

IN THE MATTER OF

\*

BEFORE THE

JOHNS HOPKINS  
PHARMAQUIP, INC.

\*

MARYLAND BOARD  
OF PHARMACY

\*

Respondent

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Permit Number: PW0013

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CONSENT ORDER

Based on information received and a subsequent investigation by the Maryland State Board of Pharmacy (the "Board"), and subject to Md. Health Occ. Code Ann. § 12-411, (the "Act"), the Board charged Johns Hopkins Pharmaquip, Inc., Permit Number PW0013 ("Pharmaquip" or the "Respondent Pharmacy") with violations of § 12-409 of the Act.

Specifically, the Board charged the Respondent with violation of the following provisions:

§ 12-409(a) Subject to the hearing provisions of § 12-411<sup>1</sup> of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:

(2) Violates any of the standards specified in § 12-403 of this subtitle[.]

§ 12-403 Required standards

(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. Denials, reprimands, suspensions, and revocations- Grounds

<sup>1</sup> § 12-410. Penalty instead of suspension or in addition to suspension or revocation.

(a) If after a hearing under § 12-411 of this subtitle the Board finds that there are grounds under § 12-409 of this subtitle to suspend or revoke a permit, the Board may impose a penalty not exceeding \$10,000:

(1) Instead of suspending the permit; or

(2) In addition to suspending or revoking the permit.

(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:

(24) Violates any rule or regulation adopted by the Board.

The regulation that the Board charges the Respondent with violating are Code Md. Regs. tit. 10, § 34.19 – Parenteral/Sterile Enteral Compounding. Specifically, the Board charges the Respondent-Pharmacy with violating Code Md. Regs. tit. 10, § 34.19.04 D which states in pertinent part:

D. A pharmacist shall maintain a policy and procedure manual in current status at each pharmacy which is available for inspection by authorized agents of the Board of Pharmacy and the Department of Health and Mental Hygiene. The policy and procedure manual shall include:

- (1) Detailed objectives and operational guidelines of the pharmacy permit holder;
- (2) A quality assurance program which monitors:
  - (a) Personnel qualifications,
  - (b) Training and performance
  - (c) Equipment facilities[.]

The Respondent was given notice of the charges and the issues underlying the charges by letter and charging document sent to the Respondent on April 5, 2005. A case resolution conference on those charges was held on May 26, 2005.

Following the case resolution conference, the parties and the Board agreed to resolve the administrative charges with the following Consent Order. As part of the resolution, the Board ordered that as one of the terms of the

Consent Order the Findings of Fact include safety measures implemented by the Respondent Pharmacy since December 2003.

### **FINDINGS OF FACT**

The Board makes the following findings of fact:

#### **Procedural Background**

1. Johns Hopkins Pharmaquip, Inc., the home infusion pharmacy component of the Johns Hopkins Home Care Group ("JHHCG"), provides pharmacy services to patients receiving care by JHHCG, including Pediatrics at Home.
2. On December 19, 2003, a newspaper article in the *Baltimore Sun*, entitled "Medical Error Kills Hopkins Cancer Patient," reported the unanticipated death of a two-year old female patient ("Patient A") who was receiving care from JHHCG, specifically Pediatrics at Home. The article stated that an intravenous solution that was prepared by JHHCG and administered to Patient A contained nearly five (5) times the prescribed amount of potassium. Hospital officials speculated that the elevated potassium level caused an arrhythmia that resulted in Patient A's death.
3. Thereafter, the State Office of Health Care Quality ("OHCQ"), in conjunction with the Board, initiated an investigation of Patient A's death, as well as the care of ten (10) other patients. OHCQ's investigation was completed on or about January 8, 2004.<sup>2</sup>
4. By letter dated February 18, 2004, OHCQ issued to JHHCG a Statement

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<sup>2</sup> By letter dated December 17, 2003, JHHCG reported the event to OHCQ.

of Deficiencies in which was contained the findings of OHCQ's investigation and required JHHCG to submit a Plan of Correction within ten (10) days.

5. On March 3, 2004, JHHCG submitted a Plan of Correction, which was initially rejected by OHCQ as unacceptable because it lacked, *inter alia*, the requisite degree of specificity and projected completion dates.
6. On April 26, 2004, OHCQ determined that the revised Plan of Correction submitted by JHHCG to be acceptable.
7. The Board, upon being advised of Patient A's death, had serious concerns regarding Pharmaquip's practice and thereafter conducted an independent investigation of Pharmaquip. To this end, and pursuant to its authority of entry and inspection as set forth at H.O. § 12-413, the Board directed the inspection of Pharmaquip by a licensed pharmacist who was knowledgeable and experienced in the practice of infusion pharmacy. The investigation was directed toward Pharmaquip's practices in general, with specific focus on the circumstances surrounding Patient A's death.

