WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

Wisconsin Department of Safety and Professional Services
Access to the Public Records of the Reports of Decisions

This Reports of Decisions document was retrieved from the Wisconsin Department of Safety and Professional Services website. These records are open to public view under Wisconsin's Open Records law, sections 19.31-19.39 Wisconsin Statutes.

Please read this agreement prior to viewing the Decision:

- The Reports of Decisions is designed to contain copies of all orders issued by credentialing authorities within the Department of Safety and Professional Services from November, 1998 to the present. In addition, many but not all orders for the time period between 1977 and November, 1998 are posted. Not all orders issued by a credentialing authority constitute a formal disciplinary action.
- Reports of Decisions contains information as it exists at a specific point in time in the Department of Safety and Professional Services data base. Because this data base changes constantly, the Department is not responsible for subsequent entries that update, correct or delete data. The Department is not responsible for notifying prior requesters of updates, modifications, corrections or deletions. All users have the responsibility to determine whether information obtained from this site is still accurate, current and complete.
- There may be discrepancies between the online copies and the original document. Original documents should be consulted as the definitive representation of the order's content. Copies of original orders may be obtained by mailing requests to the Department of Safety and Professional Services, PO Box 8935, Madison, WI 53708-8935. The Department charges copying fees. *All requests must cite the case number, the date of the order, and respondent's name* as it appears on the order.
- Reported decisions may have an appeal pending, and discipline may be stayed during the appeal. Information about the current status of a credential issued by the Department of Safety and Professional Services is shown on the Department's Web Site under "License Lookup."

  The status of an appeal may be found on court access websites at: http://ccap.courts.state.wi.us/InternetCourtAccess and http://www.courts.state.wi.us/wscca

- Records not open to public inspection by statute are not contained on this website.

By viewing this document, you have read the above and agree to the use of the Reports of Decisions subject to the above terms, and that you understand the limitations of this on-line database.

Correcting information on the DSPS website: An individual who believes that information on the website is inaccurate may contact DSPS@wisconsin.gov

1995

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	FINAL DECISION AND ORDER
WALLACE L. SIMONS, R.Ph., WOMEN'S INTERNATIONAL PHARMACY, INC. RESPONDENTS	:	88 PHM 25, 90 PHM 70 ~~90 PHM 70~~, 94 PHM 66 ~~94 PHM 111~~ LS9312291PHM LS9405231PHM

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

Wallace L. Simons, R.Ph.
3305 Leyton Lane
Madison, WI 53713

Women's International Pharmacy, Inc.
5708 Monona Drive
Madison, WI 53716

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

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

RECEIVED
AUG 17 1995
Dept. of Regulation & Licensing
Division of Enforcement

COPY

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

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

FINDINGS OF FACT

1. Respondent Wallace L. Simons (dob 7/10/40) is and was at all times relevant to the facts set forth herein a registered pharmacist licensed in the State of Wisconsin pursuant to license #7258. At all times material, respondent Simons was the managing pharmacist of co-respondent Women's International Pharmacy, which was at all times relevant to the facts set forth herein a pharmacy licensed in the State of Wisconsin pursuant to license #7091.

2. The Respondents are charged in 88 PHM 25 and 90 PHM 70 with exceeding the legal limits for compounding and thus being manufacturers, of making certain recordkeeping errors with respect to controlled substances dispensed by them and their staff, and dispensing in a manner inconsistent with state law and the Food Drug & Cosmetic Act. Respondents deny all these allegations, but desire to settle this matter solely to avoid the expenses and uncertainties of litigation.

CONCLUSIONS OF LAW

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

4. The Board concludes that respondents did in the past commit errors with respect to their dispensing of compounded testosterone prescriptions by failing to stamp some hard-copy prescriptions for controlled substances with a red "C" although they were combined with non-controlled substance records, failing to keep their hard copy prescription records in chronological order, and dispensing more than a 34 day supply at one time, all in violation of ch. Phar 8, Wis. Adm. Code. The Board has no evidence that such violations continued after June, 1993, when respondents adopted a new recordkeeping system.

5. The Board concludes that routinely dispensing large quantities of compounded drug products to practitioners (except as permitted in this Order) and respondents' providing compounded drug products to Health Pharmacies, Inc. in 1992-93, is not compounding for dispensing to a patient.

6. The Board concludes that if Women's International Pharmacy complies with this Final Decision and Order, its actions to be undertaken under this Order will be in conformance with applicable state and local laws regulating the practice of pharmacy, that it will be regularly engaged in dispensing prescription drugs upon the prescriptions of practitioners licensed to administer such drugs to patients under their care in the course of their professional practice, and that it will not be manufacturing under §450.01(13), Wis. Stats.

