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FILE COPY

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	FINAL DECISION AND ORDER
JOHN J. WOLFF, R.Ph., RESPONDENT.	:	LS9510042PHM

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 department for rehearing and the petition for judicial review are set forth on the attached "Notice of Appeal Information."

Dated this 9TH day of July 1996.

John K. Wolff

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST JOHN J. WOLFF, R. Ph., RESPONDENT.	:	**PROPOSED DECISION** Case No. LS-9510042-PHM (DOE Case No. 94 PHM 116)

PARTIES

The parties in this matter under § 227.44, Stats., and § RL 2.037, Wis. Admin. Code, and for purposes of review under § 227.53, Stats., are:

Complainant:
Division of Enforcement
Department of Regulation and Licensing
Madison, WI 53708-8935

Respondent:
John J. Wolff, R.Ph.
1507 Capitol Drive
Green Bay, WI 54303

Disciplinary Authority:
Pharmacy Examining Board
1400 East Washington Ave.
Madison, WI 53703

PROCEDURAL HISTORY

A. This case was initiated by the filing of a complaint with the Pharmacy Examining Board on October 4, 1995. A disciplinary proceeding (hearing) was to be scheduled. Notice of Hearing was prepared by the Division of Enforcement of the Department of Regulation and Licensing and sent by certified mail on October 4, 1995 to John J. Wolff, who received it on October 10, 1995.

B. On October 31, 1995, an answer was filed on Mr. Wolff's behalf by attorney Joseph Pozorski of Kaminski, Pozorski & Grieg, 846 North Eighth Street, Manitowoc, WI 54221-0609.

C. A prehearing conference was held on November 7, 1995 and a hearing was scheduled for February 19th and 20th, 1996. Another prehearing conference was held on January 9, 1996. Another prehearing conference was held on February 12, 1996.

D. Mr. Wolff's attorney, Mr. Pozorski, was unable for medical reasons to attend the hearing, and the hearing was cancelled and later rescheduled for April 8, 1996.

F. The disciplinary proceeding was held as re-scheduled on April 8, 1996. Mr. Wolff appeared in person and represented by attorney Pozorski. The Pharmacy Examining Board was represented by attorney Arthur Thexton of the Department's Division of Enforcement. The hearing was recorded. No transcript was prepared. The testimony and exhibits entered into evidence at the hearing form the basis for this Proposed Decision.

FINDINGS OF FACT

1. The respondent, John J. Wolff, is a pharmacist licensed in the state of Wisconsin, under license number 10942, which he has held continuously since it was originally granted on March 17, 1987.

2. In September and October, 1994, Mr. Wolff was employed as a pharmacist by Walgreen's Pharmacy #3088 in Green Bay, Wisconsin.

3. On September 19, 1994, Mr. Wolff received a request from a patient, J.C., to refill a prescription for #100 hydrocodone 7.5 mg, a Schedule III controlled substance, with dosage instructions "Take one as needed every four hours for pain." At that time, J.C.'s profile showed that he had previously filled this prescription on 8/19/94 and 9/3/94 and that he was also taking Monopril.

4. Mr. Wolff refilled the prescription as requested on 9/19/94 without consulting with the prescriber, and without discussing the high rate of use of this medication with the patient in the consultation.

5. On October 11, 1994, Mr. Wolff received another request from the patient to refill the same prescription. Mr. Wolff refilled the prescription without consulting with the prescriber.

6. The medication was prescribed "as needed every four hours for pain", and the patient's use of his prescription over the course of the original filling and three refillings showed that he was using the medication at almost exactly the maximum rate prescribed by the physician (i.e. six per day).

7. The patient's usage rate did not exceed either the prescription, the legal limits for Schedule III controlled substances, or the guidelines for the drug's use as published by the American Hospital Formulary Service.