#### **Relevant Findings of OHCQ's Investigation Regarding Patient A**

8. The OHCQ investigation of Johns Hopkins Hospital ("JHH") records revealed in pertinent part that Patient A had been diagnosed in April 2003 with a brain tumor and had undergone resection of the tumor with chemotherapy and radiation therapy. Patient A had been admitted to JHH on October 28, 2003 for pre-transplant chemotherapy. On November 3, 2003, Patient A underwent an autologous stem cell transplant. On

December 1, 2003, Patient A was assessed to be sufficiently stable to be discharged to home. Due to her poor oral intake throughout her hospitalization, Patient A had been administered Total Parenteral Nutrition ("TPN").

9. TPN is an intravenous solution containing vitamins, minerals, electrolytes, dextrose, amino acids and fats. At the time of these events, TPNs for home infusion of JHHCG patients, including Patient A, were prepared by Pharmaquip.<sup>3</sup>
10. Upon Patient A's December 1, 2003 discharge from JHH, the order for TPN was continued.
11. On December 1, 2003, Pharmaquip personnel prepared five (5) bags of Patient A's TPN based on formulas calculated and transmitted to Pharmaquip by a pharmacist employed by the Johns Hopkins Hospital's infusion pharmacy.<sup>4</sup> This was a sufficient quantity of TPN for five (5) days of treatment.
12. On December 2, 2003, Patient A returned to the JHH Pediatric Oncology Clinic where she was assessed. On that date, her potassium level had increased from a level of 4.4 MEQ/L on December 1 to 4.9 MEQ/L on December 2, 2003 (normal range = 3.5 – 5.0 MEQ/L).
13. On December 3, 2003, Patient A returned to JHH Pediatric Oncology

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<sup>3</sup> The Board has charged the pharmacist then employed at Pharmaquip who supervised the preparation of Patient A's TPN with violations of the Maryland Pharmacy Act. Those charges are set forth in a separate charging document.

<sup>4</sup> The Board has charged the pharmacist at Johns Hopkins Pharmacy who formulated Patient A's TPN with violations of the Maryland Pharmacy Act. Those charges are contained in a separate charging document.

Clinic. Her serum potassium was elevated at 5.5; her serum magnesium level was also elevated at 2.1 (normal range = 1.3 – 2.0). As a result of Patient A's elevated potassium and magnesium levels, her physician ordered a new mixture of TPN with the potassium and magnesium additives reduced significantly.

14. The physician assistant ("PA") who was present at Patient A's December 3, 2003 visit telephoned the additive changes to Patient A's TPN as a verbal order to the JHH infusion pharmacist. The order was entered into the hospital's computer system which then generated an order summary and order recipe that was sent by fax to Pharmaquip.
15. A review of Patient A's Pediatric Oncology Clinic Discharge Form dated December 3, 2003, revealed that the oncology nurse stated in the discharge instructions: "TPN x 12 hrs overnight – use new TPN tonight."
16. A Pharmaquip Progress Note dated December 3, 2003 (time: 15:22) written by Pharmaquip's clinical pediatric pharmacist stated:

Pt's K+ = 5.5 and Mag = 2.1 per [JHH infusion pharmacist] Rph. Plan to change TPN formulation for those two electrolytes. Pt to be instructed to discard TPN bags for [T]hursday and [F]riday and start new bags on [T]hurs. 12/4/03. Sending meds tomorrow.
17. Patient A's father was interviewed by OHCQ staff during its investigation. He reported that on the evening of December 3, 2003, Pharmaquip staff had telephoned Patient A's mother and advised her to use the TPN that had been delivered on December 1 that evening because Pharmaquip had been unable to deliver the new TPN.

18. The OHCQ investigation revealed that there was no documentation in either the patient's outpatient records or in Pharmaquip records to indicate that the physician or the physician's assistant was contacted by the pharmacist prior to determining that the existing TPN could be administered to Patient A on the evening of December 3, 2003.
19. On the evening of December 3, 2003, based on the instructions received from Pharmaquip staff, Patient A's parents infused her with the existing TPN.
20. On December 4, 2003, at approximately 6:00 a.m., Patient A's parents found her to be unresponsive and without a pulse or respiration. Patient A was transported to an acute care hospital other than JHH; however, efforts to resuscitate her failed and she was pronounced dead at 7:02 a.m.
21. At the request of Patient A's oncologist, an analysis of the remaining TPN which had been administered to Patient A, was conducted by JHH. It was determined that the TPN administered on the evening of December 3, 2003 contained greater than five (5) times the potassium that had been required by the December 1 TPN order. The analysis was unable to determine whether administration of the revised TPN would have changed the outcome.
22. With regard to Pharmaquip staff, the OHCQ Statement of Deficiencies further stated:

Based on review of the RSA's [Residential Services Agency] job description for "Clinical Staff Pharmacist/Infusion Pharmacist," the minimal work experience required for staff and contractual personnel was 2 years of experience in hospital/home care

pharmacy or equivalent experience and thorough knowledge of the use of IV medications, especially the application in the home care setting.

