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STATE OF WISCONSIN

BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF

DISCIPLINARY PROCEEDINGS AGAINST:

WALLACE L. SIMONS, R.Ph.,	**FINAL DECISION AND ORDER**
CAROL L. PETERSEN, R.Ph., and	
WOMEN'S INTERNATIONAL PHARMACY, INC.,	
RESPONDENTS	LS9806121PHM

PARTIES

The parties in this matter under section 227.44 of the Statutes and section RL 2.037 of the Wisconsin Administrative Code, and for purposes of review under sec. 227.53, Stats. are:

Disciplinary Authority:

Pharmacy Examining Board

1400 East Washington Ave.

Madison, WI 53703

The board and the division are represented by:

Attorney Arthur Thexton

Division of Enforcement

Department of Regulation and Licensing

1400 E. Washington Ave.

Madison, WI 53703

Complainant:

Division of Enforcement

Department of Regulation and Licensing

Madison, WI 53708-8935

Respondents:

Wallace L. Simons, R.Ph.

5852 East Dalea Drive

P.O. Box 2125

Carefree, AZ 85377

Carol L. Petersen, R.Ph.

5708 Monona Drive

Madison, WI 53716

Women’s International Pharmacy, Inc.

5708 Monona Drive

Madison, WI 53716

The respondents are represented by:

Attorney Colleen O'Connor Patzer

Michael Best & Friedrich, LLP

100 E. Wisconsin Ave.

Milwaukee, WI 53202

Based on the entire record of this case, the board makes the following Findings of Fact, Conclusions of Law, and Order.

APPLICABLE STATUTES AND RULES

Wisconsin Statute

450.10 Disciplinary proceedings; immunity; orders.

(1) (a) In this subsection, "unprofessional conduct" includes, but is not limited to:

…

2. Violating this chapter or, subject to s. 961.38 (4r), ch. 961 or any federal or state statute or rule which substantially relates to the practice of the licensee.

…

6. Engaging in conduct in the practice of the licensee which evidences a lack of knowledge or ability to apply professional principles or skills.

…

Wisconsin Administrative Code

Phar 7.07 Medication profile record system.

…

(2) The following minimum information shall be retrievable:

…

(h) Directions for use.

…

Phar 10.03 Unprofessional conduct.

The following without limitation because of enumeration, are violations of standards of professional conduct and constitute unprofessional conduct in addition to those grounds specified under s. 450.10 (1), Stats.:

…

(2) 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;

…

(18) Violating or attempting to violate any formal disciplinary order of the board.

Federal Statute

Section 301 (l) of the Food, Drug & Cosmetic Act, 21 USC §331 (l) (repealed effective 11/21/97) The following acts and the causing thereof are hereby prohibited:

…

(l) The using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 505, 515, or 520(g), as the case may be, or that such drug or device complies with the provisions of such section.

FINDINGS OF FACT

1. The respondent, Wallace L. Simons, R.Ph., is licensed as a registered pharmacist in the state of Wisconsin, under license number 7258.

2. The respondent, Carol L. Petersen, R.Ph., is licensed as a registered pharmacist in the state of Wisconsin, under license number 8487.

3. The respondent, Women's International Pharmacy, Inc., is licensed as a pharmacy in the state of Wisconsin, under license number 7091. At all times material to this matter, the license issued to Women's International Pharmacy was limited pursuant to a board order dated August 16, 1995 [exhibit 102].

4. At all times material to this matter, Mr. Simons was the president and 50% owner of Women's International Pharmacy, Inc., and he was responsible for its policies.

5. At all times material to this matter, Ms. Petersen was the managing pharmacist of Women's International Pharmacy, Inc., and she was responsible for its professional operations.

6. Women's International Pharmacy specializes in the compounding and sale and distribution of micronized progesterone.

<u>Regarding count 1 of the complaint, D.O.E. informal complaint # 96 PHM 40</u>

7. The order issued by the board on August 16, 1995 states

> C. No compounded drug product shall be delivered, dispensed, or otherwise transferred to another pharmacy for dispensing to a patient unless respondent has informed that pharmacy that the portion of the medication container label showing the name, address and telephone number of Women's International Pharmacy must appear on the medication container dispensed to the patient, and Women's International Pharmacy makes and documents direct telephone contact with each patient to provide a consultation.

8 (by stipulation). From August 16, 1995 until approximately September 3, 1996, pursuant to paragraph C of the board order, Women's International Pharmacy attempted to contact by telephone all patients who received prescriptions compounded by Women's International Pharmacy through another pharmacy. During these attempts, many patients stated that they were confused by the phone calls and reacted negatively.

