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8
9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

Case No. 4860

12 **THOMAS MCGOWAN,**
13 **DBA JTM INFUSION**
14 **12225 World Trade Drive, Suite G**
San Diego, CA 92128

A C C U S A T I O N

15 **Pharmacy Permit No. PHY 43622**

16 **and**

17 **JOHN ROSSI**
18 **2858 Loker Ave East**
Carlsbad, CA 92010

19 **Pharmacist License No. RPH 33107**

20 Respondents.

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22
23 Complainant alleges:

24 **PARTIES**

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

27 2. On or about October 20, 1998, the Board of Pharmacy issued Pharmacy Permit
28 Number PHY 43622 to Thomas McGowan, doing business as JTM Infusion. John Rossi has

1 been the Pharmacist-in-Charge since October 20, 1998. The Pharmacy Permit was in full force
2 and effect at all times relevant to the charges brought herein and will expire on October 1, 2013,
3 unless renewed.

4 3. On or about August 14, 1979, the Board of Pharmacy issued Pharmacist License
5 Number RPH 33107 to John Rossi. The Pharmacist License was in full force and effect at all
6 times relevant to the charges brought herein and will expire on May 31, 2015, unless renewed.

7 JURISDICTION

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

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

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

16 7. Section 4300.1 of the Code states:

17 The expiration, cancellation, forfeiture, or suspension of a board-issued license
18 by operation of law or by order or decision of the board or a court of law, the
19 placement of a license on a retired status, or the voluntary surrender of a license by a
20 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.

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

22 Any person who has been denied a license or whose license has been revoked
23 or is under suspension, or who has failed to renew his or her license while it was
24 under suspension, or who has been a manager, administrator, owner member, officer,
25 director, associate, or partner of any partnership, corporation, firm, or association
26 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:

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

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

2 **STATUTORY PROVISIONS**

3 9. Section 4022 of the Code states:

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

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

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

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

12 10. Section 4043 of the Code, in pertinent part, defines "wholesaler" to mean and include
13 "a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor,
14 agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes
15 possession of, any drug or device included in Section 4022."

16 11. Section 4059.5(a) states:

17 Except as otherwise provided in this chapter, dangerous drugs or dangerous
18 devices may only be ordered by an entity licensed by the board and shall be delivered
19 to the licensed premises and signed for and received by a pharmacist. Where a
licensee is permitted to operate through a designated representative, the designated
representative shall sign for and receive the delivery.

20 12. Section 4081 of the Code states:

21 (a) All records of manufacture and of sale, acquisition, or disposition of
22 dangerous drugs or dangerous devices shall be at all times during business hours
open to inspection by authorized officers of the law, and shall be preserved for at
23 least three years from the date of making. A current inventory shall be kept by
24 every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer,
physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution,
25 or establishment holding a currently valid and unrevoked certificate, license,
permit, registration, or exemption under Division 2 (commencing with Section
26 1200) of the Health and Safety Code or under Part 4 (commencing with Section
16000) of Division 9 of the Welfare and Institutions Code who maintains a stock
27 of dangerous drugs or dangerous devices.

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

5 13. Section 4105, subdivision (a) of the Code states: "All records or other documentation
6 of the acquisition and disposition of dangerous drugs and dangerous devices by any entity
7 licensed by the board shall be retained on the licensed premises in a readily retrievable form" and
8 section 4105, subdivision (c) of the Code states: "The records required by this section shall be
9 retained on the licensed premises for a period of three years from the date of making."

10 14. Section 4110(a) of the Code states:

11 No person shall conduct a pharmacy in the State of California unless he or she
12 has obtained a license from the board. A license shall be required for each pharmacy
13 owned or operated by a specific person. A separate license shall be required for each
14 of the premises of any person operating a pharmacy in more than one location. The
15 license shall be renewed annually. The board may, by regulation, determine the
16 circumstances under which a license may be transferred.

17 ...

18 15. Section 4113(c) of the Code states:

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

21 16. Section 4126.5(a), of the Code states:

22 (a) A pharmacy may furnish dangerous drugs only to the following:

23 (1) A wholesaler owned or under common control by the wholesaler from
24 whom the dangerous drug was acquired.

25 (2) The pharmaceutical manufacturer from whom the dangerous drug was
26 acquired.

27 (3) A licensed wholesaler acting as a reverse distributor.

28 (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a
dangerous drug that could result in the denial of health care. A pharmacy furnishing
dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to
alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise
authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to
purchase dangerous drugs.

