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

In the Matter of the Accusation Against:

MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER

Pharmacy Permit No. PHY 43950
Sterile Compounding License No. LSC 99004,

and

SI VAN PHAM

Pharmacist License No. RPH 49833

Respondents.

Agency Case No. 7176

OAH No. 2021120276

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 at 5:00 p.m. on March 1, 2023.

It is so ORDERED on January 30, 2023.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
DESIREE I. KELLOGG
Deputy Attorney General
State Bar No. 126461
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9429
Facsimile: (619) 645-2061

JOSHUA A. ROOM
Supervising Deputy Attorney General
State Bar No. 214663
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102
Telephone: (415) 510-3512
Facsimile: (415) 703-5480
Attorneys for Complainant

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

In the Matter of the Accusation Against: **MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER** **2921 West MacArthur Blvd., Ste. 142 (139-143)** **Santa Ana, CA 92704** **Pharmacy Permit No. PHY 43950** **Sterile Compounding License No. LSC 99004,** **and** **SI VAN PHAM** **2921 W. MacArthur Blvd., #142** **Santa Ana, CA 92704** **Pharmacist License No. RPH 49833** Respondents.	Case No. 7176 OAH No. 2021120276 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibility of the Board of Pharmacy, Department of Consumer Affairs, the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will be submitted to the Board for approval and adoption as the final disposition of the Accusation with respect to Respondents McGuff Compounding Pharmacy Services Inc. and Si Van Pham.

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Desiree I. Kellogg, Deputy Attorney General, and Joshua A. Room, Supervising Deputy Attorney General.

2. Respondents are represented in this proceeding by attorney Tony J. Park, Pharm.D., J..D., whose address is: California Pharmacy Lawyers, Law Offices of Tony J. Park, Inc., 9090 Irvine Center Drive, Irvine, CA 92618, telephone (949) 336-7854.

3. On or about March 9, 1999, the Board issued Pharmacy Permit Number PHY 43950 to McGuff Compounding Pharmacy Services Inc. Ronald M. McGuff has served or been listed in Board records as the sole shareholder and President, Vice-President, and Secretary of McGuff Compounding Pharmacy Services Inc. (Respondent McGuff Compounding aka MCPS). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

4. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99004 to Respondent McGuff Compounding aka MCPS. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

5. On or about September 3, 1997, the Board issued Pharmacist License Number RPH 49833 to Si Van Pham (Respondent Pham). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2022, unless renewed. Respondent Pham has served and been listed in Board records as Pharmacist-in-Charge of Respondent McGuff Compounding aka MCPS since July 9, 2016.

JURISDICTION

6. Accusation No. 7176 was filed before the Board, against Respondents. Accusation No. 7176 and all other statutorily required documents were properly served on Respondents on October 28, 2021. Respondents timely filed their Notice(s) of Defense contesting the Accusation. First Amended Accusation No. 7176 was filed before the Board, and is currently pending against Respondents. The First Amended Accusation and all other statutorily required documents were properly served on Respondents on April 21, 2022. A copy of First Amended Accusation No. 7176 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 7176. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order on their respective permits and licenses.

8. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel attendance of witnesses and 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.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

10. Respondents understand and agree that the charges and allegations in First Amended Accusation No. 7176, if proven at a hearing, constitute cause for imposing discipline upon their Pharmacy Permit, Sterile Compounding License, and Pharmacist License. For the purposes of resolving this matter without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for charges in the First Amended Accusation, and Respondents hereby give up their right to contest those charges.

11. Respondents agree that their Pharmacy Permit, Sterile Compounding License, and Pharmacist License are each and severally subject to discipline and they agree to be bound by the Board's disciplinary terms as set forth in the Disciplinary Order below.

DESIRED LICENSE CATEGORY TRANSITION

12. Respondent MCPS has decided to seek a transition from being a licensed pharmacy engaged in compounding (a Section 503A facility under federal law) to being a registered and licensed outsourcing facility (a Section 503B facility under federal law). This will entail an application to the Food and Drug Administration (FDA) for registration under Section 503B as an outsourcing facility, and then an application to the Board to be licensed in California as an outsourcing facility. It could take some significant time for MCPS to prepare for and make these applications. In the interim, the MCPS facility will cease functioning as a pharmacy on the effective date of the Decision and Order by the Board of Pharmacy adopting this stipulation.

13. This settlement of the First Amended Accusation does not depend on whether MCPS, any successor or assign thereof, or any entity sharing ownership or management with MCPS, actually submits a subsequent application to the Board for licensure as an outsourcing facility. In the event such application is submitted, the Board will give it the same consideration it would any other application to be licensed as an outsourcing facility. This settlement does not preclude the Board from granting that license. Nor is the Board under any obligation from this settlement to grant that license. Any such application will receive ordinary and fair consideration for licensure. If such an outsourcing facility license is granted, there is one term below that will be applied by the Board to that license, and which Respondent MCPS acknowledges will apply to itself, any successor or assign, or any entity sharing ownership or management with Respondent MCPS.

