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

| | |
|---|---|
| In the Matter of the Accusation Against:<br><br>**SAN DIEGO HOSPICE CORP.**<br>**DBA SAN DIEGO HOSPICE PHARMACY**<br>4311 Third Avenue<br>San Diego, CA 92103<br><br>Pharmacy Permit No. PHY 37157<br>Sterile Compounding License No. LSC 99299<br><br>and<br><br>**ROSENE DOBNICK PIRRELLO**<br>3863-3 California Street<br>San Diego, CA 92110<br><br>Pharmacist License No. RPH 36880<br><br>Respondents. | Case No. 4461<br><br>**As to Respondent San Diego Hospice Corp. dba San Diego Hospice Pharmacy only.** |

## DECISION AND ORDER

The attached Stipulated Surrender of License and 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 April 15, 2014.

It is so ORDERED on April 10, 2014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STANLEY C. WEISSER
Board President

KAMALA D. HARRIS
Attorney General of California
JAMES M. LEDAKIS
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*Attorneys for Complainant*

**BEFORE THE**
**BOARD OF PHARMACY**
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| In the Matter of the Accusation Against:<br><br>**SAN DIEGO HOSPICE CORP.**<br>**DBA SAN DIEGO HOSPICE PHARMACY**<br>**4311 Third Avenue**<br>**San Diego, CA 92103**<br><br>**Pharmacy Permit No. PHY 37157**<br><br>**Sterile Compounding License No. LSC 99299**<br><br>**and**<br><br>**ROSENE DOBNICK PIRRELLO**<br><br>Respondent. | Case No. 4461<br><br>**STIPULATED SURRENDER OF LICENSE AND ORDER** |

IT IS HEREBY STIPULATED AND AGREED by and between Complainant Virginia Herold and Respondent San Diego Hospice Corp., doing business as San Diego Hospice Pharmacy, through its undersigned Liquidating Trustee, that the following matters are true:

PARTIES

1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Nicole R. Trama, Deputy Attorney General.

2. On or about February 4, 2013, San Diego Hospice Corp., doing business as San Diego Hospice Pharmacy (Respondent) filed for Chapter 11 bankruptcy in the matter entitled *In re San Diego Hospice & Palliative Care Corporation*, United States District Court Case No. 13-01179-MM11. Pursuant to the September 23, 2014 Order of the United States Bankruptcy Court in *In re San Diego Hospice & Palliative Care Corporation*, United States District Court Case No. 13-01179-MM11, Richard M. Kipperman was appointed as the Liquidating Trustee of the San Diego Hospice & Palliative Care Corporation Trust, successor in interest of Respondent ("the Trustee"). Therefore, the Trustee represents that he has the authority to enter into this Stipulated Settlement and to bind and make admissions as set forth below, on behalf of Respondent. The Trustee is specially represented in this proceeding by Gerald P. Kennedy of Procopio, Cory, Hargreaves & Savitch LLP, whose address is, 525 B Street, Suite 2200, San Diego, CA 92101.

3. On or about July 24, 1991, the Board of Pharmacy issued to Respondent, Hospital Pharmacy Permit No. HSP 37157, which was subsequently converted to Pharmacy Permit No. PHY 37157. The Permits were in full force and effect at all times relevant to the charges brought in Accusation No. 4461 and expired on June 1, 2013. The Pharmacy Permit was cancelled by the Board on January 28, 2014.

4. On or about May 26, 2005, the Board of Pharmacy issued Sterile Compounding License Number LSC 99299 to Respondent. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought in Accusation No. 4461 and expired on June 1, 2013. The Sterile Compounding License was cancelled by the Board on January 28, 2014.

JURISDICTION

5. Accusation No. 4461 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 February 10, 2014. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 4461 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

6. The Trustee, on behalf of Respondent, has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4461. He also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.

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

8. The Trustee, on behalf of Respondent, voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

9. The Trustee, on behalf of Respondent, understands and agrees that the charges and allegations in Accusation No. 4461, if proven at a hearing, constitute cause for imposing discipline upon Pharmacy Permit No. PHY 37157 and Sterile Compounding License Number LSC 99299.

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

11. The Trustee, on behalf of Respondent, understands that by signing this stipulation it enables the Board to issue an order accepting the surrender of Pharmacy Permit No. PHY 37157 and Sterile Compounding License Number LSC 99299 without further process.

