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FILE COPY

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY
PROCEEDINGS AGAINST

MICHAEL W. RIPP, R.Ph.,
RESPONDENT.

:
:
:
:
:

FINAL DECISION
AND ORDER
LS9112113PHM

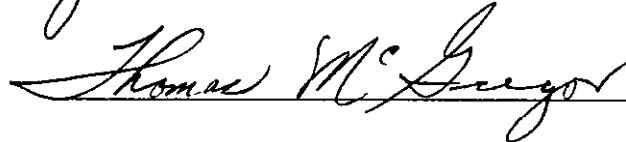
The State of Wisconsin, Pharmacy Examining Board, having considered the above-captioned matter and having reviewed the record and the Proposed Decision of the Administrative Law Judge, makes the following:

ORDER

NOW, THEREFORE, it is hereby ordered that the Proposed Decision annexed hereto, filed by the Administrative Law Judge, shall be and hereby is made and ordered the Final Decision of the State of Wisconsin, Pharmacy Examining Board.

The rights of a party aggrieved by this Decision to petition the board for rehearing and the petition for judicial review are set forth on the attached "Notice of Appeal Information."

Dated this 22nd day of July, 1992.


Thomas M. Geyer

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF	:	
DISCIPLINARY PROCEEDINGS AGAINST	:	PROPOSED DECISION
	:	Case No. LS-9112113-PHM
MICHAEL W. RIPP, R.PH.,	:	(DOE case number 89 PHM 24)
RESPONDENT.	:	

PARTIES

The parties in this matter under sec. 227.44, Wis. Stats. and sec. RL 2.036, Wis. Adm. Code, and for purposes of review under sec. 227.53, Wis. Stats. are:

Michael W. Ripp, R.Ph.
426 West Walnut Street
River Falls, WI 54022

Pharmacy Examining Board
1400 East Washington Ave.
Madison, WI 53708

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

POSTURE OF CASE

A. This case was initiated by the filing of a complaint with the Pharmacy Examining Board on December 11, 1991. A disciplinary proceeding (hearing) was scheduled for March 16, 1992. Notice of Hearing was prepared by the Division of Enforcement of the Department of Regulation and Licensing and sent by certified mail on December 11, 1991 to Michael W. Ripp, who received it on December 14, 1991.

B. No written answer was filed by Mr. Ripp.

C. A prehearing conference was held by telephone on March 3, 1992. On March 9, 1992 Attorney Ralph Topinka of Quarles & Brady, 1 South Pinckney St., Madison, WI 53703 notified the Board that Mr. Ripp had retained him as counsel. Another telephone prehearing conference was held on March 10, 1992, and the hearing was rescheduled to May 4, 1992.

D. All time limits and notice and service requirements having been met, the disciplinary proceeding was held as rescheduled on May 4, 1992. Respondent Michael W. Ripp appeared in person and represented by Attorney Topinka. The Pharmacy Examining Board was represented by Attorney Arthur Thexton of the Department's Division of Enforcement. The hearing was recorded, and a transcript of the hearing was prepared and delivered on June 11, 1992. The testimony and exhibits entered into evidence at the May 4th hearing form the basis for this Proposed Decision.

FINDINGS OF FACT

1. Respondent Michael W. Ripp is and was at all times relevant to the facts set forth herein licensed as a registered pharmacist in the state of Wisconsin, under license number 8741.
2. At all times relevant to the facts of this case, Mr. Ripp worked as a pharmacist for Erickson's Valu-Drug at 109 Second Street, Hudson, Wisconsin.
3. On January 19, 1989, Mr. Ripp was managing pharmacist for Erickson's Valu-Drug.
4. On January 19, 1989, either Mr. Ripp or a pharmacist under his supervision filled a prescription for Karen Meyer (exhibit 1). The prescription was for twenty Isoclor capsules. The prescribing physician did not include "No substitutions" or "N.S." on the prescription. The prescription was filled with twenty Deconamine SR capsules. The label on the prescription bottle (exhibit 2) was typed and dated 1/19/89 and read "20 ISOCLOR TIMESULE CAPSULFISON". The notation "Different look same thing" was hand-written by Mr. Ripp on the computer-generated receipt (exhibit 3) before the prescription was picked up.
5. The prescription for Karen Meyer was picked up on January 19, 1989 by her husband, Richard Meyer. After picking it up, Mr. Meyer initiated a conversation with a pharmacist at Erickson's Valu-Drug, in which he informed the pharmacist that his wife had had problems in the past taking Deconamine. The pharmacist informed Mr. Meyer that the ingredients in Isoclor and Deconamine were identical, that the pharmacy had no Isoclor in stock, and that he would order Isoclor if requested by Mrs. Meyer.
6. Isoclor Timesule capsules and Deconamine SR capsules contain identical active ingredients and differ only in their inert ingredients, including dyes. The two drugs are both branded generics and are equivalents of each other.
7. Mrs. Meyer accepted and took the Deconamine.

