

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

In the Matter of the Accusation Against:

Case No. 3769

**PRECISION PHARMACY LLC DBA
PRECISION PHARMACY**

5301 Young Street
Bakersfield, CA 93309

Original Pharmacy Permit No. PHY 47310
Sterile Compounding License No. LSC 99351

Respondent.

DECISION AND ORDER

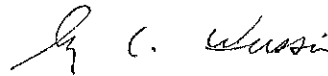
The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on February 11, 2014.

It is so ORDERED on February 4, 2014.

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 GREGORY J. SALUTE
Supervising Deputy Attorney General
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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. 3769

11 **PRECISION PHARMACY LLC DBA**
12 **PRECISION PHARMACY**
13 **4000 Empire Drive, Suite 200**
Bakersfield, CA 93309
14 **Original Permit No. PHY 47310**
Sterile Compounding License No. LSC
15 **99351**

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

16 Respondents.

17
18 In the interest of a prompt and speedy settlement of this matter, consistent with the public
19 interest and the responsibility of the Board of Pharmacy of the Department of Consumer Affairs,
20 the parties hereby agree to the following Stipulated Settlement and Disciplinary Order which will
21 be submitted to the Board for approval and adoption as the final disposition of the Accusation
22 solely with respect to Precision Pharmacy.

23 **PARTIES**

24 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.
25 She brought this action solely in her official capacity and is represented in this matter by Kamala
26 D. Harris, Attorney General of the State of California, by M. Travis Peery, Deputy Attorney
27 General.

28 ///

2. Respondent Precision Pharmacy LLC dba Precision Pharmacy ("Respondent") is represented in this proceeding by attorney Jonathan Klein, whose address is: One Sansome Street, Suite 1800, San Francisco, CA 94104.

3. On or about October 7, 2005, the Board of Pharmacy issued Original Permit No. PHY 47310 to Precision Pharmacy LLC dba Precision Pharmacy (Respondent). The Original Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 3769 and will expire on October 1, 2014, unless renewed.

4. On or about May 8, 2006, the Board of Pharmacy issued Sterile Compounding License Number LSC 99351 to Respondent. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought in Accusation No. 3769 and will expire on October 1, 2014, unless renewed.

JURISDICTION

5. Accusation No. 3769 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on June 6, 2013. Respondent timely filed its Notice of Defense contesting the Accusation.

6. A copy of Accusation No. 3769 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

7. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 3769. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

8. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and

1 court review of an adverse decision; and all other rights accorded by the California
2 Administrative Procedure Act and other applicable laws.

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

5 CULPABILITY

6 10. Respondent understands and agrees that the charges and allegations in Accusation
7 No. 3769, if proven at a hearing, constitute cause for imposing discipline upon its Original
8 Permit and Sterile Compounding License.

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

13 12. Respondent agrees that its Original Permit and its Sterile Compounding License are
14 subject to discipline and they agree to be bound by the Board's probationary terms as set forth in
15 the Disciplinary Order below.

16 CONTINGENCY

17 13. 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 its counsel. By signing the stipulation, Respondent understands
21 and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the
22 time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its
23 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 14. 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.

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

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

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Permit No. PHY 47310 and Sterile Compounding License LSC 99351 issued to Respondent Precision Pharmacy LLC dba Precision Pharmacy (Respondent) are revoked. However, the revocations are stayed and Respondent is placed on probation for three (3) years on the following terms and conditions.

1. Obey All Laws

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

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

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

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

2 **2. Report to the Board**

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

11 **3. Interview with the Board**

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

17 **4. Cooperate with Board Staff**

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

21 **5. Reimbursement of Board Costs**

22 As a condition precedent to successful completion of probation, respondent owner shall pay
23 to the board its costs of investigation and prosecution in the amount of \$10,000.00. Respondent
24 owner shall make said payments as follows: thirty-two (32) monthly payments of \$312.50
25 beginning thirty (30) days after the effective date of the decision and order. There shall be no
26 deviation from this schedule absent prior written approval by the board or its designee. Failure to
27 pay costs by the deadline(s) as directed shall be considered a violation of probation.

28 The filing of bankruptcy by respondent owner shall not relieve respondent of their

responsibility to reimburse the board its costs of investigation and prosecution.

6. Probation Monitoring Costs

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

7. Status of License

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

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

8. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

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

Respondent owner shall also, by the effective date of this decision, arrange for the

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

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

13 Respondent owner further stipulates that he or she shall reimburse the board for its costs of
14 investigation and prosecution prior to the acceptance of the surrender.

15 **9. Notice to Employees**

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

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

1 **10. Owners and Officers: Knowledge of the Law**

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

8 **11. Posted Notice of Probation**

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

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

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

17 **12. Violation of Probation**

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

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

1 automatically extended until the petition to revoke probation or accusation is heard and decided.


2 13. Completion of Probation

3 Upon written notice by the board or its designee indicating successful completion of
4 probation, respondent's license will be fully restored.

5 ACCEPTANCE

6 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
7 discussed it with my attorney, Jonathan Klein. I understand the stipulation and the effect it will
8 have on my Original Permit and Sterile Compounding License. I enter into this Stipulated
9 Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be
10 bound by the Decision and Order of the Board of Pharmacy.

11
12 DATED: 12/20/13

13 
PRECISION PHARMACY LLC DBA PRECISION
14 PHARMACY
Respondent

15 I have read and fully discussed with Respondent Precision Pharmacy LLC dba Precision
16 Pharmacy the terms and conditions and other matters contained in the above Stipulated
17 Settlement and Disciplinary Order. I approve its form and content.

18
19 DATED: _____

20 Jonathan Klein
Attorney for Respondent

21 ///

22 ///

23 ///

24 ///

25 ///

26 ///

27 ///

28

1 automatically extended until the petition to revoke probation or accusation is heard and decided.

2 13. **Completion of Probation**

3 Upon written notice by the board or its designee indicating successful completion of
4 probation, respondent's license will be fully restored.

5 ACCEPTANCE

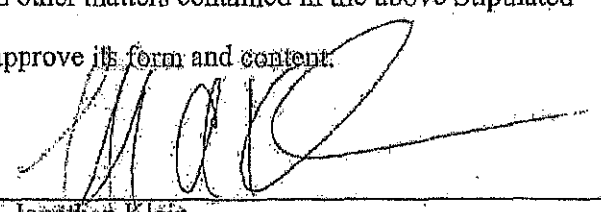
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10 bound by the Decision and Order of the Board of Pharmacy.

11
12 DATED: _____

PRECISION PHARMACY LLC DBA PRECISION
13 PHARMACY
14 Respondent

15 I have read and fully discussed with Respondent Precision Pharmacy LLC dba Precision
16 Pharmacy the terms and conditions and other matters contained in the above Stipulated
17 Settlement and Disciplinary Order. I approve its form and content.

18
19 DATED: 12/20/13


Jonathan Klein
20 Attorney for Respondent

21 ///

22 ///

23 ///

24 ///

25 ///

26 ///

27 ///

28


1 ENDORSEMENT

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

4 Dated: 12/30/13

Respectfully submitted,

6 KAMALA D. HARRIS
Attorney General of California
7 GREGORY J. SALUTE
Supervising Deputy Attorney General

8 
9 M. TRAVIS PEERY
10 Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 3769

1 KAMALA D. HARRIS
Attorney General of California
2 GREGORY J. SALUTE
Supervising Deputy Attorney General
3 M. TRAVIS PEERY
Deputy Attorney General
4 State Bar No. 242920
300 So. Spring Street, Suite 1702
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13 **4000 Empire Drive, Suite 200**
Bakersfield, CA 93309
14 **Original Permit No. PHY 47310**
Sterile Compounding License No. LSC
99351

A C C U S A T I O N

15 **PATRICIA WALDRIP-HELGREN**
16 **11916 Old Town Rd**
Bakersfield, CA 93312
17 **Original Pharmacist License No. RPH 42842**

18 Respondents.

19
20 Complainant alleges:

21 **PARTIES**

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

24 2. On or about October 7, 2005, the Board of Pharmacy issued Original Permit Number
25 PHY 47310 to Precision Pharmacy LLC dba Precision Pharmacy (Respondent Precision
26 Pharmacy). The Original Permit was in full force and effect at all times relevant to the charges
27 brought herein and will expire on October 1, 2013, unless renewed.

