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

12 In the Matter of the Statement of Issues
Against:

Case No. 5469

13 **PARALLAX HEALTH SCIENCES, INC.;**
14 **JOSEPH MICHAEL REDMOND, Chief**
15 **Executive Officer, President; CALLI**
16 **BUCCI, a.k.a. CALLI SPIETH, Chief**
17 **Financial Officer; FARSHAD NAYSA**

STATEMENT OF ISSUES

[Gov. Code, § 11504.]

18 **Applicant for Community Pharmacy Permit**
19 **and Sterile Compounding Pharmacy**
20 **License**

Respondent.

21 Complainant alleges:

PARTIES

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

25 2. On or about October 10, 2014, the Board received an application for a Community
26 Pharmacy Permit and Sterile Compounding Pharmacy License from Parallax Health Sciences,
27 Inc. (Respondent). Respondent's application was submitted by its president and Chief Executive
28 Officer, Joseph Michael Redmond, and its Chief Financial Officer, Calli Bucci, also known as

1 Calli Spieth. Licensed pharmacist Naysan Farshad is designated as the qualifying Pharmacist-in-
2 Charge. On or about October 7, 2014, Roxsan Pharmacy, Inc., acting through its corporate
3 officers, certified under penalty of perjury to the truthfulness of all statements, answers, and
4 representations in the application. The Board denied the application on February 13, 2015.

5 **JURISDICTION**

6 3. This Statement of Issues is brought before the Board under the authority of the
7 following laws. All section references are to the Business and Professions Code unless otherwise
8 indicated.

9 **STATUTES**

10 4. Code section 4100 states, in pertinent part:

11 (a) No person shall conduct a pharmacy in the State of California unless he
12 or she has obtained a license from the board. A license shall be required for each
13 pharmacy owned or operated by a specific person. A separate license shall be
14 required for each of the premises of any person operating a pharmacy in more than
15 one location. The license shall be renewed annually. The board may, by regulation,
16 determine the circumstances under which a license may be transferred.

15 5. Code section 4302 states:

16 The board may deny, suspend, or revoke any license of a corporation where
17 conditions exist in relation to any person holding 10 percent or more of the
18 corporate stock of the corporation, or where conditions exist in relation to any
19 officer or director of the corporation that would constitute grounds for disciplinary
20 action against a licensee.

20 **REGULATIONS**

21 6. California Code of Regulations, title 16, section 1709 states, in pertinent part:

22 (c) The following shall constitute a transfer of permit and require application
23 for a change of ownership: any transfer of a beneficial interest in a business entity
24 licensed by the board, in a single transaction or in a series of transactions, to any
25 person or entity, which transfer results in the transferee's holding 50% or more of
26 the beneficial interest in that license.

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1 **STATEMENT OF FACTS**

2 **A. Parties to Purchase Agreement**

3 7. Shahla Keyvanfar Melamed (Shahla Melamed or Melamed) is the Chief Executive
4 Officer, president, secretary and treasurer of Roxsan Pharmacy, Inc. (Roxsan Pharmacy). On
5 August 19, 1988, the Board issued Pharmacist License Number RPH 42096 to Shahla Melamed.
6 Said license was in full force and effect at all times relevant to the allegations brought hereunder,
7 and will expire on July 31, 2016 unless it is renewed. Melamed was the Pharmacist-in-Charge of
8 Roxsan Pharmacy from November 3, 1992 through December 2, 2012. She has been a director
9 and officer of Roxsan Pharmacy since August 5, 2003.

10 8. Roxsan Pharmacy is a California corporation with its principal address at 465 North
11 Roxbury Drive, Beverly Hills, CA 90210. On November 3, 1992, the Board issued Pharmacy
12 Permit Number PHY 38297 to Shahla Melamed to do business as Rox San Pharmacy.
13 On September 30, 2003, the license holder changed its name to Roxsan Pharmacy, Inc.
14 The Pharmacy Permit was in full force and effect at all times relevant to the allegations brought
15 hereunder, and will expire on November 1, 2015 unless it is renewed.

16 9. Shahla Melamed is the sole shareholder of Roxsan Pharmacy's stock.