APPLICABLE STATUTES AND RULES

The following statutes and rules were in effect at the time of the alleged violation, and govern this case.

Section 450.09, Wis. Stats.

450.09 Pharmacy practice. (1) Managing Pharmacist. (a) ... The managing pharmacist shall be responsible for the professional operations of the pharmacy. ...

Section 450.10, Wis. Stats.

450.10 Disciplinary proceedings; immunity; orders. (1) (a) In this section, "unprofessional conduct" includes, but is not limited to:

2. Violating this chapter or ch. 161 or any federal or state statute or rule which substantially relates to the practice of pharmacy.

Section 450.11, Wis. Stats.

450.11 Prescription drugs and prescription devices.

(7) Prohibited acts.

(f) No person may wilfully affix any false or forged label to a package or receptacle containing prescription drugs.

Section Phar 7 02, Wis. Admin Code.

Phar 7.02 Prescription label; name of drug or drug product dispensed. No prescription drug may be dispensed unless the prescription label discloses the generic or brand name of the drug or drug product dispensed. If the product dispensed is not the brand prescribed, the label may include the statement, "substituted for prescribed brand."

Section 10.03, Wis. Admin. Code.

Phar 10.03 Unprofessional conduct. The following, without limitation because of enumeration, are violations of standards of professional conduct and constitute unprofessional conduct under s. 450.02(7)(b), Stats.:

(4) Engaging in any pharmacy practice which constitutes a danger to the health, welfare or safety of patient or public, including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist which harmed or could have harmed a patient;

(5) Dispensing a drug which the pharmacist should have known would harm the patient for whom the medication was prescribed.

CONCLUSIONS OF LAW

I. The Pharmacy Examining Board has personal jurisdiction over the Respondent, based on fact #1 above and paragraph A above under "Posture of Case".

II. The Pharmacy Examining Board has jurisdiction over the subject-matter of this complaint, under sec. 15.08(5)(c), Wis. Stats, sec. 450.10(1)(b), Wis. Stats, and sec. Phar 10.03, Wis. Admin. Code.

III. Respondent as managing pharmacist of Erickson's Valu-Drug on January 19, 1989 was responsible for the professional operation of the pharmacy on that date.

IV. Respondent violated sec. Phar 7.02, Wis. Admin. Code by failing to disclose a substitution of Deconamine SR for Isochlor Timesules on the label of a prescription for Karen Meyer on January 19, 1989. In violating Phar 7.02, Respondent did not violate sec. 450.11(7)(f), Wis. Stats., but his action did constitute unprofessional conduct under sec. 450.10(1)(a)2, Wis. Stats.

V. Respondent did not violate sec. Phar 10.03(4) or Phar 10.03(5), Wis. Admin. Code.

ORDER

THEREFORE, IT IS ORDERED that the Respondent, Michael W. Ripp, be reprimanded for his violation of sec. Phar. 7.02, Wis. Admin. Code., and that he pay the costs of this proceeding and a forfeiture of \$250.

IT IS FURTHER ORDERED that if he fails to pay either the costs or the forfeiture within twenty days of the date the final decision is signed on behalf of the Board, his license shall be suspended until payment is complete.

OPINION

Mislabeling.

