

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

In the Matter of the Accusation Against:

**SUPER CARE, INC. DBA SUPERCARE
Gabriel Cassar, President;
Michelline Cassar, Chief Executive Officer;
John L. Cassar, Vice President;
Michael Cassar, Shareholder
Permit No. PHY 45943**

**GABRIEL JOHN CASSAR, AKA
GABRIEL CASSAR
Pharmacist License No. RPH 25650**

**KATHERINE THU LE, AKA
KATHERINE LE
Pharmacist-in-Charge
Pharmacist License No. 57903**

**TUAN KIEU NGUYEN
Pharmacy Technician Registration
No. TCH 89616**

Respondents.

Case No. 4566

OAH No. 2014030278

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

As to: **KATHERINE THU LE, AKA
KATHERINE LE, RPH 57903**

DECISION AND ORDER

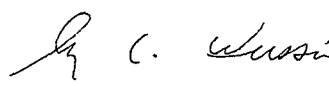
The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on February 4, 2015.

It is so ORDERED on January 28, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By



STAN C. WEISSER, Board President

1 KAMALA D. HARRIS
Attorney General of California
2 ARMANDO ZAMBRANO
Supervising Deputy Attorney General
3 LINDA L. SUN
Deputy Attorney General
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300 So. Spring Street, Suite 1702
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Attorneys for Complainant

7
8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:

Case No. 4566

11 **SUPER CARE, INC. DBA SUPERCARE**
12 **Gabriel Cassar, President;**
13 **Micheline Cassar, Chief Executive Officer;**
14 **John L. Cassar, Vice President;**
15 **Michael Cassar, Shareholder**
16017 Valley Blvd.
City of Industry, CA 91745
Permit No. PHY 45943

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DISCIPLINARY ORDER**

As to: KATHERINE THU LE, AKA
KATHERINE LE, RPH 57903

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17 **GABRIEL CASSAR**
18017 Valley Blvd.
City of Industry, CA 91745
Pharmacist License No. RPH 25650

19 **KATHERINE THU LE, AKA**
20 **KATHERINE LE**
Pharmacist-in-Charge
8151 Whitmore Street, #A
21 Rosemead, CA 91770
Pharmacist License No. RPH 57903

22 **TUAN KIEU NGUYEN**
23 19563 Cronin Drive
24 Rowland Heights, CA 91748
Pharmacy Technician Registration
25 No. TCH 89616

26 Respondents.

1 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
2 entitled proceedings that the following matters are true:

3 **PARTIES**

4 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.
5 She brought this action solely in her official capacity and is represented in this matter by Kamala
6 D. Harris, Attorney General of the State of California, by Linda L. Sun, Deputy Attorney General.

7 2. Respondent Katherine Thu Le, a.k.a. Katherine Le ("Respondent") is represented in
8 this proceeding by attorney Tony J. Park, Esq., whose address is: 6789 Quail Hill Parkway, #405,
9 Irvine, CA 92603.

10 3. On or about November 23, 2005, the Board issued Registered Pharmacist License
11 Number RPH 57903 to Respondent. The License was in full force and effect at all times relevant
12 to the charges brought herein and will expire on May 31, 2015, unless renewed.

13 **JURISDICTION**

14 4. Accusation No. 4566 was filed before the Board and is currently pending against
15 Respondent. The Accusation and all other statutorily required documents were properly served
16 on Respondent on January 29, 2014. Respondent timely filed her Notice of Defense contesting
17 the Accusation.

18 5. A copy of Accusation No. 4566 is attached as Exhibit A and incorporated herein by
19 reference.

20 **ADVISEMENT AND WAIVERS**

21 6. Respondent has carefully read, fully discussed with counsel, and understands the
22 charges and allegations in Accusation No. 4566. Respondent has also carefully read, fully
23 discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary
24 Order.

25 7. Respondent is fully aware of her legal rights in this matter, including the right to a
26 hearing on the charges and allegations in the Accusation; the right to be represented by counsel at
27 her own expense; the right to confront and cross-examine the witnesses against her; the right to
28 present evidence and to testify on her own behalf; the right to the issuance of subpoenas to

1 compel the attendance of witnesses and the production of documents; the right to reconsideration
2 and court review of an adverse decision; and all other rights accorded by the California
3 Administrative Procedure Act and other applicable laws.

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

6 **CULPABILITY**

7 9. Respondent understands and agrees that the charges and allegations in Accusation
8 No. 4566, if proven at a hearing, constitute cause for imposing discipline upon her Pharmacist
9 License.

10 10. For the purpose of resolving the Accusation without the expense and uncertainty of
11 further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual
12 basis for the charges in the Accusation, and that Respondent hereby gives up her right to contest
13 those charges.

14 11. Respondent agrees that her Pharmacist License is subject to discipline and agrees to
15 be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

16 **CONTINGENCY**

17 12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent
18 understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may
19 communicate directly with the Board regarding this stipulation and settlement, without notice to
20 or participation by Respondent or her counsel. By signing the stipulation, Respondent
21 understands and agrees that she may not withdraw her agreement or seek to rescind the stipulation
22 prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation
23 as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or
24 effect, except for this paragraph, it shall be inadmissible in any legal action between the parties,
25 and the Board shall not be disqualified from further action by having considered this matter.

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

1 14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an
2 integrated writing representing the complete, final, and exclusive embodiment of their agreement.
3 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
4 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary
5 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a
6 writing executed by an authorized representative of each of the parties.

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

DISCIPLINARY ORDER

10
11 IT IS HEREBY ORDERED that Pharmacist License No. RPH 57903 issued to Respondent
12 Katherine Thu Le (Respondent) is revoked. However, the revocation is stayed and Respondent is
13 placed on probation for five (5) years on the following terms and conditions.

14 **1. Obey All Laws**

15 Respondent shall obey all state and federal laws and regulations.

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

- 18 • an arrest or issuance of a criminal complaint for violation of any provision of the
19 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
20 substances laws
- 21 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
22 criminal complaint, information or indictment
- 23 • a conviction of any crime
- 24 • discipline, citation, or other administrative action filed by any state or federal agency
25 which involves Respondent’s pharmacist license or which is related to the practice of
26 pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging
27 for any drug, device or controlled substance.

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

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2. Public Letter

Respondent shall provide a public letter of apology to the Board within thirty (30) days of the effective date of the Decision. The letter shall be approved by the Board or its designee prior to being published by the Board. This letter shall detail what Respondent has learned from this experience. The Board may print/reprint this letter in Board communication and on its website, for deterrent and/or educational purposes.

Failure to timely compose and submit for approval shall be considered a violation of probation.

3. Report to the Board

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

4. 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.

5. Cooperate with Board Staff

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

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6. Continuing Education

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

7. Notice to Employers

During the period of probation, Respondent shall notify all present and prospective employers of the Decision in Case Number 4566 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in Case Number 4566, and terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If Respondent works for or is employed by or through a pharmacy employment service, Respondent must notify her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the Decision in Case Number 4566 in advance of the Respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this Decision, and within fifteen (15) days of Respondent undertaking any new employment by or through a pharmacy employment service, Respondent shall cause her direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that she has read the Decision in Case Number 4566 and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

1 Failure to timely notify present or prospective employer(s) or to cause that/those
2 employer(s) to submit timely acknowledgments to the Board shall be considered a violation of
3 probation.

4 "Employment" within the meaning of this provision shall include any full-time,
5 part-time, temporary, relief or pharmacy management service as a pharmacist or any
6 position for which a pharmacist license is a requirement or criterion for employment,
7 whether the Respondent is an employee, independent contractor or volunteer:

8 **8. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as**
9 **Designated Representative-in-Charge, or Serving as a Consultant**

10 During the period of probation, Respondent shall not supervise any intern pharmacist, be
11 the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the
12 Board nor serve as a consultant unless otherwise specified in this order. Assumption of any such
13 unauthorized supervision responsibilities shall be considered a violation of probation.

14 **9. Reimbursement of Board Costs**

15 As a condition precedent to successful completion of probation, Respondent shall pay to the
16 Board its costs of investigation and prosecution in the amount of \$6,310.80 (six thousand three
17 hundred ten dollars and eighty cents). The costs may be paid on a payment plan approved by the
18 Board. There shall be no deviation from the payment plan schedule absent prior written approval
19 by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be
20 considered a violation of probation.

21 The filing of bankruptcy by Respondent shall not relieve Respondent of her responsibility
22 to reimburse the Board its costs of investigation and prosecution.

23 **10. Probation Monitoring Costs**

24 Respondent shall pay any costs associated with probation monitoring as determined by the
25 Board each and every year of probation. Such costs shall be payable to the Board on a schedule
26 as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed
27 shall be considered a violation of probation.

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1 **11. Status of License**

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

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

9 **12. License Surrender While on Probation/Suspension**

10 Following the effective date of this Decision, should Respondent cease practice due to
11 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
12 Respondent may tender her license to the Board for surrender. The Board or its designee shall
13 have the discretion whether to grant the request for surrender or take any other action it deems
14 appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent
15 will no longer be subject to the terms and conditions of probation. This surrender constitutes a
16 record of discipline and shall become a part of the Respondent's license history with the Board.

17 Upon acceptance of the surrender, Respondent shall relinquish her pocket and wall license
18 to the Board within ten (10) days of notification by the Board that the surrender is accepted.
19 Respondent may not reapply for any license from the Board for three (3) years from the effective
20 date of the surrender. Respondent shall meet all requirements applicable to the license sought as
21 of the date the application for that license is submitted to the Board, including any outstanding
22 costs.

23 **13. Notification of a Change in Name, Residence Address, Mailing Address or**
24 **Employment**

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

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

5 **14. Tolling of Probation**

6 Except during periods of suspension, Respondent shall, at all times while on probation, be
7 employed as a pharmacist in California for a minimum of forty (40) hours per calendar month.

