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

In the Matter of the Accusation Against: **THE REGENTS OF THE UNIVERSITY OF CALIFORNIA DBA UCLA MEDICAL CENTER PHARMACEUTICAL TECHNOLOGY** **1010 Veteran Ave.** **Los Angeles, CA 90095** **Pharmacy Permit No. PHE 45579** **Sterile Compounding Permit No. LSE 100359** **RICHARD CHARLES GRAUL** **(Pharmacist-in-Charge)** **432 Diamond St.** **Arcadia, CA 91006** **Pharmacist License No. RPH 52282** Respondents.	Case No. 6106 **ACCUSATION**

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.

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2. On or about September 21, 2001, the Board of Pharmacy issued Pharmacy Permit Number PHE 45579 to The Regents of the University of California dba UCLA Medical Center Pharmaceutical Technology (Respondent UCLA PTL). The Pharmacy Permit expired on December 15, 2016 and was cancelled, effective October 25, 2016.

3. On or about June 18, 2014, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 100359 to Respondent UCLA PTL. The Sterile Compounding Permit expired on December 15, 2016 and was cancelled, effective October 25, 2016.

4. On or about March 2, 2001, the Board of Pharmacy issued Pharmacist License Number RPH 52282 to Richard Charles Graul (Respondent Graul) with an expiration date of February 29, 2019, unless renewed. Respondent Graul was the Pharmacist-in-Charge from October 17, 2005 to October 25, 2016.

JURISDICTION

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

STATUTORY PROVISIONS

6. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self use in humans or animals, and includes the following:

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

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7. Section 4300 of the Code states in relevant part:

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

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

(1) Suspending judgment.

(2) Placing him or her upon probation.

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

(4) Revoking his or her license.

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

* * *

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

8. Section 4300.1 of the Code states: "The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

9. Section 4342 of the Code states in relevant part:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the

Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

10. Section 4128 of the Code states:

"(a) Notwithstanding Section 4029, a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and located within a 75-mile radius of each other:

(1) Preparing unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to Section 4128.4.

(2) Preparing sterile compounded unit dose drugs for administration to inpatients, if each compounded unit dose drug is barcoded pursuant to Section 4128.4.

(3) Preparing compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.

(b) For purposes of this article, "common ownership" means that the ownership information on file with the board pursuant to Section 4201 for the licensed pharmacy is consistent with the ownership information on file with the board for the other licensed pharmacy or pharmacies for purposes of preparing medications pursuant to this section."

11. Section 4128.2 of the Code states in relevant part:

"(a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128."

12. Section 4169 of the Code states in relevant part:

"(a) A person or entity shall not do any of the following:

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

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

13. Section 4301 of the Code states in relevant part:

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

* * *

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

* * *

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

14. Section 111250 of the Health and Safety Code states: "Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance."

15. Section 111295 of the Health and Safety Code states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

16. Section 111330 of the Health and Safety Code states: "Any drug or device is misbranded if its labeling is false or misleading in any particular."

17. Section 111440 of the Health and Safety Code states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

REGULATORY PROVISIONS

18. California Code of Regulations, title 16, section 1735.2, states in relevant part:

"(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved

use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1), means that amount of compounded drug product that:

(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and

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

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product."

19. California Code of Regulations, title 16, section 1751.7, states in relevant part:

"(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed

medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations."

CONTROLLED SUBSTANCES/DANGEROUS DRUGS

20. Monosodium glutamate monohydrate (MSG) used for cardioplegia is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

21. Monosodium aspartate monohydrate (MSA) used for cardioplegia is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

22. Hydroxyprogesterone caproate (brand name, Progestin) is a hormone that is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

23. Estradiol (brand name, Estrace) is a hormone that is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

24. Clopidogrel (brand name, Plavix) used for blood clot prevention is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

25. Mexiletine (brand name, Mexitil) used for arrhythmia is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.

COST RECOVERY

26. Section 125.3 of the Code states, 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.

STATEMENT OF FACTS

27. On or about October 12, 2016, a Board Inspector completed a routine sterile compounding license renewal inspection at UCLA Medical Center Pharmaceutical Technology Laboratory Pharmacy (UCLA PTL). Pharmacist-in-Charge (PIC), Respondent Graul was present and assisted during the inspection. Pharmacist C.C. also assisted during the inspection.

