



OHIO STATE BOARD OF PHARMACY

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ORDER OF THE STATE BOARD OF PHARMACY

(Docket No. D-950502-055)

In The Matter Of:

BAXTER HEALTHCARE CORPORATION

E. Gerald Parker, R.Ph.
5532 Spellmire Drive
Cincinnati, Ohio 45246

INTRODUCTION

THE MATTER OF BAXTER HEALTHCARE CORPORATION, CINCINNATI, OHIO, CAME TO HEARING ON JUNE 29, 1995, BEFORE THE FOLLOWING MEMBERS OF THE BOARD: RUTH A. PLANT, R.Ph. (presiding); ROBERT B. CAVENDISH, R.Ph.; JOHN L. HANNA, R.Ph.; PAUL F. LAMPING, R.Ph.; AMONTE B. LITTLEJOHN, R.Ph.; JOSEPH J. MASLAK, R.Ph.; WAYNE C. MILLER, R.Ph.; SUZANNE L. NEUBER, R.Ph.; AND NICHOLAS R. REPKE, PUBLIC MEMBER.

BAXTER HEALTHCARE CORPORATION WAS REPRESENTED BY JAMES T. O'NEILL, JOHN A. HERRMANN, AND IRENE P. JAKIMCIUS, AND THE STATE OF OHIO WAS REPRESENTED BY ROBERT J. McCLAREN, ASSISTANT ATTORNEY GENERAL.

SUMMARY OF EVIDENCE

(A) Testimony

State's Witnesses:

- (1) Joann Predina, R.Ph., Compliance Specialist, Ohio State Board of Pharmacy
- (2) William T. Winsley, R.Ph., M.S., Asst. Executive Director, Ohio State Board of Pharmacy

Respondent's Witnesses:

- (1) Dr. William Howard Bay, Div. of Nephrology, Dept. of Medicine, Ohio State University Medical Center
- (2) Robert L. Wilkinson, RAC, Director, Regulatory Affairs, Renal Division, Baxter Healthcare Corporation
- (3) Ms. McCarthy, Director, Regulatory Affairs, Distribution Division, Baxter Healthcare Corporation
- (4) Judith A. Zitnik, R.Ph., Responsible Pharmacist, Baxter Healthcare Corporation, Obetz, Ohio

(B) Exhibits

State's Exhibits:

- (1) Exhibit 1--Proposal to Deny Application for Registration as a Terminal Distributor of Dangerous Drugs/Notice of Opportunity letter of Baxter Healthcare Corporation, Solon, Ohio dated May 2, 1995.
- (2) Exhibit 1A--Notice of Opportunity letter regarding the Wholesale Distributor License of Baxter Healthcare Corporation, Solon, Ohio dated May 2, 1995.
- (3) Exhibit 1B--Proposal to Deny Application for Registration as a Terminal Distributor of Dangerous Drugs/Notice of Opportunity letter of Baxter Healthcare Corporation, Obetz, Ohio dated May 2, 1995.
- (4) Exhibit 1C--Notice of Opportunity letter regarding the Wholesale Distributor License of Baxter Healthcare Corporation, Obetz, Ohio dated May 2, 1995.
- (5) Exhibit 1D--Proposal to Deny Application for Registration as a Terminal Distributor of Dangerous Drugs/Notice of Opportunity letter of Baxter Healthcare Corporation, Cincinnati, Ohio dated May 2, 1995.
- (6) Exhibit 1E--Notice of Opportunity letter regarding the Wholesale Distributor License of Baxter Healthcare Corporation, Cincinnati, Ohio dated May 2, 1995.
- (7) Exhibit 1F--Two-page Hearing Request letter dated May 23, 1995.