IMMEDIATE CEASE AND DESIST

14. As of the last date of all signatures on this Stipulated Settlement and Disciplinary Order, both Respondents agree to voluntarily and completely cease and desist compounding, or sales or transfers of compounded preparations, using any active ingredients or drug products named or identified in First Amended Accusation No. 7176, or any other active ingredient or drug product that is not graded for pharmaceutical use.

15. Any compounding by Respondents, or sales or transfers of compounded preparations, using such active ingredients or drug products after that date shall constitute unprofessional conduct and further cause for discipline by both Respondents, and may be considered by the Board in deciding whether to grant or deny any subsequent application by Respondent MCPS, its successor or assign, or any entity sharing ownership or management with Respondent MCPS, including but not limited to a subsequent application for an outsourcing facility license.

CONTINGENCY

16. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their 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.

17. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

18. 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.

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

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DISCIPLINARY ORDER

AS TO RESPONDENT MCGUFF COMPOUNDING AKA MCPS

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 43950, and Sterile Compounding License No. LSC 99004, both issued to Respondent McGuff Compounding aka MCPS, are each and severally surrendered and accepted by the Board.

20. **Definition: Respondent**

For the purposes of paragraphs 20-33, "Respondent" shall refer to Respondent McGuff Compounding aka MCPS. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by Respondent to or before the Board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

21. The surrender of Respondent's Pharmacy Permit and Sterile Compounding License and the acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

22. Respondent shall lose all rights and privileges as a pharmacy and to perform sterile compounding in California as of the effective date of the Board's Decision and Order.

23. Respondent shall be jointly and severally liable to the Board, along with Respondent Pham, for costs of investigation and enforcement of $95,104.75. Respondent shall cause that amount to be paid, in full, on or before the effective date of the Decision and Order.

24. Within (5) business days of the date this Stipulated Settlement and Disciplinary Order is fully executed, Respondent shall submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer within five (5) days. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs and/or devices to premises licensed and approved by the Board. Any transfers of drug inventory shall be conducted in compliance with state and federal law.

25. If permitted by state and federal law, Respondent may transfer current inventory to its commonly-owned facilities as necessary to prepare for testing and other requirements to establish subsequent eligibility for an outsourcing facility registration and/or license.

26. Respondent shall cause to be delivered to the Board its pocket license and, if any were issued, its wall certificates, on or before the effective date of the Decision and Order.

27. Respondent shall also, by the effective date of the Decision and Order, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of its written notice to the Board. For purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

28. Respondent shall also, by the effective date of the Decision and Order, prepare and submit to the Board, on the letterhead for Respondent MCPS, a letter jointly signed by Ronald McGuff and Respondent Pham, in substantially the form attached as exhibit B hereto. The Board may make whatever use of that letter it sees fit, including but not limited to publication in *The Script* or other publication(s), distribution or copying, or submission into evidence in other cases. There shall be no limit to the number of times the Board may publish or otherwise use this letter.

29. Neither Respondent nor its successor or assign, nor any entity sharing ownership or management with Respondent, shall apply to the Board for any permit, license, or registration issued by the Board for a period of three (3) years, except that at any time it is eligible for same:

- Respondent may submit an application for an outsourcing facility license;
- Respondent may apply for a change of location for its wholesaler license (WLS 2947), so long as there is no change in ownership or management structure, or any other substantive change aside from the change in location; and
- Should the Board change the name or category of licensure applicable to the WLS license, Respondent may apply to adopt this change, so long as there is no change in ownership or management structure, or other substantive change.

30. If Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, ever applies for licensure, including as an outsourcing facility, or petitions for reinstatement, the Board shall treat it as a new application for licensure. The applicant/petitioner must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and charges and allegations in First Amended Accusation No. 7176 shall be deemed to be supported by a factual basis and not contested by Respondent when the Board determines whether to grant or deny the application or petition.

31. If an application for an outsourcing facility license is submitted by Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, the Board may in addition consider, in deciding whether to grant or deny that license: whether Respondent met its agreement for the pharmacy to cease and desist compounding, sales, or transfers of drug preparations using active ingredients or drug products named or identified in First Amended Accusation No. 7176, or that are not graded for pharmaceutical use; and whether the Board has received full payment of the costs of investigation and enforcement in this case.

32. If an outsourcing facility license is granted by the Board to Respondent, its successor or assign, or an entity sharing ownership or management with Respondent, that applicant/licensee shall retain, at its own expense, for a period of one (1) year after licensure, an independent consultant for the outsourcing facility approved in advance by the Board or its designee.

33. That independent consultant shall be a pharmacist licensed in good standing by the Board, and shall be responsible for conducting in-person inspections to review the operations of the outsourcing facility on a monthly basis for compliance with applicable state and federal laws. The independent consultant shall prepare and submit written reports directly to Board staff; such reports shall not go first to or be made available to the licensee by the independent consultant.