8 Any month during which this minimum is not met shall toll the period of probation, i.e., the
9 period of probation shall be extended by one month for each month during which this minimum is
10 not met. During any such period of tolling of probation, Respondent must nonetheless comply
11 with all terms and conditions of probation.

12 Should Respondent, regardless of residency, for any reason (including vacation) cease
13 practicing as a pharmacist for a minimum of forty (40) hours per calendar month in California,
14 Respondent must notify the Board in writing within ten (10) days of the cessation of practice, and
15 must further notify the Board in writing within ten (10) days of the resumption of practice. Any
16 failure to provide such notification(s) shall be considered a violation of probation.

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

20 "Cessation of practice" means any calendar month during which Respondent is
21 not practicing as a pharmacist for at least forty (40) hours, as defined by Business and
22 Professions Code section 4000 et seq . "Resumption of practice" means any calendar
23 month during which Respondent is practicing as a pharmacist for at least forty (40)
24 hours as a pharmacist as defined by Business and Professions Code section 4000 et
25 seq.

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1 **15. Violation of Probation**

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

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

14 **16. Completion of Probation**

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

17 **17. Restricted Practice**

18 Respondent's practice of pharmacy shall not include sterile compounding until completion
19 of thirty (30) hours of training during the first year of probation. Respondent shall submit proof
20 satisfactory to the Board of compliance with this term of probation.

21 Respondent shall not prepare, oversee or participate in the preparation of sterile products
22 during the first year of probation. Respondent shall submit proof satisfactory to the Board of
23 compliance with this term of probation. Failure to abide by this restriction or to timely submit
24 proof to the Board of compliance therewith shall be considered a violation of probation.

25 **18. Community Services Program**

26 Within sixty (60) days of the effective date of this Decision, Respondent shall submit to the
27 Board or its designee, for prior approval, a community service program in which Respondent
28 shall provide free health-care related services on a regular basis to a community or charitable

1 facility or agency for at least thirty (30) hours per year during the period of probation. Within
2 thirty (30) days of Board approval thereof, Respondent shall submit documentation to the Board
3 demonstrating commencement of the community service program. A record of this notification
4 must be provided to the Board upon request. Respondent shall report on progress with the
5 community service program in the quarterly reports. Failure to timely submit, commence, or
6 comply with the program shall be considered a violation of probation.

7 **19. Remedial Education**

8 Within sixty (60) days of the start of the third year of probation, Respondent shall submit to
9 the Board or its designee, for prior approval, an appropriate program of remedial education
10 related to sterile compounding. The program of remedial education shall consist of at least ten
11 (10) units per year, which shall be completed within the third year through the fifth year of
12 probation at Respondent's own expense. All remedial education shall be in addition to, and shall
13 not be credited toward, continuing education (CE) courses used for license renewal purposes.

14 Failure to timely submit or complete the approved remedial education shall be considered a
15 violation of probation. The period of probation will be automatically extended until such
16 remedial education is successfully completed and written proof, in a form acceptable to the
17 Board, is provided to the Board or its designee.

18 Following the completion of each course, the Board or its designee may require the
19 Respondent, at her own expense, to take an approved examination to test the Respondent's
20 knowledge of the course. If Respondent does not achieve a passing score on the examination, this
21 failure shall be considered a violation of probation. Any such examination failure shall require
22 Respondent to take another course approved by the Board in the same subject area.

23 **20. Supervised Practice**

24 During the period of probation, Respondent shall practice only under the supervision of a
25 licensed pharmacist not on probation with the Board. Upon and after the effective date of this
26 Decision, Respondent shall not practice pharmacy and her license shall be automatically
27 suspended until a supervisor is approved by the Board or its designee. The supervision shall be,
28 as required by the Board or its designee, either:

1 Continuous – At least 75% of a work week

2 Substantial - At least 50% of a work week

3 Partial - At least 25% of a work week

4 Daily Review - Supervisor's review of probationer's daily activities within 24 hours

5 Within thirty (30) days of the effective date of this Decision, Respondent shall have her
6 supervisor submit notification to the Board in writing stating that the supervisor has read the
7 Decision in Case Number 4566 and is familiar with the required level of supervision as
8 determined by the Board or its designee. It shall be Respondent's responsibility to ensure that her
9 employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the
10 Board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely
11 acknowledgements to the Board shall be considered a violation of probation.

12 If Respondent changes employment, it shall be Respondent's responsibility to ensure that
13 her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to
14 the Board. Respondent shall have her new supervisor, within fifteen (15) days after employment
15 commences, submit notification to the Board in writing stating the direct supervisor and
16 pharmacist-in-charge have read the Decision in Case Number 4566 and is familiar with the level
17 of supervision as determined by the Board. Respondent shall not practice pharmacy and her
18 license shall be automatically suspended until the Board or its designee approves a new
19 supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely
20 acknowledgements to the Board shall be considered a violation of probation.

21 Within ten (10) days of leaving employment, Respondent shall notify the Board in writing.

22 During suspension, Respondent shall not enter any pharmacy area or any portion of the
23 licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of
24 drugs which is licensed by the Board, or any manufacturer, or where dangerous drugs and devices
25 or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act
26 involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient
27 consultation; nor shall Respondent manage, administer, or be a consultant to any licensee of the
28 Board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs

1 and controlled substances. Respondent shall not resume practice until notified by the Board.

2 During suspension, Respondent shall not engage in any activity that requires the
3 professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the
4 practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a
5 designated representative for any entity licensed by the Board.

6 Subject to the above restrictions, Respondent may continue to own or hold an interest in
7 any licensed premises in which she holds an interest at the time this Decision becomes effective
8 unless otherwise specified in this order.

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

10 **21. No Ownership of Licensed Premises**

11 Respondent shall not own, have any legal or beneficial interest in, or serve as a manager,
12 administrator, member, officer, director, trustee, associate, or partner of any business, firm,
13 partnership, or corporation currently or hereinafter licensed by the Board. Respondent shall sell
14 or transfer any legal or beneficial interest in any entity licensed by the Board within ninety (90)
15 days following the effective date of this Decision and shall immediately thereafter provide written
16 proof thereof to the Board. Failure to timely divest any legal or beneficial interest(s) or provide
17 documentation thereof shall be considered a violation of probation.

18 **22. Ethics Course**

19 Within sixty (60) calendar days of the effective date of this Decision, Respondent shall
20 enroll in a course in Ethics, at Respondent's expense, approved in advance by the Board or its
21 designee. Failure to initiate the course during the first year of probation, and complete it within
22 the second year of probation, is a violation of probation.

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

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tony J. Park, Esq.. 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.

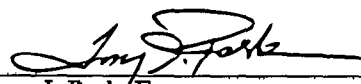
DATED: 12/31/2014



KATHERINE THU LE, AKA, KATHERINE LE
Respondent

I have read and fully discussed with Respondent Katherine Thu Le, aka, Katherine Le the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/31/2014



Tony J. Park, Esq.
Attorney for Respondent

ENDORSEMENT

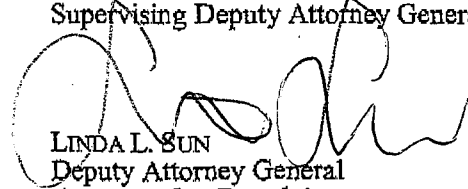
The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated:

Respectfully submitted,

1/5/2015

KAMALA D. HARRIS
Attorney General of California
ARMANDO ZAMBRANO
Supervising Deputy Attorney General



LINDA L. SUN
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 4566

1 KAMALA D. HARRIS
Attorney General of California
2 ARMANDO ZAMBRANO
Supervising Deputy Attorney General
3 LINDA L. SUN
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6 Facsimile: (213) 897-2804
Attorneys for Complainant
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Permit No. PHY 45943

A C C U S A T I O N

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Pharmacist License No. RPH 57903

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23 **19563 Cronin Drive**
24 **Rowland Heights, CA 91748**
25 **Pharmacy Technician Registration**
No. TCH 89616

26 Respondents.
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1 Complainant alleges:

2 **PARTIES**

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

5 Super Care, Inc., dba Supercare ("Respondent Pharmacy")

6 2. On or about July 23, 2002, the Board issued Permit Number PHY 45943 to Super
7 Care, Inc. dba Supercare; Gabriel Cassar, President; Micheline Cassar, Chief Executive Officer;
8 John L. Cassar, Vice President; Michael Cassar, Shareholder; Katherine Le, Pharmacist-in-
9 Charge (collectively "Respondent Pharmacy"). The Permit was in full force and effect at all
10 times relevant to the charges brought herein and will expire on July 1, 2014, unless renewed.

11 Gabriel John Cassar ("Respondent Cassar")

12 3. On or about June 10, 1968, the Board issued Registered Pharmacist License Number
13 25650 to Gabriel John Cassar, a.k.a. Gabriel Cassar ("Respondent Cassar"). The License was in
14 full force and effect at all times relevant to the charges brought herein and will expire on August
15 31, 2015, unless renewed.

16 Katherine Thu Le ("Respondent Le")

17 4. On or about November 23, 2005, the Board issued Registered Pharmacist License
18 Number RPH 57903 to Katherine Thu Le, a.k.a. Katherine Le ("Respondent Le"). The License
19 was in full force and effect at all times relevant to the charges brought herein and will expire on
20 May 31, 2015, unless renewed.

21 Tuan Kieu Nguyen ("Respondent Nguyen")

22 5. On or about March 10, 2009, the Board issued Pharmacy Technician Registration
23 Number TCH 89616 to Tuan Kieu Nguyen ("Respondent Nguyen"). The Registration was in full
24 force and effect at all times relevant to the charges brought herein and will expire on November
25 30, 2014, unless renewed.