CONTINGENCY

12. This stipulation shall be subject to approval by the Board of Pharmacy. The Trustee on behalf of Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondent or its counsel. By signing the stipulation, The Trustee on behalf of Respondent understands and agrees that Respondent may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

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

14. This Stipulated Surrender of License and 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 Surrender of License and 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.

15. 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 Order:

**ORDER**

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 37157 and Sterile Compounding License Number LSC 99299, each issued to Respondent are each and both surrendered and accepted by the Board of Pharmacy.

1. The surrender of Respondent's Pharmacy Permit No. PHY 37157 and Sterile Compounding License Number LSC 99299 and the acceptance of the surrendered licenses by the

Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board of Pharmacy.

2. Respondent shall lose all rights and privileges as a Pharmacy and a Sterile Compounding Pharmacy in California as of the effective date of the Board's Decision and Order.

3. The Trustee, on behalf of Respondent, shall deliver to the Board, if available, the wall licenses and renewal licenses on or before the effective date of the Decision and Order.

4. Respondent may not apply, reapply, or petition for any licensure or registration of the Board for three (3) years from the effective date of the Decision and Order.

5. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 4461 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

6. Respondent shall pay the Board its costs of investigation and enforcement in the amount of $8,845.00 prior to issuance of a new or reinstated license.

7. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation No. 4461 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

8. Respondent shall, within ten (10) days of the effective date, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

ACCEPTANCE

On behalf of Respondent, I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Gerald P. Kennedy. I understand the stipulation and the effect it will have on Respondent's Pharmacy Permit No. PHY 37157 and Sterile Compounding License Number LSC 99299. On behalf of Respondent, I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree that Respondent will be bound by the Decision and Order of the Board of Pharmacy.

DATED: 6 March 14

RICHARD M. KIPPERMAN, as the authorized agent for and the Liquidating Trustee of the San Diego Hospice Corp. Liquidating Trust, successor in interest of the bankruptcy estate of Respondent

I have read and fully discussed with the Liquidating Trustee, the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: 3-10-14

GERALD P. KENNEDY
Attorney for Richard M. Kipperman, Liquidating Trustee

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 3/12/2014

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
JAMES M. LEDAKIS
Supervising Deputy Attorney General

Nicole R. Trama

NICOLE R. TRAMA
Deputy Attorney General
*Attorneys for Complainant*

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# Exhibit A

**Accusation No. 4461**

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*Attorneys for Complainant*

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Complainant alleges:

**PARTIES**

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

2. On or about February 10, 1982, the Board of Pharmacy issued Pharmacist License Number RPH 36880 to Rosene Dobnick Pirrello (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2016, unless renewed.

3. On or about July 24, 1991, the Board of Pharmacy issued Hospital Pharmacy Permit Number HSP 37157 to San Diego Hospice Corp., doing business as San Diego Hospice Pharmacy (Respondent). On February 4, 2013, the Hospital Pharmacy Permit was changed to a Retail Pharmacy Permit (PHY 37157). The Permit was in full force and effect at all times relevant to the charges brought herein and expired on June 1, 2013.

4. On or about May 26, 2005, the Board of Pharmacy issued Sterile Compounding License Number LSC 99299 to San Diego Hospice Corp., doing business as San Diego Hospice Pharmacy (Respondent). The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and expired on June 1, 2013.

**JURISDICTION**

5. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

6. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

7. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

8. Section 4300.1 of the Code states:

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

## STATUTORY PROVISIONS

9. Section 4022 of the Code states:

> Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
>
> (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
>
> (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
>
> (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

10. Section 4105, subdivision (a) of the Code states: "All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form."

11. Section 4113, subdivision (c) of the Code states: "The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

12. Section 4301 of the Code states in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> . . . .
>
> (j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> . . . .
>
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
>
> . . . .

13. Section 4333, subdivision (a) of the Code states: "All prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years."

## REGULATORY PROVISIONS

14. California Code of Regulations, title 16, section 1707 states:

...

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing. . . .

15. California Code of Regulations, title 16, section 1735, subdivision (a) states in pertinent part:

"Compounding" means any of the following activates occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a drug product from chemicals or bulk drug substances

...

16. California Code of Regulations, title 16, section 1735.2(a) states:

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

17. California Code of Regulations, title 16, section 1735.3 states in pertinent part:[1]

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

(1) The master formula record.

(2) The date the drug product was compounded.

