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

In the Matter of the Accusation Against: **RONALD SCOTT COHEN, M.D.** **11230 Sorrento Valley Road, Ste. 120** **San Diego, CA 92121-1332** **Physician's and Surgeon's Certificate No. A 73894,** Respondent.	Case No. 800-2023-099422 **ACCUSATION**

PARTIES

1. Reji Varghese (Complainant) brings this Accusation solely in his official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs (Board).

2. On or about February 8, 2001, the Medical Board issued Physician's and Surgeon's Certificate No. A 73894 to Ronald Scott Cohen, M.D. (Respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2028, unless renewed.

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JURISDICTION

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

4. Section 2227 of the Code states:

> (a) A licensee whose matter has been heard by an administrative law judge of the Medical Quality Hearing Panel as designated in Section 11371 of the Government Code, or whose default has been entered, and who is found guilty, or who has entered into a stipulation for disciplinary action with the board, may, in accordance with the provisions of this chapter:
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> (1) Have his or her license revoked upon order of the board.
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> (2) Have his or her right to practice suspended for a period not to exceed one year upon order of the board.
>
> (3) Be placed on probation and be required to pay the costs of probation monitoring upon order of the board.
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> (4) Be publicly reprimanded by the board. The public reprimand may include a requirement that the licensee complete relevant educational courses approved by the board.
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> (5) Have any other action taken in relation to discipline as part of an order of probation, as the board or an administrative law judge may deem proper.
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> (b) Any matter heard pursuant to subdivision (a), except for warning letters, medical review or advisory conferences, professional competency examinations, continuing education activities, and cost reimbursement associated therewith that are agreed to with the board and successfully completed by the licensee, or other matters made confidential or privileged by existing law, is deemed public, and shall be made available to the public by the board pursuant to Section 803.1.

5. Section 2234 of the Code states, in pertinent part:

> The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:
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> (a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.
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> (b) Gross negligence.
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6. Section 2238 of the Code states:

A violation of any federal statute or federal regulation or any of the statutes or regulations of this state regulating dangerous drugs or controlled substances constitutes unprofessional conduct.

7. 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.

8. Section 4076 of the Code states, in pertinent part:

(a) A pharmacist shall not dispense a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to Section 4052 or pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant

to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to Section 4052 or pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

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9. Section 4169 of the Code states, in pertinent part:

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

(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.

(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.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

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10. Section 4170 of the Code states, in pertinent part:

(a) A prescriber shall not dispense drugs or dangerous devices to patients in the prescriber's office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless the prescriber personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, before dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

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11. 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.

12. 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.

13. 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.

14. Section 1707.5 of Title 16 of the California Code of Regulations states, in pertinent part:

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for " where the brand name is inserted and the name of the manufacturer. In the professional judgment of the pharmacist:

(i) If the brand name is no longer widely used, the label may list only the generic name of the drug, and

(ii) The manufacturer's name may be listed outside of the patient-centered area.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

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15. Section 1736 of Title 16 of the California Code of Regulations states:

The definitions in this section shall be applicable to this Article and supplement the definitions provided in United States Pharmacopeia (USP) General Chapter 797 (USP Chapter 797), titled Pharmaceutical Compounding -- Sterile Preparations for compounded sterile preparations (CSPs).

(a) "Compounding personnel" means any person involved in any procedure, activity, or direct supervision and control of preparation of CSPs.

(b) "Designated compounding area or compounding area" means a restricted location within a facility that limits personnel access, where only activities and items related to compounding are present.

(c) "Designated person(s)" means one or more individuals assigned by the pharmacist-in-charge (PIC) to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded sterile preparations. Nothing in this definition allows for the designated person to exceed the scope of their

issued license. When the designated person is not a pharmacist, the PIC must review all practices related to the operations of the facility that require the professional judgment of a pharmacist. Nothing in this definition prohibits the PIC from also serving as the designated person.

(d) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as sterile water for injection.