28. According to Respondent Graul, the lab at Respondent UCLA PTL compounds non-sterile oral and topical preparations such as creams, ointments and suspensions as well as prepares Compounded Sterile Preparations (CSPs). During the inspection, Respondent Graul informed the Board Inspector that some drugs were compounded pursuant to a prescription for an individual patient, but most of the compounds were prepared in batches for anticipatory future use for administration to patients throughout the UCLA healthcare system.

29. During the inspection, the Board Inspector reviewed compounding logs for recently prepared CSPs, expiration dates on medication, reviewed Respondent UCLA PTL's policy on batch sterility testing with Respondent Graul, and reviewed Respondent UCLA PTL's policy and training records for quality assurance and process validation with Respondent Graul.

30. The Board Inspector returned to Respondent UCLA PTL on or about October 21, 2016 for a second inspection of the pharmacy. During this inspection, Respondent Graul was not present. However, the Board Inspector was assisted by pharmacist F. H. and was later joined by UCLA Chief Pharmacy Officer D. Z., pharmacist R. Q., and pharmacist R.

31. Upon inspection of the general compounding room, the Board Inspector found expired bulk powders and medication bottles in the active medication stock.

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32. Based on the two inspections, the Board Inspector found the following:

CSP	Lot Number	Date Prepared	Assigned Beyond-Use-Date (BUD)	Number of Bags Prepared	Compounding Record Review
MSG[1] 4.28%, MSA[2] 3.92% cardioplegic solution	21-056	05/11/2016	09/11/2016	76 x 250 ml bags	Active ingredient used in compounding (sodium hydroxide pellets, lot #14A17-U07-018656) expired on 11/07/2015
MSG 4.28%, MSA 3.92% cardioplegic solution	19-125	12/08/2015	04/08/2016	80 x 250 ml bags	Active ingredient used in compounding (sodium hydroxide pellets, lot #14A17-U07-018656) expired on 11/07/2015
MSG 4.28%, MSA 3.92% cardioplegic solution	12-026	02/03/2016	06/03/2016	76 x 250 ml bags	Active ingredient used in compounding (L-glutamic acid, lot #R012M004) expired on 02/04/2016

[1] MSG – monosodium glutamate monohydrate
[2] MSA – monosodium aspartate monohydrate

CSP	Lot Number	Date Prepared	Assigned Beyond-Use-Date (BUD)	Number of Bags Prepared	Compounding Record Review
MSG 4.28%, MSA 3.92% cardioplegic solution	02-105	10/01/2015	02/01/2016	79 x 250 ml bags	Active ingredient used in compounding (L-aspartic acid, lot #R005M007) expired on 11/14/2015. Active ingredient used in compounding (sodium hydroxide pellets, lot #14A17-U07-018656) expired on 11/07/2015
CPD[3] anticoagulant solution	55-066	06/27/2016	10/27/2016	196 x 500 ml bags	Active ingredient used in compounding (sodium phosphate monobasic, lot #1077539A) expired on 06/03/2016

Drug/Chemical Name	Quantity	Expiration Date On Drug
Hydroxyprogesterone caproate, USP 25 gm	2 bottles	07/17/2016
Estradiol, USP 1 gm	1 bottle	09/2016
Clopidogrel tablets, 75 mg	2 bottles	07/2016
Mexiletine capsules, 150 mg	1 bottle	09/2016
Mexiletine capsules, 200 mg	1 bottle	09/2016

[3] CPD – citrate phosphate dextrose

CSP	Lot Number	Date Prepared	Assigned BUD	Number of Bags Prepared	Number of Bags Tested	Unlawful Findings
CPD anticoagulant solution	13-056	05/06/2016	09/06/2016	196 x 500 ml bags	1	Only one bag was tested for sterility which is less than 2% of all bags
CPD anticoagulant solution	55-066	06/27/2016	10/27/2016	196 x 500 ml bags	1	Only one bag was tested for sterility which is less than 2% of all bags
CPD anticoagulant solution	54-096	09/14/2016	01/14/2017	189 x 500 ml bags	1	Only one bag was tested for sterility which is less than 2% of all bags
CPD anticoagulant solution	27-076	07/27/2016	11/27/2016	198 x 500 ml bags	1	Only one bag was tested for sterility which is less than 2% of all bags