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

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

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

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

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

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

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

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

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

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a 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.

(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.

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

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

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

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

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

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

## FACTUAL ALLEGATIONS

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

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

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

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

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

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

| 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 |

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

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

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

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 |

39. The total number of each type of non-patient specific compounded drug products which Respondents ordered and purchased from UCP and VDC, were as follows:

| Compounded Product | Total Units Purchased |
|---|---|
| Suppositories (number) | 93,290 |
| PLO Gel | 19,535gms and 10,954 mls |
| Creams (grams) | 60 |
| Solutions/suspension (mls) | 9,044 |
| Pastes (grams) | 300 |
| Capsules | 2,236 |

40. Subsequently, Respondents comingled these non-patient specific compounded drugs into their pharmacy stock and then dispensed those drugs to patients.

**FIRST CAUSE FOR DISCIPLINE**

**(Failure to Maintain Records)**

41. Respondents are subject to disciplinary action under Code sections 4301(o), for violating Code sections 4105(a) and 4333(a) and California Code of Regulations, title 16, sections 1707(e) and (f) for failing to maintain records of acquisition of dangerous drugs and controlled substances onsite at the address listed on its pharmacy license, as set forth in paragraphs 31 through 40, which are incorporated herein by reference.

**SECOND CAUSE FOR DISCIPLINE**

**(Failure to Perform End Product Testing)**

42. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1751.7(c) in that they compounded six batches of stock fentanyl 1000mcg/ml-1000mls without documentation of end product testing for sterility and pyrogens and without a quarantine of products until the end product testing confirmed sterility and acceptable levels of pyrogens, as set forth in paragraphs 31 through 40, which are incorporated herein by reference.

## THIRD CAUSE FOR DISCIPLINE

**(Failure to Keep Proper Compounding Records)**

43. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1735.3(a)(6), in that Respondents' compounding logs for three lots of stock fentanyl 1000mcg/ml and five lots of fentanyl 50 mcg/ml lacked the manufacturer and lot numbers, as set forth in paragraphs 31 through 40, which are incorporated herein by reference.

## FOURTH CAUSE FOR DISCIPLINE

**(Failure to Complete Process Validation)**

44. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1751.7(a), in that Respondents compounded nine lots of sterile to sterile fentanyl 50mcg/ml aliquots where no periodic sampling was performed in order to determine if the product met required specifications and dispensed those nine lots to patients without verifying the test results, as set forth in paragraphs 31 through 40, which are incorporated herein by reference.

## FIFTH CAUSE FOR DISCIPLINE

**(Aiding and Abetting Compounding of Drugs Prior to Receipt of Valid Prescriptions for Individual Patients)**

45. Respondents are subject to disciplinary action under Code section 4301(o), for aiding and abetting the violation of California Code of Regulations, title 16, section 1735.2(a), in that Respondents ordered and purchased drugs which were compounded by UCP and VDC prior to receipt by UCP and VDC of valid prescriptions either orally or in writing, for individual patients where the prescribers had approved use of a compounded drug product, as set forth in paragraphs 31 through 40, which are incorporated herein by reference.

## DISCIPLINARY CONSIDERATIONS

46. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges:

a. On or about June 5, 2012, the Board issued Citation number CI 2011 52741 against Rosene Dobnick Pirrello for violating California Code of Regulations, title 16, section 1714(d), for failing to provide security against theft or diversion of dangerous drugs, and ordered Respondent Pirrello to pay a fine in the amount of $1,000.00. Respondent Pirrello complied with the citation.

b. On or about June 5, 2012, the Board issued Citation number CI 2011 52740 against San Diego Hospice Corp. doing business as San Diego Hospice Pharmacy, for violating California Code of Regulations, title 16, section 1714(b), for failing to account for 4,950 tablets of hydrocodone/apap 5/500 mg, and ordered payment of a fine in the amount of $1,500.00. Respondent San Diego Hospice Corp. complied with the citation..

**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 Pharmacist License Number 36880, issued to Rosene Dobnick Pirrello, RPH;

2. Revoking or suspending Retail Pharmacy Permit Number PHY 37157 (formerly HSP 37157), issued to San Diego Hospice Corp. doing business as San Diego Hospice Pharmacy;

3. Revoking or suspending Sterile Compounding License Number LSC 99299, issued to San Diego Hospice Corp. doing business as San Diego Hospice Pharmacy;

4. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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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