28 ///

1 9. Section 4040, subdivision (a)¹ of the Codes states:

2 “(a) ‘Prescription’ means an oral, written, or electronic transmission order that is both of the
3 following:

4 (1) Given individually for the person or persons for whom ordered that includes all of the
5 following:

6 (A) The name or names and address of the patient or patients.

7 (B) The name and quantity of the drug or device prescribed and the directions for use.

8 (C) The date of issue.

9 (D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and
10 telephone number of the prescriber, his or her license classification, and his or her federal registry
11 number, if a controlled substance is prescribed.

12 “(E) A legible, clear notice of the condition for which the drug is being prescribed, if
13 requested by the patient or patients.

14 “(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife,
15 nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to
16 Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug
17 order pursuant to either Section 4052.1 or 4052.2.

18 “(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic
19 doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51,
20 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or
21 naturopathic doctor licensed in this state, or pursuant to either subparagraph (d) of paragraph (4)
22 of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 by a
23 pharmacist licensed in this state.”

24 10. Section 4043, subdivision (a) of the Code states the term “wholesaler” as “a person
25 who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a

26 _____
27 ¹ Though Business and Professions Code section 4040 has been subsequently amended,
28 the following language reflects the version of section 4040 which was in effect at the time that the
facts giving rise to the allegations asserted in this Accusation took place.

1 nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of,
2 any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler
3 may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at
4 any location not licensed by the board."

5 11. Section 4052 of the Code states, in pertinent part:

6 "(a) Notwithstanding any other provision of law, a pharmacist may:

7 (1) Furnish a reasonable quantity of compounded drug product to a prescriber for office
8 use by the prescriber."

9 12. Section 4059.5 of the Code states, in pertinent part:

10 "(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices
11 may only be ordered by an entity licensed by the board and shall be delivered to the licensed
12 premises and signed for and received by a pharmacist. . . .

13

14 "(e) A dangerous drug . . . shall not be transferred, sold, or delivered to a person outside this
15 state, . . . unless the transferor, seller, or deliverer does so in compliance with the laws of this state
16 and of the United States and of the state . . . to which the dangerous drugs . . . are to be
17 transferred, sold, or delivered. Compliance with the laws of this state and the United States and
18 of the state . . . to which the dangerous drugs . . . are to be delivered shall include, but not be
19 limited to, determining that the recipient of the dangerous drugs . . . is authorized by law to
20 receive the dangerous drugs

21 "(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and
22 dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the
23 following requirements are met:

24 (1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

25 (2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge
26 has access to the secure storage facility after dangerous drugs or dangerous devices have been
27 delivered."

28 ///

1 13. Section 4078 of the Code states:

2 “(a)

3 (1) No person shall place a false or misleading label on a prescription.

4 (2) No prescriber shall direct that a prescription be labeled with any information that is
5 false or misleading.

6 “(b) Notwithstanding subdivision (a), a person may label a prescription, or a prescriber may
7 direct that a prescription be labeled, with information about the drug that is false under either of
8 the following circumstances:

9 (1) If the labeling is a necessary part of a clinical or investigational drug program approved
10 by the federal Food and Drug Administration or a legitimate investigational drug project
11 involving a drug previously approved by the federal Food and Drug Administration.

12 (2) If, in the medical judgment of the prescriber, the labeling is appropriate for the proper
13 treatment of the patient.

14 “(c) The furnisher of a prescription labeled pursuant to subdivision (b) shall make, and
15 retain for three years from the date of making, a record stating the manner in which the
16 information on the prescription label varies from the actual drug in the container and
17 documenting the order of the prescriber to so label the container. The prescriber shall make, and
18 retain for at least three years, a record of his or her order to so label the container.

19 14. Section 4113, subdivision (c) of the Code states: “The pharmacist-in-charge shall be
20 responsible for a pharmacy’s compliance with all state and federal laws and regulations pertaining
21 to the practice of pharmacy.”

22 15. Section 4115 of the Code states:

23 “(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other
24 nondiscretionary tasks, only while assisting, and while under the direct supervision and control of
25 a pharmacist.

26 “(b) This section does not authorize the performance of any tasks specified in subdivision
27 (a) by a pharmacy technician without a pharmacist on duty.

28

1 “(c) This section does not authorize a pharmacy technician to perform any act requiring the
2 exercise of professional judgment by a pharmacist.

3 “(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a
4 pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that
5 employs a pharmacy technician shall do so in conformity with the regulations adopted by the
6 board.

7 “(e) No person shall act as a pharmacy technician without first being licensed by the board
8 as a pharmacy technician.

9 “(f) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy
10 technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians
11 performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed
12 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to
13 Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a
14 licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2),
15 an inmate of a correctional facility of the Department of the Youth Authority or the Department
16 of Corrections, and for a person receiving treatment in a facility operated by the State Department
17 of Mental Health, the State Department of Developmental Services, or the Department of
18 Veterans Affairs.

19 (2) The board may adopt regulations establishing the ratio of pharmacy technicians
20 performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of
21 prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home
22 health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a
23 minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two
24 pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to
25 personnel performing clerical functions pursuant to Section 4116 or 4117.

26 (3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to
27 supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her
28 professional judgment, that permitting the second pharmacy technician to be on duty would

1 interfere with the effective performance of the pharmacist's responsibilities under this chapter. A
2 pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in
3 charge in writing of his or her determination, specifying the circumstances of concern with
4 respect to the pharmacy or the pharmacy technician that have led to the determination, within a
5 reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity
6 employing a pharmacist may discharge, discipline, or otherwise discriminate against any
7 pharmacist in the terms and conditions of employment for exercising or attempting to exercise in
8 good faith the right established pursuant to this paragraph.

9 “(g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish
10 conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant
11 to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without
12 closing the pharmacy. During these temporary absences, a pharmacy technician may, at the
13 discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary
14 tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task
15 performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this
16 subdivision shall be construed to authorize a pharmacist to supervise pharmacy technicians in
17 greater ratios than those described in subdivision (f).

18 “(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy
19 technician supervised by that pharmacist.”

20 16. Section 4169 of the Code states:

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

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

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

27 ///

28 ///

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

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

6 (5) Fail to maintain records of the acquisition or disposition of dangerous drugs or
7 dangerous devices for at least three years.

8 "(b) Notwithstanding any other provision of law, a violation of this section or of
9 subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the
10 violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence,
11 pursuant to a citation issued by the board.

12 "(c) Amounts due from any person under this section shall be offset as provided under
13 Section 12419.5 of the Government Code. Amounts received by the board under this section shall
14 be deposited into the Pharmacy Board Contingent Fund.

15 "(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and
16 Drug Administration or by the State Department of Public Health."

17 17. Section 4300 of the Code states:

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

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

22 (1) Suspending judgment.

23 (2) Placing him or her upon probation.

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

25 (4) Revoking his or her license.

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

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1 “(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The
2 board may, in its sole discretion, issue a probationary license to any applicant for a license who is
3 guilty of unprofessional conduct and who has met all other requirements for licensure. The board
4 may issue the license subject to any terms or conditions not contrary to public policy, including,
5 but not limited to, the following:

- 6 (1) Medical or psychiatric evaluation.
- 7 (2) Continuing medical or psychiatric treatment.
- 8 (3) Restriction of type or circumstances of practice.
- 9 (4) Continuing participation in a board-approved rehabilitation program.
- 10 (5) Abstention from the use of alcohol or drugs.
- 11 (6) Random fluid testing for alcohol or drugs.
- 12 (7) Compliance with laws and regulations governing the practice of pharmacy.

13 “(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary
14 certificate of licensure for any violation of the terms and conditions of probation. Upon
15 satisfactory completion of probation, the board shall convert the probationary certificate to a
16 regular certificate, free of conditions.

17 “(e) The proceedings under this article shall be conducted in accordance with Chapter 5
18 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board
19 shall have all the powers granted therein. The action shall be final, except that the propriety of
20 the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of
21 Civil Procedure.”

22 18. Section 4301 of the Code states:

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

26 “(a) Gross immorality;

27 “(b) Incompetence.

28 “(c) Gross negligence.

1 "(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a)
2 of Section 11153 of the Health and Safety Code.

3 "(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a)
4 of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining
5 whether the furnishing of controlled substances is clearly excessive shall include, but not be
6 limited to, the amount of controlled substances furnished, the previous ordering pattern of the
7 customer (including size and frequency of orders), the type and size of the customer, and where
8 and to whom the customer distributes its product.

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

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

14 "(h) The administering to oneself, of any controlled substance, or the use of any dangerous
15 drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to
16 oneself, to a person holding a license under this chapter, or to any other person or to the public, or
17 to the extent that the use impairs the ability of the person to conduct with safety to the public the
18 practice authorized by the license.

19 "(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or
20 administering or offering to sell, furnish, give away, or administer any controlled substance to an
21 addict.

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

24 "(k) The conviction of more than one misdemeanor or any felony involving the use,
25 consumption, or self-administration of any dangerous drug or alcoholic beverage, or any
26 combination of those substances.

27 "(l) The conviction of a crime substantially related to the qualifications, functions, and
28 duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13

1 (commencing with Section 801) of Title 21 of the United States Code regulating controlled
2 substances or of a violation of the statutes of this state regulating controlled substances or
3 dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the
4 record of conviction shall be conclusive evidence only of the fact that the conviction occurred.
5 The board may inquire into the circumstances surrounding the commission of the crime, in order
6 to fix the degree of discipline or, in the case of a conviction not involving controlled substances
7 or dangerous drugs, to determine if the conviction is of an offense substantially related to the
8 qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or
9 a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning
10 of this provision. The board may take action when the time for appeal has elapsed, or the
11 judgment of conviction has been affirmed on appeal or when an order granting probation is made
12 suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of
13 the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not
14 guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or
15 indictment.

16 "(m) The cash compromise of a charge of violation of Chapter 13 (commencing with
17 Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter
18 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code
19 relating to the Medi-Cal program. The record of the compromise is conclusive evidence of
20 unprofessional conduct.

21 "(n) The revocation, suspension, or other discipline by another state of a license to practice
22 pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

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

27 "(p) Actions or conduct that would have warranted denial of a license.

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1 "(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the
2 board.

3 "(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section
4 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should
5 have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a)
6 of Section 256b of Title 42 of the United States Code.

7 "(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that
8 primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to
9 be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall
10 include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that
11 primarily or solely dispenses prescription drugs to patients of long-term care facilities, the
12 previous ordering pattern of the pharmacy, and the general patient population to whom the
13 pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a
14 tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be
15 considered in determining whether there has been a violation of this subdivision. This provision
16 shall not be interpreted to require a wholesaler to obtain personal medical information or be
17 authorized to permit a wholesaler to have access to personal medical information except as
18 otherwise authorized by Section 56 and following of the Civil Code. "

19 19. Section 4076 of the Code states:

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

22 (1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a
23 standardized procedure or protocol described in Section 2746.51, the nurse practitioner who
24 functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the
25 physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who
26 functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the
27 pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either
28 subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of,

subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1., the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

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

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

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1 (ii) An exemption from the requirements of this paragraph shall be granted to a new drug
2 for the first 120 days that the drug is on the market and for the 90 days during which the national
3 reference file has no description on file.

4 (iii) Dispensed medications for which no physical description exists in any commercially
5 available database.

6 (B) This paragraph applies to outpatient pharmacies only.

7 (C) The information required by this paragraph may be printed on an auxiliary label that is
8 affixed to the prescription container.

9 (D) This paragraph shall not become operative if the board, prior to January 1, 2006,
10 adopts regulations that mandate the same labeling requirements set forth in this paragraph.

11 "(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system,
12 as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or
13 other health care facility, the requirements of this section will be satisfied if the unit dose
14 medication system contains the aforementioned information or the information is otherwise
15 readily available at the time of drug administration.

16 "(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to
17 Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose
18 containers for a specific patient, the name of the certified nurse-midwife who functions pursuant
19 to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who
20 functions pursuant to a standardized procedure described in Section 2836.1, the physician
21 assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions
22 pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist
23 who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of
24 paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section
25 4052,

26 "(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to
27 Section 1250 of the Health and Safety Code, it is not necessary to include the information
28 required in paragraph (11) of subdivision (a) when the prescription drug is administered to a

1 patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with
2 Section 2000), the Nursing Practice Act (Chapter 6 (commencing with Section 2700), or the
3 Vocational Nursing Act (Chapter 6.5 (commencing with Section 2840), who is acting within his
4 or her scope of practice."

5 20. Section 11170 of the Health & Safety Code states that "[n]o person shall prescribe,
6 administer, or furnish a controlled substance for himself."

7 REGULATORY PROVISIONS

8 21. California Code of Regulations, title 16, section 1714, subdivision (b) states, in
9 pertinent part:

10 "Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and
11 equipment so that drugs are safely and properly prepared, maintained, secured and distributed."

12 22. California Code of Regulations, title 16, section 1716.1², states:

13 "As used in Business and Professions Code section 4052(a)(1), the following terms have
14 the indicated meaning concerning the compounding of unapproved drugs for prescriber office
15 use:

16 "(a) 'Reasonable quantity' means that quantity of an unapproved drug which:

17 "(1) is sufficient for that prescriber's office use consistent with the expiration date of the
18 product as set forth in section 1716.2(a)(3); and

19 "(2) is reasonable considering the intended use of the compounded medication and nature
20 of the prescriber's practice; and

21 "(3) for any individual prescriber and for all prescribers taken as a whole, is an amount
22 which the pharmacy is capable of compounding in compliance with pharmaceutical standards for
23 identity, strength, quality and purity of the compounded medication.

24 "(b) 'Compounded medication' means medications actually compounded by the pharmacy
25 supplying them to a prescriber.

26 ///

27 ² Though 16 CCR 1716.1 has been repealed, it was in effect at the time that the facts
28 giving rise to the allegations asserted in this Accusation took place.

1 “(c) ‘Prescriber office use’ means application or administration in the prescriber’s office, or
2 for distribution of not more than a 72 hour supply to the prescriber’s patients as estimated by the
3 prescriber.”

4 23. California Code of Regulations, title 16, section 1716.2³, states:

5 “(a) For the purpose of compounding in quantities larger than required for immediate
6 dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain
7 records that include, but are not limited to:

8 (1) The date of preparation.

9 (2) The lot numbers. These may be the manufacturer's lot numbers or new numbers
10 assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also
11 record the original manufacturer's lot numbers and expiration dates, if known. If the original
12 manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the
13 source and acquisition date of the components.

14 (3) The expiration date of the finished product. This date must not exceed 180 days or the
15 shortest expiration date of any component in the finished product unless a longer date is
16 supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter
17 dating than set forth in this subsection may be used if it is deemed appropriate in the professional
18 judgment of the responsible pharmacist.

19 (4) The signature or initials of the pharmacist performing the compounding.

20 (5) A formula for the compounded product. The formula must be maintained in a readily
21 retrievable form.

22 (6) The name(s) of the manufacturer(s) of the raw materials.

23 (7) The quantity in units of finished products or grams of raw materials.

24 (8) The package size and the number of units prepared.”

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26 ///

27 ³ Though 16 CCR 1716.2 has been repealed, it was in effect at the time that the facts
28 giving rise to the allegations asserted in this Accusation took place.

1 24. California Code of Regulations, title 16, section 1717, states:

2 "(a) No medication shall be dispensed on prescription except in a new container which
3 conforms with standards established in the official compendia.

4 "Notwithstanding the above, a pharmacist may dispense and refill a prescription for
5 non-liquid oral products in a clean multiple-drug patient medication package (patient med pak),
6 provided:

7 (1) a patient med pak is reused only for the same patient;

8 (2) no more than a one-month supply is dispensed at one time; and

9 (3) each patient med pak bears an auxiliary label which reads, store in a cool, dry place.

10 "(b) In addition to the requirements of Section 4040, Business and Professions Code, the
11 following information shall be maintained for each prescription on file and shall be readily
12 retrievable:

13 (1) The date dispensed, and the name or initials of the dispensing pharmacist. All
14 prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising
15 pharmacist before they are dispensed.

16 (2) The brand name of the drug or device; or if a generic drug or device is dispensed, the
17 distributor's name which appears on the commercial package label; and

18 (3) If a prescription for a drug or device is refilled, a record of each refill, quantity
19 dispensed, if different, and the initials or name of the dispensing pharmacist.

20 (4) A new prescription must be created if there is a change in the drug, strength, prescriber
21 or directions for use, unless a complete record of all such changes is otherwise maintained.

22 "(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce
23 it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription
24 is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the
25 prescription to identify him or herself.

26 "All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior
27 to compounding, filling, dispensing, or furnishing.

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1 "Chart orders as defined in Section 4019 of the Business and Professions Code are not
2 subject to the provisions of this subsection.

3 "(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a
4 prescriber licensed in a State other than California in accordance with Business and Professions
5 Code Section 4005.

6 "(e) A pharmacist may transfer a prescription for Schedule III, IV, or V controlled
7 substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal
8 Regulations, section 1306.26.

9 " Prescriptions for other dangerous drugs which are not controlled substances may also be
10 transferred by direct communication between pharmacists or by the receiving pharmacist's access
11 to prescriptions or electronic files that have been created or verified by a pharmacist at the
12 transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it
13 as a transferred prescription; and record the date of transfer and the original prescription number.
14 When a prescription transfer is accomplished via direct access by the receiving pharmacist, the
15 receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the
16 transferring pharmacy shall then assure that there is a record of the prescription as having been
17 transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and
18 pharmacist accountability and dispense in accordance with the provisions of section 1716 of this
19 Division. Information maintained by each pharmacy shall at least include:

- 20 (1) Identification of pharmacist(s) transferring information;
21 (2) Name and identification code or address of the pharmacy from which the prescription
22 was received or to which the prescription was transferred, as appropriate;
23 (3) Original date and last dispensing date;
24 (4) Number of refills and date originally authorized;
25 (5) Number of refills remaining but not dispensed;
26 (6) Number of refills transferred.

27 "(f) The pharmacy must have written procedures that identify each individual pharmacist
28 responsible for the filling of a prescription and a corresponding entry of information into an

1 automated data processing system, or a manual record system, and the pharmacist shall create in
2 his/her handwriting or through hand-initializing a record of such filling, not later than the
3 beginning of the pharmacy's next operating day. Such record shall be maintained for at least three
4 years."

5 25. California Code of Regulations, title 16, section 1718.1, states:

6 "All prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21,
7 Code of Federal Regulations, section 211.137 are deemed to have expired and may not be
8 manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor,
9 pharmacist, pharmacy or other persons authorized to dispense such drugs in California."

10 26. California Code of Regulations, title 16, section 1751.2, states:

11 "In addition to the labeling information required under Business and Professions Code
12 section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall
13 include the following information on the labels for those products:

14 "(a) Telephone number of the pharmacy, except for sterile injectable products dispensed for
15 inpatients of a hospital pharmacy.

16 "(b) Name and concentrations of ingredients contained in the sterile injectable product.

17 "(c) Instructions for storage and handling.

18 "(d) All cytotoxic agents shall bear a special label which states 'Chemotherapy - Dispose of
19 Properly.'"

20 27. California Code of Regulations, title 16, section 1751.3⁴, states:

21 "(a) Pharmacies compounding sterile injectable products for future use pursuant to section
22 1716.1 shall, in addition to those records required by section 1716.2, have records indicating the
23 name, lot number, amount, and date on which the products were provided to a prescriber.

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27 ⁴ Though 16 CCR 1751.3 has been subsequently amended and renumbered as 16 CCR
28 1751.1, the following language reflects the version of section 1751.3 which was in effect at the
time that the facts giving rise to the allegations asserted in this Accusation took place

1 “(b) In addition to the records required by subdivision (a), for sterile products compounded
2 from one or more non-sterile ingredients the following records must be maintained for at least
3 three years:

4 “(1) The training and competency evaluation of employees in sterile product procedures.

5 “(2) Refrigerator and freezer temperatures.

6 “(3) Certification of the sterile compounding environment.

7 “(4) Other facility quality control logs specific to the pharmacy’s policies and procedures
8 (e.g., cleaning logs for facilities and equipment).

9 “(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.

10 “(6) Preparation records including the master work sheet, the preparation work sheet, and
11 records of end-product evaluation results.

12 “(c) Pharmacies shall maintain records of validation processes as required by section
13 1751.7(b) for three years.”

14 “(c) Pharmacies compounding sterile injectable products shall have written policies and
15 procedures for the disposal of infectious materials and/or materials containing cytotoxic residues.
16 The written policies and procedures shall describe the pharmacy protocols for cleanups and spills
17 in conformity with local health jurisdiction standards.”

18 28. California Code of Regulations, title 16, section 1751.7, states:

19 “(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain,
20 as part of its written policies and procedures, a written quality assurance plan including, in
21 addition to the elements required by section 1735.8, a documented, ongoing quality assurance
22 program that monitors personnel performance, equipment, and facilities. The end product shall be
23 examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it
24 meets required specifications. The Quality Assurance Program shall include at least the
25 following:

26 (1) Cleaning and sanitization of the parenteral medication preparation area.

27 (2) The storage of compounded sterile injectable products in the pharmacy and periodic
28 documentation of refrigerator temperature.

1 (3) Actions to be taken in the event of a drug recall.

2 (4) Written justification of the chosen expiration dates for compounded sterile injectable
3 products.

4 "(b) Each individual involved in the preparation of sterile injectable products must first
5 successfully complete a validation process on technique before being allowed to prepare sterile
6 injectable products. The validation process shall be carried out in the same manner as normal
7 production, except that an appropriate microbiological growth medium is used in place of the
8 actual product used during sterile preparation. The validation process shall be representative of all
9 types of manipulations, products and batch sizes the individual is expected to prepare. The same
10 personnel, procedures, equipment, and materials must be involved. Completed medium samples
11 must be incubated. If microbial growth is detected, then the sterile preparation process must be
12 evaluated, corrective action taken, and the validation process repeated. Personnel competency
13 must be revalidated at least every twelve months, whenever the quality assurance program yields
14 an unacceptable result, when the compounding process changes, equipment used in the
15 compounding of sterile injectable drug products is repaired or replaced, the facility is modified in
16 a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are
17 observed. Revalidation must be documented.

18 "(c) Batch-produced sterile injectable drug products compounded from one or more non-
19 sterile ingredients shall be subject to documented end product testing for sterility and pyrogens
20 and shall be quarantined until the end product testing confirms sterility and acceptable levels of
21 pyrogens.

22 "(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through
23 process validation for sterility as determined by the pharmacist-in-charge and described in the
24 written policies and procedures."

25 29. California Code of Regulations, title 16, section 1770, states:

26 "For the purpose of denial, suspension, or revocation of a personal or facility license
27 pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a
28 crime or act shall be considered substantially related to the qualifications, functions or duties of a

1 licensee or registrant if to a substantial degree it evidences present or potential unfitness of a
2 licensee or registrant to perform the functions authorized by his license or registration in a manner
3 consistent with the public health, safety, or welfare."

4 REASONABLE COSTS

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

9 CONTROLLED SUBSTANCES AND DANGEROUS DRUGS

10 31. Superiorbute power, whose generic name is Phenylbutazone, is a dangerous drug
11 within the meaning of section 4022.

12 STATEMENT OF FACTS

13 32. From on or about October 7, 2005, to February 1, 2009, Bart Tipton was the
14 Pharmacist-in-Charge (PIC) of Respondent Precision Pharmacy.

15 33. From on or about February 1, 2009 through the present, Respondent Waldrup-Helgren
16 has been the PIC of Respondent Precision Pharmacy.

17 May 2009 Consumer Complaint⁵

18 34. On or about May 7, 2009, D.G. of Superior Equine Pharmaceuticals, Inc. submitted a
19 consumer complaint with the Board alleging that in violation of a January 2008 Food and Drug
20 Administration (FDA) "Cease and Desist" letter, Respondent Precision Pharmacy continued to
21 illegally manufacture apple-flavored Phenylbutazone powder from bulk materials and sell the
22 product to veterinarians around the country. D.G. had a patent for apple flavored Superiorbute®
23 powder.