CONCLUSIONS OF LAW

I. The Pharmacy Examining Board is the legal authority responsible for issuing and controlling credentials for pharmacists, under ch. 450, Stats. The Pharmacy Examining Board has subject-matter jurisdiction over a complaint alleging unprofessional conduct, under sec. 15.08(5)(c), Stats., sec. 450.10, Stats., and ch. Phar 10, Wis. Admin. Code. The Pharmacy Examining Board has personal jurisdiction over the respondent, John J. Wolff, under sec. 801.04 (2), Stats., based on his receiving notice of the proceeding, and his holding a credential issued by the board.

II. None of the actions of the respondent, John J. Wolff, as alleged in the complaint constitute unprofessional conduct.

ORDER

THEREFORE, IT IS ORDERED that this action be dismissed.

OPINION

This is a disciplinary proceeding conducted under the authority of ch. 227, Stats. and ch. RL 2, Wis. Admin. Code. The Division of Enforcement in the Department of Regulation and Licensing filed a complaint with the Pharmacy Examining Board alleging that the respondent, John J. Wolff, acted unprofessionally in refilling a prescription. The burden of proof is on the complainant in this proceeding, and I conclude that there is insufficient evidence to prove that Mr. Wolff violated any rule of professional conduct for pharmacists.

As pointed out by Mr. Wolff's attorney, the language contained in Phar 10.03 (2), Wis. Admin. Code, requires a "substantial" departure from the standard of care. To their credit, none of the pharmacists who testified in the hearing was comfortable making a distinction between a substantial departure and a trivial departure, for even the smallest error creates a danger to the public. Nevertheless, the word "substantial" in the rule should be given some weight. Although logically it should not increase the burden of proof, it implies that a certain magnitude or weight of offense should be found to justify discipline.

There is no dispute over the essential facts. Both parties agree that in his professional capacity as a pharmacist, Mr. Wolff twice refilled a prescription for hydrocodone, a Schedule III controlled substance, on September 19, 1994 and on October 11, 1994. The prescription was for 100 7.5 mg. doses of hydrocodone, with dosage instructions to "take one as needed every four hours for pain." The parties agreed, at least tacitly, that a Schedule III controlled substance has a fairly high potential for abuse, and that such abuse would pose a danger to both the patient and the public. The prescription had been filled originally on August 19, 1994, and it had been refilled once before, on September 3, 1994. Mr. Wolff did not question the patient about his use of the drug, nor did Mr. Wolff contact and consult with the prescribing physician.

"Once every four hours" translates into a maximum dosage of six doses per day, at which rate 100 doses would last 16 2/3 days. The first refilling on September 3, 1994 (by someone other than Mr. Wolff) was on the 15th day after the prescription was originally filled (and I take official notice that 9-3-94 was the Saturday of the Labor Day holiday). The next refilling on September 19th (the first by Mr. Wolff) was on the 16th day after the previous refilling, and the last refilling on October 11th (by Mr. Wolff) was on the 22nd day after the previous one.

The allegation in the complaint is that "This is an unusual amount of hydrocodone to be prescribed at one time. This amount, and the continued use of hydrocodone at the maximum or near-maximum rate permitted by the prescription and product labeling (6 per day), should suggest to the competent pharmacist that the patient is in severe continuous pain, such that he is even rising from night sleep to take this pain medication. Such use is not normally expected to continue for more than a few days before tapering. The continuing use of this drug by this patient at this maximum or near-maximum rate required a competent pharmacist to consult with the prescriber or patient or both about this unusual rate of use."

