

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

In the Matter of the Accusation Against:

SWAPNIL VISHWASROA PATIL
1680 Rio Vista Way
Yuba City, CA 95993

Original Pharmacist License No. RPH 56473

Respondent.

Case No. 5592

OAH No. 2016030796

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on January 23, 2017.

It is so ORDERED on December 23, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

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10 **DEPARTMENT OF CONSUMER AFFAIRS**
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11 In the Matter of the Accusation Against:

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15 Respondent.

Case No. 5592

OAH No. 2016030796

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

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17
18 **IT IS HEREBY STIPULATED AND AGREED** by and between the parties to the above-
19 entitled proceedings that the following matters are true:

20 **PARTIES**

21 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy
22 ("Board"), Department of Consumer Affairs. She brought this action solely in her official
23 capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of
24 California, by Leslie A. Burgermyer, Deputy Attorney General.

25 2. Respondent Swapnil Vishwasroa Patil ("Respondent") is represented in this
26 proceeding by attorney Tony Park, Esq. and Ivan Petrzelka, Esq. whose address is: California
27
28

1 Pharmacy Lawyers, California Pharmacy Lawyers, 2855 Michelle Drive Suite 180, Irvine, CA
2 92606-1027.

3 3. On or about October 19, 2004, the Board issued Original Pharmacist License No.
4 RPH 56473 to Respondent. The Original Pharmacist License was in full force and effect at all
5 times relevant to the charges brought in the original Accusation No. 5592 and First Amended
6 Accusation No. 5592, and will expire on October 31, 2018, unless renewed.

7 **JURISDICTION**

8 4. Accusation No. 5592 was filed before the Board, and is currently pending against
9 Respondent. The Accusation and all other statutorily required documents were properly served
10 on Respondent on February 8, 2016. Respondent timely filed his Notice of Defense contesting
11 the Accusation. On or about August 24, 2016, the First Amended Accusation No. 5592 was filed
12 and served on September 2, 2016, served along with a Supplemental Statement to Respondent.
13 The First Amended Accusation supersedes the original Accusation in all respects.

14 5. A true and correct copy of First Amended Accusation No. 5592 is attached hereto,
15 marked Exhibit A, and incorporated herein by reference.

16 **ADVISEMENT AND WAIVERS**

17 6. Respondent has carefully read, fully discussed with counsel, and understands the
18 charges and allegations in First Amended Accusation No. 5592. Respondent has also carefully
19 read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and
20 Disciplinary Order.

21 7. Respondent is fully aware of his legal rights in this matter, including the right to a
22 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine
23 the witnesses against him; the right to present evidence and to testify on his own behalf; the right
24 to the issuance of subpoenas to compel the attendance of witnesses and the production of
25 documents; the right to reconsideration and court review of an adverse decision; and all other
26 rights accorded by the California Administrative Procedure Act and other applicable laws.

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

1 CULPABILITY

2 9. Respondent admits the truth of each and every charge and allegation in First
3 Amended Accusation No. 5592.

4 10. Respondent agrees that his Original Pharmacist License is subject to discipline and he
5 agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

6 RESERVATION

7 11. The admissions made by Respondent herein are only for the purposes of this
8 proceeding, or any other proceedings in which the Board of Pharmacy or other professional
9 licensing agency is involved, and shall not be admissible in any other criminal or civil
10 proceeding.

11 CONTINGENCY

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

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

24 14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an
25 integrated writing representing the complete, final, and exclusive embodiment of their agreement.
26 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
27 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary
28

1 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a
2 writing executed by an authorized representative of each of the parties.

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

6 **DISCIPLINARY ORDER**

7 **IT IS HEREBY ORDERED** that Original Pharmacist License No. RPH 56473 issued to
8 Respondent Swapnil Vishwasroa Patil ("Respondent") is revoked. However, the revocation is
9 stayed and Respondent is placed on probation for four (4) years on the following terms and
10 conditions.

11 1. **Obey All Laws.** Respondent shall obey all state and federal laws and regulations.
12 Respondent shall report any of the following occurrences to the Board, in writing, within seventy-
13 two (72) hours of such occurrence:

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

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

25 2. **Report to the Board.** Respondent shall report to the Board quarterly, on a schedule
26 as directed by the Board or its designee. The report shall be made either in person or in writing,
27 as directed. Among other requirements, Respondent shall state in each report under penalty of
28 perjury whether there has been compliance with all the terms and conditions of probation. Failure

1 to submit timely reports in a form as directed shall be considered a violation of probation. Any
2 period(s) of delinquency in submission of reports as directed may be added to the total period of
3 probation. Moreover, if the final probation report is not made as directed, probation shall be
4 automatically extended until such time as the final report is made and accepted by the Board.

