IN THE MATTER OF	*	**BEFORE THE**
MEDICINE SHOPPE, #1521	*	**STATE BOARD**
Permit No.: P01709	*	**OF**
Respondent-Pharmacy	*	**PHARMACY**

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ORDER FOR SUMMARY SUSPENSION

Pursuant to Md. State Govt. Code Ann. ' 10-226 (c)(2004 Repl. Vol. and 2007 Supp.), the State Board of Pharmacy (the "Board") hereby suspends the permit to operate as a pharmacy in Maryland issued to The Medicine Shoppe #1521, (the "Respondent-Pharmacy) (under the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. § 12-101, et seq., (2005 Repl. Vol. and 2007 Supp.). This Order is based on the following investigative findings, which the Board has reason to believe are true:

BACKGROUND

1. At all times relevant hereto, the Respondent-Pharmacy was permitted to operate as a pharmacy in Maryland. The Respondent-Pharmacy was first issued a permit on June 22, 1992. The Respondent's permit expires on December 31, 2009.

2. At all times relevant hereto, Pamela Arrey owned the Respondent-Pharmacy located at the Milford Mill Shopping Center on Liberty Road in Baltimore County, Maryland.

3. On February 1, 2002, the Board issued an unexecuted Summary Suspension Order and on September 15, 2002, the Board issued charges against the Respondent-Pharmacy. On November 22, 2002, the Respondent-Pharmacy signed a Consent Order

based upon the following Findings of Fact found in the Summary Suspension and Charges:

A. On June 22, 2001, at approximately 9:00 a.m., Larry Friedman, Division of Drug Control (D.D.C) Inspector, observed pharmacist Oluwatosin Adekoya open the Respondent-Pharmacy. Mr. Friedman entered the pharmacy where he conducted an inspection, which disclosed, among other things, a number of faxed prescriptions for Schedule II Controlled Dangerous Substances (CDS) without a corresponding hard copy of the original. Mr. Friedman took twenty-two of these to D.D.C.;

B. On January 4, 2002, Deitra Gale, Compliance Specialist, arrived at the Respondent-Pharmacy at approximately 2:15 p.m., finding the store unlocked and open for business. There was no pharmacist on duty at that time--only a technician. Ms. Gale was told that the pharmacist would be "right back." Approximately 10 minutes lapsed, at which time Ms. Arrey arrived and explained that she had entrusted the technician to "lock the door." Ms. Gale explained to the Respondent that a technician could not be left alone in the pharmacy area, regardless of whether or not it was locked. The technician stated, under oath, that the other technician, "Emmanuel," had a key to the store.

C. The Respondent allowed unlicensed individuals to be in the pharmacy when no licensed pharmacist was present and allowed an unlicensed individual access to the pharmacy by giving him the key.

D. The work schedule provided to the Board by the Respondent-Pharmacy listed pharmacist Bonnie Enwezor as the pharmacist on duty for October 5 and November 16, 2001. Ms. Enwezor stated under oath that she did not, in fact, work at

the Respondent-Pharmacy on those dates. Therefore, according to the records supplied to the Board by Ms. Arrey, the Respondent-Pharmacy did not have a pharmacist on duty during those dates, as required, or Ms. Arrey provided false information to the Board during its investigation.

D. Due to the Board's concerns about adequate pharmacist coverage for all Ms. Arrey's pharmacies, the Board requested that Ms. Arrey supply to the Board an accounting of the licensed pharmacists who worked at each of her three pharmacies, including the Respondent-Pharmacy, and the hours that they worked at each store, for October, November and December, 2001. Ms. Arrey belatedly supplied schedules, purporting to show that the Respondent-Pharmacy was, in fact, staffed by Maryland licensed pharmacists during that time period. Based upon interviews with the pharmacists, discrepancies were disclosed between Ms. Arrey's list and the actual work schedules of the pharmacists.

E. Ms. Arrey submitted false documentation showing that pharmacists were on duty when, in fact, none was on duty at the Respondent-Pharmacy, as claimed on several occasions from June 2001 through January 14, 2002.

F. During the aforecited times and dates, at the Respondent-Pharmacy, several unlicensed persons were either opening or closing the Respondent-Pharmacy, or were alone in the Respondent-Pharmacy without a licensed pharmacist on the premises.