(e) "Essentially a copy" of a commercially available drug product means a preparation that includes the same active pharmaceutical ingredient(s) (API(s)) as the commercially available drug product, except that it does not include any preparation in which there has been a change made for an identified individual patient that produces for that patient a clinically significant difference, as verified and documented by the pharmacist, between that compounded preparation and the comparable commercially available drug product.

(f) "Integrity" means retention of strength until the beyond use date provided on the label, when the preparation is stored and handled according to the label directions.

(g) "Quality" means the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP Chapter 797.

(h) "Strength" means amount of active ingredient per unit of a compounded drug preparation.

16. Section 1736.13 of Title 16 of the California Code of Regulations states:

In addition to the requirements in USP Chapter 797, the following requirements apply to sterile compounding.

(a) A CSP label shall also include all of the following:

(1) Route of intended administration;

(2) For CSPs administered by infusion, the solution utilized;

(3) Instructions for administration;

(A) For CSPs administered by infusion, the rate of infusion, or range of rates of infusion as prescribed, or the duration for the entire CSP to be administered. A health care facility licensed pursuant to Health and Safety Code Section 1250 may reference the patient's chart in lieu of rate of infusion when a patient's condition requires a variable rate.

(4) Name of compounding facility and dispensing facility (if different).

(b) The label for any CSP dispensed or ready to be dispensed to a patient shall also include the information required by Business and Professions Code section 4076 and section 1707.5. A CSP that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility shall be labeled with the patient's name, the directions for the use of the drug, and the date of issuance, but is otherwise exempt from these requirements.

17. Section 351 of Title 21 of the U.S. Code states, in pertinent part:

A drug or device shall be deemed to be adulterated -

(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or

(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

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18. Section 353a of Title 21 of the U.S. Code states, in pertinent part:

(a) In general

Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding-

(1) is by-

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between-

(i) the licensed pharmacist or licensed physician; and

(ii) (I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) Compounded Drug

(1) Licensed pharmacist and licensed physician
A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician –

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations

(i) that-

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

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(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

COST RECOVERY

19. Section 125.3 of the Code states:

(a) Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the department or before the Osteopathic Medical Board, upon request of the entity bringing the proceeding, the administrative law judge may direct a licensee 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.

(b) In the case of a disciplined licensee that is a corporation or a partnership, the order may be made against the licensed corporate entity or licensed partnership.

(c) A certified copy of the actual costs, or a good faith estimate of costs where actual costs are not available, signed by the entity bringing the proceeding or its designated representative shall be prima facie evidence of reasonable costs of investigation and prosecution of the case. The costs shall include the amount of investigative and enforcement costs up to the date of the hearing, including, but not limited to, charges imposed by the Attorney General.

(d) The administrative law judge shall make a proposed finding of the amount of reasonable costs of investigation and prosecution of the case when requested pursuant to subdivision (a). The finding of the administrative law judge with regard to costs shall not be reviewable by the board to increase the cost award. The board may reduce or eliminate the cost award, or remand to the administrative law judge if the proposed decision fails to make a finding on costs requested pursuant to subdivision (a).

(e) If an order for recovery of costs is made and timely payment is not made as directed in the board's decision, the board may enforce the order for repayment in any appropriate court. This right of enforcement shall be in addition to any other rights the board may have as to any licensee to pay costs.

(f) In any action for recovery of costs, proof of the board's decision shall be conclusive proof of the validity of the order of payment and the terms for payment.

(g)(1) Except as provided in paragraph (2), the board shall not renew or reinstate the license of any licensee who has failed to pay all of the costs ordered under this section.

(2) Notwithstanding paragraph (1), the board may, in its discretion, conditionally renew or reinstate for a maximum of one year the license of any licensee who demonstrates financial hardship and who enters into a formal agreement with the board to reimburse the board within that one-year period for the unpaid costs.

(h) All costs recovered under this section shall be considered a reimbursement for costs incurred and shall be deposited in the fund of the board recovering the costs to be available upon appropriation by the Legislature.

(i) Nothing in this section shall preclude a board from including the recovery of the costs of investigation and enforcement of a case in any stipulated settlement.