- (8) Exhibit 1G--Two-page Hearing Schedule letter dated May 30, 1995.
- (9) Exhibit 1H--Two-page Application for Registration as a Terminal Distributor of Dangerous Drugs of Baxter Healthcare Corporation, Solon, Ohio, dated February 24, 1995, with attachments as follows: letter from E. Gerald Parker dated February 24, 1995; copy of explanation to Section E of the application; letter from LeMarr L. French dated October 15, 1994; two-page letter from Robert L. Wilkinson dated September 27, 1994; copy of second page of Application for Registration as a Terminal Distributor of Dangerous Drugs dated August 25, 1994; Administrative Communication of the Ohio State Board of Pharmacy, Notice of Incomplete Application for Registration form; copy of explanation to Section E of the application; copy of front and back of pocket identification card of Thomas Jeffrey Migliore, No. 03-3-11923, expiration date of September 15, 1995, with copy of photograph; letter from Thomas J. Migliore dated October 18, 1994; and copy of second page of Application for Registration as a Terminal Distributor of Dangerous Drugs dated September 16, 1994.
- (10) Exhibit 1I--Renewal Application for DDD License, No. 01-010900, for a Wholesale Distributor of Dangerous Drugs License from July 1, 1995, through June 30, 1996, of Baxter Healthcare Corporation, Solon, Ohio dated April 24, 1995.
- (11) Exhibit 1J--Two-page Application for Registration as a Terminal Distributor of Dangerous Drugs of Baxter Healthcare Corporation, Obetz, Ohio, dated February 24, 1995.
- (12) Exhibit 1K--Renewal Application for DDD License, No. 01-349000, for a Wholesale Distributor of Dangerous Drugs License from July 1, 1995, through June 30, 1996, of Baxter Healthcare Corporation, Obetz, Ohio dated May 11, 1995.
- (13) Exhibit 1L--Two-page Application for Registration as a Terminal Distributor of Dangerous Drugs of Baxter Healthcare Corporation, Cincinnati, Ohio, dated September 16, 1994; two-page fax as follows: page one-cover sheet to William T. Winsley from E. Gerald Parker dated January 30, 1995; page two-letter from Ernest Gerald Parker dated January 30, 1995; and copy of explanation to Section E of the application.
- (14) Exhibit 1M--Renewal Application for DDD License, No. 01-026050, for a Wholesale Distributor of Dangerous Drugs License from July 1, 1995, through June 30, 1996, of Baxter Healthcare Corporation, Cincinnati, Ohio dated May 15, 1995, with attachments: copy of explanation to the legal question on the application; and copy of Baxter Healthcare Corporation Officers and Directors.
- (15) Exhibit 2--Five-page Dangerous Drug Distributor Inspection Report of Baxter Healthcare Corporation, Solon, Ohio, Wholesale Distributor No. 01-010900, dated May 26, 1994.
- (16) Exhibit 2A--Copies of two Baxter Healthcare Corporation, Straight Bill of Lading, Nos. CV302907A and CV305936A.
- (17) Exhibit 2B--Pull tab from the top of a Baxter Healthcare Corporation cardboard shipping box showing patient specific information.
- (18) Exhibit 2C--Two-page Baxter Healthcare Corporation Route Sheet/Work & Load Record dated May 26, 1994.
- (19) Exhibit 3--Two-page letter from Robert L. Wilkinson dated June 6, 1994.
- (20) Exhibit 4--Letter from David L. Rowland dated June 14, 1994.
- (21) Exhibit 5--Four-page letter from Robert L. Wilkinson dated June 15, 1994.
- (22) Exhibit 6--Two-page fax from Robert L. Wilkinson dated August 2, 1994.
- (23) Exhibit 7--Dangerous Drug Distributor Inspection Report of Baxter Healthcare Corporation, Solon, Ohio, Wholesale Distributor No. 01-010900, dated August 10, 1994.
- (24) Exhibit 7A--Copy of Baxter Healthcare Corporation Message Receive Screen regarding patient William Elliott dated February 27, 1995.
- (25) Exhibit 7B--Copy of Pick-Up or Delivery Record, No. 412090 dated March 7, 1995.
- (26) Exhibit 7C--Baxter Healthcare Corporation red quarantine sign.
- (27) Exhibit 7D--Copy of Baxter Healthcare Corporation Product Integrity Criteria.
- (28) Exhibit 7E--Copy of Baxter Healthcare Corporation Customer Service/Carrier Guidelines.
- (29) Exhibit 7F--Copy of Back-To-Baxter Return Goods Form, Customer No. A412090, dated March 14, 1995.
- (30) Exhibit 7G--Pull tab from the top of a Baxter Healthcare Corporation cardboard shipping box with patient specific information marked over with cardboard-colored spray paint.
- (31) Exhibit 7H--Section of a Baxter Healthcare Corporation cardboard shipping box marked CV in red, and labeled Dianeal® PD-2, . . . , Lot ZP060863, EXP SEP 95.
- (32) Exhibit 8--Dangerous Drug Distributor Inspection Report of Baxter Healthcare Corporation, Solon, Ohio, Wholesale Distributor No. 01-010900, dated September 2, 1994.
- (33) Exhibit 9--Two-page letter from Robert L. Wilkinson dated September 14, 1994.
- (34) Exhibit 10--Copy of letter from Franklin Z. Wickham dated September 19, 1994.
- (35) Exhibit 11--Copy of two-page letter from Robert L. Wilkinson dated September 26, 1994.
- (36) Exhibit 12--Two-page fax as follows: page one-cover sheet to Joann Predina from E. Gerald Parker dated February 27, 1995, and page two-Violated Regulations and Codes as Cited May 26, 1994.
- (37) Exhibit 13--Two-page Dangerous Drug Distributor Inspection Report of Baxter Healthcare Corporation, Solon, Ohio, Wholesale Distributor No. 01-010900, dated March 15, 1995.
- (38) Exhibit 14--Two-page Dangerous Drug Distributor Inspection Report of Baxter Healthcare Corporation, Obetz, Ohio, Wholesale Distributor No. 01-349000, dated March 17, 1995.
- (39) Exhibit 15--Two-page letter from E. Gerald Parker dated March 21, 1995.