9 (by stipulation). In response to these statements of patients and their negative reaction to the telephone calls, between approximately September 3, 1996 and July 19, 1999, Women's International Pharmacy ceased telephoning, and routinely sent cards to patients receiving prescriptions through other pharmacies [exhibit 103]. The complete text of the postcard is:

> Dear _____

> Women's International Pharmacy recently mailed to your pharmacy, _____, a prescription for you compounded by our pharmacy. Our state pharmacy regulations require that we contact you to offer consultation services regarding any questions you may have about your medication. Therefore, if you would like to consult with a pharmacist, please call our toll free number, (800) 279-5708 and follow the menu instructions.
>
> It is our goal to provide the highest quality prescriptions and service available.
>
> Thank you,
>
> Customer Service

10 (by stipulation). Neither Mr. Simon nor Ms. Petersen informed the board or the department of this change in their procedure at the time it was implemented. During an investigative interview by Investigator Karen Fahlgren on March 26, 1997, Ms. Petersen told Ms. Fahlgren of this change in policy and the rationale for the change. Following the investigative interview, respondents' counsel had telephone discussions with the board's prosecuting attorney regarding the investigation which was open in this matter. In April, 1997, respondents' counsel attempted to discuss these changes in policy and the reasons therefor directly with the board [exhibits 104 - 107]. Since July 19, 1999, Women's International Pharmacy has both sent cards and telephoned all patients.

11. The order issued by the board on August 16, 1995 states

> F. Respondents shall not provide reprints, articles or other printed materials purporting to state that the active ingredients in respondent's products, or formulae similar to those used by respondents, are safe and effective unless those articles were published in refereed journals. Respondents shall not promote directly or through Genesis Systems Corporation or another, any particular formula or dosage of any drug or drug product which they compound, and shall advise and counsel Genesis Systems Corporation not to so promote. Upon request, respondents shall submit all promotional and informational materials in use at that time (and for the year preceding the request) to the Board for review by the Board or its designee. Such submission is for informational purposes only. All material intended to be sent to practitioners or patients shall bear the date of printing after 12/1/95. All reprints of articles or similar materials shall bear the disclaimer: "Reprinted for promotional purposes by Genesis Systems Corporation for Women's International Pharmacy" or similar wording, after 12/1/95.

12 (by stipulation). Between December 1, 1995 and March 27, 1999, Women's International Pharmacy routinely sent a promotional brochure [exhibit 108] and a document entitled "Business Policies" [exhibit 113] to new patients and new prescribers. A cover letter [exhibit 109] and a document entitled "News You Can Use" [exhibit 110] were sent only to new prescribers. A chart of a study [exhibit 111] was sent to new and current prescribers. A cover letter [exhibit 112] was sent only to new patients. A cover letter [exhibit 114], a reprint entitled "Estrogen Replacement Therapy" [exhibit 115], a reprint entitled "New Therapy for Menopause Reduces Risks" [exhibit 116], and a report entitled " The Postmenopausal Estrogen/Progestin Interventions (PEPI) Trial" [exhibit 117] were sent to prescribers, patients, and physicians who requested information from Women's International Pharmacy.

13. Exhibits 108, 109, 110, 111, 112, 113, 114, and 115 contain no date of printing. Exhibit 115 is a reprint entitled "Estrogen Replacement Therapy", apparently excerpted from a book. Exhibit 116 is a reprint from the New York Times entitled "New Therapy for Menopause Reduces Risks"; it contains a date of (original) printing. Exhibit 117 is a report from the National Heart, Lung and Blood Institute entitled " The Postmenopausal Estrogen/Progestin Interventions (PEPI) Trial"; it contains a date of (original) printing.

14. The order issued by the board on August 16, 1995 states

> H. All products containing progesterone or any estrogen shall contain a Patient Package Insert containing all FDA-required content no later than August 1, 1995. If, for reasons beyond respondents' control, the PPI cannot be made ready by this date, a reasonable extension shall be granted.

15 (by stipulation). Between August 1, 1995 and the date of the stipulation, December 22, 1999, Women's International Pharmacy routinely provided patients with the same Patient Package Insert with all of its products containing estrogen or progesterone [exhibit 118]. The insert included all required FDA text. The language at the top of the insert which is not in columnar format was not part of the required FDA text, and was created by Mr. Simon and Ms. Petersen in consultation with their attorneys. The complete text of the added portion is:

> Enclosed you will find copies of the FDA approved package inserts for estrogens and gestational products. While we are complying with FDA rules by providing these inserts, we would like to clarify that the FDA gathered this information based upon the usage of the traditional hormone replacement therapies. This includes using estrogen without properly balancing it with progesterone and also includes the use of synthetic analog hormones. As you will note, the FDA indicates that the usage of

such agents, as described, on the attached inserts can be problematic. Please also note that the natural hormone therapy you are receiving has not as yet been evaluated by the FDA. Natural progesterone and estrogens are identical to the molecules formed in the human body.

