 11/10/2009