5 **3. Interview with the Board.** Upon receipt of reasonable prior notice, Respondent
6 shall appear in person for interviews with the Board or its designee, at such intervals and
7 locations as are determined by the Board or its designee. Failure to appear for any scheduled
8 interview without prior notification to Board staff, or failure to appear for two (2) or more
9 scheduled interviews with the Board or its designee during the period of probation, shall be
10 considered a violation of probation.

11 **4. Cooperate with Board Staff.** Respondent shall cooperate with the Board's
12 inspection program and with the Board's monitoring and investigation of Respondent's
13 compliance with the terms and conditions of his probation. Failure to cooperate shall be
14 considered a violation of probation.

15 **5. Continuing Education.** Respondent shall provide evidence of efforts to maintain
16 skill and knowledge as a pharmacist as directed by the Board or its designee.

17 **6. Notice to Employers.** During the period of probation, Respondent shall notify all
18 present and prospective employers of the decision in First Amended Accusation Case No. 5592
19 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

20 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
21 Respondent undertaking any new employment, Respondent shall cause his direct supervisor,
22 pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent's
23 tenure of employment) and owner to report to the Board in writing acknowledging that the listed
24 individual(s) has/have read the decision in First Amended Accusation Case No. 5592, and terms
25 and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his
26 employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

27 If Respondent works for or is employed by or through a pharmacy employment service,
28 then Respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every

1 entity licensed by the Board of the terms and conditions of the decision in First Amended
2 Accusation Case No. 5592 in advance of the Respondent commencing work at each licensed
3 entity. A record of this notification must be provided to the Board upon request.

4 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
5 (15) days of Respondent undertaking any new employment by or through a pharmacy
6 employment service, Respondent shall cause his direct supervisor with the pharmacy employment
7 service to report to the Board in writing acknowledging that he has read the decision in First
8 Amended Accusation Case No. 5592 and the terms and conditions imposed thereby. It shall be
9 Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely
10 acknowledgment(s) to the Board.

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

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

18 **7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as**
19 **Designated Representative-in-Charge, or Serving as a Consultant.** During the period of
20 probation, Respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or
21 designated representative-in-charge of any entity licensed by the Board nor serve as a consultant
22 unless otherwise specified in this order. Assumption of any such unauthorized supervision
23 responsibilities shall be considered a violation of probation.

24 **8. Reimbursement of Board Costs.** As a condition precedent to successful completion
25 of probation, Respondent shall pay to the Board its costs of investigation and prosecution in the
26 amount of \$11,203.75 pursuant to a payment plan approved by the Board.

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1 There shall be no deviation from this schedule absent prior written approval by the Board or
2 its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of
3 probation.

4 The filing of bankruptcy by Respondent shall not relieve Respondent of his responsibility to
5 reimburse the Board its costs of investigation and prosecution.

6 9. **Probation Monitoring Costs.** Respondent shall pay any costs associated with
7 probation monitoring as determined by the Board each and every year of probation. Such costs
8 shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to
9 pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10 10. **Status of License.** Respondent shall, at all times while on probation, maintain an
11 active, current license with the Board, including any period during which suspension or probation
12 is tolled. Failure to maintain an active, current license shall be considered a violation of
13 probation.

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

18 11. **License Surrender While on Probation/Suspension.** Following the effective date
19 of this decision, should Respondent cease practice due to retirement, or health, or be otherwise
20 unable to satisfy the terms and conditions of probation, Respondent may tender his license to the
21 Board for surrender. The Board or its designee shall have the discretion whether to grant the
22 request for surrender or take any other action it deems appropriate and reasonable. Upon formal
23 acceptance of the surrender of the license, Respondent will no longer be subject to the terms and
24 conditions of probation. This surrender constitutes a record of discipline and shall become a part
25 of the Respondent's license history with the Board.

26 Upon acceptance of the surrender, Respondent shall relinquish his pocket and wall license
27 to the Board within ten (10) days of notification by the Board that the surrender is accepted,
28 Respondent may not reapply for any license from the Board for three (3) years from the effective

1 date of the surrender. Respondent shall meet all requirements applicable to the license sought as
2 of the date the application for that license is submitted to the Board, including any outstanding
3 costs.