- (40) Exhibit 16--Two-page Dangerous Drug Distributor Inspection Report of Baxter Healthcare Corporation, Cincinnati, Ohio, Wholesale Distributor No. 01-026050, dated March 27, 1995.
- (41) Exhibit 17--Three-page letter from Robert L. Wilkinson dated April 4, 1995, with attachments: Number 1: six-page Summary of Violations and Recommended Procedures for Compliance; and Number 2: three-page Composite Action Plan.
- (42) Exhibit 18--Two-page letter from E. Gerald Parker dated April 5, 1995.

Respondent's Exhibits:

- (1) Exhibit A--Baxter Healthcare Pharmacy Services Prescription Order Flowchart.
- (2) Exhibit B--Baxter Healthcare Pharmacy Services Prescription Order Flowchart Notes.
- (3) Exhibit C--Baxter Healthcare Pharmacy Services-Ohio Facilities Procedures for Compliance.
- (4) Exhibit D--Baxter Renal Division Pharmacy Patient Profile Information Form.
- (5) Exhibit E--Baxter Renal Division Offer to Counsel.
- (6) Exhibit F--Two-page form letter from Joseph G. Orlando dated June 2, 1995; Baxter Renal Division Fax Form; Form letter from Joseph G. Orlando dated July x, 1995; Baxter Renal Division Fax Form; and Baxter Renal Division Pharmacy Patient Profile Information Form.
- (7) Exhibit G--Copy of two-page letter from Robert L. Wilkinson dated June 6, 1994.
- (8) Exhibit H--Letter from David L. Rowland dated June 14, 1994.
- (9) Exhibit I--Copy of four-page letter from Robert L. Wilkinson dated June 15, 1994; copy of three Applications For Registration As A Terminal Distributor dated June 16, 1994; copy of Baxter Healthcare Corporation Wholesale Distributor License No. 01-010900; copy of explanation to Section E of the application; and copy of Baxter Healthcare Corporation Wholesale Distributor License No. 01-349000.
- (10) Exhibit J--Copy of fifteen-page letter from Robert L. Wilkinson dated June 23, 1994.
- (11) Exhibit K--Pertinent wording from Sections 4729.02, 4729.28, and 4729.29 of the Ohio Revised Code.
- (12) Exhibit L--Two-page letter from Robert L. Wilkinson dated July 8, 1994.
- (13) Exhibit M--Two-page letter from Robert L. Wilkinson dated August 2, 1994; Seven-page draft of Petition to Adopt Administrative Rule; three-page copy of faxed draft of new law regarding statutory exemption; two-page copy of faxed Senate Bill 671 dated 4/20/89.
- (14) Exhibit N--Letter from John Chmel dated August 11, 1994; two-page Regulatory Inspection Checklist/Report and twenty-three pages of attachments.
- (15) Exhibit O--Copy of two-page letter from Robert L. Wilkinson dated August 25, 1994; copy of Application For Registration As A Terminal Distributor dated August 25, 1994; and copy of explanation to Section E of the application.
- (16) Exhibit P--Copy of two-page letter from Robert L. Wilkinson dated September 14, 1994.
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- (18) Exhibit R--Copy of two-page letter from Robert L. Wilkinson dated September 27, 1994; copy of Application For Registration As A Terminal Distributor dated September 16, 1994; and copy of explanation to Section E of the application; copy of Application For Registration As A Terminal Distributor dated August 25, 1994; and copy of explanation to Section E of the application.
- (19) Exhibit S--Copy of two-page letter from Robert L. Wilkinson dated January 16, 1995.
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- (21) Exhibit U--Two Baxter Healthcare Corporation pamphlets titled: "When Kidneys Fail" and "Treating Kidney Disease".
- (22) Exhibit V--Three-page copy of Curriculum Vitae of William Howard Bay, M.D.
- (23) Exhibit W--Copy of Baxter Healthcare Corporation Renal Division Invoice No. H48433 dated 06/27/95; copy of Baxter Healthcare Corporation Renal Division Invoice No. H05991 dated 06/06/95.