ORDER

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

IT IS FURTHER ORDERED, that respondents are REPRIMANDED for their actions described in ¶4, above.

IT IS FURTHER ORDERED, that the licenses of Wallace L. Simons, R.Ph., to practice pharmacy, and of Women's International Pharmacy to be a pharmacy are LIMITED in that all compounding performed by either is limited to the following:

A. No compounded drug or drug product shall be dispensed unless all active ingredients are legally obtainable in the United States and of USP or equivalent grade and all inactive ingredients are either food grade or customarily used in the profession.

B. No prescription drug shall be dispensed except directly to a patient in the pharmacy or delivered to a patient's home by an agent of the pharmacist, including a common carrier or the US Postal Service, or pursuant to this Order.

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.

D. No substance shall be delivered, dispensed, or otherwise transferred to a practitioner's office more than once unless the practitioner certifies in writing that in-office administration of the substance to the practitioner's patients is medically necessary, and the quantities of such substance are reasonable under the circumstances to provide only that amount of product which will carry the patient from the time the practitioner administers the drug until a prescription can be presented to, and dispensed by, a pharmacy for that patient. In the absence of other evidence, such a period of time shall be presumed to be ten calendar days. The form of such certification shall be approved by the Board or its designee, which approval shall not be unreasonably withheld. The amount, if any, to be charged by respondents for the above permitted transfer of office supplies is within respondents' discretion. Except as permitted above, respondents shall not provide any "office samples" or other free or reduced-price products to practitioners. Records of office supplies provided to practitioners shall be clearly distinguishable from prescription dispensing records, and shall be readily retrievable and verifiable.

E. Respondents shall compound only the number or quantity of medication called for by the initial-fill quantities stated on the prescriptions respondents have actually received at the time the compounding is commenced, or on the basis of prescriptions respondents have received in the past 30 days. Respondents may, in the case of capsules, round that number up to the number of capsules held by the pharmacy's equipment. Respondents shall not accept, compound or dispense two or more prescriptions for the same formula to the same patient at the same time, in an effort to evade the limitations of this paragraph. All drug products shall be dispensed and labeled with "beyond use" dates of six months from the date of compounding or 25% of the time before the expiration date of any component used in the compounding, whichever is nearer: any medication which will not be so used shall be discarded. Respondents may use any other beyond-use date which can be supported by reasonable stability testing.

F. Respondents shall not provide reprints, articles or other printed materials purporting to state that the active ingredients in respondents' products, or formulae similar to those used by respondents, are safe or 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 preceeding 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.

G. Respondents shall provide to any requesting licensed pharmacy (or pharmacist) which a patient desires to use with respondents' complete ingredient list and formula for any prescription which it has compounded for that patient, and shall make no statement concerning price, difficulty, or other issue which could reasonably be interpreted as an attempt to discourage the patient-selected pharmacy or pharmacist from compounding the prescription. If, in the course of transmitting all information necessary to truthfully describe the compounding process, respondents accurately apprise the pharmacy or pharmacist of the complexity of the process, such a statement does not violate this paragraph.

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.

J. Third party claims submitted by respondent may include the NDC numbers of the active ingredients if the claim processor has been informed that the product was compounded, that the NDC numbers refer only to the ingredients and not to the final product, and the processor has consented to the claim being filed in such fashion.

IT IS FURTHER ORDERED, that in 94 PHM 66, a distributor license shall be granted to respondents upon updating the application to answer all questions with currently accurate and complete information.

IT IS FURTHER ORDERED that the complaints in 88 PHM 25, 90 PHM 70, and 90 PHM 70a is DISMISSED and will not be reopened as long as the parties comply with this Stipulation and Final Decision and Order.

IT IS FURTHER ORDERED that 94 PHM 111 is CLOSED without disciplinary action.

IT IS FURTHER ORDERED, that the settlement agreement incorporated into this Order is binding upon respondents and their successors, and upon the Department of Regulation & Licensing and Pharmacy Examining Board and their successors, but without prejudice to the right of the legislature or Board to adopt statutory and administrative rules which may modify or change public policy as to future actions by licensees.

Dated this 16 day of August, 1995.

