BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: LIFE WELLNESS PHARMACY, INC. dba LIFE WELLNESS PHARMACY, INC., PRESIDENT, MICHAEL LENZNER 1932 Kellogg Avenue Carlsbad, CA 92008 Original Pharmacy Permit No. PHY 45971, MICHAEL LENZNER 6743 Follette Street Carlsbad, CA 92009 Pharmacist License No. RPH 33245, and AMANDA L. CANALES, RPH aka AMANDA L. CAMARIGG 31312 Avenida Terramar San Juan Capistrano, CA 92675 Pharmacist License No. RPH 44504 Respondent.	Case No. 3000 OAH No. L-2007080042

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective on October 3, 2008.

It is so ORDERED September 3, 2008.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

KENNETH H. SCHELL
Board President

EDMUND G. BROWN JR., Attorney General
of the State of California
LINDA K. SCHNEIDER
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Attorneys for Complainant

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IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Edmund G. Brown Jr., Attorney General of the State of California, by Rita M. Lane, Deputy Attorney General.

2. Respondent Amanda L. Canales, RPH, a.k.a. Amanda L. Camarigg is represented in this proceeding by attorney Herbert L. Weinberg, whose address is 1800 Century Park East, 8th Floor, Los Angeles, CA 90067.

3. On or about August 9, 1991, the Board of Pharmacy issued Pharmacist License No. RPH 44504 to Amanda L. Canales, RPH, a.k.a. Amanda L. Camarigg (Respondent). The license was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2008, unless renewed.

JURISDICTION

4. Accusation No. 3000 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on June 8, 2007. Respondent timely filed her Notice of Defense contesting the Accusation. A copy of Accusation No. 3000 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 3000. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

6. Respondent is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at her own expense; the right to confront and cross-examine the witnesses against her; the right to present evidence and to testify on her own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to

reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent admits the truth of each and every charge and allegation in the Thirteenth Cause for Discipline in Accusation No. 3000.

9. Respondent agrees that her Pharmacist License is subject to discipline and she agrees to be bound by the Board's imposition of discipline as set forth in the Disciplinary Order below.

CONTINGENCY

10. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that she may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

11. The parties understand and agree that facsimile copies of this Stipulated Settlement and Disciplinary Order, including facsimile signatures thereto, shall have the same force and effect as the originals.

12. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

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DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 44504 issued to Respondent Amanda L. Canales, RPH, a.k.a. Amanda L. Camarigg is revoked. However, the revocation is stayed and Respondent is placed on probation for four (4) years on the following terms and conditions.

1. **Actual Suspension - Pharmacist.** Pharmacist License No. RPH 44504, issued to Respondent Amanda L. Canales, RPH, a.k.a. Amanda L. Camarigg is suspended for a period of 60 days.

During suspension, Respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the Board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall Respondent manage, administer, **or** be a consultant to any licensee of the Board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or an exemptee for any entity licensed by the Board. Subject to the above restrictions, Respondent may continue to own or hold an interest in any pharmacy in which they holds an interest at the time this decision becomes effective unless otherwise specified in this order.

2. **Obey All Laws.** Respondent shall obey all state and federal laws and regulations substantially related to or governing the practice of pharmacy.

Respondent shall report any of the following occurrences to the Board, in writing, within 72 hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal

controlled substances laws

- a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state and federal agency which involves Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for any drug, device or controlled substance.

3. **Reporting to the Board.** Respondent shall report to the Board quarterly. The report shall be made either in person or in writing, as directed. Respondent shall state under penalty of perjury whether there has been compliance with all the terms and conditions of probation. If the final probation report **is not** made as directed, probation shall be extended automatically until such time as the final report is made and accepted by the Board.

4. **Interview with the Board.** Upon receipt of reasonable notice, Respondent shall appear in person for interviews with the Board upon request at various intervals at a location to be determined by the Board. Failure to appear for a scheduled interview without prior notification to Board staff shall be considered a violation of probation.

5. **Cooperation with Board Staff.** Respondent shall cooperate with the Board's inspection program and in the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of her probation. Failure to comply shall be considered a violation of probation.

6. **Continuing Education.** Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board.

