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

In the Matter of the Accusation Against:

Case No. 4671

SOUTHERN CALIFORNIA COMPOUNDING PHARMACY LLC 11125 Flintkote Ave. #F San Diego, CA 92121

Pharmacy Permit No. PHY 49147 Sterile Compounding License No. LSC 99510 STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR SOUTHERN CALIFORNIA COMPOUNDING PHARMACY LLC ONLY

Respondent.

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 December 15, 2014.

It is so ORDERED on December 9, 2014.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

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By

STAN C. WEISSER Board President

| 1 2 3 4 5 6 | KAMALA D. HARRIS Attorney General of California JAMES LEDAKIS Supervising Deputy Attorney General ANTOINETTE B. CINCOTTA Deputy Attorney General State Bar No. 120482 110 West "A" Street, Suite 1100 San Diego, CA 92101 P.O. Box 85266 San Diego, CA 92186-5266 Telephone: (619) 645-2095 | | | |
|----------------------------|---|--|--|--|
| 7 | Facsimile: (619) 645-2061 Attorneys for Complainant | | | |
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| 9 | BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS | | | |
| 10 | STATE OF CALI | FORNIA | | |
| 11 | To the Motter of this Appropriate Against: | Case No. 4671 | | |
| 12 | all the lyttees of the later and a second | STIPULATED SETTLEMENT AND | | |
| 13 | COMPOUNDING PHARMACY LLC 1 | DISCIPLINARY ORDER FOR - SOUTHERN CALIFORNIA | | |
| 14 | San Diego, CA 92121 | COMPOUNDING PHARMACY LLC | | |
| 15 | Pharmacy License No. PHY 49147 | ONLY | | |
| 16 | Sterile Compounding License No. LSC 99510 | | | |
| 17 | Respondent. | | | |
| 18 | IT IS HEREBY STIPULATED AND AGREED | D by and between the parties to the above- | | |
| 19 | entitled proceedings that the following matters are tru | ue: | | |
| 20 | PARTIE | <u>s</u> | | |
| 21 | 1. Virginia Herold (Complainant) is the Ex | ecutive Officer of the Board of Pharmacy | | |
| 22 | (Board). She brought this action solely in her official capacity and is represented in this matter by | | | |
| 23 | Kamala D. Harris, Attorney General of the State of California, by Antoinette B. Cincotta, Deputy | | | |
| 24 | Attorney General. | | | |
| 25 | 2. Respondent Southern California Compounding Pharmacy LLC (Respondent) is | | | |
| 26 | represented in this proceeding by attorneys John A. Cronin and Peter S. Gregorovic, whose | | | |
| 27 | address is: 5720 Oberrlin Drive, San Diego, CA 92121. | | | |
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| | STIPULATED SETTLEMENT FOR SOUTHERN CALIFORNIA COMPOUNDING PHARMACY LLS ONLY (4671) | | | |

- 3. On or about October 29, 2008, the Board issued Pharmacy License No. PHY 49147 to Southern California Compounding Pharmacy LLC (Respondent). Ollen Williams and Mark J. Badria, Pharmacist License No. RPH 41678, have been members since October 29, 2008. The Pharmacy License was in full force and effect at all times relevant to the charges brought in Accusation No. 4671 and will expire on October 1, 2014, unless renewed.
- 4. On or about December 2, 2008, the Board issued Sterile Compounding License No. LSC 99510 to Southern California Compounding Pharmacy LLC (Respondent). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought in Accusation No. 4671, and will expire on October 1, 2014, unless renewed.

JURISDICTION

- 5. Accusation No. 4671 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on September 16, 2014. Respondent timely filed its Notice of Defense contesting the Accusation.
- 6. A copy of Accusation No. 4671 is attached as Exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 7. Respondent, by and through its members, has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4671. Respondent, by and through its members, has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 8. Respondent, by and through its members, is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to 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.

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Respondent, by and through its members, voluntarily, knowingly, and intelligently 9. waives and gives up each and every right set forth above.

CULPABILITY

- Respondent, by and through its members, understands and agrees that the charges and 10. allegations in Accusation No. 4671, if proven at a hearing, constitute cause for imposing discipline upon its Pharmacy Permit as well as for its Sterile Compounding License.
- For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent, by and through its members, agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up its right to contest those charges.
- Respondent, by and through its members, agrees that its Pharmacy License is subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

- 13. This stipulation shall be subject to approval by the Board. Respondent, by and through its members, understands and agrees 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 Respondent or its counsel. By signing the stipulation, Respondent, by and through its members, 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.
- 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.