On January 19, 1989, the Respondent, Michael W. Ripp, was managing pharmacist of Erickson's Valu-Drug when a prescription was filled for Karen Meyer. The facts do not show clearly whether Mr. Ripp filled the prescription in person, but the actual identity of the pharmacist is unimportant, as Mr. Ripp was responsible for the professional operation of the pharmacy at the time, and any errors or oversights in its operation may properly be ascribed to him.

Mrs. Meyer's prescription was for Isoclor, but it was filled with a pharmacological equivalent, Deconamine, because the pharmacy was out of Isoclor. The label on the prescription bottle (exhibit 2) was typed and dated 1/19/89 and read "20 ISOCLOR TIMESULE CAPSULFISON" No note of the substitution was made on the label. This was a violation of sec. Phar 7.02, Wis. Admin. Code.

The notation "Different look same thing" was written by hand on the computer-generated receipt for the prescription (exhibit 3), and was present on that receipt at the time it was picked up by Mr. Meyer. The receipt does not qualify as part of the label, and therefore the hand-written notation is inadequate as notice to the consumer under Phar 7.02. However, it is important evidence of the good faith of the pharmacy in its substitution, and it ameliorates the offense greatly.

In mislabeling an equivalent drug, the pharmacy created the potential for exactly the sort of problem which is alleged to have occurred: a reaction by a patient whose system was sensitive to the different inert ingredients in a drug. no intent to deceive was shown, though, nor was any suggestion made that the mislabeling was done for any improper motive, such as to profit from the substitution of a lower-priced equivalent. The mislabeling was alleged to be a violation of sec. 450.11(7)(f), Wis. Stats., which speaks of "wilfully" affixing a "false or forged label", but the mislabeling in this case does not rise, or descend, to that level of quasi-criminal activity. However, it is a violation of a Board rule and as such it is unprofessional conduct under sec. 450.10(1)(a)2, Wis. Stats.

Danger to the Patient.

With regard to whether the pharmacists at Erickson's Valu-Drug placed Mrs. Meyer's health, welfare or safety in danger, the evidence shows that Karen Meyer's husband, Richard Meyer, initially picked up the prescription from "the girl behind the counter", but that after looking at the pills and recognizing them as Deconamine, he spoke to one of the pharmacists and informed him that his wife had had problems in the past taking Deconamine. This case does raise a valid concern over the fact that Mrs. Meyer was not informed of the substitution in a sufficient way. The statement "substituted for prescribed brand" was not included on the label

as required. However, that issue by itself is covered by the finding made here that Mr. Ripp violated sec. Phar 7.02. The further concern in this case is whether the pharmacist was wrong to substitute a pharmacologically equivalent drug, even after being informed by Mr. Meyer that his wife had had problems with Deconamine in the past. The pharmacy's position would be more defensible if the substitution had been brought to Mr. Meyer's attention when he picked the pills up, especially since Mr. Ripp stated (transcript, p. 29) that the purpose of handwritten notations was as a reminder to talk to customers when they come in, but the oversight was at least partly compensated for by the handwritten notation itself. In response to Mr. Meyer's expression of concern, the pharmacist accurately stated that the active ingredients of the two drugs were identical. The pharmacist may have been inadequately sensitive to Mr. Meyer's position and the possibility of a reaction to an inert ingredient, and he apparently discounted Mr. and Mrs. Meyers' concerns, but he did explain that the substitution had been made because the pharmacy had no Isoclor in stock, he offered to order Isoclor if requested by Mrs. Meyer, and he left the decision in the Meyers' hands.

