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

In the Matter of the Accusation Against: **HARROW HEALTH INC.** **DBA IMPRIMIS NJOF LLC;** **JOHN PHILLIP SAHAREK, PRESIDENT** **1705 Route 46, Ste. 6B** **Ledgewood, NJ 07862** **Nonresident Outsourcing Facility Permit No. NSF 133** **HARROW HEALTH INC.** **and IMPRIMISRX NJ LLC** **DBA IMPRIMISRX** **JOHN PHILLIP SAHAREK, PRESIDENT** **1705 Route 46, Ste. 4** **Ledgewood, NJ 07854** **Nonresident Pharmacy Permit No. NRP 2062** **Nonresident Sterile Compounding Permit No. NSC 101151** Respondents.	Case No. 7456 **FIRST AMENDED ACCUSATION**

PARTIES

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

2. On or about December 9, 2019, the Board issued Nonresident Outsourcing Facility Permit number NSF 133 to Harrow Health Inc. doing business as (dba) Imprimis NJOF LLC; John Phillip Saharek, President (Respondent Outsourcer). The Nonresident Outsourcing Facility Permit was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2025, unless renewed.

3. On or about April 10, 2019, the Board issued Nonresident Pharmacy Permit number NRP 2062 to Harrow Health Inc., 100% shareholder and ImprimisRX NJ LLC dba ImprimisRx, John Phillip Saharek, President (Respondent Pharmacy). The Nonresident Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2026, unless renewed.

4. On or about April 10, 2019, the Board issued Nonresident Sterile Compounding Pharmacy Permit number NSC 101151 to Harrow Health Inc., 100% shareholder, and ImprimisRX NJ LLC dba ImprimisRx, John Phillip Saharek, President (Respondent Pharmacy). The Nonresident Sterile Compounding Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2026, unless renewed.

JURISDICTION

5. 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.

6. Section 4300 of the Code states in pertinent part:

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

7. 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.

8. Code section 4011 states:

The board shall administer and enforce this chapter and the Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).

9. Code section 4302 states:

The board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee.

10. Code section 4303 states in pertinent part:

(b) The board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.

11. Code section 4307 states in pertinent part:

(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 in any other position 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.

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STATUTORY PROVISIONS

12. Section 4301 of the Code states:

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:

…

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

…

(j) 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.

…

13. 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.

14. Section 4059 of the Code states in pertinent part:

(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

…

15. Section 4126.8 of the Code states:

The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding drug preparations.

16. Section 4129.2 of the Code states in pertinent part:

…

(b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.

…

(e) A nonresident outsourcing facility licensed pursuant to this section shall provide the board with all of the following:

(1) A copy of any disciplinary or other action taken by another state or the FDA within 10 days of the action.

…

17. Section 4156 of the Code states:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

18. Section 4169 of the Code states in pertinent part:

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

…

(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.

…

HEALTH AND SAFETY CODE

19. Health and Safety Code section 111250 states:

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 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

21. Health and Safety Code section 111285 states:

Any drug or device is adulterated if its strength differs from, or its purity or quality is below, that which it is represented to possess.

22. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

23. Health and Safety Code section 111335 states:

Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

24. Health and Safety Code section 111550 states in pertinent part:

No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:

(a) It is one of the following:

(1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).

(2) A new biologic product for which a license has been issued as required by the federal Public Health Service Act (42 U.S.C. Sec. 262).

…

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(b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended.

…

FEDERAL REGULATIONS

25. Code of Federal Regulations (C.F.R.), title 21, section 211.22 states:

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

(b) Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit.

(c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

(d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.

26. C.F.R., title 21, section 211.25 states:

(a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

(b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.

(c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product.

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27. C.F.R., title 21, section 211.42 states in pertinent part:

(c) Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures:

…

(10) Aseptic processing, which includes as appropriate:

…

A system for monitoring environmental conditions;

…

28. C.F.R., title 21, section 211.67 states:

(a) Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

(b) Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following:

(1) Assignment of responsibility for cleaning and maintaining equipment;

(2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules;

(3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;

(4) Removal or obliteration of previous batch identification;

(5) Protection of clean equipment from contamination prior to use;

(6) Inspection of equipment for cleanliness immediately before use.

(c) Records shall be kept of maintenance, cleaning, sanitizing, and inspection as specified in §§ 211.180 and 211.182.

