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

In the Matter of the Accusation Against: **ANATOMY RX LLC DBA ANATOMY PHARMACY, BERRY KABOV, MEMBER, DALIBOR DABO KABOV, MEMBER** **1544 Purdue Avenue** **Los Angeles, CA 90025** **Permit No. PHY 50713** **Sterile Compounding Pharmacy No. LSC 99715,** **MICHAEL PAUL LOWE** **5414 Newcastle Ave, #42** **Encino, CA 91316** **Pharmacist License No. RPH 37609,** **HARSHAD H. GAJJAR** **20608 Vercelli Way** **Porter Ranch, CA 91326** **Pharmacist License No. RPH 41722,** **KIMBERLY BIRANO AKSENTIJEVIC** **14441 Benefit St., #4** **Sherman Oaks, CA 91423** **Pharmacist License No. RPH 38483,** **and**	Case No. 5987 **FIRST AMENDED ACCUSATION**

DALIBOR DABO KABOV
11693 San Vicente Blvd, #506
Los Angeles, CA 900549
Pharmacy Technician Registration No. TCH 114849,

Respondents.

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 3, 2012, the Board of Pharmacy issued Permit Number PHY 50713 to Global Compounding Pharmacy LLC, Berry Kabov, Member, Dalibor Dabo Kabov, Member, which subsequently changed its name on or around October 30, 2015, to Anatomy RX LLC, dba Anatomy Pharmacy, Berry Kabov, Member, Dalibor Dabo Kabov, Member ("Anatomy Pharmacy"). The Permit was in full force and effect at all times relevant to the charges brought herein and expired on February 1, 2017.

3. On or about February 6, 2012, the Board of Pharmacy issued Sterile Compounding Pharmacy Number LSC 99715 to Anatomy Pharmacy. The Sterile Compounding Pharmacy was in full force and effect at all times relevant to the charges brought herein and expired on February 1, 2016.

4. On or about March 30, 1983, the Board of Pharmacy issued Pharmacist License Number RPH 37609 to Michael Paul Lowe ("Pharmacist Lowe"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2020, unless renewed. Pharmacist Lowe was the Pharmacist-in-Charge at Anatomy Pharmacy from approximately February 3, 2012, to November 15, 2015.

5. On or about April 23, 1988, the Board of Pharmacy issued Pharmacist License Number RPH 41722 to Harshad H. Gajjar ("Pharmacist Gajjar"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and was voluntarily surrendered, which was accepted by the Board by a decision that became effective on or about

August 2, 2018. Pharmacist Gajjar was the Pharmacist-in-Charge at Anatomy Pharmacy from approximately November 16, 2015, to February 12, 2016.

6. On or about March 27, 1984, the Board of Pharmacy issued Pharmacist License Number RPH 38483 to Kimberly Briano Aksentijevic ("Pharmacist Aksentijevic"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2019, unless renewed. Pharmacist Aksentijevic was a consultant for Anatomy Pharmacy.

7. On or about October 10, 2011, the Board of Pharmacy issued Pharmacy Technician Registration Number TCH 114849 to Dalibor Dabo Kabov ("Tech. Kabov"). The Pharmacy Technician Registration was in full force and effect at all times relevant to the charges brought herein and expired on September 30, 2017. Tech. Kabov is an owner of Anatomy Pharmacy.

JURISDICTION

8. 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 ("Code") unless otherwise indicated.

9. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board, Registrar, or Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

10. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law, Business and Professions Code, § 4000, *et seq.*, and the Uniform Controlled Substances Act, Health and Safety Code, § 11000, *et seq.*

11. Section 4300.1 of the Business and Professions Code ("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.

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STATUTORY PROVISIONS[1]

12. Section 4081 of the Code provides, in pertinent part, that:

> (a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices. . . .

13. Section 4127.7 of the Code provides that:

> On and after July 1, 2005, a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments:
>
> (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
>
> (b) An ISO class 5 cleanroom.
>
> (c) A barrier isolator that provides an ISO class 5 environment for compounding.

14. Section 4169 of the Code provides, in pertinent part, that:

> (a) A person or entity shall not do any of the following:
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> (1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy. . . .

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[1] All statutory references included in the First Amended Accusation are to the 2016 version of the codes referenced herein.

15. Section 4301 of the Code provides, in pertinent part, that:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
> . . . .
> (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
> . . . .
> (i) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
> . . . .
> (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. . . .

16. Section 4304 of the Code provides that, "The board may deny, revoke, or suspend any license issued pursuant to Section 4161 for any violation of this chapter or for any violation of Park 5 (commencing with Section 109875) of Division 4 of the Health and Safety Code."

17. Section 4307 provides, in relevant part, that:

> (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee as follows:
> (1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
> (2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.
> (b) Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee. . . .

18. Section 4332 of the Code provides that, "Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor."

19. Health and Safety Code section 111250 provides that, "Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance."

20. Health and Safety Code section 111295 provides that, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

21. Health and Safety Code section 111397, subdivision (a), provides that, "Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded."

22. Health and Safety Code section 111440 provides that, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

REGULATORY PROVISIONS[2]

23. California Code of Regulations, title 16, section 1714, subdivision (c), provides, in pertinent part, that: "The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition."

24. California Code of Regulations, title 16, section 1718, provides that:

> "Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.
>
> The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

[2] All regulatory references included in the First Amended Accusation are to the 2016 version of the regulations referenced herein.

25. California Code of Regulations, title 16, section 1735.1, subdivision (d), provides that, "'Quality' means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label."

26. California Code of Regulations, title 16, section 1735.2, provides, in pertinent part, that:

> . . . .
> (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
> (1) Active ingredients to be used.
> (2) Equipment to be used.
> (3) Expiration dating requirements.
> (4) Inactive ingredients to be used.
> (5) Process and/or procedure used to prepare the drug.
> (6) Quality reviews required at each step in preparation of the drug.
> (7) Post-compounding process or procedures required, if any.
> . . . .
> (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
> . . . .
> (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist. . . .

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27. California Code of Regulations, title 16, section 1735.3, subdivision (a), provides that:

> (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, expiration date 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 seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia--National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
>
> (7) A pharmacy assigned reference or lot number for the compounded drug product.
>
> (8) The expiration date of the final compounded drug product.
>
> (9) The quantity or amount of drug product compounded. . . .

28. California Code of Regulations, title 16, section 1735.6, subdivision (b), provides that, "Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications."

29. California Code of Regulations, title 16, section 1735.7, subdivision (a), provides that, "Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding."

30. California Code of Regulations, title 16, section 1751.4, subdivision (a), provides that:

> No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

31. California Code of Regulations, title 16, section 1751.6, subdivision (a), provides that, "Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy."

32. California Code of Regulations, title 16, section 1751.7, subdivision (c), provides that:

> 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

33. 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.

COMMON ALLEGATIONS

34. The Board conducted inspections at Anatomy Pharmacy on January 11, 2016, and April 26, 2016. Both inspections revealed multiple violations of Pharmacy Law as described herein.

The First Inspection, January 11, 2016

35. During the first inspection on January 11, 2016, the inspector observed three different sections of the pharmacy, one of which was designated for compounding medications. Tech. Kabov informed the inspector that Anatomy Pharmacy specialized in both sterile and non-sterile (general) compounding of numerous commercially unavailable products. However, in preparing compounded sterile preparations ("CSPs"), including injectable CSPs, Tech. Kabov admitted to the inspector that initial preparation steps (*e.g.*, weighing, dissolving, and mixing of non-sterile ingredients, adjusting solutions to proper pH levels, and bringing solutions to an appropriate final volume) took place in the general compounding area outside the ISO ("International Organization for Standardization") Class 5 Compounding Aseptic Isolator ("CAI"), and that once these steps were completed the final product was subjected to terminal sterilization.

36. The inspector reviewed Anatomy Pharmacy's sterile compounding policies and procedures, including, but not limited to, Chapter II titled "Operational Procedures for Sterile

Compounding." The inspector found that the pharmacy was not in compliance with said policies and procedures in a number of aspects. For example, according to the inspector's observations and discussions with Pharmacist Gajjar and Tech. Kabov, the inspector found that the pharmacy did not comply with policies and procedures concerning the clearing and cleaning of the buffer areas near the ISO Barrier Unit, verifying that all CSP equipment was in good working order and sterilized to an ISO 5 level, verifying master formulas before compounding occurred, complying with various checklists before compounding occurred, ensuring that end-product sterility testing occurred, assigning appropriate beyond use dates ("BUDs") according to drug stability information and/or sterility considerations, and ensuring that all required personnel become familiar with and acquire competency in CSP processing steps and procedures.