16. Prior to November 21, 1997, section 301 (1) of the Food, Drug & Cosmetic Act, 21 USC section 331 (1) prohibited:

> (l) The using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 505, 515, or 520(g), as the case may be, or that such drug or device complies with the provisions of such section.

17 (by stipulation). From as early as 1988 to the date of the stipulation, December 22, 1999, Women's International Pharmacy routinely sent an informational sheet headed "most asked questions about natural oral progesterone" [exhibit 119] to patients. The sheet included the following:

> Question: Is the oral form of natural progesterone approved by the F.D.A.?
>
> Answer: Natural micronized progesterone has F.D.A. approval. The oral form of natural progesterone is compounded from a physician's prescription by a licensed pharmacist using F.D.A. approved ingredients. Therefore, it does not require separate F.D.A. approval.

Regarding count 2 of the complaint, D.O.E. informal complaint # 97 PHM 54

18. A patient in Ashland, Oregon, Gayle Vezie, obtained a prescription from Dr. Linda Harris in a nearby town, for progesterone in dosages of 100 mg to be taken twice a day orally.

19. Women's International Pharmacy filled the prescription and provided Ms. Vezie with capsules containing 100 mg of micronized progesterone in oil. This dispensing is within the authorized scope of Women's International Pharmacy's license.

20. On June 10th or 11th, 1997, Ms. Vezie, concerned over a perceived side-effect of the medication, called both Dr. Harris's office and Women's International Pharmacy, leaving messages for a return call at both locations.

21. On the same day, an employee of Women's International Pharmacy, who was almost certainly a staff pharmacist, returned the call to Ms. Vezie and spoke to her about her concern.

22. In the conversation above, the employee told Ms. Vezie of an alternative route of administration of the progesterone which might reduce the unwanted side effect. The employee explained that instead of taking the progesterone orally, Ms. Vezie could remove the progesterone from the capsules and rub it on her skin, specifically on her wrist.

23. In the same conversation, Ms. Vezie most likely told the employee that she had called her prescribing doctor's office and was expecting a call back, and the employee most likely expected Ms. Vezie to discuss her concerns and the alternative route of administration with her doctor.

24. On June 11, 1997, a nurse from Dr. Harris's office made the following note in Ms. Vezie's record: "TC: pt c/o being 'tired & very drowsy' for the 8d that she's been taking Progesterone - pt states she called WIP & they told her that can be a side effect – WIP rec to pt to open capsule & put gel on skin instead – pt is concerned about this side effect, but will finish the x14d of it anyway & see if she has period. K. Peel, MA".

25. Dr. Harris did not return Ms. Vezie's call for over a month.

26. Based on the information she was given by the employee of Women's International Pharmacy, and without a return call from her physician, Ms. Vezie changed the route of administration.

27. When Dr. Harris did return Ms. Vezie's call in late July, Ms. Vezie had been applying the progesterone topically for a month and a half. Dr. Harris became upset over what she perceived as an unauthorized change in the route of administration.

CONCLUSIONS OF LAW

I. The Pharmacy Examining Board has personal jurisdiction over the respondents, based on their each holding a credential issued by the board, and based on notice under sec. 801.04 (2), Stats.

II. The Pharmacy Examining Board is the legal authority responsible for issuing and controlling credentials for pharmacists and pharmacies, under ch. 450, Stats., and it has jurisdiction over the subject-matter of a complaint alleging unprofessional conduct, under sec. 15.08(5)(c), Stats., sec. 450.10, Stats., and ch. Phar 10, Wis.

Admin. Code.

III. By only sending post cards and not telephoning patients between approximately September 3, 1996 and July 19, 1999, Women's International Pharmacy violated paragraph C of the board's August 16, 1995 order.

IV. By sending undated material, Women's International Pharmacy violated paragraph F of the board's August 16, 1995 order.

V. By sending reprints of articles not published in refereed journals, Women's International Pharmacy violated paragraph F of the board's August 16, 1995 order.

VI. By including its preface to the required FDA text, Women's International Pharmacy vitiated paragraph H of the board's August 16, 1995 order.

VII. The violations of a board order in conclusions of law III, IV, V and VI constitute unprofessional conduct, under sec. Phar 10.03 (18), Wis. Admin. Code.

VIII. By stating that natural micronized progesterone has F.D.A. approval, Women's International Pharmacy violated section 301 (1) of the Food, Drug & Cosmetic Act, 21 USC section 331 (1) during the period when it was in effect, i.e., prior to November 21, 1997.

