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STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	FINAL DECISION AND ORDER
FRANKLIN LaDIEN, R.Ph., GARY P. MILLER, R.Ph. and ROGER L. ARONSON, R.Ph., RESPONDENTS.	:	LS9404071PHM LS9409094PHM

The parties to this proceeding for the purposes of sec. 227.53, Stats., are:

Franklin LaDien
W150 N7809 Hilltop Drive
Menomonee Falls, WI 53051

Gary P. Miller, R.Ph.
8611 West Glendale Avenue
Milwaukee, WI 53225

Roger L. Aronson, R.Ph.
W61-N353 Washington Avenue
Cedarburg, WI 53012

Pharmacy Examining Board
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708

Department of Regulation and Licensing
Division of Enforcement
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708

This matter was commenced by the filing of a Complaint dated March 29, 1994, captioned *In the Matter of Disciplinary Proceedings Against Franklin LaDien, R.Ph., and Walgreens;* and by Complaints dated August 31, 1994, captioned *In the Matter of Disciplinary Proceedings Against Gary P. Miller, R.Ph.*, and *In the Matter of Disciplinary Proceedings Against Roger L. Aronson, R.Ph.* The Walgreens matter was settled by stipulation, and the remaining actions were consolidated for the purposes of hearing.

The hearing was conducted on November 9, 1994, and January 12 and 13, 1995. Complainant appeared by Attorney Arthur Thexton. Respondent Franklin LaDien appeared by Attorney Edward S. Marion. Respondents Miller and Aronson appeared by Attorney Gregory J. Meeker. The hearing transcript was received on March 23, 1995. The administrative law judge filed his Proposed Decision on July 24, 1995. Complainant's attorney submitted objections to the Proposed Decision on August 11, 1995. Responses to the objections were submitted on behalf of Respondent LaDien on August 15, 1995, and Respondents Miller and Aronson on August 21, 1995.

The Pharmacy Examining Board considered the matter and based upon the entire record herein makes the following Findings of Fact, Conclusions of Law, and Order.

FINDINGS OF FACT

1. Franklin LaDien, R.Ph. (Mr. LaDien), W150 N7809 Hilltop Drive, Menomonee Falls, WI 53051, was at all times material to this matter licensed as a pharmacist in the State of Wisconsin by license #9295, issued on December 10, 1977.

2. Gary P. Miller, R.Ph. (Mr. Miller), 8611 West Glendale Avenue, Milwaukee, WI 53225 was at all times relevant to this matter licensed as a pharmacist in the State of Wisconsin by license #8731, issued on January 9, 1975.

3. Roger L. Aronson, R.Ph. (Mr. Aronson), W61 N353 Washington Avenue, Cedarburg, WI 53012, was at all times relevant hereto licensed as a pharmacist in the State of Wisconsin by license #10098, issued on March 26, 1982.

4. At all times material to this matter, Mr. LaDien was the managing pharmacist, as defined at sec. Phar 1.02(6), Code, at Walgreens #34, a community Pharmacy located at 7713 West Capitol Drive, Milwaukee, WI 53222, and licensed by the State of Wisconsin to operate as a pharmacy by license #6064, issued on May 18, 1979 (Walgreens #34).

5. At all times material to this matter, Mr. Miller and Mr. Aronson were staff pharmacists at Walgreens #34.

6. On September 14, 1993, the Pharmacy Examining Board (board) issued its Final Decision and Order in a case captioned *In the Matter of Disciplinary Proceedings Against Franklin J. LaDien, R.Ph.* The decision, which was entered pursuant to a Stipulation executed by Mr. LaDien and Mr. Arthur Thexton, attorney with the Department of Regulation and Licensing Division of Enforcement (department), found that on four occasions in late 1992 and early 1993, department investigators had observed patients at Walgreens #34 receiving prescription medications being

transferred to the patients by a non-pharmacist and without any consultation by a pharmacist. It was found further that those stipulated facts constituted a violation of sec. Phar 7.01(1)(e), Code.[1] Mr. LaDien, as managing pharmacist, was ordered reprimanded and to pay a $250 forfeiture.

7. Both prescription drugs and nonprescription drugs dispensed from the pharmacy area at Walgreens #34 are delivered to customers packaged in white paper bags. No more than five percent of drugs dispensed from the pharmacy area are nonprescription drugs.

8. On November 11, 1993, at around 12:30 p.m., department investigator Vint Quamme (Mr. Quamme), observed consulting practices at Walgreens #34. Mr. Quamme observed Mr. Aronson and Mr. Miller on duty at that time, and observed Mr. Aronson transfer at least two or three medication packages to customers without providing any apparent consultation. Mr. Quamme did not observe Mr. Miller transfer any medication package to any customer. Mr. Quamme observed a female wearing a nametag which read "Virginia R., Technician" transfer between 8 and 20 medication packages to customers without a pharmacist being present and without any consultation being provided to those customers at the time of transfer.

9. On November 17, 1993, department investigator Steven Rohland (Mr. Rohland) observed consultation practices at Walgreens #34 for approximately 15 minutes. Mr. Rohland reported that he witnessed three transactions in which medications were dispensed from the pickup window of the pharmacy area; that two of the transactions were handled by a pharmacy technician without any consultation, and that the third transaction was handled by a person of unknown qualifications without any apparent consultation. Mr. Rohland does not recall seeing any of the respondents in this matter in attendance at the store on that date.

10. On February 3, 1994, Mr. Rohland returned to Walgreens #34 to observe consultation practices at that pharmacy. At the time of the visit, the pharmacy was very busy, and there were two pharmacy technicians and one pharmacist at the prescription pickup window. Mr. Rohland observed each of the pharmacy technicians complete two transactions and did not observe the pharmacy technicians provide any consultation. In a fifth transaction handled by one of the pharmacy technicians, a prescription for

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[1] Phar 7 01 Minimum procedures for compounding and dispensing. (1) Except as provided in sub. (4), a pharmacist or pharmacist-intern who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. The pharmacist or pharmacist-intern as directed by a pharmacist shall:

* * * *

(e) Transfer the prescription to the patient or agent of the patient and give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a patient's residence if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist.

Amoxicillin was dispensed, and the technician asked the patient whether she had received that medication before and received an affirmative response. Mr. Rohland also witnessed two transactions completed by the pharmacist. In both instances, the pharmacist provided a proper consultation. Mr. Rohland did not observe whether the pharmacist present at the pickup window was one of the respondents in this matter.

11. Mr. Rohland returned to Walgreens #34 on February 10, 1994, along with another investigator, Sherri Johnson (Ms. Johnson), to again observe their consultation practices. During the time of this visit, a single pharmacy technician handled all transactions. Mr. Rohland and Ms. Johnson observed approximately eight to ten transactions and did not observe that any consultations took place. Mr. Rohland did not observe any of the respondents to be present in the pharmacy area.

12. Both Mr. Miller and Mr. Aronson were on duty at the times the department investigators visited Walgreens #34, except that Mr. Aronson was not on duty on February 3, 1994. Mr. LaDien was not present on any of the occasions.

13. The department investigators identified three of the patients receiving medication packages on February 3, 1994, and February 10, 1994, for whom consultations were not apparently provided. In a telephone conversation on February 21, 1994, Mr. Rohland requested that Mr. LaDien provide patient profiles for the three patients. Mr. LaDien's response, as contained in his letter of March 4, 1994, states in part as follows:

> Patients Schmidt and Schneider have been on these medications for approximately 3 years for chronic, prevailing conditions. Mr. Brushafer was picking up a refill for a medication he'd been taking since January 1994.
>
> Our management and store staff have made significant efforts in changing our workflow and service to give our customers the best service they deserve. This includes our willingness and openness to accept any suggestions your department may wish to make in helping our practice.
>
> I, personally, was not on duty on those dates in question. However, I will gladly cooperate with any continuing investigations concerning the matter.

The department never responded to Mr. LaDien's letter.

14. On April 7, 1993, Mr. Rohland spoke with Lance Bangen, a supervisor with the Walgreens Company and former member of the Pharmacy Examining Board, concerning the investigation of an unrelated matter. The memo of his conversation with Mr. Bangen concludes in part as follows:

> I then spoke to Mr. Bangen concerning pharmacist/customer consultations. . . . I advised Mr. Bangen that the pharmacy board has been concerned for some time about pharmacist/customer consultations, and the board encourages pharmacist consultations on all new and refill prescriptions. Mr. Bangen replied he would note this back to all his area Walgreens.

