

IN THE MATTER OF	*	BEFORE THE
STATE PHARMACY	*	STATE BOARD
PERMIT NO.: P00771	*	OF
Respondent -Pharmacy	*	PHARMACY
	*	Case No. PI-08-020

* * * * *

FINAL CONSENT ORDER

Based on information received and a subsequent investigation by the State Board of Pharmacy (the "Board"), and subject to Md. Health Occ. Ann. § 12-101, *et seq.*, (2005 Repl. Vol. and 2007 Supp.) (the "Act"), the Board charged State Pharmacy, (the "Respondent-Pharmacy"), with violations of the Act. Specifically, the Board charged the Respondent-Pharmacy with violation of the following provisions of the Act:

§ 12-409 of the Act:

- (a) 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) 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;

- (7) May not offer pharmaceutical services under any term or condition that tends to interfere with or impair the free and complete exercise of professional pharmaceutical judgment or skill;
- (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) Shall store all prescription or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board[;].

Also, the Respondent-Pharmacy was charged with the following violations of §12-313:

(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:

- (7) Willfully fails to file or record any report that is required by law;
- (20) Is professionally . . . incompetent;
- (24) Violates any rule or regulation adopted by the Board;
- (28) Fails to cooperate with a lawful investigation conducted by the Board or the Division of Drug Control.

The Board further charged the Respondent-Pharmacy with violations of its Code of Conduct, Code Md. Regs. tit.10. §34.10. 10A. (1) and (3) and B. (1) – (3):

.01 Patient Safety and Welfare.

A. A pharmacist shall:

(1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:

- (a) United States Code, Title 21,

(b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,

(c) Health Occupations Article, Title 12, Annotated Code of Maryland,

(d) Criminal Law Article, Title 5, Annotated Code of Maryland, and

(e) COMAR 10.19.03;

(3) Maintain proper sanitation, hygiene, biohazard precautions, and infection control when performing tasks in the prescription process.

B. A pharmacist may not:

(1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist;

(2) Practice pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or

(3) Engage in unprofessional conduct.

The Respondent-Pharmacy was given notice of the issues underlying the Board's charges by letter dated August 1, 2008. Accordingly, a Case Resolution Conference was held on September 17, 2008, and was attended by Mayer Handelman, P.D., and Alland Leandre, Board members, and, Linda Bethman, Assistant Attorney General, Counsel to the Board. Also in attendance was Jerome Berger on behalf of the Respondent-Pharmacy, who knowingly and voluntarily waived its right to an attorney, and the Administrative Prosecutor, Roberta Gill, Assistant Attorney General.

Following the Case Resolution Conference, the parties and the Board agreed to resolve the matter by way of settlement. The parties and the Board agreed to the following:

FINDINGS OF FACT

1. At all times relevant to the charges herein, the Respondent-Pharmacy was permitted to operate as a pharmacy in the State of Maryland. The Respondent-Pharmacy was first issued a permit in 1978. The Respondent-Pharmacist's permit expires on December 31, 2008.

2. At all times relevant hereto, Jerome Berger, P.D., was the 25% owner and President of the Respondent-Pharmacy in Baltimore County, Maryland. Mr. Berger was also a dispensing pharmacist of the Respondent-Pharmacy, along with another pharmacist-employee.

3. On November 16, 2007, a Division of Drug Control (DDC) Inspector inspected the Respondent-Pharmacy while Mr. Berger was present. The Inspector found that the CDS biennial inventory was not properly completed. The main area of non-compliance, however, which could present a public safety issue, was the presence of scores of outdated drugs adjacent to the unexpired drugs. The Respondent-Pharmacy was informed that the outdated drugs had to be removed and listed prior to wasting them or properly disposing of them.

4. As a result of this report, the Deputy Director of DDC informed the Inspector that the outdated drugs should be listed and that she should return to do a re-inspection to determine if the outdated drugs were removed.

5. When the Inspector returned to Respondent-Pharmacy on February 11, 2008—almost three months later—Mr. Berger was not there, but the other dispensing pharmacist was. When the Inspector looked to see if all of the expired drugs had been

removed, she found the condition to be the same as it was on the previous inspection. As a result, she removed all of the outdated drugs and listed them, as required by law. It took the Inspector four hours to perform this task, which should have been performed by Mr. Berger or a designee.

6. As a result of being informed of the outdated drugs, on February 20, 2008, the Board wrote the Respondent-Pharmacy a letter stating that it needed to show how the deficiencies have been corrected and what steps have been taken to ensure that they will not recur in the future.

7. By an undated letter, which may have been received by the Board on March 17, 2008, Mr. Berger informed the Board that henceforth he would be using a removal service and that he and the other pharmacist will alternate monthly on the first of every month to inspect the dates on all prescriptions.¹

8. As set forth above, the Respondent-Pharmacy is in violation of the Act and regulations thereunder.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact, the Board finds that Respondent-Pharmacy violated §12-313 (b) (7), (20), (24) and (28) and Code Md. Regs. tit. 10 § 34.10A. (1) and (3) and B. (1) – (3).

¹ When the Inspector returned for a third inspection on June 10, 2008, she found that the Respondent-Pharmacy had begun using the returns specialists and that there were no longer any outdated drugs in the Respondent-Pharmacy.