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(j) This section does not apply to any board if a specific statutory provision in that board's licensing act provides for recovery of costs in an administrative disciplinary proceeding.

DEFINITIONS

20. Semaglutide is a prescription medicine used for weight loss and type 2 diabetes management. It is a dangerous drug pursuant to Code section 4022.

21. Tirzepatide is a prescription medicine used for weight loss and type 2 diabetes management. It is a dangerous drug pursuant to Code section 4022.

22. L-carnitine, commonly known as levocarnitine, is a natural amino acid derivative that supports heart and brain function, helps turn fat into energy, and aids in muscle movement.

FACTUAL ALLEGATIONS

23. In or around February of 2023, Respondent entered into a verbal agreement with his companion (Companion), who was, at the time, a licensed pharmacist, to allow Companion to compound semaglutide with L-carnitine using Respondent's clean room located within Respondent's medical office. According to the verbal agreement, Companion was to obtain all the materials necessary to conduct sterile compounding, including, but not limited to, the vials, the labels, and the raw non-sterile product, also referred to as active pharmaceutical ingredient (API) or bulk drug substance. According to their agreement, Companion would bring the API to Respondent's clean room to compound semaglutide with L-carnitine. According to their agreement and understanding, Companion would leave some of the compounded drugs at Respondent's medical office for Respondent to administer and/or dispense to Respondent's patients, and Companion would take the remaining compounded drugs to another location where Companion would provide them to Respondent's patients. On occasion, Companion would bring another person to Respondent's clean room to assist in the compounding process. On occasion, this person compounded drugs in Respondent's clean room without Companion present. At the time, this person's identity, training and background was unknown to Respondent.

24. In or around November of 2023, Respondent and Companion agreed to expand Respondent's compounding practice to also include tirzepatide with L-carnitine using

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Respondent's clean room located within Respondent's medical office, in accordance with the same agreement and understanding as with the compounding of semaglutide with L-carnitine.

25. The compounded drugs prepared by Companion in Respondent's clean room were placed into vials with minimal information on the label, such as the name of the compounded drug, lot number, and expiration date. The expiration dates assigned were 6 months from production. The vials of the compounded drugs were not childproof containers. The labels on the vials did not include patient names, the dates of issue, the prescriber's name, or the conditions or purposes of the compounded drugs.

26. The vials containing the compounded drugs were stored in a refrigerator in Respondent's clean room for Respondent to access to administer and/or dispense to his patients. Respondent would use syringes to draw the compounded drugs from the vials prepared by Companion and administer and/or dispense the compounded drugs to Respondent's patients. The syringes used by Respondent to administer and/or dispense the compounded drugs to his patients did not contain any labels.

27. In or around June of 2025, Companion started labeling the compounded drug vials with "Gram Peptides" listed on the labels.

28. On or about July 16, 2025, Companion surrendered his pharmacist license to resolve a pending accusation and petition to revoke probation filed against his pharmacist license.

29. In or around August of 2025, Companion continued compounding tirzepatide with L-carnitine and semaglutide with L-carnitine in a larger clean room built by Respondent within his medical office.

30. According to records, Respondent allowed Companion to continue compounding tirzepatide with L-carnitine and semaglutide with L-carnitine in Respondent's clean room through in or around October of 2025, and Respondent continued dispensing these compounded drugs prepared by Companion to Respondent's patients through in or around November of 2025.

31. On or about June 4, 2025, Board investigators conducted a site visit at Respondent's medical clinic, during which time investigators inspected Respondent's clean room. During this site visit, investigators noted Respondent's compounding environment lacked, among other

things, the necessary hygiene equipment, air filtration system, and easily cleanable surface areas, to ensure the sterility of compounded drugs. Personnel were permitted to enter the clean room after putting on "booties and a hair cap" without any further garbing requirements, and there were no standard operating procedures in place to ensure quality assurance and/or quality control programs were developed and/or followed.