17 10. Respondent Parallax Health Sciences, Inc. is a Nevada corporation with its principal
18 address at One Boston Place, Suite 2600, Boston, MA 02108. Respondent's president and Chief
19 Executive Officer is Joseph Michael Redmond. Its Chief Financial Officer is Calli Bucci, also
20 known as Calli Spieth.

21 **B. Terms of Purchase Agreement**

22 11. On March 27, 2014, Respondent entered into an agreement to purchase all of the
23 issued and outstanding shares of Roxsan Pharmacy and all of its assets and inventory.

24 12. Respondent was required to apply for a change of ownership under California Code
25 of Regulations, title 16, section 1709 because the purchase agreement would result in the transfer
26 of more than fifty percent of a beneficial interest in Roxsan Pharmacy.

27 13. Respondent agreed to employ Shahla Melamed as its president and to appoint her as a
28 director on Respondent's board of directors. Respondent is obligated to employ Melamed in this

1 capacity and guarantee her position on the board of directors until July 14, 2018. The purchase
2 agreement between Roxsan Pharmacy and Respondent is fully executed, except that the parties
3 have no duty to perform if Respondent's application is not approved.

4 **C. Shahla Melamed's Wrongful Conduct**

5 14. Shahla Melamed committed acts that would constitute grounds for disciplinary action
6 against a licensee, as follows:

7 **1. Shahla Melamed Falsified Documents, Subverted an Investigation, and**
8 **Committed a Dishonest Act**

9 15. On June 23, 2011, Shahla Melamed knowingly falsified a Drug Enforcement
10 Administration (DEA) biennial controlled substance inventory during an inspection of Roxsan
11 Pharmacy, in violation of section 4301, subdivision (g). She also attempted to subvert a Board
12 investigation, in violation of section 4301, subdivision (q); and committed an act involving
13 dishonesty, fraud, deceit and corruption, in violation of section 4301, subdivision (f).

14 16. During an inspection of Roxsan Pharmacy on June 23, 2011, a Board inspector
15 requested the pharmacy's DEA biennial controlled substance inventory. Pharmacist K.B. (not a
16 party to this action) produced a spiral notebook containing handwritten controlled substance
17 counts. The dates of the inventories were June 7, 2007, May 6, 2009 and June 1, 2011. For the
18 biennial periods ending in 2007 and 2009, the inventories included Schedule II through V
19 controlled substances. For the period ending in 2011, the inventory recorded only Schedule II
20 controlled substances; missing were drug counts for Schedule III through V controlled
21 substances.

22 17. At some point during the inspection, Shahla Melamed, the Pharmacist-in-Charge,
23 arrived at the pharmacy. The Board inspector asked her for the pharmacy's self assessment and
24 DEA inventory. Shahla Melamed produced the same spiral notebook as before. The inspector
25 noticed that within the 2009 inventory, the header had been changed to include the date of June 1,
26 2011 for Scheduled drugs not listed in the 2011 inventory. The Board inspector asked Shahla
27 Melamed if she added the 2011 date to the 2009 inventory. After first denying the charge, Shahla
28 Melamed admitted adding "6/1/11" to the 2009 controlled substance inventory. The modification

1 gave the appearance that Roxsan Pharmacy maintained a count of Schedule III through V
2 controlled substances for the biennial reporting period ending in 2011.

3 **2. Roxsan Pharmacy Made Illegal Out-of-State Drug Sales While Shahla**
4 **Melamed was the Pharmacist-in-Charge**

5 18. Section 4059.5, subdivision (e), prohibits the transfer, sale or delivery of dangerous
6 drugs and devices to persons outside California unless the transfer, sale or delivery complies with
7 California law, federal law, and the law of the state into which the dangerous drug or device is
8 delivered. Shahla Melamed violated section 4059.5, subdivision (e), by selling dangerous drugs in
9 other states in contravention of the laws of those states and in violation of the laws of this State.

10 **a. Louisiana Drug Sales**

11 19. On September 28, 2012, September 31, 2012, October 18, 2012, and November 13,
12 2012, Roxsan Pharmacy dispensed four prescriptions for dangerous drugs to patients in the state
13 of Louisiana without being licensed in accordance with the Louisiana Pharmacy Practice Act.
14 All of the prescriptions contained ketamine, a Schedule III controlled substance.