7. **Notice to Employers.** Respondent shall notify all present and prospective employers of the decision in case number 3000 and the terms, conditions and restrictions imposed on Respondent by the decision. Within 30 days of the effective date of this decision, and within 15 days of Respondent undertaking new employment, Respondent

shall cause her direct supervisor, pharmacist-in-charge and/or owner to report to the Board in writing acknowledging the employer has read the decision in case number 3000.

If Respondent works for or is employed by or through a pharmacy employment service, Respondent must notify the direct supervisor, pharmacist-in-charge, and/or owner at every pharmacy of the and terms conditions of the decision in case number 3000 in advance of the Respondent commencing work at each pharmacy.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist, whether the Respondent is considered an employee or independent contractor.

8. **No Preceptorships, Supervision of Interns, Being Pharmacist-in-Charge (PIC), or Serving as a Consultant.** Respondent shall not supervise any intern pharmacist or perform any of the duties of a preceptor, nor shall Respondent be the pharmacist-in-charge of any entity licensed by the Board unless otherwise specified in this order.

9. **Reimbursement of Board Costs.** Respondent shall pay to the Board its costs of investigation and prosecution in the amount of $4,000. Respondent may make payments to the Board to be arranged with the Board.

The filing of bankruptcy by Respondent shall not relieve Respondent of her responsibility to reimburse the Board its costs of investigation and prosecution.

10. **Probation Monitoring Costs.** Respondent shall pay the costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board at the end of each year of probation. Failure to pay such costs shall be considered a violation of probation.

11. **Status of License**. Respondent shall, at all times while on probation, maintain an active current license with the Board, including any period during which suspension or probation is tolled.

If Respondent's license expires or is cancelled by operation of law or otherwise, upon renewal or reapplication, Respondent's license shall be subject to all terms and

conditions of this probation not previously satisfied.

12. **License Surrender while on Probation/Suspension.** Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may tender her license to the Board for surrender. The Board shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, Respondent shall relinquish her pocket license to the Board within 10 days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

13. **Notification of Employment/Mailing Address Change.** Respondent shall notify the Board in writing within 10 days of any change of employment. Said notification shall include the reasons for leaving and/or the address of the new employer, supervisor or owner and work schedule if known. Respondent shall notify the Board in writing within 10 days of a change in name, mailing address or phone number.

14. **Tolling of Probation.** Should Respondent, regardless of residency, for any reason cease practicing pharmacy for a minimum of 40 hours per calendar month in California, Respondent must notify the Board in writing within10 days of cessation of the practice of pharmacy or the resumption of the practice of pharmacy. Such periods of time shall not apply to the reduction of the probation period. It is a violation of probation for Respondent's probation to remain tolled pursuant to the provisions of this condition for a period exceeding three years.

"Cessation of practice" means any period of time exceeding 30 days in which Respondent is not engaged in the practice of pharmacy as defined in Section 4052 of the Business and Professions Code.

15. **Violation of Probation.** If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order which was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, the Board shall have continuing jurisdiction and the period of probation shall be extended, until the petition to revoke probation or accusation is heard and decided.

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty which was stayed.

16. **Completion of Probation.** Upon successful completion of probation, Respondent's license will be fully restored.

17. **No Ownership of Premises.** Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the Board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the Board within 90 days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the Board.

18. **Tolling of Suspension.** If Respondent leaves California to reside or practice outside this state, for any period exceeding 10 days (including vacation), Respondent must notify the Board in writing of the dates of departure and return. Periods of residency or practice outside the state - or any absence exceeding a period of 10 days shall not apply to the reduction of the suspension period.

Respondent shall not practice pharmacy upon returning to this state until notified by the Board that the period of suspension has been completed.

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Herbert L. Weinberg. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 5-10-08

Amanda L. Canales, RPH,
a.k.a. Amanda L. Camarigg
Respondent

I have read and fully discussed with Respondent Amanda L. Canales, RPH, a.k.a. Amanda L. Camarigg, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 5-10-08

HERBERT L. WEINBERG
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 5-10-08

EDMUND G. BROWN JR., Attorney General
of the State of California

LINDA K. SCHNEIDER
Supervising Deputy Attorney General

RITA M. LANE
Deputy Attorney General

Attorneys for Complainant

DOJ Matter ID: SD2006801263

PAGE 1/1 * RCVD AT 5/12/2008 10:29:21 AM [Eastern Daylight Time] * SVR:RIGHTFAX/8 * DNIS:7854 * CSID:949 248 5775 * DURATION (mm-ss):00-38

Exhibit A

Accusation No. 3000

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Attorneys for Complainant

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Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about July 12, 2002, the Board of Pharmacy issued Original Pharmacy Permit No. PHY 45971 to Life Wellness Pharmacy, Inc., d.b.a. Life Wellness Pharmacy, Inc., President, Michael Lenzner (Respondent Life Wellness). The Original Pharmacy permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2007, unless renewed.