15. On June 9, 1993, Mr. Rohland spoke to Mr. LaDien by telephone. In a memorandum to the investigative file dated June 11, 1993, Mr. Rohland states as follows:

> Mr. LaDien then related there recently was a meeting with all the Walgreens managers and Mr. Bangen. It was relayed to them that pharmacy/customer consultations are to be concentrated on and strongly encouraged. Mr. LaDien related at his store they do stamp every new prescription, and that the clerk or pharmacy technician working knows to contact a pharmacist and a consultation is always given. Mr. LaDien stated that he is trying very hard, on refills, to always offer consultations, and that he is trying to get this information through to all his pharmacists.

The June 9, 1993, memorandum indicates that Mr. Rohland did not respond to the information provided by Mr. LaDien except that Mr. Rohland "thanked Mr. LaDien for his information and for his cooperation."

16. Under cover of a memorandum to Mr. Rohland dated June 18, 1993, Mr. LaDien provided a policy directive for Walgreens #34 establishing duties for pharmacists performing consulting duties. The memo states: "Pursuant to our previous discussions, I have sent you a copy of changes we made at our 7713 W. Capitol location. These changes in our practice should ensure compliance with PEB regulations with regards to pharmacist consultation . . . Please call or write if you have further requests." The attachment, captioned "Consulting Pharmacist Store #34," states in part, "1. Primary Responsibility - perform all consulting functions on all prescriptions in cashier area pursuant to Wisconsin PEB regulations."

17. Also in June, 1993, Mr. LaDien posted in the pharmacy area of Walgreens #34 a copy of the "Consulting Pharmacist Procedure #34," a "Consulting Pharmacist Schedule" listing the pharmacist assigned to provide consultations each hour of each day, and a copy of the board's consulting rule. The initial handwritten consulting schedule carries the notation, "Consulting = never leaving cashier area unless no customers are present + present for <u>every prescription</u> (new and refill)."

18. Establishment of the consulting pharmacist procedure was the culmination of discussions Mr. LaDien had had with Mr. Rohland, Mr. Thexton and Mr. Bangen; which discussions had resulted in Mr. LaDien coming to largely understand for the first time that the consultation rule was being interpreted by the Pharmacy

Examining Board to require that a dispensing pharmacist provide a consultation for all prescriptions dispensed, including refills. It was Mr. LaDien's impression that the posted "Consulting Pharmacist Procedure #34" established the requirement that the consulting pharmacist provide a consultation for each prescription dispensed, including refills. That posting states in part, "Primary responsibility - perform all consulting function on ALL prescriptions in the cashier area pursuant to Wisconsin PEB regulation 7.01e [sic] (See posted copy)."

19. At the time of the posting of the "Consulting Pharmacist Procedure #34," Mr. LaDien spoke with staff pharmacists about the procedure. The purpose of the conversations with the staff pharmacists was to communicate to them that they were required to provide a consultation for each prescription dispensed, including refills.

20. At some time between November, 1993, and February, 1994, the consultation procedure was modified to require that the consulting pharmacist actually station himself or herself at the pickup window.

21. By letter dated March 18, 1994, Mr. LaDien submitted his resignation as managing pharmacist at Walgreens #34 effective on that date. The following are excerpts from that letter:

> Despite the numerous efforts on my part to emphasize the importance of consulting practices to the entire pharmacy staff, those consulting challenges still prevail within our profession. . . .
>
> Presently, a second investigation is on-going at Store #34 by the Dept. of Regulation and Licensing. Once again I was not on duty on the dates in question, but as pharmacy manager I will again be held accountable for other licensed pharmacists' actions. . . .
>
> I do feel threatened by a technicality of Wisconsin law that holds me personally accountable for all other licensed pharmacists' actions. Therefore, it is with grave concern, I am submitting this request for transfer to function as a staff pharmacist at a mutually agreed upon location in the Milwaukee Metro area.

22. During a period including the period of the events herein, the Pharmacy Examining Board made various attempts to clarify its position on consultation requirements through articles in its Regulatory Digest, and through oral presentations made by board member Tom McGregor and by Mr. Thexton. Examples include the following:

(a) An article in the board's Wisconsin Regulatory Digest for April 1990, states in part:

> DISPENSING FUNCTIONS FOR PHARMACISTS ONLY (or interns practicing under the supervision of a pharmacist). It is very important that Phar 7.01(1) be used as a reference to be certain that several of the procedures involved in compounding and dispensing not be assigned to non-pharmacist personnel. Of particular importance is sub.(e): "Transfer the prescription to the patient or agent of the patient and give the patient or agent appropriate consultation. . . ." (Emphasis in original)

(b) An article in the board's Wisconsin Regulatory Digest for April 1992, entitled Official Notice for Managing Pharmacists, states in part:

> The managing pharmacist shall be responsible for the professional operations of the pharmacy. Assurance that your pharmacy facilitates compliance with minimum practice procedures is essential. Please refer to Phar 7.01(1)(e), appropriate consultation. . . . Consumer complaints involving failure to provide consultation and/or brand/generic choice information may involve the managing pharmacist if procedures are not established for staff pharmacists to offer appropriate professional services.

(c) An article in the board's Wisconsin Regulatory Digest for June 1993, states in part:

> OBRA 90 AND COMMUNITY PHARMACY. Patient consultation standards have been established by the PEB for **ALL patients**. Phar 7.01 and Phar 7.07 clearly identify the pharmacist's responsibilities. . . . The PEB expects pharmacists to consider all of the above and then decide "appropriate consultation" as stated in Phar 7.01(e) [sic, 7.01(1)(e)]. HCFA says "document refusals to your offer to counsel." Phar 7.02 [sic, 7.01] does not offer any exceptions. [Emphasis in original].

(d) In a speech delivered in 1993 by board member Tom McGregor at the annual Symposium sponsored by the University of Wisconsin School of Pharmacy, he explained the consultation rule as follows:

> Now I can tell you what the board's interpretation of what appropriate consultation is. It is what you say it is. It is what you decide is appropriate. It is your patient. It is your practice. You know what communication needs to go on, the level of communication that needs to go on, the capacity of the patient or the agent of the patient to accept and receive and interpret and understand the medications, you understand the complexity of the medication. . . . What needs to go on? The board does not have a cookbook, a checklist. We don't have any intention of having a cookbook or a checklist. We think that is a professional judgment. . . . If appropriate consultation under your interpretation is provided,

> which means that consultation did occur, which means that the pharmacist was there and provided the communication, does not mean that you didn't tell -- that you told them everything there was to know about it? It means that you provided in your interpretation appropriate consultation and you the pharmacist were there to do it and nobody did it for you.

(e) In a written handout provided to attendees at the same symposium, written by Arthur Thexton, the following comments were made:

> The content of the consultation is governed by professional standards of practice, and therefore varies with the patient, medication and time. . . . [B]ecause the content of the consultation is left to the professional judgment of the pharmacist, you will be judged on the basis of whether or not it met the standard of care which would be deemed appropriate for the patient, at that time. . . . We recognize that 150 prescriptions per day does not leave a lot of time for extensive consultation, but with the effective use of auxiliary personnel the board feels that time can be made for appropriate consultations.
>
> Recent [disciplinary] cases usually involve giving no consultation at all, usually accompanied by dispensing error. . . .

23. In the December, 1994, issue of the Wisconsin Regulatory Digest, which contained an article entitled "Transfer of prescription to Patient and Give Appropriate Consultation." The body of the article states as follows:

> Many licensees have received an update from the Federal level pertaining to HCFA and 42CFE Ch. IV. For reason of clarification, HCFA terminology is "offer to counsel." However, PEB rules are more stringent, and protect the consumer, by requiring the pharmacist to transfer the prescription to the patient and that consultation will be given (not offered) with every prescription dispensed by a registered pharmacist licensed in the State of Wisconsin. Refer to PHAR 7.01(1)(e), Wis. Adm. Code.

24. At the time of the events herein, the understanding of respondents Aronson and Miller was that while the existing policy was to provide a consultation whenever possible, personal professional judgment could be utilized in determining whether a consultation must be provided when dispensing prescription refills.