29. C.F.R., title 21, section 211.68 states in pertinent part:

…

(b) Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Input to and output from the computer or related system of formulas or other records or data shall be checked for accuracy. The degree and frequency of input/output verification shall be based on the complexity

and reliability of the computer or related system. A backup file of data entered into the computer or related system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes. In such instances a written record of the program shall be maintained along with appropriate validation data. Hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and that it is secure from alteration, inadvertent erasures, or loss shall be maintained.

…

30. C.F.R., title 21, section 211.84 states in pertinent part:

(a) Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit.

…

(d) Samples shall be examined and tested as follows:

(2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

…

31. C.F.R., title 21, section 211.100 states, in pertinent part:

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

…

32. C.F.R., title 21, section 211.103 states:

Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment under § 211.68, be independently verified by one person.

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33. C.F.R., title 21, section 211.113 states, in pertinent part:

…

(b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes.

34. C.F.R., title 21, section 211.137 states in pertinent part:

(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in § 211.166. (b) Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process

…

35. C.F.R., title 21, section 211.150 states in pertinent part:

Written procedures shall be established, and followed, describing the distribution of drug products. They shall include:

…

(b) A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary.

36. C.F.R., title 21, section 211.160 states in pertinent part:

…

(b) Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(1) Determination of conformity to applicable written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adequately identified. Such procedures shall also require appropriate retesting of any component, drug product container, or closure that is subject to deterioration.

(2) Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples shall be representative and properly identified.

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(3) Determination of conformance to written descriptions of sampling procedures and appropriate specifications for drug products. Such samples shall be representative and properly identified.

(4) The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used.

37. C.F.R., title 21, section 211.166 states in pertinent part:

(a) There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include:

(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability;

(2) Storage conditions for samples retained for testing;

(3) Reliable, meaningful, and specific test methods;

(4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed;

(5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted.

…

38. C.F.R., title 21, section 211.192 states:

All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup.

39. C.F.R., title 21, section 211.198 states:

(a) Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an

investigation in accordance with § 211.192. Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with §§ 310.305 and 514.80 of this chapter.

(b) A written record of each complaint shall be maintained in a file designated for drug product complaints. The file regarding such drug product complaints shall be maintained at the establishment where the drug product involved was manufactured, processed, or packed, or such file may be maintained at another facility if the written records in such files are readily available for inspection at that other facility. Written records involving a drug product shall be maintained until at least 1 year after the expiration date of the drug product, or 1 year after the date that the complaint was received, whichever is longer. In the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, such written records shall be maintained for 3 years after distribution of the drug product.

(1) The written record shall include the following information, where known: the name and strength of the drug product, lot number, name of complainant, nature of complaint, and reply to complainant.

(2) Where an investigation under § 211.192 is conducted, the written record shall include the findings of the investigation and followup. The record or copy of the record of the investigation shall be maintained at the establishment where the investigation occurred in accordance with § 211.180(c).

(3) Where an investigation under § 211.192 is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination.

STATE REGULATIONS

40. California Code of Regulations, title 16, (Regulations) section 1711 states in pertinent part:

…

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy.

41. Regulations section 1735.1 states in pertinent part:

…

(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

…

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42. Regulations section 1735.2 states in pertinent part:

…

(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

43. Regulations section 1751.7 states in pertinent part:

…

(e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), 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. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

44. Regulations section 1793.1 states:

Only a pharmacist, or an intern pharmacist acting under the supervision of a pharmacist, may:

(a) Receive a new prescription order orally from a prescriber or other person authorized by law.

(b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(c) Identify, evaluate and interpret a prescription.

(d) Interpret the clinical data in a patient medication record system or patient chart.

(e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.

(f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

(g) Perform all functions which require professional judgment.

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45. Regulations section 1793.3 states in pertinent part:

(a) In addition to employing a pharmacy technician to perform the tasks specified in section 1793.2, a pharmacy may employ a non-licensed person to type a prescription label or otherwise enter prescription information into a computer record system, but the responsibility for the accuracy of the prescription information and the prescription as dispensed lies with the registered pharmacist who initials the prescription or prescription record. At the direction of the registered pharmacist, a non-licensed person may also request and receive refill authorization.

(b) A pharmacist may supervise the number of non-licensed personnel performing the duties specified in subdivision (a) that the pharmacist determines, in the exercise of his or her professional judgment, does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law.

