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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. 4624

12 **MCGOWAN ENTERPRISES INC., DBA**  
13 **MCGOWAN ENTERPRISES INC./**  
14 **ACUTE CARE PHARMACEUTICALS**  
12225 World Trade Drive, Suites A, B, C, D, E  
15 San Diego, CA 92128

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

16 **Wholesaler Permit No. WLS 3336**

17 **and**

18 **THOMAS MICHAEL MCGOWAN**  
12225 World Trade Center Drive, Suite A  
19 San Diego, CA 92128

20 **Designated Representative No. EXC 13963**

21 Respondents.

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24 Complainant alleges:

25 **PARTIES**

26 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity  
27 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.  
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1 8. Section 4307(a) of the Code states that:

2 Any person who has been denied a license or whose license has been revoked  
3 or is under suspension, or who has failed to renew his or her license while it was  
4 under suspension, or who has been a manager, administrator, owner member, officer,  
5 director, associate, or partner of any partnership, corporation, firm, or association  
6 whose application for a license has been denied or revoked, is under suspension or  
7 has been placed on probation, and while acting as the manger, administrator, owner,  
8 member, officer, director, associate, or partner had knowledge or knowingly  
9 participated in any conduct for which the license was denied, revoked, suspended, or  
10 placed on probation, shall be prohibited from serving as a manger, administrator,  
11 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.

#### 11 STATUTORY PROVISIONS

12 9. Section 4022 of the Code states:

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

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

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

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

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

25 11. Section 4053(a) of the Code states:

26 Notwithstanding Section 4051, the board may issue a license as a designated  
27 representative to provide sufficient and qualified supervision in a wholesaler or  
28 veterinary food-animal drug retailer. The designated representative shall protect the  
public health and safety in the handling, storage, and shipment of dangerous drugs  
and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

1 12. Section 4081 of the Code states:

2 (a) All records of manufacture and of sale, acquisition, or disposition of  
3 dangerous drugs or dangerous devices shall be at all times during business hours  
4 open to inspection by authorized officers of the law, and shall be preserved for at  
5 least three years from the date of making. A current inventory shall be kept by  
6 every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer,  
7 physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution,  
8 or establishment holding a currently valid and unrevoked certificate, license,  
9 permit, registration, or exemption under Division 2 (commencing with Section  
10 1200) of the Health and Safety Code or under Part 4 (commencing with Section  
11 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock  
12 of dangerous drugs or dangerous devices.

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

17 13. Section 4105, subdivision (a) and (c) of the Code states:

18 (a) All records or other documentation of the acquisition and disposition of  
19 dangerous drugs and dangerous devices by any entity licensed by the board shall be  
20 retained on the licensed premises in a readily retrievable form.”

21 ....

22 (c) The records required by this section shall be retained on the licensed  
23 premises for a period of three years from the date of making.

24 14. Section 4126.5, subdivision (a), of the Code states:

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

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

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

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

(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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15. 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.

16. Section 4163(a) of the Code states:

(a) A manufacturer, wholesaler, repackager, or pharmacy may not furnish a dangerous drug or dangerous device to an unauthorized person.

17. 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.

....

18. 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.

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## REGULATORY PROVISIONS

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

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

21. California Code of Regulations, title 16, section 1784 states in part:

(a) The designated representative-in-charge of each wholesaler as defined under section 4160 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

...

(c) The components of this assessment shall be on Form 17M-26 (Rev. 01/11) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

...

(e) The wholesaler is jointly responsible with the designated representative-in-charge for compliance with this section.

## COST RECOVERY

22. 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.

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1 **FACTUAL ALLEGATIONS**

2 23. Since September 2, 1997 and at all times referenced herein, Respondent McGowan  
3 was the Designated Representative-in-Charge (DRIC) of Respondent McGowan Enterprises, Inc.  
4 doing business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals (Respondent  
5 McGowan Enterprises).