- 15. 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.
- 16. 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 Pharmacy License No. PHY 49147 and Sterile Compounding License No. LSC 99510 to Respondent Southern California Compounding Pharmacy LLC (Respondent) is revoked. However, the revocation is stayed, and Respondent is placed on probation for four (4) years on the following terms and conditions.

1. 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 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 Pharmacy License and Sterile Compounding 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 such occurrence shall be considered a violation of probation.

2. 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.

3. 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.

4. 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.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent Southern California Compounding Pharmacy LLC and Respondent Mark Badria shall be jointly and severally responsible to pay to the Board its costs of investigation and prosecution the amount of \$5,551.00. Respondent shall make equal monthly payments of \$154.20 for the first 36 months of probation.

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There shall be no deviation from this schedule absent prior written approval by the Board or its designee. 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 its responsibility to reimburse the Board its costs of investigation and prosecution.

6. **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.

7. Status of License

Respondent shall, at all times while on probation, maintain an active, current 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 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.

License Surrender While on Probation/Suspension 8.

Following the effective date of this decision, should Respondent owner discontinue business, Respondent owner may tender the premises 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.

Upon acceptance of the surrender, Respondent owner shall relinquish the premises wall and renewal license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer.

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27 28. Respondent owner shall also, by the effective date of this decision, 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 days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the Board. For the 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.

Respondent owner may not apply for any new licensure from the Board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

Respondent owner further stipulates that he shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. Notice to Employees

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent owner shall submit written notification to the Board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the Board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in Respondent or Respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. Posted Notice of Probation

Respondent owner shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other persons(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. Violation of Probation

If Respondent owner 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 owner violates probation in any respect, the Board, after giving Respondent owner 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, all charges and allegations in Accusation No. 4671 shall be deemed true and correct,

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. Completion of Probation Upon written notice by the board or its designee indicating successful completion of probation. Respondent's license will be fully restored. ACCEPTANCE I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorneys, John A. Cronin and Peter S. Gregorovic. I understand the stipulation and the effect it will have on my Pharmacy License and Sterile Compounding 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. SOUTHERN CALIFORNIA COMPOUNDING PHARMACY LLC Respondent 10/27/14 18 DATED: Mark J. Badria, Member SOUTHERN CALIFORNIA COMPOUNDING PHARMACY LLC 20 Respondent /// 22 /// 23 /// 24 /// 25 26 111 27 28

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| 1 | I have read and fully discussed with Respondent Southern California Compounding | | | | |
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| 2 | Pharmacy LLC the terms and conditions and other matters contained in the above Stipulated | | | | |
| 3 | Settlement and Disciplinary Order. I approve its form and content. | | | | |
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| 5 | DATED: 10/27/2014 - | ļ | | | |
| 6 | JOHN A. CRONIN Attorney for Respondent | | | | |
| 7 | | | | | |
| 8 | DATED: 10/27/2014 Jet Ship orour | | | | |
| 9 | PETER S. GREGOROVIC Attorney for Respondent | | | | |
| 10 | | | | | |
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| 12 | ENDORSEMENT | | | | |
| 13 | The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully | | | | |
| 14 | submitted for consideration by the Board of Pharmacy. | | | | |
| 15 | Dated: Respectfully submitted, | | | | |
| 16 | KAMALA D. HARRIS Attorney General of California | Ì | | | |
| 17 | JAMES LEDAKIS Supervising Deputy Attorney General | | | | |
| 18 | Supervising Deputy Attorney Central | | | | |
| 19 | | | | | |
| 20 | ANTOINETTE B. CINCOTTA Deputy Attorney General | ŀ | | | |
| 21 | Attorneys for Complainant | | | | |
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| | STIPULATED SETTLEMENT FOR SOUTHERN CALIFORNIA COMPOUNDING PHARMACY LLS ONLY | | | | |
| | (4671) | ۱ (| | | |

