

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

In the Matter of the Accusation Against:

INNOVRX INC. DBA MED SPECIALITIES
4862 Olinda Street
Yorba Linda, CA 92886

Pharmacy Permit No. PHY 44221
Sterile Compounding License No. LSC 99056

And

MARK ANTHONY GONZALEZ
4862 Olinda Street
Yorba Linda, CA 92886

Pharmacist License No. RPH 50523

Respondents.

Case No. 5898

OAH No. 2016120090

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on May 17, 2017.

It is so ORDERED on April 17, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

1 XAVIER BECERRA
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 DESIREE I. KELLOGG
Deputy Attorney General
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Attorneys for Complainant

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9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

12 **INNOVRX INC. DBA MED SPECIALTIES**
13 **COMPOUNDING PHARMACY**

14 4862 Olinda Street
Yorba Linda, CA 92886

15 Pharmacy Permit No. PHY 44221
16 Sterile Compounding License No. LSC
99056

17 **MARK ANTHONY GONZALEZ**
18 4862 Olinda Street

Yorba Linda, CA 92886

19 Pharmacist License No. RPH 50523

20 Respondents.

Case No. 5898

OAH No. 2016120090

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER FOR PUBLIC
REPROVAL**

[Bus. & Prof. Code § 495]

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

25 PARTIES

26 1. Virginia K. Herold (Complainant) is the Executive Officer of the Board of Pharmacy
27 (Board). She brought this action solely in her official capacity and is represented in this matter by
28

1 Xavier Becerra, Attorney General of the State of California, by Desiree I. Kellogg, Deputy
2 Attorney General.

3 2. Respondents Innovrx Inc. dba Med Specialties Compounding Pharmacy and Mark
4 Anthony Gonzalez are represented in this proceeding by attorney Ivan Petrzelka, Pharm.D., J.D.
5 of California Pharmacy Lawyers whose address is: 2855 Michelle Drive, Suite 180, Irvine, CA
6 92606-1027.

7 JURISDICTION

8 3. On or about August 29, 1999, the Board of Pharmacy issued Pharmacy Permit
9 Number PHY 44221 to Innovrx Inc., doing business as Med Specialties Compounding Pharmacy
10 (Med Specialties Compounding Pharmacy). The Pharmacy Permit was in full force and effect at
11 all times relevant to the charges brought herein and will expire on April 1, 2017, unless renewed.
12 Mark Anthony Gonzalez was and is the fifty one percent owner of Med Specialties Compounding
13 Pharmacy.

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

18 5. On or about October 19, 1998, the Board of Pharmacy issued Pharmacist License
19 Number RPH 50523 to Mark Anthony Gonzalez (Mark Gonzalez). The Pharmacist License was
20 in full force and effect at all times relevant to the charges brought herein and will expire on
21 February 28, 2018, unless renewed.

22 6. Accusation No. 5898 was filed before the Board of Pharmacy (Board), Department of
23 Consumer Affairs and is currently pending against Respondents. The Accusation and all other
24 statutorily required documents were properly served on Respondents on August 11, 2016.
25 Respondents timely filed their Notice of Defense contesting the Accusation. A copy of
26 Accusation No. 5898 is attached as exhibit A and incorporated herein by reference.
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ADVISEMENT AND WAIVERS

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2 7. Respondents have carefully read, fully discussed with counsel, and understands the
3 charges and allegations in Accusation No. 5898. Respondents have also carefully read, fully
4 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
5 Order for Public Repeval.

6 8. Respondents are fully aware of their legal rights in this matter, including the right to a
7 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine
8 the witnesses against them; the right to present evidence and to testify on its own behalf; the right
9 to the issuance of subpoenas to compel the attendance of witnesses and the production of
10 documents; the right to reconsideration and court review of an adverse decision; and all other
11 rights accorded by the California Administrative Procedure Act and other applicable laws.

12 9. Respondents voluntarily, knowingly, and intelligently waives and gives up each and
13 every right set forth above.

CULPABILITY

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15 10. Respondents understand and agree that the charges and allegations in Accusation No.
16 5898, if proven at a hearing, constitute cause for imposing discipline upon their respective
17 Pharmacy Permit, Sterile Compounding License and Pharmacist License.

18 11. For the purpose of resolving the Accusation without the expense and uncertainty of
19 further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual
20 basis for the charges in the Accusation, and that Respondents hereby give up their rights to
21 contest those charges.