15 **b. Connecticut Drug Sales**

16 20. From approximately May 21, 2012 to December 2, 2012, Roxsan Pharmacy
17 dispensed 128 prescriptions for dangerous drugs to patients in the state of Connecticut without
18 being licensed in accordance with the Connecticut Pharmacy Practice Act.

19 **c. Florida Drug Sales**

20 21. From approximately January 10, 2012 to December 2, 2012, Roxsan Pharmacy
21 dispensed 4,604 prescriptions for dangerous drugs to patients in the state of Florida without being
22 licensed in accordance with the Florida Pharmacy Act.

23 **d. Maryland Drug Sales**

24 22. From approximately February 9, 2012 to December 2, 2012, Roxsan Pharmacy
25 dispensed 1,152 prescriptions for dangerous drugs to patients in the state of Maryland without
26 proper licensure.

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e. Shahla Melamed's Responsibility as Pharmacist-in-Charge

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2 23. Under Code sections 4036.5 and 4113, subdivision (c), Shahla Melamed had a duty
3 while she served as the Pharmacist-in-Charge to ensure that Roxsan Pharmacy dispensed drugs in
4 accordance with the Pharmacy Law, federal law, and the law of every state in which the
5 pharmacy did business.

f. As CEO and President of Roxsan Pharmacy, Shahla Melamed Knew About Ongoing Illegal Drug Sales

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7 24. Shahla Melamed ceased being the Pharmacist-in-Charge of Roxsan Pharmacy on
8 December 3, 2012, but she remained the pharmacy's president, Chief Executive Officer, secretary
9 and treasurer. As a corporate officer, she had knowledge that Roxsan Pharmacy continued to
10 dispense dangerous drugs to residents of Connecticut, Florida, Louisiana and Maryland without
11 being licensed in those states, even after she ceased being the Pharmacist-in-Charge.

3. Roxsan Pharmacy Failed to Keep Records of the Sale and Disposition of Dangerous Drugs While Shahla Melamed was the Pharmacist-in-Charge

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14 25. Sections 4081, subdivision (a), and 4105 require a pharmacy to maintain all records
15 of sale, acquisition, receipt, shipment, or disposition of dangerous drugs for three years from the
16 date of making. The records must be open to inspection during the pharmacy's business hours. On
17 March 28, 2014, the Board requested original prescription records for 41 prescriptions dispensed
18 between June 1 and December 31, 2012. Roxsan Pharmacy produced six original dispensing
19 records but did not produce records for the remaining 35 prescriptions. Roxsan Pharmacy failed
20 to keep and maintain records of sale, acquisition, receipt, shipment and disposition for those 35
21 prescriptions, all of which were dangerous drugs.

22 26. Roxsan Pharmacy dispensed 33 of the undocumented prescriptions prior to December
23 3, 2012, during which time Shahla Melamed was the Pharmacist-in-Charge. The remaining two
24 undocumented prescriptions were dispensed on December 17 and 26, 2012, during which time
25 another pharmacist was the Pharmacist-in-Charge.

26 27. Under Code sections 4036.5 and 4113, subdivision (c), Shahla Melamed had a duty,
27 during the time in which she served as the Pharmacist-in-Charge, to maintain all records of sale,
28 acquisition, receipt, shipment and disposition of dangerous drugs.

4. **Roxsan Pharmacy Stored Expired Drug Stock with Active Compounding Stock While Shahla Melamed was the Pharmacist-in-Charge**

28. Section 4342 empowers the Board to act to prevent the sale of pharmaceutical preparations and drugs that fail to conform to the standard and tests as to quality and strength. On June 23, 2011, a Board inspection revealed that Roxsan Pharmacy stored 17 expired ingredients in its active compounding stock, as set forth in the table below. Shahla Melamed was the Pharmacist-in-Charge at the time of the acts in question and, under Code sections 4036.5 and 4113, subdivision (c), she had the responsibility of ensuring that pharmaceutical preparations and drugs dispensed by the pharmacy conformed to the standard and tests as to quality and strength.