26 **JURISDICTION**

27 6. This Accusation is brought before the Board under the authority of the following
28 laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

1
2 7. Section 4300 of the Code states:

3 "(a) Every license issued may be suspended or revoked."

4 8. Section 4300.1 of the Code states:

5 "The expiration, cancellation, forfeiture, or suspension of a board-issued license by
6 operation of law or by order or decision of the board or a court of law, the placement of a license
7 on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board
8 of jurisdiction to commence or proceed with any investigation of, or action or disciplinary
9 proceeding against, the licensee or to render a decision suspending or revoking the license."

10 9. Section 4076 of the Code states:

11 "(a) A pharmacist shall not dispense any prescription except in a container that meets the
12 requirements of state and federal law and is correctly labeled with all of the following:

13 ...

14 "(9) The expiration date of the effectiveness of the drug dispensed."

15 10. Section 4084 of the Code provides:

16 "(a) When a board inspector finds, or has probable cause to believe, that any dangerous drug
17 or dangerous device is adulterated, misbranded, or counterfeit, the board inspector shall affix a tag
18 or other marking to that dangerous drug or dangerous device. The board inspector shall give
19 notice to the person that the dangerous drug or dangerous device bearing the tag or marking has
20 been embargoed."

21 11. Section 4104 of the Code provides, in pertinent part:

22 ...

23 "(b) Every pharmacy shall have written policies and procedures for addressing chemical,
24 mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs,
25 among licensed individuals employed by or with the pharmacy."

26 12. Section 4116 of the Code provides:

27 "(a) No person other than a pharmacist, an intern pharmacist, an authorized officer of the
28 law, or a person authorized to prescribe shall be permitted in that area, place, or premises

1 described in the license issued by the board wherein controlled substances or dangerous drugs or
2 dangerous devices are stored, possessed, prepared, manufactured, derived, compounded,
3 dispensed, or repackaged. However, a pharmacist shall be responsible for any individual who
4 enters the pharmacy for the purposes of receiving consultation from the pharmacist or performing
5 clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to
6 the pharmacy if the pharmacist remains present in the pharmacy during all times as the authorized
7 individual is present.”

8 13. Section 4169 of the Code provides:

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

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

12 ...

13 “(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably
14 should have known were misbranded, as defined in Section 111335 of the Health and Safety
15 Code.

16 “(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the
17 beyond use date on the label.”

18 14. Section 4301 of the Code states:

19 "The board shall take action against any holder of a license who is guilty of unprofessional
20 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

21 Unprofessional conduct shall include, but is not limited to, any of the following:

22 ...

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

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

28 ...

1 pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the
2 key to a pharmacist or 2) providing access in case of emergency. An emergency would include
3 fire, flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a
4 way that the pharmacist may readily determine whether the key has been removed from the
5 container.”

6 17. CCR section 1714.1 provides:

7 “This section is to ensure that pharmacists are able to have duty free breaks and meal
8 periods to which they are entitled under Section 512 of the Labor Code and the orders of the
9 Industrial Welfare Commission, without unreasonably impairing the ability of a pharmacy to
10 remain open.

11 ...

12 “(f) The pharmacy shall have written policies and procedures regarding the operations of
13 the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The
14 policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's
15 responsibilities for checking all work performed by ancillary staff and the pharmacist's
16 responsibility for maintaining the security of the pharmacy. The policies and procedures shall be
17 open to inspection by the board or its designee at all times during business hours.”

18 18. CCR section 1735.1 provides:

19 ...

20 “(c) “Quality” means the absence of harmful levels of contaminants, including filth,
21 putrid, or decomposed substances, and absence of active ingredients other than those noted on
22 the label.”

23 19. CCR section 1735.2 provides:

24 ...

25 “(f) The pharmacist performing or supervising compounding is responsible for the
26 integrity, potency, quality, and labeled strength of a compounded drug product until it is
27 dispensed.

28 ...

1 “(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-
2 in-charge shall complete a self-assessment form for compounding pharmacies developed by the
3 board Form 17M-39 (Rev. 01/11). That form contains a first section applicable to all
4 compounding, and a second section applicable to sterile injectable compounding. The first
5 section must be completed by the pharmacist-in-charge before any compounding is performed in
6 the pharmacy. The second section must be completed by the pharmacist-in-charge before any
7 sterile injectable compounding is performed in the pharmacy. The applicable sections of the
8 self- assessment shall subsequently be completed before July 1 of odd-numbered each year,
9 within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of
10 a new pharmacy license. The primary purpose of the self-assessment is to promote compliance
11 through self-examination and education.”

12 20. CCR section 1735.3 provides:

13 “(a) For each compounded drug product, the pharmacy records shall
14 include:

15 ...

16 “(3) The identity of the pharmacy personnel who compounded the drug
17 product.

18 “(4) The identity of the pharmacist reviewing the final drug product.

19 ...

20 “(6) The manufacturer and lot number of each component. If the manufacturer name
21 is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the
22 requirements in this paragraph are sterile products compounded on a one-time basis for
23 administration within twenty-four hours to an inpatient in a health care facility licensed under
24 section 1250 of the Health and Safety Code.

25 “(7) The equipment used in compounding the drug product.

26 ...

27 “(9) The expiration date of the final compounded drug product.

28 ...

1 “(c) Chemicals, bulk drug substances, drug products, and components used to compound
2 drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain
3 any available certificates of purity or analysis for chemicals, bulk drug substances, drug products,
4 and components used in compounding. Certificates of purity or analysis are not required for
5 products that are approved by the Food and Drug Administration.”

6 21. CCR section 1735.4 provides:

7 ...

8 “(c) Drug products compounded into unit-dose containers that are too small or
9 otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with
10 at least the name(s) of the active ingredient(s), concentration of strength, volume or weight,
11 pharmacy reference or lot number, and expiration date.”

12 22. CCR section 1735.5 provides:

13 “(a) Any pharmacy engaged in compounding shall maintain a written policy and
14 procedure manual for compounding that establishes procurement procedures,
15 methodologies for the formulation and compounding of drugs, facilities and equipment
16 cleaning, maintenance, operation, and other standard operating procedures related to
17 compounding.

18 “(b) The policy and procedure manual shall be reviewed on an annual basis by the
19 pharmacist-in-charge and shall be updated whenever changes in processes are implemented.”

20 23. CCR section 1735.6 provides:

21 “(a) Any pharmacy engaged in compounding shall maintain written documentation
22 regarding the facilities and equipment necessary for safe and accurate compounded drug
23 products. Where applicable, this shall include records of certification(s) of facilities or
24 equipment.

25 “(b) Any equipment used to compound drug products shall be stored, used, and
26 maintained in accordance with manufacturers’ specifications.

27 “(c) Any equipment used to compound drug products for which calibration or
28 adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of

1 each such calibration shall be recorded in writing and these records of calibration shall be
2 maintained and retained in the pharmacy.”

3 24. CCR section 1735.7 provides:

4 “(a) Any pharmacy engaged in compounding shall maintain written documentation
5 sufficient to demonstrate that pharmacy personnel have the skills and training required to
6 properly and accurately perform their assigned responsibilities relating to compounding.

7 “(b) The pharmacy shall develop and maintain an on-going competency evaluation
8 process for pharmacy personnel involved in compounding, and shall maintain documentation of
9 any and all training related to compounding undertaken by pharmacy personnel.”

10 25. CCR section 1735.8 provides:

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

14 ...

15 “(c) The quality assurance plan shall include written standards for qualitative and
16 quantitative integrity, potency, quality, and labeled strength analysis of compounded drug
17 products. All qualitative and quantitative analysis reports for compounded drug products shall
18 be retained by the pharmacy and collated with the compounding record and master formula.”

19 26. CCR section 1751.4 provides:

20 “(d) Exterior workbench surfaces and other hard surfaces in the designated area, such
21 as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any
22 unanticipated event that could increase the risk of contamination.”

23 27. CCR section 1751.6 provides:

24 ...

25 “(b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel
26 engaging in compounding sterile injectable drug products shall have training and demonstrated
27 competence in the safe handling and compounding of sterile injectable products, including
28 cytotoxic agents if the pharmacy compounds products with cytotoxic agents.”

1 28. CCR section 1793.7 provides:

2 “(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in
3 such a relationship that the supervising pharmacist is fully aware of all activities involved in the
4 preparation and dispensing of medications, including the maintenance of appropriate records.”

5 **HEALTH AND SAFETY CODE**

6 29. Health and Safety Code section 111335 states:

7 “Any drug or device is misbranded if its labeling or packaging does not conform to the
8 requirements of Chapter 4 (commencing with Section 110290).”

9 **COST RECOVERY PROVISION**

10 30. Section 125.3 of the Code states, in pertinent part, that the Board may request the
11 administrative law judge to direct a licensee found to have committed a violation or violations of
12 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
13 enforcement of the case.

14 **DRUG CLASSIFICATIONS**

15 31. Xopenex, brand name for Levalbuterol, is a dangerous drug under Code section 4022.
16 It is used as an inhalation therapy for asthma.

17 32. Symbicort, brand name for Formoterol/Budesonide, is a dangerous drug pursuant to
18 Code section 4022. It is used as an inhalation therapy for asthma.

19 33. Atrovent Nebules, brand name for Levalbuterol/Ipratropium, is a dangerous drug
20 pursuant to Code section 4022. It is used as an inhalation therapy for asthma.

21 34. Perforomist, brand name for Formoterol, is a dangerous drug pursuant to Code
22 section 4022. It is a long acting inhalation therapy for asthma.