3. On or about August 21, 1979, the Board of Pharmacy issued Pharmacist License No. RPH 33245 to Michael Lenzner, RPH (Respondent Lenzner). The license was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2008, unless renewed. At all times relevant herein, Lenzner was and is the Pharmacist-in-Charge (PIC) at Respondent Life Wellness.

4. On or about August 9, 1991, the Board of Pharmacy issued Pharmacist License No. RPH 44504 to Amanda L. Canales, RPH, a.k.a. Amanda L. Camarigg (Respondent Canales). The license was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2008, unless renewed.

JURISDICTION

5. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws of the Business and Professions Code (Code):

A. Section 118(b) of the Code provides that the expiration of a license without the written consent of the Board shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the Board of its authority to institute or continue a disciplinary proceeding against a licensee.

B. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations

of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

C. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

D. Section 4052 of the Code states in pertinent part:

(a) Notwithstanding any other provision of law, a pharmacist may:

. . . .

(5)(A) Perform the following procedures or functions as part of the care provided by a . . .physician, in accordance, as applicable, with policies, procedures, or protocols of that . . .physician . . .

. . . .

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the . . .physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.[1]

E. Section 4059 of the Code states in pertinent part:

(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

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1. The above provisions are contained currently in Code §4052(a)(5) plus §4052.2(a)(4) and (c)(3).

F. Section 4063 of the Code states:

No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.

G. Section 4081 of the Code states in pertinent part:

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

H. Section 4113 of the Code states in pertinent part:

(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

I. Section 4115 of the Code states in pertinent part:

(f) The performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist. The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician. A pharmacy technician may perform the duties, as specified in subdivision (a), only under the immediate, personal supervision and control of a pharmacist. Any pharmacist responsible for a pharmacy technician shall be on the premises at all times, and the pharmacy technician shall be without the pharmacist's view. . . .

(g)(1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). . . .

J. Section 4156 of the Code states:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

K. Section 4300 of the Code provides in pertinent part that every license issued by the Board may be suspended or revoked.

L. Section 4301 of the Code states in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> . . . .
>
> (j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> . . . .
>
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
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> . . . .

M. Section 4342 of the Code states in pertinent part:

> (a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

6. This Accusation also refers to the following sections of California Code of Regulations, title 16 (CCR):

A. CCR section 1717, states in pertinent part:

> (b) In addition to the requirements of Section 4040, Business and Professions Code, the following information shall be maintained for each prescription on file and shall be readily retrievable:
>
> (1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.
>
> (2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and

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(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

B. CCR section 1716 states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code. Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

C. CCR section 1716.2 states in pertinent part:

(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:

. . . .

(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.

(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(4) The signature or initials of the pharmacist performing the compounding.

. . . .

(6) The name(s) of the manufacturer(s) of the raw materials.

. . . .

(8) The package size and the number of units prepared.

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D. CCR section 1761 states:

(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

7. This Accusation also refers to the following sections of the Health & Safety Code (H&S Code):

A. H&S Code section 11164 states:

Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b)(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone

number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.

B. H&S Code section 11200 states:

(a) No person shall dispense or refill a controlled substance prescription more than six months after the date thereof.

(b) No prescription for a Schedule III or IV substance may be refilled more than five times and in an amount, for all refills of that prescription taken together, exceeding a 120-day supply .

8. This Accusation also refers to Code of Federal Regulations, title 21, section 310.515(a) that states:

(a) *Requirement for a patient package insert.* FDA concludes that the safe and effective use of drug products containing estrogens requires that patients be fully informed of the benefits and risks involved in the use of these drugs. Accordingly, except as provided in paragraph (e) of this section [not relevant here], each estrogen drug product restricted to prescription distribution, including products containing estrogens in fixed combinations with other drugs, shall be dispensed to patients with a patient package insert containing information concerning the drug's benefits and risks. An estrogen drug product that does not comply with the requirements of this section is misbranded under section 502(a) of the Federal Food, Drug, and Cosmetic Act.