37. The inspector examined the pharmacy's Fischer Scientific dry heat oven and observed that it had dark yellow-brown sticky stains on the inside and did not look clean. There were no cleaning records available for inspection.

38. The inspector observed a cabinet in the pharmacy's compounding area marked "Quarantine Compounds." Pharmacist Gajjar informed the inspector that he did not know the purpose of storing CSPs in that area, and he did not know whether the pharmacy was waiting to receive test results back before releasing CSP lots from the quarantine area. Pharmacist Gajjar further admitted that CSPs from the quarantine area were actually dispensed to patients.

39. The inspector examined Anatomy Pharmacy's compounding area and all CSP lots and CRs. A broad range of deficiencies were discovered, including, but not limited to, missing compounding records ("CRs"), missing documentation of testing for sterility and pyrogens, missing or incomplete documentation of master formulas, missing or incomplete documentation of quality assurance, and unsubstantiated BUDs. The following chart summarizes the inspector's findings:

Table 1: CSP Lots at Anatomy Pharmacy on January 11, 2016

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
1	Alprostadil Injection 60 mcg/ml Exp.: 08/16 (found inside refrigerator)	2013	Not available.	Not available.	Date prepared: 01/06/16. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 03/16. However, BUD listed on bottle was 08/16 (more than 180 days from the date prepared). Active ingredients listed in CR expired: mannitol on 06/14, bacteriostatic on 03/16. No method of terminal sterilization indicated. *Dispensed* on 2/22/16 by RX No. 500111.
2	Ascorbic Acid Injection 500 mg/ml Exp.: 09/16	2007	Not available.	Not available.	CR not available.
3	DHEA Injection 50 mg/ml Exp.: 09/16	2003	Passed sterility via ARL on 12/17/15. Pyrogen test not available.	Not available.	Date prepared: 12/01/15. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 03/16. However, BUD listed on bottle was 09/16 (more than 180 days from the date prepared). Active ingredients listed in CR expired on 05/16. Two active ingredients have no manufacturer listed. No method of terminal sterilization indicated.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
4	Estradiol Injection 20 mg/ml Exp.: 09/16	2004	Passed sterility via ARL on 12/17/15. Pyrogen test not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 90 days, which should be 03/16. However, BUD listed on bottle was 09/16 (more than 180 days from the date prepared). Four active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated.
5	FBA (Fat Burning Accelerator) Injection Exp.: 08/16 (found inside refrigerator)	2002	Not available.	Available.	CR not available.
6	Fat Shredder Injection Exp.: 09/16	2017	Not available.	Not available.	CR not available. *Dispensed* on 12/16/15 by RX No. 500065. *Dispensed* on 01/15/16 by RX No. 500088.
7	Glutathione Injection 200 mg/ml Exp.: 09/16	2012	Not available.	Not available.	CR not available.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
8	Methyl-cobalamine (vit. B12) Injection 1000 mcg/ml Exp.: 09/16	2006	55	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Active ingredient listed in CR: (i) B12 powder had no expiration date; (ii) pyridoxine expired on 04/16; (iii) bacteriostatic water expired on 03/16. No method of terminal sterilization indicated.
9	Oxytocin Injection 10iu/ml Exp.: 01/16 (found inside refrigerator)	2001	Not available.	Not available.	CR not available. *Dispensed* on 12/16/15 by RX No. 500040.
10	Progesterone Injection 50 mg/ml Exp.: 09/16	2005	Passed sterility via ARL on 12/17/15. Pyrogen test not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Four active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
11	Pyridoxine (vit. B6) Injection 100 mg/ml Exp.: 09/16	2004	Not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Active ingredient has no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated.
12	Quad Mix Injection (Lyophilized) Exp.: 03/16	1014	Not available.	Not available.	Date prepared: 07/22/15. Prepared by Tech. Kabov. Checked by PIC Lowe. BUD listed in CR: 180 days, which should be 01/16. However, BUD listed on bottle was 03/16 (more than 180 days from the date prepared). Active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated. *Dispensed* on 09/30/15 by RX No. 0153. *Dispensed* on 12/16/15 by RX No. 500064.
13	Semoreline Injection 6 mg – 3 ml Exp.: 07/16	898	Not available.	Not available.	CR not available.
14	Semoreline/ GHRP2/ GHRP6 9mg/3mg Exp.: 05/16	983	Not available.	Not available.	CR not available.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
15	Super Shot Injection 30 ml Exp.: 08/16	2000	Not available.	Not available.	Date prepared: 11/13/15. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 90 days, which should be 02/16. However, BUD listed on bottle was 08/16 (more than 180 days from the date prepared). Active ingredients listed in CR: (i) choline chloride expired on 3/11/16; (ii) dexpanthenol expired on 02/28/16; (iii) bacteriostatic water expired on 02/01/16; (iv) thiamine expired on 03/30/15; (v) l-canitine expired on 05/31/16; and (vi) methylcobalamine had no lot number and expiration date listed. No method of terminal sterilization indicated. *Dispensed* on 11/16/15 by RX No. 500003 and 500004. *Dispensed* on 11/17/15 by RX No. 500006. *Dispensed* on 12/17/15 by RX No. 500067.

40. The inspector asked to review Pharmacist Gajjar's training records. The records identified thirteen different procedures or tasks upon which training had been purportedly completed in December 2015. However, during the inspector's review, Pharmacist Gajjar admitted that he never actually completed the training for the "glove fingertip test," which was listed on his records as having been "done" on December 15, 2015, "OK for CSP" on December 18, 2015, and "Recert OK" on December 30, 2015. Pharmacist Gajjar further admitted to the inspector that he could not remember which of the other training sessions listed he actually completed. Nevertheless, Pharmacist Gajjar participated in compounding sessions at Anatomy

Pharmacy from the date of hire on November 16, 2015, through the date of the first inspection, as identified in Table 1, without having records of training and demonstrated competence.

41. The inspector asked to review Tech. Kabov's training records. The records identified thirteen different procedures or tasks upon which training had been purportedly completed in December 2015. However, during the inspector's review, Tech. Kabov admitted that he never actually completed the training for the "glove fingertip test," which was listed on his records as having been "done" on December 8, 2015, "OK for CSP" on December 11, 2015, and "Recert OK" on December 11, 2015. Nevertheless, Tech. Kabov participated in compounding sessions at Anatomy Pharmacy up until the date of the first inspection, as identified in Table 1, without having records of training and demonstrated competence.

42. The inspector found that Anatomy Pharmacy produced CSPs when they did not have competent personnel on staff. For example, Pharmacist Gajjar began working at Anatomy Pharmacy as its sole pharmacist on November 16, 2015, and, according to the training records, Pharmacist Gajjar first began to complete his employee training on CSPs on December 15, 2015. Notwithstanding, Anatomy Pharmacy produced multiple CSP lots on December 1, 2015, that were verified by Pharmacist Gajjar, as identified in Table 1.

43. The inspector asked Pharmacist Gajjar if consultation was made available to Anatomy Pharmacy's patients and/or primary caregivers concerning the proper use, storage, handling and disposal of CSPs and related supplies furnished by the pharmacy. Pharmacist Gajjar admitted that no such consultations were made available to patients receiving CSPs by mail.

44. After the first inspection was concluded, the Board received a letter from Anatomy Pharmacy's sterile compounding consultant, Pharmacist Aksentijevic, dated February 1, 2016. In that letter, Pharmacist Aksentijevic made several statements of fact that were not accurate or truthful when compared against the inspector's findings on January 11, 2016, as identified in Table 1. For example, Pharmacist Aksentijevic wrote that each batch of the pharmacy's CSPs are "quarantined until sterility results are confirmed by an outside laboratory." She also wrote that the pharmacy performed "end product testing – endotoxin results were observed on file." She further wrote that she reviewed all "BUD determination with reference materials."

The Second Inspection, April 26, 2016

45. During the second inspection on April 26, 2016, the inspector examined a cabinet in the pharmacy's compounding area marked "Quarantine Compounds." The inspector asked the then pharmacist-in-charge, Sheila Damaris Colon ("Pharmacist Colon" or "PIC Colon") whether the CSP lots therein were in fact quarantined or whether they were being dispensed to patients. Pharmacist Colon informed the inspector that all CSP lots found therein were ready to be dispensed, and she admitted that several vials had already been dispensed from these lots.