FINDINGS OF FACT

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

- (1) Baxter Healthcare Corporation submitted an Application for Registration as a Terminal Distributor of Dangerous Drugs for the facility located at 5532 Spellmire Drive, Cincinnati, Ohio 45246, on or about October 6, 1994. On May 2, 1995, the Board proposed to deny the application submitted by Baxter Healthcare Corporation, Cincinnati, Ohio.
- (2) Baxter Healthcare Corporation, while not a licensed terminal distributor or practitioner, and not in accordance with Chapters 3719., 4715., 4729., 4731., and 4741. of the Ohio Revised Code, continuously possessed and/or sold at retail dangerous drugs, to wit: after numerous warnings by Board of Pharmacy Compliance Specialists, Baxter Healthcare Corporation, Cincinnati, Ohio, continued to sell dangerous drugs directly to end-

stage renal disease patients in their homes without a prescription from a practitioner and without a pharmacist to dispense the medication. Such conduct is in violation of Section 4729.51(C) of the Ohio Revised Code.

ACTION OF THE BOARD

Pursuant to Section 4729.55 of the Ohio Revised Code, the State Board of Pharmacy hereby approves the Application for Registration as a Terminal Distributor of Dangerous Drugs submitted by Baxter Healthcare Corporation, Cincinnati, Ohio. The license will be issued by a Board Compliance Specialist upon conducting an inspection on or before July 15, 1995, and the Board Compliance Specialist determines that adequate safeguards are assured to prevent the recurrence of such violations, and that the facility is in compliance with all federal and state laws and regulations governing the legal distribution of drugs.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.



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(Docket No. D-950502-056)

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5532 Spellmire Drive

Cincinnati, Ohio 45246

(Wholesale Distributor No. 01-026050)

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- (1) Baxter Healthcare Corporation, while not a licensed terminal distributor or practitioner, and not in accordance with Chapters 3719., 4715., 4729., 4731., and 4741. of the Ohio Revised Code, has continuously possessed and/or sold at retail dangerous drugs, to wit: after numerous warnings by Board of Pharmacy

Compliance Specialists, Baxter Healthcare continues to sell dangerous drugs directly to end-stage renal disease patients in their homes without a prescription from a practitioner and without a pharmacist to dispense the medication. Such conduct is in violation of Section 4729.51(C) of the Ohio Revised Code.

CONCLUSION OF LAW

- (1) Upon consideration of the record as a whole, the State Board of Pharmacy concludes that the Finding of Fact constitutes violating provisions of Chapter 4729. of the Revised Code as provided in Division (A)(2) of Section 4729.56 of the Ohio Revised Code.

ACTION OF THE BOARD

Pursuant to Section 4729.56 of the Ohio Revised Code, the State Board of Pharmacy hereby takes the following actions in the matter of Baxter Healthcare Corporation, Cincinnati, Ohio:

- (A) On the basis of the Finding of Fact and Conclusion of Law set forth above, the State Board of Pharmacy hereby imposes a monetary penalty of fifteen thousand dollars (\$15,000.00) 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, 17th Floor, Columbus, Ohio 43266-0320.
- (B) Further, the State Board of Pharmacy hereby places Baxter Healthcare Corporation, Wholesale Distributor License No. 01-026050, on probation for five years, effective as of the date of the mailing of this Order. The terms of probation are as follows:
 - (1) Pursuant to paragraph (C) of Rule 4729-3-01 of the Ohio Administrative Code, the State Board of Pharmacy hereby declares that Baxter Healthcare Corporation is not in good standing and thereby denies the privilege of being a training site for pharmacy interns;
 - (2) Baxter Healthcare Corporation must not violate the drug laws of the state of Ohio, any other state, or the federal government;
 - (3) Baxter Healthcare Corporation must abide by the rules of the Ohio State Board of Pharmacy; and
 - (4) Baxter Healthcare Corporation must comply with the terms of this Order.

The Board may at any time revoke probation for cause, modify the conditions of probation, and reduce or extend the period of probation. At any time during this period of probation, the Board may revoke probation for a violation occurring during the probation period.

THIS ORDER WAS APPROVED BY A VOTE OF THE STATE BOARD OF PHARMACY.

MOTION CARRIED.

SO ORDERED.