DRUGS

9. T-4 is a name for L-Thyroxine, a thyroid hormone and a dangerous drug pursuant to Code section 4022.

10. T-3 is a name for Triiodo-L-Thyronine, a thyroid hormone and a dangerous drug pursuant to Code section 4022.

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11. Biest is a brand name for estriol + estradiol that are estrogens and dangerous drugs pursuant to Code section 4022.

12. Testosterone is an androgen hormone. It is a Schedule II controlled substance pursuant to H&S Code section 11056 and a dangerous drug pursuant to Code section 4022.

13. Progesterone is a hormone and a dangerous drug pursuant to Code section 4022.

14. Armour Thyroid is T-3/T-4 in fixed ratio and is a dangerous drug pursuant to Code section 4022.

15. Triest is a brand name for estriol + estradiol + estrone that are estrogens and dangerous drugs pursuant to Code section 4022.

CHARGES AND ALLEGATIONS

RESPONDENT MICHAEL LENZNER, RPH

First Cause for Discipline

(Unprofessional Conduct: Prescribing & Furnishing Prescriptions for Dangerous Drugs Without an Authorized Prescription & Without Written Policies, Procedures, or Protocols)

16. Respondent Lenzner, RPH is subject to disciplinary action under sections 4301(o) in conjunction with section 4052(a)(5)(A)(iv) because Lenzner initiated prescriptions that were furnished at Life Wellness for drug regiments for patients without policies, procedures, or protocols and without a prescription from a licensed prescriber as specified in the Business and Professions Code Section 4052 (a)(5)(A)(iv). The following prescriptions were written by Lenzner and dispensed at Life Wellness without an authorized prescription and without written policies, procedures or protocol from a physician:

A. For E.D. of Hollywood, Florida - On 4/16/04, two prescriptions were prescribed and written by Lenzner for this customer for Biest (70/30) 1.25mg + Progesterone 40mg Cream and for Estriol 2mg Vaginal Cream, that were not signed by the prescriber physician. The subsequent dispensing and furnishing from Life Wellness Pharmacy on RX 103490 for 30gm-Biest (70/30)/ Progesterone 1.25mg/40mg Cream and RX 103492 for 24gm-Estriol 0.2% Vaginal Cream was without authorization.

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B. For T.L. of San Bernardino, California - On 7/5/04, a prescription was prescribed and written by Lenzner for this customer that was not signed by a physician. The subsequent dispensing and furnishing at Life Wellness Pharmacy on RX 104801 for 15gm of Progesterone 5% Cream was without authorization.

C. For C.D. of San Diego, California - On 11/4/04, a prescription was prescribed and written with 3 refills by Lenzner for this customer for Biest (80/20) 2.5mg + Progesterone 40mg + Testosterone 0.5mg Cream (a schedule III controlled substance) that was not signed by a physician. The subsequent dispensing and furnishing from Life Wellness Pharmacy on RX 106634 for 30gm-Biest (80/20) 2.5mg + Progesterone 40mg + Testosterone 0.5mg Cream (a schedule III controlled substance) was without authorization.

Second Cause for Discipline

(Unprofessional Conduct: Dispensing Controlled Substances Without a Prescription)

17. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(j) and 4113(b) in conjunction with sections 4059 and H&S Code section 11164, because pharmacy staff dispensed controlled substances without a prescription as follows:

A. For R.D.L. of San Diego, California - on 1/5/04, RX C101017 was updated to RX C102476 but not re-written, and there are no written documents authorizing the dispensing of 30gm-Testosterone 0.4% Cream. On 7/20/04, RX C102476 was updated to RX C104779 but not re-written, and there were no written documents authorizing the dispensing of 30gm-Testosterone 0.4% Cream.

B. For C. D.M. of Fullerton, California - there were no signed documents authorizing the initial dispensing of this customer's 30gm-Testosterone 10%Cream on prescription RX 100196 for 2/3/03, and there was no re-written documentation or authorization for the subsequent dispensing on the updated prescriptions RX 100899 on 6/5/03 and again on the updated prescription RX 105032 on 8/2/04.