6 24. On or about October 20, 1998, the Board issued Pharmacy License No. PHY 43622  
7 to Thomas McGowan, doing business as JTM Infusion (JTM Infusion). Thomas McGowan,  
8 doing business as JTM Infusion, is the same individual who owned Respondent McGowan  
9 Enterprises and is the DRIC of Respondent McGowan Enterprises. JTM Infusion was physically  
10 located within Respondent McGowan Enterprises. Its premises were approximately the size of a  
11 closet and there was no separate ingress or egress. JTM Infusion had no pharmacy staff other  
12 than a Pharmacist-in-Charge who was rarely present at JTM Infusion’s premises.

13 25. On or about September 20, 2012, the Board conducted a routine inspection of  
14 Respondent McGowan Enterprises. During that inspection, the Board inspector requested records  
15 of Respondent McGowan Enterprises’ compliance with federal and state pharmacy law related to  
16 the self-assessment required of Respondent McGowan. Respondent McGowan had not  
17 completed the self-assessment.

18 26. After the September 20, 2012 inspection, Respondent McGowan completed a self-  
19 assessment and answered “yes” to Question No 8.5.3, “Does your business only receive drugs  
20 from a pharmacy if: the drugs are needed to alleviate a shortage? (and only a quantity sufficient  
21 to alleviate a specific shortage.) (B&PC 4126.5[a]).” He also answered “yes” to Question No.  
22 8.6.1, “Are the drugs that are purchased from another business or that are sold, traded or  
23 transferred to your business: transacted with a business licensed with this board as a wholesaler or  
24 pharmacy?”

25 27. Respondents ordered dangerous drugs using JTM Infusion’s Pharmacy License and  
26 re-sold the drugs “purchased” or furnished by JTM Infusion. Respondents never paid JTM  
27 Infusion for the dangerous drugs that they “purchased” or obtained from JTM Infusion.  
28 Respondents also did not maintain the records of acquisition for dangerous drugs “purchased” or

1 furnished by JTM Infusion except for pedigrees.<sup>1</sup> Respondent McGowan was unaware of the  
2 extent to which Respondent McGowan Enterprises was “purchasing” or obtaining drugs from  
3 JTM Infusion.

4 28. Respondents had also purchased dangerous drugs from Advanced Pharmacy  
5 Homecare (Advanced) and Green Valley Drugs, an entity which is not licensed in California. For  
6 example, Respondents “purchased” or obtained from JTM Infusion 2,408 dangerous drugs in 466  
7 transactions during the period from March 9, 2010 through September 20, 2012. Respondents  
8 purchased at least 4,296 dangerous drugs in 742 transactions from the three pharmacies during the  
9 period from November 2, 2009 through September 20, 2012.

10 29. Respondents’ employees were given access to Advanced’s AmerisourceBergen on-  
11 line account, which allowed Respondents to submit drug orders directly to Advanced’s primary  
12 wholesaler, AmerisourceBergen, using Advanced’s account information. The Board inspector  
13 confirmed this practice with Respondents’ purchasing agent.

14 30. Respondents also purchased 100 Afluria Influenza vaccines, 10 dose vials on  
15 September 10, 2009 and 80 Fluzone vaccines, 5mls on December 30, 2009 from Green Valley  
16 Drugs, an entity which is not licensed in California.

17 **FIRST CAUSE FOR DISCIPLINE**

18 **(Failure to Keep Records of Acquisition Open for Inspection and to Keep Current**  
19 **Inventory)**

20 31. Respondents are subject to disciplinary action under Code sections 4301(o), for  
21 violating Code sections 4081(a) and (b) in that they failed to keep records of the acquisition of  
22 dangerous drugs open for inspection or keep a current inventory as defined by California Code of  
23 Regulations, title 16, section 1718 for the dangerous drugs “purchased” or furnished by JTM  
24 Infusion from at least September 19, 2009 through September 20, 2012, as set forth in paragraphs  
25 23 through 30, which are incorporated herein by reference.