G. As set forth in the regulations governing the operation of a pharmacy in Maryland, only licensed pharmacists may have access, e.g., the keys or security code, to the pharmacy area.

H. In addition, Ms. Arrey allowed her minor daughter to sign for pharmaceutical supplies--something which only a licensed pharmacist should do.

I. At the above Respondent-Pharmacy, serious discrepancies were disclosed by the D.D.C. personnel on more than one occasion, including the dispensing of drugs by fax without a hard copy; a technician's dispensing prescriptions; and, unaccounted for Schedule IIs.

4. As a result of the above Findings, the Respondent-Pharmacy's permit was Suspended, and that suspension was Stayed: and it was further Ordered that the Respondent-Pharmacy comply with all laws and regulations governing the operation of a pharmacy in Maryland.

CURRENT INVESTIGATION

5. On July 7, 2008, an inspection of the Respondent-Pharmacy was performed by Ann Taylor, Pharmacist Compliance Officer. During the inspection, Ms. Taylor noted the following:

A. The Respondent-Pharmacy was unkempt, to the point where, in the backroom, there was nowhere for the staff to walk. The rear exit was completely obstructed by delivery totes, boxes and barrels;

B. Medications were stored everywhere, including the bathroom, which was unsanitary;

C. An inspection of the totes, barrels and shelves disclosed expired medication in manufacturers' bottles, which had expiration dates

removed either chemically or by cutting. The imprints of the dates were visible on many bottles where the expiration dates were chemically removed. Several of these bottles had stickers that had the lot number and a new expiration date covering the location where the manufacturer's imprint had been. Many of these medications were in a bag with a page of labels which would, apparently, be later affixed to the medication bottles. A total of 283 bottles of various expired medications were identified, of which 107 bottles did not have expiration dates on the bottles;

D. There were eleven bulk barrels in the pharmacy containing large quantities of loose tablets (approximately 20,000 to 30,000 tablets per container). The label of the containers identified the tablets inside as Glucophage 500ER (30,720 caplets), Glucovance 125mg/500mg (20,280 tablets), diclofenac 50mg (20,000 tablets), metoprolol 50mg (20,280 caplets), Nifedipine 30mg (20,000 tablets), Gabapentin 100mg (24,000 tablets), Gabapentin 400mg (24,000 capsules), "Cabapentin 300mg" (20,000 tablets), lisinopril 20mg (20,000 tablets) and "Guaifenesin/Dextromethorphane HBR" (20,000 tablets). A pair of Latex gloves were found in several of the open containers. All of the barrels were labeled with a drug name, manufacturer's name, strength, lot number, National Drug Code (NDC) number, expiration date and quantity. All manufacturers that

were identified were subsequently contacted to determine if the NDC number on the labels matched the NDC number for their products. All manufacturers indicated that the NDC numbers did not match the NDC numbers for their products;

E. When Ms. Arrey was asked where these medications came from, she provided documentation that showed that she received the medication in the bulk barrels from a company named e-Meditech. This company is operated by Mr. Frank Egbe, but is not a licensed distributor in the State of Maryland. Ms. Arrey stated that the medication comes from Catholic Charities Medical Missions Board (CCMMB) by way of Mr. Egbe and she pays the donation fees. There were medications in the pharmacy that had the CCMMB labeling, however, most (but not all) were within date; and all of them had the appropriate NDC numbers;

F. Ms. Arrey could not provide a copy of an invoice; however, she was able to provide a printout of the medication list that she stated she used to select the medications that she needed. She also provided a document that demonstrated payment to Mr. Egbe for the medication;

G. Bulk medication bottles were reused by relabeling and filling with different medication than that intended by the manufacturers. These bulk bottles were on the pharmacy shelves. The new labels

covered the manufacturers' labels. The handwritten or typed labels identified the medication with the same information as on the bulk barrels and also indicated the (real) NDC numbers of the same medication.