24 35. The FDA "Cease and Desist" letter was sent to several pharmacies around the country
25 and to the Executive Directors of various boards of pharmacy in several states. It stated, in

26 ⁵ The facts alleged in this Accusation are based on four investigative reports. In the
27 interests of clarity, Complainant will provide a footnote referencing the source of the facts alleged
28 in each section. The facts pertaining to the May 2009 consumer complaint can be found in
Investigative Report 2009 40885.

1 pertinent part, that Superior Equine Pharmaceutical, Inc. manufactured the one FDA-approved
2 version of sweetened, apple-flavored Phenylbutazone powder in horse feed for the relief of
3 inflammatory conditions associated with the musculoskeletal system, and that accordingly, any
4 firms that were engaged in the compounding⁶ of any of the apple-flavored Phenylbutazone
5 powder products were in violation of the Federal Food, Drug, and Cosmetic Act. It specifically
6 stated that if a firm was engaged in the compounding and/or sale of these illegal phenylbutazone
7 products, it should immediately cease that activity.

8 **September 2009 Inspection**⁷

9 36. On or about September 1, 2009, two (2) Board inspectors conducted an inspection of
10 Respondent Precision Pharmacy. Immediately upon entering, the inspectors noticed several
11 people around several open containers of powders on a large table. Along side of the table were
12

13
14 ⁶ The FDA issued a Compliance Policy Guidance (CPG) regarding the compounding of drugs for
15 use in animals that stated, in pertinent part, that the:

16 FDA is greatly concerned about veterinarians and pharmacies that are engaged in
17 manufacturing and distributing unapproved new animal drugs in a manner that is clearly
18 outside the bounds of traditional pharmacy practice and that violates the Act (e.g.,
19 compounding that is intended to circumvent the drug approval process and provide for the
20 mass marketing of products that have been produced with little or no quality control or
21 manufacturing standards to ensure the purity, potency, and stability of the product). These
22 activities are the focus of this guidance. Pharmacies and veterinarians who engage in
23 activities analogous to manufacturing and distributing drugs for use in animals may be
24 held to the same provisions of the Act as manufacturers.

25 With regard to compounding from bulk drug substances, two Federal Appeals Court
26 decisions, United States v. Algon Chemical Inc., 879 F.2d 1154 (3d Cir. 1989) and United
27 States v. 9/1 Kg. Containers, 854 F.2d 173 (7th Cir. 1988), affirmed the FDA position that
28 the Act does not permit veterinarians to compound unapproved finished drug products
from bulk drug substances, unless the finished drug is not a new animal drug. The
principle established by the court applies equally to compounding by pharmacists.

29 CPG Sec. 608.400 - Compounding of Drugs for Use in Animals (CPG 7125.40), available at:
30 [http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074656.
31 htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=compounding&utm_content=1](http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074656.htm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=compounding&utm_content=1).

32 ⁷ These facts can be found in Investigative Report 2009 40885.

1 drums of powders. The inspectors observed the employees compounding apple flavored
2 phenylbutazone powder. The inspectors did not see any gowns, masks, or gloves.

3 37. The inspectors introduced themselves and met the pharmacist-in-charge (PIC),
4 Respondent Patricia Waldrip-Helgren. The inspectors determined that there was one (1)
5 pharmacist supervising one (1) pharmacist intern, five (5) technicians, and two (2) clerks, which
6 was in violation of the pharmacist:technician ratio of 1:1 for the practice setting. The inspectors
7 observed that compounding was taking place in three (3) different areas in the pharmacy (lobby,
8 pharmacy, and back room).

9 *Illegal Manufacture of Drugs*

10 38. The inspectors observed that there were a large amount of compounded items, made
11 in large enough amounts to have shelves full of product. Records obtained by the inspectors that
12 reflected that Respondent Precision Pharmacy sold the majority of drugs to veterinarians,
13 hospitals, clinics, and rarely to the ultimate consumer, which would be either a horse or a horse
14 owner. In addition, Respondent PIC Waldrip-Helgren told one of the Board inspectors that "a lot
15 of Precision's business is selling directly to veterinarians. Respondent Waldrip-Helgren stated to
16 the Board inspectors that "[Respondent] Precision also fills some prescriptions per specific
17 animal, but that was not the majority of Precision's business." This statement and review of
18 pharmacy records showing the majority of sales to other than a specific patient, strengthens the
19 proof that Precision Pharmacy is manufacturing for office use, rather than selling to ultimate
20 consumer.

21 39. The inspectors observed that there were large amounts of both commercially
22 available medications, such as Itraconazole 100 mg, DES 3mg, and Griseofulvin 250 mg, as well
23 as large amounts of some medications that are not commercially available, such as Domperidone
24 10 mg, Estradiol 1mg/Progesterone 100 mg/Testosterone SR 1mg. This demonstrated that
25 Respondent Precision Pharmacy was manufacturing commercially available drugs, which it
26 cannot by law. In addition, it demonstrates that Respondent Precision Pharmacy was
27 compounding large amounts of non-commercially available drugs, which circumvents the FDA
28 process for approving new drugs and is in direct contradiction to the FDA's intent when

1 permitting pharmacies to compound medication, which is to allow them to create non-
2 commercially available medications to meet specific patient needs.

3 ***Illegally Acting as a Wholesaler***

4 40. During the September 2009 inspection, the inspectors observed that though
5 Respondent Precision Pharmacy labeled their Phenylbutazone product as if they were
6 compounding for "office use", in actuality Respondent Precision Pharmacy was not compounding
7 for "office use" because the product was not being applied or administered in the prescriber's
8 office (the patients are horses) and because the product was made in jars and bottles which hold
9 more than a 72 hour supply. Specifically, a printout for all Phenylbutazone 100gm powder sold
10 by Respondent Precision Pharmacy from August 17, 2009, through September 1, 2009, showed
11 that during those two (2) weeks, there were 108 orders filled, and a total of 762 jars dispensed.
12 33 prescriptions were written for a veterinarian (the veterinarian was listed as the patient), 28
13 prescriptions were filled for a hospital or clinic, several other prescriptions were filled for equine
14 service or businesses, and only two (2) were written for a specific horse. The 762 containers
15 dispensed each had 100gm of Phenylbutazone powder, thus in a two (2) week period, Respondent
16 Precision Pharmacy dispensed 76,200 grams or 76.2 kg (167 pounds) of Phenylbutazone. The
17 normal dosing of Phenylbutazone in horses is 2-4 grams per 1000 pounds of body weight. Since
18 horses weigh an average of 900-1500 pounds, the dosing is 1.8-6 grams/day. A 72-hour supply of
19 Phenylbutazone for one horse would be 5.4-18 grams/day. Because Precision Pharmacy has 100
20 gram jars of Phenylbutazone, for each jar Respondent is dispensing a 5.5-18 day supply for one
21 horse which is in excess of a 72 hour supply. Additionally, only one scoop was provided with
22 each jar of Phenylbutazone. Since the dosing of the drug was in scoops, if the prescriber divided
23 what was contained in the large container and placed it in smaller containers, he would not have a
24 scoop to provide with the extra containers of the medication provided. The presence of only one
25 scoop indicates the container was intended for only one patient.

26 ***Violations of Prescription Requirements***

27 41. During the September 2009 inspection, one (1) of the inspectors reviewed a sampling
28 of written prescriptions for Phenylbutazone powder and observed that they were not received

1 telephonically by a pharmacist, did not have a patient name on them and did not have directions
2 for use or strength. The inspector also reviewed a sampling of prescriptions about to be dispensed
3 and observed the following: extra drug coming out near the metal ring which seals the amber
4 bottle, prescription label with no directions or patient name, and sterile compounding labels with
5 no drug names or concentrations of ingredients contained in product.

6 ***Discrepancies in Master Formula and Logged Formula Worksheets***

7 42. During the September 2009 inspection, the inspectors found that Respondent
8 Precision Pharmacy's Logged Formula Worksheets did not follow the PCCA (Professional
9 Compounding Centers of America) Master Formulas, despite the fact that Respondent Precision
10 Pharmacy belonged to PCCA. During the inspection, one of the inspectors found vials of the
11 drug Trimethoprim/Sulfadiazine 80/400 Injection Suspension ready to be shipped out to
12 veterinarian, G.W., located in Texas. The vials did not have the lot and expiration stickers that
13 the pharmacy usually puts on the bottom of the vials, but on the dispensing label, there was a lot
14 number of 05152009@12, expiration of 2/27/10, Rx number #134900 and date of 8/31/09, the
15 day before the September 2009 inspection.

