

IN THE MATTER OF	*	BEFORE THE
ASCO HEALTHCARE LLC,	*	STATE BOARD
d/b/a NEIGHBORE CARE/OMNICARE	*	OF
PHARMACIES	*	PHARMACY
PERMIT NOS. PW0153 & PW0140	*	Case Nos.: 07-014, 07-015, 07-020,
Respondent-Pharmacies	*	07-021 and 07-040
* * * * *		

**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., (2009 Repl. Vol.) (the "Act"), the Board charged Asco Healthcare LLC, d/b/a Neighborcare/Omnicare Pharmacies, Pharmacy Permit Holder (the "Respondent-Pharmacies"), with violations of the Act. Specifically, the Board charged the Respondent-Pharmacies with violation of the following provisions of § 12-409:

- (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 Board also charged the Respondent-Pharmacies with violation of the following section of its Act:

§ 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;
  - (4) Shall be supervised by a licensed pharmacist who is responsible for the operations of the pharmacy at all times the pharmacy is in operation;
  - (5) Shall provide complete pharmaceutical service by preparing and dispensing all prescriptions that reasonably may be expected of a pharmacist;
  - (9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12-313 of this title;
  - (16) Shall provide such personnel, automation, and technology as are necessary to allow the licensed pharmacist employee to comply with the labeling requirements specified in § 12-505 of this title [;].

The Board further charged the Respondent-Pharmacies with 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:
  - (16) Violates any provision of § 12-505 of this title, which concerns the labeling requirements for prescriptions for drugs, devices, or diagnostics;
  - (20) Is professionally, physically, or mentally incompetent;
  - (24) Violates any rule or regulation adopted by the Board;

- (26) Violates any provision of § 12-507 of this title;
- (27) Provides or causes to be provided confidential patient information to any person without first having obtained the patient's consent, as required by § 12-403(b)(13) of this title and by Title 4, Subtitle 3 of the Health - General Article; or
- (28) Fails to cooperate with a lawful investigation conducted by the Board or the Division of Drug Control.

The Board further charged the Respondent-Pharmacies with violation of its Code of Conduct, Code Md. Regs tit. 10. §34.10 (February 19, 1990):

.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;

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-Pharmacies were given notice of the issues underlying the Board's charges by letter dated February 25, 2010. Accordingly, a Case Resolution Conference was held on March 24, 2010, and was attended by Rodney Taylor, Pharm. D., Harry Finke, P.D., Board members, Kimberly France, P. D., Compliance Officer of the Board, and Linda Bethman, Counsel to the Board. Also in attendance were the Respondent-Pharmacies, represented by Mark Schroder, P.D., Regional Vice President, Mid-Atlantic Region, Arnold E. Clayman, P.D., FASCP, Vice President, Infusion Services, Roseann Barto, R.Ph., Director of Operations, Daniel Baker, General Manager, and their attorney, Laurence B. Russell, and the Administrative Prosecutor, Roberta Gill.

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-Pharmacies were authorized to operate as pharmacies in the State of Maryland. The Respondent-Pharmacies were first issued a permit by the Board, as

follows:

- A. Omnicare of Annapolis Junction, located at 9036 Junction Drive in Annapolis, Anne Arundel County, Maryland, was first issued permit #PW0140 on August 12, 2008. The permit expires on December 31, 2009;
  - B. Neighborcare/Omnicare, located in Salisbury, Wicomico, Maryland, was first issued permit #PW0153 on March 10, 2003. The permit expired on December 31, 2005;
2. The Respondent-Pharmacies serviced more than twenty long-term care centers.

#### **ALLEGATIONS REGARDING MALLARD BAY**

3. On July 6, 2005, the Chief Nurse of the Office of Health Care Quality (OHCQ) reported medication errors on the part of the Respondent-Pharmacies for Mallard Bay Care Center, a 160-bed facility, in Cambridge, Maryland. Specifically, the Respondent-Pharmacies mislabeled repackaged blister packs on two occasions for two separate patients in March 2005. The specifics are as follows:
- A. Glimerpride is an anti-diabetic oral drug used to control high blood sugar and used in residents' non-insulin-dependent diabetes. The medication should be taken with the first meal of the day.
  - B. Levoxil is a medication used to replace the hormone that is normally

produced by the thyroid gland for a condition know as hypothyroidism, and is normally given on an empty stomach;