NEW JERSEY STATE LAW AND REGULATION

46. New Jersey Pharmacy Practice Act, title 45, section 45:14-75 states in pertinent part:

…

b. The board may suspend, revoke, deny, restrict, or refuse to renew the permit of any pharmacy practice site on any of the following grounds:

(1) Findings by the board that any conduct of the permit holder or applicant is violative of any federal, State, or local laws or regulations relating to the practice of pharmacy;

…

(9) Violation of any of the provisions of the "New Jersey Controlled Dangerous Substance Act," P.L.1970, c.226 (C.24:21-1 et seq.) by the applicant, permit holder or occurring at the pharmacy practice site; or…

47. New Jersey Administrative Code, title 13, Law and Public Safety, Chapter 39, section 13:39-4.18 states:

a) All permit holders shall be responsible for compliance with all the rules, regulations and laws governing the practice of pharmacy.

b) Any permit holder may be held liable for violations of the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., and the rules in this chapter and may be subject to disciplinary action.

48. New Jersey Administrative Code, title 13, Law and Public Safety, Chapter 39, section 13:39-6.5 states:

a) A pharmacy intern, pharmacy extern, pharmacy technician, or pharmacy technician applicant in any pharmacy may perform the component functions of prescription handling described in N.J.A.C. 13:39-4.19, consistent with the requirements of this chapter. All steps performed by a pharmacy technician, pharmacy technician applicant, pharmacy intern, or pharmacy extern shall be documented in the pharmacy audit trail consistent with the requirements of N.J.A.C. 13:39-7.6.

b) Pharmacy interns and pharmacy externs may assist the pharmacist in performing the following tasks:

1) Retrieval of prescription files, patient files, and profiles and other such records pertaining to the practice of pharmacy;

2) Data entry of prescription medication information, including the original or refill date of the prescription, the number or designation identifying the prescription, the practitioner's information, and the name, strength, and quantity of the prescribed medication;

3) The collection of the following demographic information for the patient profile: the name, address, and telephone number of the patient; the patient's age, date of birth; or age group (infant, child, adult); gender; any allergies and idiosyncrasies of the patient; and any medical conditions that may relate to drug utilization;

4) Transcription of scanned prescription or medication order information into the patient record;

5) Label preparation;

6) The counting, weighing, measuring, pouring, and compounding of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system; and

7) Accepting authorization from a patient for a prescription refill, or from a practitioner or his or her agent for a prescription renewal, provided that the prescription remains unchanged.

c) The collection of the demographic information under (b)3 above may be performed by unlicensed or unregistered personnel.

49. New Jersey Administrative Code, title 13, Law and Public Safety, Chapter 39, section 13:39-7.1 states in pertinent part:

a) A pharmacist shall only fill a prescription issued by a practitioner licensed to issue prescriptions in New Jersey and practicing in New Jersey if the prescription is on a New Jersey Uniform Prescription Blank pursuant to N.J.S.A. 45:14-55 and N.J.A.C. 13:45A27, except as provided in N.J.A.C. 13:39-7.10 and 7.11.

50. New Jersey Administrative Code, title 13, Law and Public Safety, Chapter 39, section 13:39-7.5 states in pertinent part:

a) No drug or medicine other than a compounded prescription order, consistent with (c) below, shall be sold or dispensed in any pharmacy within the State of New Jersey until such drug or medicine has received New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Investigational New Drug Application (INDA) or other Federal Food and Drug Administration (FDA) approval, where required.

51. New Jersey Administrative Code, title 13, Law and Public Safety, Chapter 39, section 13:39-11.23 states in pertinent part:

> a) The pharmacy's policy and procedures manual shall set forth in detail the pharmacy's standard operating procedures with regard to compounded sterile preparations.
>
> b) The policy and procedures manual shall include policies and procedures governing the following:
>
> 1) A risk-management program, including, but not limited to, documentation of incidents, adverse drug reactions, and product contamination.
>
> …
>
> 9) A quality assurance program as set forth in N.J.A.C. 13:39-11.24;
>
> …

52. New Jersey Administrative Code, title 13, Law and Public Safety, Chapter 39, section 13:39-11.24 states in pertinent part:

> a) The pharmacy's quality assurance program shall require, at a minimum, that:
>
> 1) A reasonable effort shall be made by the pharmacist to assure that compounded sterile preparations shall be kept under appropriate controlled conditions at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration as set forth by the product manufacturer, with each compounded sterile preparation dispensed;
>
> 2) The quality assurance program encompasses all phases of sterile compounding for each unique type of compounded sterile preparation dispensed;
>
> 3) After the preparation of every admixture, the contents of the container are thoroughly mixed and then visually inspected to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, or any other defects, and the accuracy and thoroughness of labeling;
>
> 4) All pharmacists, pharmacy technicians, pharmacy interns, and pharmacy externs involved in compounding sterile preparations shall have their aseptic technique tested consistent with the requirements of N.J.A.C. 13:39-11.16;
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> 5) All high-risk level compounded sterile preparations that are prepared in groups of more than 25 identical individual single-dose packages (for example, ampules, bags, syringes, vials), or in multiple-dose vials for administration to multiple patients, or that are exposed longer than 12 hours at two degrees to eight degrees Celsius and longer than six hours at warmer than eight degrees Celsius before they are sterilized, and all compounded sterile preparations whose beyond-use date has been exceeded, shall be tested to ensure that they are sterile before they are dispensed or administered. The USP membrane filtration method shall be used where feasible. Another method may be used if verification results demonstrate that the alternative is at least as effective and reliable as the membrane filtration method or the USP direct inoculation of the culture medium method, consistent with the

standards set forth in USP 797 concerning "Sterility Testing," 2012 edition, incorporated herein by reference, as amended and supplemented, and available for purchase at the United States Pharmacopeia website, www.usp.org.

i. When high-risk level compounded sterile preparations are dispensed before receiving the results of the sterility tests set forth in (a)5 above, the written quality assurance procedure shall require daily observation of the incubating test specimens and immediate recall of the dispensed compounded sterile preparations when there is any evidence of microbial growth in the test specimens. The patient and the physician of the patient to whom a potentially contaminated compounded sterile preparation was administered shall be notified immediately of the potential risk. Positive sterility tests shall require rapid and systematic investigation of aseptic technique, environmental control, and other sterility assurance controls in order to identify sources of contamination and to take corrective action.

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COST RECOVERY

53. 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.

INTRODUCTION

54. This case is about the compounding of prescription drugs, including those designated for sterile administration, in either a pharmacy or an outsourcing facility. Compounding is a form of drug manufacturing subject to the drug manufacturing requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 301 et seq.].

55. No drug may be manufactured and sold within the United States without going through the Food and Drug Administration (FDA) new drug approval process under Section 505 of the federal act (21 U.S.C. § 355). California law has a similar new drug approval law which defers to the federal statute. (Health and Safety Code § 111550.) New Jersey law also has a similar new drug approval law which also defers to the federal statute. (New Jersey Administrative Code, title 13, Law and Public Safety, Chapter 39, § 13:39-7.5.)

56. There is an exception to the new drug approval process in federal law for sterile compounding pharmacies and outsourcing facilities, known as the 503A exception for sterile compounding pharmacies and the 503B exception for outsourcing facilities. (21 U.S.C. §§ 353a,

353b.) Under these exceptions, sterile compounding pharmacies and outsourcing facilities may perform sterile and nonsterile compounding of drugs that are not approved by the FDA, so long as they follow the restrictions and guidelines set forth in their respective exceptions.

57. For outsourcing facilities, the facility must register as an outsourcing facility with the FDA and compound all drugs in accordance with current good manufacturing practices (CGMP), among other compounding-specific requirements.

58. For sterile compounding pharmacies, the pharmacy must be licensed by the state in which they are physically located, as well as licensed by any other state as a nonresident pharmacy if the pharmacy intends to dispense, mail, ship, or otherwise deliver drugs into that state. There are additional compounding specific requirements similar to the compounding requirements for outsourcing facilities with one major difference being that sterile compounding pharmacies are not required to follow CGMP. Instead, sterile compounding pharmacies follow United States Pharmacopeia (USP) chapters which provide independent, peer-reviewed guidance for handling non-sterile compounding, sterile compounding, hazardous compounding, drug product testing, quality assurance, and much more. USP chapters essentially set an industry standard in these matters.

59. Compounds may be either "non-sterile" or "sterile," depending on the intended route of drug administration. Sterile drugs are those intended for parenteral administration (i.e., other than through the digestive system), including injectables and ophthalmic or inhalation drugs in aqueous format. It is important that these drugs be sterile and uncontaminated, because they bypass some of the body's natural defenses against pathogens and impurities.

60. Both sterile compounding pharmacies and outsourcers are prohibited from compounding any drug that is essentially a copy of an already approved drug. Thus, any drug already approved by the FDA shall not be compounded.[1] Non-FDA-approved drugs pose a greater risk to patients than FDA-approved drugs. These drugs have not undergone FDA review for safety, effectiveness, or quality, and have not been inspected for manufacturing quality, unlike

[1] There are limited exceptions, the most commonly used exception is if the drug being compounded is on the drug shortage list maintained online by the FDA at the time of compounding, distributing, and dispensing.