23 **FIRST CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

24 **(Failure to Maintain Compounding Training Documentation)**

25 35. Respondent Pharmacy is subject to disciplinary action under Code section 4301,
26 subdivision (o) and CCR sections 1735.7, subdivisions (a) and (b), and 1751.6, subdivision (b), in
27 that Respondent Pharmacy failed to maintain written documentation and on-going competency
28 evaluation to demonstrate its staff had the skills and training required to properly and accurately

1 perform their assigned responsibilities relating to compounding. The circumstances are as
2 follows:

3 a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy
4 located in the City of Industry, its Pharmacist-in-Charge Respondent Le failed to maintain
5 training records and documented competency testing for Respondent Pharmacy's licensed
6 employees compounding sterile injectable since October 13, 2009, and failed to maintain training
7 records for the staff compounding inhaled respiratory drugs from powder to solutions.

8 **SECOND CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

9 **(Misbranded Drugs)**

10 36. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
11 subdivisions (j) and (o), in conjunction with 4169, subdivision (a)(3), as defined under Health and
12 Safety Code section 111335, in that during the Board's inspection on December 19, 2011, its
13 Pharmacist-in-Charge Respondent Le allowed the selling of misbranded drugs with the expiration
14 dates greater than the ingredients' expiration as shown on the following compounded drug
15 products:

16 a. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL001 was prepared
17 on 06/17/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an
18 original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's
19 expiration dates were altered to reflect later dates, such that the compound was issued an
20 expiration date of 09/16/11, resulting in one (1) patient receiving an expired drug.

21 b. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL002 was prepared
22 on 06/17/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an
23 original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's
24 expiration dates were altered to reflect later dates, such that the compound was issued an
25 expiration date of 09/16/11, resulting in six (6) patients receiving an expired drug.

26 c. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL003 was prepared
27 on 08/10/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an
28 original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's

1 expiration dates were altered to reflect later dates, such that the compound was issued an
2 expiration date of 11/09/11, resulting in eighteen (18) patients receiving an expired drug.

3 d. Compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml inhalation solution in Lot
4 #LP013 was prepared on 08/11/11 with the ingredient levalbuterol powder by Spectrum under
5 Lot #VJ1342 with an original expiration date in 08/11, both the levalbuterol powder and the
6 Ipratropium expiration dates were altered to reflect later dates such that the compound was issued
7 an expiration date of 11/10/11, resulting in ten (10) patients receiving an expired drug.

8 e. Compounded Formoterol 12mcg/Budesonide 500mcg/2.5ml inhalation solution in
9 Lot #FBB009 was prepared on 11/18/11 with the ingredient polysorbate 80 by Letco listed under
10 Lot #10200811 with an original expiration date of 12/11, but the ingredient's expiration date was
11 altered to reflect a later date, such that the compound was issued an expiration date of 01/17/12,
12 resulting in thirty (30) patients receiving an expired drug.

13 **THIRD CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

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

15 37. Respondent Pharmacy is subject to disciplinary action under Code section 4301,
16 subdivision (o) and CCR section 1735.2, subdivision (j), in that its Pharmacist-in-Charge
17 Respondent Le failed to complete a self-assessment. The circumstances are as follows:

18 a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy,
19 Respondent Le failed to complete the first section of the compounding self-assessment prior to
20 compounding orally-inhaled products, and failed to complete the second section prior to
21 compounding sterile injectable drugs and TPN admixtures.

22 b. On or about December 10, 2012, during a second Board inspection at Respondent
23 Pharmacy, Respondent Le failed to complete the first section of the compounding self-assessment
24 prior to compounding, and failed to complete the second section prior to compounding sterile
25 injectable drugs and TPN admixtures.

26 ///

27 ///

28 ///

1 **FOURTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

2 **(Failure to Maintain Records for Compounded Products)**

3 38. Respondent Pharmacy is subject to disciplinary action under Code section 4301,
4 subdivision (o) and CCR section 1735.3, subdivision (c), in that it failed to maintain proper
5 records for chemical products as follows:

6 a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy,
7 Respondent Le failed to maintain the Certificates of Analysis as required for chemicals, bulk
8 drugs substances, drug products, and components used in compounding.

9 **FIFTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

10 **(Failure to Maintain Compounding Policies and Procedures)**

11 39. Respondent Pharmacy is subject to disciplinary action under Code section 4301,
12 subdivision (o) and CCR section 1735.5, subdivisions (a) and (b), in that during a Board
13 inspection at Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain a
14 written policies and procedures manual related to compounding that establishes procurement
15 procedures, methodologies for formulation and compounding drugs, facilities and equipment
16 cleaning, maintenance, operation, and other standard operating procedures related to
17 compounding.

18 **SIXTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

19 **(Failure to Maintain Licensed Employee Policies and Procedures)**

20 40. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
21 subdivisions (j) and (o), and 4104, subdivision (b), in that during a Board inspection at
22 Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain a written policies
23 and procedures manual addressing chemical, mental, or physical impairment, theft, diversion, or
24 self-use of dangerous drugs for the licensed employees.

25 ///

26 ///

27 ///

28 ///

1 **SEVENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

2 **(Failure to Maintain Facilities and Equipment Records)**

3 41. Respondent Pharmacy is subject to disciplinary action under Code section 4301,
4 subdivision (o) and CCR section 1735.6, subdivisions (a), (b) and (c), in that during a Board
5 inspection at Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain
6 written documentation for monitoring the safe use of compounding facilities and equipment,
7 failed to maintain written documentation for the calibration or adjustment of the equipment
8 including the scales, incubator, the TPN compounded, and failed to maintain documentation
9 related to the cleaning of the pharmacy's facilities and equipment.

10 **EIGHTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

11 **(Failure to Maintain Compounding Quality Assurance Plan)**

12 42. Respondent Pharmacy is subject to disciplinary action under Code section 4301,
13 subdivision (o) and CCR section 1735.8, subdivisions (a) and (c), in that during Board
14 inspections at Respondent Pharmacy on December 19, 2011 and December 10, 2012, Respondent
15 Le failed to maintain a written quality assurance plan, and failed to conduct qualitative or
16 quantitative analysis of the pharmacy's compounded drug products to ensure the integrity,
17 potency, quality, and labeled strength.

18 **NINTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

19 **(Unprofessional Conduct: Act of Moral Turpitude, Dishonesty, Fraud, Deceit, Corruption)**

20 43. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
21 subdivision (f) and 4301, subdivision (q) for unprofessional conduct, in that during a Board
22 inspection at Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy
23 technician Respondent Nguyen committed an act of moral turpitude, dishonesty, fraud, deceit, or
24 corruption, which attempted to subvert the Board's investigation. The circumstances are as
25 follows:

26 ///

27 ///

28 ///

1 a. Respondent Le requested Respondent Nguyen to make copies of the original
2 compounding records upon request by the Board Inspector. Respondent Nguyen altered the
3 expiration dates on the ingredients levalbuterol, lpratropium, polysorbate and citric acid on the
4 pharmacy's compounding records at Respondent Le's request.

5 b. Complainant refers to and incorporates the allegations contained in the Second Cause
6 for Discipline, as though set forth fully.

7 **TENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

8 **(Unprofessional Conduct: False Document/Misrepresentation)**

9 44. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
10 subdivision (g) and 4301, subdivision (q) for unprofessional conduct, in that during a Board
11 inspection at Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy
12 technician Respondent Nguyen knowingly made documents which falsely represented the
13 existence or non-existence of facts in an attempt to subvert the Board's investigation. The
14 circumstances are as follows:

15 a. Respondent Le requested Respondent Nguyen to make copies of the original
16 compounding records upon request by the Board Inspector. Respondent Nguyen altered the
17 expiration dates on the ingredients levalbuterol, lpratropium, polysorbate and citric acid on the
18 pharmacy's compounding records at Respondent Le's request.

19 b. Complainant refers to and incorporates the allegations contained in the Second Cause
20 for Discipline, as though set forth fully.

21 **ELEVENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

22 **(Failure to Maintain Security of Dangerous Drugs)**

23 45. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
24 subdivisions (j) and (o), and 4116, subdivision (a), in conjunction with CCR section 1714,
25 subdivision (d), in that Respondent Pharmacy failed to ensure that the area where dangerous
26 drugs was stored, possessed, prepared, manufactured, derived, compounded, disposed or
27 repackaged was restricted to a pharmacist, and that a pharmacist remained present when other
28 individuals were present. The circumstances are as follows:

1 a. On or about December 10, 2012, during a second Board inspection, Respondent
2 Pharmacy granted the following employees access to the pharmacy where dangerous drugs were
3 stored by using name badge keyless entry during after hours:

4 (i) Name: "Cleaning Personnel" had access to the pharmacy after closing from
5 "6pm to 2am on Tues/Thurs/Sat."

6 (ii) Name: "Information Technology" (IT) had 24 hour access to pharmacy
7 "Always On."

8 (iii) Name: "Managers" had 24 hour access to pharmacy "Always On."

9 (iv) Name: "Master" had 24 hour access to pharmacy "Always On."

10 (v) Name: "Pharmacists" had 24 hour access to pharmacy "Always On."

11 (vi) Name: "Pharmacy Staff" had access to pharmacy "7am-7pm M-F/Sat/Sun."

12 b. On or about December 10, 2012, during a second Board inspection, before
13 Respondent Le arrived at the pharmacy at 09:35 a.m., there were 6 pharmacy staff inside the
14 pharmacy without a pharmacist present, and 9 pharmacy staff present by 09:35 a.m. when
15 Respondent Le arrived.

