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

In the Matter of the Accusation Against:	Case No. 4643
INLAND COMPOUNDING PHARMACY 24747 Redlands Blvd., #F Loma Linda, CA 92354 **Pharmacy Permit No. PHY 45758** and **RAYLENE LOUISE MOTE** 24747 Redlands Blvd., #F Loma Linda, CA 92354 **Pharmacist License No. RPH 30439** Respondents.	OAH No. 2015030299 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RAYLENE LOUISE MOTE ONLY**

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 March 11, 2016.

It is so ORDERED on February 10, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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In the Matter of the Accusation Against: **INLAND COMPOUNDING PHARMACY** 24747 Redlands Blvd., #F Loma Linda, CA 92354 **Pharmacy Permit No. PHY 45758** and **RAYLENE LOUISE MOTE** 24747 Redlands Blvd., #F Loma Linda, CA 92354 **Pharmacist License No. RPH 30439** Respondents.	Case No. 4643 OAH No. 2015030299 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RAYLENE LOUISE MOTE ONLY**

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 (Board), Department of Consumer Affairs. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Bora S. McCutcheon, Deputy Attorney General.

2. Respondents Inland Compounding Pharmacy and Raylene Louise Mote (collective, Respondents) are represented in this proceeding by attorney Tony J. Park, whose address is: California Pharmacy Lawyers, 2855 Michelle Drive, Suite 180, Irvine, CA 92606-1027.

3. On or about February 8, 2002, the Board issued Pharmacy Permit No. PHY 45758 to Inland Compounding Pharmacy Inc., doing business as Inland Compounding Pharmacy (Respondent ICP) with Gordon E. Mote as the President/Treasurer and Raylene Mote as the Secretary and Pharmacist-in-Charge. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 4643 and will expire on February 1, 2016, unless renewed.

4. On or about August 5, 1976, the Board issued Pharmacist License Number RPH 30439 to Raylene Louise Mote (Respondent Mote). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2016, unless renewed.

JURISDICTION

5. Accusation No. 4643 was filed before the Board and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on February 11, 2015. Respondents timely filed a Notice of Defense contesting the Accusation.

6. A copy of Accusation No. 4643 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondent Mote has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4643. Respondent Mote has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

8. Respondent Mote 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.

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

CULPABILITY

10. Respondent Mote understands and agrees that the charges and allegations in Accusation No. 4643, if proven at a hearing, constitute cause for imposing discipline upon her Pharmacist License.

11. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent Mote agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent Mote hereby gives up her right to contest those charges.

12. Respondent Mote agrees that her Pharmacist License is subject to discipline and she agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board. Respondent Mote understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent Mote or her counsel. By signing the stipulation, Respondent Mote understands and agrees that she may not withdraw her 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.

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14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

16. 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:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 30439 issued to Respondent Mote is revoked. However, the revocation is stayed and Respondent Mote is placed on probation for three (3) years on the following terms and conditions.

1. **Obey All Laws**

Respondent Mote shall obey all state and federal laws and regulations.

Respondent Mote shall report any of the following occurrences to the board, in writing, within seventy-two (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 contendre 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 or federal agency which involves Respondent Mote's pharmacist license or which is related to the

practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. **Report to the Board**

Respondent Mote shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent Mote shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent Mote shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. **Cooperate with Board Staff**

Respondent Mote shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of her probation. Failure to cooperate shall be considered a violation of probation.

5. **Continuing Education**

Respondent Mote shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

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6. **Notice to Employers**

During the period of probation, Respondent Mote shall notify all present and prospective employers of the decision in case number 4643 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, Respondent Mote shall cause her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4643, and terms and conditions imposed thereby. It shall be Respondent Mote's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If Respondent Mote works for or is employed by or through a pharmacy employment service, Respondent Mote must notify her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 4643 in advance of Respondent Mote commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent Mote undertaking any new employment by or through a pharmacy employment service, Respondent Mote shall cause her direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that she has read the decision in case number 4643 and the terms and conditions imposed thereby. It shall be Respondent Mote's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for

which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. **No Supervision of Interns or Serving as a Consultant**