H. Many times the medication currently in the bottles were not the same as what was previously in the bottle (i.e., the manufacturer's label for Roxicet was replaced by a handwritten or typed label covering the manufacturer's label and indicated Gabapentin 400mg). Some bottles, however, were refilled with the medication from the bulk containers and relabeled as such;

I. Medication repackaged in blister cards was found in some of the delivery totes. Many of the medications were the same as the medications that were identified as expired and in the bulk barrels;

J. The label on the blister card included the address of the Respondent-Pharmacy; a DEA number that did not have the appropriate number and type of digits; a prescription number; the name "Dr. P. Arrey"; the term "Med-Shoppe Cameroon", with the address there and a foreign phone number; directions for use; manufacturer's name; medication name; medication quantity; initials; the date that the prescription written; the original fill date; the dispensing date; and, the discard date;

K. Ms. Arrey was unable to provide a prescription for any of the

prescription numbers on the blister cards. There was no patient name associated with the medications prepared in the blister cards. The Respondent-Pharmacy could not produce a record or log for the 114 repackaged medications cards (a total of 7972 doses of medication). There were no cautionary labels on the blister cards;

L. Ms. Arrey did not have an exporter's license or permit. When asked for her permit, she presented the inspector with a document entitled "SGS Government & Institutions Services";

M. Mr. Arrey was unable to locate any policy and procedures for the operations for the pharmacy;

N. Mr. Arrey was unable to provide a biennial inventory of the CDS in the Respondent-Pharmacy and a perpetual inventory was not used. The Schedule II prescriptions were not filed and hard copy prescription files were not readily retrievable. Many of the Schedule II prescriptions did not bear the name of a prescriber;

5. On or around July 11, 2008, the DDC ordered and undertook an impoundment of the relabeled prescription and non-prescription drugs, expired prescription and non-prescription drugs, and the barrels of prescription drugs that originated from the CCMMB.

6. A follow-up consultation occurred with Matthew Rosenberg at the Food and Drug Administration (FDA). Ms. Taylor was informed that the FDA had taken samples of the medication in the bulk barrels impounded from the

Respondent-Pharmacy and was performing chemical assays to determine the chemicals/ drugs in each of the tablet samples.

7. The DDC also reported that the dumpsters connected to the building where the Respondent-Pharmacy is located were emptied and the FDA found other misbranded medication consistent with that found in the store in the dumpster.

8. Mr. Rosenberg reported that a search warrant was executed on August 6, 2008 for the Respondent-Pharmacy, as well as in Ms. Arrey's home, where similar expired and relabeled medications were retrieved.

9. The Respondent was subsequently arrested and charged with altering labels of drugs, removing the expiration dates from the labels of drugs, and placing the labels on stock bottles of drugs that were did not match the NDC numbers on the bulk drums, in violation of Federal Law.

FINDINGS OF FACT

1. As set forth above, the Respondent-Pharmacy's possession of hundreds of expired, re-labeled and/or misbranded drugs, and its failure to adhere to policies to protect the public safety and the safety of its employees, is a threat to the public health, safety or welfare.

2. The above actions also constitute violations of the Act. Specifically, the Respondent-Pharmacy violated the following provisions of § 12–403:

(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 or a registered pharmacy technician under § 12-6B-09 of this title;

(10) (i) Shall maintain at all times a current reference library that is appropriate to meet the needs of:

1. The practice specialty of that pharmacy; and
2. The consumers the pharmacy serves; and

(ii) Shall comply with any regulations adopted by the Board establishing the types of texts required to be included in the reference libraries in each of the various practice specialty pharmacies;

(11) (i) Shall maintain at all times the minimum professional and technical equipment and sanitary appliances that are necessary in a pharmacy:

1. To prepare and dispense prescriptions properly; and
2. To otherwise operate a pharmacy; and

(ii) Shall:

2. Be kept in a clean and orderly manner;

(12) Shall store all prescription or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board;

The Respondent-Pharmacy is also in violation of the following provisions of §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.

The Respondent-Pharmacy also violated §12-313 of the Act:

(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 permit to any applicant, reprimand any permit, place any permit on probation, or suspend or revoke a permit if the applicant or permit:

(2) Fraudulently or deceptively uses a permit;

(7) Willfully makes or files a false report or record as part of practicing pharmacy;

(8) Willfully fails to file or record any report that is required by law;

(15) Dispenses any drug, device, or diagnostic for which a prescription is required without a written, oral, or electronically transmitted prescription from an authorized prescriber;

(17) Violates any provision of § 12-503 of this title, which concerns the labeling requirements for prescriptions for drugs, devices, or diagnostics;

(21) Is professionally, physically, or mentally incompetent;

(25) Violates any rule or regulation adopted by the Board;

Furthermore, the Respondent violated §12–503 of the Act:

(a) An authorized prescriber who issues a prescription shall indicate on the prescription the date of its issuance.