16 **TWELFTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

17 **(Failure to Maintain Operational Standards and Security)**

18 46. Respondent Pharmacy is subject to disciplinary action under Code section 4301,
19 subdivision (o) and CCR section 1714, subdivision (e), in that it allowed multiple personnel to
20 have possession of a key to the pharmacy which was not maintained in a tamper evident
21 container. The circumstances are as follows:

22 a. On or about December 10, 2012, during a second Board inspection, Respondent Le
23 allowed the owners, family members, and/or managers of Respondent Pharmacy to set the
24 "Access Levels" for the scanned name badge keyless entry into the pharmacy without creating a
25 tamper evident process which would restrict entry into the pharmacy to only the pharmacist or
26 during an emergency.

27 ///
28 ///

1 **THIRTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

2 **(Failure to Maintain Operations Policy During Pharmacist Absence)**

3 47. Respondent Pharmacy is subject to disciplinary action under Code section 4301,
4 subdivision (o) and CCR section 1714.1, subdivision (f), in that on or about December 10, 2012,
5 during a second Board inspection, it failed to maintain written policies and procedures regarding
6 the operations of the pharmacy during the temporary absence of the pharmacist.

7 **FOURTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

8 **(Failure to Maintain Proper Records of Compounded Drug Products/Supervision)**

9 48. Respondent Pharmacy is subject to disciplinary action under Code section 4301,
10 subdivision (o) and CCR section 1735.3, subdivisions (a)(3), a(4), a(6), a(7), and a(9), in
11 conjunction with CCR section 1793.7, subdivision (b), in that on or about December 10, 2012,
12 during a second Board inspection, Respondent Pharmacy failed to maintain proper records of the
13 compounded drug products, and maintain proper supervision of the pharmacy technicians. The
14 circumstances are as follows:

15 a. From about November 14, 2012 to about December 7, 2012, Pharmacist-in-Charge
16 Respondent Le allowed pharmacy technician A.Y. to compound non-sterile to sterile filtered unit
17 dose oral inhalation drugs without documenting on the compounding form the manufacturer and
18 Lot numbers for each ingredient, the equipment used in compounding, the expiration date of each
19 ingredient to confirm the final compounded drug product's expiration date.

20 b. From about November 14, 2012 to about December 7, 2012, pharmacy technician
21 A.Y. did not sign the compounding forms identifying that he compounded the drug products, and
22 Respondent Le did not sign the compounding forms identifying that she reviewed the final drug
23 product, or that she was directly supervising A.Y. in the maintenance of the compounding
24 records. As a result of the lack of supervision, Respondent Le allowed the following to occur:

25 (i) Two (2) patients received the batch of compounded Levalbuterol
26 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12
27 without documentation on the compounding records of any of the drug manufacturers, lot
28 numbers, or expiration dates for any of the ingredients used in the compound. There was no

1 record of who compounded the drug or who verified the end product. The drug was dispensed to
2 both patients before completion of an end product testing for sterility.

3 (ii) Five (5) patients received the batch of compounded Formoterol
4 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12
5 without documentation on the compounding records of any of the drug manufacturers, lot
6 numbers, or expiration dates for any of the ingredients used in the compound. There was no
7 record of who compounded the drug or who verified the end product. The drug was dispensed to
8 all five (5) patients before completion of an end product testing for sterility.

9 (iii) Fifty (50) patients received the batch of compounded Levalbuterol
10 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12 without
11 documentation on the compounding records of any of the drug manufacturers, lot numbers, or
12 expiration dates for any of the ingredients used in the compound. There was no record of who
13 compounded the drug or who verified the end product. The drug was dispensed to thirty-three
14 (33) of the fifty (50) patients before completion of an end product testing for sterility.

15 (iv) Seven (7) patients received the batch of compounded Levalbuterol 1mg/3ml
16 under Lot #LL012 which was compounded on 12/05/12 without documentation on the
17 compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any
18 of the ingredients used in the compound. There was no record of who compounded the drug or
19 who verified the end product. The drug was dispensed to all seven (7) patients before completion
20 of an end product testing for sterility.

21 (v) Twenty-nine (29) patients received the batch of compounded Levalbuterol
22 1mg/3ml under Lot #LL011 which was compounded on 11/14/12 without documentation on the
23 compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any
24 of the ingredients used in the compound. There was no record of who compounded the drug or
25 who verified the end product. The drug was dispensed to nineteen (19) of the twenty-nine (29)
26 patients before completion of an end product testing for sterility.

27 (vi) One hundred and forty (140) patients received the batches of compounded
28 Formoterol 12mcg/Budesonide 0.5mg/2.5ml all recorded under Lot #FBB00022 which were

1 compounded on 12/07/12, 12/05/12, 11/26/12 and 11/23/12 without documentation on the
2 compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any
3 of the ingredients used in the compound. There was no record of who compounded the drug or
4 who verified the end product. The drug was dispensed to all one hundred and forty (140) patients
5 before completion of an end product testing for sterility.

6 **FIFTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

7 **(Failure to Ensure Compounding Limitations and Requirements)**

8 49. Respondent Pharmacy is subject to disciplinary action under Code section 4301,
9 subdivision (o) and CCR section 1735.2, subdivision (f), in conjunction with CCR section 1735.1,
10 subdivision (c), in that on or about December 10, 2012, during a second Board inspection,
11 Respondent Pharmacy failed to ensure the integrity, potency, quality, and labeled strength of the
12 compounded drug products until they were dispensed. The circumstances are as follows:

13 a. Respondent Le conducted quality testing on the end product of the compounded non-
14 sterile to sterile orally inhaled filtered drugs by using a tryptic soy broth medium to confirm the
15 absence of harmful bacteria contaminants. These batches were not quarantined but instead
16 dispensed to patients before the fourteen (14) day testing period for sterility and prior to
17 confirming the "Quality" was sterile for the following batches:

18 (i) Two (2) patients received the batch of compounded Levalbuterol
19 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12.
20 The drug was dispensed to both patients before completion of an end product testing for sterility.

21 (ii) Five (5) patients received the batch of compounded Formoterol
22 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12.
23 The drug was dispensed to all five (5) patients before completion of an end product testing for
24 sterility.

25 (iii) Fifty (50) patients received the batch of compounded Levalbuterol
26 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12. The
27 drug was dispensed to thirty-three (33) of the fifty (50) patients before completion of an end
28 product testing for sterility.

1 (iv) Seven (7) patients received the batch of compounded Levalbuterol 1mg/3ml
2 under Lot #LL012 which was compounded on 12/05/12. The drug was dispensed to all seven (7)
3 patients before completion of an end product testing for sterility.

4 (v) Twenty-nine (29) patients received the batch of compounded Levalbuterol
5 1mg/3ml under Lot #LL011 which was compounded on 11/14/12. The drug was dispensed to
6 nineteen (19) of the twenty-nine (29) patients before completion of an end product testing for
7 sterility.

8 (vi) One hundred and forty (140) patients received the batches of compounded
9 Formoterol 12mcg/Budesonide 0.5mg/2.5ml all recorded under Lot #FBB00022 which were
10 compounded on 12/07/12, 12/05/12, 11/26/12 and 11/23/12. The drug was dispensed to all one
11 hundred and forty (140) patients before completion of an end product testing for sterility.

12 **SIXTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

13 **(Dispensing/Sale of Expired Drug)**

14 50. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
15 subdivisions (j) and (o), and 4169, subdivision (a)(4) as defined under Code section 4076,
16 subdivision (a)(9), in that on or about December 10, 2012, during a second Board inspection,
17 Respondent Le allowed the selling of a compounded drug labeled with an expired date on the
18 3000ml batch of Levalbuterol 0.63/Ipratropium 0.5mg/3ml under Lot #LP016 which was
19 compounded on 11/23/12 with an expiration date of 01/23/12. This drug was dispensed as
20 follows:

- 21 a. On 11/23/12 to Patient E.D. on RX 058028 with an expiration date of 01/23/12;
22 b. On 12/07/12 to Patient L.L. on RX 48575 with an expiration date of 01/23/12.

23 **SEVENTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

24 **(Failure to Include Expiration Date on Labels)**

25 51. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
26 subdivisions (j) and (o), and 4169, subdivision (a)(3) as defined under Health and Safety Code
27 section 111335 and CCR section 1735.4, subdivision (c), in that on or about December 10, 2012,
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1 during a second Board inspection, Respondent Le allowed the dispensing of misbranded unit-dose
2 containers of the following drugs which contained no expiration dates on the labels:

- 3 a. Compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml;
- 4 b. Compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml;
- 5 c. Compounded Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 6 d. Compounded Levalbuterol 1mg/3ml.

7 **EIGHTEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

8 **(Purchase of Dangerous Drugs from Unlicensed Entity)**

9 52. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
10 subdivisions (j) and (o), and 4169, subdivision (a)(1), in that on or about December 10, 2012,
11 during a second Board inspection, Board inspectors discovered that Respondent Le purchased
12 Levalbuterol powder from a non-licensed wholesale distributor – Compounding Direct in Quebec
13 Canada, which was manufactured by AARTI Industries without first confirming that the
14 manufacturer was licensed by the Food and Drugs Administration. The circumstances are as
15 follows:

- 16 a. On or about 12/02/2011, Respondent Pharmacy purchased from Compounding Direct
17 Levalbuterol Powder USP 3x100gms for \$4,500.
- 18 b. On or about 07/13/2012, Respondent Pharmacy purchased from Compounding Direct
19 Levalbuterol Powder USP 3x100gms for \$4,500.

20 **NINETEENTH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

21 **(Embargoed Misbranded Dangerous Drugs)**

22 53. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
23 subdivisions (j) and (o), and 4169, subdivision (a) and 4084, subdivisions (a) and (f), in that on or
24 about December 10, 2012, during a second Board inspection, Board inspectors sealed and
25 embargoed the following compounded unit-dose vials for destruction for lacking expiration dates
26 on the labels:

- 27 a. 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 28 b. 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;

1 c. 1083 vials of Levalbuterol 1mg/3ml.

