



OHIO STATE BOARD OF PHARMACY

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ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-040810-012)

In The Matter Of:

PAUL WILLIAM WOODRUFF, R.Ph.

3663 Durham Drive

Norton, Ohio 44203-6338

(R.Ph. No. 03-3-09616)

INTRODUCTION

THE MATTER OF PAUL WILLIAM WOODRUFF CAME FOR HEARING ON DECEMBER 8, 2004, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: LAWRENCE J. KOST, R.Ph. (presiding); GREGORY BRAYLOCK, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ELIZABETH I. GREGG, R.Ph.; NATHAN S. LIPSYC, R.Ph.; KEVIN J. MITCHELL, R.Ph.; DOROTHY S. TEATER, PUBLIC MEMBER; AND JAMES E. TURNER, R.Ph.

PAUL WILLIAM WOODRUFF WAS REPRESENTED BY CATHERINE M. BALLARD AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

State's Witnesses

1. Louis Robert Mandi, R.Ph., Ohio State Board of Pharmacy

Respondent's Witnesses

1. Paul William Woodruff, R.Ph., Respondent
2. Willard Roderick, President & CEO, Barberton Citizens Hospital

State's Exhibits

- 1A. Notice of Opportunity For Hearing letter for Barberton Citizens Hospital [08-10-04]
- 1B. Notice of Opportunity For Hearing letter for Paul William Woodruff, R.Ph. [08-10-04]
- 1C-1E. Procedurals
2. Barberton Citizens Hospital Department of Pharmacy Policies & Procedures for "Floor Stock Medications" [Reviewed April 26, 2002]
3. Barberton Citizens Hospital Department of Pharmacy Policies & Procedures for "Scope of Care" [Reviewed December 20, 2001]

4. Barberton Citizens Hospital Department of Pharmacy Policies & Procedures for "Surgery Order" [Reviewed and Revised May 14, 2002]
5. Surgery (Eye Section) Stock Order Form for Barberton Citizens Hospital [not dated]
6. Cardinal Health Computer Screen Print for Inventory Program showing generic products for BSS [not dated]
7. Surgery (Eye Section) Stock Order Form for Barberton Citizens Hospital [01-15-04 to 03-22-04]
8. Cardinal Health Pharmaceutical Distribution Original Invoice Copy 6798917 and Original Invoice Copy 6800206 for Barberton Citizens Hospital [03-12-04]
9. Nine Barberton Citizens Hospital Operating Room Record Cataract Procedures completed forms [03-25-04]
10. Notarized Statement of Marlene L. Garrett [04-16-04]
11. Two Cardinal Health Computer Screen Prints for Inventory Program showing products matching BSS and generic products matching BSS [not dated]
12. Physicians Desk Reference (PDR) Product Information for Eye-Stream® [not dated]
13. Manufacturer's Product Package Insert for Eye Stream® [Revised September 1992]
14. Drug Facts and Comparisons Ophthalmic Non-Surgical Adjuncts for Eye Stream® [January 2000]

Respondent's Exhibits

- A. Barberton Citizens Hospital Board of Managers/Board of Trustees Members [08/31/04]
- B. Resume of Paul Woodruff [not dated]
- C. Barberton Citizens Hospital Department of Pharmacy Policies & Procedures for "Drug Substitution, Procurement" [Revised August 24, 2004]; "Surgery Order" [Revised August 16, 2004]; "Stock Orders" [Revised August 16, 2004]; "Deliveries, Wholesale" [Revised June 16, 2004]; "Medication Errors" [Revised April 23, 2004]; "Communication Forms, Pharmacy Medication" [Revised June 22, 2004]; "Balanced Salt Solution with Vancomycin & Gentamicin" [Revised April 23, 2004]; and Barberton Citizens Hospital Policy No. 714, "Medication Management: Administration of Medications" [Reviewed/Revised April 2004]
- D. Letter to patient from Willard P. Roderick, President, Chief Executive Officer, Barberton Citizens Hospital [04-05-04]
- E. Letter to Patients and Community from Willard P. Roderick, President & CEO, Barberton Citizens Hospital [04-06-04]; and Letter to Employees [04-05-04]
- F. Letter from Jacqueline Lewis to Willard Roderick [05-03-04]
- G. Statement of Willard P. Roderick [not dated]
- H. Statement of Paul Woodruff [not dated]
- I-1-5. Five Letters of Support in re Paul W. Woodruff [11-24-04 to 12-04-04]
- J. Statement of Michael R. Cohen, R.Ph., Sc.D. [not dated]; Curriculum Vitae of Michael R. Cohen [not dated]
- K. Statement of Geraldine H. Amori, Ph.D., ARM, CPHRM, DFASHRM [not dated]