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27 <sup>1</sup> 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)**

32. 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 “purchased” or furnished by JTM Infusion from at least September 19, 2009 through September 20, 2012 on its licensed premises, as set forth in paragraphs 23 through 30, which are incorporated herein by reference.

**THIRD CAUSE FOR DISCIPLINE**

**(Failure to Maintain Records of Acquisition of Dangerous Drugs)**

33. 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 “purchased” or furnished by JTM Infusion from at least September 19, 2009 through September 20, 2012, as set forth in paragraphs 23 through 30, which are incorporated herein by reference.

**FOURTH CAUSE FOR DISCIPLINE**

**(Aiding or Abetting Unlicensed Wholesalers)**

34. 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 section 4160 of the Code, in that pharmacies that purchased dangerous drugs on behalf of Respondents, and/or sold dangerous drugs to Respondents for re-sale, by so doing acted as unlicensed wholesalers, as set forth in paragraphs 23 through 30, which are incorporated herein by reference.

**FIFTH CAUSE FOR DISCIPLINE**

**(Purchasing Dangerous Drugs Under Unauthorized Conditions)**

35. 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,

1 assisted in, abetted, or conspired toward, transactions violating section 4126.5 of the Code, by  
2 purchasing dangerous drugs from and/or on behalf of pharmacies under unauthorized conditions,  
3 as set forth in paragraphs 23 through 30, which are incorporated herein by reference.

4 **SIXTH CAUSE FOR DISCIPLINE**

5 **(Unauthorized Use of Other Entity's Credit for Purchase of Drugs)**

6 36. Respondents are subject to disciplinary action under Code section 4301(o), for  
7 violating and/or attempting to violate, directly or indirectly, assisted in or abetted the violation of,  
8 or conspired to violate, the laws governing pharmacy, when Respondents solicited, encouraged,  
9 assisted in, abetted, or conspired toward, transactions violating California Code of Regulations,  
10 title 16, section 1783(d), by causing the purchase of dangerous drugs by client pharmacies from  
11 primary wholesalers on pharmacy accounts controlled by Respondents, as set forth in paragraphs  
12 23 through 30, which are incorporated herein by reference.

13 **SEVENTH CAUSE FOR DISCIPLINE**

14 **(Failure to Supervise)**

15 37. Respondent McGowan is subject to disciplinary action under Code section 4301(o),  
16 for violating Code section 4053(a) when he failed to supervise Respondent McGowan  
17 Enterprises' purchase and re-sale of dangerous drugs, as set forth in paragraphs 23 through 30,  
18 which are incorporated herein by reference.

19 **EIGHTH CAUSE FOR DISCIPLINE**

20 **(Purchasing Drugs from Unlicensed Entity)**

21 38. Respondents are subject to disciplinary action under Code section 4301(o), for  
22 violating Code sections 4163(a) and 4169 (a)(1) in that Respondents purchased drugs from an  
23 entity, Green Valley Drugs, which was not licensed in California as a pharmacy or wholesaler, as  
24 set forth in paragraphs 23 through 30, which are incorporated herein by reference.

25 **NINTH CAUSE FOR DISCIPLINE**

26 **(Failure to Complete Self-Assessment)**

27 39. Respondents are subject to disciplinary action under Code section 4301(o), for  
28 violating California Code of Regulations, title 16, section 1784, in that Respondent McGowan

1 failed to complete a self-assessment of Respondent McGowan Enterprises' compliance with  
2 federal and state laws, as set forth in paragraphs 23 through 30, which are incorporated herein by  
3 reference.

4 **TENTH CAUSE FOR DISCIPLINE**

5 **(Knowingly Making or Signing Document Falsely Representing Existence**  
6 **or Nonexistence of Facts)**

7 40. Respondents are subject to disciplinary action under Code section 4301(g), for  
8 making or signing a self-assessment form that falsely represented the existence or nonexistence of  
9 facts, as set forth in paragraphs 23 through 30, which are incorporated herein by reference.