2 **TWENTIETH CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

3 **(Failure to Maintain Facility and Equipment Standards)**

4 54. Respondent Pharmacy is subject to disciplinary action under Code section 4301,
5 subdivision (o), and CCR section 1751.4, subdivision (d), in that on or about December 10, 2012,
6 during a second Board inspection, Respondent Le advised the Board inspectors that the walls and
7 ceiling in the cleanroom for sterile injectable compounding had not been cleaned, and there was
8 no cleaning record.

9 **TWENTY-FIRST CAUSE FOR DISCIPLINE (RESPONDENT PHARMACY)**

10 **(Drugs Lacking Quality and Strength)**

11 55. Respondent Pharmacy is subject to disciplinary action under Code sections 4301,
12 subdivisions (j) and (o), and 4342, subdivision (a), in that on or about December 10, 2012, during
13 a second Board inspection, Board Inspectors discovered drugs maintained at Respondent
14 Pharmacy that did not conform to the standard and tests as to quality and strength, as follows:

- 15 a. Unlabeled Formoterol 2.5 Stock Solution was in the refrigerator with no label to
16 identify the date the drug was compounded or the expiration date;
- 17 b. Unlabeled Benzalkonium Chloride 17% bottle was in the refrigerator with no label to
18 identify the date the drug was compounded or the expiration date;
- 19 c. Expired tryptic soy broth solutions were used to test if the drugs were sterile. The
20 solutions expired on 02/24/11 and 05/18/12;
- 21 d. The embargoed misbranded compounded drugs which lacked compounding records
22 to determine the quality and strength included:
- 23 (i) 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 24 (ii) 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;
- 25 (iii) 1083 vials of Levalbuterol 1mg/3ml.

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1 **TWENTY-SECOND CAUSE FOR DISCIPLINE (RESPONDENT LE)**

2 **(Failure to Maintain Compounding Training Documentation)**

3 56. Respondent Le is subject to disciplinary action under Code section 4301, subdivision
4 (o), in conjunction with CCR sections 1735.7, subdivisions (a) and (b), and 1751.6, subdivision
5 (b), in that Respondent Le failed to maintain written documentation and on-going competency
6 evaluation to demonstrate her staff had the skills and training required to properly and accurately
7 perform their assigned responsibilities relating to compounding. The circumstances are as
8 follows:

9 a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy,
10 Respondent Le failed to complete the first section of the compounding self-assessment prior to
11 compounding orally-inhaled products, and failed to complete the second section prior to
12 compounding sterile injectable drugs and TPN admixtures.

13 b. On or about December 10, 2012, during a second Board inspection at Respondent
14 Pharmacy, Respondent Le failed to complete the first section of the compounding self-assessment
15 prior to compounding, and failed to complete the second section prior to compounding sterile
16 injectable drugs and TPN admixtures.

17 **TWENTY-THIRD CAUSE FOR DISCIPLINE (RESPONDENT LE)**

18 **(Misbranded Drugs)**

19 57. Respondent Le is subject to disciplinary action under Code sections 4301,
20 subdivisions (j) and (o), and 4169, subdivision (a)(3), as defined under Health and Safety Code
21 section 111335, in that during the Board's inspection on December 19, 2011, she allowed the
22 selling of misbranded drugs with the expiration dates greater than the ingredients' expiration as
23 shown on the following compounded drug products:

24 a. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL001 was prepared
25 on 06/17/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an
26 original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's
27 expiration dates were altered to reflect later dates, such that the compound was issued an
28 expiration date of 09/16/11, resulting in one (1) patient receiving an expired drug.

1 b. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL002 was prepared
2 on 06/17/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an
3 original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's
4 expiration dates were altered to reflect later dates, such that the compound was issued an
5 expiration date of 09/16/11, resulting in six (6) patients receiving an expired drug.

6 c. Compounded Levalbuterol 1mg/3ml inhalation solution in Lot #LL003 was prepared
7 on 08/10/11 with the ingredient levalbuterol powder by Spectrum under Lot #VJ1342 with an
8 original expiration date in 08/11, but the levalbuterol powder and citric acid anhydrous powder's
9 expiration dates were altered to reflect later dates, such that the compound was issued an
10 expiration date of 11/09/11, resulting in eighteen (18) patients receiving an expired drug.

11 d. Compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml inhalation solution in Lot
12 #LP013 was prepared on 08/11/11 with the ingredient levalbuterol powder by Spectrum under
13 Lot #VJ1342 with an original expiration date in 08/11, both the levalbuterol powder and the
14 Ipratropium expiration dates were altered to reflect later dates such that the compound was issued
15 an expiration date of 11/10/11, resulting in ten (10) patients receiving an expired drug.

16 e. Compounded Formoterol 12mcg/Budesonide 500mcg/2.5ml inhalation solution in
17 Lot #FBB009 was prepared on 11/18/11 with the ingredient polysorbate 80 by Letco listed under
18 Lot #10200811 with an original expiration date of 12/11, but the ingredient's expiration date was
19 altered to reflect a later date, such that the compound was issued an expiration date of 01/17/12,
20 resulting in thirty (30) patients receiving an expired drug.

21 **TWENTY-FOURTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

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

23 58. Respondent Le is subject to disciplinary action under Code section 4301, subdivision
24 (o) and CCR section 1735.2, subdivision (j), in that she failed to complete a self-assessment. The
25 circumstances are as follows:

26 a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy,
27 Respondent Le failed to complete the first section of the compounding self-assessment prior to
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1 compounding orally-inhaled products, and failed to complete the second section prior to
2 compounding sterile injectable drugs and TPN admixtures.

3 b. On or about December 10, 2012, during a second Board inspection at Respondent
4 Pharmacy, Respondent Le failed to complete the first section of the compounding self-assessment
5 prior to compounding, and failed to complete the second section prior to compounding sterile
6 injectable drugs and TPN admixtures.

7 **TWENTY-FIFTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

8 **(Failure to Maintain Records for Compounded Products)**

9 59. Respondent Le is subject to disciplinary action under Code section 4301, subdivision
10 (o), and CCR section 1735.3, subdivision (c), in that she failed to maintain proper records for
11 chemical products as follows:

12 a. On or about December 19, 2011, during a Board inspection at Respondent Pharmacy,
13 Respondent Le failed to maintain the Certificates of Analysis as required for chemicals, bulk
14 drugs substances, drug products, and components used in compounding.

15 **TWENTY-SIXTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

16 **(Failure to Maintain Compounding Policies and Procedures)**

17 60. Respondent Le is subject to disciplinary action under Code section 4301, subdivision
18 (o), and CCR section 1735.5, subdivisions (a) and (b), in that during a Board inspection at
19 Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain a written policies
20 and procedures manual related to compounding that establishes procurement procedures,
21 methodologies for formulation and compounding drugs, facilities and equipment cleaning,
22 maintenance, operation, and other standard operating procedures related to compounding.

23 **TWENTY-SEVENTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

24 **(Failure to Maintain Licensed Employee Policies and Procedures)**

25 61. Respondent Le is subject to disciplinary action under Code sections 4301,
26 subdivisions (j) and (o), and 4104, subdivision (b), in that during a Board inspection at
27 Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain a written policies
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1 and procedures manual addressing chemical, mental, or physical impairment, theft, diversion, or
2 self-use of dangerous drugs for the licensed employees.

3 **TWENTY-EIGHTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

4 **(Failure to Maintain Facilities and Equipment Records)**

5 62. Respondent Le is subject to disciplinary action under Code section 4301, subdivision
6 (o), and CCR section 1735.6, subdivisions (a), (b) and (c), in that during a Board inspection at
7 Respondent Pharmacy on December 19, 2011, Respondent Le failed to maintain written
8 documentation for monitoring the safe use of compounding facilities and equipment, failed to
9 maintain written documentation for the calibration or adjustment of the equipment including the
10 scales, incubator, the TPN compounded, and failed to maintain documentation related to the
11 cleaning of the pharmacy's facilities and equipment.

12 **TWENTY-NINTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

13 **(Failure to Maintain Compounding Quality Assurance Plan)**

14 63. Respondent Le is subject to disciplinary action under Code section 4301, subdivision
15 (o), and CCR section 1735.8, subdivisions (a) and (c), in that during Board inspections at
16 Respondent Pharmacy on December 19, 2011 and December 10, 2012, Respondent Le failed to
17 maintain a written quality assurance plan, and failed to conduct qualitative or quantitative
18 analysis of the pharmacy's compounded drug products to ensure the integrity, potency, quality,
19 and labeled strength.

20 **THIRTIETH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

21 **(Unprofessional Conduct: Act of Moral Turpitude, Dishonesty, Fraud, Deceit, Corruption)**

22 64. Respondent Le is subject to disciplinary action under Code sections 4301, subdivision
23 (f) and 4301, subdivision (q) for unprofessional conduct, in that during a Board inspection at
24 Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy technician
25 Respondent Nguyen committed an act of moral turpitude, dishonesty, fraud, deceit, or corruption,
26 which attempted to subvert the Board's investigation. The circumstances are as follows:

27 a. Respondent Le requested Respondent Nguyen to make copies of the original
28 compounding records upon request by the Board Inspector. Respondent Nguyen altered the

1 expiration dates on the ingredients levalbuterol, lpratropium, polysorbate and citric acid on the
2 pharmacy's compounding records at Respondent Le's request.

3 b. Complainant refers to and incorporates the allegations contained in the Second Cause
4 for Discipline, as though set forth fully.