16 43. Respondent Precision Pharmacy's records showed that they made excipient stock
17 solution on September 2, 2008. PCCA master formulas stated that excipient stock solution
18 should expire in thirty days from that date (October 2, 2008), however, Respondent Precision's
19 logged formula worksheets stated that the excipient stock solution expired in 180 days (March 2,
20 2009). No reason was given as to why the date was extended. The excipient solution was used to
21 compound Sulfadiazine/Trimethoprim on May 15, 2009, after it was already expired (no matter
22 which expiration date was chosen). The PCCA master formula said compounded
23 Sulfadiazine/Trimethoprim expires 90 days after being made (August 15, 2009). Respondent
24 Precision logged formula worksheets said that Sulfadiazine/Trimethoprim expires 180 days after
25 being made (November 11, 2009). The expired excipient that was used to make the
26 Sulfadiazine/Trimethoprim could have posed a serious health hazard, and should not have been
27 dispensed.

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1 44. When the product was used to dispense Dr. G.W.'s prescription on August 31, 2009,
2 the original lot and expiration sticker which would have shown an expiration of November 11,
3 2009, was ripped off, and the dispensing prescription label gave the product an expiration date of
4 February 27, 2010, 180 days from the date of the dispensed prescription. Accordingly, expired
5 drugs were being dispensed to unsuspecting consumers.

6 45. The Logged Formula Worksheets that the investigators secured for the following
7 drugs reflected that each of these drugs had already expired before they were used to make
8 another drug:

9 a. Edetate disodium expired in May 2009, but was used to make Acetyl-L-Cysteine 20%
10 on August 10, 2009. The new drug was given an expiration date February 6, 2010.

11 b. Preserved water expired on August 29, 2009, but Respondent Precision Pharmacy
12 pharmacists used it to make Omeprazole 220mg/ml suspension on August 24, 2009. The new
13 drug was given an expiration date of November 22, 2009 by Respondent Precision Pharmacy
14 staff.

15 c. Preserved water expired on August 29, 2009, but Respondent Precision Pharmacy
16 pharmacists used it to make Rifampin 100mg/ml suspension on August 25, 2009. The new drug
17 was given an expiration date of October 24, 2009, by Respondent Precision Pharmacy staff.

18 d. Simple syrup expired on October 30, 2009, but Respondent Precision Pharmacy
19 pharmacists used it to make Chloramphenicol 500mg/ml suspension on August 25, 2009. The
20 new drug was given an expiration date of February 21, 2010, by Respondent Precision Pharmacy
21 staff.

22 e. Simple syrup expired on October 30, 2009, and Fluoxetine had no expiration date, but
23 Respondent Precision Pharmacy pharmacists used both to make Fluoxetine 10mg/ml suspension
24 on August 25, 2009. The new drug was given an expiration date of December 23, 2009, by
25 Respondent Precision Pharmacy staff.

26 f. Valerian root, passion flower, chamomile powder Apple Vet Paste and Kava Kava
27 root powder expired on September 1, 2009, but Respondent Precision Pharmacy pharmacists used
28 these items to make Valpassikavacam sedative 3/2/0.5gm/1gm/15ml on August 17, 2009. The

1 new drug was given an expiration date of February 23, 2010, by Respondent Precision Pharmacy
2 staff.

3 g. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy
4 pharmacists used it to make Griseofulvin 25gm/60ml paste on August 21, 2009. The new drug
5 was given an expiration date of August 26, 2009, or February 17, 2010 (both dates appeared on
6 the sheet).

7 h. Apple vet paste expired on August 26, 2009, and Glycerin expired on January 1,
8 2010, but Respondent Precision Pharmacy pharmacists used both to make Rifampin 200mg/ml
9 paste on August 21, 2009. The new drug was given an expiration date of February 17, 2010.

10 i. Simple syrup expired on October 30, 2009, but Respondent Precision Pharmacy
11 pharmacists used it to make Isoxsuprine 50mg/ml suspension on August 21, 2009. The new drug
12 was given an expiration date of February 17, 2010.

13 j. Famotidine USP expired on September 1, 2009, but Respondent Precision Pharmacy
14 pharmacists used it to make Famotidine 2mg/ml suspension on August 25, 2009. The new drug
15 was given an expiration date of December 23, 2009.

16 k. Simple syrup expired on October 30, 2009, but Respondent Precision Pharmacy
17 pharmacists used it to make Pentoxifylline 4gm/30ml suspension on August 21, 2009. The new
18 drug was given an expiration date of November 11, 2009.

19 l. Distilled water expired on January 1, 2010, but Respondent Precision Pharmacy
20 pharmacists used it to make Zinc sulfate/lead acetate (white lotion) 4.7%/5.7% suspension on
21 August 21, 2009. The new drug was given an expiration date of February 17, 2010.

22 m. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy
23 pharmacists used it to make Omeprazole 2.2gm/10ml on August 24, 2009. The new drug was
24 given an expiration date of November 22, 2009.

25 n. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy
26 pharmacists used it to make Omeprazole 2.2gm/10ml on August 24, 2009 [1]. The new drug
27 was given an expiration date of November 22, 2009.

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1 o. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy
2 pharmacists used it to make Omeprazole 2.2gm/10ml on August 24, 2009 [19]. The new drug
3 was given an expiration date of November 22, 2009.

4 p. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy
5 pharmacists used it to make Clarithromycin/Rifampin 100mg/100mg/ml paste on August 24,
6 2009. The new drug was given an expiration date of December 22, 2009.

7 q. Tangerine flavor expired on January 1, 2010 but Respondent Precision Pharmacy
8 pharmacists used it to make Pergolide in oil 2mg/ml on August 24, 2009. The new drug was
9 given an expiration date of February 20, 2010.

10 r. Apple vet paste expired on August 26, 2009, but Respondent Precision Pharmacy
11 pharmacists used it to make Chloramphenicol apple flavor 25gm/80gm paste on August 24, 2009.
12 The new drug was given an expiration date of February 20, 2010.

13 s. Glycerol formal expired on August 29, 2009, but Respondent Precision Pharmacy
14 pharmacists used it to make Altrenogest 225mg/ml injectable on August 21, 2009. The new drug
15 was given an expiration date of February 17, 2010.

16 ***Additional Violations Discovered During September 2009 Inspection***

17 46. During the September 2009 inspection, the inspectors interviewed Respondent
18 Waldrip-Helgren who admitted that Respondent Precision Pharmacy does not test drugs for
19 pyrogens and that some of the expiration dates for some of the drugs were inaccurate because
20 Respondent Precision Pharmacy staff had not updated the inventory.

21 47. During the September 2009 inspection, the inspectors also noted that Respondent
22 Precision Pharmacy had failed to include either the lot number or expiration date on the
23 component products, failed to refrigerate drums of large material that were labeled "refrigerate",
24 failed to include lot numbers and expiration dates on all products for future furnishing,
25 maintained drugs with missing manufacturer expiration dates, made, manufactured and/or
26 compounded apple flavored Phenylbutazone powder and maintained drug labels with no route
27 (oral, injection).

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1 **FIRST CAUSE FOR DISCIPLINE**

2 **(Against Respondents Precision Pharmacy and Waldrip-Helgren)**

3 **(Acting as a Manufacturer Without a License)**

4 52. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to
5 disciplinary action under section 4033, subdivision (a)(1) in that Respondent was acting as a
6 manufacturer without a license in that during inspections of Respondent Precision Pharmacy on
7 or about September 1, 2009, and November 10, 2009, Board inspectors noted large amounts of
8 compounded drugs which were sold to veterinarians nationwide who then sold and/or dispensed
9 them to the ultimate consumer. Complainant refers to and incorporates all the allegations
10 contained in paragraphs 32 through 47 above, as though set forth fully.