25. At all times material to the events herein, respondent LaDien, as managing pharmacist, had policies and procedures in place intended to meet the requirements of sec. Phar 7.01(1)(e), Code, as he understood them.

CONCLUSIONS OF LAW

1. The Pharmacy Examining Board has jurisdiction in this matter pursuant to sec. 450.10, Stats.

2. Sec. Phar 7.01(1)(e), Code, providing that a licensed pharmacist transfer a prescription to a patient or agent of the patient and give the patient or agent "appropriate consultation relative to the prescription," requires that a licensed pharmacist affirmatively provide consultation upon all prescriptions transferred to a patient or agent of the patient, and that the consultation provided shall be appropriate to the relevant circumstances in the minimally competent exercise of professional judgment by a licensed pharmacist.

3. There is sufficient evidence in this record to establish by a preponderance of the evidence that during the period from November, 1993, through February, 1994, respondent Aronson was on notice that the Pharmacy Examining Board's interpretation of sec. Phar 7.01(1)(e), Code required that a pharmacist provide a consultation on every prescription dispensed, including refills, and that a pharmacist was therefore precluded from using personal professional judgment in determining whether a consultation was required when dispensing a refill, and respondent Aronson has therefore violated sec. Phar 7.01(1)(e), Code.

4. There is sufficient evidence in this record to establish by a preponderance of the evidence that during the period from November, 1993, through February, 1994, respondent Miller was on notice that the Pharmacy Examining Board's interpretation of sec. Phar 7.01(1)(e), Code, required that a pharmacist provide a consultation on every prescription dispensed, including refills, and that a pharmacist was therefore precluded from using personal professional judgment in determining whether a consultation was required when dispensing a refill, and respondent Miller has therefore violated sec. Phar 7.01(1)(e), Code.

5. Respondent LaDien's actions as managing pharmacist in attempting to communicate to staff pharmacists his understanding of consulting requirements under sec. Phar 7.01(1)(e), Code, and in establishing a consulting policy consistent with that understanding, and in putting in place procedures designed to implement that policy, complied with his duty as managing pharmacist under sec. 450.09(1)(a), Stats., to be responsible for the professional operations of Walgreens #34, and respondent LaDien has therefore not violated sec. 450.10(1)(a)6., Stats., sec. Phar 7.01(1)(e), Code, or Phar 10.03(2), Code.

ORDER

NOW, THEREFORE, IT IS ORDERED that the disciplinary proceedings against FRANKLIN LaDIEN, R.Ph., be, and hereby are, DISMISSED.

IT IS FURTHER ORDERED that GARY P. MILLER, R.Ph., and ROGER L. ARONSON, R.Ph., each be, and hereby are REPRIMANDED.

IT IS FURTHER ORDERED that GARY P. MILLER, R.Ph., and ROGER L. ARONSON, R.Ph., shall FORFEIT $250 each, to be paid within 30 days of this Order.

IT IS FURTHER ORDERED that GARY P. MILLER, R.Ph., and ROGER L. ARONSON, R.Ph., shall pay the COSTS of these proceedings fairly attributable to each within 45 days of the mailings of the affidavits of costs submitted by the division of enforcement and office of board legal services.

EXPLANATION OF VARIANCE

The Pharmacy Examining Board has adopted the provisions within the Proposed Decision supporting the recommendation that the disciplinary proceedings against Franklin LaDien be dismissed. However, in considering the objections filed, it has varied from portions of that proposal and found that respondents, Gary P. Miller and Roger L. Aronson failed to follow the consultation requirement mandated under the administrative rules.

One of the primary issues in the case is the extent to which the language within the consultation rule of the board requires that patient consultation be provided by a pharmacist, both upon the initial dispensing of a prescription as well as to each of a prescription order's authorized refills. Coextensively, another determining issue is whether the board's interpretation of that rule is reasonable.

Section Phar 7.01(1)(e), of the Wisconsin Administrative Code, as relevant to these proceedings, provides as follows:

> ". . . The pharmacist . . . shall . . . (t)ransfer the prescription to the patient or agent of the patient and give the patient or agent appropriate consultation relative to the prescription. . . ."

The clear and unambiguous language of the rule mandates that a pharmacist, not a an unlicensed clerk, shall both transfer and give appropriate consultation relating to prescriptions. A "prescription" refers to the medication to be provided the patient. See, sec. 450.01(19), Stats. Thus, the rule requires that prescribed medications are to be provided to the patient by the pharmacist.

Coincidental with transfer by the pharmacist of the medication is the obligation for the pharmacist to "give . . . appropriate consultation". Contrary to the argument advanced by respondents, the rule does not state nor reasonably imply that the act of consultation, itself, is discretionary with the pharmacist. If this were the case, the rule would read more along the lines of requiring "consultation, if appropriate." It does not say that. The rule requires "consultation". The contents, or "appropriateness" of the consultation is within the sound professional judgment of the minimally competent pharmacist under the specific circumstances.[2] The professional judgment factor discussed at the hearing relates to the *content of the consultation;* which is clearly the information communicated by both the board member and complainant's attorney in the statements quoted in the Findings of Fact. Neither the language of the rule, nor the information provided by agents of the board state that professional judgment may be utilized to determine whether consultation is to occur at all.

In this specific case, Respondent LaDien testified and the ALJ found that the establishment of the consulting pharmacist procedure at Walgreens #34 in June, 1993, "was the culmination of discussions Mr. LaDien had with Mr. Rohland, Mr. Thexton and Mr. Bangen; which discussions had resulted in Mr. LaDien coming to largely understand for the first time that the consultation rule was being interpreted by the (board) to require that a dispensing pharmacist provide a consultation for all prescriptions dispensed, including refills." (Finding of Fact #18). Accordingly, the extent to which it could be argued that somehow it is necessary that the board or its agents successfully communicate to its licensees that "appropriate consultation" means just that, "appropriate consultation", on all medications transferred, as specifically stated in the rules, is irrelevant to the determination of this specific case.

By June, 1993, Mr. LaDien was aware of the board's interpretation of the rule. Whether the respondents felt the workload at the pharmacy made compliance with the consultation requirement easily attainable in all instances due to an apparent lack of adequate pharmacist staffing is not relevant. What is pertinent is that LaDien testified that he had informed both respondents Miller and Aronson that they were required to consult on every prescription, new and refill. Mr. LaDien had written notices posted to that effect. Mr. LaDien testified that he understood the board's interpretation of the rule, and communicated that interpretation to each of the staff pharmacists. The notices posted were produced at hearing, and corroborate Mr. LaDien's version of the events.

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[2] Respondents' argument is not unlike contending that a law requiring a motorist to exercise "appropriate caution at intersections", would grant discretion to the motorist to determine whether caution is necessary in the first place. However, such language clearly conveys the obligation for always exercising caution at intersections, with the degree of caution necessary (or "appropriate") to be determined by the existing circumstances.

Mr. Miller and Mr. Aronson were aware of the conduct required by virtue of the written notices. They were to be at the counter to transfer the prescriptions to patients and provide consultation. Even to the extent one may believe that Mr. LaDien's oral restatement of the consultation rule may have been less than crystal clear, the written notices clearly dictated the conduct to be undertaken by staff pharmacists. The notices clearly provide that staff pharmacists must consult on all medications transfers, and even required that pharmacists physically station themselves at the pickup window when customers were present to ensure that the pharmacist transfer and consultation requirements were met. These notices, posted at the pharmacy in June, 1993, contain the consultation policies prepared by Mr. LaDien, and included the specific statements:

> "1. Primary Responsibility - perform all consulting functions on ALL prescriptions in cashier area pursuant to Wisconsin PEB regulations", and
>
> "Consulting = never leaving cashier area unless no customers are present + present for every prescription (new and refill)."

Contrary to respondents' position, both statements are clear expressions of Mr. LaDien's understanding that consultation was to be provided by staff pharmacists with the transfer of every prescription.