10 **ELEVENTH CAUSE FOR DISCIPLINE**

11 **(Unprofessional Conduct)**

12 41. Respondents are each and severally subject to discipline under section 4301 of the  
13 Code, in that the acts described in paragraphs 23 through 30 constitute unprofessional conduct.

14 **OTHER MATTERS**

15 42. Pursuant to Code section 4307, if discipline is imposed on Wholesaler Permit  
16 Number WLS 3336, issued to McGowan Enterprises Inc., doing business as McGowan  
17 Enterprises, Inc./Acute Care Pharmaceuticals and Thomas McGowan while acting as the  
18 manager, administrator, owner, member, officer, director, associate, or partner of McGowan  
19 Enterprises, doing business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals had  
20 knowledge of or knowingly participated in any conduct for which Wholesaler Permit Number  
21 WLS 3336 was revoked, suspended or placed on probation, Thomas McGowan shall be  
22 prohibited from serving as a manager, administrator, owner, member, officer, director, associate,  
23 or partner of a licensee for five years if Wholesaler Permit Number WLS 3336 is placed on  
24 probation or until Wholesaler Permit Number WLS 3336 is reinstated if it is revoked.

25 43. Pursuant to Code section 4307, if discipline is imposed on Designated  
26 Representative License No. EXC 13963 issued to Thomas Michael McGowan, 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 Designated Representative License

1 Number EXC 13963 is placed on probation or until Designated Representative License Number  
2 EXC 13963 is reinstated if it is revoked.

3 **DISCIPLINARY CONSIDERATIONS**

4 44. To determine the degree of discipline, if any, to be imposed on Respondents,  
5 Complainant alleges that on or about July 16, 2013, the Board issued Modified Citation number  
6 CI 2012 55994 against Thomas Michael McGowan for violating California Code of Regulations,  
7 title 16, section 1708.2 and Business and Professions Code section 4312(b), in that he failed to  
8 notify the Board prior to the transferring or selling of dangerous drugs, devices or hypodermics  
9 inventory to another licensee. He paid the fine.

10 **PRAYER**

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

13 1. Revoking or suspending Wholesaler Permit Number WLS 3336, issued to McGowan  
14 Enterprises Inc., doing business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals;

15 2. Revoking or suspending Designated Representative License No. EXC 13963, issued  
16 to Thomas Michael McGowan;

17 3. Prohibiting Thomas McGowan from serving as a manager, administrator, owner,  
18 member, officer, director, associate, or partner of a licensee for five years if Wholesaler Permit  
19 Number WLS 3336 is placed on probation or until Wholesaler Permit Number WLS 3336 is  
20 reinstated if Wholesaler Permit Number WLS 3336 issued to McGowan Enterprises, Inc., doing  
21 business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals is revoked;

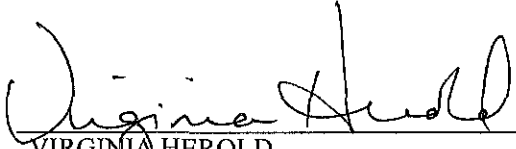
22 4. Prohibiting Thomas McGowan from serving as a manager, administrator, owner,  
23 member, officer, director, associate, or partner of a licensee for five years if Designated  
24 Representative License Number EXC 13963 if placed on probation or until Designated  
25 Representative License Number EXC 13963 is reinstated if Designated Representative License  
26 Number EXC 13963 issued to Thomas McGowan is revoked;

27 5. Ordering McGowan Enterprises Inc., doing business as McGowan Enterprises,  
28 Inc./Acute Care Pharmaceuticals and Thomas Michael McGowan to pay the Board of Pharmacy

1 the reasonable costs of the investigation and enforcement of this case, pursuant to Business and  
2 Professions Code section 125.3;

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

4  
5 DATED: 2/14/14



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

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