46. The inspector examined Anatomy Pharmacy's compounding area and all CSP lots and CRs. A broad range of continuing and new deficiencies were discovered. The following chart summarizes the inspector's findings:

Table 2: CSP Lots at Anatomy Pharmacy on April 26, 2016

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
1	Alprostadil Injection 60 mcg/ml Exp.: 08/16 (found inside refrigerator)	2013	Not available.	Not available.	Date prepared: 01/06/16. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD isted in CR: 03/16. However, BUD listed on bottle was 08/16 (more than 180 days from the date prepared). Active ingredients listed in CR expired: mannitol on 06/14, bacteriostatic on 03/16. No method of terminal sterilization indicated. *Dispensed* on 2/22/16 by RX No. 500111.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
2	DHEA Injection 50 mg/ml Exp.: 09/16	2003	Passed sterility via ARL on 12/17/15. Pyrogen test not available.	Not available.	Date prepared: 12/01/15. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 03/16. However, BUD listed on bottle was 09/16 (more than 180 days from the date prepared). Active ingredients listed in CR expired on 05/16. No method of terminal sterilization indicated.
3	Energy Cocktail Injection Exp.: 05/16 (found inside refrigerator)	2025	Not available.	Not available.	Date prepared: 01/30/16. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 04/16. However, BUD listed on bottle was 05/16. Dry oven listed for terminal sterilization, however, no records of sterilization temperature and duration. Under storage requirements – room temp was circled, however, this product was found inside the refrigerator. *Dispensed* on 03/07/16 by RX No. 500123.
4	Fat Shredder Injection Exp.: 09/16	2017	Not available.	Not available.	CR not available. *Dispensed* on 12/16/15 by RX No. 500065. *Dispensed* on 01/15/16 by RX No. 500088.
5	Glutathione Injection 200 mg/ml Exp.: 09/16	2012	Not available.	Not available.	CR not available.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
6	Methyl-cobalamine (vit. B12) Injection 1000 mcg/ml Exp.: 09/16	2006	Not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Active ingredient listed in CR: (i) B12 powder had no expiration date; (ii) pyridoxine expired on 04/16; (iii) bacteriostatic water expired on 03/16. No method of terminal sterilization indicated.
7	Methyl-cobalamine Injection 25 mg/ml Exp.: 09/16	2013	Not available.	Not available.	CR not available.
8	Methyl-cobalamine Injection 5 mcg/ml Exp.: 10/16	2014	Not available.	Not available.	CR not available.
9	Oxytocin Injection 10iu/ml Exp.: 04/16 (found inside refrigerator)	2022	Not available.	Not available.	Date prepared: 01/24/16. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 90 days. Dry oven listed for terminal sterilization, however, no records of sterilization temperature and duration. *Dispensed* on 02/29/16 by RX No. 500116.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
10	Oxytocin Injection 10iu/ml Exp.: 01/16 (found inside refrigerator)	2001	Not available.	Not available.	CR not available. *Dispensed* on 12/16/15 by RX No. 500040.
11	Progesterone Injection 50 mg/ml Exp.: 09/16	2005	Passed sterility via ARL on 12/17/15. Pyrogen test not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Four active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated.
12	Pyridoxine (vit. B6) Injection 100 mg/ml Exp.: 09/16	2004	Not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Active ingredient has no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated. No lot number for the compounded product available (this CR submitted by PIC Colon in response to inspector's request for lot 2004)

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
13	Quad Mix Injection (Lyophilized) Exp.: 03/16	1014	Not available.	Not available.	Date prepared: 07/22/15. Prepared by Tech. Kabov. Checked by PIC Lowe. BUD listed in CR: 180 days, which should be 01/16. However, BUD listed on bottle was 03/16 (more than 180 days from the date prepared). Active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated. *Dispensed* on 09/30/15 by RX No. 0153. *Dispensed* on 12/16/15 by RX No. 500064.
14	Semoreline Injection 6 mg – 3 ml Exp.: 07/16	898	Not available.	Not available.	CR not available.
15	Semoreline/ GHRP2/ GHRP6 9mg/3ml Exp.: 05/16	981	Passed sterility and pyrogens testing via ARL on 01/18/16 and 01/26/16.	Not available.	CR not available.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
16	Super B Complex Injection Exp.: 09/16	2011	Not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD not listed in CR. BUD listed on vials: 09/16 (more than 180 days from the date prepared). Active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated. No lot number for the compounded product available (this CR submitted by PIC Colon in response to inspector's request for lot 2011)
17	Super Shot Injection Exp.: 04/16	2020	Not available.	Not available.	Date prepared: 01/24/16. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 90 days. No method of terminal sterilization indicated. *Dispensed* on 02/26/16 by RX No. 50011. *Dispensed* on 03/18/16 by RX No. 500138. *Dispensed* on 04/01/16 by RX No. 500147. *Dispensed* on 04/05/16 by RX No. 500155. *Dispensed* on 04/08/16 by RX No. 500159.

47. With respect to the CSP lots identified in Table 2, Pharmacist Colon admitted to the inspector that Anatomy Pharmacy continued to dispense injectable CSPs to patients without having performed sterility or pyrogens tests on all lots, without having first preparing all master

formulas, without having validation studies or references to justify the BUDs exceeding 180 days, and without having complete CRs for all CSPs.

The DEA Investigation

48. In or around August 2013, Anatomy Pharmacy became the subject of an investigation by the United States Drug Enforcement Administration ("DEA"), which culminated in a criminal proceeding entitled *United States of America v. Kabov, et al.* (USDC, C.D. Cal., No. 2:15cr511, filed Sept. 22, 2015). During the DEA investigation, the Board learned that Berry Kabov and Tech. Kabov were using Anatomy Pharmacy to unlawfully obtain, compound, and traffic large amounts of dangerous drugs and/or controlled substances.

49. As a result of the DEA investigation, a Board inspector conducted a zero based audit for all oxycodone 30mg tablets in the pharmacy, but which were not compounded by Anatomy Pharmacy, as of October 1, 2015. The inspector determined that the pharmacy had an inventory shortage of approximately 1,618 tablets of oxycodone 30mg. Concomitantly, the inspector also found that the pharmacy failed to maintain adequate records of acquisition and disposition to account for the shortage and its current inventory of oxycodone.

50. In conjunction with the DEA investigation, the Board inspector learned that Anatomy Pharmacy purchased dangerous drugs at wholesale from foreign entities that were not licensed with the Board as authorized wholesalers. For example, in May 2013, the pharmacy purchased sermorelin acetate (a discontinued drug in the United States), GHRP-2 acetate, and GHRP-6 acetate from Attix Pharmaceuticals, an unlicensed entity with the Board, located in Canada. As another example, between 2012 and 2014, the pharmacy purchased and/or received quantities of anabolic steroids from wholesale drug distributors located in China.

51. In conjunction with the DEA investigation, the Board inspector asked the pharmacy to produce all records for the dangerous drugs that were compounded at Anatomy Pharmacy, including, but not limited to, oxycodone 30mg. Records provided by Pharmacist Colon on or around April 26, 2016, revealed a number of deficiencies. For example, the pharmacy's compounding records were missing the date of compounding, the identity of the pharmacist reviewing the final drug product, the identity of the pharmacy personnel who compounded the

drug product, the manufacture, expiration date, and lot number of each component, and the expiration date of the final compounded drug product.

FIRST CAUSE FOR DISCIPLINE

Compounding Area for Parentheral Solutions

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

52. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code sections 4127.7 and 4301, subdivision (o), on the grounds that they compounded sterile injectable productions from one or more non-sterile ingredients in an unauthorized environment. Complainant refers to and expressly incorporates the allegations contained within paragraph 35 above as though set forth fully herein.

SECOND CAUSE FOR DISCIPLINE

Facility and Equipment Standards for Sterile Injectable Compounding

(Against Respondent Anatomy Pharmacy)

53. Respondent Anatomy Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1751.4, subdivision (a), on the grounds that Respondent Anatomy Pharmacy knew, or reasonably should have known, that Respondent Anatomy Pharmacy prepared injectable CSPs in an environment that failed to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products. Complainant refers to and expressly incorporates the allegations contained within paragraphs 36 and 37 above as though set forth fully herein.

THIRD CAUSE FOR DISCIPLINE

Compounding Facilities and Equipment

(Against Respondent Anatomy Pharmacy)

54. Respondent Anatomy Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1714, subdivision (c), on the grounds that the dry heat oven that Respondent Anatomy Pharmacy used in the compounding of injectable CSPs was found to be an unclean and disorderly condition.

Complainant refers to and expressly incorporates the allegations contained within paragraph 37 above as though set forth fully herein.

FOURTH CAUSE FOR DISCIPLINE

Sterile Injectable Compounding Quality Assurance and Process Validation

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

55. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1751.7, subdivision (c), on the grounds that Respondents failed to subject batch-produced injectable CSPs, which were compounded from one or more non-sterile ingredients, to documented end product testing for sterility and pyrogens and/or Respondents failed to properly quarantine those batch-produced injectable CSPs until end product testing confirmed sterility and acceptable levels of pyrogens. Complainant refers to and expressly incorporates the allegations contained within paragraphs 38, 39, 45, 46, 47, and Table 1 and Table 2 above as though set forth fully herein.