A number of facts act to exonerate the pharmacy in this case. Sec. 450.13, Wis. Stats. specifically authorizes dispensing a drug product equivalent in place of a prescribed drug product under appropriate circumstances, and Isoclor and Deconamine are equivalent drugs with identical active ingredients. No notation had been made on Dr. Sabnis' prescription restricting the substitution of Deconamine (Incidentally, the letter from Dr. Sabnis, exhibit 7, cannot be considered as evidence on the question of whether Mrs. Meyer was likely to suffer a reaction to Deconamine, as we know nothing about what Dr. Sabnis was responding to when he wrote the letter.) And finally, once the pharmacist was informed of Mrs. Meyer's past problems with Deconamine, he gave a sufficient response, offering to order Isoclor and stating accurately that from a pharmacological point of view the two were identical. At that point, Mr. or Mrs. Meyer was free to decline the Deconamine, and although the responsibility for making wise choices cannot be laid entirely on consumers, who will normally rely on professional advice, the Meyers did assent to the dispensing of Deconamine. Testimony by Mr. Meyer (exhibit 4, p. 5) establishes that at least one other pharmacy does business in Hudson, and that on other occasions, Erickson's pharmacy had to get Mrs. Meyer's pills from another pharmacy, so in a practical sense the Meyers were not unduly constrained by geography.

The question of whether or not Mrs. Meyer suffered an allergic reaction is legally irrelevant to the issue here, as the standard is not whether Mr. Ripp's actions in fact affected the health, welfare or safety of a patient, but whether they placed the patient in danger. Arguably, when faced with actual evidence of problems with a particular drug in the past, the pharmacist should have been more concerned about the possibility of an allergic reaction to an inert ingredient. Nevertheless, an actual or potential allergic reaction to an inert ingredient in a pharmacologically equivalent drug, when there was no restriction by the prescribing doctor, when the substitution was noted on the receipt, when the pharmacy offered to order the prescribed drug, and when the decision to use the substituted drug was left up to the patient and

her husband, does not rise to the level of endangering the health, welfare or safety of a patient. The failure to put a statement of substitution on the label itself has already been found to be a violation of Phar 7.02, but the facts presented fail to show by a preponderance of the evidence that Mr. Ripp's actions violated Phar 10.03(4), much less that he violated Phar 10.03(5).


Discipline.

Within the wide variety of violations which can be, and occasionally are, committed by pharmacists, the violation committed by Erickson Valu-Drug under Mr. Ripp's management on January 19, 1989 was minor. Discipline should be imposed to protect the public, to rehabilitate the offender, and to deter others in the profession from similar unprofessional conduct. State v. Kelly, 39 Wis.2d 171, 158 N.W.2d 554 (1968), State v. MacIntyre, 41 Wis.2d 481, 164 N.W.2d 235 (1969), State v. Corry, 51 Wis.2d 124, 186 N.W.2d 325 (1970), and State v. Aldrich, 71 Wis.2d 206, 237 N.W.2d 689 (1976). Mr. Ripp has undoubtedly been sensitized to the importance of labeling drugs accurately through this disciplinary proceeding itself, and no further discipline would be needed if the only question were his "rehabilitation." In order to bring this issue to the attention of other practitioners, though, it must be visible, and for that reason, a reprimand should be imposed. The effect of a reprimand on Mr. Ripp and on other practitioners should sufficiently protect the interest of the public.

A forfeiture under sec. 450.10(2), Wis. Stats. and ch. Phar 14, Wis. Admin. Code is also appropriate in this case because this is a second disciplinary action against Mr. Ripp. Given the nature of the offense found here, a forfeiture in the amount of \$250 is appropriate, corresponding to a category "I" offense under Phar 14.02(1), which addresses violations of ch. 450, Wis. Stats. which do not substantially threaten the health, safety or welfare of a patient or the public. Under Phar 14, such forfeitures are due within twenty days of receipt of notice of forfeiture.

With regard to costs, the investigation and prosecution of this case was legitimate, and the Board's concern was well-founded, although in the end the more serious allegation was not sufficiently proven. The profession as a whole should not have to bear the cost of a legal action based on an individual's misconduct. Mr. Ripp should pay the costs of this proceeding.

Dated June 16, 1992.