FINDINGS OF FACT

After having heard the testimony, observed the demeanor of the witnesses, considered the evidence, and weighed the credibility of each, the State Board of Pharmacy finds the following to be fact:

- (1) Records of the State Board of Pharmacy indicate that Paul William Woodruff was originally licensed by the State of Ohio as a pharmacist on July 27, 1970, pursuant to examination, and is currently licensed to practice pharmacy in Ohio. Records further reflect that, during the relevant time periods stated herein, Paul William Woodruff was the Responsible Pharmacist at Barberton Citizens Hospital, 155 Fifth Street N.E., Barberton, Ohio, pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-17-02 of the Ohio Administrative Code.
- (2) Paul William Woodruff as the Responsible Pharmacist at Barberton Citizen Hospital failed to implement policies and procedures consistent with federal and state laws and rules, and/or to adhere to such policies and procedures, so as to provide for the safe and effective distribution of drugs, to wit: hospital and pharmacy policy allowed non-pharmacists to order replacement drugs to be sent to the hospital floors, allowing a situation in March, 2004, which sent Eye Stream® to replace the depleted stock of BSS™. These two drugs are not generically equivalent; and, the use of the former as a substitute for the latter caused patient injury. Such conduct is in violation of Rule 4729-17-02(C)(3) of the Ohio Administrative Code.
- (3) Paul William Woodruff as the Responsible Pharmacist at Barberton Citizen Hospital maintained supplies of dangerous drugs in patient care areas according to written policies; however, the policies, and adherence thereto, failed to provide for the proper storage and labeling of such drugs, to wit: the policies permitted a situation in March, 2004, which sent Eye Stream® to replace the depleted stock of BSS™, but storage and labeling failed to indicate that the drugs were not generically equivalent. Such conduct is in violation of Rule 4729-17-03(B)(2) of the Ohio Administrative Code.
- (4) Paul William Woodruff as the Responsible Pharmacist at Barberton Citizen Hospital maintained supplies of dangerous drugs in patient care areas according to written policies; however, the policies, and adherence thereto, failed to provide for the proper replacement of drugs used and for the drug supply to be re-sealed. The policies allowed for interchanges of non-generically equivalent drugs for floor stock. Such conduct is in violation of Rule 4729-17-03(B)(5) of the Ohio Administrative Code.

CONCLUSION OF LAW

The State Board of Pharmacy concludes that paragraphs (2) through (4) of the Findings of Fact constitute being guilty of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of any rule adopted by the Board as provided in Division (A)(5) of Section 4729.16 of the Ohio Revised Code.

DECISION OF THE BOARD

Pursuant to Section 4729.16 of the Ohio Revised Code, and after consideration of the record as a whole, the State Board of Pharmacy hereby imposes a monetary penalty of one thousand dollars (\$1,000.00) on Paul William Woodruff and payment of the monetary penalty is due and

owing within thirty days of the mailing of this Order. The remittance should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 South High Street, Room 1702, Columbus, Ohio 43215-6126.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY (Aye-7/Nay-0).

MOTION CARRIED.

SO ORDERED.

It is hereby certified by this Board that the preceding language is a copy of the Order entered upon its journal in this case.

Section 119.12 of the Ohio Revised Code authorizes an appeal from this Order. An order that denied admission to an examination, or denied the issuance or renewal of a license or registration, or revoked or suspended a license, may be appealed to the court of common pleas in the Ohio county of your place of business or in your Ohio county of residence. Any other order may be appealed to the Court of Common Pleas of Franklin County, Ohio.

Such an appeal, setting forth the order appealed from and the grounds of the appeal, must be commenced by the filing of a Notice of Appeal with both the State Board of Pharmacy and the appropriate court within fifteen (15) days after the mailing of this Order and in accordance with the requirements of Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE STATE BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: JANUARY 6, 2005

CERTIFIED MAIL / Return Receipt
7003 0500 0002 4347 2825

WTW/lf

By: _____
William T. Winsley, M.S., R.Ph., Executive Director

c: Sally Ann Steuk, Assistant Attorney General
Catherine M. Ballard, Attorney for Respondent; Bricker & Eckler LLP;
100 South Third Street; Columbus, Ohio 43215-4291