4 **12. Notification of a Change in Name, Residence Address, Mailing Address or**
5 **Employment.** Respondent shall notify the Board in writing within ten (10) days of any change of
6 employment. Said notification shall include the reasons for leaving, the address of the new
7 employer, the name of the supervisor and owner, and the work schedule if known. Respondent
8 shall further notify the Board in writing within ten (10) days of a change in name, residence
9 address, mailing address, or phone number.

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

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

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

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

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

1 month during which Respondent is practicing as a pharmacist for at least forty (40)
2 hours as a pharmacist as defined by Business and Professions Code section 4000 et
3 seq.

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

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

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

19 **16. Remedial Education.** Within sixty (60) days of the effective date of this decision,
20 Respondent shall submit to the Board or its designee, for prior approval, an appropriate program
21 of remedial education related to compounding and/or pharmacy math before supervising or
22 performing compounding functions. The program of remedial education shall consist of at least
23 forty (40) hours of in person training which shall be completed within forty-two (42) months of
24 the end of Respondent's probation, and at Respondent's own expense. All remedial education
25 shall be in addition to, and shall not be credited toward, continuing education ("CE") courses used
26 for license renewal purposes.

27 Failure to timely submit or complete the approved remedial education shall be considered a
28 violation of probation. The period of probation will be automatically extended until such

1 remedial education is successfully completed and written proof, in a form acceptable to the
2 Board, is provided to the Board or its designee.

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

8 Respondent shall be restricted from the practice of compounding drugs until the remedial
9 education program has been successfully completed.

10 **17. No Ownership of Licensed Premises.** Respondent shall not own, have any legal or
11 beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee,
12 associate, or partner of any business, firm, partnership, or corporation currently or hereinafter
13 licensed by the Board. Respondent shall sell or transfer any legal or beneficial interest in any
14 entity licensed by the Board within ninety (90) days following the effective date of this decision
15 and shall immediately thereafter provide written proof thereof to the Board. Failure to timely
16 divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a
17 violation of probation.

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

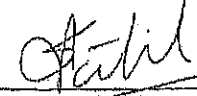
26 **18. Ethics Course.** Within sixty (60) calendar days of the effective date of this decision,
27 Respondent shall enroll in a course in ethics, at Respondent's expense, approved in advance by
28 the Board or its designee. Failure to initiate the course during the first year of probation, and

1 complete it within the second year of probation, is a violation of probation.

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

4 ACCEPTANCE

5 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
6 discussed it with my attorney, Tony Park, Esq. and/or Ivan Petrzelka. I understand the stipulation
7 and the effect it will have on my Original Pharmacist License. I enter into this Stipulated
8 Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be
9 bound by the Decision and Order of the Board of Pharmacy.

10
11 DATED: 11/30/2016 
12 SWAPNIL VISHWASROA PATIL
Respondent

13 I have read and fully discussed with Respondent Swapnil Vishwasroa Patil the terms and
14 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.
15 I approve its form and content.

16 DATED: 11-30-16 
17 TONY PARK, ESQ.
18 IVAN PETRZELKA, ESQ.
Attorneys for Respondent

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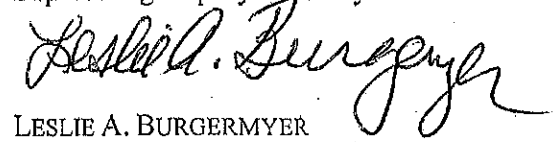
ENDORSEMENT

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

Dated: 11-30-2016

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General



LESLIE A. BURGERMYER
Deputy Attorney General
Attorneys for Complainant

SA2015105023
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Exhibit A

First Amended Accusation No. 5592

1 KAMALA D. HARRIS
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2 KENT D. HARRIS
Supervising Deputy Attorney General
3 LESLIE A. BURGERMYER
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Attorneys for Complainant

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FIRST AMENDED
ACCUSATION

14 **Original Pharmacist License No. RPH 56473**

15 Respondent.

16
17 Complainant alleges:

18 **PARTIES**

19 1. Virginia Herold ("Complainant") brings this First Amended Accusation solely in her
20 official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer
21 Affairs.