Drug	Expiration Date	Days Expired at Time of Inspection
Sorbitol	5/2/2008	Three years, 52 days
Sorbitan Monooleate	10/10/2008	Two years, 256 days
Potassium Azelaoyl	11/19/2008	Two years, 216 days
Versabase Foam	2/26/2010	One year, 117 days
Sardine Flavor	3/1/2010	One year, 114 days
Kaolin	4/30/2010	One year, 54 days
Rapeseed Oil	6/1/2010	One year, 22 days
PCCA ¹ Vanpen	10/13/2010	253 days
Cocamide DEA	10/14/2010	252 days
Dow Corning 1501 Fluid	10/17/2010	249 days
Versabase Shampoo	11/6/2010	229 days
Gelatin	11/19/2010	216 days
Arginine	11/23/2010	212 days
PCCA ² Anhydrous Lipoderm	1/27/2011	147 days
Ascorbyl Palmitate	2/11/2011	132 days
PCCA ² Natapres	3/26/2011	89 days
Panthenol	4/30/2011	54 days

¹ Professional Compounding Centers of America

1 **5. Roxsan Pharmacy Sold a Misbranded, FDA-Unapproved Drug While**
2 **Shahla Melamed was the Pharmacist-in-Charge**

3 29. Health and Safety Code section 111400 defines as “misbranded” any drug that is
4 dangerous to health when used in the dosage, or with the frequency or duration prescribed,
5 recommended or suggested in its labeling. From approximately August 4, 2005 to September 2,
6 2011, Roxsan Pharmacy compounded and dispensed 452 misbranded prescriptions containing
7 Domperidone. Domperidone is not approved for any purpose in the United States and no safe
8 dosage has been established.

9 30. As the Pharmacist-in-Charge at the time of the acts in question, Shahla Melamed was
10 responsible, under Code sections 4036.5 and 4113, subdivision (c), for preventing the sale of a
11 drug dangerous to human health.

12 **6. Roxsan Pharmacy Dispensed Non-Conforming Drugs While Shahla**
13 **Melamed was the Pharmacist-in-Charge**

14 31. California Code of Regulations, title 16, section 1716 prohibits deviation from the
15 requirements of a prescription except upon the prior consent of the prescriber or in accordance
16 with section 4073 of the Code. Section 4073 allows a pharmacist to select a generic drug that
17 boasts the same effectiveness as the brand name drug subject to the prescriber’s order not to
18 substitute. On February 21, 2011, Roxsan Pharmacy dispensed a Follistim Pen for injecting
19 Omnitrope 5mg per 1.5ml and failed to provide appropriate use instructions. The Follistim Pen is
20 not designed for Omnitrope injectable medication and cannot be substituted for the Omnitrope
21 Pen 5. Roxsan Pharmacy deviated from the requirements of the patient’s prescription without
22 prior prescriber consent and in violation of section 4073.

23 32. Shahla Melamed was the Pharmacist-in-Charge at the time of the conduct in question
24 and had the responsibility, under Code sections 4036.5 and 4113, subdivision (c), to ensure that
25 the dispensed medication conformed to the patient’s prescription.

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1 **7. Roxsan Pharmacy Failed to Maintain Temperature Records of Cold**
2 **Storage Containing Sterile Compounded Products While Shahla Melamed**
3 **was the Pharmacist-in-Charge**

4 33. California Code of Regulations, title 16, section 1751.1, subdivision (b), requires
5 pharmacies to maintain temperature records for all refrigerators and freezers in which sterile
6 compounded products are stored. An inspection on June 23, 2011 revealed that Roxsan Pharmacy
7 did not maintain temperature records for the freezer that it used to store sterile injectable
8 products.

9 34. As the Pharmacist-in-Charge at the time of the acts in question, Shahla Melamed was
10 responsible, under Code sections 4036.5 and 4113, subdivision (c), for ensuring that adequate
11 temperature readings of the freezer were recorded and maintained for inspection.

12 **8. Roxsan Pharmacy Failed to Test Sterile Injectable Drugs for Sterility and**
13 **Pyrogens While Shahla Melamed was the Pharmacist-in-Charge**

14 35. California Code of Regulations, title 16, section 1751.7, subdivision (c), requires a
15 compounding pharmacy to perform end-product testing for sterility and pyrogens (bacterial
16 toxins) whenever it compounds sterile injectable drug products from one or more non-sterile
17 ingredients. The regulation requires the pharmacy to quarantine injectable drug products until
18 end-product testing confirms their sterility and acceptable levels of pyrogens.