A review of the personnel file of the pharmacist on duty at the time of the complaint revealed that the contractual infusion pharmacist had less than one year of experience in a hospital/home health setting at initiation of the contract.

23. By letter dated January 26, 2004, JHHCG provided to OHCQ the findings and recommendations of a Root Cause Analysis ("RCA") conducted by JHHCG and JHH. With regard to TPN production, the RCA report stated that all production of pediatric TPN by Pharmaquip was halted on December 11, 2003 and that production of adult TPN was halted on December 12, 2003.
24. The RCA report also stated that many issues were raised regarding Pharmaquip's process of producing TPN, including documentation standards, the creation and use of an electrolyte pool to dispense electrolytes into multi-day orders for TPN, and the lack of end product testing. The report stated that should Pharmaquip resume TPN production, new policies, procedures, trainings and competencies would be created.

### **Relevant Findings of the Board's Investigation**

#### **a. TPN Production**

25. The Board's pharmacist expert/inspector conducted an inspection of Pharmaquip on August 20, 2004, and noted safety measures undertaken by Pharmaquip.
26. The Board's expert confirmed that Pharmaquip had terminated production

of pediatric and adult TPN. Pharmaquip's TPN production is currently outsourced to a TPN compounding pharmacy with end product testing.

27. The Board's expert reviewed Pharmaquip's former TPN production process. According to Pharmaquip's policy entitled, "TPN Compounding," the pharmacist is responsible for entering TPN orders into a database for dispensing. TPN orders are compounded using the electrolyte pool method by which more than one (1) TPN bag is prepared at a time. The total electrolytes required for the pool are calculated by multiplying quantity needed for each bag by the number of bags to be processed plus one (1) additional bag. The policy continues:

The pharmacist technician then draws up individual electrolyte quantities needed for the pool and arranges them for a final check by the pharmacist. Syringes containing fluid to be used in the pool are placed by the vial from which it was drawn with the needle pointing into the hood. Syringes containing excess fluid to be discarded are placed by the vial from which the fluid was withdrawn with needles pointing out of the hood. Once the pharmacist has checked the pool, syringes or vials to be discarded are removed from the hood.

28. In 1997, the American Society for Parenteral and Enteral Nutrition ("ASPEN")<sup>5</sup> issued a Special Report entitled, *Safe Practices for Parenteral Nutrition Formulations*. With regard to parenteral nutrition ("PN"), the report stated, in pertinent part: "The responsibility of the dispensing pharmacist is to ensure that the PN is prepared, labeled, controlled, stored, dispensed and distributed properly."

29. The Board expert noted that Pharmaquip's TPN policy in effect at the time

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<sup>5</sup> ASPEN is an organization of health care professionals representing the fields of medicine, nursing, pharmacy and dietetics. Specific practice guidelines are based on a consensus of ASPEN's National Advisory Group.

of Patient A's death does not specify whether the pharmacist or the pharmacist technician is responsible for performing this task.

**b. Employment of Infusion Pharmacist**

30. The job description for a JHHCG Staff Pharmacist- Infusion pharmacy requires in pertinent part, two (2) years work experience in a hospital/home care pharmacy or equivalent experience.

31. The subcontracted production pharmacist who was responsible for ensuring the accuracy of Patient A's TPN bag on December 1, 2003 did not have the requisite work experience. The majority of his work experience was as a retail pharmacist, which experience is not equivalent to a hospital/home care pharmacist.

**Safety Measures Implemented by the Respondent Since December 2003**

**a. Prevention of Medication Errors**

i. A double check of calculations by a pharmacist occurs for new and changed orders. A third pharmacist does a final check of calculations in the preparation process. Routine audits are taking place. Also, infusion pump programs are double checked by pharmacists;

ii. TPN preparation continues to be outsourced. There are double checks performed by pharmacists before the order is sent and after the TPN bags are received by Pharmaquip. For electrolyte solutions containing potassium, a pharmacist oversees the entire preparation process;

iii. High alert medications are clearly labeled. All inventories are maintained in a separate bin to reduce the risk of pulling the incorrect medication from the shelf. Hood design for pediatric and chemotherapy products preparation is in place and audits are completed on a routine basis;

iv. Pharmacists complete training modules related to home infusion therapy and there seems to be a good sense of group

support for the team pharmacists and the Director for Infusion Services.

v. All personnel are encouraged to record any type of error they notice on an error log. Pharmacists and technicians then have open discussions on system improvement to prevent the error in the future. There is also a confidential reporting system in place for technicians and pharmacists to report concerns related to personnel competency.