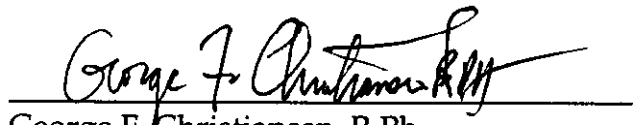
The board's requirement for consultation upon the transfer of all prescriptions, as transformed into a mandated procedure for staff pharmacists at Walgreens #34, was disregarded by Mr. Miller and Mr. Aronson. There is no indication that Mr. LaDien had any knowledge that Mr. Miller and Mr. Aronson had acted in violation of the written procedure he had established. There is, however, evidence that Mr. LaDien did confront another staff pharmacist when he learned that the consultation requirement had been violated. Under such circumstances, the board is of the opinion that Mr. LaDien has met the reasonable requirements of a managing pharmacist under sec. 450.09(1)(a), Stats. Accordingly, the proceedings against Mr. LaDien are dismissed.

With respect to Mr. Miller and Mr. Aronson, the question becomes the appropriate discipline, if any, to be imposed. In this regard, it is recognized that the interrelated purposes for applying disciplinary measures are: 1) to promote the rehabilitation of the licensee, 2) to protect the public, and 3) to deter other licensees from engaging in similar misconduct. *State v. Aldrich,* 71 Wis. 2d 206, 209 (1976). Punishment of the licensee is not an appropriate consideration. *State v. MacIntyre,* 41 Wis. 2d 481, 485 (1969).

In this case, the board accepts the recommendation of the complainant's attorney that Mr. Miller and Mr. Aronson each be reprimanded, ordered to pay a forfeiture in the amount of $250 and pay their respective shares of the costs in this proceeding. This sanction is sufficient to deter these specific licensees from engaging in similar conduct in the future, as well as to deter other licensees.

Dated this 12th day of October, 1995.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD



George F. Christiansen, R.Ph.
Vice Chair

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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.

Serve Petition for Rehearing or Judicial Review on:

THE STATE OF WISCONSIN PHARMACY EXAMINING BOARD

1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708.

The Date of Mailing this Decision is:

OCTOBER 13, 1995

1. REHEARING

Any person aggrieved by this order may file a written petition for rehearing within 20 days after service of this order, as provided in sec. 227.49 of the *Wisconsin Statutes*, a copy of which is reprinted on side two of this sheet. The 20 day period commences the day of personal service or mailing of this decision. (The date of mailing this decision is shown above.)

A petition for rehearing should name as respondent and be filed with the party identified in the box above.

A petition for rehearing is not a prerequisite for appeal or review.

2. JUDICIAL REVIEW.

Any person aggrieved by this decision may petition for judicial review as specified in sec. 227.53, *Wisconsin Statutes* a copy of which is reprinted on side two of this sheet. By law, a petition for review must be filed in circuit court and should name as the respondent the party listed in the box above. A copy of the petition for judicial review should be served upon the party listed in the box above.

A petition must be filed within 30 days after service of this decision if there is no petition for rehearing, or within 30 days after service of the order finally disposing of a petition for rehearing, or within 30 days after the final disposition by operation of law of any petition for rehearing.

The 30-day period for serving and filing a petition commences on the day after personal service or mailing of the decision by the agency, or the day after the final disposition by operation of the law of any petition for rehearing. (The date of mailing this decision is shown above.)

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	NOTICE OF FILING PROPOSED DECISION
FRANKLIN LaDIEN, R.Ph., GARY P. MILLER, R.Ph. and ROGER L. ARONSON, R.Ph., RESPONDENTS.	:	LS9404071PHM LS9409094PHM

TO: Gregory J. Meeker, Attorney
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Arthur Thexton, Attorney
Department of Regulation and Licensing
Division of Enforcement
P.O. Box 8935
Madison, WI 53708

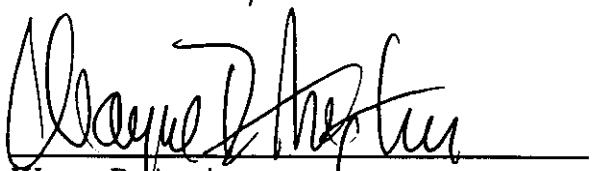
PLEASE TAKE NOTICE that a Proposed Decision in the above-captioned matter has been filed with the Pharmacy Examining Board by the Administrative Law Judge, Wayne R. Austin. A copy of the Proposed Decision is attached hereto.

If you have objections to the Proposed Decision, you may file your objections in writing, briefly stating the reasons, authorities, and supporting arguments for each objection. If your objections or argument relate to evidence in the record, please cite the specific exhibit and page number in the record. Your objections and argument must be received at the office of the Pharmacy Examining Board, Room 178, 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708, on or before August 11, 1995. You must also provide a copy of your objections and argument to all other parties by the same date.

You may also file a written response to any objections to the Proposed Decision. Your response must be received at the office of the Pharmacy Examining Board no later than seven (7) days after receipt of the objections. You must also provide a copy of your response to all other parties by the same date.

The attached Proposed Decision is the Administrative Law Judge's recommendation in this case and the Order included in the Proposed Decision is not binding upon you. After reviewing the Proposed Decision, the Pharmacy Examining Board will issue a binding Final Decision and Order.

Dated at Madison, Wisconsin this 24th day of July, 1995.



Wayne R. Austin
Administrative Law Judge

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF
DISCIPLINARY PROCEEDINGS AGAINST

FRANKLIN LaDIEN, R.Ph.,	LS9404071PHM
GARY P. MILLER, R.Ph. and	LS9409094PHM
ROGER L. ARONSON, R.Ph.	

Respondents

PROPOSED DECISION

The parties to this matter for the purposes of sec. 227.53, Stats., are:

Franklin LaDien
W150 N7809 Hilltop Drive
Menomonee Falls, WI 53051

Gary P. Miller, R.Ph.
8611 West Glendale Avenue
Milwaukee, WI 53225

Roger L. Aronson, R.Ph.
W61-N353 Washington Avenue
Cedarburg, WI 53012

State of Wisconsin Pharmacy Examining Board
Division of Enforcement
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708

Department of Regulation & Licensing
Division of Enforcement
1400 East Washington Avenue
P.O. Box 8935
Madison, WI 53708

This matter was commenced by the filing of a Complaint dated March 29, 1994, captioned *In the Matter of Disciplinary Proceedings Against Franklin LaDien, R.Ph. and Walgreens*; and by Complaints dated August 31, 1994, captioned *In the Matter of Disciplinary Proceedings Against Gary P. Miller, R.Ph.*, and *In the Matter of Disciplinary Proceedings Against Roger L. Aronson, R.Ph.* The Walgreens matter was settled by stipulation, and the remaining actions were consolidated for the purposes of hearing.

The hearing was conducted on November 9, 1994, and January 12 & 13, 1995. Complainant appeared by Attorney Arthur Thexton. Respondent Franklin LaDien appeared by Attorney Edward S. Marion. Respondents Miller and Aronson appeared by Attorney Gregory J. Meeker. The hearing transcript was received on March 23, 1995.

Based upon the entire record in this matter, the administrative law judge recommends that the Pharmacy Examining Board adopt as its final decision in the matter the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Franklin LaDien, R.Ph. (Mr. LaDien), 150 N7809 Hilltop Drive, Menomenee Falls, WI 53051, was at all times material to this matter licensed as a pharmacist in the State of Wisconsin by license # 9295, issued on December 10, 1977.

2. Gary P. Miller, R.Ph. (Mr. Miller) 8611 West Glendale Avenue, Milwaukee, WI 53225 was at all times relevant to this matter licensed as a pharmacist in the State of Wisconsin by license #8731, issued on January 9, 1975.

3. Roger L. Aronson, R.Ph. (Mr. Aronson), W61 N353 Washington Avenue, Cedarburg, WI 53012, at all times relevant hereto licensed as a pharmacist in the State of Wisconsin by license # 10098, issued on March 26, 1982.

4. At all times material to this matter, Mr. LaDien was the managing pharmacist, as defined at sec. Phar 1.02(6), Code, at Walgreens # 34, a community Pharmacy located at 7713 West Capitol Drive, Milwaukee, WI 53222, and licensed by the State of Wisconsin to operate as a pharmacy by license #6064, issued on May 18, 1979 (Walgreens #34).