ORDER

Based on the foregoing Findings of Fact, Conclusions of Law and agreement of the parties, it is this 19th day of November, 2008, by a majority of a quorum of the Board,

ORDERED that the Respondent-Pharmacy's license to practice as a pharmacy is hereby placed on **PROBATION** for one year, subject to the following conditions:

- A. The Respondent-Pharmacy shall be subject to at least two random inspections specifically focusing on outdated drugs;
- B. The Respondent-Pharmacy shall pay a fine to the Board of \$1500, due within 90 days of the effective date of the Order.

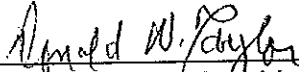
ORDERED that the Consent Order is effective as of the date of its signing by the Board; and be it

ORDERED that should the Board receive a report that the Respondent-Pharmacy has violated the Act or if the Respondent-Pharmacy violates any conditions of this Order or of Probation, after providing the Respondent-Pharmacy with notice and an opportunity for a hearing, the Board may take further disciplinary action against the Respondent-Pharmacy, including suspension or revocation. The burden of proof for any action brought against the Respondent-Pharmacy as a result of a breach of the conditions of the Order or of Probation shall be on the Respondent-Pharmacy to demonstrate compliance with the Order or conditions; and be it

ORDERED that the Respondent-Pharmacy shall operate in accordance with the laws and regulations governing the practice of pharmacy in Maryland; and be it further

ORDERED that, at the end of the Probationary period, the Respondent-Pharmacy may petition the Board to terminate the Probation, without any conditions or restrictions on its license, provided that it can demonstrate compliance with the conditions of this Order and there are no additional complaints against it. Should the Respondent-Pharmacy fail to demonstrate compliance, the Board may impose additional terms and conditions of Probation, as it deems necessary;

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



Don Taylor, P.D., President
State Board of Pharmacy

CONSENT OF STATE PHARMACY

I, Jerome Berger, on behalf of State Pharmacy, by affixing my signature hereto, acknowledge that:

1. I am not represented by an attorney and have knowingly and voluntarily waived that right;

2. I am aware that without my consent, the Respondent-Pharmacy's permit to operate as a pharmacy in this State cannot be limited except pursuant to the provisions of § 12-313 of the Act and the Administrative Procedure Act (APA) Md. State Govt. Code Ann. §10-201, et seq., (2004 Repl. Vol.).

3. I am aware that the Respondent-Pharmacy is entitled to a formal evidentiary hearing before the Board.

By this Consent Order, I hereby consent and admit to the foregoing Findings of Fact, Conclusions of Law and Order, provided the Board adopts the foregoing Consent Order in its entirety. By doing so, the Respondent-Pharmacy waives its right to a formal hearing as set forth in § 12-315 of the Act and §10-201, et seq., of the APA, and any right to appeal as set forth in § 12-316 of the Act and §10-201, et seq., of the APA. I acknowledge that my failure to abide by the conditions set forth in this Order and following proper procedures, the Respondent-Pharmacy may suffer disciplinary action, possibly including revocation, against its permit to operate as a pharmacy in the State of Maryland.

10/23/2008
Date

Jerome Berger, P.D.
Jerome Berger, P.D.
President of State Pharmacy

STATE OF Maryland :

CITY/COUNTY OF Baltimore :

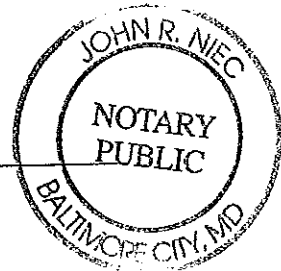
I HEREBY CERTIFY that on this 23rd day of October, 2008, before me, John R. Niec, a Notary Public of the foregoing State and (City/County),
(Print Name)
personally appeared Jerome Berger, P.D., License No.6065, and made oath in due form of law that signing the foregoing Consent Order was his voluntary act and deed on behalf of the Respondent-Pharmacy, and the statements made herein are true and correct.

AS WITNESSETH my hand and notarial seal.

John R. Niec
Notary Public

JOHN R. NIEC,
Notary Public State of Maryland
My Commission Expires January 1, 2010

My Commission Expires: _____



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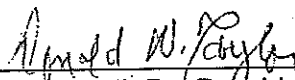
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Don Taylor, P.D., President
State Board of Pharmacy

CONSENT OF STATE PHARMACY

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1. I am not represented by an attorney and have knowingly and voluntarily waived that right;

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10/23/2008
Date

Jerome Berger, P.D.
Jerome Berger, P.D.
President of State Pharmacy

STATE OF Maryland :

CITY/COUNTY OF Baltimore :

I HEREBY CERTIFY that on this 23rd day of October, 2008, before me, John R. Niec, a Notary Public of the foregoing State and (City/County),
(Print Name)
personally appeared Jerome Berger, P.D., License No.6065, and made oath in due form of law that signing the foregoing Consent Order was his voluntary act and deed on behalf of the Respondent-Pharmacy, and the statements made herein are true and correct.

AS WITNESSETH my hand and notarial seal.

John R. Niec
Notary Public

JOHN R. NIEC
Notary Public State of Maryland
My Commission Expires January 1, 2010

My Commission Expires: _____