FDA-approved drugs. Due to this greater risk, drugs should only be compounded to fulfill the needs of patients whose medical needs cannot be met by an FDA-approved drug.

61. An outsourcing facility is also prohibited from wholesaling, so the facility may not compound any drug if the drug will be sold by any entity other than the outsourcing facility that compounded the drug. In other words, the facility must sell, dispense, or otherwise deliver the drug directly to the end user, which may be the patient or may be to a prescriber or health clinic for administration in a clinic, hospital, or prescriber's office setting.

62. Prior to January 1, 2022, outsourcing facilities registered in California were prohibited from acting as a pharmacy, specifically they could not sell drugs directly to an individual patient. Outsourcing facilities could only sell their compounded drugs to a prescriber or other health care facility for administration to the patients of that prescriber or health care facility. On January 1, 2022, the law changed, and now currently allows outsourcing facilities to also dispense drugs to a prescriber or to a patient pursuant to a patient-specific prescription written by a prescriber who is licensed in the State of California.

63. Sterile compounding pharmacies, by contrast, are primarily pharmacies with an additional permit to perform sterile compounding. Pharmacies, and by extension, sterile compounding pharmacies may only dispense drugs to patients pursuant to patient-specific prescriptions.

64. Respondent Outsourcer and Respondent Pharmacy both have physical locations in the State of New Jersey. Therefore, they both have nonresident licenses in the State of California. Based on Code section 4303, subdivision (b), in order for discipline to be imposed by the California Board, any violation under California law that is a cause for discipline must also be a violation under New Jersey law. In this case, the California laws, rules, and regulations cited all have parallel statutes or regulations in New Jersey law.

NOVEMBER 30, 2022, INVESTIGATION REPORT (CI 2021 94550)

65. On or about December 22, 2021, A.H., a customer care representative, received a complaint from a patient about mold in the cap of her sterile compounded eye drops. A.H. is not

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licensed as a pharmacist, was not supervised by a pharmacist, and was working in an unlicensed call center located separately from Respondent Outsourcer and Respondent Pharmacy.

66. On or about December 28, 2021, A.Z., a quality assurance specialist forwarded the customer complaint to F.Z., a quality assurance post market surveillance specialist. Neither A.Z. nor F.Z. are licensed as a pharmacist, and were not supervised by a pharmacist, and were working in an unlicensed call center located separately from Respondent Outsourcer and Respondent Pharmacy.

67. Despite all three of the individuals who had handled this patient's complaint not being licensed as a pharmacist, one of them was apparently able to process a replacement order and approve a shipment of this prescription medication to the patient without the involvement of any licensed pharmacist.

68. F.Z. determined, by reviewing the patient's complaint, without any input from a pharmacist, that the mold under the cap was likely caused by the patient contaminating the container.

69. Between January 24, 2022, and February 3, 2022, K.F., a pharmacist employed by Respondent Outsourcer became involved with this complaint and apparently reached out to the patient, though no response by the patient was documented. On February 3, 2022, K.F. and F.Z. signed off on the patient complaint and considered the matter closed. At no time was any staff employed by Respondent Pharmacy contacted, even though Respondent Pharmacy had dispensed the medication.

70. During the Board's investigation, Inspector P.P-S. requested Respondent Outsourcer to provide information about the relationship between Respondent Outsourcer and Respondent Pharmacy, and information about the unlicensed call center, which Respondent Outsourcer refers to as the "customer service department."

71. Respondent Outsourcer explained that they do not sell directly to the patients. Instead, they transfer all of their stock of compounded medications to Respondent Pharmacy for dispensing. However, Respondent Outsourcer frequently gets complaint calls because their contact information is on the medication label as required by law.

72. Respondent Outsourcer and Respondent Pharmacy essentially "share" the unlicensed call center personnel, with some being designated to one Respondent or the other, but the unlicensed call center is not located in a licensed location. Additionally, there were at least two unlicensed call center locations, designated as "north" and "south." Later, a corporate organization chart was provided which showed unlicensed call centers in Nashville, Tennessee and Tijuana, Mexico. The call center in Tijuana, Mexico, is noted to be an outsourced call center.

