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

In the Matter of the Accusation Against:

Case No. 4624

MCGOWAN ENTERPRISES INC., DBA MCGOWAN ENTERPRISES, INC./ ACUTE CARE PHARMACEUTICALS 12225 World Trade Drive, Suites A,B,C,D, E San Diego, CA 92128 STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO THOMAS MCGOWAN ONLY

Wholesaler Permit No. WLS 3336

and

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

Designated Representative No. EXC 13963

Respondents.

DECISION AND ORDER

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

This Decision shall become effective on June 11, 2015.

It is so ORDERED on May 28, 2015.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

STAN C. WEISSER, Board President

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1 2 3 4 5 6	KAMALA D. HARRIS Attorney General of California MARC D. GREENBAUM Supervising Deputy Attorney General MORGAN MALEK Deputy Attorney General State Bar No. 223382 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 897-2643 Facsimile: (213) 897-2804		
7	Attorneys for Complainant		
8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10			
11	In the Matter of the Accusation Against:	Case No. 4624	
12	MCGOWAN ENTERPRISES INC., DBA MCGOWAN ENTERPRISES INC./ ACUTE CARE PHARMACEUTICALS 12225 World Trade Drive, Suites A, B, C, D,	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO THOMAS MCGOWAN ONLY	
14	E San Diego, CA 92128		
15	Wholesaler Permit No. WLS 3336		
16	and		
17 18	THOMAS MICHAEL MCGOWAN 12225 World Trade Center Drive, Suite A San Diego, CA 92128		
19	Designated Representative No. EXC 13963		
20	Respondents.		
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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	<u>PARTIES</u>		
26	1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.		
27	She brought this action solely in her official capacity and is represented in this matter by Kamala		
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]		STIPULATED SETTLEMENT (4624)	

D. Harris, Attorney General of the State of California, by Morgan Malek, Deputy Attorney

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present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- 9. Respondent admits the truth of each and every charge and allegation in Accusation No. 4624.
- 10. Respondent agrees that his Designated Representative License is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

- 11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions,

negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Designated Representative License No. EXC 13963 issued to Respondent Thomas McGowan is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

1. Suspension

As part of probation, respondent is suspended from working as a designated representative for thirty (30) days beginning the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs licensed by the board, or any drug manufacturer, or any other location where dangerous drugs and devices or controlled substances are maintained. Respondent shall not perform any of the duties of a designated representative, nor do any act involving drug selection, selection of stock, manufacturing, dispensing; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices and controlled substances. Respondent shall not resume work until notified by the board.

Respondent shall not direct, control or perform any aspect involving the distribution of dangerous drugs and devices and controlled substances. Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed entity in which he or she holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

2. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
 - an arrest or issuance of a criminal complaint for violation of any state or federal law
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
 - □ a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Designated Representative license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distribution or billing or charging for of any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

3. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

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4. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, upon request at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 4624 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause their direct supervisor, designated representative-in-charge (including each new designated representative-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4624 and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify their direct supervisor, designated representative-in-charge and owner at each entity licensed by the board of the terms and conditions of the decision in case number 4624 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment

service, respondent shall cause their direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that they has read the decision in case number 4624 and the terms and conditions imposed thereby. It shall be the respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a designated representative or in any position for which a designated representative license is a requirement or criterion for employment, whether the respondent is considered an employee or independent contractor or volunteer.

7. No Being Designated Representative-in-Charge

During the period of probation, respondent shall not be the designated representative-incharge of any entity licensed by the board unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board his costs of investigation and prosecution in the amount of \$12,242.00, jointly and severally with Respondent McGowan Enterprises Inc. dba McGowan Enterprises Inc./Acute Care Pharmaceuticals. Respondent may make said payments on a payment plan approved by the Board. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of their responsibility to reimburse the board its costs of investigation and prosecution.

9. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as

directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. Status of License

Respondent shall, at all times while on probation, maintain an active, current designated representative license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's designated representative license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease work due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender their designated representative license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish their designated representative license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license, permit, or registration from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

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12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving and the address of the new employer, supervisor and owner and work schedule, if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address and mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a designated representative in California for a minimum of forty (40) hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease working as a designated representative for a minimum of forty (40) hours in California, respondent must notify the board in writing within ten (10) days of cessation of work and must further notify the board in writing within ten (10) days of the resumption of work. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of work" means any calendar month during which respondent is not working as a designated representative for at least forty (40) hours as a designated representative as defined by Business and Professions Code section 4053. "Resumption of work" means any calendar

month during which respondent is working as a designated representative for at least forty (40) hours as a designated representative as defined by Business and Professions Code section 4053.

14. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction, and the period of probation shall be automatically extended, until the petition to revoke probation or accusation is heard and decided.

15. Completion of Probation

Upon written notice by the board indicating successful completion of probation, respondent's designated representative license will be fully restored.

16. No New Ownership of Licensed Premises

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

17. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

18. Tolling of Suspension

During the period of suspension, respondent shall not leave California for any period exceeding fifteen (15) days, regardless of purpose (including vacation). Any such absence in excess of fifteen (15) days during suspension shall be considered a violation of probation.

Moreover, any absence from California during the period of suspension exceeding fifteen (15) days shall toll the suspension, i.e., the suspension shall be extended by one day for each day over fifteen (15) days respondent is absent from California, During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation.

Respondent must notify the board in writing within fifteen (15) days of departure, and must further notify the board in writing within fifteen (15) days of return. The failure to provide such notification(s) shall constitute a violation of probation. Upon such departure and return, respondent shall not resume work until notified by the board that the period of suspension has been satisfactorily completed.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Earll M. Pott, Esq.. I understand the stipulation and the effect it will have on my Wholesaler Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order

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1	of the Board of Pharmacy,		
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3	DATED: 4-27-15 Transmin Mc Jan		
4	THOMAS MCGOWAN Respondent		
5	I have read and fully discussed with Respondent McGowan Enterprises Inc. dba McGowan		
6	Enterprises Inc./Acute Care Pharmacouticals the terms and conditions and other matters contained		
7	in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.		
8	()		
9	DATED: W/28/2015 Early M. Pott, Esq.		
10	Attomney for Respondent Thomas McGowan		
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	12 STIPULATED SETTLEMENT (4624)		

ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy. Respectfully submitted, Dated: Kamala D, Harris Attorney General of California MARC D. GREENBAUM Supervising Deputy Attorney General Morgan Malek Deputy Attorney General Attorneys for Complainant SD2013705177 51728988.doc

Exhibit A

Accusation No. 4624

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3	Supervising Deputy Attorney General DESIREE I. KELLOGG				
4	Deputy Attorney General				
	State Bar No. 126461 110 West "A" Street, Suite 1100				
5	San Diego, CA 92101 P.O. Box 85266				
6	San Diego, CA 92186-5266 Telephone: (619) 645-2996				
7	Facsimile: (619) 645-2061				
8	Attorneys for Complainant				
9	BEFORE THE BOARD OF PHARMACY				
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA				
11					
12	In the Matter of the Accusation Against: Case No. 4	524			
13	MCGOWAN ENTERPRISES INC., DBA				
	ACUTE CARE PHARMACEUTICALS A C C U S	ATION			
14	San Diego, CA 92128				
15	Wholesaler Permit No. WLS 3336				
16	and				
17	THOMAS MICHAEL MCGOWAN				
18	12225 World Trade Center Drive, Suite A				
19	II I				
20	Designated Representative No. EXC 13963				
21	Respondents.				
22					
23					
	Complainant alleges:	Complainant alleges:			
24	PARTIES				
25	1. Virginia Herold (Complainant) brings this Accusation	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity			
26	as the Executive Officer of the Board of Pharmacy, Department	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.			
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j		Accusation			