32. On or about November 10, 2025, Respondent participated in a subject interview with Board investigators. During this interview, Respondent admitted Companion's compounding activities taking place in Respondent's clean room were under Respondent's direction. However, Respondent admitted he was not familiar with the compounding process and sterility requirements. Respondent admitted he relied on Companion to oversee and operate the compounding process taking place in Respondent's clean room and relied on Companion to obtain all the materials necessary for the compounding process. According to Respondent, Companion developed the formulas for the compounded drugs and frequently changed the labels used on the vials of the compounded drugs.

33. During the subject interview, Respondent admitted he was not aware of the quantity of drugs compounded by Companion in Respondent's clean room, nor was he aware of the types of other drugs Companion was also compounding in Respondent's clean room. Respondent admitted he did not have records to document the compounded drugs prepared in his clean room.

34. During the subject interview, Respondent further admitted he was aware Companion was facing licensing issues with the Board of Pharmacy and was aware Companion surrendered his pharmacist license, but that he continued to allow Companion to continue compounding semaglutide with L-carnitine and tirzepatide with L-carnitine for Respondent to dispense to Respondent's patients in Respondent's clean room.

35. At no time while Companion engaged in compounding activities in Respondent's clean room under Respondent's direction did Respondent implement procedures and/or protocols to ensure the compounded drugs prepared by Companion and the unidentified person were prepared in accordance with state and federal statutes and regulations to ensure the compounded drugs were properly labeled, unadulterated and sterile.

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

36. Respondent has subjected his Physician's and Surgeon's Certificate No. A 73894 to disciplinary action under sections 2227 and 2234, as further defined by section 2234, subdivision (b), of the Code, in that Respondent committed gross negligence in his medical practice when he directed and/or engaged in compounding, administering, and/or dispensing dangerous drugs, as more particularly alleged hereinafter.

37. Paragraphs 23 through 35, above, are hereby incorporated by reference and realleged as if fully set forth herein.

38. Respondent directed and/or engaged in compounding, administering, and/or dispensing dangerous drugs in a manner that failed to comply with labeling and dispensing requirements for compounded medications as provided for in numerous federal and/or state regulations and statutes regulating sterile compounding of dangerous drugs, including, but not limited to, USP 797, sections 4076 and 4170 of the Code, and sections 1736.13 and 1707.5 of title 16 of the California Code of Regulations. Specifically, Respondent failed to properly label compounded medications by failing to include patient names, prescriber name, date of issue, directions for use, identifying information for the prescription, and/or condition or purpose of the prescription; and, Respondent failed to ensure all compounded medications were dispensed by Respondent himself, that the compounded medications were necessary for treatment, and that compounded medications were packaged in accordance with good pharmaceutical practice, including the use of childproof containers.

SECOND CAUSE FOR DISCIPLINE

(Compounding Dangerous Drugs in Violation of State and/or Federal Laws and/or Regulations Regarding Dangerous Drugs)

39. Respondent has further subjected his Physician's and Surgeon's Certificate No. A 73894 to disciplinary action under sections 2227 and 2234, as further defined by section 2238, of the Code, section 1736.13 of title 16 of the California Code of Regulations, section 353a of

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title 21 of the U.S. Code, and USP 797, in that Respondent violated state and/or federal laws and/or regulations regarding dangerous drugs, as more particularly alleged hereinafter.

40. Paragraphs 23 through 35, above, are hereby incorporated by reference and realleged as if fully set forth herein.

41. Respondent failed to comply with section 1.1.2 of USP 797 by failing to implement procedures and protocols to clean and disinfect the compounding environment to ensure biohazard materials did not cross contaminate the compounded medications.

42. Respondent failed to comply with section 2 of USP 797 by failing to ensure his office staff demonstrated the necessary knowledge and competence in sterile compounding practices.

43. Respondent failed to comply with section 3.1 of USP 797 by failing to implement procedures and protocols to require proper personnel preparation prior to entering the compounding environment, including, but not limited to, the requirement to remove all outer garments, cosmetics, exposed jewelry, etc.

44. Respondent failed to comply with section 3.2 of USP 797 by failing to provide the necessary equipment to allow staff entering the compounding environment to perform the necessary hand hygiene procedures, including, but not limited to, a hands-free faucet, a disposable nail cleaner and low-lint disposable towels or wipers.