AS TO RESPONDENT PHAM

IT IS HEREBY ORDERED that Pharmacist License No. RPH 49833, issued to Respondent Pham, is revoked. However, the revocation is stayed and Respondent Pham is placed on probation for thirty-five (35) months on the following terms and conditions:

34. **Definition: Respondent**

For the purposes of paragraphs 34-52, "Respondent" shall refer to Respondent Pham.

35. **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;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime;
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves Respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

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

36. **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 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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37. **Continuing Education**

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

38. **Interview with the Board**

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the Board or its designee, 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.

39. **Cooperate with Board Staff**

Respondent shall timely 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 probation, including but not limited to: timely responses to requests for information by Board staff; timely compliance with directives from Board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

40. **Status of License**

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

If Respondent's pharmacist 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.

41. **Submission of Letter to Board**

Respondent shall, by the effective date of the Decision and Order, prepare and submit to the Board, on the letterhead for Respondent MCPS, a letter jointly signed by Ronald McGuff and Respondent Pham, in substantially the form attached as exhibit B hereto. The Board may make

whatever use of that letter it sees fit, including but not limited to publication in *The Script* or other publication(s), distribution or copying, or submission into evidence in other cases. There shall be no limit to the number of times the Board may publish or otherwise use this letter.

42. **Reimbursement of Board Costs**

Respondent shall be jointly and severally liable to the Board, along with Respondent MCPS, for costs of investigation and enforcement of $95,104.75. Respondent shall cause that amount to be paid, in full, on or before the effective date of the Decision and Order. It shall be a condition precedent to successful completion of probation that these costs were timely paid. Failure to pay costs by the deadline shall also be considered a violation of probation.

43. **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.

44. **Practice Requirement – Extension of Probation**

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of one hundred (100) hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent receives a waiver in writing from the Board or its designee.

If Respondent does not practice as a pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent shall notify the board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume practice at the required level. Respondent shall further notify the board in writing within ten (10) days following the next calendar month during which respondent practices as a pharmacist in

California for the minimum of one hundred (100) hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The Board or its designee may post a notice of the extended probation period on its website.

45. **Ethics Course**

Within sixty (60) calendar days of the effective date of this decision, Respondent shall enroll, at Respondent's expense, in a course in ethics approved in advance by the Board or its designee, that complies with California Code of Regulations, title 16, section 1773.5. Respondent shall provide proof of enrollment upon request. Within five (5) days of completion, Respondent shall submit a copy of the certificate of completion to the Board or its designee. Failure to timely enroll in an approved ethics course, to initiate the course during the first year of probation, to successfully complete it before the end of the second year of probation, or to timely submit proof of completion to the Board or its designee, shall be considered a violation of probation.

46. **No Ownership or Management of Licensed Premises**

Respondent shall not own, have any legal or beneficial interest in, nor 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 shall sell or transfer any legal or beneficial interest in any entity licensed by the Board within ninety (90) days of the effective date of this decision and provide written proof thereof to the Board.

Failure to timely divest any legal or beneficial interest(s) or to immediately provide documentation thereof to the Board shall be considered a violation of probation.

47. **Notification of Change(s) in Name, Address(es), or Phone Number(s)**

Respondent shall notify the Board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address, or phone number.

Failure to timely notify the board of any change in name, residence or mailing address, email address, or phone number, shall be considered a violation of probation.

48. **Reporting of Employment and Notice to Employers**

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 7176 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 ten (10) days of undertaking any new employment, Respondent shall report to the Board in writing the name, physical address, and mailing address of each employer(s), and the name(s) and telephone number(s) of all direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s), and Respondent's work schedule, if known. Respondent shall also include reason(s) for leaving the prior employment. Respondent shall sign and return to the Board a written consent authorizing the Board or its designee to communicate with all of Respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the Board or its designee concerning Respondent's work status, performance, and monitoring.

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 his (a) direct supervisor, (b) pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of his employer, to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 7176, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent shall cause the person(s) taking over the role(s) to report to the Roard in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 7176, and the terms and conditions imposed thereby.

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If Respondent works for or is employed by or through an employment service, Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the Board of the decision in case number 7176, and the terms and conditions imposed thereby, in advance of Respondent commencing work at such 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 an employment service, Respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 7176, and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board.

Failure to timely notify present or prospective employer(s), or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the Board, shall be considered a violation of probation. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a pharmacist license is a requirement or criterion for employment, whether Respondent is an employee, independent contractor, or volunteer.

49. **Restrictions on Supervision and Oversight of Licensed Facilities –**

During the period of probation, Respondent shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board. Respondent may be a pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any single entity licensed by the Board, but only if Respondent or that entity retains, at his/its expense, an independent consultant who shall be responsible for reviewing the operations of the entity on a monthly basis for compliance by Respondent and the entity with state and federal laws and regulations governing the practice of the entity, and compliance by Respondent with the obligations of his supervisory position, for the duration of Respondent's probation period.