**b. Other Safety Measures**

i. A Patient Safety Committee was formulated to include representatives across the organization as well as the Johns Hopkins Health System to share experience, concerns and solutions to safety issues.

ii. A Safety Culture Assessment was performed to identify areas for focus using a non-punitive proactive approach.

iii. Johns Hopkins Home Care Executive Staff implemented "safety rounds" to allow the staff opportunity to voice concerns, improve the safety culture and identify opportunities for improvement.

iv. A Patient Safety Committee was formulated to include representatives across the organization as well as the Johns Hopkins Health System to share experience, concerns and solutions to safety issues.

v. A new employee orientation and aseptic technique observation checklist has been implemented.

**CONCLUSIONS OF LAW**

Based on the foregoing Findings of Fact, the Board concludes as a matter of law that the Respondent pharmacy violated H.O. § 12-409(a)(2), H.O. § 12-403 (9), H.O. § 12-313(b)(24) and Code Md. Regs. tit. 10, § 34.19.04D.

**ORDER**

Based on the foregoing Findings of Fact, Conclusions of Law and agreement of the parties, it is this 21<sup>st</sup> day of Sept., 2005, by a

majority of a quorum of the Board, hereby

ORDERED that Respondent Pharmacy be suspended three (3) years, all of which are stayed, and it is further

ORDERED that the Respondent Pharmacy shall pay to the Board a fine of ten thousand dollars (\$10,000.00) of payment into the General Fund of the State; and it is further

ORDERED that the Respondent Pharmacy submit to the Board for review and approval revised employment policies and TPN production policies, if the Respondent Pharmacy plans to resume production of TPNs; and it is further

ORDERED that the Findings of Fact section of this Consent Order include safety measures implemented by the Respondent Pharmacy since December 2003, as are incorporated above; and it is further

ORDERED that this is a FINAL ORDER and as such is a public document pursuant to Md. State Gov't Code Ann. § 10-611 *et seq.* (2004 Repl.).

9/21/05  
Date

  
John H. Balch, P.D.  
President  
Maryland Board of Pharmacy

**CONSENT OF JOHNS HOPKINS PHARMAQUIP, INC.**

I, Daniel Smith, the President of Johns Hopkins Pharmaquip, Inc. ("Respondent Pharmacy") and on behalf of same, by affixing my signature hereto, acknowledge that :

1. Pharmaquip is represented by counsel and has been advised of the legal implications of signing this Consent Order.

2. Pharmaquip is aware that without its consent, the permit to operate a pharmacy in this State cannot be limited except pursuant to the provisions of § 12-409 of the Act and the Administrative Procedure Act, Md. State Gov't Code Ann. §§ 10-205 *et seq.*

3. Pharmaquip acknowledges the validity of this Consent Order as if it were made after a hearing in which the Respondent Pharmacy would have the right to counsel, to confront witnesses on its own behalf, and to all other procedural protections provided by law.

4. Pharmaquip acknowledges the legal authority and jurisdiction of the Board to enter into and enforce this Consent Order.

5. Pharmaquip acknowledges that, by entering into this Consent Order, the Respondent Pharmacy is waiving the right to appeal any adverse ruling of the Board that might have followed an evidentiary hearing.

6. Pharmaquip acknowledges that the Respondent Pharmacy's failure to abide by the conditions set forth in this Order may result in additional disciplinary action, possibly including revocation, of the permit to operate the Respondent Pharmacy.

7. On behalf of Pharmaquip, I sign this Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. I fully understand the language, meaning and effect of this Consent Order and understand that its terms are binding upon the Respondent Pharmacy and my successors.

9/8/05  
Date

Daniel B. Smith  
Daniel Smith  
President  
Johns Hopkins Pharmaquip, Inc.

**STATE OF MARYLAND  
COUNTY/CITY OF BALTIMORE:**

I hereby certify that on this 8<sup>th</sup> day of SEPTEMBER, 2005, before me, a Notary Public of the State of Maryland and County/City aforesaid, personally appeared DAN SMITH and made an oath in due form that the foregoing Consent was his voluntary act and deed on behalf of Johns Hopkins Pharmaquip, Inc.

Notary Public: Christina Marroquin  
My commission expires: 11/05