FIFTH CAUSE FOR DISCIPLINE

Compounding Master Formulas Requirements

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

56. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.2, subdivision (d), on the grounds that complete master formulas for injectable CSPs were not available for review upon request by Board inspectors. Complainant refers to and expressly incorporates the allegations contained within paragraphs 36 and 47, and Table 1 and Table 2 above as though set forth fully herein.

SIXTH CAUSE FOR DISCIPLINE

Compounding Limitations and Requirements

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

57. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16,

section 1735.2, subdivision (h), on the grounds that they maintained CSP lots with BUDs that exceeded 180 days from the date of preparation, or the shortest expiration date of any component in the CSP, without any support from stability and/or sterility studies. In doing so, Respondents failed to exercise the appropriate professional judgment of a responsible pharmacist. Complainant refers to and expressly incorporates the allegations contained within paragraphs 36 and 47, and Table 1 and Table 2 above as though set forth fully herein.

SEVENTH CAUSE FOR DISCIPLINE

Records of Compounded Drug Products

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

58. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.3, subdivision (a), on the grounds that multiple CSPs had CRs that were missing statutorily required information, such as the master formula record, the date the drug was compounded, the identity of the personnel who compounded the product, the identity of the pharmacist reviewing the final product, the quantity of each component used in the product, the manufacturer and lot number of each component, the equipment used in compounding, a product lot number, an expiration date, and/or the quantity of product compounded. Complainant refers to and expressly incorporates the allegations contained within paragraphs 36 and 47, and Table 1 and Table 2 above as though set forth fully herein.

EIGHTH CAUSE FOR DISCIPLINE

Training of Compounding Staff

(Against Respondent Anatomy Pharmacy)

59. Respondent Anatomy Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.7, subdivision (a), on the grounds that Respondent Anatomy Pharmacy did not maintain written documentation sufficient to demonstrate that pharmacy personnel had the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding. Complainant refers

to and expressly incorporates the allegations contained within paragraphs 40 through 42 above as though set forth fully herein.

NINTH CAUSE FOR DISCIPLINE

Unprofessional Conduct

(Against Respondents Anatomy Pharmacy, Pharmacist Aksentijevic, and Tech. Kabov)

60. Respondents Anatomy Pharmacy, Pharmacist Aksentijevic, and Tech. Kabov are subject to disciplinary action under Code section 4301, subdivision (g), for committing acts of unprofessional conduct in that they falsely represented the existence or nonexistence of a state of facts. Complainant refers to and expressly incorporates the allegations contained within paragraphs 40, 41, and 44 above as though set forth fully herein.

TENTH CAUSE FOR DISCIPLINE

Training of Sterile Injectable Compounding Staff, Patient, and Caregiver

(Against Respondent Anatomy Pharmacy)

61. Respondent Anatomy Pharmacy is subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1751.6, subdivision (a), on the grounds that Respondent Anatomy Pharmacy failed to make consultations available to their patients and/or primary caregivers concerning the proper use of injectable CSPs furnished by Anatomy Pharmacy. Complainant refers to and expressly incorporates the allegations contained within paragraph 43 above as though set forth fully herein.

ELEVENTH CAUSE FOR DISCIPLINE

Adulterated Medications

(Against Respondents Anatomy Pharmacy)

62. Respondent Anatomy Pharmacy is subject to disciplinary action under Code section 4301, subdivision (j), and Health and Safety Code sections 111250 and 111295 on the grounds that Respondent Anatomy Pharmacy maintained expired CSP lots and CSP lots compounded with expired ingredients in the pharmacy's active drug inventory. Complainant refers to and expressly incorporates the allegations contained within paragraphs 36 and 47, and Table 1 and Table 2 above as though set forth fully herein.

TWELFTH CAUSE FOR DISCIPLINE

Failure to Maintain Records

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

63. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code sections 4081 and 4332, and California Code of Regulations, title 16, section 1718, on the grounds that they failed to maintain a current inventory and all records of manufacture, sale, acquisition, receipt, shipment, or disposition of dangerous drugs for a period of three years from the date of making. Complainant refers to and expressly incorporates the allegations contained within paragraph 49 above as though set forth fully herein.

THIRTEENTH CAUSE FOR DISCIPLINE

Prohibited Acts

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

64. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code section 4169, subdivision (a)(1), on the grounds that they engaged in prohibited acts by purchasing, trading, and/or transferring dangerous drugs at wholesale with entities in Canada and China that were not licensed with the Board as a wholesaler, third-party logistics provider, or pharmacy. Complainant refers to and expressly incorporates the allegations contained within paragraph 50 above as though set forth fully herein.

FOURTEENTH CAUSE FOR DISCIPLINE

Misbranded Drugs

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

65. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Health and Safety Code sections 111397, subdivision (a), and 111440, on the grounds that they manufactured, sold, delivered, held, or offered to sell drugs that were misbranded because they were obtained outside

of the licensed supply chain regulated by the Board. Complainant refers to and expressly incorporates the allegations contained within paragraph 50 above as though set forth fully herein.

FIFTEENTH CAUSE FOR DISCIPLINE

Records of Compounded Drug Products

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

66. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.3, subdivision (a), on the grounds that compounding records produced on April 26, 2016, for oxycodone 30mg were incomplete in that they were missing the date of compounding, the identity of the pharmacist reviewing the final drug product, the identity of the pharmacy personnel who compounded the drug product, the manufacture, expiration date, and lot number of each component, and the expiration date of the final compounded drug product. Complainant refers to and expressly incorporates the allegations contained within paragraph 51 above as though set forth fully herein.

OTHER MATTERS

67. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50713 issued to Respondent Anatomy Pharmacy, then Respondent Anatomy Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50713 is placed on probation or until Pharmacy Permit Number PHY 50713 is reinstated if it is revoked.

68. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50713 issued to Respondent Anatomy Pharmacy while Berry Kabov and/or Dalibor Dabo Kabov, Pharmacy Technician Registration Number TCH 114849, have been officers and/or owners and had knowledge or knowingly participated in any conduct for which the licensee was disciplined, then Berry Kabov and/or Dalibor Dabo Kabov shall be prohibited from serving as managers, administrators, owners, members, officers, directors, associates, or partners of a licensee for five years if Pharmacy Permit Number PHY 50713 is placed on probation or until Pharmacy Permit Number PHY 50713 is reinstated if it is revoked.

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 Permit Number PHY 50713, issued to Anatomy RX LLC, dba Anatomy Pharmacy, Berry Kabov, Member, Dalibor Dabo Kabov, Member;

2. Revoking or suspending Sterile Compounding Pharmacy Number LSC 99715, issued to Anatomy RX LLC, dba Anatomy Pharmacy, Berry Kabov, Member, Dalibor Dabo Kabov, Member;

3. Revoking or suspending Pharmacist License Number RPH 37609, issued to Michael Paul Lowe;

4. Revoking or suspending Pharmacist License Number RPH 38483, issued to Kimberly Birano Aksentijevic;

5. Revoking or suspending Pharmacy Technician Registration Number TCH 114849, issued to Dalibor Dabo Kabov;

6. Prohibiting Berry Kabov from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacy Permit Number PHY 50713 is placed on probation or until Pharmacy Permit Number PHY 50713 is reinstated if it is revoked;

7. Prohibiting Dalibor Dabo Kabov, Pharmacy Technician Registration Number TCH 114849, from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacy Permit Number PHY 50713 is placed on probation or until Pharmacy Permit Number PHY 50713 is reinstated if it is revoked;

8. Ordering Anatomy Pharmacy, Michael Paul Lowe, Dalibor Dabo Kabov, and Kimberly Briano Aksentijevic 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; and,

///

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

DATED: 12/11/18

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

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

In the Matter of the Accusation Against: **ANATOMY RX LLC DBA ANATOMY PHARMACY, BERRY KABOV, MEMBER, DALIBOR DABO KABOV, MEMBER** **1544 Purdue Avenue** **Los Angeles, CA 90025** **Permit No. PHY 50713** **Sterile Compounding Pharmacy No. LSC 99715,** **MICHAEL PAUL LOWE** **5414 Newcastle Ave, #42** **Encino, CA 91316** **Pharmacist License No. RPH 37609,** **HARSHAD H. GAJJAR** **20608 Vercelli Way** **Porter Ranch, CA 91326** **Pharmacist License No. RPH 41722,** **KIMBERLY BIRANO AKSENTIJEVIC** **14441 Benefit St., #4** **Sherman Oaks, CA 91423** **Pharmacist License No. RPH 38483,** **and**	Case No. 5987 **A C C U S A T I O N**

DALIBOR DABO KABOV
11693 San Vicente Blvd, #506
Los Angeles, CA 900549
Pharmacy Technician Registration No. TCH 114849,

Respondents.

