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

In the Matter of the Accusation Against: **INNOVRX INC. DBA MED SPECIALTIES COMPOUNDING PHARMACY** **4862 Olinda Street** **Yorba Linda, CA 92886** **Pharmacy Permit No. PHY 44221** **Sterile Compounding License No. LSC 99056** **MARK ANTHONY GONZALEZ** **4862 Olinda Street** **Yorba Linda, CA 92886** **Pharmacist License No. RPH 50523** Respondents.	Case No. 5898 **ACCUSATION**

Complainant alleges:

PARTIES

1. Virginia K. 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 August 29, 1999, the Board of Pharmacy issued Pharmacy Permit Number PHY 44221 to Innovrx Inc., doing business as Med Specialties Compounding Pharmacy

(Med Specialties Compounding Pharmacy). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2017, unless renewed. Mark Anthony Gonzalez was and is the fifty one percent owner of Med Specialties Compounding Pharmacy.

3. On or about June 3, 2004, the Board of Pharmacy issued Sterile Compounding License Number LSC 99056 to Med Specialties Compounding Pharmacy. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2017, unless renewed.

4. On or about October 19, 1998, the Board of Pharmacy issued Pharmacist License Number RPH 50523 to Mark Anthony Gonzalez (Mark Gonzalez). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on February 28, 2018, 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. All section references are to the Business and Professions Code unless otherwise indicated.

6. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

7. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

8. Section 4300.1 of the Code 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

9. Section 4013(a) of the Code states:

> Any facility licensed by the board shall join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.

10. Section 4113, subdivision (c) of the Code 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."

11. Section 4169(a)(3) states;

> (a) A person or entity shall not do any of the following:
>
> . . .
>
> (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

12. 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.
>
> . . . .

13. Section 4307(a) of the Code states that:

> Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer,

director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

14. Health and Safety Code section 111335 provides that any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290.)

15. Health and Safety Code section 111400 provides that any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

16. Health and Safety Code section 111440 provides that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

17. Health and Safety Code section 111450 provides that it is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

18. Title 21 United States Code section 352 states:

A Drug or device shall be deemed to be misbranded—

...

(f) Directions for use and warnings on label

Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords

such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

. . .

REGULATORY PROVISIONS

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

> "Compounding" means any of the following activates 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

20. Section 125.3 of the Code provides, 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.

DRUG

21. Domperidone is a drug not approved for use in humans in the United States by the Food and Drug Administration. Drug products compounded using domperiodone are subject to the approval requirements of the Federal Food, Drug and Cosmetic Act.

FACTUAL ALLEGATIONS

22. At all times relevant herein, Respondent Mark Gonzalez has been and is the Pharmacist-in-Charge (PIC) of Respondent Med Specialties Compounding Pharmacy Compounding.

23. 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 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."

24. 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 and stated that compounding drugs using domperiodone was inappropriate.

25. 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.

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."

27. On or about April 14, 2015, the Board sent a subscriber alert, providing notice to licensees that "domperidone is not FDA-approved for any use in humans in the United States. Drug products compounded using domperidone are subject to the approval requirements of the federal Food, Drug and Cosmetic Act."

28. Respondents did not possess a FDA-approved Investigational New Drug application, allowing them expanded access for domperiodone.

29. From March 4, 2014 through March 30, 2015, Respondents compounded and dispensed 4610 capsules of domperidone ranging in strengths from 5mg to 30mg, 66 suspensions

of domperidone ranging in strengths from 1mg/ml to 30mg/ml and various units between 30 and 1030 to patients.

FIRST CAUSE FOR DISCIPLINE

(Sold Misbranded Drugs)

30. Respondents are subject to disciplinary action under Code section 4301(j) for violating statutes regulating controlled substances and dangerous drugs, in that Respondents sold misbranded drugs, as defined by Health & Safety Code section 111400 and United States Code, title 21, section 352(f) in violation of Health and Safety Code section 111440, as set forth in paragraphs 22 through 29, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Delivered or Proffered for Delivery Misbranded Drugs)

31. Respondents are subject to disciplinary action under Code section 4301(j), for violating statutes regulating controlled substances and dangerous drugs, in that Respondents delivered or proffered for delivery misbranded drugs, as defined by Health & Safety Code section 111400, in violation of Health and Safety Code section 111450, as set forth in paragraphs 22 through 29, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Commission of Prohibited Acts)

32. Respondents are subject to disciplinary action under Code sections 4301(o) and/or 4169(a)(3), and Health and Safety Code section 11335, in that Respondents purchased domperidone powder and dispensed compounded drug capsules containing domperidone without having an approved Investigational New Drug application on file, as set forth in paragraphs 21 through 28, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

33. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities described in paragraphs 21 through 28 above, which are incorporated herein by reference.

OTHER MATTERS

34. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 44221 and Sterile Compounding License Number LSC 99056 issued to Innovrx Inc. doing business as Med Specialties Compounding Pharmacy, Innovrx Inc. doing business as Med Specialties Compounding Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 are placed on probation or until Pharmacy Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 are reinstated if they are revoked.

35. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 44221 and Sterile Compounding License Number LSC 99056 issued to Innovrx Inc. doing business as Med Specialties Compounding Pharmacy while Mark Anthony Gonzalez has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Mark Anthony Gonzalez shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 placed on probation or until Pharmacy Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 are reinstated if they are revoked.

36. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 50523 issued to Mark Anthony Gonzalez, Mark Anthony Gonzalez shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 50523 is placed on probation or until Pharmacist License Number RPH 50523 is reinstated if it is revoked.

DISCIPLINARY CONSIDERATIONS

37. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about July 2, 2014, the Board issued Modified Citation Numbers CI 2012 55089 and CI 2013 58136 and fines against Med Specialties Compounding Pharmacy and Mark Gonzalez for violating California Code of Regulations, title 16, section 1735.2(a)(1), in

that they compounded drugs prior to receipt of valid prescriptions for individual patients and Business and Professions Code sections 4081(a) and 4105(a) for failure to maintain accurate records of acquisition and disposition for phentermine powder in December 2011. They paid the fines.

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 Pharmacy Permit Number PHY 44221, issued to Innovrx Inc. doing business as Med Specialties Compounding Pharmacy;

2. Revoking or suspending Sterile Compounding License Number LSC 99056, issued to Innovrx Inc. doing business as Med Specialties Compounding Pharmacy;

3. Revoking or suspending Pharmacist License Number RPH 50523, issued to Mark Anthony Gonzalez;

4. Prohibiting Innovrx Inc. doing business as Med Specialties Compounding Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 are placed on probation or until Pharmacy Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 are reinstated if Pharmacy Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 issued to Innovrx Inc. doing business as Med Specialties Compounding Pharmacy are revoked;

5. Prohibiting Mark Anthony Gonzalez from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 are placed on probation or until Pharmacy Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 are reinstated if Pharmacy Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 issued to Innovrx Inc. doing business as Med Specialties Compounding Pharmacy are revoked;

6. Prohibiting Mark Anthony Gonzalez from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 50523 is placed on probation or until Pharmacist License Number RPH 50523 is reinstated if Pharmacist License Number RPH 50523 issued to Mark Anthony Gonzalez is revoked;

7. Ordering Innovrx Inc. doing business as Med Specialties Compounding Pharmacy and Mark Anthony Gonzalez 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;

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

DATED: 7/30/16

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

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