5. At all times material to this matter, Mr. Miller and Mr. Aronson were staff pharmacists at Walgreens #34.

6. On September 14, 1993, the pharmacy Examining Board (board) issued its Final Decision and Order in a case captioned In the Matter of Disciplinary Proceedings Against Franklin J. LaDien, R.Ph. The decision, which was entered pursuant to a Stipulation executed by Mr. LaDien and Mr. Arthur Thexton, attorney with the Department of Regulation & Licensing Division of Enforcement (department), found

that on four occasions in late 1992 and early 1993, department investigators had observed patients at Walgreens #34 receiving prescription medications being transferred to the patients by a non-pharmacist and without any consultation by a pharmacist. It was found further that those stipulated facts constituted a violation of sec. Phar 7.01(1)(e), Code.[1] Mr. LaDien, as managing pharmacist, was ordered reprimanded and to pay a $250 forfeiture.

7. Both prescription drugs and nonprescription drugs dispensed from the pharmacy area at Walgreens #34 are delivered to customers packaged in white paper bags. No more than five percent of drugs dispensed from the pharmacy area are nonprescription drugs.

8. On November 11, 1993, at around 12:30 p.m., department investigator Vint Quamme (Mr. Quamme), observed consulting practices at Walgreens #34. Mr. Quamme observed Mr. Aronson and Mr. Miller on duty at that time, and observed Mr. Aronson transfer at least two or three medication packages to customers without providing any apparent consultation. Mr. Quamme did not observe Mr. Miller transfer any medication package to any customer.

9. On November 17, 1993, department investigator Steven Rohland (Mr. Rohland) observed consultation practices at Walgreens #34 for approximately 15 minutes. Mr. Rohland reported that he witnessed three transactions in which medications were dispensed from the pickup window of the pharmacy area; that two of the transactions were handled by a pharmacy technician without any consultation, and that the third transaction was handled by a person of unknown qualifications without any apparent consultation. Mr. Rohland does not recall seeing any of the respondents in this matter in attendance at the store on that date.

10. On February 3, 1994, Mr. Rohland returned to Walgreens #34 to observe consultation practices at that pharmacy. At the time of the visit, the pharmacy was very busy, and there were two pharmacy technicians and one pharmacist at the prescription pickup window. Mr. Rohland observed each of the pharmacy technicians complete two transactions and did not observe the pharmacy technicians provide any consultation. In a fifth transaction handled by one of the pharmacy technicians, a prescription for Amoxicillin was dispensed, and the technician asked the patient whether she had received that medication before and received an affirmative response. Mr. Rohland also

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[1] Phar 7.01 Minimum procedures for compounding and dispensing. (1) Except as provided in sub. (4), a pharmacist or pharmacist-intern who compounds or dispenses according to a prescription order shall follow the procedures described in this rule and other applicable procedures. The pharmacist or pharmacist-intern as directed by a pharmacist shall.

* * * *

(e) Transfer the prescription to the patient or agent of the patient and give the patient or agent appropriate consultation relative to the prescription except that prescriptions may be delivered by an agent of the pharmacist to a patient's residence if the delivery is accompanied by appropriate directions and an indication that consultation is available by contacting the pharmacist.

witnessed two transactions completed by the pharmacist. In both instances, the pharmacist provided a proper consultation. Mr. Rohland did not observe whether the pharmacist present at the pickup window was one of the respondents in this matter.

11. Mr. Rohland returned to Walgreens #34 on February 10, 1994, along with another investigator, Sherri Johnson, to again observe their consultation practices. During the time of this visit, a single pharmacy technician handled all transactions. Rohland and Johnson observed approximately eight to ten transactions and did not observe that any consultations took place. Mr. Rohland did not observe any of the respondents to be present in the pharmacy area.

12. Both Mr. Miller and Mr. Aronson were on duty at the times the department investigators visited Walgreens #34, except that Mr. Aronson was not on duty on February 3, 1994. Mr. LaDien was not present on any of the occasions.

13. The department investigators identified three of the patients receiving medication packages on February 3, 1994, and February 10, 1994, for whom consultations were not apparently provided. In a telephone conversation on February 21, 1994, Mr. Rohland requested that Mr. LaDien provide patient profiles for the three patients. Mr. LaDien's response, as contained in his letter of March 4, 1994, states in part as follows:

> Patients Schmidt and Schneider have been on these medications for approximately 3 years for chronic, prevailing conditions. Mr. Brushafer was picking up a refill for a medication he'd been taking since January 1994.
>
> Our management and store staff have made significant efforts in changing our workflow and service to give our customers the best service they deserve. This includes our willingness and openness to accept any suggestions your department may wish to make in helping our practice.
>
> I, personally, was not on duty on those dates in question. However, I will gladly cooperate with any continuing investigations concerning the matter.

The department never responded to Mr. LaDien's letter.

14. On April 7, 1993, Mr. Rohland spoke with Lance Bangen, a supervisor with the Walgreens Company and former member of the Pharmacy Examining Board, concerning the investigation of an unrelated matter. The memo of his conversation with Mr. Bangen concludes in part as follows:

> I then spoke to Mr. Bangen concerning pharmacist/customer consultations. . . . I advised Mr. Bangen that the pharmacy board has been concerned for some time about pharmacist/customer consultations, and the board encourages

pharmacist consultations on all new and refill prescriptions. Mr. Bangen replied he would note this back to all his area Walgreens.

15. On June 9, 1993, Mr. Rohland spoke to Mr. LaDien by telephone. In a memorandum to the investigative file dated June 11, 1993, Mr. Rohland states as follows:

> Mr. LaDien then related there recently was a meeting with all the Walgreens managers and Mr. Bangen. It was relayed to them that pharmacy/customer consultations are to be concentrated on and strongly encouraged. Mr. LaDien related at his store they do stamp every new prescription, and that the clerk or pharmacy technician working knows to contact a pharmacist and a consultation is always given. Mr. LaDien stated that he is trying very hard, on refills, to always offer consultations, and that he is trying to get this information through to all his pharmacists.

The June 9, 1993, memorandum indicates that Mr. Rohland did not respond to the information provided by Mr. LaDien except that Mr. Rohland "thanked Mr. LaDien for his information and for his cooperation."

16. Under cover of a memorandum to Mr. Rohland dated June 18, 1993, Mr. LaDien provided a policy directive for Walgreens #34 establishing duties for pharmacists performing consulting duties. The memo states: "Pursuant to our previous discussions, I have sent you a copy of changes we made at our 7713 W. Capitol location. These changes in our practice should ensure compliance with PEB regulations with regards to pharmacist consultation . . . Please call or write if you have further requests." The attachment, captioned "Consulting Pharmacist Store #34," states in part, "1. Primary Responsibility - perform all consulting functions on all prescriptions in cashier area pursuant to Wisconsin PEB regulations."

17. Also in June, 1993, Mr. LaDien posted in the pharmacy area of Walgreens #34 a copy of the "Consulting Pharmacist Procedure #34," a "Consulting Pharmacist Schedule" listing the pharmacist assigned to provide consultations each hour of each day, and a copy of the board's consulting rule. The initial handwritten consulting schedule carries the notation, "Consulting = never leaving cashier area unless no customers are present + present for <u>every prescription</u> (new and refill)."

18. Establishment of the consulting pharmacist procedure was the culmination of discussions Mr. LaDien had had with Mr. Rohland, Mr. Thexton and Mr. Bangen; which discussions had resulted in Mr. LaDien coming to largely understand for the first time that the consultation rule was being interpreted by the Pharmacy Examining Board to require that a dispensing pharmacist provide a consultation for all prescriptions dispensed, including refills. It was Mr. LaDien's impression that that the posted "Consulting Pharmacist Procedure #34" established the requirement that the consulting pharmacist provide a consultation for each prescription dispensed, including

refills. That posting states in part, "Primary responsibility - perform all consulting functions on ALL prescriptions in the cashier area pursuant to Wisconsin PEB regulation 7.01e [sic] (See posted copy)."

19. At the time of the posting of the "Consulting Pharmacist Procedure #34," Mr. LaDien spoke with staff pharmacists about the procedure. There is insufficient evidence to establish whether his conversations with staff pharmacists effectively communicated to them that they were required to provide a consultation for each prescription dispensed, including refills.

20. At some time between November, 1993, and February, 1994, the consultation procedure was modified to require that the consulting pharmacist actually station himself or herself at the pickup window.