During the period of probation, Respondent Mote shall not supervise any intern pharmacist or be the designated representative-in-charge of any entity licensed by the Board, nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. **Reimbursement of Board Costs**

As a condition precedent to successful completion of probation, Respondent Mote shall pay to the board its costs of investigation and prosecution in the amount of $9,359.50. Respondents shall be jointly and severally liable to pay this amount and shall make said payments according to a payment plan approved by the Board or its designee. There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

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

9. **Probation Monitoring Costs**

Respondent Mote shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. **Status of License**

Respondent Mote 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. Failure to maintain an active, current license shall be considered a violation of probation.

If Respondent Mote's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise,

upon renewal or reapplication Respondent Mote's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent Mote cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent Mote may tender her license to the board for surrender. The board or its designee 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 Mote will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of Respondent Mote's license history with the board.

Upon acceptance of the surrender, Respondent Mote shall relinquish her pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent Mote may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent Mote shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

12. **Notification of a Change in Name, Residence Address, Mailing Address or Employment**

Respondent Mote shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent Mote shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

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13. **Tolling of Probation**

Except during periods of suspension, Respondent Mote shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should Respondent Mote, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, Respondent Mote must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent Mote's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which Respondent Mote is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code, section 4000, et seq . "Resumption of practice" means any calendar month during which Respondent Mote is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code, section 4000, et seq.

14. **Violation of Probation**

If a Respondent Mote has not complied with any term or condition of probation, the board shall have continuing jurisdiction over Respondent Mote, 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 that was stayed.

If Respondent Mote 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

that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against Respondent Mote during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in the Accusation shall be deemed true and correct.

15. **Completion of Probation**

Upon written notice by the board or its designee indicating successful completion of probation, Respondent Mote's license will be fully restored.

16. **Remedial Education**

Within 60 days of the effective date of this decision, Respondent Mote shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to the grounds for discipline. The program of remedial education shall consist of at least 10 hours, which shall be completed within 30 months at Respondent Mote's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require Respondent Mote, at her own expense, to take an approved examination to test Respondent Mote's knowledge of the course. If Respondent Mote does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require Respondent Mote to take another course approved by the board in the same subject area.

17. **No New Ownership of Licensed Premises**

Respondent Mote shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any

additional business, firm, partnership, or corporation licensed by the board. If Respondent Mote currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, Respondent Mote may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

18. **Consultant for Owner or Pharmacist-In-Charge**

During the period of probation, Respondent Mote shall not supervise any intern pharmacist, or serve as a consultant to any entity licensed by the board. In the event that Respondent Mote is currently the pharmacist-in-charge (PIC) of a pharmacy, the pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent Mote with state and federal laws and regulations governing the practice of pharmacy and for compliance by Respondent Mote with the obligations of a pharmacist-in-charge. The monthly reviews may be reduced to quarterly reviews at the discretion of the Board of its designee. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval within thirty (30) days of the effective date of this decision. Respondent Mote shall not be a PIC at more than one pharmacy or at any pharmacy of which she is not the current PIC. The board may, in case of an employment change by Respondent Mote or for other reasons as deemed appropriate by the board or its designee, preclude Respondent Mote from acting as a PIC. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tony J. Park. 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: 10/30/15

Raylene Louise Mote

INLAND COMPOUNDING PHARMACY;
RAYLENE LOUISE MOTE
Respondent

I have read and fully discussed with Respondent Inland Compounding Pharmacy; Raylene Louise Mote the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 10/30/2015

Tony J. Park
Attorney for Respondent

ENDORSEMENT

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

Dated: 11/2/15

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
LINDA L. SUN
Supervising Deputy Attorney General

BORA S. MCCUTCHEON
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4643

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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 February 8, 2002, the Board of Pharmacy (Board) issued Permit Number PHY 45758 to Inland Compounding Pharmacy Inc., doing business as Inland Compounding Pharmacy (ICP) with Gordon D. Mote as the President/Treasurer and Raylene Mote as the

Secretary and Pharmacist-in-Charge. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2014, unless renewed.