- 2. On or about September 2, 1997, the Board of Pharmacy issued Wholesaler Permit Number WLS 3336 to McGowan Enterprises Inc., doing business as C.A.T. Kits (Respondent McGowan Enterprises). On or about September 27, 2012, McGowan Enterprises Inc. changed its name to do business to McGowan Enterprises, Inc./Acute Care Pharmaceuticals. Since on or about October 6, 2011, Thomas M. McGowan, EXC 13963 has been the Chief Executive Officer of McGowan Enterprises, Inc., doing business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals. The Wholesaler Permit was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2014, unless renewed.
- 3. On or about September 2, 1997, the Board issued Designated Representative License No. EXC 13963 to Thomas Michael McGowan (Respondent McGowan). The Designated Representative License was in full force and effect at all times relevant herein and will expire on September 1, 2014, unless renewed. Since on or about August 13, 2002, Thomas McGowan has been the Designated Representative-in-Charge of McGowan Enterprises, Inc., doing business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals.

JURISDICTION

- 4. 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.
- 5. 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.].
- 6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.
 - 7. 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.

8. 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.

STATUTORY PROVISIONS

9. Section 4022 of the Code states:

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

- (a) Any drug that bears the legend; "Caution; federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
- (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or 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.
- 10. Section 4043 of the Code, in pertinent part, defines "wholesaler" to mean and include "a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022."

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

Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or 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.

12. Section 4081 of the Code states:

- (a) All records of manufacture and of sale, acquisition, or disposition of 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 least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 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 of dangerous drugs or dangerous devices.
- (b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.
- 13. Section 4105, subdivision (a) and (c) of the Code states:
- (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form."
- (c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.
- 14. Section 4126.5, subdivision (a), of the Code states:
 - (a) A pharmacy may furnish dangerous drugs only to the following:
- (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
- (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.

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-incharge 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.

FACTUAL ALLEGATIONS

- 23. Since September 2, 1997 and at all times referenced herein, Respondent McGowan was the Designated Representative-in-Charge (DRIC) of Respondent McGowan Enterprises, Inc. doing business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals (Respondent McGowan Enterprises).
- 24. On or about October 20, 1998, the Board issued Pharmacy License No. PHY 43622 to Thomas McGowan, doing business as JTM Infusion (JTM Infusion). Thomas McGowan, doing business as JTM Infusion, is the same individual who owned Respondent McGowan Enterprises and is the DRIC of Respondent McGowan Enterprises. JTM Infusion was physically located within Respondent McGowan Enterprises. Its premises were approximately the size of a closet and there was no separate ingress or egress. JTM Infusion had no pharmacy staff other than a Pharmacist-in-Charge who was rarely present at JTM Infusion's premises.
- 25. On or about September 20, 2012, the Board conducted a routine inspection of Respondent McGowan Enterprises. During that inspection, the Board inspector requested records of Respondent McGowan Enterprises' compliance with federal and state pharmacy law related to the self-assessment required of Respondent McGowan. Respondent McGowan had not completed the self-assessment.
- 26. After the September 20, 2012 inspection, Respondent McGowan completed a self-assessment and answered "yes" to Question No 8.5.3, "Does your business only receive drugs from a pharmacy if; the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage.) (B&PC 4126.5[a])." He also answered "yes" to Question No. 8.6.1, "Are the drugs that are purchased from another business or that are sold, traded or transferred to your business: transacted with a business licensed with this board as a wholesaler or pharmacy?"
- 27. Respondents ordered dangerous drugs using JTM Infusion's Pharmacy License and re-sold the drugs "purchased" or furnished by JTM Infusion. Respondents never paid JTM Infusion for the dangerous drugs that they "purchased" or obtained from JTM Infusion. Respondents also did not maintain the records of acquisition for dangerous drugs "purchased" or

 furnished by JTM Infusion except for pedigrees. Respondent McGowan was unaware of the extent to which Respondent McGowan Enterprises was "purchasing" or obtaining drugs from JTM Infusion.