21. By letter dated March 18, 1994, Mr. LaDien submitted his resignation as managing pharmacist at Walgreens # 34 effective on that date. The following are excerpts from that letter:

> Despite the numerous efforts on my part to emphasize the importance of consulting practices to the entire pharmacy staff, those consulting challenges still prevail within our profession. . . .
>
> Presently, a second investigation is on-going at Store #34 by the Dept. of Regulation and Licensing. Once again I was not on duty on the dates in question, but as pharmacy manager I will again be held accountable for other licensed pharmacists' actions. . . .
>
> I do feel threatened by a technicality of Wisconsin law that holds me personally accountable for all other licensed pharmacists' actions. Therefore, it is with grave concern, I am submitting this request for transfer to function as a staff pharmacist at a mutually agreed upon location in the Milwaukee Metro area.

22. During a period including the period of the events herein, the Pharmacy Examining Board made various attempts to clarify its position on consultation requirements through articles in its Regulatory Digest, and through oral presentations made by board member Tom McGregor and by Mr. Thexton. Examples include the following:

(a) An article in the board's Wisconsin Regulatory Digest for April 1992, entitled Official Notice for Managing Pharmacists, states in part:

> The managing pharmacist shall be responsible for the professional operations of the pharmacy. Assurance that your pharmacy facilitates compliance with minimum practice procedures is essential. Please refer to Phar 7.01(1)(e), appropriate consultation. . . . Consumer complaints involving failure to provide consultation and/or brand/generic choice information may involve the

managing pharmacist if procedures are not established for staff pharmacists to offer appropriate professional services.

(b) In a speech delivered in 1993 by board member Tom McGregor at the annual Symposium sponsored by the University of Wisconsin - Milwaukee School of Pharmacy, he explained the consultation rule as follows:

> Now I can tell you what the board's interpretation of what appropriate consultation is. It is what you say it is. It is what you decide is appropriate. It is your patient. It is your practice. You know what communication needs to go on, the level of communication that needs to go on, the capacity of the patient or the agent of the patient to accept and receive and interpret and understand the medications, you understand the complexity of the medication. . . . What needs to go on? The board does not have a cookbook, a checklist. We don't have any intention of having a cookbook or a checklist. We think that is a professional judgment. . . . If appropriate consultation under your interpretation is provided, which means that consultation did occur, which means that the pharmacist was there and provided the communication, does not mean that you didn't tell – that you told them everything there was to know about it? It means that you provided in your interpretation appropriate consultation and you the pharmacist were there to do it and nobody did it for you.

(c) In a speech delivered at the same symposium by Arthur Thexton, the following comments were made:

> The content of the consultation is governed by professional standards of practice, and therefore varies with the patient, medication and time. . . . [B]ecause the content of the consultation is left to the professional judgment of the pharmacist, you will be judged on the basis of whether or not it met the standard of care which would be deemed appropriate for that patient, at that time. . . . We recognize that 150 prescriptions per day does not leave a lot of time for extensive consultation, but with the effective use of auxiliary personnel the board feels that time can be made for appropriate consultations.
>
> Recent [disciplinary] cases usually involve giving no consultation at all, usually accompanied by dispensing error . . . .

23. There is no evidence in this record to establish that prior to December, 1994, the Pharmacy Examining Board clearly enunciated its position that a consultation was required to be given by a pharmacist in every instance when a prescription drug, including a refill, was delivered to a customer. The first arguably clear general notice of that position was included in the December, 1994, issue of the Wisconsin Regulatory Digest, which contained an article entitled "Transfer of prescription to Patient and Give Appropriate Consultation." The body of the article states as follows:

> Many licensees have received an update from the Federal level pertaining to HCFA and 42CFE Ch. IV. For reason of clarification, HCFA terminology is

"offer to counsel." However, PEB rules are more stringent, and protect the consumer, by requiring the pharmacist to transfer the prescription to the patient and that consultation will be given (not offered) with every prescription dispensed by a registered pharmacist licensed in the State of Wisconsin. Refer to PHAR 7.01(1)(e), Wis. Adm. Code.

24. At the time of the events herein, the understanding of respondents Aronson and Miller was that while the existing policy was to provide a consultation whenever possible, personal professional judgment could be utilized in determining whether a consultation must be provided when dispensing prescription refills.

25. At all times material to the events herein, respondent LaDien, as managing pharmacist, had policies and procedures in place intended to meet the requirements of sec. Phar 7.01(1)(e), Code, as he understood them.

CONCLUSIONS OF LAW

1. The Pharmacy Examining Board has jurisdiction in this matter pursuant to sec. 450.10, Stats.

2. Sec. Phar 7.01(1)(e), Code, requiring that a licensed pharmacist transfer a prescription to a patient or agent of the patient and give the patient or agent "appropriate consultation relative to the prescription," may reasonably be interpreted to permit a pharmacist to exercise personal professional judgment in determining whether a consultation should be provided when dispensing a prescription refill.

3. There is insufficient evidence in this record to establish by a preponderance of the evidence that during the period from November, 1993, through February, 1994, respondent Aronson was on notice that the Pharmacy Examining Board's interpretation of sec. Phar 7.01(1)(e), Code required that a pharmacist provide a consultation on every prescription dispensed, including refills, and that a pharmacist was therefore precluded from using personal professional judgment in determining whether a consultation was required when dispensing a refill, and respondent Aronson has therefore not violated sec. Phar 7.01(1)(e), Code.

4. There is insufficient evidence in this record to establish by a preponderance of the evidence that during the period from November, 1993, through February, 1994, respondent Miller was on notice that the Pharmacy Examining Board's interpretation of sec. Phar 7.01(1)(e), Code, required that a pharmacist provide a consultation on every prescription dispensed, including refills, and that a pharmacist was therefore precluded from using personal professional judgment in determining whether a consultation was required when dispensing a refill, and respondent Miller has therefore not violated sec. Phar 7.01(1)(e), Code.

5. Respondent LaDien's actions as managing pharmacist in attempting to communicate to staff pharmacists his understanding of consulting requirements under sec. Phar 7.01(1)(e), Code, and in establishing a consulting policy consistent with that understanding, and in putting in place procedures designed to implement that policy, substantially complied with his duty as managing pharmacist under sec. 450.09(1)(a), Stats., to be responsible for the professional operations of Walgreens #34, and respondent LaDien has therefore not violated sec. 450.10(1)(a)6., Stats., sec. Phar 7.01(1)(e), Code, or Phar 10.03(2), Code.

ORDER

NOW, THEREFORE, IT IS ORDERED that disciplinary proceedings against Franklin LaDien, R.Ph., be, and hereby are, dismissed.

IT IS FURTHER ORDERED that disciplinary proceedings against Gary P. Miller, R.Ph., be, and hereby are, dismissed.

IT IS FURTHER ORDERED that disciplinary proceedings against Roger L. Aronson, R.Ph., be, and hereby are, dismissed.

OPINION

Mr. LaDien is charged with failing to fulfill his duties as managing pharmacist by failing to have procedures in place at Walgreens #34 which would ensure that staff pharmacists provide a consultation on every prescription dispensed, including refills. Messrs. Aronson and Miller are each charged with failing to fulfill his duty to provide a consultation with every prescription dispensed, including refills. While no one disputes the board's authority to interpret its own rule, the problem is that there is a failure of proof in this matter that the board had, at the time in question, provided clear notice to Walgreens #34, or to the Wisconsin pharmacy community generally, of its interpretation of the rule, and evidence in this record that Walgreens management was in fact misled in that regard.

Throughout the course of the hearing, reference was made to the "judgment rule" and the "flat rule" in terms of the manner in which sec. Phar 7.01(1)(e), Code was to be interpreted. To interpret that section as requiring that a consultation be provided by a pharmacist with each and every prescription dispensed is to interpret it as a "flat rule." To interpret the rule to provide a pharmacist to exercise professional discretion in determining whether a consultation is necessary is to interpret Phar 7.01(1)(e) as a "judgment rule." The prosecution took the position that Phar 7.01(1)(e) may not be interpreted to permit no consultation because the rule requires that an appropriate consultation be given and failure to give any consultation at all cannot by definition be an appropriate consultation. Respondent's position was that if the rule permits a

pharmacist to exercise professional judgment, then inherent in that exercise of discretion is the right to determine when no consultation is necessary.