Respondent may serve in such a position at only one entity licensed by the Board, only upon approval by the Board or its designee. Any such approval shall be site specific. The consultant shall be a pharmacist licensed by and not on probation with the Board, who has been approved by the Board or its designee to serve in this position. Respondent shall submit the name of the proposed consultant to the Board or its designee for approval within thirty (30) days of the effective date of the decision or prior to assumption of duties allowed in this term. Assumption of any unauthorized supervision responsibilities shall be considered a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure timely reporting by the consultant shall be considered a violation of probation.

50. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish his pharmacist license, including any indicia of licensure issued by the Board, along with a request to surrender the license. The Board or its designee shall have the discretion whether to accept the 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 will constitute 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 his pocket and/or wall license, including any indicia of licensure not previously provided to the Board, within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license 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, including any outstanding costs.

51. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

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52. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that 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. The Board or its designee may post a notice of the extended probation period on its website.

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. If a petition to revoke probation or accusation is filed against Respondent, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

ACCEPTANCE

I am authorized to sign for and bind Respondent McGuff Compounding aka MCPS, as well as its successor or assign, and any entity sharing ownership or management with same. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on the current Pharmacy Permit and Sterile Compounding License, as well as on any subsequent outsourcing facility license that may be issued by the Board of Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

_____

Ronald M. McGuff, President & Owner, for
MCGUFF COMPOUNDING PHARMACY
SERVICES INC.
Respondent

52. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that 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. The Board or its designee may post a notice of the extended probation period on its website.

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. If a petition to revoke probation or accusation is filed against Respondent, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

ACCEPTANCE

I am authorized to sign for and bind Respondent McGuff Compounding aka MCPS, as well as its successor or assign, and any entity sharing ownership or management with same. I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on the current Pharmacy Permit and Sterile Compounding License, as well as on any subsequent outsourcing facility license that may be issued by the Board of Pharmacy. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/14/22

Ronald M. McGuff, President & Owner, for
MCGUFF COMPOUNDING PHARMACY
SERVICES INC.
Respondent

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney Tony J. Park, Pharm.D., J..D. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

SI VAN PHAM
Respondent

I have read and fully discussed with Respondent McGuff Compounding aka MCPS and Respondent Pham the terms and conditions and other matters contained in this Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

TONY J. PARK, PHARM.D., J..D.
CALIFORNIA PHARMACY LAWYERS
Attorney for Respondent

ENDORSEMENT

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

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
JOSHUA A. ROOM
Supervising Deputy Attorney General

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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DATED: December 14, 2022

Respectfully submitted,

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
JOSHUA A. ROOM
Supervising Deputy Attorney General

/s/ Desiree I. Kellogg

DESIREE I. KELLOGG
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 7176

ROB BONTA
Attorney General of California
GREGORY J. SALUTE
Supervising Deputy Attorney General
DESIREE I. KELLOGG
Deputy Attorney General
State Bar No. 126461
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9429
Facsimile: (619) 645-2061
Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **MCGUFF COMPOUNDING PHARMACY SERVICES INC., RONALD M. MCGUFF, OWNER AND OFFICER** **2921 West MacArthur Blvd., Ste. 142 (139-143)** **Santa Ana, CA 92704** **Pharmacy Permit No. PHY 43950** **Sterile Compounding License No. LSC 99004,** **and** **SI VAN PHAM** **2921 W. MacArthur Blvd., #142** **Santa Ana, CA 92704** **Pharmacist License No. RPH 49833** Respondents.	Case No. 7176 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about March 9, 1999, the Board issued Pharmacy Permit Number PHY 43950 to McGuff Compounding Pharmacy Services Inc., Ronald M. McGuff, sole shareholder and President, Vice-President and Secretary and Si Pham, Pharmacist-in-Charge since July 9, 2016 (McGuff Compounding). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

3. On or about July 1, 2003, the Board issued Sterile Compounding License Number LSC 99004 to McGuff Compounding Pharmacy Services Inc. (MCPS). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2023, unless renewed.

4. On or about September 3, 1997, the Board issued Pharmacist License Number RPH 49833 to Si Van Pham (Si Pham). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on November 30, 2022, unless renewed.

JURISDICTION

5. This First Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

6. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law (Bus. & Prof. Code, § 4000 *et seq*.) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000 *et seq*.).

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

8. Code section 4300.1 states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license

by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

9. Code section 4022 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.

10. Code section 4023.5 states:

For the purposes of this chapter, "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist.