11 **SECOND CAUSE FOR DISCIPLINE**

12 **(Against Respondents Precision Pharmacy and Waldrip-Helgren)**

13 **(Acting as a Wholesaler Without a License)**

14 53. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to
15 disciplinary action under section 4043 which provides the definition of "wholesaler." During an
16 inspection of Respondent Precision Pharmacy on September 1, 2009, one of the Board Inspectors
17 determined that the overwhelming majority of Phenylbutazone "prescriptions" (106 prescriptions
18 out of 108) that Respondent Precision Pharmacy filled between August 17, 2009, and September
19 1, 2009, were not "prescriptions" as defined in Business and Professions Code section 4040 in
20 that they were not given individually for the person or persons for whom they were ordered.
21 Respondent Precision Pharmacy actually filled the orders and then sent them to the prescriber,
22 which is the business of a wholesaler. Complainant refers to and incorporates all the allegations
23 contained in paragraphs 32 through 47 above, as though set forth fully.

24 **THIRD CAUSE FOR DISCIPLINE**

25 **(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)**

26 **(Filling Prescriptions with Missing Prescription Requirements/Components)**

27 54. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to
28 disciplinary action under section 4040, subdivisions (a)(1)(A) and (a)(1)(B) which requires that

1 prescriptions contain the name or names and addresses of the patient or patients, name and
2 quantity of the drug prescribed and the directions for use, the date of issue, and the name, address
3 and telephone number of the prescriber. Specifically, during an inspection of Respondent
4 Precision Pharmacy on September 1, 2009, Board inspectors secured prescriptions that were
5 missing some of the information required pursuant to section 4040. Complainant refers to and
6 incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth
7 fully.

8 **FOURTH CAUSE FOR DISCIPLINE**

9 **(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)**

10 **(Filling Prescription With Missing Prescription Label Requirements)**

11 55. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to
12 disciplinary action under section 4076, subdivision (a)(2) and (a)(3) which requires a prescription
13 label to have the directions for use, name of the patient or patients, and strength of drug
14 dispensed. Specifically, during an inspection of Respondent Precision Pharmacy on September 1,
15 2009, Board inspectors secured prescription labels that were missing some of the information
16 required pursuant to section 4076. Complainant refers to and incorporates all the allegations
17 contained in paragraphs 32 through 47 above, as though set forth fully.

18 **FIFTH CAUSE FOR DISCIPLINE**

19 **(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)**

20 **(Failure to Meet Sterile Injectable Product Label Requirements)**

21 56. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to
22 disciplinary action under section 1751.2, subdivision (b) of California Code of Regulations,
23 which requires that the name and concentrations of ingredients contained in the sterile injectable
24 product be included on the label. Specifically, during an inspection of Respondent Precision
25 Pharmacy on September 1, 2009, Board inspectors located labels for sterile injectable products
26 that were not in compliance with 1751.2, subdivision (b) of California Code of Regulations.
27 Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47
28 above, as though set forth fully.

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EIGHTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Failure to Include Written Justification of Chosen Expiration Dates)

59. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 1751.7, subdivision (a)(4) of California Code of Regulations, which requires compounders to have written justification of the chosen expiration dates for compounded sterile injectable products. Specifically, Respondent Precision Pharmacy assigned several drugs expiration dates which did not use the expiration date of the earliest component to expire and there is no written justification for the choice in date. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

NINTH CAUSE FOR DISCIPLINE

(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)

(Failure to Include/Provide Policies & Procedures for Master Formulas and Worksheets)

60. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to disciplinary action under section 1751.02, subdivision (c)(3)(I) of California Code of Regulations, which requires sterile injectable compounders to have written policies and procedures for sterile injectable compounders to have written policies and procedures for sterile batch compounding use of master formulas and worksheets. Specifically, during an inspection of Respondent Precision Pharmacy on September 1, 2009, Board inspectors obtained a sample of Master Formulas and Logged Formula Worksheets which had different beyond use dates from the Master Formulas and Logged Formula Worksheets. There were no explanation or policies and procedures on how to use the Master formulas and Logged Formula Worksheets. Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

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1 **TENTH CAUSE FOR DISCIPLINE**

2 **(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)**

3 **(Failure to Conduct End Product Testing for Sterility on All Batches)**

4 61. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to
5 disciplinary action under section 4342, subdivision (a) as it relates to Business and Professions
6 Code section 4169, subdivisions (a)(3) and (a)(4) which prohibits a person or entity from
7 purchasing, selling, or trading a dangerous drug which the person knew or reasonably should
8 have known were misbranded, and if a drug was purchased, sold, or traded after the beyond use
9 date on the label. Specifically, during an inspection at Precision Pharmacy on September 1, 2009,
10 a Board inspector observed an order for Sulfadiazine Sodium/Trimeth 437/80, prescription
11 #134900 prepared on May 15, 2009, which was given an expiration date of February 27, 2010;
12 however, further research revealed that the drug had actually expired on October 2, 2008. The
13 flagged lot and expiration date labels were not on the vial, suggesting they were removed before
14 dispensing. In addition, several other drugs were found on the shelves of the pharmacy with no
15 expiration date or lot number. Complainant refers to and incorporates all the allegations
16 contained in paragraphs 32 through 47 above, as though set forth fully.

17 **ELEVENTH CAUSE FOR DISCIPLINE**

18 **(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)**

19 **(Sale of Misbranded Drugs)**

20 62. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to
21 disciplinary action under section 1751.7, subdivision (c) of California Code of Regulations, which
22 requires batch produced sterile injectable drugs compounded from one or more non-sterile
23 ingredients to be subject to documented end product testing for sterility and pyrogens and shall be
24 quarantined until the end product testing confirms sterility and acceptable level of pyrogens.
25 Specifically, during an inspection of Respondent Precision Pharmacy on September 1, 2009, a
26 Board inspector noted a large amount of sterile injectable products on the pharmacy shelves and
27 requested proof of pyrogen testing. Respondent Waldrip-Helgren stated that they were not doing
28 pyrogen testing on all items. Later Respondent Waldrip-Helgren admitted that Respondent

1 Precision Pharmacy was not doing pyrogen testing at all prior to September 1, 2009 Board
2 inspection. Complainant refers to and incorporates all the allegations contained in paragraphs 32
3 through 47 above, as though set forth fully.

4 **TWELFTH CAUSE FOR DISCIPLINE**

5 **(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)**

6 **(Failure to Keep Lot and Expiration Date on Logged Formula Worksheets)**

7 63. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to
8 disciplinary action under section 1716.2, subdivision (a)(2) of California Code of Regulations,
9 which requires records, including lot numbers and expiration dates, be kept when compounding in
10 quantities larger than required for immediate dispensing by a prescriber or for future dispensing
11 upon a prescription. Specifically, during an inspection at Respondent Precision Pharmacy on
12 September 1, 2009, Board inspectors located Logged Formula Worksheets for various
13 medications/drugs with missing lot and/or expiration dates. Complainant refers to and
14 incorporates all the allegations contained in paragraphs 32 through 47 above, as though set forth
15 fully.

16 **THIRTEENTH CAUSE FOR DISCIPLINE**

17 **(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)**

18 **(Knowingly Making a False Document)**

19 64. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to
20 disciplinary action under section 4301, subdivision (g) which defines unprofessional conduct as
21 knowingly making or signing any certificate or other document that falsely represents the
22 existence or non-existence of a state of facts. Specifically, during an inspection at Respondent
23 Precision Pharmacy on September 1, 2009, Board inspectors secured Logged Formula
24 Worksheets for various medications/drugs where the expiration date of the finished product did
25 not correspond with the earliest expiring product. Complainant refers to and incorporates all the
26 allegations contained in paragraphs 32 through 47 above, as though set forth fully.

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1 **FOURTEENTH CAUSE FOR DISCIPLINE**

2 **(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)**

3 **(Keeping Refrigerated Drugs at Room Temperature)**

4 65. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to
5 disciplinary action under section 4169, subdivision (a)(2) which states no person or entity shall
6 purchase, sell or transfer drugs the person knew or reasonably should have known were
7 adulterated. Specifically, during an inspection at Respondent Precision Pharmacy on September
8 1, 2009, Board inspectors noted that there was one (1) drum of griseofulvin and two (2) drums of
9 omeprazole which stated "REFRIGERATE" but which were kept at room temperature in the
10 pharmacy. Complainant refers to and incorporates all the allegations contained in paragraphs 32
11 through 47 above, as though set forth fully.