The first question thus becomes whether respondent's interpretation is a reasonable one, and it seems clear that it is. There is satisfactory evidence in this record that Wisconsin, if not unique in requiring pharmacist consultation in every instance of dispensing, is one of very few jurisdictions with such a requirement. That evidence demonstrates that the usual and normal procedure within the industry is to trust pharmacists to exercise sound judgment in determining whether a direct consultation is necessary. In demonstration of that fact, the federal Omnibus Budget Reconciliation Act of 1990 (OBRA '90) established new and more restrictive standards for pharmacist consultation for Medicaid patients. In an article appearing in the December 14, 1992, issue of Drug Store News for the Pharmacist (exh. 22) the requirements imposed are explained as follows:

> First, state regulations must "require pharmacists to offer to counsel" each Medicaid patient or caregiver who presents a prescription. . . . Although the actual counseling must be performed by the pharmacist personally, the required offer to discuss the patient's medication may be made by ancillary personnel. (p.8)

At page 147 of the same issue, the following appears:

> OBRA '90 recognizes the pharmacist's professional judgment and requires only those items "the pharmacist deems significant" to be included in individual counseling. It is possible a pharmacist could decide, in his or her professional judgment, not to counsel a particular patient.

The January, 1993, issue of the Wisconsin Pharmacist (exh. 18), after citing sec. Phar 7.01(1)(e), Code, comments "Wisconsin regulations are in compliance with OBRA 90. Federal law requires that the pharmacist to provide direct oral (face-to-face) counseling to Medicaid patients or caregivers unless neither is available."

Walgreens internal policy relating to patient counseling also recognizes that where professional judgment is permitted to be exercised by pharmacists, consultation need not necessarily be required for prescription refills. In its policy bulletin dated October 15, 1993, that policy is stated as, "All patients with new prescriptions (*and refills in some states*) must be offered counseling." (exh. 7).

Accepting that the rule could be interpreted as permitting a pharmacist to exercise professional judgment in determining whether a consultation is necessary, at what point in time does the evidence establish that Mr. LaDien in fact became aware that the provision should be interpreted to require a consultation in every case? Mr. LaDien testified that by approximately June, 1993, he had come to the reluctant conclusion that consultations were always required.

Q. (by Mr. Meeker) Now, you had a conversation with Mr. Thexton in June of 1993 that changed your understanding of what the consultation rule required, correct?

A. (by Mr. LaDien) I don't remember dates. I know I talked to Mr. Thexton somewhere in that time frame.

* * * *

Q. I refer you to Exhibit 42 [Consulting Pharmacist Procedure #34]. And I take it that what you're saying is that Exhibit 42 states the flat rule.

A. If that's the way you want to -- Yes, sir.

Q. Okay. And so you got that understanding of the flat rule at least as early as of June, 1993, when this document was drafted up?

A. This is what I could draw out of my conversations with Mr. Thexton, Mr. Rohland, Mr. Bangen. I tried to get as much information as I could to come to this conclusion.

Q. Okay. And you came to that conclusion that there was a flat rule by the time you drafted up Exhibit 42 here, correct?

A. That's what led to that, yes, sir.

Q. Okay, great. Prior to coming to this new understanding, your old understanding about the requirements was that you had to consult on all new prescriptions, correct?

A. Yes, sir. (tr., pp. 164-165)

It is perhaps questionable whether Mr. LaDien was fully cognizant by June, 1993, that the flat rule was also a hard and fast rule. Mr. Rohland's memo to the file dated June 11, 1993, recounts the following telephone conversation with LaDien, whose comments do not reflect that he fully understood the board's position:

> Mr. LaDien then related there recently was a meeting with all the Walgreens managers and Mr. Bangen. It was relayed to them that the pharmacist/customer consultations are to be concentrated on and strongly encouraged. Mr. LaDien related at his store they do stamp every new prescription, and that the clerk or pharmacy technician working knows to contact the pharmacist and a consultation is then always given. Mr. LaDien stated that he is trying very hard, on refills, to always offer consultations, and that he has tried to get this information through to all his pharmacists. (Exh. 29)

If Mr. LaDien was in fact aware of the board's interpretation as early as June, that is surprising, for the board was doing nothing if not sending mixed messages as to the

requirements under the rule. As recounted in the Findings of Fact, In April, 1993, Steve Rohland spoke with Lance Bangen, a Walgreens supervisor, and told him that "the board encourages pharmacist consultations on all new and refill prescriptions." Mr. Bangen dutifully passed along to all Walgreens managers that the board "strongly encouraged" consultations. On June 9, Rohland spoke to LaDien by telephone, at which time Mr. LaDien described a new system by which all new prescriptions were stamped "consult pharmacist" to ensure that a consultation was given on all *new* prescriptions. Mr. LaDien also notified Mr. Rohland that he was "trying very hard, on refills, to always *offer* consultations. Mr. Rohland merely thanked Mr. LaDien for his information and for his cooperation.

Nor were the board's efforts during this period to communicate to its licensees its interpretation of the rule effective in that regard. An April, 1992, article in the board's Regulatory Digest stated merely "Consumer complaints involving failure to provide consultation and/or brand/generic choice information may involve the managing pharmacist if procedures are not established for staff pharmacists to offer appropriate professional services." The article does not describe what "appropriate professional services" means in terms of the consultation requirement except to cite to the rule.

A speech delivered by board member Tom McGregor at the 1993 Symposium sponsored by the U.W. - Milwaukee pharmacy school was similarly unenlightening. The first three sentences of his explanation of the consultation rule are typical of his remarks: "Now I can tell you what the board's interpretation of what appropriate consultation is. It is what you say it is. It is what you decide is appropriate." Mr. Thexton, who also spoke at the symposium, stated in part "...[B]ecause the content of the consultation is left to the professional judgment of the pharmacist, you will be judged on the basis of whether or not it met the standard of care which would be deemed appropriate for that patient at that time." Margaret LeDoux, a Walgreens pharmacist who attended the symposium, credibly testified that she came away from the meeting believing that professional judgment could be exercised in terms of consulting on refills. (tr., p.307)

But whether Mr. LaDien was or was not in fact fully aware by June, 1993, that the board's interpretation required consultations in every case, the evidence is that he worked diligently to establish procedures and policies implementing his understanding of the consultation requirements. In June, he posted a written policy and procedure for consultation by staff pharmacists captioned "Consulting Pharmacist Procedure #34." The first three directives established by that posting were as follows:

> 1. Primary responsibility -- perform all consulting functions on ALL prescriptions in prescription area pursuant to Wisconsin PEB regulation 7.01e [sic] (See posted copy).
>
> 2. Adhere to posted consultant schedule and consulting responsibility and not to leave cashier area until consulting shift is over (See posted schedule).

3. Lack of adherence to schedule and consulting responsibility may lead to disciplinary action by the pharmacy manager. (Exh. 42)

Also posted was a "Consulting Schedule #34" listing the pharmacist assigned to provide consultations each hour of each day.

About the time of establishing the consulting procedure, Mr. LaDien also orally notified staff pharmacists of his understanding of the consulting rule and of their responsibilities in that regard. In his testimony, LaDien was asked whether he was sure that he had spoken to Mr. Miller and Mr. Aronson about the consulting policy at about the time in question:

> A. I'm sure I talked to them because I remember conversations. I had a very set script that I used. I know -- I took them around the back of the corner in our compounding area, or sometimes I took some people out into the waiting room area.
>
> Q. (by Mr. Meeker) Tell me what the set script was that you used.
>
> A. For the most part, I would appeal to their professional help in this situation. We have a big job ahead of us. I know we have a very busy store.[2] Consulting on all prescriptions will include refills. It's going to be tough. I realize that. We're going to have to grow and work on this, I don't know how we're going to do it; I have no guidelines. Let's try and do the best we can. (tr., p. 189)

Sometime after November, 1993, Mr. LaDien modified the consultation procedure to require that the pharmacist assigned to provide consultations actually post himself or herself in the cashier area to ensure that the pharmacist was immediately available to provide consultations.