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Third Cause for Discipline

(Unprofessional Conduct: Dispensing a Dangerous Drug Without a Prescription)

18. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(o) in conjunction with section 4059 because he, either directly as the dispensing pharmacist or as the PIC in conjunction with section 4113(b), is responsible for the unauthorized dispensing of dangerous drugs without a prescription at Life Wellness Pharmacy by pharmacist Amanda Canales (formerly Camarigg) as follows:

A. For R.D.L. of San Diego, California - On 6/21/04, Rx 101016 was updated to RX 104240 for this customer's 30m-Triest (70-20-10)/Progesterone 2.5mg/100mg Cream, but there was no documentation or written prescription record authorizing the dispensing and furnishing.

B. For S.D. of Olivenhain, California - On 2/13/03, an unsigned medication order for S.D. from a naturopathic doctor requested Life Wellness Pharmacy to compound a combination of T-4/T-3 as T-4 as 9.5mcg and T-3 as 2.5mcg which was errantly compounded, dispensed and furnished on RX 100233.

C. For R.D. of Trabuco Canyon, California - On 8/10/04, an unsigned prescription was written by a naturopathic doctor for this customer for 30gm Estriol Vaginal Cream 0.5mg/gm with 3 refills. It was dispensed and furnished on 8/11/04 on prescription number RX 105200 with the prescriber labeled both as the naturopathic doctor and a physician, but the prescription order from the naturopathic doctor was not signed by the named physician or any other licensed prescriber.

D. For S.D. of Coronado, California - On 10/6/04, two unsigned prescriptions were written by a naturopathic doctor for this customer for #30 Armour Thyroid 60mg (1gr) and #30 Armour Thyroid 15mg (¼ gr). They were dispensed and furnished by PIC Lenzner on 10/7/04 on RX 106327 for Armour Thyroid ¼ gr and on RX 106328 for Armour Thyroid 1gr with the prescriber labeled both as the naturopathic doctor and a physician, but the prescription order from the naturopathic doctor was not signed by the named physician or any other licensed prescriber.

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Fourth Cause for Discipline

(Unprofessional Conduct: Unauthorized Refill Prescription Dispensing)

19. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(o) and 4113(b) in conjunction with section 4063 for the dispensing of unauthorized refill prescriptions, as more particularly alleged below:

A. For G.D. of New Vernon, New Jersey - On 9/30/04, RX 105173 for 30gm-Progesterone 4% Cream for this customer was dispensed without authorization.

B. For D.D. of Holtsville, New York - On 1/20/05, RX C107103 for Biest (80/20) 1.25mg + Progesterone 40mg + Testosterone 0.5mg (a schedule III controlled substance) was dispensed without authorization and shipped to this customer in Clearwater Florida.

C. For E.D. of Hollywood, Florida - The refills for this customer on RX 103490 for 30gm of Biest (70/30) /Progesterone 1.25mg/40mg were refilled without authorization on 5/25/04, 5/27/04, 6/24/04, 7/20/04, 8/30/04, and 9/23/04 and on RX 103492 for 24gm Estriol 0.2% Vaginal Cream were dispensed without authorization on 6/24/04 and 8/30/04.

D. For C.D.L. of San Clemente, California - On 12/23/04, the refill for this customer for prescription RX 106494 for 30gm-Biest (80/20)/DHEA/Testosterone 1.25/10/2mg/gm Cream (containing a schedule III controlled substance) was dispensed without authorization.

E. For R.D.L. of San Diego, California - The refills for this customer for 30gm-Testosterone 0.4% Cream on RX C102476 for 6/1/04 and 6/21/04 and on RX C104799 for 8/18/04 for the schedule III controlled substance and for 30m-Triest (70-20-10)/Progesterone 2.5mg/100mg Cream on RX104240 for 7/20/04 and 8/18/04 were dispensed without authorization.

F. For C.D.M. of Fullerton, California - There were no written documents authorizing the refill dispensing of this customer's 30gm-Testosterone 10% Cream for prescription RX 100196 on 3/11/03, 4/7/03, and 5/1/0; for prescription RX 100899 on 7/3/03, 8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, and 6/2/04; and for prescription RX 105032 on 9/30/04, 11/29/04, and 2/5/05 for the schedule III controlled substance.

