

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

In the Matter of the Accusation Against:

Case No. 4461

**SAN DIEGO HOSPICE CORP.
DBA SAN DIEGO HOSPICE PHARMACY**

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER AS TO
ROSENE DOBNICK PIRRELLO ONLY**

Pharmacy Permit No. PHY 37157

Sterile Compounding License No.
LSC 99299

and

ROSENE DOBNICK PIRRELLO
3863-3 California Street
San Diego, CA 92110

Pharmacy License No. RPH 36880

Respondents.

DECISION AND ORDER

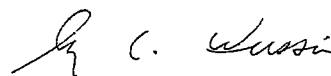
The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on July 9, 2014.

It is so ORDERED on July 2, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By



STAN C. WEISSER
Board President

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10 **DEPARTMENT OF CONSUMER AFFAIRS**
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14 **Pharmacy Permit No. PHY 37157**

15 **Sterile Compounding License No. LSC**
99299

16 **and**

17 **ROSENE DOBNICK PIRRELLO**
18 **3863-3 California Street**
19 **San Diego, CA 92110**

20 **Pharmacist License No. RPH 36880**

21 Respondents.

22
23 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
24 entitled proceedings that the following matters are true:

25 PARTIES

26 1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.
27 She brought this action solely in her official capacity and is represented in this matter by Kamala
28

1 D. Harris, Attorney General of the State of California, by Nicole R. Trama, Deputy Attorney
2 General.

3 2. Rosene Dobnick Pirrello (Respondent) is representing herself in this proceeding and
4 has chosen not to exercise her right to be represented by counsel.

5 3. On or about February 10, 1982, the Board of Pharmacy issued Pharmacist License
6 No. RPH 36880 to Rosene Dobnick Pirrello (Respondent). The Pharmacist License was in full
7 force and effect at all times relevant to the charges brought in Accusation No. 4461 and will
8 expire on January 31, 2016, unless renewed.

9 JURISDICTION

10 4. Accusation No. 4461 was filed before the Board of Pharmacy (Board), Department of
11 Consumer Affairs, and is currently pending against Respondent. The Accusation and all other
12 statutorily required documents were properly served on Respondent on February 10, 2014.
13 Respondent timely filed her Notice of Defense contesting the Accusation.

14 5. A copy of Accusation No. 4461 is attached as exhibit A and incorporated herein by
15 reference.

16 ADVISEMENT AND WAIVERS

17 6. Respondent has carefully read, and understands the charges and allegations in
18 Accusation No. 4461. Respondent also has carefully read, and understands the effects of this
19 Stipulated Settlement and Disciplinary Order

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

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

1 CULPABILITY

2 9. Respondent understands and agrees that the charges and allegations in Accusation
3 No. 4461, if proven at a hearing, constitute cause for imposing discipline upon her Pharmacist
4 License.

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

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

11 CONTINGENCY

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

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

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

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

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

6 **DISCIPLINARY ORDER**

7 IT IS HEREBY ORDERED that Pharmacist License No. RPH 36880 issued to Respondent
8 Rosene Dobnick Pirrello (Respondent) is revoked. However, the revocation is stayed and
9 Respondent is placed on probation for four (4) years on the following terms and conditions.

10 1. **Obey All Laws**

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

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

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

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

25 2. **Report to the Board**

26 Respondent shall report to the board quarterly, on a schedule as directed by the board or its
27 designee. The report shall be made either in person or in writing, as directed. Among other
28 requirements, respondent shall state in each report under penalty of perjury whether there has

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

6 **3. Interview with the Board**

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

12 **4. Cooperate with Board Staff**

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

16 **5. Continuing Education**

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

19 **6. Notice to Employers**

20 During the period of probation, respondent shall notify all present and prospective
21 employers of the decision in case number 4461 and the terms, conditions and restrictions imposed
22 on respondent by the decision, as follows:

23 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
24 respondent undertaking any new employment, respondent shall cause her direct supervisor,
25 pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's
26 tenure of employment) and owner to report to the board in writing acknowledging that the listed
27 individual(s) has/have read the decision in case number 4461, and terms and conditions imposed
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1 thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s)
2 submit timely acknowledgment(s) to the board.

3 If respondent works for or is employed by or through a pharmacy employment service,
4 respondent must notify her direct supervisor, pharmacist-in-charge, and owner at every entity
5 licensed by the board of the terms and conditions of the decision in case number 4461 in advance
6 of the respondent commencing work at each licensed entity. A record of this notification must be
7 provided to the board upon request.