Testimony was received from Danny R. Reynolds, R.Ph., who served on the Pharmacy Examining Board for four years and chaired it in 1991. Mr. Reynolds practices in an independent pharmacy in Whitewater, Wisconsin, and he expressed his opinion that refilling this prescription without checking with the prescriber was outside the standard of care for a pharmacist. This opinion was based at least partly on his opinion that the prescription itself was unusual. In fact, Mr. Reynolds stated that he has never dispensed hydrocodone in that dosage at that quantity. On the other hand, Mr. Wolff testified that he sees prescriptions for 100 doses of hydrocodone regularly, that it is the medication most commonly prescribed by a number of emergency rooms and express care clinics in the Green Bay area, and that it is not unusual in his practice to see a prescription for 100 hydrocodone to be refilled three times. Both Mr. Reynolds and Mr. Wolff were credible witnesses, and the disagreements in their testimony can best be understood as being based on their experience in different geographic areas and in different practice settings. Accepting Mr. Wolff's statement as accurate, it is understandable that he would see nothing unusual in the prescription itself, and the statement that "this is an unusual amount of hydrocodone to be prescribed at one time" cannot be accepted as proven.

The complaint further alleges that "the continued use of hydrocodone at the maximum or near-maximum rate permitted by the prescription and product labeling (6 per day), should suggest to the competent pharmacist that the patient is in severe continuous pain". This statement contains two separate issues. The first is whether the pattern of use is itself suspicious because it is at the "maximum or near-maximum rate". The second is whether a competent pharmacist has some duty based upon a patient's being in "severe continuous pain". It is true that the refill pattern shows use of the drug at the rate prescribed, and since the directions note that it should be taken "as needed" the rate can be described as a "maximum or near-maximum" rate. Nevertheless, the prescription is well within FDA limits for controlled substances, as a prescription for a Schedule III controlled substance can extend for up to six months, and can be refilled up to five times. The prescription is also well within the guidelines for use of the medication published by the American Hospital

Formulary Service (AHFS), which says "the usual adult dosage of hydrocodone bitartrate for relief of moderate to moderately severe pain is 5-10 mg. every 4-6 hours as necessary. ... In patients with more severe pain or in those who have become tolerant to the analgesic effect of opiate agonists, it may be necessary to exceed the usual dosage." [exhibit 4] The dosage (7.5 mg.) was in the middle of the dosage range for adults, and the rate (every 4 hours as necessary) was within the recommended range. Being well within what appear to be normal bounds for this drug's use, the patient's pattern of usage was not an obvious red flag. Additionally, even if the pattern of use did suggest that the patient was in severe continuous pain (which is not necessarily so, since the AHFS excerpt shows that if the patient were in "severe" pain, an even higher dosage might be prescribed), such an inference does not necessarily lead to the conclusion that the pharmacist must call the prescriber. Conditions for which hydrocodone would be prescribed were listed in the hearing as industrial accidents, headache syndrome, any pain-related injury, sports injuries, and chronic pain such as associated with cancer, and not all of these could be expected to improve over a period of weeks. The implication in the complaint is that if a pharmacist suspects that a person for whom pain medication is prescribed is in "severe continuous pain", the pharmacist has a duty (failing which he will be subject to discipline) to consult with the prescriber or the patient. I find no such duty in the rules.

The allegation in the complaint stated that if the patient followed the prescribed rate, it would mean "that he is even rising from night sleep to take this pain medication." That is one possibility, which would be a perfectly acceptable use of the drug, but at least three others are equally plausible. First, the patient's discomfort might be such that he was unable to sleep through the night. Second, the patient could be taking six doses per day, but at irregular intervals, such as upon retiring to bed and upon waking. Third, the patient could indeed be misusing or abusing the medication and taking it at an average rate of six doses per day even though his need for the medication had subsided. This would be the one situation which would pose a danger to the patient and to the public, but the evidence pointing toward this was simply too weak to lead Mr. Wolff to have serious concerns about this patient. Theodore Regalia, a Pharmacy Supervisor in the Wauwatosa District Office of Walgreen's Pharmacies, expressed his opinion that a pharmacist would have a duty to inform the prescriber if the usage exceeded the prescription or FDA guidelines, or if there was an unusual pattern of usage. Even Mr. Reynolds said that he would contact the prescribing physician if the patient exceeded the prescribed usage or if he observed some notable irregularity in the pattern of usage, but neither of those occurred in this case. Mr. Reynolds agreed that there was no irregularity in this patient's pattern of usage, and although the first refill on September 3rd was one day early, on both occasions when Mr. Wolff refilled the prescription, the patient had not exceeded the prescribed usage.