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G. For M.D. of San Diego, California - On 1/19/05, the refill for this customer on RX 106996 for Progesterone 3% Cream was refilled without authorization.

H. For C.D. of San Diego, California -The refills for this customer on RX 106634 for Biest (80/20) 2.5mg + Progesterone 40mg + Testosterone 0.5mg Cream (a schedule III controlled substance) on 12/3/04, 1/6/05, and 2/9/05 were dispensed without authorization.

I. For E.D.R. of Port Jefferson, New York -The refills for this customer on RX 104332 for 15gm Progesterone 5% Cream on 11/8/04 and 12/20/04 were dispensed without authorization.

J. For A.D.P. of San Diego, California -The refills for this customer on RX 103685 for 1-30gm Progesterone 6% Cream dispensed on 8/26/04, for 2-30gm Progesterone 6% Cream dispensed on 10/25/04, and for 2-30gm Progesterone 6% Cream dispensed on 1/27/05 were dispensed without authorization.

K. For R.D. of Trabuco Canyon, California - On 10/15/04, the refill for this customer on RX 105200 for Estriol Vaginal Cream 0.5mg was dispensed without authorization.

L. For L.D. of Port Jefferson, New York - The refills for this customer dispensed on 11/22/04 and 12/21/04 for RX 106461 for 15gm of Progesterone 3% Cream and for RX 106462 for #60 T-3 SR 5mcg capsules were dispensed without authorization.

M. For T.L. of San Bernardino, California - The refills for this customer dispensed on 8/24/04, 9/24/04, 10/18/04, 11/15/04, and 1/25/05 for 15gm of Progesterone 5% Cream were dispensed without authorization.

Fifth Cause for Discipline

(Unprofessional Conduct: Dispensing of Medications of Uncertain Strength)

20. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(o) in conjunction with CCR section 1761(a) because Lenzner dispensed a prescription of uncertain strength in that he dispensed a prescription which contained a significant error, omission, irregularity, uncertainty, or alteration. Specifically, on 9/7/04 at Life Wellness, a prescription of T-3 was compounded using the compounding lot # 09072004@6 for the T-3 SR 7.5 mg capsules for customer S.D. of San Diego, California on RX 105840. This compound record was missing

during the Board's investigation, yet the customer's Universal Claim Form for a Compounded Medication prepared by Life Wellness on 9/7/04 showed the strength of the T-3 SR 7.5mcg capsules contained a 500% error. Additionally, the T-3 1:10 triturate used to compound the T-3 SR 7.5mcg capsules showed an errant triturate formula and calculations on their logged formula worksheets dated 6/30/04 and 1/12/05 and the expiration date placed on the prescription label for RX 105840 exceeded the 180 day limit.

Sixth Cause for Discipline

(Unprofessional Conduct: Incomplete & Erroneous Compounding Records for Future Use)

21. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(o) and 4113(b) in conjunction with CCR section 1716.2(a)(2),(3),(4),(6), and (8) in that a pharmacy, for the purpose of compounding for future dispensing, shall maintain records that include (2) the manufacturers lot number and expiration dates, (3) the expiration date not to exceed 180 days or the shortest expiration date of any component in the finished product, (4) signature or initials of the compounding pharmacist, (6) manufacturer's name of the raw ingredients, (8) package sized and the number of units prepared. Specifically, on 2/16/05 and on 3/11/05, during the complaint investigation at Life Wellness, many of the logged formula worksheets lacked the manufacturer's lot number and expiration dates; gave a one year expiration date to a finished compound instead of 180 days or the shortest expiration date of the ingredients; the compounding pharmacist failed to sign or initial the logged formula worksheet; the manufacturer's name of the active chemicals was omitted or inconsistent with inventory; and the units prepared were inaccurate. Furthermore, the pharmacy was compounding dangerous drugs from formulas containing errors that were noted in the Biest (80-20)/Prog/Test 0.625/50/1Cream and the stock formula called Tri-iodo-L-Thyronine (T3) 1:10 Triturate 10mg:1mg powder dated 6/30/04 and 1/12/05.