5 **THIRTY-FIRST CAUSE FOR DISCIPLINE (RESPONDENT LE)**

6 **(Unprofessional Conduct: False Document/Misrepresentation)**

7 65. Respondent Le is subject to disciplinary action under Code sections 4301, subdivision
8 (g) and 4301, subdivision (q) for unprofessional conduct, in that during a Board inspection at
9 Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy technician
10 Respondent Nguyen knowingly made documents which falsely represented the existence or non-
11 existence of facts in an attempt to subvert the Board's investigation. The circumstances are as
12 follows:

13 a. Respondent Le requested Respondent Nguyen to make copies of the original
14 compounding records upon request by the Board Inspector. Respondent Nguyen altered the
15 expiration dates on the ingredients levalbuterol, lpratropium, polysorbate and citric acid on the
16 pharmacy's compounding records at Respondent Le's request.

17 b. Complainant refers to and incorporates the allegations contained in the Second Cause
18 for Discipline, as though set forth fully.

19 **THIRTY-SECOND CAUSE FOR DISCIPLINE (RESPONDENT LE)**

20 **(Failure to Maintain Security of Dangerous Drugs)**

21 66. Respondent Le is subject to disciplinary action under Code sections 4301,
22 subdivisions (j) and (o), and 4116, subdivision (a), in conjunction with CCR section 1714,
23 subdivision (d), in that she failed to ensure that the area where dangerous drugs was stored,
24 possessed, prepared, manufactured, derived, compounded, disposed or repackaged was restricted
25 to a pharmacist, and that a pharmacist remained present when other individuals were present. The
26 circumstances are as follows:

1 a. On or about December 10, 2012, during a second Board inspection, Respondent
2 Pharmacy granted the following employees access to the pharmacy where dangerous drugs were
3 stored by using name badge keyless entry during after hours:

4 (i) Name: "Cleaning Personnel" had access to the pharmacy after closing from
5 "6pm to 2am on Tues/Thurs/Sat."

6 (ii) Name: "Information Technology" (IT) had 24 hour access to pharmacy
7 "Always On."

8 (iii) Name: "Managers" had 24 hour access to pharmacy "Always On."

9 (iv) Name: "Master" had 24 hour access to pharmacy "Always On."

10 (v) Name: "Pharmacists" had 24 hour access to pharmacy "Always On."

11 (vi) Name: "Pharmacy Staff" had access to pharmacy "7am-7pm M-F/Sat/Sun."

12 b. On or about December 10, 2012, during a second Board inspection, before
13 Respondent Le arrived at the pharmacy at 09:35 a.m., there were 6 pharmacy staff inside the
14 pharmacy without a pharmacist present, and 9 pharmacy staff present by 09:35 a.m. when
15 Respondent Le arrived.

16 **THIRTY-THIRD CAUSE FOR DISCIPLINE (RESPONDENT LE)**

17 **(Failure to Maintain Operational Standards and Security)**

18 67. Respondent Le is subject to disciplinary action under Code section 4301, subdivision
19 (o), and CCR section 1714, subdivision (e), in that she allowed multiple personnel to have
20 possession of a key to the pharmacy which was not maintained in a tamper evident container.

21 The circumstances are as follows:

22 a. On or about December 10, 2012, during a second Board inspection, Respondent Le
23 allowed the owners, family members, and/or managers of Respondent Pharmacy to set the
24 "Access Levels" for the scanned name badge keyless entry into the pharmacy without creating a
25 tamper evident process which would restrict entry into the pharmacy to only the pharmacist or
26 during an emergency.

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1 **THIRTY-FOURTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

2 **(Failure to Maintain Operations Policy During Pharmacist Absence)**

3 68. Respondent Le is subject to disciplinary action under Code section 4301, subdivision
4 (o), and CCR section 1714.1, subdivision (f), in that on or about December 10, 2012, during a
5 second Board inspection, she failed to maintain written policies and procedures regarding the
6 operations of the pharmacy during the temporary absence of the pharmacist.

7 **THIRTY-FIFTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

8 **(Failure to Maintain Proper Records of Compounded Drug Products/Supervision)**

9 69. Respondent Le is subject to disciplinary action under Code section 4301, subdivision
10 (o), and CCR section 1735.3, subdivisions (a)(3), (4), (6), (7), and (9), in conjunction with CCR
11 section 1793.7, subdivision (b), in that on or about December 10, 2012, during a second Board
12 inspection, Respondent Le failed to maintain proper records of the compounded drug products,
13 and maintain proper supervision of the pharmacy technicians. The circumstances are as follows:

14 a. From about November 14, 2012 to about December 7, 2012, Respondent Le allowed
15 pharmacy technician A.Y. to compound non-sterile to sterile filtered unit dose oral inhalation
16 drugs without documenting on the compounding form the manufacturer and Lot numbers for each
17 ingredient, the equipment used in compounding, the expiration date of each ingredient to confirm
18 the final compounded drug product's expiration date.

19 b. From about November 14, 2012 to about December 7, 2012, pharmacy technician
20 A.Y. did not sign the compounding forms identifying that he compounded the drug products, and
21 Respondent Le did not sign the compounding forms identifying that she reviewed the final drug
22 product, or that she was directly supervising A.Y. in the maintenance of the compounding
23 records. As a result of the lack of supervision, Respondent Le allowed the following to occur:

24 (i) Two (2) patients received the batch of compounded Levalbuterol
25 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12
26 without documentation on the compounding records of any of the drug manufacturers, lot
27 numbers, or expiration dates for any of the ingredients used in the compound. There was no
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1 record of who compounded the drug or who verified the end product. The drug was dispensed to
2 both patients before completion of an end product testing for sterility.

3 (ii) Five (5) patients received the batch of compounded Formoterol
4 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12
5 without documentation on the compounding records of any of the drug manufacturers, lot
6 numbers, or expiration dates for any of the ingredients used in the compound. There was no
7 record of who compounded the drug or who verified the end product. The drug was dispensed to
8 all five (5) patients before completion of an end product testing for sterility.

9 (iii) Fifty (50) patients received the batch of compounded Levalbuterol
10 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12 without
11 documentation on the compounding records of any of the drug manufacturers, lot numbers, or
12 expiration dates for any of the ingredients used in the compound. There was no record of who
13 compounded the drug or who verified the end product. The drug was dispensed to thirty-three
14 (33) of the fifty (50) patients before completion of an end product testing for sterility.

15 (iv) Seven (7) patients received the batch of compounded Levalbuterol 1mg/3ml
16 under Lot #LL012 which was compounded on 12/05/12 without documentation on the
17 compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any
18 of the ingredients used in the compound. There was no record of who compounded the drug or
19 who verified the end product. The drug was dispensed to all seven (7) patients before completion
20 of an end product testing for sterility.

21 (v) Twenty-nine (29) patients received the batch of compounded Levalbuterol
22 1mg/3ml under Lot #LL011 which was compounded on 11/14/12 without documentation on the
23 compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any
24 of the ingredients used in the compound. There was no record of who compounded the drug or
25 who verified the end product. The drug was dispensed to nineteen (19) of the twenty-nine (29)
26 patients before completion of an end product testing for sterility.

27 (vi) One hundred and forty (140) patients received the batches of compounded
28 Formoterol 12mcg/Budesonide 0.5mg/2.5ml all recorded under Lot #FBB00022 which were

1 compounded on 12/07/12, 12/05/12, 11/26/12 and 11/23/12 without documentation on the
2 compounding records of any of the drug manufacturers, lot numbers, or expiration dates for any
3 of the ingredients used in the compound. There was no record of who compounded the drug or
4 who verified the end product. The drug was dispensed to all one hundred and forty (140) patients
5 before completion of an end product testing for sterility.

6 **THIRTY-SIXTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

7 **(Failure to Ensure Compounding Limitations and Requirements)**

8 70. Respondent Le is subject to disciplinary action under Code section 4301, subdivision
9 (o), and CCR section 1735.2, subdivision (f), in conjunction with CCR section 1735.1,
10 subdivision (c), in that on or about December 10, 2012, during a second Board inspection,
11 Respondent Le failed to ensure the integrity, potency, quality, and labeled strength of the
12 compounded drug products until they were dispensed. The circumstances are as follows:

13 a. Respondent Le conducted quality testing on the end product of the compounded non-
14 sterile to sterile orally inhaled filtered drugs by using a tryptic soy broth medium to confirm the
15 absence of harmful bacteria contaminants. These batches were not quarantined but instead
16 dispensed to patients before the fourteen (14) day testing period for sterility and prior to
17 confirming the "Quality" was sterile for the following batches:

18 (i) Two (2) patients received the batch of compounded Levalbuterol
19 0.63mg/Ipratropium 0.5mg/3ml under Lot #LP016 that which was compounded on 11/23/12.
20 The drug was dispensed to both patients before completion of an end product testing for sterility.

21 (ii) Five (5) patients received the batch of compounded Formoterol
22 12mcg/Budesonide 0.5mg/2.5ml under Lot #FBB00021 which was compounded on 12/05/12.
23 The drug was dispensed to all five (5) patients before completion of an end product testing for
24 sterility.

25 (iii) Fifty (50) patients received the batch of compounded Levalbuterol
26 1.25mg/Ipratropium 0.5mg/3ml under Lot #LPP310 which was compounded on 11/20/12. The
27 drug was dispensed to thirty-three (33) of the fifty (50) patients before completion of an end
28 product testing for sterility.

1 (iv) Seven (7) patients received the batch of compounded Levalbuterol 1mg/3ml
2 under Lot #LL012 which was compounded on 12/05/12. The drug was dispensed to all seven (7)
3 patients before completion of an end product testing for sterility.

4 (v) Twenty-nine (29) patients received the batch of compounded Levalbuterol
5 1mg/3ml under Lot #LL011 which was compounded on 11/14/12. The drug was dispensed to
6 nineteen (19) of the twenty-nine (29) patients before completion of an end product testing for
7 sterility.