- 28. Respondents had also purchased dangerous drugs from Advanced Pharmacy
 Homecare (Advanced) and Green Valley Drugs, an entity which is not licensed in California. For example, Respondents "purchased" or obtained from JTM Infusion 2,408 dangerous drugs in 466 transactions during the period from March 9, 2010 through September 20, 2012. Respondents purchased at least 4,296 dangerous drugs in 742 transactions from the three pharmacies during the period from November 2, 2009 through September 20, 2012.
- 29. Respondents' employees were given access to Advanced's AmerisourceBergen online account, which allowed Respondents to submit drug orders directly to Advanced's primary wholesaler, AmerisourceBergen, using Advanced's account information. The Board inspector confirmed this practice with Respondents' purchasing agent.
- 30. Respondents also purchased 100 Afluria Influenza vaccines, 10 dose vials on September 10, 2009 and 80 Fluzone vaccines, 5mls on December 30, 2009 from Green Valley Drugs, an entity which is not licensed in California.

FIRST CAUSE FOR DISCIPLINE

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

31. Respondents are subject to disciplinary action under Code sections 4301(o), for violating Code sections 4081(a) and (b) in that they failed to keep records of the acquisition of dangerous drugs open for inspection or keep a current inventory as defined by California Code of Regulations, title 16, section 1718 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.

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

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,

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

SIXTH CAUSE FOR DISCIPLINE

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

36. 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 causing the purchase of dangerous drugs by client pharmacies from primary wholesalers on pharmacy accounts controlled by Respondents, as set forth in paragraphs 23 through 30, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Supervise)

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

EIGHTH CAUSE FOR DISCIPLINE

(Purchasing Drugs from Unlicensed Entity)

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

NINTH CAUSE FOR DISCIPLINE

(Failure to Complete Self-Assessment)

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

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

TENTH CAUSE FOR DISCIPLINE

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

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

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

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

OTHER MATTERS

- 42. Pursuant to Code section 4307, if discipline is imposed on Wholesaler Permit Number WLS 3336, issued to McGowan Enterprises Inc., doing business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals and Thomas McGowan while acting as the manager, administrator, owner, member, officer, director, associate, or partner of McGowan Enterprises, doing business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals had knowledge of or knowingly participated in any conduct for which Wholesaler Permit Number WLS 3336 was revoked, suspended or placed on probation, Thomas McGowan shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesaler Permit Number WLS 3336 is placed on probation or until Wholesaler Permit Number WLS 3336 is reinstated if it is revoked.
- 43. Pursuant to Code section 4307, if discipline is imposed on Designated Representative License No. EXC 13963 issued to Thomas Michael McGowan, Thomas McGowan shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Designated Representative License

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

DISCIPLINARY CONSIDERATIONS

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

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 Wholesaler Permit Number WLS 3336, Issued to McGowan Enterprises Inc., doing business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals;
- 2. Revoking or suspending Designated Representative License No. EXC 13963, issued to Thomas Michael McGowan;
- 3. Prohibiting Thomas McGowan from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesaler Permit Number WLS 3336 is placed on probation or until Wholesaler Permit Number WLS 3336 is reinstated if Wholesaler Permit Number WLS 3336 issued to McGowan Enterprises, Inc., doing business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals is revoked;
- 4. Prohibiting Thomas McGowan from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Designated Representative License Number EXC 13963 if placed on probation or until Designated Representative License Number EXC 13963 is reinstated if Designated Representative License Number EXC 13963 issued to Thomas McGowan is revoked;
- 5. Ordering McGowan Enterprises Inc., doing business as McGowan Enterprises, Inc./Acute Care Pharmaceuticals and Thomas Michael McGowan to pay the Board of Pharmacy

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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 (haine Hud)		
6	VIRGINIA HEROLD		
7	Executive Officer Board of Pharmacy Department of Consumer Affairs		
8	Department of Consumer Affairs State of California Complainant		
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