FIRST CAUSE FOR DISCIPLINE

(Acting Outside Scope of Current Licenses and Failure to Obtain Required Specialty License)

33. Respondents UCLA PT and Graul are subject to disciplinary action under sections 4128 and 4128.2, subdivision (a) for acting outside the scope of the compounding limitations and requirements imposed by California Code of Regulations, title 16, section 1735.2, subdivisions (a), (b), and (c); and for failure to obtain a specialty license from the Board prior to engaging in activities outside the compounding limitations and restrictions imposed by law. Specifically,

Respondents were acting as a centralized hospital packaging pharmacy because although some drugs were compounded pursuant to a prescription for an individual patient, most of the compounds were prepared in batches for anticipatory future use for administration to patients throughout the UCLA healthcare system. A specialty license is required to operate as a centralized hospital packaging pharmacy, which Respondents failed to obtain from the Board. Complainant refers to and by this reference incorporates allegations of paragraphs 27 through 32 above as though fully set forth.

SECOND CAUSE FOR DISCIPLINE

(Failure to Meet Standards for Sterile Injectable Compounding Quality Assurance and Process Validation)

34. Respondents UCLA PT and Graul are subject to disciplinary action under section 4301, subdivision (j) and (o) for violating California Code of Regulations, title 16, sections 1751.7, subdivisions (b) and (c) for failing to meet standards for sterile injectable compounding quality assurance and process validation. Specifically, there are no records indicating each individual involved in the preparation of sterile injectable products completed a validation process that demonstrates competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. Additionally, the following CSPs compounded from one or more non-sterile ingredients were not subjected to proper end-product testing for batch sterility:

CSP	Lot Number	Date Prepared	Assigned BUD	Number of Bags Prepared	Number of Bags Tested	Unlawful Findings
CPD anticoagulant solution	13-056	05/06/2016	09/06/2016	196 x 500 ml bags	1	Only one bag was tested for sterility which is less than 2% of all bags

CSP	Lot Number	Date Prepared	Assigned BUD	Number of Bags Prepared	Number of Bags Tested	Unlawful Findings
CPD anticoagulant solution	55-066	06/27/2016	10/27/2016	196 x 500 ml bags	1	Only one bag was tested for sterility which is less than 2% of all bags
CPD anticoagulant solution	54-096	09/14/2016	01/14/2017	189 x 500 ml bags	1	Only one bag was tested for sterility which is less than 2% of all bags
CPD anticoagulant solution	27-076	07/27/2016	11/27/2016	198 x 500 ml bags	1	Only one bag was tested for sterility which is less than 2% of all bags

35. Complainant refers to and by this reference incorporates allegations of paragraphs 27 through 32 above as though fully set forth.

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THIRD CAUSE FOR DISCIPLINE

(Adulterated Medications)

36. Respondents UCLA PT and Graul are subject to disciplinary action under section 4169, subdivision (a)(2) and Health and Safety Code sections 111250 and 111295 for compounding drugs using expired ingredients. Specifically, the following were compounded with expired ingredients and then delivered to patients:

CSP	Lot Number	Date Prepared	Assigned Beyond-Use-Date (BUD)	Number of Bags Prepared	Compounding Record Review
MSG 4.28%, MSA 3.92% cardioplegic solution	21-056	05/11/2016	09/11/2016	76 x 250 ml bags	Active ingredient used in compounding (sodium hydroxide pellets, lot #14A17-U07-018656) expired on 11/07/2015
MSG 4.28%, MSA 3.92% cardioplegic solution	19-125	12/08/2015	04/08/2016	80 x 250 ml bags	Active ingredient used in compounding (sodium hydroxide pellets, lot #14A17-U07-018656) expired on 11/07/2015
CPD anticoagulant solution	55-066	06/27/2016	10/27/2016	196 x 500 ml bags	Active ingredient used in compounding (sodium phosphate monobasic, lot #1077539A) expired on 06/03/2016

37. Complainant refers to and by this reference incorporates allegations of paragraphs 27 through 32 above as though fully set forth.

