IN THE MATTER OF

* BEFORE THE

JOHNS HOPKINS UNIVERSITY

* MARYLAND

BEHAVIORAL PHARMACOLOGY

* BOARD OF

RESEARCH UNIT

* PHARMACY

Permit No. PW0337

PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Johns Hopkins University's Behavioral Pharmacology Research Unit (the "Pharmacy"), Permit No. PW0337, on October 27, 2011, with follow-up inspections on November 4 and 22, 2011. The inspection report from the November 4, 2011 follow-up inspection indicated that the Pharmacy was not in compliance with the Board's laws and regulations requiring that a licensed pharmacist be on the premises at all times the pharmacy is in operation. Md. Code Ann., Health Occ. § 12-403(b)(3); COMAR 10.34.05.02(A)(3). The inspector noted that a registered pharmacy technician, but no licensed pharmacist, was on the premises when she arrived for the inspection.

In lieu of instituting formal proceedings against the Pharmacy, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 et seq., the Board held a Pre-Charge Case Resolution Conference ("CRC") with the Pharmacy and its counsel on March 14, 2012. As a result, the Board and the Pharmacy have agreed to resolve this matter as set forth in this Consent Order.

FINDINGS OF FACT

- At all times relevant hereto, the Pharmacy possessed a Maryland pharmacy permit,
 Permit No. PW0337, and operated on the campus located at 5510 Nathan Shock Drive,
 Baltimore, Maryland.
- 2. On October 27, 2011, the Board performed an annual inspection of the Pharmacy, with follow-up inspections on November 4 and 22, 2011, in accordance with Md. Code Ann., Health Occ. § 12-604(b).
- 3. The Board's inspector arrived for the follow-up inspection on November 4, 2011, at 1:40 p.m. The inspector was greeted by a pharmacy technician who conveyed the inspector to the Pharmacy and informed the inspector that the full-time pharmacist was out that day, but coverage was being provided by a pharmacist from another pharmacy. The pharmacy technician also informed the inspector that although the pharmacist had left at noon when pharmacy operations concluded for the day, he was available by pager.
- 4. Following two phone calls from the pharmacy technician, the pharmacist appeared at the Pharmacy at 2:05 p.m.
- 5. The Pharmacy's stated hours at the time were "Variable and as needed, typically: Monday-Friday 6 a.m. to 2:30 p.m."
- 6. At the CRC, the Pharmacy confirmed that pharmacy operations had concluded at noon on November 4, 2011, and admitted that the pharmacy technician was present in the prescription area without the presence of a licensed pharmacist.
- 7. The Pharmacy also reported that between the follow-up inspection on November 4, 2011, and the CRC on March 14, 2012, security to the prescription area was enhanced by the installation of a deadbolt lock, to which only licensed pharmacists have keys, to go along

with the pre-existing restricted card-activated entry. The Pharmacy is now locked at all times a pharmacist is not present.

- 8. Finally, the Pharmacy reported that it updated its policies and procedures to clarify the security requirement that no individual be allowed in the prescription area unless a licensed pharmacist is immediately available on the premises.
- 9. Both before and after the November 4, 2011 inspection, the Pharmacy had a narcotics vault for added security after the Pharmacy closes.

CONCLUSION OF LAW

Based on the foregoing Findings of Fact, the Board concludes that the Pharmacy is subject to disciplinary action in accordance with Md. Code Ann., Health Occ. §§12-403(b)(3) and COMAR 10.34.05.02(A)(3).

ORDER

Based on an affirmative vote of a majority of the Board, it is this 24th day of May, 2012, hereby:

ORDERED that the Pharmacy shall pay a fine in the amount of \$1,500.00, payable to the Maryland Board of Pharmacy, within thirty (30) days of the date of this Order; and be it further,

ORDERED that failure to pay in full the above fine within thirty (30) days of the date of this Order shall be considered a violation of this Order, and after notice and opportunity for a show cause hearing shall subject the Pharmacy to further discipline such as suspension, revocation or further fines based on the violations cited in this Order; and be it further,

ORDERED that the Pharmacy shall restate its hours of operation more clearly such that they include a minimum defined period of time the Pharmacy is open; and be it further,

ORDERED that this is a formal order of the Maryland Board of Pharmacy and as such is a public document pursuant to the Maryland Annotated Code, State Government Article, Section 10-617(h).

May 24, 2012
Date

Michael Souranis, P.D.

President, Maryland Board of Pharmacy

CONSENT

- 1. By signing this Consent, the Pharmacy submits to the foregoing Consent Order as a resolution of this matter in lieu of formal charges, which process would have afforded the Pharmacy the right to a full evidentiary hearing. The Pharmacy consents and submits to the foregoing Findings of Fact, Conclusions of Law, and Order as if made after a full evidentiary hearing in which the Pharmacy would have the right to counsel, to confront witnesses, to give testimony, to call witnesses on the Pharmacy's behalf and to all other substantive and procedural protections provided by law.
- 2. By signing this Consent, the Pharmacy waives any rights it may have had to contest the findings and determinations contained in this Consent Order.
- 3. The Pharmacy acknowledges that this is a formal order of the Board and as such is a public document.
- 4. The Pharmacy acknowledges the legal authority and the jurisdiction of the Board to enter into and enforce this Consent Order
- 5. The Pharmacy signs this Consent Order freely and voluntarily and after having had the opportunity to consult with counsel. The Pharmacy fully understands the language, meaning, and effect of this Consent Order.
- 6. I affirm that I am a duly authorized representative of the Pharmacy and am legally authorized to sign this Consent Order on behalf of the Pharmacy.

JOHNS HOPKINS UNIVERSITY BEHAVIORAL PHARMACOLOGY

RESEARCH UNIT Permit No. PW0337

Daniel Ford, M.D.

Vice Dean for Clinical Investigation

5-16-12

STATE OF MARYLAND
COUNTY/CITY OF Baltimore

Notary Public

My Commission Expires August 20, 2012

My commission expires: