



OHIO STATE BOARD OF PHARMACY

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-Equal Opportunity Employer and Service Provider-

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ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-000530-064)

In The Matter Of:

BETHESDA HOSPITAL-NORTH

c/o Steve Porowski, R.Ph.

10500 Montgomery Road

Cincinnati, Ohio 45242

(Terminal Distributor No. 02-0032100)

INTRODUCTION

THE MATTER OF BETHESDA HOSPITAL-NORTH CAME FOR HEARING ON OCTOBER 4, 2000, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: SUZANNE L. NEUBER, R.Ph. (presiding); ANN D. ABELE, R.Ph.; SUZANNE R. EASTMAN, R.Ph.; ROBERT P. GIACALONE, R.Ph.; LAWRENCE J. KOST, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; AND JAMES E. TURNER, R.Ph.

BETHESDA HOSPITAL-NORTH WAS NOT REPRESENTED BY COUNSEL, AND THE STATE OF OHIO WAS REPRESENTED BY SALLY ANN STEUK, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) William F. McMillen, R.Ph., Ohio State Board of Pharmacy
- (2) Elaine Jones, R.Ph., Ohio State Board of Pharmacy

Respondent's Witnesses:

- (1) Steve Porowski, Responsible Pharmacist, Bethesda Hospital-North
- (2) Susan McBeth, R.Ph., Responsible Pharmacist, Good Samaritan Hospital

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Copy of four-page Notice of Opportunity for Hearing letter dated May 30, 2000.
- (2) Exhibit 1A--Hearing Request letter dated June 27, 2000.
- (3) Exhibit 1B--Copy of Hearing Schedule letter dated June 30, 2000.

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- (4) Exhibit 1C--Copy of Renewal Application for DDD License, No. 02-0032100, for a terminal distributor of dangerous drugs license from January 1, 2000, to December 31, 2000, of Bethesda Hospital-North signed and dated by Stephen Porowski on September 13, 1999.
- (5) Exhibit 2--Copy of four-page Settlement Agreement with the State Board of Pharmacy, Docket No. D-970121-028, in the matter of Bethesda Hospital-North effective June 16, 1997.
- (6) Exhibit 3--Copy of Incident Form of Bethesda North Hospital, Complaint No. 17327, dated December 20, 1999.
- (7) Exhibit 4--Copy of Ohio State Board of Pharmacy Report of Investigation regarding Theft of Drugs from Bethesda North Hospital, Case No. 99-2261, by Specialist Elaine Jones dated February 24, 2000.
- (8) Exhibit 5--Copy of ten-page Dangerous Drug Distributor Inspection Report of Bethesda North Hospital dated December 16, 1999, and attached copy of Seniority List - North Pharmacy R.Ph.'s dated November, 1999.
- (9) Exhibit 6--Copy of page one of ten-page Dangerous Drug Distributor Inspection Report of Bethesda North Hospital dated December 16, 1999, and copy of four pages of response to pink sheet dated January 3, 2000.
- (10) Exhibit 7--Copy of five-page Dangerous Drug Distributor Inspection Report of Bethesda Hospital-North dated February 7, 1996.
- (11) Exhibit 8--Copy of Memorandum regarding Procedure for Signing in Narcotics on the Floors dated February 23, 1996; copy of blank Narcotic Checklist log sheet; copy of blank Drug Disposition and Controlled Substance Audit Record form; copy of front side of DEA Form 106 of Bethesda North Hospital dated January 1, 1995, through December 31, 1995; and copy of front side of DEA Form 106 of Bethesda North Hospital dated January 1, 1996, through February 29, 1996.
- (12) Exhibit 9--Copy of four-page Dangerous Drug Distributor Inspection Report of Bethesda Hospital-North dated November 5, 1986.
- (13) Exhibit 10--Copy of four-page response to pink sheet items with the following attachments: copy of letter from Peter D. Reeme dated November 18, 1986; copy of memo from David Day regarding retention of fill lists and chart check records dated November 5, 1986; and copy of memo from David Day regarding clarification of documentation requirements on cart fill lists dated November 6, 1986.
- (14) Exhibit 11--Copy of eight-page Dangerous Drug Distributor Inspection Report of Bethesda Hospital-North dated October 1, 1998; and attached copy of Licensure Information Form of Bethesda North, not dated.
- (15) Exhibit 12--Copy of three-page Dangerous Drug Distributor Inspection Report of Bethesda Hospital-North dated August 26, 1997, and attached page titled "Changes Made to Increase Security and Recordkeeping at Bethesda North Hospital," not dated.
- (16) Exhibit 13--Copy of two-page Dangerous Drug Distributor Inspection Report of Bethesda Hospital-North dated August 2, 1994.

Respondent's Exhibits:

- (1) Exhibit A--Copy of four-page Notice of Opportunity for Hearing letter dated May 30, 2000.
- (2) Exhibit B--Copy of two-page Response to Opportunity for Hearing, not dated.

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- (3) Exhibits C1 and C2--Copy of two-page Controlled Drug Update, not dated.
- (4) Exhibit C3--Copy of Changes Made to Increase Security and Recordkeeping at Bethesda North Hospital, not dated.
- (5) Exhibits C4 through C6--Copy of three-page Dangerous Drug Distributor Inspection Report of Bethesda Hospital-North dated August 26, 1997.
- (6) Exhibits C7 through C14--Copy of eight-page Dangerous Drug Distributor Inspection Report of Bethesda Hospital-North dated October 1, 1998.
- (7) Exhibit C15--Copy of notes regarding the State Board of Pharmacy Visit of September 29, 1998.
- (8) Exhibit C16--Copy of memo from Steve Porowski regarding controlled substance storage dated June 17, 1999.
- (9) Exhibit C17--Copy of procedure for common controlled substances floor-stocking, not dated.
- (10) Exhibit C18--Copy of procedure for placing ties on returned anesthesia kits, not dated.
- (11) Exhibits C19 through C28--Copy of ten-page Dangerous Drug Distributor Inspection Report of Bethesda North Hospital dated December 16, 1999.
- (12) Exhibit C29--Copy of response to the State Board Inspection of December 16, 1999, not dated.
- (13) Exhibit D1--Copy of TriHealth Hospitals Pharmacy Department Control Drug Discrepancy Report of Bethesda Hospital-North dated December 3, 1999.
- (14) Exhibits D2 and D3--Two-page copy of DEA Form 106, Report of Theft or Loss of Controlled Substances, of Bethesda North Hospital dated December 14, 1999.
- (15) Exhibit D4--Copy of two-page letter from Diana L. Housman dated October 1, 2000.
- (16) Exhibit E1--Copy of TriHealth Records Center Transfer List of North Pharmacy dated September, 1999.
- (17) Exhibit E2--Copy of TriHealth Records Center Transfer List of Rx-Pharmacy dated January 18, 2000.
- (18) Exhibit F1--Copy of Bethesda Hospital Controlled Drug Record of Administration/ Destruction, Anesthesia Department, for Kit A, Number 186, dated September, 2000.
- (19) Exhibit F2--Copy of table for drug records of anesthesia kits dated September 20, 2000.
- (20) Exhibit F3--Copy of Pharmacy Narcotic Record of Fentanyl 2ml Amp dated from September 14, 2000, through September 25, 2000.
- (21) Exhibit G1--Copy of Surgery North Anesthesia Kit Sign-Out Sheet dated September 19, 2000.
- (22) Exhibit G2--Copy of Pyxis Corporation Supplement to Purchase and Customer Support Agreement sold to Bethesda North Hospital, not dated.
- (23) Exhibit H--Copy of letter from G. Keith Bullock dated May 28, 1999.

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:

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- (1) Records of the State Board of Pharmacy indicate that Steve Porowski is the Responsible Pharmacist at Bethesda Hospital-North pursuant to Sections 4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-17-02 of the Ohio Administrative Code; and, Mr. Porowski has held that position since June 18, 1988.
- (2) Records further indicate that Bethesda Hospital-North entered into a Settlement Agreement with the State Board of Pharmacy, Docket No. D-970121-028, effective June 16, 1997. The terms of the Settlement Agreement included: a monetary penalty of ten thousand dollars (\$10,000.00); and proof of compliance with Ohio and federal laws, rules, and regulations. Contrary to the terms of the Settlement Agreement, Bethesda Hospital-North has failed to show compliance with Ohio and federal laws, rules, and regulations. Such conduct is in violation of the terms of its Settlement Agreement with the Board.
- (3) Bethesda Hospital-North, an institutional pharmacy, did, on or about July 1999, through December 16, 1999, fail to maintain records of all drug orders and records relating to the practice of pharmacy, to wit: the Responsible Pharmacist at Bethesda Hospital-North, Steve Porowski, failed to maintain physician drug orders and/or other adequate system of recordkeeping. Such conduct is in violation of Rule 4729-17-04(B) of the Ohio Administrative Code.
- (4) Bethesda Hospital-North, on or about December 16, 1999, and dates preceding, failed to provide controls adequate to prevent diversion of drugs; failed to institute recordkeeping procedures to account adequately for the drugs when used and who obtained the drugs from the drug supply; failed to ensure that such drugs are properly labeled and packaged in sufficient quantities to provide drug therapy during the period when the institutional pharmacy is not open; and failed to provide procedures for the inspection of the contingency drug inventory to assure proper utilization and replacement of the drug supply, to wit: Bethesda Hospital-North technicians obtained, restocked, and returned contingency drugs or anesthesia trays and, at no time during this process, were the trays checked by a pharmacist. Further, Bethesda Hospital-North did not maintain documentation for accountability of such procedures. Such conduct is in violation of Rule 4729-17-03(A)(2) of the Ohio Administrative Code.
- (5) Bethesda Hospital-North, on or about December 16, 1999, and dates immediately preceding, failed to provide storage of its contingency trays in a secure area and/or in containers with tamper-evident seals; failed to provide adequate recordkeeping procedures to document the disposition of the drugs in supply; and failed to maintain security, to wit: the surgery unit's anesthesia cabinet at Bethesda Hospital-North was left unlocked during the day and unused drugs on the anesthesiologist's drug trays were left unsecured, allowing anyone in the surgery area to gain access to controlled substances. Such conduct is in violation of paragraphs (B) and (C) of Rule 4729-17-03 of the Ohio Administrative Code.

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- (6) Bethesda Hospital-North did, prior to December 16, 1999, cease to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in Section 4729.55 of the Revised Code, to wit: Bethesda Hospital-North failed to provide adequate safeguards to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs. Further, Bethesda Hospital-North has not instituted proper policies and procedures to maintain supervision and control of the possession and custody of all dangerous drugs acquired by the institutional facility. Such conduct is in violation of Rule 4729-17-02(A) of the Ohio Administrative Code, and not in accordance with Section 4729.55(C) of the Ohio Revised Code.
- (7) Bethesda Hospital-North, an institutional pharmacy, did, on or about December 16, 1999, and dates immediately preceding, fail to maintain records of positive identification of the pharmacist responsible for performing all activities relating to the practice of pharmacy when entering prescription information into the recordkeeping system, to wit: Bethesda Hospital-North pharmacists used a password without a second means to meet positive identification requirements. Such conduct is in violation of Rule 4729-5-27(A) of the Ohio Administrative Code.

CONCLUSION OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that paragraphs (3) through (7) of the Findings of Fact constitute violating rules of the Board as provided in Division (A)(2) of Section 4729.57 of the Ohio Revised Code.

ACTION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code, and on the basis of the Findings of Fact and Conclusion of Law set forth above, the State Board of Pharmacy takes the following actions in the matter of Bethesda Hospital-North:

- (A) The State Board of Pharmacy hereby imposes a monetary penalty of six thousand dollars.
- (B) Further, the Board will suspend three thousand dollars of the six thousand dollar monetary penalty provided that Bethesda Hospital-North comply with the terms of this Order. The monetary penalty of three thousand dollars (\$3,000.00) is due and owing within thirty days of the issuance of this Order. The monetary penalty 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. Other terms of this Order are as follows:

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- (1) Bethesda Hospital-North must correct the violations noted in the Findings of Fact stated herein within ninety days of the effective date of this Order and notify the Ohio State Board of Pharmacy Compliance Specialist in its area that the corrections have been made. The specialist will conduct an inspection within the ninety-day period. The inspection must show compliance with Ohio and federal laws, rules and regulations.
- (2) Bethesda Hospital-North Pharmacy will be subject to inspection annually for three years.
- (3) Bethesda Hospital-North Pharmacy must notify the Board of any proposed changes to its policies and procedures before implementation.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY (Aye-5/Nay-1).

MOTION CARRIED.

SO ORDERED.

It is hereby certified by this Board that the above 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

VIA CERTIFIED MAIL
#7099 3400 0006 4919 3118
Return Receipt Requested

ORDER MAILED
AND EFFECTIVE: NOVEMBER 8, 2000

WTW/sr

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

c: Sally Ann Steuk, Assistant Attorney General



OHIO STATE BOARD OF PHARMACY

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SETTLEMENT AGREEMENT WITH THE STATE BOARD OF PHARMACY

(Docket No. D-970121-028)

In The Matter Of:

BETHESDA HOSPITAL-NORTH

c/o Stephen Porowski, R.Ph.