- C. One resident is an 86 year old who had an order for Synthroid 25 mg by mouth every day. On 3/30/05, the pharmacy sent a reordered blister pack of her medication, with the patient's name, medication name and dose, physician's name, expiration date and a description of the medication;
- D. On 4/1/05, the patient's husband notified the staff that she had glassy eyes. On checking, the staff found the patient unresponsive and clammy and her blood sugar was 23 mg/dl, whereas a normal reading is 70-120. The patient's physician was contacted and she was given twice as much medication to treat severe hypoglycemia, and orange juice and sugar. She was admitted to the hospital and found to have a diagnoses which included hypoglycemic coma;
- E. Once re-admitted to the Home, on 4/17/05, the patient refused breakfast and her husband reported that she was "staring off into space." She was found to have a blood sugar of 52 mg/dl and was administered orange juice and two packs of sugar; her blood sugar was rechecked in 1/2 hour and found to be at 74 mg/dl.
- F. At 1:30 on the 17<sup>th</sup>, the patient's blood sugar registered low on the monitoring machine and she was given Glucagon IM and oxygen was applied. When her blood sugar was rechecked, it was found to be 23

mg/dl. She was sweating and non-responsive. Consequently, she was sent out via 911 and admitted to the hospital, where her diagnosis was hypoglycemia;

- G. On 4/28/05, at 1:00 pm, the patient's blood sugar was found to be at 63 mg/dl and she was given Glucagon via physician's order. At 4:00 pm, it was found to be 44mg/dl and the patient was given orange juice. The patient was non-verbal. At 9:30 pm, the patient's blood sugar was at 41 mg/dl and orange juice was given;
- H. On 5/25/05, it was discovered that the blister pack labeled Synthroid actually contained Amaryl, a diabetic medication;
- I. The patient was actually administered a total of 24 doses of the medication before the error was found;
- J. The Respondent-Pharmacies had mislabeled and repacked Amaryl instead of the Synthroid the patient needed. The other patient involved that needed the diabetes medication received the thyroid medication for 22 doses;
- K. The contract between Mallard Bay and the Respondent-Pharmacies was terminated by Mallard Bay on June 13, 2005.

#### **ALLEGATIONS REGARDING ST. CATHERINE'S NURSING CENTER**

- 4. On February 22, 2006, St. Catherine's Nursing Center, a 69-bed facility in Emmitsburg, Maryland, sent a complaint to the Chief Nurse of the OHCQ

complaining about medications ordered from Neighborcare/Omnicare, as follows:

- A. When the Respondent-Pharmacies shut down its "Yellow Brick Road" location and started delivering medications from the "Annapolis Junction" location, it resulted in the untimely receipt of medications for the residents;
- B. St. Catherine's indicated that a "re-order" on February 11, 2006 was supposed to be received within 48 hours. As of February 13, 2006, medications such as Tramadol HC, Zantac, Tylenol, Actonel, Vitamin C and Certagen, were not received. Once the medications were not received on the 13<sup>th</sup>, the staff of the facility was told to "re-fax" the order sheets and to expect delivery of medication in the evening of the 13<sup>th</sup>. As of February 14, 2006, the medications that were originally ordered on the 11<sup>th</sup> had not been received by the Center. The Respondent-Pharmacies directed the Nursing staff to refax the documents for a third time, which it did. As of February 15<sup>th</sup>, the medication originally ordered on the 11<sup>th</sup> still had not been delivered. After contacting the Respondent-Pharmacies again, an order was received at 2:30 pm, and was incomplete, which necessitated a second delivery in the evening of the 15<sup>th</sup>;
- C. After being contacted by the Administrator at St. Catherine's, the Chief Nurse at OHCQ then contacted other facilities in the Washington



County area that were also served by the Respondent-Pharmacies and was told that similar problems existed in those facilities as well. The Chief Nurse was assured that the residents continued to receive ordered medications through various alternative sources.

#### **ALLEGATIONS REGARDING COFFMAN NURSING HOME**

5. On July 17, 2006, OHCQ's Chief Nurse alerted the Board's Executive Director about Coffman Nursing in Hagerstown, Maryland, in that he recently conducted a survey of the Home and uncovered continuing problems with the services provided by the Respondent-Pharmacies. In one instance a resident was ordered Aricept, but the Respondent-Pharmacies filled the prescription with Zoloft.<sup>1</sup> In another case, the pharmacy label read "Acetaminophen 500 mg", but the box was filled with Acetaminophen 325 mg.