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FOURTH CAUSE FOR DISCIPLINE

(Misbranded Medications)

38. Respondents UCLA PT and Graul are subject to disciplinary action under section 4169, subdivision (a)(3) and Health and Safety Code sections 111330 and 111440 for labeling CSPs with misleading and false BUDs. Specifically, the following CSPs were found to be misbranded:

CSP	Lot Number	Date Prepared	Assigned Beyond-Use-Date (BUD)	Number of Bags Prepared	Compounding Record Review
MSG 4.28%, MSA 3.92% cardioplegic solution	21-056	05/11/2016.	09/11/2016	76 x 250 ml bags	Active ingredient used in compounding (sodium hydroxide pellets, lot #14A17-U07-018656) expired on 11/07/2015
MSG 4.28%, MSA 3.92% cardioplegic solution	19-125	12/08/2015	04/08/2016	80 x 250 ml bags	Active ingredient used in compounding (sodium hydroxide pellets, lot #14A17-U07-018656) expired on 11/07/2015
MSG 4.28%, MSA 3.92% cardioplegic solution	12-026	02/03/2016	06/03/2016	76 x 250 ml bags	Active ingredient used in compounding (L-glutamic acid, lot #R012M004) expired on 02/04/2016

CSP	Lot Number	Date Prepared	Assigned Beyond-Use-Date (BUD)	Number of Bags Prepared	Compounding Record Review
MSG 4.28%, MSA 3.92% cardioplegic solution	02-105	10/01/2015	02/01/2016	79 x 250 ml bags	Active ingredient used in compounding (L-aspartic acid, lot #R005M007) expired on 11/14/2015. Active ingredient used in compounding (sodium hydroxide pellets, lot #14A17-U07-018656) expired on 11/07/2015
CPD anticoagulant solution	55-066	06/27/2016	10/27/2016	196 x 500 ml bags	Active ingredient used in compounding (sodium phosphate monobasic, lot #1077539A) expired on 06/03/2016

39. Complainant refers to and by this reference incorporates allegations of paragraphs 27 through 32 above as though fully set forth.

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FIFTH CAUSE FOR DISCIPLINE

(Expired Drugs In Pharmacy's Active Drug Stock)

40. Respondents UCLA PT and Graul are subject to disciplinary action under section 4342, subdivision (a) and Health and Safety Code sections 111250 and 111295 for allowing the following expired drugs and bulk chemicals to remain in Respondents' active drug stock:

Drug/Chemical Name	Quantity	Expiration Date On Drug
Hydroxyprogesterone caproate, USP 25 gm	2 bottles	07/17/2016
Estradiol, USP 1 gm	1 bottle	09/2016
Clopidogrel tablets, 75 mg	2 bottles	07/2016
Mexiletine capsules, 150 mg	1 bottle	09/2016
Mexiletine capsules, 200 mg	1 bottle	09/2016

41. Complainant refers to and by this reference incorporates allegations of paragraphs 27 through 32 above as though fully set forth.

SIXTH CAUSE FOR DISCIPLINE

(Improperly Verifying Adulterated and Misbranded Non-Sterile to Sterile Compounds Without Compliant End Product Tests)

42. Respondent Graul is subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with section 4342, subdivision (a) for verifying at least eight (8) batches of adulterated or misbranded non-sterile to sterile compounds without compliant end product tests. Complainant refers to and by this reference incorporates allegations of paragraphs 27 through 32 above as though fully set forth.

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PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHE 45579, issued to The Regents of the University of California dba UCLA Medical Center Pharmaceutical Technology;

2. Revoking or suspending Sterile Compounding Permit Number LSC 100359, issued to The Regents of the University of California dba UCLA Medical Center Pharmaceutical Technology;

3. Revoking or suspending Pharmacist License Number RPH 52282 issued to Richard Charles Graul;

4. Ordering The Regents of the University of California, dba UCLA Medical Center Pharmaceutical Technology and Richard Charles Graul 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

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

DATED: 7/11/17

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

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