45. Respondent failed to comply with section 3.3 of USP 797 by failing to implement procedures and protocols to require proper garbing requirements, including, but not limited to, requiring low-lint garment with sleeves that fit snugly around the wrists, an enclosed neck, low-lint covers for shoes, low-lint covers for hair and ears, etc.

46. Respondent failed to comply with sections 4, 4.2.2, 4.2.4, 4.2.5, 4.2.6, and 4.3 of USP 797 by failing to ensure his compounding environment satisfied the necessary requirements to ensure his facilities were designed, outfitted, and maintained properly to minimize the risk for contamination, including, but not limited to, failing to show any certification to show his

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compounding environment met the necessary ISO[1] classifications, air exchange requirements, pressure differentials, and areas with easily cleanable conditions.

47. Respondent failed to comply with section 5 of USP 797 by failing to obtain an independent certification that included airflow testing, HEPA filter integrity testing, total particle count testing, and dynamic airflow smoke pattern test.

48. Respondent failed to comply with section 6 of USP 797 by failing to maintain documentation to show microbiological air and surface monitoring procedures were implemented.

49. Respondent failed to comply with section 7 of USP 797 by failing to implement procedures and protocols to require disinfecting with sporicidal disinfection in Respondent's cleanroom.

50. Respondent failed to comply with section 8 of USP 797 by failing to implement procedures and protocols to require disinfecting with sporicidal disinfectant of any items introduced into Respondent's cleanroom.

51. Respondent failed to comply with section 9 of USP 797 by failing to implement procedures and protocols to ensure all equipment and supplies in direct contact with compounding medications were sterilized and depyrogenated.[2]

52. Respondent failed to comply with section 10 of USP 797 by failing to implement procedures and protocols to ensure his office staff received the necessary training and maintained competence in sterilization and depyrogenation methods.

53. Respondent failed to comply with section 10.2 of USP 797 by failing to implement procedures and protocols to sterilize the API.

54. Respondent failed to comply with section 11 of USP 797 by failing to create a master formulation record and compounding record before allowing compounding of medications from nonsterile ingredients.

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[1] ISO refers to air cleanliness classifications established by the International Organization for Standardization (ISO) with classifications ranking from 1 through 9 based upon the number of airborne particles per cubic meter, ISO class 1 being the lowest.

[2] Depyrogenation is a process in which high temperatures are used to remove pyrogens, or endotoxins. In contrast to sterilization, which destroys all viable microorganisms, depyrogenation removes the remaining debris.

55. Respondent failed to comply with section 12 of USP 797 by failing to implement procedures and protocols to require visual inspection of the compounded medications during the compounding process and sterility testing.

56. Respondent failed to comply with section 13 of USP 797 by failing to label all compounded medications contained in vials and syringes with the necessary identifying information, including, but not limited to, storage conditions, dosage form, and notation that the vials were multiple-dose containers.

57. Respondent failed to comply with sections 14 and 14.3 of USP 797 by failing to consider the compounding environment when determining the Beyond-Use-Date (BUD) for each compounded medication, instead assigning 180-day BUD to all compounded medications, instead of 4 hours.

58. Respondent failed to comply with section 17 of USP 797 by failing to establish standard operating procedures for his compounding activities.

59. Respondent failed to comply with section 18 of USP 797 by failing to develop, establish and/or follow a quality assurance and quality control programs in the standard operating procedures for his compounding activities to ensure all aspects of compounding were in accordance with USP 797.

60. Respondent failed to comply with section 20 of USP 797 by failing to maintain any documentation to demonstrate compliance with USP 797.

THIRD CAUSE FOR DISCIPLINE

(Labeling Dangerous Drugs in Violation of State and/or Federal Laws and/or Regulations Regarding Dangerous Drugs)

61. Respondent has further subjected his Physician's and Surgeon's Certificate No. A 73894 to disciplinary action under sections 2227 and 2234, as further defined by sections 2234, subdivision (a), 2238, 4076, and 4170, subdivision (a)(4), of the Code, and sections 1707.5, subdivision (a), and 1736.13 of title 16 of the California Code of Regulations, in that Respondent violated state and/or federal laws and/or regulations regarding dangerous drugs, as more particularly alleged hereinafter.