#### **ALLEGATIONS REGARDING ST. VINCENT CARE CENTER**

6. An investigation was performed at St. Vincent Care Center in Emmitsburg, Maryland regarding the quality of service being provided by the Respondent-Pharmacies. During the investigation, the facility Administrator and the Director of Nursing provided documentation of the decline in services since the Yellow Brick Road pharmacy merged with the

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<sup>1</sup>Aricept is for the treatment of Alzheimer's disease. Zoloft is an antidepressant and anti-anxiety drug.

Annapolis Junction pharmacy. During the last quarter of 2005, a total of four medications errors were documented.

7. Since the merger, a significant volume of occurrence of declining quality of services was documented. These included incorrect medications, incorrect dosage forms, significant delays in receiving medications ordered, medication received that was never ordered, duplication of medication orders received, and unreturned telephone calls.
8. The facility received a letter, dated May 8, 2006 stating that the current program of reporting occurrences would be terminated and that problems should now be reported by telephone and the problems would be acted upon immediately. The documentation provided clearly shows that this system was not effective and the problems continued. On August 10, 2006, the facility received a letter indicating that new management was hired to correct the problems with the Respondent-Pharmacies and that that manager would contact the Home. No contact was made.
9. The Board received a letter (excerpted below) from a representative of the facility describing the problems the facility had experienced since January 2006:

Colin Eversley  
DHMH  
Board of Pharmacy  
4201 Patterson Avenue  
Baltimore, MD 21215

Dear Colin,

On August 10, 2006, the facility received information from Pat Keaton, the Nurse Account Manager, that she was leaving Neighborcare and she extended her apologies for not being able to be successful in assisting with recent pharmacy issues. She also stated that a new Executive Director, Tom Hanzel, had arrived and would be working on improving pharmacy operations. Ms. McCann and Ms. Kressley have stated that they have not heard from any management official from Neighborcare and that improvements have not been noted.

Following is a brief sampling of some of the problems experienced since January 2006:

Wrong packaging	3
Wrong medication in repackaged card	3
Wrong medication	9
Wrong dosage form	4
Wrong dose	3
Wrong quantity	4
Non-receipt of order	6
Stock bottle sent with repackaged drug	1
Duplicate delivery of medication	4
Duplicate delivery of C-II medication	4
Refrigerated items not clearly identified	7
Interim Box medications missing	1
Wrong patient name on medication	2
Non-receipt of needed authorization	1
Received medication not ordered	7

1. Conduct an inspection of the Neighborcare Annapolis Junction Pharmacy to determine the cause and frequency of the noted errors.
2. Require written statement from Neighborcare management of the intended course of action and the time frame to correct deficiencies noted at St Vincent Care Center be forwarded to the Board of Pharmacy.
3. Encourage the development of a more effective method of evaluating, correcting and notifying customers concerning pharmacy occurrences.
4. Encourage establishing a single point of contact for customer concerns.

Respectfully,



Fred Evans, RPh

## **ALLEGATIONS REGARDING HOMEWOOD AT CRUMLAND FARMS**

10. By a form dated September 6, 2006, the Director of Nursing at Homewood at Crumland Farms in Frederick, Maryland sent a complaint to the Board which stated that, on 8/31/06, a resident of the Home was sent there from the hospital. The day before, her physician had called to see if the Home could obtain her antibiotic, Ayvox, upon her return. A nurse called the Respondent-Pharmacies to inquire whether the medication was available to be sent to the Home on 8/31/06. She was told it was in stock and would be sent when the order was received.

The physician's order was faxed to the Respondent-Pharmacies on the 31<sup>st</sup> and she was told it had been received and would be delivered at 5:00pm. However, the medication did not arrive. The Respondent-Pharmacies were called again and told that it was critical that the resident receive these meds tonight. The staff was told that the patient would receive the meds at the next delivery; however, the meds were not received then, meaning that the patient had missed the second dose for that day.

A call was placed to the Respondent-Pharmacies for the third time at 7:30 am the next day and the caller told them to send the meds stat. However, when the stat delivery arrived at 10 am on 9/1/06, the patient received Milk of Magnesia, Alupent, Advair and Vicodin. The facility once

again called the Respondent-Pharmacies about the critical need for the antibiotic and talked to a very "rude" person who identified herself as a pharmacist. Staff was advised that the meds would arrive by 3:00pm., which finally occurred.