22 12. Respondents agree that their respective Pharmacy Permit, Pharmacist License and
23 Sterile Compounding License are subject to discipline and they agree to be bound by the
24 Disciplinary Order below.

CONTINGENCY

25
26 13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents
27 understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may
28 communicate directly with the Board regarding this stipulation and settlement, without notice to

1 or participation by Respondents or their counsel. By signing the stipulation, Respondents
2 understand and agree that they may not withdraw their agreement or seek to rescind the
3 stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this
4 stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public
5 Repeval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any
6 legal action between the parties, and the Board shall not be disqualified from further action by
7 having considered this matter.

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

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

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

22 **DISCIPLINARY ORDER**

23 IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 44221 issued to Innovrx Inc.,
24 doing business as Med Specialties Compounding Pharmacy, Pharmacist License No. RPH 50523
25 issued to Mark Anthony Gonzalez, and Sterile Compounding License No. 99056 issued to
26 Innovrx Inc., doing business as Med Specialties Compounding Pharmacy shall be publicly
27 reprovred by the Board of Pharmacy under Business and Professions Code section 495 in
28 resolution of Accusation No. 5898, attached as exhibit A.

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ENDORSEMENT

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

DATED: 3/13/17

Respectfully submitted,
XAVIER BECERRA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General

DESIREE J. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5898

1 KAMALA D. HARRIS
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9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

Case No. 5898

12 **INNOVRX INC. DBA MED SPECIALTIES**
13 **COMPOUNDING PHARMACY**
14 **4862 Olinda Street**
Yorba Linda, CA 92886

ACCUSATION

15 **Pharmacy Permit No. PHY 44221**
16 **Sterile Compounding License No. LSC**
99056

17 **MARK ANTHONY GONZALEZ**
18 **4862 Olinda Street**
Yorba Linda, CA 92886

19 **Pharmacist License No. RPH 50523**

20 Respondents.

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22
23 Complainant alleges:

24 **PARTIES**

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

27 2. On or about August 29, 1999, the Board of Pharmacy issued Pharmacy Permit
28 Number PHY 44221 to Innovrx Inc., doing business as Med Specialties Compounding Pharmacy

1 (Med Specialties Compounding Pharmacy). The Pharmacy Permit was in full force and effect at
2 all times relevant to the charges brought herein and will expire on April 1, 2017, unless renewed.

3 Mark Anthony Gonzalez was and is the fifty one percent owner of Med Specialties
4 Compounding Pharmacy.

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

9 4. On or about October 19, 1998, the Board of Pharmacy issued Pharmacist License
10 Number RPH 50523 to Mark Anthony Gonzalez (Mark Gonzalez). The Pharmacist License was
11 in full force and effect at all times relevant to the charges brought herein and will expire on
12 February 28, 2018, unless renewed.

13 JURISDICTION

14 5. This Accusation is brought before the Board of Pharmacy (Board), Department of
15 Consumer Affairs, under the authority of the following laws. All section references are to the
16 Business and Professions Code unless otherwise indicated.

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

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

22 8. Section 4300.1 of the Code states:

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

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

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

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

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

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

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

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

24 18. Title 21 United States Code section 352 states:

25 A Drug or device shall be deemed to be misbranded—

26 ...

27 (f) Directions for use and warnings on label

28 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

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

3 **REGULATORY PROVISIONS**

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

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

- 9 (1) Altering the dosage form or delivery system of a drug
10 (2) Altering the strength of a drug
11 (3) Combining components or active ingredients
12 (4) Preparing a drug product from chemicals or bulk drug substances

13 **COST RECOVERY**

14 20. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
15 administrative law judge to direct a licensee found to have committed a violation or violations of
16 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
17 enforcement of the case.

18 **DRUG**

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

22 **FACTUAL ALLEGATIONS**

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

26 23. On June 7, 2004, the FDA issued a talk paper titled, "FDA Warns Against Women
27 Using Unapproved Drug, Domperidone, to Increase Milk Production." The paper stated in
28

1 pertinent part that domperidone is an “unapproved drug” and that it is “not approved in the U.S.
2 for any indication.” It also warned breast feeding women not to use the product because of safety
3 concerns, and that FDA field personnel were alerted to be on the lookout for attempts to import
4 domperidone so it could be detained. The paper stated, “[t]he letters issued by FDA today stated
5 that all drug products containing domperidone (whether compounded or not) violate the Federal
6 Food, Drug, and Cosmetic Act (the Act) because they are unapproved new drugs and misbranded.
7 In addition, distribution within the U.S., or importation of domperidone-containing products,
8 violates the law.”