3. On or about August 5, 1976, the Board issued Pharmacist License Number RPH 30439 to Raylene Louise Mote. The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2014, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board, under the authority of the following laws.

5. Business and Professions Code section 4011[1] provides that the Board shall administer and enforce both the Pharmacy Law [Bus. and Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health and Saf. Code, § 11000 et seq.].

6. Section 4300, subdivision (a) provides that every license issued by the Board may be suspended or revoked.

7. Section 4300.1 states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

8. Section 4033, subdivision (a)(1), defines the terms "manufacturer" as "every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

9. Section 4113, subdivision (c), states, "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."

[1] All further statutory references are to the Business and Professions Code unless otherwise indicated.

10. Section 4301 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:

. . .

(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.

11. Section 4025 states:

"Drug" means any of the following:

(a) Articles recognized in the official United States Pharmacopoeia, official National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement of any of them.

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(c) Articles (other than food) intended to affect the structure or any function of the body of humans or other animals.

(d) Articles intended for use as a component of any article specified in subdivision (a), (b), or (c).

12. Health and Safety Code section 111550 provides,

No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

(a) It is one of the following:

(1) A new drug, and a new drug application has been approved for it and tat approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).

. . .

(b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended . . . .

13. Section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(p)) provides, in pertinent part:

(p) The term "new drug" means--

(1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . .

(2) Any drug . . .the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

14. Section 505 of the Act (21 U.S.C. § 355) provides, in pertinent part, "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."

REGULATORY PROVISIONS

15. California Code of Regulations, title 16, section 1735, subdivision (a), states in pertinent part:

"Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a drug product from chemicals or bulk drug substances

COST RECOVERY

16. Section 125.3 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.

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DRUG: DOMPERIDONE

17. Domperidone is an anti-dopaminergic drug that acts as an antiemetic and a prokinetic agent. It is widely used in many countries, but it is not a drug approved by the Food and Drug Administration (FDA) in the United States.

FACTUAL ALLEGATIONS

18. On June 7, 2004, the FDA issued a talk paper titled, "FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase Milk Production." The paper stated in pertinent part that domperidone is an "unapproved drug" and that it is "not approved in the U.S. for any indication." It also warned breast feeding women not to use the product because of safety concerns, and that FDA field personnel were alerted to be on the lookout for attempts to import domperidone so it could be detained. The talk paper indicated that the FDA issued six letters to pharmacies that compound products containing domperidone and firms that supply domperidone for use in compounding. The paper stated, "[t]he letters issued by FDA today stated that all drug products containing domperidone (whether compounded or not) violate the Federal Food, Drug, and Cosmetic Act (the Act) because they are unapproved new drugs and misbranded. In addition, distribution within the U.S., or importation of domperidone-containing products, violates the law."

19. On June 7, 2004, the FDA issued warning letters to several pharmacy owners and Spectrum Chemicals & Laboratory Products regarding the compounding of domperidone. The letters explained the health risks associated with domperidone, and stated that all products compounded and containing domperidone are new drugs since they are not generally recognized by qualified experts as safe and effective for their labeled use. The letters also explained that domperidone was not an active ingredient contained in any FDA approved drug product and that the FDA did not sanction its use in pharmacy compounding. Specifically, the letters stated that domperidone products are new drugs as defined by Section 201(p) (21 U.S.C. § 321(p)) of the Act, there was no approved application pursuant to Section 505 of the Act (21 U.S.C. § 355) effective with respect to domperidone, and that introduction or delivery for introduction into interstate commerce of domperidone is a violation of the law.