11. Code section 4113, subdivision (c) states:

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

12. Code section 4115, subdivision (a) states:

A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

13. Code section 4116, subdivision (a) states:

No person other than a pharmacist, an intern pharmacist, an authorized officer of the law, or a person authorized to prescribe shall be permitted in that area, place, or premises described in the license issued by the board wherein controlled substances or dangerous drugs or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, dispensed, or re-packaged. However, a pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized individual is present.

///

14. Code section 4127.1, subdivisions (e)(3) and (f) state:

(e)(3) Provide to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded.

(f) Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

15. Code section 4127.8, subdivision (a) states:

A pharmacy licensed pursuant to Section 4127.1 or 4127.2 that issues a recall notice regarding a sterile compounded drug shall, in addition to any other duties, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both of the following apply:

(1) Use of or exposure to the recalled drug may cause serious adverse health consequences or death.

(2) The recalled drug was dispensed, or is intended for use, in this state.

16. Section 4169 subdivision (a)(2) of the Code state:

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

…

(2) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

17. Code section 4301 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:

…

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

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

…

(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

…

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or any other state or federal regulatory agency.

…

18. Section 4306.5, subdivision (a) of the Code states, in pertinent part:

Unprofessional conduct for a pharmacist may include any of the following:

Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

…

19. Code section 4307, subdivision (a) states:

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.

20. Health and Safety Code section 111250 states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

21. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

22. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated.

23. Section 501(a)(2)(A) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 351(a)(2)(A)) states:

A drug or device shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

REGULATORY PROVISIONS

24. California Code of Regulations, title 16, section 1714, subdivision (d) states:

Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

25. California Code of Regulations, title 16, section 1735.1, subdivision (ae) states:

"Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

26. California Code of Regulations, title 16, section 1735.2, subdivisions (e), (g) and (h) state:

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

…

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength.

27. California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F) states:

For each compounded drug preparation, pharmacy records shall include: A compounding log consisting of a single document containing all of the following: the manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

28. California Code of Regulations, title 16, section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

(c) The policies and procedures shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.

(2) A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(5) Documentation of the methodology used to validate integrity, potency,

quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

29. California Code of Regulations, title 16, section 1735.8, subdivision (a) states:

Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

30. California Code of Regulations, title 16, section 1751.3, subdivision (a) states:

Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled

areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable).

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

///

31. California Code of Regulations, title 16, section 1751.4, subdivision (f) states:

> Pharmacies preparing-g sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:
>
> (1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
>
> (2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.
>
> (3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations. Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

COST RECOVERY

32. 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.

DEFINITIONS

33. Hydrogen peroxide infusions may be used to treat inflammation, are not Food and Drug Administration (FDA) approved for any indication, and are dangerous drugs as defined under Business and Professions Code section 4022.

34. Dimercapto-propane sulfonic acid (DMPS) infusions may be used to treat mercury and other metal poisoning, are not FDA approved for any indication, and are dangerous drugs as defined under Business and Professions Code section 4022.

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35. Glutathione infusions are prescribed to improve "wellness and health," are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

36. Lipoic acid infusions may be used to treat nerve pain, are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

37. Methylcobalamin infusions may be used to treat neurological conditions and pain, are not FDA approved for any indication, and are dangerous drugs as defined by Business and Professions Code section 4022.

38. Disodium nicotinamide adenine dinucleotide (NADH) infusions may be used to treat Alzheimer's disease and dementia, are not FDA approved for any indication, and are dangerous drugs as defined by Business and Professions Code section 4022.

39. Taurine infusions are prescribed to improve "wellness and health," are not FDA approved for any indication and are dangerous drugs as defined under Business and Professions Code section 4022.

FACTUAL ALLEGATIONS

40. MCPS is a sterile compounding pharmacy located in Santa Ana, California. It compounds non-sterile to sterile compounded sterile preparations and furnishes sterile injectable drugs (i.e., infusion therapies) to physicians and clinics for administration to patients. At all times relevant herein, Si Pham was the Pharmacist-in-Charge and Ronald McGuff was the sole shareholder and an officer of the corporation that owns MCPS. Board inspections revealed the following violations of Pharmacy Law.

41. Pharmacy technicians, facility foremen, plant managers, corporate representatives, chemists, engineers and/or other non-licensed staff possessed keys and alarm codes for areas where dangerous drugs were compounded and accessed those areas when pharmacists were not present.

42. In 2017 and 2018, MCPS received reports of adverse drug effects (i.e., headaches, high fevers, diarrhea, extreme fatigue, loss of consciousness, chills and nausea) suffered by patients after being administered infusions of lipoic acid compounded and dispensed by MCPS.

43. In January 2019, the Board issued Compounding Safety Alerts about the use of inappropriate ingredients to compound sterile injectable drugs and strongly encouraged sterile compounding pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action was required. The Board noted that dietary supplements, food grade chemicals, and cosmetic grade ingredients may have as much as ten times more impurities when compared to pharmaceutical grade ingredients, increasing the risk of patient harm. On February 1, 2019, the FDA warned compounders not to use a dietary grade bulk substance distributed by a manufacturer to compound sterile injectable drugs for patients due to higher levels of endotoxins in that dietary grade bulk substance.