(7) To another pharmacy under common control.

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17. Section 4160 of the Code provides, in pertinent part, that a wholesaler license shall be required for a person or entity to act as a wholesaler, that every wholesaler shall be supervised or managed by a Designated Representative in Charge, and that the Designated Representative in Charge shall be responsible for the wholesaler's compliance with state and federal laws.

18. Section 4169 of the Code states in pertinent part:

(a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

....

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

....

19. 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:

....

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

....

(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.

....

20. Section 4312(b) of the Code states that:

...

In the event that the license of a wholesaler, pharmacy, or veterinary food-

1 animal drug retailer is cancelled pursuant to subdivision (a) or revoked pursuant to
2 Article 19 (commencing with Section 4300), or a wholesaler, pharmacy, or veterinary
3 food-animal drug retailer notifies the board of its intent to remain closed or to
4 discontinue business, the licensee shall, within 10 days thereafter, arrange for the
5 transfer of all dangerous drugs and controlled substances or dangerous devices to
6 another licensee authorized to possess the dangerous drugs and controlled substances
7 or dangerous devices. The licensee transferring the dangerous drugs and controlled
8 substances or dangerous devices shall immediately confirm in writing to the board
9 that the transfer has taken place.

10 ...

11 21. Section 4328 of the Code states that:

12 Except as otherwise provided in this chapter, any person who permits the
13 compounding or dispensing of prescriptions, or the furnishing of dangerous drugs in
14 his or her pharmacy, except by a pharmacist, is guilty of a misdemeanor.

15 REGULATORY PROVISIONS

16 22. California Code of Regulations, title 16, section 1709.1(a) states that “[t]he
17 pharmacist-in-charge of a pharmacy shall be employed at that location and shall have
18 responsibility for the daily operation of the pharmacy.”

19 23. California Code of Regulations, title 16, section 1718 states in pertinent part that
20 “Current Inventory” as used in Sections 4081 and 4332 of the Business and Professions Code
21 shall be considered to include complete accountability for all dangerous drugs handled by every
22 licensee enumerated in Sections 4081 and 4332.”

23 24. California Code of Regulations, title 16, section 1783, subdivision (d) provides, in
24 pertinent part, that a manufacturer or wholesaler shall not accept payment for, or allow the use of
25 an entity’s credit to establish an account for, the purchase of dangerous drugs or devices from any
26 person other than the owner(s) or executive officer(s) listed on the permit, on a permit’s account.

27 COST RECOVERY

28 25. 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.

1 **FACTUAL ALLEGATIONS**

2 26. Since October 20, 1998 and at all times referenced herein, Respondent John Rossi
3 (Respondent Rossi) was the Pharmacist-in-Charge (PIC) of Respondent Thomas McGowan,
4 doing Business as JTM Infusion (Respondent JTM Infusion). On January 7, 2011, Respondent
5 Rossi completed, initialed and executed a self-assessment form representing Respondent JTM
6 Infusion's compliance with federal and state pharmacy laws. In response to the question,
7 "[d]angerous drugs and Dangerous devices are only delivered to the licensed premise, and signed
8 for and received by a pharmacist," Respondent Rossi answered "N/A." In response to the
9 question, "[t]he pharmacy has a PIC that is responsible for the daily operation of the pharmacy,"
10 Respondent Rossi answered "[y]es." In response to the question "[t]his pharmacy furnishes
11 dangerous drugs in compliance with B&PC 4126.5...", Respondent Rossi answered "N/A." In
12 response to the question, "[a]ll drug acquisition and disposition records (complete accountability)
13 are maintained for at least three years..." Respondent Rossi answered "[y]es."

14 27. Respondent Thomas McGowan, doing business as JTM Infusion (Respondent JTM
15 Infusion) is the same individual who owned McGowan Enterprises, doing business as McGowan
16 Enterprises, Inc./Acute Care Pharmaceuticals (McGowan Enterprises), a person licensed as a
17 wholesaler with the Board.

18 28. In or about November 2011, Respondent JTM Infusion moved its premises from
19 Suite G to Suite C at the same street address without notifying the Board. Its premises were
20 located within Respondent McGowan Enterprises and were approximately the size of a closet.
21 There was no separate ingress or egress to its premises. Respondent JTM Infusion had no
22 pharmacy staff other than Respondent Rossi who was rarely present at Respondent JTM
23 Infusion's premises. Respondent Rossi, the PIC, did not possess a key to the premises of
24 Respondent JTM Infusion.

