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STATE OF WISCONSIN

BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY

PROCEEDINGS AGAINST

PHARMACY CORPORATION OF	**FINAL DECISION AND ORDER**
AMERICA (MILWAUKEE)	
RESPONDENT.	96 PHM 53
	LS9909131PHM

The parties to this action for the purposes of §227.53, Wis. Stats., are:

Pharmacy Corporation of America
1720 W. Florist Ave
Glendale, WI 5320

Wisconsin Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708-8935

Department of Regulation and Licensing
Division of Enforcement
P.O. Box 8935
Madison, WI 53708-8935

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Board. The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Respondent Pharmacy Corporation of America (Milwaukee) is and was at all times relevant to the facts set forth herein a pharmacy licensed in the State of Wisconsin pursuant to license #7717 or 7268, and is an institutional pharmacy specializing in supplying nursing homes.

2. Respondent did, on April 30, 1996, employ staff pharmacists to check medications prepared by auxiliary personnel. On that day, one such pharmacist was assigned to check a package to be sent to an area nursing home for resident Anna H. This patient was prescribed Coumadin 0.5mg, every other day. Coumadin is a powerful anti-coagulant commonly prescribed for older persons with heart conditions, phlebitis, and other conditions, and is familiar to all practicing pharmacists. It is also familiar to many consumers as Warfarin, a rodenticide. Its dosage must be carefully controlled, as overdoses are known to cause hemorrhage. A prescription for 0.5 mg is an unusually small dosage, but not unheard of, and in fact respondent had other patients who were taking this dosage at that time. Coumadin is not manufactured in a 0.5 mg dosage, and therefore this prescription required that a 1 mg tablet (which is scored) be broken into two halves. The 1 mg tablet is a bright pink color, and is a commonly used dosage: this tablet is familiar to every practicing dispensing pharmacist. The 5 mg tablet (another common dosage level) is a light peach color with a "5" embossed upon it, and is also familiar to every practicing dispensing pharmacist.

3. Through error, the auxiliary person who had prepared the package of Coumadin for the patient had selected a pre-prepared "blister" or "bubble" package of 5 mg tablets, instead of selecting a prepared package of the 0.5mg dosages which had been prepared in advance, or selecting 1 mg tablets and breaking each in half and preparing a new blister package.

4. The prescription label read: "Coumadin 0.5mg. 1 tab every other day PO for deep vein thrombosis take at 4pm.." Respondent's staff pharmacist failed to detect the error, and the incorrect dosage of Coumadin was dispensed to the patient through the nursing home.

5. The determination to use these dosage descriptions and instructions was made by respondent's staff several years previously, and was a general policy choice made after considering the alternative labeling of the manufactured dosage unit with an indication that the manufactured dosage was to be modified manually. In this case, the alternative policy would result in the patient's label reading: "Coumadin 1.0mg. 1/2 tab every other day [etc.]."

6. The nursing home staff also failed to detect the error. The patient was administered the incorrect dosage of Coumadin on 7 occasions over a 14 day period, and died on May 14, 1996 as a result of gastrointestinal bleeding.

7. The Board has reviewed records of a number of other dispensing errors, including a number of incidents where Ultram® was dispensed instead of Risperdal® or vice versa. A number of other errors were also noted involving incorrect dosage amounts and incorrect medications. During the investigation, respondent was requested to provide information to the Board on all medication errors known to it for 1996 and 1997. Respondent provided information in response to this request, and stated that the information was complete. In fact, the information was not complete and at least seven other errors had been made and reported to respondent by respondent's nursing home customers. Respondent’s position is that any failure to provide complete information was done without any intent to deceive the Board and was due to, at least partially, previous inadequate recordkeeping, which respondent has taken steps to address.

8. In mitigation, respondent calls the Board's attention to the fact that it has become Joint Commission accredited, and that it has changed the policy regarding entry of prescriptions for half-tablets with intent to make the dosage instructions more clear.

CONCLUSIONS OF LAW

A. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to §450.10, Wis. Stats. and is authorized to enter into the attached Stipulation pursuant to §227.44(5), Wis. Stats.

B. The conduct described in paragraphs 3-5, above, violated § 450.10(1)(a)6., Wis. Stats., and § § Phar 7.01(1)(c) and (d) and 10.03(2), Wis. Adm. Code. Such conduct constitutes unprofessional conduct within the meaning of the Code and statutes.

C. The conduct described in paragraph 7, above, violated § Phar 10.03(8), Wis. Adm. Code. Such conduct constitutes unprofessional conduct within the meaning of the Code and statutes.

ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED, that the attached Stipulation is accepted.

IT IS FURTHER ORDERED, that the license of Pharmacy Corporation of America is LIMITED in the following manner:

A. Respondent and/or respondent’s counsel shall forthwith contract with the Institute for Safe Medication Practices, or a similar organization acceptable to the Board (which acceptance shall not be unreasonably withheld), to conduct a full on-site evaluation of all of respondent's operations, for the purpose of, within 120 days of this order, respondent submitting to the Board and implementing an operations policy satisfactory to the Board, which is designed to prevent medication errors. Respondent shall also report to the Board quarterly thereafter on its implementation of other recommendations of the evaluating organization. The report of the evaluation by the outside organization shall be confidential to respondent, and shall not be subject to release to the Board or any other entity.

B. Respondent shall also submit to the Board, on a monthly basis, a report listing:

1. All medication errors detected by its own staff or by nursing home (or other institutional customer) staff or patients or others, together with all reports prepared in connection with such errors, and a statement by respondent on how such errors will be prevented in the future. A medication error is defined for purposes of this Order as any incident in which an incorrect drug (including an incorrect dosage) or device leaves the pharmacy, or a drug or device leaves the pharmacy incorrectly packaged or labeled, irrespective of whether the patient is administered the medication or the device is used.

1. All customers (meaning institutions, not individual patients of the institutional customers) of respondent who received medications that month.

Such reports are due by the 15th day of the month following.

After two years of practice under these limitations, respondent may petition the Board to modify or terminate any or all of these requirements, but the Board shall have complete discretion to grant or deny, in whole or in part, any such petition and the denial, in whole or in part, of such a petition shall not be deemed a denial of a license and shall not be subject to the right of appeal or hearing under ch. RL 1, Wis. Adm. Code.

IT IS FURTHER ORDERED, that respondent shall FORFEIT $7,000, consisting of $1,000 per error not disclosed pursuant to the Board's investigative request, to be paid within 30 days of this order.

IT IS FURTHER ORDERED, that respondent shall pay COSTS in this matter in the amount of $1,400, within 30 days of this order.

IT IS FURTHER ORDERED, that pursuant to §227.51(3), Wis. Stats., and ch. RL 6, Wis. Adm. Code, if the Board determines that there is probable cause to believe that respondent has violated any term of this Final Decision and Order, the Board may order that the license of respondent be summarily suspended pending investigation of the alleged violation.

Dated this September 14, 1999

WISCONSIN PHARMACY EXAMINING BOARD

s/ Daniel F. Luce, R.Ph.

a member of the board