44. MCPS compounded and dispensed sterile injectable drugs including hydrogen peroxide 3%, lipoic acid 40mg/ml, DMPS 50mg/ml, NADH 50 mg/ml and methylcobalamin 5mg/ml 30ml using ingredients (i.e., dietary grade, topical grade and ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, bacteria and mold and higher bioburden levels (i.e., the number of bacteria living on a surface or in a substance that has not been sterilized), than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

45. On November 13, 2019, the Board issued an Order of Correction to MCPS for this unsafe practice and directed Si Pham to send a plan of correction.

46. On November 22, 2019, the FDA issued a Form FDA 483 to MCPS observing among other violations, that MCPS compounded and dispensed sterile injectable drugs with non-pharmaceutical grade ingredients containing high levels of contaminants (MCPS "currently uses …dietary grade bulk substances in sterile injectable drug products") and observed that the use of non-pharmaceutical grade bulk substances in MCPS's products resulted in a recall of Lipoic Acid 40 mg/ml, 30 ml vials due to a "filmy wispy precipitate" found in on-hand vials of released product and the discontinued production of NADH disodium 50 mg/ml due to out of specification endotoxin results.

47. During the "closeout" meeting on November 22, 2019, both the FDA and Board informed Ronald McGuff and Si Pham about the safety risks associated with MCPS's practice of

compounding sterile injectable drugs with inappropriate ingredients containing higher levels of contaminants and higher bioburden levels than pharmaceutical grade ingredients.

48. On December 5, 2019, MCPS wrote the Board that it was MCPS's "continuing desire and intention to comply with all requirements of California pharmacy laws and expectations of the Board of Pharmacy" and it had stopped the dispensing and compounding of sterile preparations compounded with dietary grade and non-compendial grade raw materials "regardless of whether the bulk drug substance appears on the FDA's Category 1 list until further guidance and/or clarification from both the FDA and CA BOP." On December 16, 2019, MCPS wrote the FDA that "[i]n the near term, MCPS has suspended compounding drug preparations containing the components listed in the observation and all USP dietary grade supplements. Drug preparation lots compounded with the listed components will not be dispensed…Corrective Actions for Observation 7: Suspend compounding and dispensing drug preparations utilizing non-pharmaceutical grade components until pharmaceutical grade replacements can be procured or until alternate assurance of material quality and fitness for intended used can be established."

49. However, MCPS continued to compound and dispense a large volume of sterile injectable drugs from inappropriate ingredients, including methylcobalamin and lipoic acid after making those representations to the Board and FDA and receiving the Compounding Safety Alerts.

50. MCPS compounded sterile injectable lipoic acid 40mg/ml 30 ml MDV (Lot No. 18M0991) and DMPS 50mg/ml 5ml SDV (Lot No. 18J1081) containing particulate or precipitate but failed to provide the Board with notice of the recalls of those drugs within twelve hours as required.

51. Patients reported to MCPS that they suffered adverse drug effects (i.e., excruciating pain) from one of its sterile injectable drug products, vitamin D3 10,00IU/ML 30ML MDV (Lot No. 20F1501:0920) but it failed to report those adverse effects to the Board within twelve hours as required.

///

///

52. MCPS compounded sterile injectable chromium (Lot No. 19K411) without a master formula describing the equipment to be used, inactive ingredients to be used and the specific and essential compounding steps used to prepare that infusion.

53. MCPS did not possess all of the policies and procedures required to compound sterile injectable drugs, including procedures for quality assurance programs, cleaning and maintenance of ISO environments and for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process. It also did not possess a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

54. From January 17 through February 23, 2018, there was a 12.6% patch in the HEPA filter of MCPS's primary engineering control devices in Room 107 which was not completely repaired. Yet, MCPS continued to compound at least ten sterile injectable drugs with that primary engineering control device before it was re-certified and tested on February 23, 2018.

55. In November 2019, pharmacy technicians performed prefatory compounding functions, (washed and prepared empty vials) without a pharmacist being present on the premises.

56. In August and September 2020, MCPS failed to document the manufacturer of at least one component for the sterile injectable drug, methylcobalamin.

57. Despite the filing of the Accusation, the discussions with the FDA and Board about safety risks associated with using inappropriate ingredients, the receipt of the FDA Form 483, the receipt of the Board's Order of Correction and the Written Notice and Respondents' promises to cease compounding and dispensing sterile injectable drugs with dietary grade and non-compendial substances, from at least June 1, 2021 through December 1, 2021, MCPS continued to compound and dispense sterile injectable drugs, methylcobalamin 5mg/mL, glutathione 200mg/mL, taurine, lipoic acid and DMPS using inappropriate ingredients (i.e., dietary grade and ungraded bulk substances) likely containing higher levels of contaminates or impurities, including heavy metals, bacteria and mold and higher bioburden levels (i.e., the number of bacteria living

on a surface or in a substance that has not been sterilized), than pharmaceutical grade ingredients, therefore potentially placing patients at risk.