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 3, 2012, the Board of Pharmacy issued Permit Number PHY 50713 to Global Compounding Pharmacy LLC, Berry Kabov, Member, Dalibor Dabo Kabov, Member, which subsequently changed its name on or around October 30, 2015, to Anatomy RX LLC, dba Anatomy Pharmacy, Berry Kabov, Member, Dalibor Dabo Kabov, Member ("Anatomy Pharmacy"). The Permit was in full force and effect at all times relevant to the charges brought herein and expired on February 1, 2017.

3. On or about February 6, 2012, the Board of Pharmacy issued Sterile Compounding Pharmacy Number LSC 99715 to Anatomy Pharmacy. The Sterile Compounding Pharmacy was in full force and effect at all times relevant to the charges brought herein and expired on February 1, 2016.

4. On or about March 30, 1983, the Board of Pharmacy issued Pharmacist License Number RPH 37609 to Michael Paul Lowe ("Pharmacist Lowe"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on October 31, 2018, unless renewed. Pharmacist Lowe was the Pharmacist-in-Charge at Anatomy Pharmacy from approximately February 3, 2012, to November 15, 2015.

5. On or about April 23, 1988, the Board of Pharmacy issued Pharmacist License Number RPH 41722 to Harshad H. Gajjar ("Pharmacist Gajjar"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on December

31, 2017, unless renewed. Pharmacist Gajjar was the Pharmacist-in-Charge at Anatomy Pharmacy from approximately November 16, 2015, to February 12, 2016.

6. On or about March 27, 1984, the Board of Pharmacy issued Pharmacist License Number RPH 38483 to Kimberly Briano Aksentijevic ("Pharmacist Aksentijevic"). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2017, unless renewed. Pharmacist Aksentijevic was a consultant for Anatomy Pharmacy.

7. On or about October 10, 2011, the Board of Pharmacy issued Pharmacy Technician Registration Number TCH 114849 to Dalibor Dabo Kabov ("Tech. Kabov"). The Pharmacy Technician Registration was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2017, unless renewed. Tech. Kabov is an owner of Anatomy Pharmacy.

JURISDICTION

8. 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 ("Code") unless otherwise indicated.

9. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board, Registrar, or Director of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

10. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law, Business and Professions Code, § 4000, *et seq.*, and the Uniform Controlled Substances Act, Health and Safety Code, § 11000, *et seq.*

11. Section 4300.1 of the Business and Professions Code ("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

12. Section 4127.7 of the Code provides that:

> On and after July 1, 2005, a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments:
>
> (a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
>
> (b) An ISO class 5 cleanroom.
>
> (c) A barrier isolator that provides an ISO class 5 environment for compounding.

13. Section 4301 of the Code provides, in pertinent part, that:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> . . . .
>
> (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
>
> . . . .
>
> (i) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> . . . .
>
> (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. . . .

14. Section 4304 of the Code provides that, "The board may deny, revoke, or suspend any license issued pursuant to Section 4161 for any violation of this chapter or for any violation of Park 5 (commencing with Section 109875) of Division 4 of the Health and Safety Code."

15. Section 4307 provides, in relevant part, that:

> (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under

> suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee as follows:
>
> (1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
>
> (2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.
>
> (b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee. . . .

16. Section 4332 of the Code provides that, "Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor."

17. Health and Safety Code section 111250 provides that, "Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance."

18. Health and Safety Code section 111295 provides that, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

19. Health and Safety Code section 111397 provides that, "Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded."

20. Health and Safety Code section 111440 provides that, "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

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REGULATORY PROVISIONS

21. California Code of Regulations, title 16, section 1718, provides that:

> "Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.
>
> The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

22. California Code of Regulations, title 16, section 1735.1, subdivision (d), provides that, "'Quality' means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label."

23. California Code of Regulations, title 16, section 1735.2, provides, in pertinent part, that:

> . . . .
> (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
> (1) Active ingredients to be used.
> (2) Equipment to be used.
> (3) Expiration dating requirements.
> (4) Inactive ingredients to be used.
> (5) Process and/or procedure used to prepare the drug.
> (6) Quality reviews required at each step in preparation of the drug.
> (7) Post-compounding process or procedures required, if any.
> . . . .
> (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
> . . . .
> (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist. . . .

24. California Code of Regulations, title 16, section 1735.3, subdivision (a), provides that:

> (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, expiration date 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 seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia--National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
>
> (7) A pharmacy assigned reference or lot number for the compounded drug product.
>
> (8) The expiration date of the final compounded drug product.
>
> (9) The quantity or amount of drug product compounded. . . .

25. California Code of Regulations, title 16, section 1735.6, subdivision (b), provides that, "Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications."

26. California Code of Regulations, title 16, section 1735.7, subdivision (a), provides that, "Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding."

27. California Code of Regulations, title 16, section 1735.8, subdivision (a), provides that, "Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products."

28. California Code of Regulations, title 16, section 1751.3, subdivision (b), provides that, "The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist."

29. California Code of Regulations, title 16, section 1751.4, subdivision (a), provides that:

> No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

30. California Code of Regulations, title 16, section 1751.6, subdivision (a), provides that, "Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy."

31. California Code of Regulations, title 16, section 1751.7, subdivision (c), provides that:

> 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

32. 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.

COMMON ALLEGATIONS

33. The Board conducted inspections at Anatomy Pharmacy on January 11, 2016, and April 26, 2016. Both inspections revealed multiple violations of Pharmacy Law as described herein.

The First Inspection, January 11, 2016

34. During the first inspection on January 11, 2016, the inspector observed three different sections of the pharmacy, one of which was designated for compounding medications. Tech.

Kabov informed the inspector that Anatomy Pharmacy specialized in both sterile and non-sterile (general) compounding of numerous commercially unavailable products. However, in preparing compounded sterile preparations ("CSPs"), including injectable CSPs, Tech. Kabov admitted to the inspector that initial preparation steps (*e.g.*, weighing, dissolving, and mixing of non-sterile ingredients, adjusting solutions to proper pH levels, and bringing solutions to an appropriate final volume) took place in the general compounding area outside the ISO ("International Organization for Standardization") Class 5 Compounding Aseptic Isolator ("CAI"), and that once these steps were completed the final product was subjected to terminal sterilization.

35. The inspector reviewed Anatomy Pharmacy's sterile compounding policies and procedures, including, but not limited to, Chapter II titled "Operational Procedures for Sterile Compounding." The inspector found that the pharmacy was not in compliance with said policies and procedures in a number of aspects. For example, according to the inspector's observations and discussions with Pharmacist Gajjar and Tech. Kabov, the inspector found that the pharmacy did not comply with policies and procedures concerning the clearing and cleaning of the buffer areas near the ISO Barrier Unit, verifying that all CSP equipment was in good working order and sterilized to an ISO 5 level, verifying master formulas before compounding occurred, complying with various checklists before compounding occurred, ensuring that end-product sterility testing occurred, assigning appropriate beyond use dates ("BUDs") according to drug stability information and/or sterility considerations, and ensuring that all required personnel become familiar with and acquire competency in CSP processing steps and procedures.

36. The inspector examined the pharmacy's Fischer Scientific dry heat oven and observed that the it had dark yellow-brown sticky stains on the inside and did not look clean. There were no cleaning records available for inspection.

37. The inspector observed a cabinet in the pharmacy's compounding area marked "Quarantine Compounds." Pharmacist Gajjar informed the inspector that he did not know the purpose of storing CSPs in that area, and he did not know whether the pharmacy was waiting to receive test results back before releasing CSP lots from the quarantine area. Pharmacist Gajjar further admitted that CSPs from the quarantine area were actually dispensed to patients.