9 24. On April 9, 2010, the FDA issued a warning letter to Alexandria Medical Arts
10 Pharmacy & Compounding Laboratory regarding the compounding of domperidone. The
11 warning letter explained the Act as it relates to compounded drugs and FDA’s regulatory
12 approach to compounding and stated that compounding drugs using domperidone was
13 inappropriate.

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

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

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

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

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

1 of domperidone ranging in strengths from 1mg/ml to 30mg/ml and various units between 30 and
2 1030 to patients.

3 **FIRST CAUSE FOR DISCIPLINE**

4 **(Sold Misbranded Drugs)**

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

10 **SECOND CAUSE FOR DISCIPLINE**

11 **(Delivered or Proffered for Delivery Misbranded Drugs)**

12 31. Respondents are subject to disciplinary action under Code section 4301(j), for
13 violating statutes regulating controlled substances and dangerous drugs, in that Respondents
14 delivered or proffered for delivery misbranded drugs, as defined by Health & Safety Code section
15 111400, in violation of Health and Safety Code section 111450, as set forth in paragraphs 22
16 through 29, which are incorporated herein by reference.

17 **THIRD CAUSE FOR DISCIPLINE**

18 **(Commission of Prohibited Acts)**

19 32. Respondents are subject to disciplinary action under Code sections 4301(o) and/or
20 4169(a)(3), and Health and Safety Code section 11335, in that Respondents purchased
21 domperidone powder and dispensed compounded drug capsules containing domperidone without
22 having an approved Investigational New Drug application on file, as set forth in paragraphs 21
23 through 28, which are incorporated herein by reference.

24 **FOURTH CAUSE FOR DISCIPLINE**

25 **(Unprofessional Conduct)**

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

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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

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

5 **PRAYER**

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

- 8 1. Revoking or suspending Pharmacy Permit Number PHY 44221, issued to Innovrx
9 Inc. doing business as Med Specialties Compounding Pharmacy;
- 10 2. Revoking or suspending Sterile Compounding License Number LSC 99056, issued to
11 Innovrx Inc. doing business as Med Specialties Compounding Pharmacy;
- 12 3. Revoking or suspending Pharmacist License Number RPH 50523, issued to Mark
13 Anthony Gonzalez;
- 14 4. Prohibiting Innovrx Inc. doing business as Med Specialties Compounding Pharmacy
15 from serving as a manager, administrator, owner, member, officer, director, associate, or partner
16 of a licensee for five years if Pharmacy Permit Number PHY 44221 and/or Sterile Compounding
17 License Number LSC 99056 are placed on probation or until Pharmacy Permit Number PHY
18 44221 and/or Sterile Compounding License Number LSC 99056 are reinstated if Pharmacy
19 Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 issued to
20 Innovrx Inc. doing business as Med Specialties Compounding Pharmacy are revoked;
- 21 5. Prohibiting Mark Anthony Gonzalez from serving as a manager, administrator,
22 owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy
23 Permit Number PHY 44221 and/or Sterile Compounding License Number LSC 99056 are placed
24 on probation or until Pharmacy Permit Number PHY 44221 and/or Sterile Compounding License
25 Number LSC 99056 are reinstated if Pharmacy Permit Number PHY 44221 and/or Sterile
26 Compounding License Number LSC 99056 issued to Innovrx Inc. doing business as Med
27 Specialties Compounding Pharmacy are revoked;

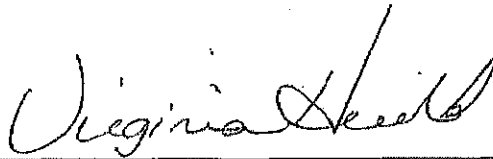
1 6. Prohibiting Mark Anthony Gonzalez from serving as a manager, administrator,
2 owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist
3 License Number RPH 50523 is placed on probation or until Pharmacist License Number RPH
4 50523 is reinstated if Pharmacist License Number RPH 50523 issued to Mark Anthony Gonzalez
5 is revoked;

6 7. Ordering Innovrx Inc. doing business as Med Specialties Compounding Pharmacy
7 and Mark Anthony Gonzalez to pay the Board of Pharmacy the reasonable costs of the
8 investigation and enforcement of this case, pursuant to Business and Professions Code section
9 125.3;

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

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14 DATED: _____

7/30/16



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

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