10500 Montgomery Road

Cincinnati, Ohio 45242

(Terminal Distributor No. 02-0032100)

This Settlement Agreement is entered into by and between Bethesda Hospital-North and the Ohio State Board of Pharmacy, a state agency charged with enforcing the Pharmacy Practice Act and Dangerous Drug Distribution Act, Chapter 4729. of the Ohio Revised Code.

Bethesda Hospital-North enters into this Agreement being fully informed of its rights afforded under Chapter 119. of the Ohio Revised Code, including the right to representation by counsel and the right to a formal adjudication hearing on the issues contained herein.

Bethesda Hospital-North is knowingly and voluntarily acknowledging that, in order to settle the charges that have been filed by the Board against Bethesda Hospital-North, and in order to obviate the need to conduct an administrative hearing to consider the disciplinary sanctions against Bethesda Hospital-North's license, this Agreement is entered into on the basis of the following stipulations, admissions, and understandings:

- (A) The Ohio State Board of Pharmacy is empowered by Section 4729.57 of the Ohio Revised Code to suspend, revoke, refuse to renew, or impose a monetary penalty on any terminal distributor of dangerous drugs for violation of any of the enumerated grounds.
- (B) On or about January 21, 1997, Bethesda Hospital-North was notified of the allegations or charges against it, its right to a hearing, its rights in such hearing, and its right to submit contentions in writing. Further, in accordance with Chapter 119. of the Ohio Revised Code, a hearing was requested and scheduled for June 18, 1997.
- (C) Bethesda Hospital-North stipulates to the allegations stated in the Notice of Opportunity letter dated January 21, 1997, and the Board herein adjudicates the same:
 - (1) Records of the Board of Pharmacy indicate that Stephen Porowski is the Responsible Pharmacist at Bethesda Hospital-North pursuant to Sections

4729.27 and 4729.55 of the Ohio Revised Code and Rule 4729-17-02 of the Ohio Administrative Code.

- (2) Bethesda Hospital-North, an institutional pharmacy, did, on or about February 5, 1996, and dates immediately preceding, fail to have a pharmacist ensure adherence to Rule 4729-17-02 of the Ohio Administrative Code, to wit: the Responsible Pharmacist did not properly:
a) assure adherence to policies and procedures for the safe and efficient distribution of drugs in all areas of the institution; b) ensure responsibility for the security and control of all drugs within the institution; missing keys were reported to the Responsible Pharmacist but no action had been taken; c) maintain all records, required by state or federal law to be kept at the licensed location, of the acquisition, use, distribution, and disposition of all drugs; d) implement the hospital's written policies and procedures which were to be consistent with Chapter 4729-17 of the Ohio Administrative Code and other applicable federal and state laws and rules governing the legal distribution of drugs. Such conduct is in violation of Rule 4729-17-02 of the Ohio Administrative Code.
- (3) Bethesda Hospital-North, an institutional pharmacy, did, on or about February 5, 1996, and dates immediately preceding, fail to maintain records of all drug orders and dispensing records for drugs for patients. Though such drug orders and dispensing records may be microfilmed or retained by any process providing an exact duplicate of the original order, the pharmacy did not maintain any such records. In addition, there was no alternate recordkeeping system utilized allowing such records to be stored on electronic, magnetic, light, laser, or optic media meeting industry standards for quality and stability for a period of at least three years. Records on an automated data processing system, or subsequent storage of such records, were not readily retrievable (via CRT display or hard-copy printout) within seventy-two hours. Records of drugs dispensed did not include the name, strength, and quantity of drugs dispensed; the date of dispensing; the name of the inpatient to whom, or for whose use, the drug was dispensed; or positive identification of the dispensing pharmacist. The pharmacy had been admonished by a Board agent for inadequate records on November 5, 1986. Such conduct is in violation of Rule 4729-17-04(B) of the Ohio Administrative Code and Section 3719.07 of the Ohio Revised Code.
- (4) Bethesda Hospital-North, an institutional pharmacy with an outpatient prescription service, did, on or about February 5, 1996, and dates immediately preceding, fail to file outpatient prescriptions in files separated by controlled substance schedule. Such conduct is in violation of Rule 4729-5-09 of the Ohio Administrative Code.
- (5) Bethesda Hospital-North, an institutional pharmacy, did, on or about February 5, 1996, and dates immediately preceding, fail to record the information for the transfer when transferring copies of prescriptions to other pharmacies, to wit: prescriptions numbered 310751, 310317,

310915, 310245, 309644, and 310026 lacked pertinent transfer information. Such conduct is in violation of Rule 4729-5-24(A)(4) of the Ohio Administrative Code.