25 29. Dangerous drug orders were signed for and received by unlicensed warehouse
26 workers, a licensed pharmacy technician, marketing staff or a designated representative for
27 McGowan Enterprises at McGowan Enterprises, without a pharmacist present to accept them.
28 Respondent JTM Infusion was not open for business at least one day per week and the last time

1 Respondent JTM Infusion filled a patient specific prescription was prior to 2000. No inventory of
2 drugs was held by Respondent JTM Infusion.

3 30. McGowan Enterprises ordered dangerous drugs using Respondent JTM Infusion's
4 Pharmacy License and re-sold the drugs "purchased" or furnished by Respondent JTM Infusion
5 without Respondent Rossi's knowledge. McGowan Enterprises never paid Respondent JTM
6 Infusion for the dangerous drugs that it "purchased" or obtained from Respondent JTM Infusion.
7 Respondents did not maintain the records of disposition for dangerous drugs "sold" or furnished
8 to McGowan Enterprises. McGowan Enterprises maintained the pedigrees involved in the drug
9 transactions.¹

10 31. Respondents allowed McGowan Enterprises to use accounts with their primary
11 wholesalers to purchase dangerous drugs for McGowan Enterprises and then "sold" or furnished
12 those drugs to McGowan Enterprises for at least three years. For example, McGowan Enterprises
13 "purchased" or obtained from Respondent JTM Infusion 2,408 dangerous drugs in 466
14 transactions during the period from March 9, 2010 through September 20, 2012.

15 **FIRST CAUSE FOR DISCIPLINE**

16 **(Failure to Keep Records of Disposition Open for Inspection and to Keep Current** 17 **Inventory)**

18 32. Respondents are subject to disciplinary action under Code sections 4301(o), for
19 violating Code section 4081(a) in that they failed to keep records of the disposition of dangerous
20 drugs open for inspection or keep a current inventory as defined by California Code of
21 Regulations, title 16, section 1718 for the dangerous drugs it "sold" or furnished to McGowan
22 Enterprises from at least September 19, 2009 through September 20, 2012, as set forth in
23 paragraphs 26 through 31, which are incorporated herein by reference.

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27 ¹ Pedigree documents record the distribution route a drug has traveled since it left the
28 manufacturer.

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SECOND CAUSE FOR DISCIPLINE

(Failure to Retain Records of Dangerous Drugs on Licensed Premises)

33. Respondents are subject to disciplinary action under Code section 4301(o), for violating Code sections 4105(a) and (c), in that Respondents failed to retain records for the dangerous drugs “sold” or furnished to McGowan Enterprises from at least September 19, 2009 through September 20, 2012 on its licensed premises, as set forth in paragraphs 26 through 31, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Disposition of Dangerous Drugs)

34. Respondents are subject to disciplinary action under Code section 4301(o), for violating Code section 4169(a)(5), in that Respondents failed to maintain records for the dangerous drugs “sold” or furnished to McGowan Enterprises from at least September 19, 2009 through September 20, 2012, as set forth in paragraphs 26 through 31, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Functioning as an Unlicensed Wholesalers)

35. Respondents are subject to disciplinary action under Code section 4301(o), for violating section 4160 of the Code, in that Respondents “sold” or furnished dangerous drugs to McGowan Enterprises and by so doing acted as an unlicensed wholesaler, as set forth in paragraphs 26 through 31, which are incorporated herein by reference.

FIFTH CAUSE FOR DISCIPLINE

(Selling Dangerous Drugs Under Unauthorized Conditions)

36. Respondents are subject to disciplinary action under Code section 4301(o), for violating section 4126.5(a) of the Code, by “selling” or furnishing dangerous drugs to McGowan Enterprises under unauthorized conditions, as set forth in paragraphs 26 through 31, which are incorporated herein by reference.

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SIXTH CAUSE FOR DISCIPLINE

(Unauthorized Use of Credit for Purchase of Drugs)

37. Respondents are subject to disciplinary action under Code section 4301(o), for violating and/or attempting to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate, the laws governing pharmacy, when Respondents solicited, encouraged, assisted in, abetted, or conspired toward, transactions violating California Code of Regulations, title 16, section 1783(d), by allowing McGowan Enterprises to purchase dangerous drugs from Respondents' primary wholesalers on Respondent's accounts with those primary wholesalers, as set forth in paragraphs 26 through 31, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Obtain Separate License for More than One Location)