Exhibit A

Accusation No. 4671

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|------|--|---------------------------------------|--|
| 1 | KAMALA D. HARRIS Attorney General of California | · · | |
| 2 | LINDA K. SCHNEIDER | | |
| 3 | Supervising Deputy Attorney General ANTOINETTE B. CINCOTTA | | |
| ا | Deputy Attorney General | , | |
| 4 | State Bar No. 120482 110 West "A" Street, Suite 1100 | | |
| 5 | San Diego, CA 92101 | | |
| | P.O. Box 85266 San Diego, CA 92186-5266 | • | |
| 6 | Telephone: (619) 645-2095 | | |
| 7 | Facsimile: (619) 645-2061 Attorneys for Complainant | 1 | |
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| 9 | BEFORE THE BOARD OF PHARM | IACY | |
| į | DEPARTMENT OF CONSUM | IER AFFAIRS | |
| 10 | STATE OF CALIFO | KNIA | |
| 11 | | Case No. 4671 | |
| 12 | In the Matter of the Accusation Against: | Case No. 4071 | |
| 13 | SOUTHERN CALIFORNIA COMPOUNDING PHARMACY LLC | | |
| נו | 11125 Flintkote Ave. #F | ACCUSATION | |
| 14 | San Diego, CA 92121 | | |
| 15 | Pharmacy Permit No. PHY 49147 | | |
| 16 | Sterile Compounding Permit No. LSC 99510 | | |
| | MARK BADRIA | | |
| 17 | 11125 Flintkoke Ave., #F San Diego, CA 92121 | · | |
| 18 | | | |
| 19 | Pharmacist License No. RPH 41678 | \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | |
| | Respondents. | | |
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| 21 | Complainant alleges: | • | |
| 22 | PARTIES | | |
| 23 | 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity | | |
| 24 | as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs. | | |
| 25 | 2. On or about October 29, 2008, the Board of Pharmacy issued Pharmacy Permit No. | | |
| 26 | PHY 49147 to Southern California Compounding Pharmacy LLC (Respondent Pharmacy). The | | |
| 27 | Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein, | | |
| 28 | - No. 1 | | |
| , | | | |

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.

STATUTORY AUTHORITY

8. Section 4301 of the Code states:

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:

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

REGULATIONS

- 9. California Code of Regulations, title 16, section 1751.7, states in relevant part:
 - (c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

COSTS

10. Section 125.3 of the Code states, 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. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Failure to Perform End Product Testing on Batch-Produced Sterile Injectable Drug Products)

- 11. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subdivision (o), for failing to perform end product testing on batch-produced sterile injectable drug products in violation of California Code of Regulations, title 16, section 1751.7, subdivision (c) as follows:
- a. On a routine inspection conducted at Respondent Pharmacy on April 19, 2013, the Board's investigators discovered that 51 sterile injectable drug products were made from batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients. Respondents dispensed these 51 sterile injectable drug products before completing end product testing for sterility and acceptable levels of pyrogens.

DISCIPLINE CONSIDERATIONS

- 12. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that on or about June 9, 2011, in a prior action, the Board of Pharmacy issued Citation Number Cl 2010 46603 charging Respondent Pharmacy with violation of California Code of Regulations, title 16, section 1714, subdivisions (b), (d) and (e), for operating standards and security violations, and California Code of Regulations, title 16, section 1716, and Business and Professions Code section 4076, subdivision (a)(2), for dispensing prescriptions not correctly labeled with directions for use of the drug. Respondent Pharmacy was ordered to pay a fine in the amount of \$1,000.00 by July 9, 2011. That Citation is now final and is incorporated by reference as if fully set forth.
- 13. To determine the degree of discipline, if any, to be imposed on Respondent Badria Complainant alleges that on or about June 9, 2011, in a prior action, the Board of Pharmacy issued Citation Number Cl 2010 48429 charging Respondent Badria with violation of California Code of Regulations, title 16, section 1714, subdivisions (b), (d) and (e), for operating standards and security violations, and California Code of Regulations, title 16, section 1716, and Business and Professions Code section 4076, subdivision (a)(2), for dispensing prescriptions not correctly

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labeled with directions for use of the drug. Respondent Badria was ordered to pay a fine in the amount of \$1,375.00 by July 9, 2011. That Citation is now final and is incorporated by reference as if fully set forth.

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:

- Revoking or suspending Pharmacy Permit No. PHY 49147 issued to Southern
 California Compounding Pharmacy LLC;
- 2. Revoking or suspending Sterile Compounding Permit No. LSC 99510, issued to Southern California Compounding Pharmacy LLC;
- 3. Revoking or suspending Pharmacist License No. RPH 41678 issued to Mark John Badria;
- 4. Ordering Respondents 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;

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| DATED: | \$127/14 | () hering a | Dust | 4 |
| , , , , | Ct til | VIRGINIA HEROLD | • | |
| | • | Executive Officer | | |
| | • | Board of Pharmacy | | |

Department of Consumer Affairs State of California Complainant

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2 ATTORYTY GENDRAL

Accusation