John N. Schweitzer
Administrative Law Judge
Department of Regulation and Licensing

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF :
DISCIPLINARY PROCEEDINGS AGAINST : AFFIDAVIT OF COSTS OF
 : OFFICE OF BOARD LEGAL SERVICES
MICHAEL W. RIPP, R.P.H., : Case No. LS-9112113-PHM
RESPONDENT. :

John N. Schweitzer affirms the following before a notary public for use in this action, subject to the penalties for perjury in sec. 946.31, Wis. Stats.:

1. He is an attorney licensed to practice law in the State of Wisconsin, and is employed by the Wisconsin Department of Regulation and Licensing, Office of Board Legal Services.
2. In the course of his employment, he was assigned as the administrative law judge in the above-captioned matter.
3. Set out below are the actual costs of the proceeding for the Office of Board Legal Services in this matter:

a. Administrative Law Judge Expense - John N. Schweitzer

3-3-92 and 3-10-92 Prepare for hearing	1/2 hour
5-4-92 Conduct hearing	2 1/2 hours
5-5-92 through 6-15-92 Prepare decision	8 3/4 hours

	11 3/4 hours

Total administrative law judge expense:


11 3/4 hours @ \$23.79/hour = \$279.53

b. Reporter Expense - Magne-Script, 112 Lathrop Street, Madison, WI 53705

Record 5-4-92 hearing	\$ 85.00
Transcribe hearing (72 pages)	\$237.60
Postage	\$ 2.90

Total reporter expense = \$325.50

Total assessable costs for Office of Board Legal Services = \$605.03


John N. Schweitzer, Administrative Law Judge

Sworn to and signed before me this 16th day of June, 1992.

David R. Rice, Notary Public, State of Wisconsin.

My commission is permanent.

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF THE DISCIPLINARY	:	
PROCEEDINGS AGAINST	:	AFFIDAVIT IN SUPPORT
	:	OF MOTION FOR COSTS
MICHAEL RIPP, R.P.H.,	:	89 PHM 024
RESPONDENT.	:	

STATE OF WISCONSIN)
) ss.
COUNTY OF DANE)

Arthur Thexton, being duly on affirmation, deposes and states as follows:

1. That I am an attorney licensed in the state of Wisconsin and am employed by the Wisconsin Department of Regulation and Licensing, Division of Enforcement:

2. That in the course of those duties I was assigned as a prosecutor in the above-captioned matter; and

3. That set out below are the costs of the proceeding accrued to the Division of Enforcement in this matter, based upon Division of Enforcement records compiled in the regular course of agency business in the above-captioned matter.

PROSECUTING ATTORNEY EXPENSE

<u>Date</u>	<u>Activity</u>	<u>Time Spent</u>
11/29/91	Review and organize file, letter to board advisor	1.3
12/3/91	Telephone conference with board advisor, draft stipulation proposal	1.0
12/9/91	Telephone conference with respondent.	0.5
12/10/91	Draft complaint and notice of hearing	1.0
12/20/91	Letter to respondent, letter to witness.	0.5
1/23/92	Meet with respondent. (Atty Berndt)	1.0
1/23/92	Review Memo from Atty Berndt, review file, letter to respondent, draft subpoena.	1.5

2/3/92	Telephone conference with R. Meyer, prepare materials for witness, arrange for lodging for witness.	1.0
2/11/92	Review PDR and Hospital Formulary, prepare for hearing.	0.5
2/13/92	Telephone conference with C. Sorkness, R.Ph., and memo of same.	0.6
2/24/92	Letter to witness.	0.5
3/3/92	Pretrial conference	0.9
3/3/92	Telephone conference with Atty Topinka, revise stipulation proposal and send.	0.5
3/4/92	Telephone conference with Atty Topinka, prepare and copy discovery materials.	0.6
3/9/92	Telephone conference with Atty Topinka.	0.3
3/10/92	Pretrial conference, arrange for deposition.	0.8
3/13/92	Depose witness.	1.0
4/23/92	Telephone conference with Atty Topinka.	0.4
4/27/92	Revise stipulation proposal, send to Atty Topinka.	0.8
5/1/92	Telephone conference with Atty Topinka, revise stipulation, telephone conference with board advisor, further telephone conference with Atty Topinka.	1.5
5/4/92	Attend and conduct hearing	2.5
6/19/92	Review ALJ proposed decision. Telephone conference with board advisor. Leave message for Atty Topinka. Send decision to board advisor.	1.0
2/23/92	Leave message for board advisor.	0.2
6/29/92	Receive and review Objections from Atty Topinka. Prepare response to objections, prepare my Objections, file and send to Atty Topinka and board advisor.	3.0
7/13/92	Review file, prepare for oral argument.	1.0
7/14/92	Meet with board re: oral argument.	0.7
7/16/92	Prepare this affidavit.	1.3