12 **FIFTEENTH CAUSE FOR DISCIPLINE**

13 **(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)**

14 **(Violation of Food, Drug, and Cosmetic Act and FDA Cease and Desist Order)**

15 66. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are not in
16 compliance with an FDA Cease and Desist letter issued for production of apple flavored
17 phenylbutazone powder. Specifically, during an inspection at Respondent Precision Pharmacy on
18 September 1, 2009, Board inspectors observed Respondent Precision Pharmacy staff
19 compounding apple flavored phenylbutazone powder. Complainant refers to and incorporates all
20 the allegations contained in paragraphs 32 through 47 above, as though set forth fully.

21 **SIXTEENTH CAUSE FOR DISCIPLINE**

22 **(Against Respondents Precision Pharmacy and Patricia Waldrip-Helgren)**

23 **(Maintaining Drugs and Other Items for Manufacture Without Expiration Date)**

24 67. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to
25 disciplinary action under section 1718.1 of the California Code of Regulations which states that
26 all prescription drugs not bearing a manufacturer's expiration date are deemed to have expired
27 and may not be manufactured, distributed, held for sale, or dispensed. Section 211.137 of title 21
28 of the Code of Federal Regulations states that all drug products must have an expiration date.

1 Specifically, during an inspection at Respondent Precision Pharmacy on September 1, 2009,
2 Board inspectors observed that the following medications were found inside of Respondent
3 Precision Pharmacy without an expiration date: Phenylbutazone apple flavored paste syringes,
4 Ranitidine 1500mg/scoop-100 scoop jar, Rifampin 300mg/scoop-100 scoop jar, Triple Antibiotic
5 ointment 454 gram jar, Isoxsuprine 600mg/scoop-100 scoop jar, Doxycycline 1gm/scoop-100
6 scoop jar, Acetylcysteine (N) 2gm/scoop-100 scoop jar, Potassium Bromide 500mg capsule-
7 bottle of 100 capsules. Complainant refers to and incorporates all the allegations contained in
8 paragraphs 32 through 47 above, as though set forth fully.

9 **SEVENTEENTH CAUSE FOR DISCIPLINE**

10 **(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)**

11 **(Placing False or Misleading Labels on Prescription)**

12 68. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to
13 disciplinary action under section 4078, subdivision (a)(1) which states that no person shall place a
14 false or misleading label on a prescription. Specifically, during an inspection at Respondent
15 Precision Pharmacy on September 1, 2009, a Board inspector located a label for apple flavored
16 bute powder with no route of administration. It did not give directions on whether it was to be
17 mixed in with food or water or taken "as is." The label stated "1gm/scoop, 100gm jar."
18 However, the "scoop size" was not defined, and if the scoop were to be misplaced, the patient
19 may potentially get a different dose of the drug. Complainant refers to and incorporates all the
20 allegations contained in paragraphs 32 through 47 above, as though set forth fully.

21 **EIGHTEENTH CAUSE FOR DISCIPLINE**

22 **(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)**

23 **(Failure to Maintain Proper Pharmacist-Technician Ratio)**

24 69. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to
25 disciplinary action under section 4115, subdivision (f)(1) as it relates to California Code of
26 Regulations section 1793.7, subdivision (b), which states that the ratio of pharmacist to
27 technicians shall not be greater than 1:1 in a retail pharmacy. Specifically, during the inspection
28 at Respondent Precision Pharmacy on September 1, 2009, there was one (1) pharmacist with one

1 (1) intern, five (5) technicians, and two (2) clerks. Another pharmacist came in an hour after the
2 inspector had been at the pharmacy. In addition, during the inspection at Respondent Precision
3 Pharmacy on November 10, 2009, there were two (2) pharmacists with one (1) intern, seven (7)
4 technicians, and one (1) clerk. The inspector found more technicians than allowed for by the
5 ratio, and not all could be supervised by the pharmacist due to the layout of the pharmacy.
6 Complainant refers to and incorporates all the allegations contained in paragraphs 32 through 47
7 above, as though set forth fully.

8 **NINETEENTH CAUSE FOR DISCIPLINE**

9 **(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)**

10 **(Orally Transmitted Prescriptions Taken by Pharmacy Technicians)**

11 70. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to
12 disciplinary action under section 1717, subdivision (c) which states an oral prescription may only
13 be taken and transcribed by a pharmacist. Specifically, during inspections at Respondent
14 Precision Pharmacy on September 1, 2009, and November 10, 2009, a Board inspector was told
15 by the technicians that they took the prescription orders and wrote them on the blanks, and that
16 the pharmacists rarely wrote the prescriptions. Complainant refers to and incorporates all the
17 allegations contained in paragraphs 32 through 47 above, as though set forth fully.

18 **TWENTIETH CAUSE FOR DISCIPLINE**

19 **(Against Respondents, Precision Pharmacy and Patricia Waldrip-Helgren)**

20 **(Dispensing Controlled Substance Prescriptions Written by Prescribers for Themselves)**

21 71. Respondent Precision Pharmacy and Respondent Waldrip-Helgren are subject to
22 disciplinary action under section 11170 of the Health and Safety Code which states that a
23 prescriber may not prescribe a controlled substance for himself. Specifically, Respondent
24 Precision Pharmacy provided a printout showing that it dispensed 14 controlled substance
25 prescriptions which had been self-prescribed. Complainant refers to and incorporates all the
26 allegations contained in paragraphs 32 through 47 above, as though set forth fully.

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1 **TWENTY-FIRST CAUSE FOR DISCIPLINE**

2 (Against Respondents Precision Pharmacy and PIC Patricia Waldrip-Helgren)
3 (Failure to Comply with Other States' Laws When Transferring Drugs to Other States)

4 72. Respondents Precision Pharmacy and Respondent Waldrip-Helgren are subject to
5 disciplinary action under section 4059.5, in that Respondent Precision Pharmacy transferred
6 medications to other states in violation of the other states' laws. The circumstances are as
7 follows:

8 a. From on or about June 15, 2007, through October 6, 2008, Respondent Precision
9 Pharmacy sent medications to North Carolina without a license in North Carolina, in violation of
10 North Carolina General Statutes sections 90-85.3(m) and 90-85.21A, and 21 North Carolina
11 Administrative Code sections 46.1601 and 1607. Complainant also refers to and incorporates all
12 the allegations contained in paragraphs 48 and 49, above, as though set forth fully.

13 b. On dates unknown prior to on or about September 14, 2009, Respondent Precision
14 Pharmacy sent approximately 1,583 prescriptions to Louisiana without a license in Louisiana, in
15 violation of title 46 of the Louisiana Administrative Code, section LIII 2301 et cetera.
16 Complainant also refers to and incorporates all the allegations contained in paragraphs 50 and 51,
17 above, as though set forth fully.

18 **DISCIPLINE CONSIDERATIONS**

19 73. To determine the degree of discipline, if any, to be imposed on Respondent Precision
20 Pharmacy, Complainant alleges that on or about July 28, 2009, in a prior action, the Board issued
21 Citation Number C1 2007 36942 and ordered Respondent to pay a total of \$3,000.00 in fines.
22 The fines were imposed for violation of Code section 4059.5(2) (i.e., subdivision (f)(2)), which
23 requires that only the PIC or the pharmacist designated by the PIC have access to the pharmacy's
24 dangerous drugs' secure storage facility; and for violation of section 1714, subdivision (b) of title
25 16 of the California Code of Regulations, which requires that pharmacies maintain their
26 dangerous drugs in a safe and secure manner. That Citation is now final and is incorporated by
27 reference as if fully set forth.

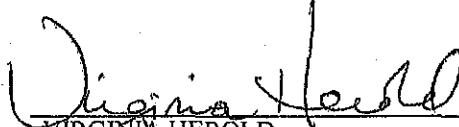
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PRAYER

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

1. Revoking or suspending Original Permit Number PHY 47310, issued to Precision Pharmacy LLC dba Precision Pharmacy;
2. Revoking or suspending Sterile Compounding License Number LSC 99351, issued to Precision Pharmacy LLC dba Precision Pharmacy;
3. Revoking or suspending Original Pharmacist License Number RPH 42842, issued to Patricia A. Waldrip-Helgren;
4. Ordering Precision Pharmacy to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Code section 125.3; and
5. Taking such other and further action as deemed necessary and proper.

DATED: 3/30/13


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

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