20. On April 9, 2010, the FDA issued a warning letter to Alexandria Medical Arts Pharmacy & Compounding Laboratory regarding the compounding of domperidone. The warning letter explained the Act as it relates to compounded drugs and FDA's regulatory approach to compounding. This warning letter also provided a factual background regarding compounding drugs using domperidone, explained that domperidone products are new drugs as defined by Section 201(p) (21 U.S.C. § 321(p)) of the Act, and stated that compounding drugs using domperidone was inappropriate. The letter stated, "[Domperidone] products may not be introduced or delivered into interstate commerce under section 505(a) of the FDCA [21 U.S.C. § 355(a)] because no approval of an application filed pursuant to section 505 of the FDCA [21 U.S.C. § 335] is in effect for these products. Their introduction or delivery for introduction into interstate commerce violates section 301(d) of the FDCA [21 U.S.C. § 331(a)]."

21. On March 18, 2011, the FDA issued an import alert for domperidone indicating the agency learned domperidone was being imported as a bulk active pharmaceutical ingredient for pharmacy compounding and presented a public health risk and violated the Act.

22. On June 17, 2011, the Board received an anonymous online complaint alleging Inland Compounding Pharmacy compounded domperidone, which was not an FDA-approved drug.

23. On February 16, 2012, Board Inspectors conducted a routine inspection and complaint investigation at ICP. Respondent Mote was present and assisted with the investigation. During the inspection, a Board Inspector inspected the pharmacy's compounding areas and found domperidone bulk powder. The Inspector asked if the pharmacy compounded domperidone and Pharmacy Technician M.M. retrieved completed domperidone capsules prepared by the pharmacy. Board Inspectors requested and received the master formula for domperidone 10 mg capsules provided by Professional Compounding Centers of America and the original compounding worksheets for the domperidone 10 mg and 20 mg capsules compounded by the pharmacy.

24. A Board Inspector informed Respondent Mote that domperidone was not FDA approved and showed Respondent Mote copies of FDA warning letters dated June 7, 2004. Respondent Mote admitted that the pharmacy compounded domperidone pursuant to a

prescription. ICP dispensed approximately 236 prescriptions of compounded domperidone to patients.

25. Based on the investigation, a Board Inspector determined that from on or about February 17, 2009 to on or about February 16, 2012, while Respondent Mote was the pharmacist-in-charge, Respondent ICP dispensed approximately 236 domperidone prescriptions to patients which were compounded from the unapproved drug, domperidone.

26. On March 12, 2012, the FDA issued a revised import alert for domperidone. This revised import alert stated that ". . . domperidone is not appropriate for pharmacy compounding use because this bulk active ingredient is not a component of an FDA approved drug, or is a component of a drug that was withdrawn or removed from the market for safety reasons."

FIRST CAUSE FOR DISCIPLINE

(Violation of Federal Regulation Governing Pharmacy)

27. Respondents ICP and Mote are subject to disciplinary action under Section 4301, subdivision (o), in that Respondents violated a Federal regulation by compounding and distributing an unapproved drug, to wit: domperidone.

28. Section 505 of the Act (21 U.S.C. § 355) states, "No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed . . . is effective with respect to such drug." On or about February 17, 2009 to on or about February 16, 2012, while Respondent Mote was the pharmacist-in-charge, Respondent ICP dispensed approximately 236 domperidone prescriptions to patients which Respondents compounded from the unapproved drug, domperidone. Respondent unlawfully introduced or delivered for introduction into interstate commerce a new drug in violation of the Act by compounding and distributing domperidone when there was not an approval of an application filed with respect to the drug. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18–25, inclusive.

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SECOND CAUSE FOR DISCIPLINE

(Violation of State Law Governing Pharmacy)

29. Respondents ICP and Mote are subject to disciplinary action under Section 4301, subdivision (o), in that Respondents violated Health and Safety Code section 111550 by selling, delivering, or giving away a new drug unapproved by the FDA, to wit: domperidone.

30. On or about February 17, 2009 to on or about February 16, 2012, while Respondent Mote was the pharmacist-in-charge, Respondent ICP dispensed approximately 236 domperidone prescriptions to patients which Respondents compounded from the unapproved drug, domperidone. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18–25, inclusive.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 45758, issued to Inland Compounding Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 30439, issued to Raylene Louise Mote;

3. Ordering Respondents ICP and Mote 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;

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

DATED: 1/17/15

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

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