#### **ALLEGATIONS REGARDING CITIZENS CARE AND REHABILITATION CENTER**

11. On a form dated September 6, 2006, Citizens Care and Rehabilitation Center in Frederick, Maryland filed a complaint with the Board about the Respondent-Pharmacies indicating a few examples of the numerous dispensing errors committed by the Respondent-Pharmacies. The Complaint stated that one resident was to receive Colace liquid: the bottle was labeled correctly, but the manufacturer's label revealed that the pharmacy had dispensed Metoclopramide liquid in error.<sup>2</sup> In addition, the Complainant stated that prescriptions were being short-filled, with 30 pills instead of 60. The facility had to obtain medication from neighborhood pharmacies because of these errors. On another occasion, the Respondent-Pharmacies dispensed Ziac, an anti-hypertensive/cardiac medication, instead of Ducolex, a laxative.

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<sup>2</sup>Colace is a stool softener. This is an antiemetic and gastroprokinetic agent, used primarily to treat nausea.

## ALLEGATIONS REGARDING HEBREW HOME OF GREATER WASHINGTON

12. By form dated October 12, 2006, a complaint was filed by the Hebrew Home of Greater Washington about the inconsistencies in the pharmacy services provided by the Respondent-Pharmacies, which affected quality assurance, patient care and service delivery. The Respondent-Pharmacies had submitted a proposed plan of correction, which had not been followed up on. Despite numerous calls to key staff of the Respondent-Pharmacies, there had been no follow-up. Specific examples cited in a letter from the facility were as follows:

Regional V.P. of Operations Omnicare  
9036 Junction Drive  
Annapolis Junction, Md. 20701

During the past two weeks, I have made several attempts to contact key staff within your organization to follow up on the next steps. To date, no one with a handle on your operations has returned my call. The following critical issues remain unresolved:

- 1) Lack of transition plan for replacement of nurse consultant and clinical support as outlined in the contract.
- 2) Ongoing delays in delivery of medications particularly for new admits. Some recent examples:
  - (8/27 - Med orders (Resident - Admitted to 289) faxed 3:00 p.m. Meds not received until 11:00 p.m.)
  - (8/29 - Med orders (Resident admitted to 258) faxed 6:50 p.m.; Received 8/30 at 11:30 a.m.)
  - (8/29- Med orders (Resident admitted to 210) faxed 6:30 p.m.; not received until 8/30 at 12:30 a.m.
  - (8/29 - Med orders (Resident admitted to Room 218) faxed 8:30 p.m.; not received until 11:30 a.m. on 8/30.
- 3) Errors in terms of medication labels not matching internal contents with no investigation follow-up. Some examples waiting for follow-up:
  - A. 8/22 - 4 West-Box read ferrous sulfate 325 mg. box - contained

- were 27 pills of furosemide 20 mg. Box said there were 30 pills.
    - B. 8/22 - 4 West Med box read Lipitor U-D 20mg. Box contained 27 pills of Lexapro, 20mg. Box also stated there were 30 pills.
    - C. 8/29 - 5 North - Box labeled ASA, 81 mg- Contained Felodipine 5 mg.
- 4) Routine tracking and trending of medication errors over time with reports submitted to our Vice President of Clinical Development...sent several requests.
- 5) Lack of ongoing support to clinical staff regarding issues relative to conversion to 30 day dispensing system. There seems to be a surplus of Tylenol from many units. Collected and given to DON. No pharmacy staff available to investigate and re-educate as needed.
- 6) Inconsistency in accuracy of POS (physician order sheets) when changes are submitted.
- 7) Delay in cassette exchange for 2nd floor Rehab carts and many meals missing for new admits.

According to the terms of our contract, we exercise the right to notify you in writing of this repeated failure to deliver products and services within a reasonable time and therefore failure to fulfill the contractual obligations of our agreement. We are very concerned about this lack of response and initiative to supply us with a performance improvement plan. I request at this time that, within the next 30 days, you provide the facility with a written, detailed plan for eliminating the deficiencies slated above. I look forward to your immediate response.

- 13. The Respondent-Pharmacies in fact addressed the service issues to the satisfaction of the Hebrew Home, and the contractual relationship was continued.

#### **GENERAL ALLEGATIONS REGARDING COMPLAINTS**

- 14. The Board's Compliance Officer obtained documentation concerning 1800 potential errors which included the following:
  - A. 78% (1400) wrong drug, including error in drug strength and active ingredient;
  - B. 19% (341) wrong or non-delivery; and,
  - C. 2%. (36) wrong package.

15. The pharmacies were acquired from Neighborcare by new ownership in July 2005. The new owners took forceful measures, including the installation of new management at the pharmacy, to correct the service issues that occurred both prior to the acquisition and during the post-acquisition transition period. There is no indication that the issues that occurred around the time of the acquisition are a continuing problem.
- 16 As set forth above, the Respondent-Pharmacies are in violation of the Act and regulations thereunder.