22 2. On or about October 19, 2004, the Board of Pharmacy ("Board") issued Original
23 Pharmacist License Number RPH 56473 to Swapnil Vishwasroa Patil ("Respondent"). The
24 Original Pharmacist License was in full force and effect at all times relevant to the charges
25 brought herein and will expire on October 31, 2016, unless renewed. At all times alleged herein,
26 Respondent was the Pharmacist-In-Charge within the meaning of Business and Professions Code
27 section 4113.

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JURISDICTION

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

4. Section 4300 of the Code states, in pertinent part:

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

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

5. Section 4300.1 of the Code states:

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

STATUTORY PROVISIONS

6. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(b) Incompetence.

(c) Gross negligence.

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

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

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

5 7. Section 4022 of the Code states, in pertinent part:

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

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

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

11 8. Section 4113 of the Code states, in pertinent part:

12 (a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days
13 thereof, shall notify the board in writing of the identity and license number of that
pharmacist and the date he or she was designated.

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

16 **REGULATORY PROVISIONS**

17 9. California Code of Regulations, title 16, section 1716 states:

18 Pharmacists shall not deviate from the requirements of a prescription except
19 upon the prior consent of the prescriber or to select the drug product in accordance
with Section 4073 of the Business and Professions Code.

20 10. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:

21 (a) For each compounded drug product, the pharmacy records shall include:

22 (1) The master formula record.

23 (2) The date the drug product was compounded.

24 (3) The identity of the pharmacy personnel who compounded the drug
product.

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

26 (5) The quantity of each component used in compounding the drug
27 product.

28 (6) The manufacturer, expiration date and lot number of each component.

1 If the manufacturer name is demonstrably unavailable, the name of the supplier
2 may be substituted. Exempt from the requirements in this paragraph are sterile
3 products compounded on a one-time basis for administration within seventy-two
4 (72) hours and stored in accordance with standards for "Redispensed CSPS"
found in Chapter 797 of the United States Pharmacopeia - National Formulary
(USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by
reference, to an inpatient in a health care facility licensed under section 1250 of
the Health and Safety Code.

5 (7) A pharmacy assigned reference or lot number for the compounded
6 drug product.

7 (8) The expiration date of the final compounded drug product.

8 (9) The quantity or amount of drug product compounded.

9 (b) Pharmacies shall maintain records of the proper acquisition, storage, and
10 destruction of chemicals, bulk drug substances, drug products, and components used
11 in compounding.

12 (c) Chemicals, bulk drug substances, drug products, and components used to
13 compound drug products shall be obtained from reliable suppliers. The pharmacy
14 shall acquire and retain any available certificates of purity or analysis for chemicals,
15 bulk drug substances, drug products, and components used in compounding.
16 Certificates of purity or analysis are not required for drug products that are approved
17 by the Food and Drug Administration.

18 (d) Pharmacies shall maintain and retain all records required by this article in the
19 pharmacy in a readily retrievable form for at least three years from the date the record
20 was created.

21 11. California Code of Regulations, title 16, section 1735.7 states:

22 (a) Any pharmacy engaged in compounding shall maintain written
23 documentation sufficient to demonstrate that pharmacy personnel have the skills and
24 training required to properly and accurately perform their assigned responsibilities
25 relating to compounding.

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

(c) Pharmacy personnel assigned to compounding duties shall demonstrate
knowledge about processes and procedures used in compounding prior to
compounding any drug product.

DRUG

25 12. **Liothyronine (T3)** is a man-made form of a hormone that is normally produced by the
26 thyroid gland to regulate the body's energy and metabolism, and is a dangerous drug within the
27 meaning of Code section 4022. It is prescribed for thyroid replacement.

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COST RECOVERY

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

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BACKGROUND

14. At all times alleged herein, Respondent was the Pharmacist-In-Charge employed by Walgreens #933 Pharmacy located at 855 Colusa Highway, Yuba City, California, ("Walgreens"). As the Pharmacist-In-Charge, Respondent was responsible for Walgreens' compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

15. On or about January 26, 2013, Dr. D. B. prescribed the drug "T(3) 22.5 MCG SR CAP," quantity of 60, and 30 days supply to Consumer K. S. for treating her thyroid condition. The prescription was submitted to Walgreens for compounding the medication. The compounded T(3) contained a previously mixed aliquot¹ prepared by an unknown person on an unknown date. The aliquot contained up to three unknown ingredients. Respondent admittedly did not maintain a worksheet verifying the person who had mixed the aliquot, its ingredients, the date prepared, and the date that the aliquot was used in the final compounded T(3), and other information required by California Code of Regulations, title 16, section 1735.5, subdivision (a).

16. On or about January 26, 2013, Respondent verified and dispensed Prescription No. RX4080895, the compounded T(3) drug, to Consumer K. S. The Consumer ingested the drug, per the prescription, for treatment of her thyroid condition. Within days of taking it, the Consumer reported to Dr. D. B. that she was not feeling well, and went on her scheduled vacation to Texas. While on vacation, Consumer K. S. was hospitalized for five days and was diagnosed that she was in "thyroid storm."² She had complaints of shortness of breath, palpitations, and

¹ An aliquot is part of a medicine or chemicals.

² "Thyroid storm," also known as "thyrotoxic crisis," is an acute, life-threatening, hypermetabolic state induced by excessive release of thyroid hormones in individuals with thyrotoxicosis. Symptoms include fever, tachycardia, hypertension, and neurological and GI abnormalities. Hypertension may be followed by congestive heart failure that is associated with hypotension and shock.

1 tachycardia (abnormally high heart rate), and went into heart failure. The Texas hospital took the
2 Consumer off the compounded T(3) drug. Upon her return to California, the Consumer exhibited
3 continued symptoms of cardiomyopathy as a result of the high levels of the compounded T(3).

4 17. On an unknown date after January 26, 2013 and after Consumer K. S. had returned from
5 Texas, Dr. D. B. obtained the Consumer's bottle of the compounded T(3) drug, took it to
6 Respondent at Walgreens, and requested an analysis be conducted on the drug. At least five
7 capsules were retained and analyzed.

8 18. On or about April 26, 2013, the Consumer received a Walgreens fax with the result of
9 the testing on the Consumer's T(3) drug capsules. The analysis disclosed that the compounded
10 T(3) capsules in Prescription RX4080895 were compounded in a formulation in which each
11 capsule contained 406.65mcg instead of the prescribed dose of 22.5mcg, which was 1807.35%
12 greater than the prescription ordered by Dr. D.B. Respondent dispensed Prescription RX4080895
13 to Consumer K. S. without properly verifying that the compounded T(3) capsules complied with
14 Dr. D. B.'s prescription for the drug "T(3) 22.5 MCG SR CAP." Respondent's failure resulted in
15 harm to Consumer K. S. as described in paragraph 16, above.

16 19. On or before June 29, 2015, during the Board's investigation of the events alleged in
17 paragraphs 15 through 18, above, Respondent admitted to the Board's investigator that he had not
18 maintained written documentation sufficient to demonstrate that the Walgreens' personnel
19 involved in compounding the T(3) for Prescription No. RX4080895 had the skills and training
20 required to properly and accurately perform their assigned responsibilities relating to
21 compounding. He also admitted that the personnel had not been trained in compounding. During
22 the investigation, Respondent attempted to blame a different Walgreens pharmacist for the active
23 compounding and verification of RX 4080895 despite the fact that Respondent was the only
24 pharmacist involved in the active compounding of T(3), signed that the compound was correct,
25 and verified the final product.

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1 FIRST CAUSE FOR DISCIPLINE

2 (Gross Negligence)

3 20. Respondent is subject to disciplinary action under Code section 4301, subdivision (b),
4 on the grounds of unprofessional conduct in that on or about January 26, 2013, while practicing as
5 a registered pharmacist, Respondent committed acts constituting gross negligence as alleged in
6 paragraphs 15, 18, and 19, above, incorporated herein by reference.

7 SECOND CAUSE FOR DISCIPLINE

8 (Incompetence)

9 21. Respondent is subject to disciplinary action under Code section 4301, subdivision (c),
10 on the grounds of unprofessional conduct in that on or about January 26, 2013, while practicing as
11 a registered pharmacist, Respondent committed acts constituting incompetence as alleged in
12 paragraphs 15, 18, and 19, above, incorporated herein by reference.

13 THIRD CAUSE FOR DISCIPLINE

14 (Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

15 22. Respondent is subject to disciplinary action under Code section 4301, subdivision (f),
16 on the grounds of unprofessional conduct in that on or before June 29, 2015, Respondent
17 committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption when he
18 blamed a different pharmacist for the active compounding of T(3). The truth is Respondent was
19 the only pharmacist involved in the active compounding of T(3) for Consumer's prescription,
20 signed the compounded drug as correct, and verified the final compounded product, as alleged in
21 paragraph 19, above, incorporated herein by reference.

22 FOURTH CAUSE FOR DISCIPLINE

23 (Deviation from Prescription Without Consent)

24 23. Respondent is subject to disciplinary action under Code section 4301, subdivisions (j)
25 and (o), in conjunction with Code of Regulations, title 16, section 1716, in that on or about
26 January 26, 2013, Respondent deviated from the requirements of a prescription without the prior
27 consent of the prescribing physician, as set forth in paragraphs 14 through 19, above, incorporated
28 herein by reference.

1 **FIFTH CAUSE FOR DISCIPLINE**

2 **(Failure to Comply With Compounding Requirements)**

3 24. Respondent is subject to disciplinary action under Code section 4301, subdivisions (j)
4 and (o), in conjunction with Code of Regulations, title 16, section 1735.3, subdivision (a), in that
5 on or about January 26, 2013; Respondent failed to maintain the required documentation for the
6 aliquot, which was compounded and contained up to three ingredients, that he used in the
7 compound of the T(3) drug for Consumer K. S., as set forth in paragraph 15, above, incorporated
8 herein by reference. Specifically,

9 a. Respondent failed to maintain a worksheet for the compounded aliquot
10 containing the master formula;

11 b. Respondent failed to maintain a worksheet stating the date the compounded
12 aliquot was compounded;

13 c. Respondent failed to maintain a worksheet stating the identity of the personnel
14 who compounded the aliquot;

15 d. Respondent failed to maintain a worksheet stating the identity of the pharmacist
16 reviewing the final compounded aliquot product;

17 e. Respondent failed to maintain a worksheet stating the quality of each drug
18 product in the compounded aliquot;

19 f. Respondent failed to maintain a worksheet stating the pharmacy reference
20 number for the compounded aliquot;

21 g. Respondent failed to maintain a worksheet stating the expiration date of the
22 final compounded aliquot; and

23 h. Respondent failed to maintain a worksheet stating the quantity or amount of the
24 compounded aliquot.

25 **SIXTH CAUSE FOR DISCIPLINE**

26 **(Failure to Train Pharmacy Personnel in Compounding)**

27 25. Respondent is subject to disciplinary action under Code section 4301, subdivisions (j)
28 and (o), in conjunction with Code of Regulations, title 16, section 1735.7, subdivision (a), in that

1 he admittedly failed to comply with this regulation, as set forth in paragraph 18, above, incorpor-
2 ated herein by reference, as follows:

3 a. Respondent failed to maintain written documentation sufficient to demonstrate that
4 pharmacy personnel have the skills and training required to properly and accurately perform their
5 assigned responsibilities relating to compounding;

6 b. Respondent failed to develop and maintain an on-going competency evaluation
7 process for pharmacy personnel involved in compounding, and failed to maintain documentation
8 of any and all training related to compounding undertaken by pharmacy personnel; and

9 c. Respondent failed to ensure that pharmacy personnel assigned to compounding
10 duties could demonstrate knowledge about the processes and procedures used in compounding
11 prior to compounding any drug product.

12 **DISCIPLINARY CONSIDERATIONS**

13 26. Complainant requests that the following be taken into consideration when
14 determining the level of discipline in this matter:

15 a. On or about July 10, 2013, the Board issued Citation No. CI 2012 57471 against
16 Respondent alleging that Respondent, while employed as a Pharmacist at Walgreens Pharmacy
17 located in Yuba City, California, had compounding equipment and instruments that were in
18 unsanitary conditions, specifically (a) the drugs were stored on equipment in the midst of
19 extremely unclean conditions; (b) the drugs were not maintained in an orderly fashion; and, (c)
20 the unsanitary conditions were easily visible to Consumers. Respondent was charged with
21 violating California Code of Regulations, title 16, section 1714, subdivisions (b) and (c), and the
22 fine of \$500.00 was imposed. Respondent timely paid the fine.

23 **PRAYER**

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

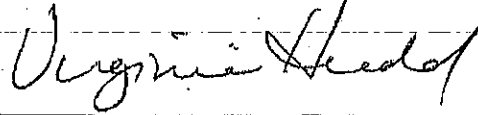
26 1. Revoking or suspending Original Pharmacist License Number RPH 56473, issued to
27 Swapnil Vishwasroa Patil;

1 2. Ordering Swapnil Vishwasroa Patil to pay the Board of Pharmacy the reasonable costs
2 of the investigation and enforcement of this case, pursuant to Business and Professions Code
3 section 125.3; and

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

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6 DATED: _____

8/24/16



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

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