Seventh Cause for Discipline

(Unprofessional Conduct: Non-compliance With Maintaining Prescription Records)

22. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(o) and 4113(b) in conjunction with CCR section 1717(b) because he failed to maintain complete and readily retrievable prescription records. The date dispensed and the name or initials of the

dispensing pharmacist shall be on each prescription on file and readily retrievable. Specifically, on 2/16/05, 3/11/05, and 3/15/05, during the complaint investigation at Life Wellness, pharmacists did not initial the prescription documents or refill logs to identify the dispensing pharmacist, and the initials in the patient's drug history do not represent the actual dispensing pharmacist, (e.g., Amanda Camarigg's initials recorded on all new and refilled prescriptions in the computer for 3/11/05 but another pharmacist was the only pharmacist working on 3/11/05.)

Eighth Cause for Discipline

(Unprofessional Conduct: Non-compliance With Pharmacy Technician Supervision)

23. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(o), 4113(b), and 4115(f) and (g) because Lenzner was not compliant with the supervision of pharmacy technicians in that the performance of duties of a pharmacy technician shall be under the direct supervision and control of a pharmacist (§4115(f)) and a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing certain tasks (§4115(g)). Specifically, on 3/11/05 and again on 3/15/05 at Life Wellness, Lenzner scheduled only one pharmacist on duty to supervise two pharmacy technicians who were both compounding and filling prescriptions.

Ninth Cause for Discipline

(Unprofessional Conduct: Non-compliance with Patient Package Inserts for Estrogen Drug Products)

24. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(o), 4113(b) and Title 21 Code of Federal Regulations section 310.515(a) because at Life Wellness he failed to provide patient package inserts for compounded estrogen drug products required by Code of Federal Regulations, title 21, section 310.515(a). Specifically, during the inspections at Life Wellness, Lenzner stated on two separate occasions that he does not supply patient package inserts to patients receiving estrogen products compounded at the pharmacy.

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Tenth Cause for Discipline

(Unprofessional Conduct: Missing Disposition Records of Dangerous Drugs)

25. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(o) and 4113(b) in conjunction with section 4081(a) because Lenzner failed to maintain all prescription records as to disposition of dangerous drugs, as required by section 4081(a), as more particularly alleged below:

A. E.D.'s prescriptions - there were no disposition documents to substantiate the dispensing on 5/25/04 and 10/29/04 as noted in the patient profile for this customer for RX 103490.

B. R.D.L.'s original prescription for 30gm-Testosterone 0.4% Cream was dispensed on 6/18/03 on RX C101017 and then was updated on 1/5/04 to RX C102476, but there was no new written prescription document in this customer's chart. Then RX C102476 was updated on 7/20/04 to RX C104799 but there is no new written prescription document in the chart. Furthermore, the original prescription for 30m-Triest (70-20-10)/Progesterone 2.5mg/100mg Cream was dispensed on 6/18/03 and then was updated on 6/21/04 to RX104240, but there is no new re-written prescription in this customer's chart.

C. C.D.M.'s original prescription document was not signed by his physician yet 30gm-Testosterone 10% (100mg/gm) Cream was dispensed on RX 100196 on 2/3/03, 3/11/03, 4/7/03 and 5/1/03 until RX 100196 was updated to RX 100899. There was no new re-written or original prescription documents to substantiate the dispensing of RX100899 for the Testosterone 10% (100mg/gm) Cream filled on 6/5/2003, 7/3/03, 8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, and 6/2/04 until RX 100899 was updated to 105032, and there is no new re-written or original prescription documents to substantiate the dispensing of RX105032 for the Testosterone 10% (100mg/gm) Cream filled on 8/2/04, 9/30/04, 11/29/04, and 2/5/05.

Eleventh Cause for Discipline

(Unprofessional Conduct: Practice in Violation of H&S Code section 11200)

26. PIC Respondent Lenzner is subject to disciplinary action under sections 4301(j) and 4113(b) in conjunction with H&S Code section 11200(a) and (b) because Lenzner is

responsible for the pharmacy staff dispensing controlled substance prescriptions beyond six months and exceeding five refills, as specified in Health and Safety Code Section 11200(a) & (b). Specifically, the dispensing records for customer C.D.M.'s 30gm-Testosterone 10% (100mg/gm) Cream were without prescription documents or authorization records but showed RX 100899 was dispensed on 6/5/03, 7/3/03, 8/5/03, 9/30/03, 11/13/03, 1/23/04, 3/25/04, and 6/2/04, which exceeds the five refill maximum and is beyond six months.