WISCONSIN PHARMACY EXAMINING BOARD

by: Thomas McGregor
a member of the board

akt
69

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST WALLACE L. SIMONS, R.Ph., WOMEN'S INTERNATIONAL PHARMACY, INC. RESPONDENTS	:	STIPULATION 88 PHM 25, 90 PHM 70 90 PHM 70a, 94 PHM 66 94 PHM 111 LS9312291PHM LS9405231PHM

It is hereby stipulated between the above Respondents and the undersigned prosecuting attorney for the Division of Enforcement of the Department of Regulation and Licensing, as follows:

1. This Stipulation is entered into as a result of a pending investigation of Respondents by the Division of Enforcement and a hearing in process. The parties consent to the resolution of the above files by agreement and without a conclusion of the ongoing hearing on the formal complaint which has been issued in this matter, or a hearing in 90 PHM 70a, and without any issuance of any other complaints in the other above-named investigations which have been opened with respect to these respondents. This agreement does not resolve the allegations of 95 PHM 25.

2. Respondents understand that by signing this Stipulation, respondents waive the following rights with respect to disciplinary proceedings: the right to a statement of the allegations against respondents; a right to a hearing at which time the State has the burden of proving those allegations; the right to confront and cross-examine the witnesses against respondents; the right to call witnesses on respondents' behalf and to compel attendance of witnesses by subpoena; the right to testify personally; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to respondents under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, and the Wisconsin Administrative Code, except as expressly reserved elsewhere herein.

3. Respondents are aware of respondents' right to seek legal representation and have obtained legal advice before signing this Stipulation.

4. Respondents assure the Board that they have at all times complied with ¶A of the Order, and that they will make every effort to ensure that Genesis Systems Corporation complies with ¶F of the Order but they do not legally control Genesis. Respondents also deny and do not agree that any violations have been committed intentionally or otherwise, except those admitted in the Answer to the Complaint in 88 PHM 25/90 PHM 70, but agree to the adoption of the attached Final Decision and Order by the Board. The parties consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation or the proposed Final Decision and Order, and the matter shall be returned to the Division of Enforcement for further proceedings, including the resumption of the currently ongoing hearings. In the event that this Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

6. The parties agree that an attorney for the Division of Enforcement may appear before the Board, in open or closed session, without the presence of Respondents or Respondents' attorney, for the purposes of speaking in support of this agreement and answering questions that the members of the Board and its staff may have in connection with their deliberations on the case. Respondents have the option of appearing with the prosecuting attorney at all open or closed sessions, and any appearance shall be preceeded by timely notice.

7. The Board Advisor in this matter may participate freely in any deliberations of the Board regarding acceptance of this Stipulation and the proposed Final Order, and may relate to the Board any knowledge and views of the case acquired during the investigation, the panel session, the hearing and the settlement negotiations.

8. The Division of Enforcement joins respondents in recommending that the Board adopt this Stipulation and issue the attached Final Decision and Order.

9. Respondents are informed that should the Board adopt this stipulation, the board's final decision and order is a public record and will be published in the Monthly Disciplinary Report issued by the department. A summary of the order will be published in the Wisconsin Regulatory Digest issued semiannually by the Board. This is standard department procedure and in no way specially directed at respondents.

10. Respondents do not waive, and may pursue any rights to reimbursement for costs, attorneys' fees, or disbursements, from any state agency, and before any forum. Any such agency may defend such claims on any grounds available. This agreement also does not preclude respondents and their attorneys from pursuing any sanctions arising out of this hearing over which the Pharmacy Examining Board has no jurisdiction.

11. The Division and its prosecuting attorney assure respondents that there are no actual or tacit agreements or understandings with the FDA, DEA, or any other state or federal agency that after the entry of this Order, the FDA, DEA, or other agency will proceed against respondents in the Division's stead, i.e. the Division and its prosecuting attorney have no agreement or understanding with another agency to undermine the finality of this Stipulation and Final Decision and Order. Respondents understand that the FDA and DEA may be conducting their own investigations, and that to the extent that they or other agencies request the cooperation of the Division, such cooperation will be provided only in a manner similar to cooperation routinely provided in other cases.

12. Any patient records, without limit as to form, in any of the above-captioned files kept by the Department of Regulation & Licensing will be released under a public records request only in accordance with §146.82, Wis. Stats. The department will notify respondent of any requests to view or copy any of the file documents received from respondents upon receipt of the request, including the identity of the requestor if known, and at least 30 days before release of any records. This does not limit the department's obligation to comply with §19.35 et seq., Wis. Stats.

13. The parties agree that the wording "Reprinted for educational and promotional purposes..." is substantially similar to the wording set forth in ¶F of the Order.

WOMEN'S INTERNATIONAL PHARMACY, INC., by:

Wallace L. Simons, President — Date
Wallace L. Simons, R.Ph., personally

Howard M. Hoffmann, Attorney for Respondent — 8/16/95
Date

Arthur Thexton, Prosecuting Attorney — 8/16/95
Division of Enforcement — Date

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:

AUGUST 17, 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.)