In the last analysis, it is difficult to determine with certainty from this record exactly when LaDien became fully aware that the board's requirement was that consultations were required with each prescription and without exception. What is clear from the record is that in the face of extremely difficult circumstances, he utilized his best efforts to bring Walgreens #34 into compliance with the requirements of the Pharmacy Examining Board as he understood them. That he was not entirely successful in that effort is regrettable, but is certainly not a basis for professional discipline. In the best of all possible worlds, the Division of Enforcement would have no case backlog and this proposed decision would have been rendered in April. One would hope, however, that the various circumstances contributing to failure to accomplish those goals would be

[2] The testimony was that at the time in question, Walgreens #34 dispensed an average of approximately 700 to 800 prescriptions per day, and was during that period the busiest Walgreens pharmacy in the country.

considered by one in a position to determine whether and where blame should be placed.

It would appear that this eminently rational approach was ignored in this matter. Instead, complainant argues that LaDien's various attempts to encourage staff pharmacists to consult on all prescriptions did not fulfill his responsibilities as managing pharmacist because, ipso facto, those efforts were not sufficient to achieve the desired result. It is not necessary to decide that sec. 450.09(1), Stats., is too vague to notify a reasonable person of what is required of a managing pharmacist to decide that a sincere and continuing effort to ensure that the professional activities of staff pharmacists comport with the board's statute and rules is sufficient to meet the managing pharmacist's duties and responsibilities. To so decide does not excuse conduct by staff pharmacists inconsistent with the pharmacy laws, but such inconsistent conduct should not and may not be imputed to the managing pharmacist absent a lack of effort on his or her part to effect corrective policies and procedures.

Accepting that Mr. LaDien exerted his best efforts to convey to staff pharmacists his understanding of the consultation rule does not lead to the conclusion that Mr. Aronson and Mr. Miller are guilty of its violation. Not, that is, unless it can be established that they were clearly notified of the board's interpretation. The evidence in this record does not establish that they were. Mr. LaDien testified that the consultation policy posted by him in June, 1993, was intended to state the flat rule. It doesn't. Again, the relevant portion of that policy states as follows:

> 1. Primary responsibility -- perform all consulting functions on ALL prescriptions in prescription area pursuant to Wisconsin PEB regulation 7.01e [sic] (See posted copy).
>
> 2. Adhere to posted consultant schedule and consulting responsibility and not to leave cashier area until consulting shift is over (See posted schedule).
>
> 3. Lack of adherence to schedule and consulting responsibility may lead to disciplinary action by the pharmacy manager. (Exh. 42)

Nor does LaDien's recollection of his oral instructions to staff pharmacists clearly enunciate the flat rule:

> We have a big job ahead of us. I know we have a very busy store. Consulting on all prescriptions will include refills. It's going to be tough. I realize that. We're going to have to grow and work on this, I don't know how we're going to do it; I have no guidelines. Let's try and do the best we can.

The testimony of Miller and Aronson would seem to confirm that while Mr. LaDien was earnestly attempting to convey to them his understanding of the consulting rule, and while he was undoubtedly at some point attempting to convey his understanding that

the rule was to be interpreted as a flat rule, he probably was unsuccessful in that regard. Excerpts from the testimony of those two respondents should perhaps suffice to demonstrate the point.

By Mr. Aronson:

> Q. (by Mr. Marion) So I take it your testimony is that you had one or more conversations with Rocky about consultation?
>
> A. (by Mr. Aronson) Correct.
>
> * * * *
>
> Q. Rocky told you, did he not, that you should look at the regs and then follow what the regs tell you?
>
> A. I don't remember those exact words, but that's possible.
>
> * * * *
>
> Q. Having to consult the way Rocky wanted all of his pharmacists to consult got to be quite difficult for you, didn't it?
>
> A. I'm not quite sure how he wanted us, in hindsight, I'm not quite sure. What I got from Rocky was consult to the best of your abilities, appropriate consultation, you know, look at the regs. This is what they want us to do. I didn't feel we were lax in consulting, so.
>
> Q. Did you once describe Rocky's talking about consultation as a mantra?
>
> A. Well, I think that -- yes, I did, in my -- in this deposition, I said that a lot of times he would say -- which I understand where he was coming from, he just said we have to be there for the people, we have to be available.
>
> * * * *
>
> Q. Is it possible, Mr. Aronson, that there was some point in time when you worked at the store -- I'm not saying exactly when right now. There was some point in time when Rocky LaDien told you that consulting includes refills?
>
> A. Each and every? Are you saying the flat rule, that he stated the flat rule?
>
> Q. Just I want to ask you as best you can recall was there ever a time when you guys worked together that Rocky told you consulting includes refills? Possible?
>
> A. Well consulting does -- that's what I've been doing. I'm not saying that I didn't consult on any refills. But consulting does include refills, even in the judgment rule. (tr., pp. 368-370)

By Mr. Miller:

Q. (by Mr. Marion) Okay. Now, it's accurate to say, is it not, that on one of the first days that you worked at store #34 Rocky talked to you about consulting?[3]

a. A. (by Mr. Miller) Yes, he did.

Q. And he said words to this effect: we're all here to do a good job for the patient; is that correct?

A. Yes.

Q. Tell you to counsel to the best of your ability?

A. That's correct.

Q. He said we're the busiest store and it's going to be hard?

A. Yes.

Q. But we have to do it?

A. Right.

Q. Looking at Exhibit 8, Mr. Miller, turn to the second page, if you would, entitled Consulting Pharmacist Store #34, You've seen that document before, have you not?

A. Yes, I have

Q. And this is something that Rocky gave you when you two talked about consultation -- when you first arrived at the store?

A. I believe he did, yes. I think it was the first meeting we had he gave me a few sheets of paper and I'm pretty sure this is one of them.

Q. Okay. And he reviewed it with you?

A. Yes.

Q. You two talked about consultation a number of times. It wasn't just this once, am I right?

A. Right. We worked together and had our same concerns over it.

[3] Mr. Miller started his employment with the Walgreens organization on October 1, 1993.

Q. Okay. And in fact you had conversations about consulting maybe five, six times?

A. I would say that's pretty close. We -- I mean, like I say, we worked together and after Rocky, you know, started to get more and more involved in this process, you know, he kind of let out to me some of his concerns and problems.

* * * *

There came a time when Rocky said to you new and refills alike have to be consulted, isn't that right?

A. The new and refill thing I think basically Rocky and I spoke to each other as equals. And, you know, it was one of those things where we're going to do the best damn job we can. You know.

Q. There came a time, though, when he said to you refills and new prescriptions?

A. He may have said refills. I couldn't tell you what time that was. But he may have said that. (tr. pp. 408-411)

It may seem somewhat disingenuous for Messrs. Aronson and Miller to deny that they were aware by late 1993 and early 1994 that the policy was to consult on every prescription. But it is apparent that there continued through that period to be misunderstanding as to what the exact policy was. Based on the evidence in this record, the Pharmacy Examining Board's interpretation of its rule as requiring consultation in every single instance was never during the period in question clearly enunciated by the board. Instead, Mr. LaDien inferred from a number of conversations with representatives of the state that the expectation was that consultation was to occur on refills as well as new prescriptions. The manner in which that was communicated to staff pharmacists, however, would appear to have been that consultation was to occur on refills to the extent possible. While that is not the judgment rule, it is also not the flat rule, for it permits some small degree of discretion. That is the approach that Mr. Aronson and Mr. Miller understood to be available to them, and that is the approach they took.

Pervasive in the record of this matter is the premise that it was simply not possible to consult on every prescription refill given the volume of prescriptions dispensed at Walgreens #34 and the staffing authorized by Walgreens at that time. This was not presented as a defense to the allegations of the Complaint nor, probably, could it be. One may well imagine, however, the perceived dilemma of these respondents, attempting on the one hand to consult on every prescription dispensed, while on the other hand attempting to provide service to 700 to 800 patients each day. The credible testimony of each of the respondents was that they did their very best to comply with

their understanding of the board's expectations on consulting. To charge them with unprofessional conduct either because they (understandably) misunderstood what those expectations were, or because they failed to meet those expectations through no fault of their own, would serve no disciplinary objective. Walgreens #34 had, at the time of hearing, authorized an additional full time pharmacist position and was consulting on every prescription. That system is apparently not working well, but the board's edict is now being complied with at that pharmacy. That should be sufficient, and the lives and careers of these three competent and obviously caring pharmacists should not be disrupted further.

Dated this 24th day of July, 1995

Respectfully submitted,

Wayne R. Austin
Administrative Law Judge

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