38. The inspector examined Anatomy Pharmacy's compounding area and all CSP lots and CRs. A broad range of deficiencies were discovered, including, but not limited to, missing compounding records ("CRs"), missing documentation of testing for sterility and pyrogens, missing or incomplete documentation of master formulas, missing or incomplete documentation of quality assurance, and unsubstantiated BUDs. The following chart summarizes the inspector's findings:

Table 1: CSP Lots at Anatomy Pharmacy on January 11, 2016

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
1	Alprostadil Injection 60 mcg/ml Exp.: 08/16 (found inside refrigerator)	2013	Not available.	Not available.	Date prepared: 01/06/16. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 03/16. However, BUD listed on bottle was 08/16 (more than 180 days from the date prepared). Active ingredients listed in CR expired: mannitol on 06/14, bacteriostatic on 03/16. No method of terminal sterilization indicated. *Dispensed* on 2/22/16 by RX No. 500111.
2	Ascorbic Acid Injection 500 mg/ml Exp.: 09/16	2007	Not available.	Not available.	CR not available.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
3	DHEA Injection 50 mg/ml Exp.: 09/16	2003	Passed sterility via ARL on 12/17/15. Pyrogen test not available.	Not available.	Date prepared: 12/01/15. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 03/16. However, BUD listed on bottle was 09/16 (more than 180 days from the date prepared). Active ingredients listed in CR expired on 05/16. Two active ingredients have no manufacturer listed. No method of terminal sterilization indicated.
4	Estradiol Injection 20 mg/ml Exp.: 09/16	2004	Passed sterility via ARL on 12/17/15. Pyrogen test not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 90 days, which should be 03/16. However, BUD listed on bottle was 09/16 (more than 180 days from the date prepared). Four active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated.
5	FBA (Fat Burning Accelerator) Injection Exp.: 08/16 (found inside refrigerator)	2002	Not available.	Available.	CR not available.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
6	Fat Shredder Injection Exp.: 09/16	2017	Not available.	Not available.	CR not available. *Dispensed* on 12/16/15 by RX No. 500065. *Dispensed* on 01/15/16 by RX No. 500088.
7	Glutathione Injection 200 mg/ml Exp.: 09/16	2012	Not available.	Not available.	CR not available.
8	Methyl-cobalamine (vit. B12) Injection 1000 mcg/ml Exp.: 09/16	2006	55	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Active ingredient listed in CR: (i) B12 powder had no expiration date; (ii) pyridoxine expired on 04/16; (iii) bacteriostatic water expired on 03/16. No method of terminal sterilization indicated.
9	Oxytocin Injection 10iu/ml Exp.: 01/16 (found inside refrigerator)	2001	Not available.	Not available.	CR not available. *Dispensed* on 12/16/15 by RX No. 500040.
10	Progesterone Injection 50 mg/ml Exp.: 09/16	2005	Passed sterility via ARL on 12/17/15. Pyrogen test not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Four active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
11	Pyridoxine (vit. B6) Injection 100 mg/ml Exp.: 09/16	2004	Not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Active ingredient has no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated.
12	Quad Mix Injection (Lyophilized) Exp.: 03/16	1014	Not available.	Not available.	Date prepared: 07/22/15. Prepared by Tech. Kabov. Checked by PIC Lowe. BUD listed in CR: 180 days, which should be 01/16. However, BUD listed on bottle was 03/16 (more than 180 days from the date prepared). Active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated. *Dispensed* on 09/30/15 by RX No. 0153. *Dispensed* on 12/16/15 by RX No. 500064.
13	Semoreline Injection 6 mg – 3 ml Exp.: 07/16	898	Not available.	Not available.	CR not available.
14	Semoreline/ GHRP2/ GHRP6 9mg/3mg Exp.: 05/16	983	Not available.	Not available.	CR not available.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
15	Super Shot Injection 30 ml Exp.: 08/16	2000	Not available.	Not available.	Date prepared: 11/13/15. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 90 days, which should be 02/16. However, BUD listed on bottle was 08/16 (more than 180 days from the date prepared). Active ingredients listed in CR: (i) choline chloride expired on 3/11/16; (ii) dexpanthenol expired on 02/28/16; (iii) bacteriostatic water expired on 02/01/16; (iv) thiamine expired on 03/30/15; (v) 1-canitine expired on 05/31/16; and (vi) methylcobalamine had no lot number and expiration date listed. No method of terminal sterilization indicated. *Dispensed* on 11/16/15 by RX No. 500003 and 500004. *Dispensed* on 11/17/15 by RX No. 500006. *Dispensed* on 12/17/15 by RX No. 500067.

39. The inspector asked to review Pharmacist Gajjar's training records. The records identified thirteen different procedures or tasks upon which training had been purportedly completed in December 2015. However, during the inspector's review, Pharmacist Gajjar admitted that he never actually completed the training for the "glove fingertip test," which was listed on his records as having been "done" on December 15, 2015, "OK for CSP" on December 18, 2015, and "Recert OK" on December 30, 2015. Pharmacist Gajjar further admitted to the inspector that he could not remember which of the other training sessions listed he actually completed. Nevertheless, Pharmacist Gajjar participated in compounding sessions at Anatomy

Pharmacy from the date of hire on November 16, 2015, through the date of the first inspection, as identified in Table 1, without having records of training and demonstrated competence.

40. The inspector asked to review Tech. Kabov's training records. The records identified thirteen different procedures or tasks upon which training had been purportedly completed in December 2015. However, during the inspector's review, Tech. Kabov admitted that he never actually completed the training for the "glove fingertip test," which was listed on his records as having been "done" on December 8, 2015, "OK for CSP" on December 11, 2015, and "Recert OK" on December 11, 2015. Nevertheless, Tech. Kabov participated in compounding sessions at Anatomy Pharmacy up until the date of the first inspection, as identified in Table 1, without having records of training and demonstrated competence.

41. The inspector found that Anatomy Pharmacy produced CSPs when they did not have competent personnel on staff. For example, Pharmacist Gajjar began working at Anatomy Pharmacy as its sole pharmacist on November 16, 2015, and, according to the training records, Pharmacist Gajjar first began to complete his employee training on CSPs on December 15, 2015. Notwithstanding, Anatomy Pharmacy produced multiple CSP lots on December 1, 2015, that were verified by Pharmacist Gajjar, as identified in Table 1.

42. The inspector asked Pharmacist Gajjar if consultation was made available to Anatomy Pharmacy's patients and/or primary caregivers concerning the proper use, storage, handling and disposal of CSPs and related supplies furnished by the pharmacy. Pharmacist Gajjar admitted that no such consultations were made available to patients receiving CSPs by mail.

43. After the first inspection was concluded, the Board received a letter from Anatomy Pharmacy's sterile compounding consultant, Pharmacist Aksentijevic, dated February 1, 2016. In that letter, Pharmacist Aksentijevic made several statements of fact that were not accurate or truthful when compared against the inspector's findings on January 11, 2016, as identified in Table 1. For example, Pharmacist Aksentijevic wrote that each batch of the pharmacy's CSPs are "quarantined until sterility results are confirmed by an outside laboratory." She also wrote that the pharmacy performed "end product testing – endotoxin results were observed on file." She further wrote that she reviewed all "BUD determination with reference materials."

The Second Inspection, April 26, 2016

44. During the second inspection on April 26, 2016, the inspector examined a cabinet in the pharmacy's compounding area marked "Quarantine Compounds." The inspector asked the then pharmacist-in-charge, Sheila Damaris Colon ("Pharmacist Colon" or "PIC Colon") whether the CSP lots therein were in fact quarantined or whether they were being dispensed to patients. Pharmacist Colon informed the inspector that all CSP lots found therein were ready to be dispensed, and she admitted that several vials had already been dispensed from these lots.

45. The inspector examined Anatomy Pharmacy's compounding area and all CSP lots and CRs. A broad range of continuing and new deficiencies were discovered. The following chart summarizes the inspector's findings:

Table 2: CSP Lots at Anatomy Pharmacy on April 26, 2016

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
1	Alprostadil Injection 60 mcg/ml Exp.: 08/16 (found inside refrigerator)	2013	Not available.	Not available.	Date prepared: 01/06/16. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD isted in CR: 03/16. However, BUD listed on bottle was 08/16 (more than 180 days from the date prepared). Active ingredients listed in CR expired: mannitol on 06/14, bacteriostatic on 03/16. No method of terminal sterilization indicated. *Dispensed* on 2/22/16 by RX No. 500111.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
2	DHEA Injection 50 mg/ml Exp.: 09/16	2003	Passed sterility via ARL on 12/17/15. Pyrogen test not available.	Not available.	Date prepared: 12/01/15. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 03/16. However, BUD listed on bottle was 09/16 (more than 180 days from the date prepared). Active ingredients listed in CR expired on 05/16. No method of terminal sterilization indicated.
3	Energy Cocktail Injection Exp.: 05/16 (found inside refrigerator)	2025	Not available.	Not available.	Date prepared: 01/30/16. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 04/16. However, BUD listed on bottle was 05/16. Dry oven listed for terminal sterilization, however, no records of sterilization temperature and duration. Under storage requirements – room temp was circled, however, this product was found inside the refrigerator. *Dispensed* on 03/07/16 by RX No. 500123.
4	Fat Shredder Injection Exp.: 09/16	2017	Not available.	Not available.	CR not available. *Dispensed* on 12/16/15 by RX No. 500065. *Dispensed* on 01/15/16 by RX No. 500088.
5	Glutathione Injection 200 mg/ml Exp.: 09/16	2012	Not available.	Not available.	CR not available.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
6	Methyl-cobalamine (vit. B12) Injection 1000 mcg/ml Exp.: 09/16	2006	Not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Active ingredient listed in CR: (i) B12 powder had no expiration date; (ii) pyridoxine expired on 04/16; (iii) bacteriostatic water expired on 03/16. No method of terminal sterilization indicated.
7	Methyl-cobalamine Injection 25 mg/ml Exp.: 09/16	2013	Not available.	Not available.	CR not available.
8	Methyl-cobalamine Injection 5 mcg/ml Exp.: 10/16	2014	Not available.	Not available.	CR not available.
9	Oxytocin Injection 10iu/ml Exp.: 04/16 (found inside refrigerator)	2022	Not available.	Not available.	Date prepared: 01/24/16. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 90 days. Dry oven listed for terminal sterilization, however, no records of sterilization temperature and duration. *Dispensed* on 02/29/16 by RX No. 500116.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
10	Oxytocin Injection 10iu/ml Exp.: 01/16 (found inside refrigerator)	2001	Not available.	Not available.	CR not available. *Dispensed* on 12/16/15 by RX No. 500040.
11	Progesterone Injection 50 mg/ml Exp.: 09/16	2005	Passed sterility via ARL on 12/17/15. Pyrogen test not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Four active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated.
12	Pyridoxine (vit. B6) Injection 100 mg/ml Exp.: 09/16	2004	Not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD listed in CR: 09/16 (more than 180 days from the date prepared). Active ingredient has no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated. No lot number for the compounded product available (this CR submitted by PIC Colon in response to inspector's request for lot 2004)

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
13	Quad Mix Injection (Lyophilized) Exp.: 03/16	1014	Not available.	Not available.	Date prepared: 07/22/15. Prepared by Tech. Kabov. Checked by PIC Lowe. BUD listed in CR: 180 days, which should be 01/16. However, BUD listed on bottle was 03/16 (more than 180 days from the date prepared). Active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated. *Dispensed* on 09/30/15 by RX No. 0153. *Dispensed* on 12/16/15 by RX No. 500064.
14	Semoreline Injection 6 mg – 3 ml Exp.: 07/16	898	Not available.	Not available.	CR not available.
15	Semoreline/ GHRP2/ GHRP6 9mg/3ml Exp.: 05/16	981	Passed sterility and pyrogens testing via ARL on 01/18/16 and 01/26/16.	Not available.	CR not available.

#	CSP Name and Listed Exp. Date	Lot No.	Lot Sterility/ Pyrogen Testing	Master Formula	CR Review/ Dispensing Dates
16	Super B Complex Injection Exp.: 09/16	2011	Not available.	Not available.	Date prepared: 12/01/15. No identity of compounding personnel and reviewing pharmacist. BUD not listed in CR. BUD listed on vials: 09/16 (more than 180 days from the date prepared). Active ingredients have no manufacturer, expiration date, and lot number listed. No method of terminal sterilization indicated. No lot number for the compounded product available (this CR submitted by PIC Colon in response to inspector's request for lot 2011)
17	Super Shot Injection Exp.: 04/16	2020	Not available.	Not available.	Date prepared: 01/24/16. Prepared by Tech. Kabov. Checked by PIC Gajjar. BUD listed in CR: 90 days. No method of terminal sterilization indicated. *Dispensed* on 02/26/16 by RX No. 50011. *Dispensed* on 03/18/16 by RX No. 500138. *Dispensed* on 04/01/16 by RX No. 500147. *Dispensed* on 04/05/16 by RX No. 500155. *Dispensed* on 04/08/16 by RX No. 500159.

46. With respect to the CSP lots identified in Table 2, Pharmacist Colon admitted to the inspector that Anatomy Pharmacy continued to dispense injectable CSPs to patients without having performed sterility or pyrogens tests on all lots, without having first preparing all master

formulas, without having validation studies or references to justify the BUDs exceeding 180 days, and without having complete CRs for all CSPs.

The DEA Investigation

47. In or around August 2013, Anatomy Pharmacy became the subject of an investigation by the United States Drug Enforcement Administration ("DEA"), which culminated in a criminal proceeding entitled *United States of America v. Kabov, et al.* (USDC, C.D. Cal., No. 2:15cr511, filed Sept. 22, 2015). During the DEA investigation, the Board learned that Berry Kabov and Tech. Kabov were using Anatomy Pharmacy to unlawfully obtain, compound, and traffic large amounts of dangerous drugs and/or controlled substances.

48. As a result of the DEA investigation, a Board inspector conducted a zero based audit for all oxycodone 30mg tablets in the pharmacy, but which were not compounded by Anatomy Pharmacy, as of October 1, 2015. The inspector determined that the pharmacy had an inventory shortage of approximately 1,618 tablets of oxycodone 30mg. Concomitantly, the inspector also found that the pharmacy failed to maintain adequate records of acquisition and disposition to account for the shortage and its current inventory of oxycodone.

49. In conjunction with the DEA investigation, the Board inspector learned that Anatomy Pharmacy purchased dangerous drugs at wholesale from foreign entities that were not licensed with the Board as authorized wholesalers. For example, in May 2013, the pharmacy purchased sermorelin acetate (a discontinued drug in the United States), GHRP-2 acetate, and GHRP-6 acetate from Attix Pharmaceuticals, an unlicensed entity with the Board, located in Canada. As another example, between 2012 and 2014, the pharmacy purchased and/or received quantities of anabolic steroids from wholesale drug distributors located in China.

50. In conjunction with the DEA investigation, the Board inspector asked the pharmacy to produce all records for the dangerous drugs that were compounded at Anatomy Pharmacy, including, but not limited to, oxycodone 30mg. Records provided by Pharmacist Colon on or around April 26, 2016, revealed a number of deficiencies. For example, the pharmacy's compounding records were missing the date of compounding, the identity of the pharmacist reviewing the final drug product, the identity of the pharmacy personnel who compounded the

drug product, the manufacture, expiration date, and lot number of each component, and the expiration date of the final compounded drug product.

FIRST CAUSE FOR DISCIPLINE

Compounding Area for Parentheral Solutions

(Against Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar)

51. Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar are subject to disciplinary action under Code sections 4127.7 and 4301, subdivision (o), on the grounds that they compounded sterile injectable productions from one or more non-sterile ingredients in an unauthorized environment. Complainant refers to and expressly incorporates the allegations contained within paragraphs 34, 35, and 46 above as though set forth fully herein.

SECOND CAUSE FOR DISCIPLINE

Facility and Equipment Standards for Sterile Injectable Compounding

(Against Respondents Anatomy Pharmacy and Pharmacist Gajjar)

52. Respondents Anatomy Pharmacy and Pharmacist Gajjar are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1751.4, subdivision (a), on the grounds that they knew, or reasonably should have known, that they prepared injectable CSPs in an environment that failed to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products. Complainant refers to and expressly incorporates the allegations contained within paragraphs 35 and 46 above as though set forth fully herein.

THIRD CAUSE FOR DISCIPLINE

Sterile Compounding Policies and Procedures

(Against Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar)

53. Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1751.3, subdivision (b), on the grounds that no pharmacist was on record as having reviewed compounding worksheets before compounding took place.

Complainant refers to and expressly incorporates the allegations contained within Table 1 and Table 2 above as though set forth fully herein.

FOURTH CAUSE FOR DISCIPLINE

Compounding Facilities and Equipment

(Against Respondents Anatomy Pharmacy and Pharmacist Gajjar)

54. Respondents Anatomy Pharmacy and Harshad H. Gajjar are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.6, subdivision (b), on the grounds that the dry heat oven used in the compounding of injectable CSPs was not found to be stored, used, and maintained in accordance with the manufacturer's recommendations. Complainant refers to and expressly incorporates the allegations contained within paragraph 36 above as though set forth fully herein.

FIFTH CAUSE FOR DISCIPLINE

Sterile Injectable Compounding Quality Assurance and Process Validation

(Against Respondents Anatomy Pharmacy, Pharmacist Lowe, Pharmacist Gajjar)

55. Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1751.7, subdivision (c), on the grounds that Respondents failed to subject batch-produced injectable CSPs, which were compounded from one or more non-sterile ingredients, to documented end product testing for sterility and pyrogens and/or Respondents failed to properly quarantine those batch-produced injectable CSPs until end product testing confirmed sterility and acceptable levels of pyrogens. Complainant refers to and expressly incorporates the allegations contained within paragraphs 34, 35, 37, 44, and 46, and Table 1 and Table 2 above as though set forth fully herein.