58. In 2021, MCPS received reports of at least six adverse drug effects, including headaches, fever, chills and nausea from sterile injectable drugs compounded and dispensed, but failed to timely report at least four of those adverse drug effects to the Board. It also failed to report at least four of the adverse drug effects immediately to the MedWatch Program of the FDA.

59. On January 24, 2022, the Board issued an Order of Correction to Respondents for their continued use of ingredients in sterile injectable products that lacked quality and a Written Notice for the failure to report adverse drug effects to the Board within twelve hours and immediately to the MedWatch Program of the FDA.

FIRST CAUSE FOR DISCIPLINE

(Manufactured, Held, Sold, Offered for Sale and Delivered Adulterated Drugs)

60. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Health and Safety Code section 111295 and Business and Professions Code section 4169, subdivision (a)(2), in that they manufactured, held (including under insanitary conditions), sold, offered for sale and/or delivered drugs that were adulterated within the meaning of Health & Safety Code sections 111250 and/or 111255 and/or 501(a)(2)(A) of the Federal Food Drug and Cosmetic Act (21 U.SC. 351(a)(2)(A)), as set forth above in paragraphs 40 through 59.

SECOND CAUSE FOR DISCIPLINE

(Compounded Sterile Injectable Drugs Lacking in Quality)

61. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating California Code of Regulations, title 16, section 1735.2, subdivisions (g) and (h), in that they compounded sterile injectable drug products lacking in quality as defined by California Code of Regulations, title 16, section 1735.1, subdivision (ae) and as set forth above in paragraphs 40 through 59.

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THIRD CAUSE FOR DISCIPLINE

(Dishonest Acts)

62. Respondents are subject to disciplinary action under Code section 4301, subdivision (f) in that those Respondents committed dishonest acts when they falsely claimed that they would cease compounding and dispensing sterile injectable drugs from non-pharmaceutical grade ingredients, as set forth above in paragraphs 40 through 59.

FOURTH CAUSE FOR DISCIPLINE

(Made Documents that Falsely Represent Facts)

63. Respondents subject to disciplinary action under Code section 4301, subdivision (g) in that those Respondents made documents that falsely represented the existence of a state of facts when they represented in writing that they would cease compounding and dispensing sterile injectable drugs from non-pharmaceutical grade ingredients, as set forth above in paragraphs 40 through 59.

FIFTH CAUSE FOR DISCIPLINE

(Lack of Security for Pharmacy Premises)

64. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4116, subdivision (a) and California Code of Regulations, title 16, section 1714, subdivision (d), in that pharmacy technicians and unlicensed personnel had access to pharmacy premises where dangerous drugs were compounded without a pharmacist being present and had keys to all of the pharmacy premises, as set forth above in paragraphs 40 through 59.

SIXTH CAUSE FOR DISCIPLINE

(Lack of Supervision of Pharmacy Technicians)

65. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4115, subdivision (a) as defined by Business and Professions Code section 4023.5, in that pharmacy technicians washed and prepared empty drug vials without a pharmacist on the premises, as set forth above in paragraphs 40 through 59.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Notify Board of Recall of Sterile Drug Products)

66. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code sections 4127.1, subdivision (e)(3) and 4127.8, subdivision (a) , in that they failed to provide to the Board, within 12 hours, recall notices issued by MCPS for sterile drug products it had compounded, as set forth above in paragraphs 40 through 59.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Report Adverse Drug Effects of Sterile Drug Product)

67. Respondents are subject to disciplinary action under Code section 4301, subdivision (j) and (o) for violating Business and Professions Code section 4127.1, subdivision (f), in that they failed to report to the Board within 12 hours and immediately to the MedWatch program of the FDA, adverse drug effects reported to MCPS, about its sterile injectable drug products, as set forth above in paragraphs 40 through 59.

NINTH CAUSE FOR DISCIPLINE

(Failed to Possess All Policies and Procedures and a Written Quality Assurance Plan for Compounding Sterile Drug Preparations)

68. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, sections 1735.5, 1735.8, subdivision (a) and 1751.3, subdivision (a) because they failed to have all required written policies and procedures for compounding sterile drug preparations and a written quality assurance plan, as set forth in paragraphs 40 through 59 above.

TENTH CAUSE FOR DISCIPLINE

(Compounded with Incomplete Master Formulas)

69. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.2, subdivision (e), in that they compounded sterile injectable drug preparations without a complete written master formula, as set forth in paragraphs 40 through 59 above.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Complete Compounding Logs)

70. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1735.3, subdivision (a)(2)(F), in that they compounded sterile injectable drug preparations without preparing complete compounding logs, as set forth in paragraphs 40 through 59 above.