Twelfth Cause for Discipline

(Unprofessional Conduct: Dispensing Error)

27. Respondent Lenzner, RPH is subject to disciplinary action under section 4301(o) in conjunction with CCR sections 1716 and 1761 in that no pharmacist shall dispense any prescription which contains any significant error, omission, irregularity, uncertainty, or alterations. Specifically, on 2/13/03 at Life Wellness Pharmacy, an unsigned medication order for S.D. from a naturopathic doctor requested Life Wellness to compound T-4/T-3 in the ratio and strengths of T-4 as 9.5mcg and T-3 as 2.5mcg but the pharmacy dispensed on 2/13/04 on RX 100233 the compounded formulation as T-3 as 2.5mcg and T-4 as 25mcg. When a physician did sign the medication order the following day on 2/14/03, that physician did not change the original medication order request.

RESPONDENT AMANDA L. CANALES

Thirteenth Cause for Discipline

(Unprofessional Conduct: Prescribing & Furnishing Prescriptions for Dangerous Drugs Without an Authorized Prescription & Without Written Policies, Procedures, or Protocols)

28. Respondent Amanda Canales (formerly Camarigg), RPH is subject to disciplinary action under sections 4301(o) in conjunction with section 4052(a)(5)(A)(iv), because she initiated prescriptions that were furnished at Life Wellness Pharmacy for drug regiments for patients without policies, procedures, or protocols and without a prescription from a licensed prescriber, as more particularly alleged below:

A. For M.D. of San Diego, California - On 12/15/04, a prescription was prescribed and written by Amanda Camarigg and dispensed at Life Wellness Pharmacy for this customer for

Progesterone 3% Cream on prescription number RX 106997 that was not signed by an authorized prescriber, and there was no documented authorization from a prescriber.

B. For L.D. of Port Jefferson, New York - On 10/19/04, two prescriptions were prescribed and written by Amanda Camarigg for this customer that were not signed by a physician; on 10/20/04 RX 106461 for 15gm of Progesterone 3% Cream and RX 106462 for #60 T-3 SR 5mcg capsules were dispensed and furnished to this customer without authorization until a 1/12/05 fax request, which resulted in a physician signing and erroneously dating it as 10/20/05.

C. For D. D. of Holtsville, New York - On 12/21/04 a new prescription was prescribed and written by Amanda Camarigg that changed the Biest (80/20) 2.5mg to Biest (80/20) 1.25mg in the compounded prescription of Biest (80/20) 1.25mg + Progesterone 40mg + Testosterone 0.5mg (a schedule III controlled substance). This was dispensed on RX C107103, which was unsigned and without a prescriber's name, signature, DEA number, or agent on the document.

D. For C.D.L. of San Clemente, California - On 10/19/04, two new prescriptions were prescribed and written by Amanda Camarigg for this customer: on 10/25/04, the first fax for authorization was sent to a physician, but the two prescriptions were dispensed without authorization that day on RX 106494 for 30gm-Biest(80/20)/DHEA/Testosterone 1.25/10/2mg/gm Cream (a schedule III controlled substance) and on RX 106493 for 15gm-Progesterone 3% Cream.

RESPONDENT LIFE WELLNESS PHARMACY, INC.

Fourteenth Cause for Discipline

(Liability of Life Wellness Pharmacy, Inc.)

29. Respondent Life Wellness Pharmacy, Inc. is subject to disciplinary action under section 4156 based on the acts and omissions alleged above in paragraphs 16 through 28, which are realleged and incorporated herein by reference.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Original Pharmacy Permit No. PHY 45971, issued to Life Wellness Pharmacy, Inc., d.b.a. Life Wellness Pharmacy, Inc., President, Michael Lenzner;

2. Revoking or suspending Pharmacist License No. RPH 33245, issued to Michael Lenzner, RPH;

3. Revoking or suspending Pharmacist License No. RPH 44504, issued to Amanda L. Canales, RPH, a.k.a. Amanda L. Camarigg;

4. Ordering Life Wellness Pharmacy, Inc., and/or Michael Lenzner, RPH, individually, and Amanda Canales to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

5. Taking such other and further action as deemed necessary and proper.

DATED: 6/6/07

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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