IX. A violation of a federal statute or rule constitutes unprofessional conduct, under sec. 450.10 (1) (a) 2., Stats.

X. There is no evidence to support the allegation that for a period of time extending over a period of years, and including the day June 10, 1997, Women's International Pharmacy had a policy of having pharmacists advise patients to alter the route of administration for hormones from oral to topical. Nor is there sufficient evidence to prove that on one occasion on June 10th or 11th, 1997, an employee of Women's International Pharmacy advised a patient, Gayle Vezie, to alter the route of administration from oral to topical without recommending that she contact her physician about the change.

ORDER

IT IS THEREFORE ORDERED that Wallace Simons be reprimanded.

IT IS FURTHER ORDERED that Women's International Pharmacy pay a forfeiture of $10,000, and if the forfeiture is not paid in full within 45 after the date this order is signed by a member of the Pharmacy Examining Board, the license issued to Women's International Pharmacy shall be suspended indefinitely, until the forfeiture is paid in full.

IT IS FURTHER ORDERED that Carol Petersen be reprimanded.

IT IS FURTHER ORDERED that Count 2 of the complaint be dismissed.

IT IS FURTHER ORDERED that the respondents pay all costs associated with count 1 of this proceeding, as authorized by sec. 440.22 (2), Stats., and sec. RL 2.18, Wis. Admin. Code. The respondents shall not be responsible to pay the costs associated with count 2 of the complaint. If there are costs which cannot be allocated either to count 1 or to count 2, one-half shall be assumed to be assigned to count 1 and one-half to count 2. The respondents shall be responsible for the costs jointly and severally, and if the costs remain unpaid 90 days after the date of the order establishing the costs, the licenses of all respondents shall be summarily suspended, under sec. 440.22 (3), Stats., until the costs are paid in full.

EXPLANATION OF VARIANCE

The board has accepted those Findings of Fact and Conclusions of Law recommended by the Administrative Law Judge (ALJ). The board has accepted the ALJ's recommended Order, but modified the ALJ's recommended Order in two respects.

First, the ALJ had proposed that:

THEREFORE, IT IS ORDERED that paragraph C of the Order issued August 16, 1995 is replaced by the following:

> *C. No compounded drug product shall be delivered, dispensed, or otherwise transferred to another pharmacy for dispensing to a patient unless*

(1) Women's International Pharmacy has informed that pharmacy that the portion of the medication container label showing the name, address and telephone number of Women's International Pharmacy must appear on the medication container dispensed to the patient;

(2) Women's International Pharmacy mails a postcard to the patient informing him or her of the availability of consultation services, and then subsequently makes and documents direct telephone contact with each patient offering consultation; and

(3) Women's International Pharmacy makes and documents a request from that pharmacy for information on the reason(s) for the prescription to be filled by Women's International Pharmacy through that pharmacy. Copies of the responses to these requests shall be made available to the board or its designee upon written request. The Pharmacy Examining Board may at any time request and review copies of the responses, and following an opportunity for Women's International Pharmacy to comment may further modify this paragraph (C.).

This part of the ALJ's proposed decision is not adopted.

Second, the ALJ recommended the suspension of respondent Wallace Simons:

IT IS FURTHER ORDERED that the license issued to Wallace Simons be suspended for a period of forty-five calendar days, effective on the date this order is signed by a member of the Pharmacy Examining Board.

This part of the ALJ's proposed decision is modified by the board as follows:

"IT IS THEREFORE ORDERED that Wallace Simons be reprimanded."

The basis for these variances in the Order are as follows:

The board has not modified paragraph C of the underlying *Order issued August 16, 1995,* because that *Order* was the result of negotiation between the parties. The respondent, Women's International Pharmacy agreed to be bound by the terms of paragraph C of the *Order* and should be held to that agreement, absent a petition for modification and the presentation of the reasons therefore. The board is not convinced based upon its review of the Findings of Fact that sufficient necessity or grounds exist requiring modification of paragraph C of the *Order* at this time in the manner the ALJ has proposed. Commencing July 19, 1999, Women's International Pharmacy has been in compliance with paragraph C of the *Order* and by this decision is required to continue to remain so.

The board has modified the discipline of Wallace Simons because the Findings of Fact do not demonstrate a difference in culpability sufficient to warrant differing discipline between Wallace Simons and Carol Petersen. The public health, safety and welfare are adequately protected by the imposition of a reprimand against both individual respondents.

Dated this 22nd day of January, 2001.

STATE OF WISCONSIN

PHARMACY EXAMINING BOARD

Susan L. Sutter, R.Ph.

Vice Chair