TWELFTH CAUSE FOR DISCIPLINE

(Compounded Sterile Drug Products in Uncertified Primary Engineering Control)

71. Respondents are subject to disciplinary action under Code section 4301, subdivision (o), for violating California Code of Regulations, title 16, section 1751.4, subdivision (f), in that they compounded sterile injectable drug preparations using an inappropriate primary engineering control device, as set forth in paragraphs 40 through 59 above.

THIRTEENTH CAUSE FOR DISCIPLINE

(Inappropriate Exercise of Education, Training or Experience as a Pharmacist Against Respondent Si Pham)

72. Respondent Si Pham is subject to disciplinary action under Code section 4301, subdivision (o), for violating Business and Professions Code section 4306.5, subdivision (a) for his inappropriate exercise of his pharmacist education, training, or experience, as set forth in paragraphs 40 through 59.

FOURTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

73. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities set forth in paragraphs 40 through 59 above.

DISCIPLINE CONSIDERATIONS

74. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that on or about April 30, 2019, the Board issued Citation Number CI 2017 80272 to MCPS under Business and Professions Code section 4301, subdivision (n) because it

was disciplined by the Alabama Board of Pharmacy for selling, offering to sell, compounding and/or dispensed drugs into Alabama without a permit. That Citation is now final.

OTHER MATTERS

75. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc., it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated if they are revoked.

76. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc. while Ronald M. McGuff has been a manager or owner and had knowledge of or knowingly participated in any conduct for which the licensees were disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding Licenses are reinstated, if they are revoked.

77. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 43950 and/or Sterile Compounding License No. LSC 99004 issued to McGuff Compounding Pharmacy Services Inc. while Si Van Pham has been a manager and had knowledge of or knowingly participated in any conduct for which the licensees were disciplined, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked.

78. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 49833 issued to Si Van Pham, he shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if

the Pharmacist License is placed on probation or until the Pharmacist License is reinstated, if it is revoked.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 43950, issued to McGuff Compounding Pharmacy Services Inc.;

2. Revoking or suspending Sterile Compounding License Number LSC 99004, issued to McGuff Compounding Pharmacy Services Inc.;

3. Revoking or suspending Pharmacist License Number RPH 49833, issued to Si Van Pham;

4. Prohibiting McGuff Compounding Pharmacy Services Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

5. Prohibiting Ronald M. McGuff from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number LSC 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

6. Prohibiting Si Van Pham from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43950 and/or Sterile Compounding License Number LSC 99004 are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated, if they are revoked;

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7. Prohibiting Si Van Pham from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 49833 is placed on probation or until the Pharmacist License is reinstated, if it is revoked;

8. Ordering McGuff Compounding Pharmacy Services Inc. and Si Van Pham to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 4/21/2022

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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Exhibit B

Text of Letter to Board

Members of the Board of Pharmacy:

We, the undersigned, write to you from the perspective of Board licensees who agreed to the imposition of discipline on our pharmacy and pharmacist licenses in the case titled *In the Matter of the Accusation Against McGuff Compounding Pharmacy Services, Inc., et al.*, Board Case No. 7176. We reached a settlement of the Accusation, of which this letter is part.

We wish to forthrightly and unequivocally state, here, that as persons with significant experience in pharmacy compounding, we agree with and support the following statements:

- All compounding pharmacies located in California or which provide services to California patients are governed both by relevant sections of federal statutes and regulations applicable to pharmacy compounding, including but not limited to section 501 [21 U.S.C. § 351] of the Federal Food, Drug, and Cosmetic Act (FDCA), which defines "adulterated" drugs to include those prepared, packed, or held under insanitary conditions, and FDCA section 503A [21 U.S.C. § 353a], which sets forth several federal requirements to engage in traditional pharmacy compounding, and by the California Pharmacy Law and its associated regulations;

- Further, best practices demand that section 503A traditional compounding pharmacies not use bulk drug substances that are not graded, nor those not designated by their manufacturers for pharmaceutical use, nor those lacking an appropriate USP/NF monograph;

- Best practices further demand that section 503A traditional compounding pharmacies only use bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph; (2) if such monograph does not exist, are drug substances that are components of FDA-approved drugs; and (3) if such monograph does not exist and the drug substance is not a component of an FDA-approved drug, then it must be on a list developed by the Secretary through regulations issued by the Secretary under subsection (c); and

- Best practices also demand that section 503A traditional compounding pharmacies: (1) only use bulk drug substances that are manufactured by an FDA-registered establishment; and (2) that are accompanied by valid certificates of analysis for each bulk drug substance.

We look forward to working with the FDA and the Board to be sure that Californians have access to prescribed medications that are held to the highest degree of quality assurance.

McGuff Compounding Pharmacy Services, Inc.

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Ronald McGuff, CEO Date Si Pham, Pharmacist-In-Charge Date