8 (vi) One hundred and forty (140) patients received the batches of compounded
9 Formoterol 12mcg/Budesonide 0.5mg/2.5ml all recorded under Lot #FBB00022 which were
10 compounded on 12/07/12, 12/05/12, 11/26/12 and 11/23/12. The drug was dispensed to all one
11 hundred and forty (140) patients before completion of an end product testing for sterility.

12 **THIRTY-SEVENTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

13 **(Dispensing/Sale of Expired Drug)**

14 71. Respondent Le is subject to disciplinary action under Code sections 4301,
15 subdivisions (j) and (o), and 4169, subdivision (a)(4) as defined under Business and Professions
16 Code section 4076, subdivision (a)(9), in that on or about December 10, 2012, during a second
17 Board inspection, Respondent Le allowed the selling of a compounded drug labeled with an
18 expired date on the 3000ml batch of Levalbuterol 0.63/Ipratropium 0.5mg/3ml under Lot #LP016
19 which was compounded on 11/23/12 with an expiration date of 01/23/12. This drug was
20 dispensed as follows:

- 21 a. On 11/23/12 to Patient E.D. on RX 058028 with an expiration date of 01/23/12;
22 b. On 12/07/12 to Patient L.L. on RX 48575 with an expiration date of 01/23/12.

23 **THIRTY-EIGHTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

24 **(Failure to Include Expiration Date on Labels)**

25 72. Respondent Le is subject to disciplinary action under Code sections 4301,
26 subdivisions (j) and (o), and 4169, subdivision (a)(3) as defined under Health and Safety Code
27 section 111335 and CCR section 1735.4, subdivision (c), in that on or about December 10, 2012,
28

1 during a second Board inspection, Respondent Le allowed the dispensing of misbranded unit-dose
2 containers of the following drugs which contained no expiration dates on the labels:

- 3 a. Compounded Levalbuterol 0.63mg/Ipratropium 0.5mg/3ml;
- 4 b. Compounded Formoterol 12mcg/Budesonide 0.5mg/2.5ml;
- 5 c. Compounded Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 6 d. Compounded Levalbuterol 1mg/3ml.

7 **THIRTY-NINTH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

8 **(Purchase of Dangerous Drugs from Unlicensed Entity)**

9 73. Respondent Le is subject to disciplinary action under Code sections 4301,
10 subdivisions (j) and (o), and 4169, subdivision (a)(1), in that on or about December 10, 2012,
11 during a second Board inspection, Board inspectors discovered that Respondent Le purchased
12 Levalbuterol powder from a non-licensed wholesale distributor – Compounding Direct in Quebec
13 Canada, which was manufactured by AARTI Industries without first confirming that the
14 manufacturer was licensed by the Food and Drugs Administration. The circumstances are as
15 follows:

- 16 a. On or about 12/02/2011, Respondent Pharmacy purchased from Compounding Direct
17 Levalbuterol Powder USP 3x100gms for \$4,500.
- 18 b. On or about 07/13/2012, Respondent Pharmacy purchased from Compounding Direct
19 Levalbuterol Powder USP 3x100gms for \$4,500.

20 **FORTIETH CAUSE FOR DISCIPLINE (RESPONDENT LE)**

21 **(Embargoed Misbranded Dangerous Drugs)**

22 74. Respondent Le is subject to disciplinary action under Code sections 4301,
23 subdivisions (j) and (o), in conjunction with 4169, subdivision (a) and 4084, subdivisions (a) and
24 (f), in that on or about December 10, 2012, during a second Board inspection, Board inspectors
25 sealed and embargoed the following compounded unit-dose vials for destruction for lacking
26 expiration dates on the labels:

- 27 a. 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 28 b. 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;

1 c. 1083 vials of Levalbuterol 1mg/3ml.

2 **FORTY-FIRST CAUSE FOR DISCIPLINE (RESPONDENT LE)**

3 **(Failure to Maintain Facility and Equipment Standards)**

4 75. Respondent Le is subject to disciplinary action under Code section 4301, subdivision
5 (o), and CCR section 1751.4, subdivision (d), in that on or about December 10, 2012, during a
6 second Board inspection, Respondent Le advised the Board inspectors that the walls and ceiling
7 in the cleanroom for sterile injectable compounding had not been cleaned, and there was no
8 cleaning record.

9 **FORTY-SECOND CAUSE FOR DISCIPLINE (RESPONDENT LE)**

10 **(Drugs Lacking Quality and Strength)**

11 76. Respondent Le is subject to disciplinary action under Code sections 4301,
12 subdivisions (j) and (o), and 4342, subdivision (a), in that on or about December 10, 2012, during
13 a second Board inspection, Board Inspectors discovered drugs maintained at Respondent
14 Pharmacy that did not conform to the standard and tests as to quality and strength, as follows:

- 15 a. Unlabeled Formoterol 2.5 Stock Solution was in the refrigerator with no label to
16 identify the date the drug was compounded or the expiration date;
- 17 b. Unlabeled Benzalkonium Chloride 17% bottle was in the refrigerator with no label to
18 identify the date the drug was compounded or the expiration date;
- 19 c. Expired tryptic soy broth solutions were used to test if the drugs were sterile. The
20 solutions expired on 02/24/11 and 05/18/12;
- 21 d. The embargoed misbranded compounded drugs which lacked compounding records
22 to determine the quality and strength included:
- 23 (i) 768 vials of Levalbuterol 1.25mg/Ipratropium 0.5mg/3ml;
- 24 (ii) 938 vials of Formoterol 12mcg/Budesonide 0.5mg/2.5ml;
- 25 (iii) 1083 vials of Levalbuterol 1mg/3ml.

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1 **FORTY-THIRD CAUSE FOR DISCIPLINE (RESPONDENT NGUYEN)**

2 **(Unprofessional Conduct: Act of Moral Turpitude, Dishonesty, Fraud, Deceit, Corruption)**

3 77. Respondent Nguyen is subject to disciplinary action under Code sections 4301,
4 subdivision (f) and 4301, subdivision (q) for unprofessional conduct, in that during a Board
5 inspection at Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy
6 technician Respondent Nguyen committed an act of moral turpitude, dishonesty, fraud, deceit, or
7 corruption, which attempted to subvert the Board's investigation. The circumstances are as
8 follows:

9 a. Respondent Le requested Respondent Nguyen to make copies of the original
10 compounding records upon request by the Board Inspector. Respondent Nguyen altered the
11 expiration dates on the ingredients levalbuterol, lpratropium, polysorbate and citric acid on the
12 pharmacy's compounding records at Respondent Le's request.

13 b. Complainant refers to and incorporates the allegations contained in the Second Cause
14 for Discipline, as though set forth fully.

15 **FORTY-FOURTH CAUSE FOR DISCIPLINE (RESPONDENT NGUYEN)**

16 **(Unprofessional Conduct: False Document/Misrepresentation)**

17 78. Respondent Nguyen is subject to disciplinary action under Code sections 4301,
18 subdivision (g) and 4301, subdivision (q) for unprofessional conduct, in that during a Board
19 inspection at Respondent Pharmacy on December 19, 2011, Respondent Le and pharmacy
20 technician Respondent Nguyen knowingly made documents which falsely represented the
21 existence or non-existence of facts in an attempt to subvert the Board's investigation. The
22 circumstances are as follows:

23 a. Respondent Le requested Respondent Nguyen to make copies of the original
24 compounding records upon request by the Board Inspector. Respondent Nguyen altered the
25 expiration dates on the ingredients levalbuterol, lpratropium, polysorbate and citric acid on the
26 pharmacy's compounding records at Respondent Le's request.

27 b. Complainant refers to and incorporates the allegations contained in the Second Cause
28 for Discipline, as though set forth fully.

1 **DISCIPLINE CONSIDERATIONS**

2 79. To determine the degree of discipline, if any, to be imposed on Respondent
3 Pharmacy, Complainant alleges that on or about February 27, 2004, in a prior action, the Board
4 issued Citation Number CI 2002 25346 in the amount of \$1,600 for violation of CCR sections
5 1751.7, subdivisions (a), (d) and (e); 1751.5; 1751.8, subdivision (f), 1716.2, 1714, subdivision
6 (b); 1715 subdivisions (a) and (b); 1793.7, subdivision (b); and Code section 4116. Respondent
7 Pharmacy has fully complied with the Citation.

8 **PRAYER**

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

11 1. Revoking or suspending Permit Number PHY 45943, issued to Super Care, Inc. dba
12 Supercare; Gabriel Cassar (President); Micheline Cassar (Chief Executive Officer); John L.
13 Cassar (Vice President); Michael Cassar (Shareholder);

14 2. Revoking or suspending Pharmacist License No. RPH 25650, issued to Gabriel John
15 Cassar, a.k.a. Gabriel Cassar;

16 3. Revoking or suspending Pharmacist License No. RPH 57903, issued to Katherine
17 Thu Le, a.k.a. Katherine Le;

18 4. Revoking or suspending Pharmacy Technician Registration TCH 89616, issued to
19 Tuan Kieu Nguyen;

20 5. Ordering Super Care, Inc. dba Supercare, Gabriel John Cassar, a.k.a. Gabriel Cassar,
21 Katherine Thu Le, a.k.a. Katherine Le, and Tuan Kieu Nguyen, to pay the Board of Pharmacy the
22 reasonable costs of the investigation and enforcement of this case, pursuant to Business and
23 Professions Code section 125.3;

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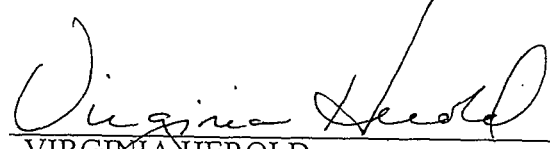
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6. Taking such other and further action as deemed necessary and proper.

DATED: 1/17/14



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

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