- (6) Bethesda Hospital-North, an institutional pharmacy, did, on or about February 5, 1996, and dates immediately preceding, knowing that a felony had been committed, knowingly fail to report such information to law enforcement authorities, to wit: pharmacy personnel, knowing that the felonious theft of drugs had occurred, or probably had occurred, failed to report the information to any law enforcement authority. Numerous thefts of controlled substances had occurred, but the hospital did not report them. Further, the pharmacy failed to notify the Board of Pharmacy and/or the federal Drug Enforcement Administration of drug thefts, and it failed to utilize the D.E.A. reporting form. Such conduct is in violation of Section 2921.22 of the Ohio Revised Code, Rule 4729-9-15 of the Ohio Administrative Code, and Section 1301.76(b) of Title 21 of the Code of Federal Regulations.
- (7) Bethesda Hospital-North, an institutional pharmacy, did, on or about February 5, 1996, and dates immediately preceding, cease to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in Section 4729.55 of the Ohio Revised Code, to wit: adequate safeguards were not assured to prevent the sale or other distribution of dangerous drugs by persons other than a pharmacist, dentist, optometrist, physician, or veterinarian in that recordkeeping, security, and control over the dangerous drugs, and/or hospital pharmacy procedures were inadequate and/or non-existent to such a degree as to permit thefts and perpetrators of thefts of controlled substances to remain undetected. Records of drugs dispensed and/or returned to the pharmacy did not exist beyond three days after the activity of dispensing; cart fill records did not exist beyond one week after the activity.

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of any formal proceedings at this time, Bethesda Hospital-North knowingly and voluntarily agrees with the State Board of Pharmacy to the following:

- (A) Bethesda Hospital-North agrees to the imposition of a monetary penalty of ten thousand dollars (\$10,000.00) due and owing within thirty days of the effective date of this Agreement. The monetary penalty should be made payable to the "Treasurer, State of Ohio" and mailed with the enclosed form to the State Board of Pharmacy, 77 S. High Street, 17th Floor, Columbus, Ohio 43266-0320.
- (B) The Board has directed Board staff to conduct an inspection within ninety days from the effective date of this Agreement. The inspection must show compliance with Ohio and federal laws, rules, and regulations. Further inspections will be held at least annually for three years thereafter.

If, in the judgment of the Board, Bethesda Hospital-North appears to have violated or breached any terms or conditions of this Agreement, the Ohio State Board of Pharmacy

reserves the right to, at any time, institute formal disciplinary proceedings for any and all possible violations or breaches, including but not limited to, alleged violation of the laws of Ohio occurring before the effective date of this Agreement.

Bethesda Hospital-North acknowledges that it has had an opportunity to ask questions concerning the terms of this agreement and that all questions asked have been answered in a satisfactory manner. Any action initiated by the Board based on alleged violation of this Agreement shall comply with the Administrative Procedure Act, Chapter 119. of the Ohio Revised Code.

Bethesda Hospital-North and its employees and agents waive any and all claims or causes of action they may claim against the State of Ohio or the Board, and members, officers, employees, and/or agents of either, arising out of matters which are the subject of this Agreement.

In the event the Board, in its discretion, does not adopt this Agreement as its Adjudication, this settlement offer is withdrawn and shall be of no evidentiary value and shall not be relied upon or introduced in any disciplinary action or appeal by either party. Bethesda Hospital-North agrees that should the Board reject this Agreement and if this case proceeds to hearing, it will assert no claim that the Board was prejudiced by its review and discussion of this Agreement or of any information relating thereto.

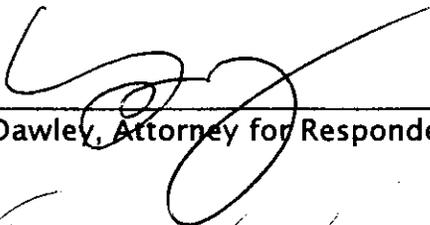
This Settlement Agreement shall be considered a public record, as that term is used in Section 149.43 of the Ohio Revised Code, and shall become effective upon the date of the Board President's signature below.



Stephen Porowski on behalf of Bethesda Hospital-North
Responsible Pharmacist

5/30/97

Date of Signature



Kris M. Dawley, Attorney for Respondent

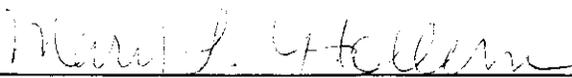
Date of Signature



Suzanne L. Neuber, President, Ohio State Board of Pharmacy

6/16/97

Date of Signature



Mary L. Hollern, Ohio Assistant Attorney General

6/16/97

Date of Signature