19 36. Roxsan Pharmacy prepared sterile injectable drug products from non-sterile sources
20 without subjecting the final product to testing. Specifically, on February 14, 2011, Roxsan
21 Pharmacy prepared mitomycin 0.2% injection solution without testing it. The pharmacy also
22 prepared but failed to test alprostadil alcohol injection solution on March 30 and June 2, 2011.

23 37. As the Pharmacist-in-Charge at the time of the acts in question, Shahla Melamed had
24 a duty, under Code sections 4036.5 and 4113, subdivision (c), to ensure that sterile injectable
25 products compounded from non-sterile ingredients were quarantined until end-product testing
26 confirmed their sterility and acceptable levels of pyrogens.

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1 **9. Roxsan Pharmacy Failed to Verify the Work of Pharmacy Technicians**
2 **While Shahla Melamed was the Pharmacist-in-Charge**

3 38. Regulation 1793.7, subdivision (a), requires a pharmacist to verify every function
4 performed by a pharmacy technician in connection with the dispensing of a prescription,
5 including repackaging from bulk and storage of pharmaceuticals. The verification must be
6 documented in writing by the verifying pharmacist on the prescription label. Roxsan Pharmacy
7 and Shahla Melamed failed to verify 14 bubble packs of medication that were prepared by a
8 pharmacy technician.

9 39. As the Pharmacist-in-Charge at the time of the acts in question, Shahla Melamed was
10 responsible, under Code sections 4036.5 and 4113, subdivision (c), for ensuring that each bubble
11 pack prepared by a pharmacy technician was verified by a pharmacist.

12 40. The prescriptions and dates of preparation for which no written verification of
13 technician work appeared on the prescription label are set forth in the table below.

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15	Date	Rx. No.	Drug	No. of Cards Per Rx.
16	2/1/2011	1238102	Atenolol 25mg	1
17	3/1/2011	1238102	Atenolol 25mg	1
18	4/1/2011	1238102	Atenolol 25mg	1
19	4/7/2011	1284869	Actos 30mg	1
20	4/11/2011	1285308	Simvastatin 20mg	1
21	4/12/2011	1285427	Metoclopramide 5mg	3
22	4/12/2011	1285430	Omeprazole 20mg	1
23	4/12/2011	1285435	Hydralazine 10mg	2
24	4/19/2011	1285431	Isosorbide 30mg	1
25	4/19/2011	1285437	Aggrenox	1
26	5/1/2011	1238102	Atenolol 25mg	1

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10. **Roxsan Pharmacy Failed to Ensure that Pharmacy Technicians Wore Identification While Shahla Melamed was the Pharmacist-in-Charge**

41. California Code of Regulations, title 16, section 1793.7, subdivision (c), requires a pharmacy technician to wear identification that clearly identifies him as a pharmacy technician. During an inspection on June 23, 2011, two pharmacy technicians were not wearing identification clearly identifying them as pharmacy technicians.

42. Shahla Melamed was the Pharmacist-in-Charge at the time of the act in question and was responsible, under Code sections 4036.5 and 4113, subdivision (c), for ensuring that pharmacy technicians were wearing proper identification.

FIRST CAUSE FOR DENIAL OF APPLICATION

(Disqualifying Officer or Director)

43. Respondent's application is subject to denial under section 4302 because conditions exist in relation to an officer or director of the corporation that would constitute grounds for disciplinary action against a licensee. By the terms of the purchase agreement between Respondent and Roxsan Pharmacy, Shahla Melamed possesses a present right to become Respondent's president and a member of its board of directors. The execution of the right is subject only to the Board's decision whether to grant or deny the permit application. Conditions exist in relation to Shahla Melamed, Respondent's incoming president and director, that would constitute grounds for disciplinary action. Complainant realleges paragraphs 7-42.

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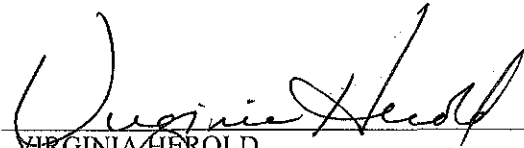
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PRAYER

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. Denying the application of Parallax Health Sciences, Inc.; J. Michael Redmond, Calli Bucci, a.k.a. Calli Spieth, Farshad Naysa, for a Community Pharmacy Permit and Sterile Compounding Pharmacy License; and,
2. Taking such other and further action as deemed necessary and proper.

DATED: 7/22/15



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

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