(b) Unless otherwise instructed by the authorized prescriber who issues the prescription, a pharmacist may not dispense any drug or device on a prescription presented more than 120 days after the date the prescription was issued.

Further, the Respondent-Pharmacy violated §12–505 of the Act:

(a) Except for a drug or device dispensed to an inpatient in a hospital or related institution, each container of a drug or device dispensed shall be labeled in accordance with this section.

(b) In addition to any other information required by law, the label shall include:

(1) The date the prescription is filled; and

(2) Unless otherwise required by the prescriber:

(i) An expiration date of the drugs or devices which shall be the lesser of:

1. 1 year from the date of dispensing;
2. The month and year when the drugs or devices expire;
3. The appropriate expiration date for repackaged drugs or devices; or
4. A shorter period as determined by the pharmacist;

(ii) Any appropriate special handling instructions regarding proper storage of the drugs or devices; and

(iii) Subject to the provisions of subsection (c) of this section, the name and strength of the drugs or devices.

(c) (1) Except as provided in paragraph (2) of this subsection, the label shall indicate the same name for the drug or device as that used by the authorized prescriber.

(2) If, under § 12-504 of this subtitle, the pharmacist substitutes a drug or device product for that named by the authorized prescriber, the label shall indicate both the name of the drug or device product and the name of the manufacturer or distributor of the drug or device dispensed.

(d) (1) Except as provided in this subsection, if an authorized prescriber dispenses a drug or device, the prescriber shall label each container of the drug or device.

(2) In addition to any other information required by law, the authorized prescriber shall include on the label:

(i) The name and strength of the drug or device;

(ii) The date the prescription is dispensed;

(iii) An expiration date of the drug or device which shall be the lesser of:

1. 1 year from the date of dispensing;
2. The month and year when the drug or device expires; or
3. A shorter period as determined by the authorized prescriber; and

(iv) Any appropriate special handling instructions regarding proper storage of the drug or device.

(3) The labeling requirements of this subsection do not apply if the authorized prescriber dispenses the drug or device:

(i) To an inpatient in a hospital or related institution;

(ii) In an emergency situation; or

(iii) As a sample drug or device dispensed in the regular course of the authorized prescriber's operate as a.

(e) So long as any of the original contents remain in the container, a person may not alter, deface, or remove any label required by this section.

The Respondent-Pharmacy further violated the Pharmacists Code of Conduct, Code Md. Regs. tit. 10. § 34.10 (July 12, 1999):

.01 Patient Safety and Welfare.

A. A pharmacist shall:

(1) Abide by all federal and State laws relating to the operation as a 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;

(2) Verify the accuracy of the prescription before dispensing the drug or device if the pharmacist has reason to believe that the prescription contains an error; and

(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) Operate as a pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or

(3) Engage in unprofessional conduct.

CONCLUSIONS OF LAW

Based on the foregoing, the Board finds that the public health, safety or welfare imperatively requires emergency action, pursuant to Md. St. Gov't. Code Ann. §10-226(c)(2) (2004 Repl. Vol.).

ORDER

Based on the foregoing, it is therefore this 20th day of **August 2008**, by a

majority vote of a quorum of the State Board of Pharmacy, by authority granted by the Board by Md. St. Govt. Code Ann. §10-226(c) (2) (2004 Repl. Vol.), the permit held by the Respondent-Pharmacy to operate as a pharmacy in Maryland, Permit No. 11345, is hereby SUMMARILY **SUSPENDED**; and be it further

ORDERED, that upon the Board's receipt of a written request from the Respondent, a Show Cause Hearing shall be scheduled within thirty days of said request, at which the Respondent-Pharmacy will be given an opportunity to be heard as to whether the Summary Suspension should be continued, regarding the Respondent-Pharmacy's fitness to operate as a pharmacy and the danger to the public; and be it further

ORDERED, that the Respondent-Pharmacy shall immediately turn over to the Board its wall certificate and wallet-sized permit to operate as a pharmacy issued by the Board; and be it further

ORDERED, that this document constitutes a final 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.).

LaVerne Naesea, Executive Director
Board of Pharmacy

NOTICE OF HEARING

A Show Cause hearing to determine whether the Summary Suspension shall be continued will be held before the Board at 4201 Patterson Avenue, Baltimore, 21215 following a written request by the Respondent for same.