38. Respondents are subject to disciplinary action under Code section 4301(o), for violating section 4110(a) of the Code in that Respondents did not obtain a separate license for operating a pharmacy at Suite C as set forth in paragraphs 26 through 31, which are incorporated herein by reference.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to File Notice of Discontinuance of Business)

39. Respondents are subject to disciplinary action under Code section 4301(o), for violating section 4312(b) of the Code in that Respondents failed to file a notice of discontinuance of business when they ceased daily operations as set forth in paragraphs 26 through 31, which are incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

(Unauthorized Receipt of Dangerous Drugs)

40. Respondents are subject to disciplinary action under Code section 4301(o), for violating section 4059.5(a) of the Code in that dangerous drugs were delivered to Respondents without being delivered to the licensed premises and signed for and received by a pharmacist as set forth in paragraphs 26 through 31, which are incorporated herein by reference.

1 **TENTH CAUSE FOR DISCIPLINE**

2 **(Failure to Supervise)**

3 41. Respondent Rossi is subject to disciplinary action under Code sections 4301(o), for
4 violating section 4113(c) of the Code and California Code of Regulations, section 1709.1(a) when
5 he failed to supervise or be responsible for JTM's sale or furnishing of dangerous drugs to
6 McGowan Enterprises, as set forth in paragraphs 26 through 31, which are incorporated herein by
7 reference.

8 **ELEVENTH CAUSE FOR DISCIPLINE**

9 **(Knowingly Making or Signing Document Falsely Representing Existence
10 or Nonexistence of Facts)**

11 42. Respondents are subject to disciplinary action under Code section 4301(g), for
12 making or signing a self-assessment form that falsely represented the existence or nonexistence of
13 facts, as set forth in paragraphs 26 through 31, which are incorporated herein by reference.

14 **TWELFTH CAUSE FOR DISCIPLINE**

15 **(Permitting Furnishing of Dangerous Drugs Without Pharmacist)**

16 43. Respondents are subject to disciplinary action under Code section 4301(o), for
17 violating Business and Professions Code section 4328 when they permitted the furnishing of
18 dangerous drugs in their pharmacy without a pharmacist, as set forth in paragraphs 26 through 31,
19 which are incorporated herein by reference.

20 **THIRTEENTH CAUSE FOR DISCIPLINE**

21 **(Unprofessional Conduct)**

22 44. Respondents are each and severally subject to discipline under section 4301 of the
23 Code, in that the acts described in paragraphs 26 through 31 constitute unprofessional conduct.

24 **OTHER MATTERS**

25 45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
26 Number PHY 43622, issued to Thomas McGowan, doing business as JTM Infusion, Thomas
27 McGowan shall be prohibited from serving as a manager, administrator, owner, member, officer,
28 director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY

1 43622 is placed on probation or until Pharmacy Permit Number PHY 43622 is reinstated if it is
2 revoked.

3 46. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License
4 Number RPH 33107, issued to John Rossi, John Rossi shall be prohibited from serving as a
5 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
6 five years if Pharmacist License Number RPH 33107 is placed on probation or until Pharmacist
7 License Number RPH 33107 is reinstated if it is revoked.

8 **PRAYER**

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

11 1. Revoking or suspending Pharmacy Permit Number PHY 43622, issued to Thomas
12 McGowan, doing business as JTM Infusion;

13 2. Revoking or suspending Pharmacist License Number 33107, issued to John Rossi;

14 3. Prohibiting Thomas McGowan from serving as a manager, administrator, owner,
15 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
16 Number PHY 43622 is placed on probation or until Pharmacy Permit Number PHY 43622 is
17 reinstated if Pharmacy Permit Number PHY 43622 issued to Thomas McGowan, doing business
18 as JTM Infusion is revoked;

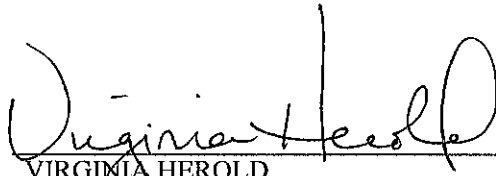
19 4. Prohibiting John Rossi from serving as a manager, administrator, owner, member,
20 officer, director, associate, or partner of a licensee for five years if Pharmacist License Number
21 RPH 33107 is placed on probation or until Pharmacist License Number RPH 33107 is reinstated
22 if Pharmacist License Number RPH 33107 issued to John Rossi is revoked;

23 5. Ordering Thomas McGowan, doing business as JTM Infusion and John Rossi to pay
24 the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,
25 pursuant to Business and Professions Code section 125.3;

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

DATED: 2/14/14



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

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