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

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 **A C C U S A T I O N**

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."

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[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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