8 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
9 (15) days of respondent undertaking any new employment by or through a pharmacy employment
10 service, respondent shall cause her direct supervisor with the pharmacy employment service to
11 report to the board in writing acknowledging that she has read the decision in case number 4461
12 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure
13 that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

14 Failure to timely notify present or prospective employer(s) or to cause that/those
15 employer(s) to submit timely acknowledgments to the board shall be considered a violation of
16 probation.

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

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

23 During the period of probation, respondent shall not supervise any intern pharmacist, be the
24 pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board
25 nor serve as a consultant unless otherwise specified in this order. Assumption of any such
26 unauthorized supervision responsibilities shall be considered a violation of probation.

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1 **8. Reimbursement of Board Costs**

2 As a condition precedent to successful completion of probation, respondent shall pay to the
3 board its costs of investigation and prosecution in the amount of \$8,845.00. Respondent shall
4 make said payments as follows: Respondent shall pay \$200.00 per month commencing on the
5 effective date of this decision, and on the first of each month thereafter until paid in full.

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

9 The filing of bankruptcy by respondent shall not relieve respondent of her responsibility to
10 reimburse the board its costs of investigation and prosecution.

11 **9. Probation Monitoring Costs**

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

16 **10. Status of License**

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

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

24 **11. License Surrender While on Probation/Suspension**

25 Following the effective date of this decision, should respondent cease practice due to
26 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
27 respondent may tender her license to the board for surrender. The board or its designee shall have
28 the discretion whether to grant the request for surrender or take any other action it deems

1 appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent
2 will no longer be subject to the terms and conditions of probation. This surrender constitutes a
3 record of discipline and shall become a part of the respondent's license history with the board.

4 Upon acceptance of the surrender, respondent shall relinquish her pocket and wall license to
5 the board within ten (10) days of notification by the board that the surrender is accepted.

6 Respondent may not reapply for any license from the board for three (3) years from the effective
7 date of the surrender. Respondent shall meet all requirements applicable to the license sought as
8 of the date the application for that license is submitted to the board, including any outstanding
9 costs.

10 **12. Notification of a Change in Name, Residence Address, Mailing Address or**
11 **Employment**

12 Respondent shall notify the board in writing within ten (10) days of any change of
13 employment. Said notification shall include the reasons for leaving, the address of the new
14 employer, the name of the supervisor and owner, and the work schedule if known. Respondent
15 shall further notify the board in writing within ten (10) days of a change in name, residence
16 address, mailing address, or phone number.

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

19 **13. Tolling of Probation**

20 Except during periods of suspension, respondent shall, at all times while on probation, be
21 employed as a pharmacist in California for a minimum of forty (40) hours per calendar month.
22 Any month during which this minimum is not met shall toll the period of probation, i.e., the
23 period of probation shall be extended by one month for each month during which this minimum is
24 not met. During any such period of tolling of probation, respondent must nonetheless comply
25 with all terms and conditions of probation.

26 Should respondent, regardless of residency, for any reason (including vacation) cease
27 practicing as a pharmacist for a minimum of forty (40) hours per calendar month in California,
28 respondent must notify the board in writing within ten (10) days of the cessation of practice, and

1 must further notify the board in writing within ten (10) days of the resumption of practice. Any
2 failure to provide such notification(s) shall be considered a violation of probation.

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

6 "Cessation of practice" means any calendar month during which respondent is
7 not practicing as a pharmacist for at least forty (40) hours, as defined by Business and
8 Professions Code section 4000 et seq . "Resumption of practice" means any calendar
9 month during which respondent is practicing as a pharmacist for at least forty (40)
10 hours as a pharmacist as defined by Business and Professions Code section 4000 et
11 seq.

12 **14. Violation of Probation**

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

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

25 **15. Completion of Probation**

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

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1 **16. Community Services Program**

2 Within sixty (60) days of the effective date of this decision, respondent shall submit to the
3 board or its designee, for prior approval, a community service program in which respondent shall
4 provide free health-care related services on a regular basis to a community or charitable facility or
5 agency for at least thirty (30) hours per year while on probation. Within thirty (30) days of board
6 approval thereof, respondent shall submit documentation to the board demonstrating
7 commencement of the community service program. A record of this notification must be
8 provided to the board upon request. Respondent shall report on progress with the community
9 service program in the quarterly reports. Failure to timely submit, commence, or comply with the
10 program shall be considered a violation of probation.

11 **17. Remedial Education**

12 Within sixty (60) days of the effective date of this decision, respondent shall submit to the
13 board or its designee, for prior approval, an appropriate program of remedial education related to
14 compounding. The program of remedial education shall consist of at least fifteen (15) hours per
15 year during the first two (2) years of probation and at respondent's own expense. All remedial
16 education shall be in addition to, and shall not be credited toward, continuing education (CE)
17 courses used for license renewal purposes.