#### **CONCLUSIONS OF LAW**

Based upon the foregoing Findings of Fact, the Board finds that Respondent violated § 12-409 (a) (1), (2) and (3); § 12-403 (b) (1), (4), (5), (9) and (16); § 12-313 (b) (16), (20), (24), (26), (27) and (28); title 10 § 34.10.01 (A) (1) (a), (b), (c), (d) and (e) and (B) (1), (2) and (3).

#### **ORDER**

Based on the foregoing Findings of Fact, Conclusions of Law and agreement of the parties, it is this 25<sup>th</sup> day of August, 2010, by a majority of a quorum of the Board,

**ORDERED** that the Respondent-Pharmacies' permits to operate as pharmacies are subject to the following conditions:



- A. Within 60 days of the effective date of the Order, the Respondent-Pharmacies shall pay a fine to the Board of \$10,000 to the Board;
- B. Within six months of the effective date of the Order, the Respondent-Pharmacies shall make charitable contributions, totaling \$20,000, to non-profit organizations in Maryland that provide services for the elderly. The Respondent-Pharmacies shall document to the Board that such donations have been made;
- C. For one year from the effective date of the Order, the Respondent-Pharmacy # PW0140 shall submit quality assurance records to the Board on a quarterly basis. Such records shall detail any and all medication errors and remedial actions taken;
- D. The Respondent-Pharmacies shall bear the costs of complying with this Order.

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

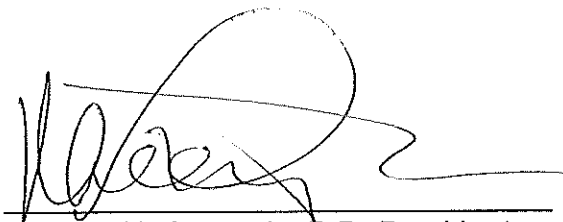
**ORDERED** that should the Board receive a report that the Respondent-Pharmacies have violated the Act or if the Respondent-Pharmacies violate any conditions of this Order, after providing the Respondent with notice and an opportunity for a hearing, the Board may take further disciplinary action against the Respondent-Pharmacies, including suspension or revocation. The burden of proof for any action

brought against the Respondent-Pharmacies as a result of a breach of the conditions of the Order shall be on the Respondent-Pharmacies to demonstrate compliance with the Order or conditions; and be it

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

**ORDERED** that, one year from the effective date of the Order, the Respondent-Pharmacies may petition the Board to have any conditions or restrictions on their permits removed, provided that they can demonstrate compliance with the conditions of this Order. Should the Respondent-Pharmacies fail to demonstrate compliance, the Board may impose additional terms and conditions, 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. 2009), 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.



Michael N. Souranis, P.D. President  
State Board of Pharmacy

**CONSENT OF ASCO HEALTHCARE, LLC  
D/B/A NEIGHBORE CARE/OMNICARE PHARMACIES**

I, Mark Schroder, by affixing my signature hereto, acknowledge that:

1. I am authorized to represent the Respondent-Pharmacies which are represented by an attorney, Laurence B. Russell, and have been advised by him of the legal implication of signing this Consent Order;

2. I am aware that without its consent, the permits to operate as pharmacies 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., (2009 Repl. Vol.).

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

By this Consent Order, I, on behalf of the Respondent-Pharmacies, hereby consent 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, I, on behalf of the Respondent-Pharmacies, waive any 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 the Respondent-Pharmacies' failure to abide by the conditions set forth in this Order and following proper procedures, they may suffer disciplinary action, possibly including revocation, against their permits to operate as pharmacies in the State of Maryland.

August 2, 2010  
Date

Mark Schroder  
Mark Schroder, P.D.,  
Regional Vice President  
Mid-Atlantic Region

STATE OF Ohio \_\_\_\_\_:

CITY/COUNTY OF Butler \_\_\_\_\_:

I HEREBY CERTIFY that on this ~~1st~~<sup>2nd</sup> day of August, 2010,  
before me, Erla Burnside, a Notary Public of the foregoing State and  
(Print Name)  
(City/County) personally appeared Mark Schroder License No. \_\_\_\_\_, on  
behalf of the Respondent-Pharmacies and made oath in due form of law that signing the  
foregoing Consent Order was his/her voluntary act and deed, and the statements made  
herein are true and correct.

AS WITNESSETH my hand and notarial seal.

My Commission Expires May 22, 2013  
In and for the State of Ohio  
ERLA A. BURNSIDE, Notary Public



Erla A. Burnside  
Notary Public

My Commission Expires: May 22, 2013