The complaint alleged that use such as demonstrated by this patient "is not normally expected to continue for more than a few days before tapering". This fact was not proved in the hearing, and it is certainly not implied in the prescription itself. If it were true that any patient for whom hydrocodone is prescribed should feel better in "a few days" (even those with headache syndrome or cancer) then it is incomprehensible that the physician, knowing the potential for abuse, would have written a prescription for up to 400 doses over a period of more than two months. The prescription

itself in this case is strong evidence that the allegation is incorrect. The fact that Mr. Wolff sees other such prescriptions in his area reinforces that conclusion.

The complaint then alleged in summary fashion that "the continuing use of this drug by this patient at this maximum or near-maximum rate required a competent pharmacist to consult with the prescriber or patient or both about this unusual rate of use". This was simply not proved. First, as a factual matter, it was not proved either that the prescription itself was unusual or that the patient's pattern of use should have raised serious suspicions. The prescription was within AHFS guidelines and FDA limits, and the patient's use was within the prescribed limit. Second, Mr. Wolff testified that the prescription did cause him to check to see if any red flags existed, and he did not uncover any. Mr. Wolff testified that upon first seeing the prescription he 1. verified the quantity (100), 2. checked the time interval since the last refill (16 days), and 3. verified that the patient did not have multiple prescriptions from multiple physicians. Whether he checked it on this occasion, or knew the information professionally, Mr. Wolff testified that he confirmed that the prescription was within the manufacturer's guidelines; it is likely that he knew this without having to look it up because of the number of such prescriptions which come to him from emergency rooms and express care clinics in the Green Bay area. He also undoubtedly knew, without having to look it up, that the prescription was within the legal limits for Schedule III controlled substances. Mr. Wolff also testified, although he had not mentioned this in earlier communications to the Division of Enforcement, that (without actually looking at the list) he mentally compared the patient's name to the names on the "hot list" of patients who should be looked at closely for signs of overuse or multiple prescriptions from different physicians[1], and he did not find the name.

Finally, as a legal matter, the alleged duty to consult with a prescriber or a patient when any factor causes suspicion, does not exist. The rule relied on in the complaint is Phar 10.03 (2), Wis. Admin. Code, which defines as unprofessional conduct "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." Mr. Reynolds expressed his opinion that the standards of professional conduct require the pharmacist to be actively engaged in the physician-pharmacist-patient triad. As an example, he said that upon refilling this prescription for 100 doses, the pharmacist "should have ascertained why [the patient] was taking the quantity he was taking". After listening to the testimony in this case, I conclude that Mr. Reynolds' vision is more the ideal than the minimally-competent. Such involvement may be more common for a pharmacist in an independent pharmacy in a small or medium-sized town, but it is not universal, and it has not been formulated into a standard of professional conduct. Along the same lines, the cross-examination of Mr. Regalia led to a question which attempted to establish the proposition that "the only way a physician is going to find out the pattern of the patient's usage is if the pharmacist calls him/her or if the patient informs him/her." Mr. Regalia did not acknowledge this as a pharmacist's responsibility, and I do not find this as a requirement in

[1] The patient was also taking Monopril, a medication for high blood pressure, but that fact is irrelevant to this proceeding, except to show that Mr. Wolff did check to see what other medications the patient was taking.

the rules. This concept of the pharmacist as an active partner with the physician may be something the board wishes to promote or mandate, but it is not a duty now. Because it would create significant new responsibilities, a carefully-formulated rule would be necessary. As it stands now, the concept has no definition and no limits, and it cannot be imposed on Mr. Wolff.

Dated and signed: May 8, 1996

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

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:

STATE OF WISCONSIN PHARMACY EXAMINING BOARD

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

The Date of Mailing this Decision is:

July 10. 1996

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.)