62. Paragraphs 23 through 60, above, are hereby incorporated by reference and realleged as if fully set forth herein.

63. Respondent failed to ensure compounded drugs prepared in his medical office contained all required labeling components, including, but not limited to:

A. Directions for the use of the drug, name of the patient, name of the prescriber, date of issue, name and address of the pharmacy and prescription number, and condition or purpose for which the drug was prescribed, in violation of Code sections 4170 and 4076; and

B. Name of the patient, directions for use of the drug, and the condition or purpose for which the drug was prescribed, and route of intended administration, in violation of sections 1707.5 and 1736.13 of title 16 of the California Code of Regulations.

FOURTH CAUSE FOR DISCIPLINE

(Dispensing and/or Administering Dangerous Drugs in Violation of State and/or Federal Laws and/or Regulations Regarding Dangerous Drugs)

64. Respondent has further subjected his Physician's and Surgeon's Certificate No. A 73894 to disciplinary action under sections 2227 and 2234, as further defined by sections 2234, subdivision (a), 2238 and 4170, of the Code, in that Respondent dispensed and/or administered dangerous drugs in violation of state and/or federal laws and/or regulations regarding dangerous drugs, as more particularly alleged hereinafter.

65. Paragraphs 23 through 63, above, are hereby incorporated by reference and realleged as if fully set forth herein.

66. Respondent failed to ensure compounded drugs prepared in his medical office were dispensed and/or administered in accordance with section 4170 of the Code, by, among other things, allowing staff to dispense and/or administer the compounded drugs to Respondent's patients, failing to comply with all labeling requirements imposed by section 4076 of the Code, and failing to package the compounded medications in childproof containers.

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FIFTH CAUSE FOR DISCIPLINE

(Dispensing and/or Administering Adulterated Dangerous Drugs in Violation of State and/or Federal Laws and/or Regulations Regarding Dangerous Drugs)

67. Respondent has further subjected his Physician's and Surgeon's Certificate No. A 73894 to disciplinary action under sections 2227 and 2234, as further defined by sections 2234, subdivision (a), 2238, and 4169, subdivision (a)(2), of the Code, section 111295 of the Health and Safety Code, and section 351 of title 21 of the U.S. Code, in that Respondent dispensed and/or administered adulterated drugs in violation of state and/or federal laws and/or regulations regarding dangerous drugs, as more particularly alleged in paragraphs 23 through 66, above, which are hereby incorporated by reference and realleged as if fully set forth herein.

SIXTH CAUSE FOR DISCIPLINE

(Dispensing and/or Administering Misbranded Dangerous Drugs in Violation of State and/or Federal Laws and/or Regulations Regarding Dangerous Drugs)

68. Respondent has further subjected his Physician's and Surgeon's Certificate No. A 73894 to disciplinary action under sections 2227 and 2234, as further defined by sections 2234, subdivision (a), 2238, and 4169, subdivision (a)(3), of the Code, and sections 111330 and 111440 of the Health and Safety Code, in that Respondent dispensed and/or administered misbranded drugs in violation of state and/or federal laws and/or regulations regarding dangerous drugs, as more particularly alleged in paragraphs 23 through 67, above, which are hereby incorporated by reference and realleged as if fully set forth herein.

PRAYER

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

1. Revoking or suspending Physician's and Surgeon's Certificate No. A 73894, issued to Respondent Ronald Scott Cohen, M.D.;
2. Revoking, suspending or denying approval of Respondent Ronald Scott Cohen, M.D.'s authority to supervise physician assistants and advanced practice nurses;

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3. Ordering Respondent Ronald Scott Cohen, M.D., to pay the Board the costs of the investigation and enforcement of this case, and if placed on probation, the costs of probation monitoring; and

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

DATED: JUN 10 2026

for

REJI VARGHESE
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

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