18 Failure to timely submit or complete the approved remedial education shall be considered a
19 violation of probation. The period of probation will be automatically extended until such
20 remedial education is successfully completed and written proof, in a form acceptable to the board,
21 is provided to the board or its designee.

22 Following the completion of each course, the board or its designee may require the
23 respondent, at his or her own expense, to take an approved examination to test the respondent's
24 knowledge of the course. If the respondent does not achieve a passing score on the examination,
25 this failure shall be considered a violation of probation. Any such examination failure shall
26 require respondent to take another course approved by the board in the same subject area.

27
28

Exhibit A

Accusation No. 4461

1 KAMALA D. HARRIS
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14 **4311 Third Avenue**
San Diego, CA 92103

A C C U S A T I O N

15 **Retail Pharmacy Permit No. PHY 37157**
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17 **and**

18 **ROSENE DOBNICK PIRRELLO**
19 **3863-3 California Street**
San Diego, CA 92110

20 **Pharmacist License No. RPH 36880**

21 Respondents.

22
23 Complainant alleges:

24 **PARTIES**

25 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
26 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
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1 17. California Code of Regulations, title 16, section 1735.3 states in pertinent part:¹

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

4 (1) The master formula record.

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

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

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

9 (5) The quantity of each component used in compounding the drug
10 product.

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

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

18 (8) A pharmacy assigned reference or lot number for the compounded
19 drug product.

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

21 (10) The quantity or amount of drug product compounded. . . .

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

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

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

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

¹ The California Code of Regulations sections listed above are from the prior version of
the Regulations, which was in effect at the time of the facts giving rise to the allegations asserted
herein. In 2013, the Regulations were renumbered and reorganized.

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

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

...

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

...

COST RECOVERY

19. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

DRUGS

20. Chlorpromazine is a dangerous drug pursuant to Business and Professions Code section 4022 and is used for the treatment of psychiatric illness and nausea or vomiting.

21. Dexamethasone is a dangerous drug pursuant to Business and Professions Code section 4022 and is used for the treatment of swelling.

22. Diazepam is a Schedule IV controlled substance pursuant to Health and Safety Code section 11057(d)(9) and a dangerous drug pursuant to Business and Professions Code section 4022. Diazepam is used for the treatment of anxiety and seizures.

23. Fentanyl is a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (c)(8), and a dangerous drug pursuant to Business and Professions Code section 4022. Fentanyl is used for the treatment of pain.

24. Haloperidol is a dangerous drug pursuant to Business and Professions Code section 4022 and is used for the treatment of psychiatric illness.

1 25. Indomethacin is a dangerous drug pursuant to Business and Professions Code section
2 4022 and is used for the treatment of inflammation.

3 26. Ketoprofen is a dangerous drug pursuant to Business and Professions Code section
4 4022 and is used for the treatment of pain.

5 27. Metoclopramide is a dangerous drug pursuant to Business and Professions Code
6 section 4022 and is used for the treatment of nausea and vomiting.

7 28. Mexiletine is a dangerous drug pursuant to Business and Professions Code section
8 4022 and is used in the treatment of heart arrhythmias and prevent transplanted organ rejection.

9 29. Phenobarbital is a Schedule IV controlled substance pursuant to Health and Safety
10 Code section 11057, subdivision (d)(26), and a dangerous drug pursuant to Business and
11 Professions Code section 4022. Phenobarbital is used in the treatment of seizures.

12 30. Phenytoin is a dangerous drug pursuant to Business and Professions Code section
13 4022 and is used for the treatment of seizures.

14 **FACTUAL ALLEGATIONS**

15 31. Since August 21, 2002 and at all times referenced herein, Rosene Pirrello
16 (Respondent) was the Pharmacist-in-Charge (PIC) of San Diego Hospice Corp., doing business as
17 San Diego Hospice Pharmacy (Respondent). On or about May 15, 2012, the Board conducted an
18 annual licensed sterile compounder inspection of Respondents.

19 32. During the inspection, the Board inspector discovered that Respondents did not
20 maintain the records for the acquisition of dangerous drugs and controlled substances on the
21 licensed premises as required by law.

22 33. During the inspection, the Board inspector also reviewed Respondents' compounding
23 records and discovered that Respondents had not followed the regulations required for
24 compounding sterile injectable drugs.² Specifically, from February 22, 2012 through May 4,

25 ² "Sterile" compounds require sterility and are typically in the form of injectables for the
26 direct administration into a sterile organ or fluid in the body. It is imperative these products
27 contain little to no contaminants for the safety of the patient.