SIXTH CAUSE FOR DISCIPLINE

Compounding Master Formulas Requirements

(Against Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar)

56. Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of

Regulations, title 16, section 1735.2, subdivision (d), on the grounds that complete master formulas for injectable CSPs were not available for review upon request by Board inspectors. Complainant refers to and expressly incorporates the allegations contained within paragraphs 35 and 46, and Table 1 and Table 2 above as though set forth fully herein.

SEVENTH CAUSE FOR DISCIPLINE

Compounding Limitations and Requirements

(Against Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar)

57. Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.2, subdivision (h), on the grounds that they maintained CSP lots with BUDs that exceeded 180 days from the date of preparation, or the shortest expiration date of any component in the CSP, without any support from stability and/or sterility studies. In doing so, Respondents failed to exercise the appropriate professional judgment of a responsible pharmacist. Complainant refers to and expressly incorporates the allegations contained within paragraphs 35 and 46, and Table 1 and Table 2 above as though set forth fully herein.

EIGHTH CAUSE FOR DISCIPLINE

Records of Compounded Drug Products

(Against Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar)

58. Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.3, subdivision (a), on the grounds that multiple CSPs had CRs that were missing statutorily required information, such as the master formula record, the date the drug was compounded, the identity of the personnel who compounded the product, the identity of the pharmacist reviewing the final product, the quantity of each component used in the product, the manufacturer and lot number of each component, the equipment used in compounding, a product lot number, an expiration date, and/or the quantity of product compounded. Complainant refers to and expressly incorporates the allegations contained within paragraphs 35 and 46, and Table 1 and Table 2 above as though set forth fully herein.

NINTH CAUSE FOR DISCIPLINE

Failure to Maintain Compounding Quality Assurance

(Against Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar)

59. Respondents Anatomy Pharmacy, Pharmacist Lowe, and Pharmacist Gajjar are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.8, subdivision (a), on the grounds that they did not maintain, as part of their written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and/or labeled strength of CSPs. Complainant refers to and expressly incorporates the allegations contained within paragraphs 35 and 46, and Table 1 and Table 2 above as though set forth fully herein.

TENTH CAUSE FOR DISCIPLINE

Training of Compounding Staff

(Against Respondents Anatomy Pharmacy and Pharmacist Gajjar)

60. Respondents Anatomy Pharmacy and Pharmacist Gajjar are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1735.7, subdivision (a), on the grounds that they did not maintain written documentation sufficient to demonstrate that pharmacy personnel had the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding. Complainant refers to and expressly incorporates the allegations contained within paragraphs 39 through 41 above as though set forth fully herein.

ELEVENTH CAUSE FOR DISCIPLINE

Unprofessional Conduct

(Against Respondents Anatomy Pharmacy, Pharmacist Gajjar, Pharmacist Aksentijevic, and Tech. Kabov)

61. Respondents Anatomy Pharmacy, Pharmacist Gajjar, Pharmacist Aksentijevic, and Tech. Kalbov are subject to disciplinary action under Code section 4301, subdivision (g), for committing acts of unprofessional conduct in that they falsely represented the existence or

nonexistence of a state of facts. Complainant refers to and expressly incorporates the allegations contained within paragraphs 39, 40 and 43 above as though set forth fully herein.

TWELFTH CAUSE FOR DISCIPLINE

Training of Sterile Injectable Compounding Staff, Patient, and Caregiver

(Against Respondents Anatomy Pharmacy and Pharmacist Gajjar)

62. Respondents Anatomy Pharmacy and Pharmacist Gajjar are subject to disciplinary action under Code section 4301, subdivision (o), and California Code of Regulations, title 16, section 1751.6, subdivision (a), on the grounds that Respondents failed to make consultations available to their patients and/or primary caregivers concerning the proper use of injectable CSPs furnished by Anatomy Pharmacy. Complainant refers to and expressly incorporates the allegations contained within paragraph 42 above as though set forth fully herein.

THIRTEENTH CAUSE FOR DISCIPLINE

Adulterated Medications

(Against Respondents Anatomy Pharmacy and Pharmacist Gajjar)

63. Respondents Anatomy Pharmacy and Pharmacist Gajjar are subject to disciplinary action under Code section 4301, subdivision (j), and Health and Safety Code sections 111250 and 111295 on the grounds that they maintained expired CSP lots and CSP lots compounded with expired ingredients in the pharmacy's active drug inventory. Complainant refers to and expressly incorporates the allegations contained within paragraphs 35 and 46, and Table 1 and Table 2 above as though set forth fully herein.

FOURTEENTH CAUSE FOR DISCIPLINE

Failure to Maintain Records

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

64. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code sections 4081 and 4332, and California Code of Regulations, title 16, section 1718, on the grounds that they failed to maintain a current inventory and all records of manufacture, sale, acquisition, receipt, shipment, or disposition of dangerous drugs for a period of three years from the date of making. Complainant

refers to and expressly incorporates the allegations contained within paragraph 48 above as though set forth fully herein.

FIFTEENTH CAUSE FOR DISCIPLINE

Prohibited Acts

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

65. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code section 4169, subdivision (a)(1), on the grounds that they engaged in a prohibited act by purchasing, trading, and/or transferring dangerous drugs at wholesale with entities in Canada and China that were not licensed with the Board as a wholesaler, third-party logistics provider, or pharmacy. Complainant refers to and expressly incorporates the allegations contained within paragraph 49 above as though set forth fully herein.

SIXTEENTH CAUSE FOR DISCIPLINE

Misbranded Drugs

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

66. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Health and Safety Code sections 111397, subdivision (a), and 111440, on the grounds that they manufactured, sold, delivered, held, or offered to sell drugs that were misbranded because they were obtained outside of the licensed supply chain regulated by the Board. Complainant refers to and expressly incorporates the allegations contained within paragraph 49 above as though set forth fully herein.

SEVENTEENTH CAUSE FOR DISCIPLINE

Records of Compounded Drug Products

(Against Respondents Anatomy Pharmacy and Pharmacist Lowe)

67. Respondents Anatomy Pharmacy and Pharmacist Lowe are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.3, subdivision (a), on the grounds that compounding records produced on April 26, 2016, for oxycodone 30mg were incomplete in that they were missing the

date of compounding, the identity of the pharmacist reviewing the final drug product, the identity of the pharmacy personnel who compounded the drug product, the manufacture, expiration date, and lot number of each component, and the expiration date of the final compounded drug product. Complainant refers to and expressly incorporates the allegations contained within paragraph 50 above as though set forth fully herein.

OTHER MATTERS

68. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50713 issued to Respondent Anatomy Pharmacy, then Respondent Anatomy Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50713 is placed on probation or until Pharmacy Permit Number PHY 50713 is reinstated if it is revoked.

69. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50713 issued to Respondent Anatomy Pharmacy while Berry Kabov and/or Dalibor Dabo Kabov, Pharmacy Technician Registration Number TCH 114849, have been officers and/or owners and had knowledge or knowingly participated in any conduct for which the licensee was disciplined, then Berry Kabov and/or Dalibor Dabo Kabov shall be prohibited from serving as managers, administrators, owners, members, officers, directors, associates, or partners of a licensee for five years if Pharmacy Permit Number PHY 50713 is placed on probation or until Pharmacy Permit Number PHY 50713 is reinstated if it is revoked.

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 Permit Number PHY 50713, issued to Anatomy RX LLC, dba Anatomy Pharmacy, Berry Kabov, Member, Dalibor Dabo Kabov, Member;

2. Revoking or suspending Sterile Compounding Pharmacy Number LSC 99715, issued to Anatomy RX LLC, dba Anatomy Pharmacy, Berry Kabov, Member, Dalibor Dabo Kabov, Member;

3. Revoking or suspending Pharmacist License Number RPH 37609, issued to Michael Paul Lowe;

4. Revoking or suspending Pharmacist License Number RPH 41722, issued to Harshad H. Gajjar;

5. Revoking or suspending Pharmacist License Number RPH 38483, issued to Kimberly Birano Aksentijevic;

6. Revoking or suspending Pharmacy Technician Registration Number TCH 114849, issued to Dalibor Dabo Kabov;

7. Prohibiting Berry Kabov from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacy Permit Number PHY 50713 is placed on probation or until Pharmacy Permit Number PHY 50713 is reinstated if it is revoked;

8. Prohibiting Dalibor Dabo Kabov, Pharmacy Technician Registration Number TCH 114849, from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee for five years if Pharmacy Permit Number PHY 50713 is placed on probation or until Pharmacy Permit Number PHY 50713 is reinstated if it is revoked;

9. Ordering Anatomy Pharmacy, Michael Paul Lowe, Dalibor Dabo Kabov, Harshad H. Gajjar, and ssKimberly Briano Aksentijevic 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; and,

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

DATED: 2/28/18

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

LA2016602481/52325597