INVESTIGATOR EXPENSE FOR JOHN G. JOHNSON

<u>Date</u>	<u>Activity</u>	<u>Time Spent</u>
4/20/89	Inspect pharmacy, review records.	5.0
4/26/89	Memo re: pharmacy inspection and records review.	0.2
4/21/89	Interview and letter.	0.7
4/26/89	Memos re: interviews.	0.5
5/2/89	Letter.	0.2
5/3/89	Telephone interviews and memo.	0.3
5/8/89	Review records received, memo.	0.8
5/24/89	Review responses, memo.	0.5
8/3/89	Telephone interview, memo.	0.5
11/27/89	Letters.	0.2
12/5/89	Interview witness.	2.0
12/6/89	Interview respondent.	2.5
12/6/89	Case Summary Memo.	2.3
12/18/89	Telephone conference, memo, do PIC summary.	1.2
1/25/90	Obtain original prescriptions at pharmacy.	3.5
5/4/92	Testify at hearing	0.5

TOTAL ATTORNEY HOURS

25.9 hours

Total attorney expense for
* hours at \$30.00 per hour
(based upon average salary and benefits
for Division of Enforcement attorneys) equals:

\$ 777.00

TOTAL INVESTIGATOR HOURS

20.9 hours

Total investigator expense for
* hours at \$18.00 per hour
(based upon average salary and benefits
for Division of Enforcement investigators) equals:

\$ 376.20

COSTS OF DEPOSITIONS

1. Depositions taken by complainant (original and one copy)

Deposition of R. Meyer \$ 112.70

MISCELLANEOUS DISBURSEMENTS

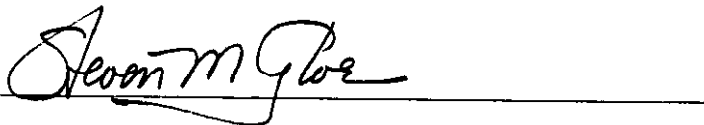
1. Investigator mileage (480 miles @ .25) \$ 120.00

TOTAL ASSESSABLE COSTS \$ 1385.90



Arthur Thexton
Prosecuting Attorney

Subscribed to and affirmed before me this 16th day of July, 1992.



Notary Public
My Commission is permanent

NOTICE OF APPEAL INFORMATION

(Notice of Rights for Rehearing or Judicial Review,
the times allowed for each, and the identification
of the party to be named as respondent)

The following notice is served on you as part of the final decision:

1. Rehearing.

Any person aggrieved by this order may petition for a rehearing within 20 days of the service of this decision, as provided in section 227.49 of the Wisconsin Statutes, a copy of which is attached. The 20 day period commences the day after personal service or mailing of this decision. (The date of mailing of this decision is shown below.) The petition for rehearing should be filed with the State of Wisconsin Pharmacy Examining Board.

A petition for rehearing is not a prerequisite for appeal directly to circuit court through a petition for judicial review.

2. Judicial Review.

Any person aggrieved by this decision has a right to petition for judicial review of this decision as provided in section 227.53 of the Wisconsin Statutes, a copy of which is attached. The petition should be filed in circuit court and served upon the State of Wisconsin Pharmacy Examining Board.

within 30 days of service of this decision if there has been no petition for rehearing, or within 30 days of service of the order finally disposing of the petition for rehearing, or within 30 days after the final disposition by operation of law of any petition for rehearing.

The 30 day period commences the day after personal service or mailing of the decision or order, or the day after the final disposition by operation of the law of any petition for rehearing. (The date of mailing of this decision is shown below.) A petition for judicial review should be served upon, and name as the respondent, the following: the State of Wisconsin Pharmacy Examining Board.

The date of mailing of this decision is July 27, 1992.