1 2012, Respondents compounded six batches of stock fentanyl 1000mcg/ml-1000mls (Assigned
2 Lot Numbers STK178-0, STK178-2, STK178-3, STK220-0, STK220-1, and STK220-2) without
3 quarantine of those six batches until end-product testing, in order to confirm sterility and
4 acceptable levels of pyrogens. Respondents did not examine on a periodic basis the end-product
5 of those six batches to ensure that they met the required specifications.

6 34. Respondents also did not perform periodic sampling to determine if the end-product
7 met required specifications for another nine lots of sterile to sterile compounded fentanyl
8 50mcg/ml aliquots, as follows:

9

Compounded date	Assigned Beyond Use Date	Assigned Lot #	Stock Lot # Used
2/22/12	3/22/12	STK179-0	STK 178-0
2/29/12	3/30/12	STK179-2	STK 178-2
3/12/12	4/11/12	STK128-12	STK 178-3
4/11/12	5/11/12	STK219-0	STK 220-0
4/12/12	5/12/12	STK219-1	STK 220-0
4/19/12	5/11/12	STK219-2	STK 220-0
4/26/12	5/26/12	STK219-3	STK 220-1
5/4/12	6/3/12	STK219-5	STK 220-2
5/7/12	6/3/12	STK219-6	STK 220-2

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15 These nine lots were dispensed to patients without Respondents' verification of the test results.

16 35. The Board inspector also determined based on her review of compounding logs that
17 Respondents did not properly record the required manufacturer and lot numbers in their
18 compounding logs for another three lots of stock fentanyl 1000 mcg/ml (Assigned Lot Numbers
19 STK178-3, STK220-0, and STK220-2) and another five lots of fentanyl 50 mcg/ml (Assigned Lot
20 Numbers STK219-0, STK219-1, STK219-2, STK219-3, and STK219-6).

21 36. In addition, the Board inspector determined that Respondents had ordered and
22 purchased non-patient specific compounded drugs (drugs compounded by pharmacies prior to
23 receipt by those pharmacies of valid prescriptions for individual patients where the prescribers
24 had approved use of a compounded drug either orally or in writing) from two pharmacies, UCP
25 and VDC.

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37. Respondents' records show that from January 2009 to April 2012, Respondents ordered and purchased the following units of non-patient specific compounded drug products from UCP:

Compounded Drug	Total Units Purchased
Chlorpromazine 50mg Suppository (number)	78,474
Chlorpromazine 25mg Suppository (number)	2,850
Chlorpromazine 100mg Suppository (number)	6,840
Chlorpromazine 100mg/ml Sol (ml)	7,344
Diph 25-Methel 10- dex 2mg Suppository (number)	360
Ketoprofen 20% PLO (grams)	11,552
Ketoprofen 10% PLO (grams)	7,800
MOHS Paste (grams)	300
Phenytoin 300mg Suppository (number)	930
Valproic Acid 250mg/5ml suspension (ml)	1,700
Ketamine 5% keto 10% Lido 5% PLO (grams)	180
Indomethacin 50mg Suppository (number)	48
Sal Acid 2% sulfur 3% HCT 0.05% Cream (grams)	60
Mexiletine 50 mg Capsules (number)	300
APAP 650MG Suppository (number)	3,000

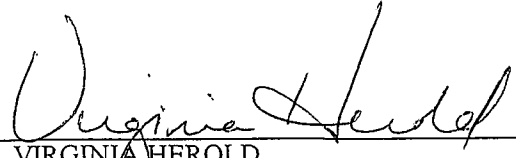
38. Respondents' records further show that from January 2009 to April 2012, Respondents ordered and purchased the following units of non-patient specific compounded drug products from VDC:

Compounded Drug	Total Units Purchased
Chlorpromazine (unknown)	20
Chlorpromazine 50mg/ml PLO gel 10ml (each)	795
Chlorpromazine 100mg/ml PLO gel 10ml (each)	1,477
Mexiletine 50mg capsules (number)	1,286
Mexiletine 100mg capsules (number)	100
Mexiletine 150mg capsules (number)	550
Dexamethasone/ diphen/ metoclopramide 2mg/25mg/10mg (1 ml) PLO (each)	1,415
Phenobarbital 60mg Suppository	490
Phenobarbital 30mg Suppository	30
Phenobarbital 180mg Suppository	72
Diazepam 5mg Suppository	30
Diazepam 10mg Suppository	150
Lorazepam 1mg/ml PLO	5
Metoclopramide 10mg/0.1ml PLO gel	44
Haloperidol 1mg/ml PLO Gel	63
Carbamazepine 200mg Suppository (each)	12

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

DATED: 2/6/14



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

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