73. During the Board's investigation, Inspector P.P-S. also requested the policies and procedures for Respondent Outsourcer's unlicensed call center, and for the complaint intake and quality control units. Respondent Outsourcer responded that they had no policies or procedures for the unlicensed call center and they "worked off training documents." Respondent Outsourcer provided policies and procedures for their "product complaint handling" but the policies and procedures were on Respondent Pharmacy's letterhead and referenced Boards of Pharmacy. The policies and procedures provided no training for staff relating to CGMP or complaint handling, any staff or contractors were authorized to receive, review, and assess product complaints, and it is unclear if the individuals analyzing complaints work for Respondent Outsourcer, Respondent Pharmacy, the unlicensed call center, or any combination of the three.

74. During the Board's investigation, Inspector C.A. requested information from Respondent Pharmacy including policies and procedures. Respondent Pharmacy provided policies and procedures on complaint handling that allowed unlicensed individuals working in unlicensed spaces to receive and process prescriptions remotely, determine whether there was sufficient information to bill the prescription, make calls to clarify prescriptions, determine if a replacement drug product is needed and contact the marketing department to cease marketing and sales within 24 hours.

75. Dispensing records from Respondent Pharmacy also showed it had dispensed 11 prescriptions to patients with invalid prescriptions in that the prescriber did not hold an active California license.

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FIRST CAUSE FOR DISCIPLINE

(Failure to Comply with CGMP: Lack of Complaint Procedures)

76. Respondent Outsourcer is subject to disciplinary action pursuant to Code sections 4301, subdivisions (j) and (o), and 4129.2, for violating laws regulating dangerous drugs and for failing to follow laws, rules, and regulations governing the practice of pharmacy, by failing to comply with CGMP when compounding, in conjunction with 21 C.F.R. section 211.198, subdivisions (a) and (b). The circumstances are as follows:

77. Respondent's staff was not trained and was not properly supervised when completing complaint forms and following up on complaints. There are no written procedures by Respondent that included provisions for review by the quality control unit, or for the quality control unit to make a determination as to the need for an investigation in accordance with 21 C.F.R. section 211.192. Finally, the procedures failed to include any review to determine whether the complaint represented a serious and unexpected adverse drug experience, which is required to be reported to the Food and Drug Administration.

SECOND CAUSE FOR DISCIPLINE

(Failure to Have Qualified Personnel)

78. Respondent Outsourcer is subject to disciplinary action pursuant to Code sections 4301, subdivisions (j) and (o), and 4129.2, for violating laws regulating dangerous drugs and for failing to follow laws, rules, and regulations governing the practice of pharmacy, by failing to comply with CGMP when compounding, in conjunction with 21 C.F.R. section 211.25, subdivision (a), setting forth the qualifications necessary for compounding personnel. The circumstances are as follows:

79. Respondent Outsourcer had untrained and unsupervised staff completing complaint forms and following up on complaints. The staff taking complaint calls had no CGMP training and were not located at Respondent Outsourcer's facility. Respondent Outsourcer's policies and procedures for complaint calls was generic across multiple entities with different, or no, licenses, and contained no mention of CGMP controls.

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THIRD CAUSE FOR DISCIPLINE

(Failure to Have Qualified Personnel)

80. Respondent Outsourcer is subject to disciplinary action pursuant to Code sections 4301, subdivisions (j) and (o), and 4129.2, for violating laws regulating dangerous drugs and failing to follow laws, rules, and regulations governing the practice of pharmacy, by failing to comply with CGMP when compounding, in conjunction with 21 C.F.R. section 211.22, subdivision (a), setting forth the responsibilities of the quality control unit. The circumstances are as follows:

81. Respondent Outsourcer had untrained and unsupervised staff completing complaint forms and following up on complaints. The staff taking complaint calls had inadequate CGMP training and were not located at Respondent Outsourcer's facility. The quality control unit had inadequate control over the untrained and unsupervised staff that worked from remote locations outside of Respondent Outsourcer's facility.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Quality of Compounded Sterile Preparations)

82. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for failing to follow laws, rules, and regulations governing the practice of pharmacy, specifically Regulations section 1735.1(ae), and Health and Safety Code section 111255, maintaining the quality of compounded preparations, in that Respondent Pharmacy compounded non-sterile to sterile injectable drugs with an ungraded[2] chemical, DMPS Sodium PF. This was true at least for lot number 021820022@2, which was dispensed into California between February 22, 2022 and November 1, 2022, pursuant to 58 prescription, for a total of 2,080ml, or 408 vials. This is also likely to be true for an additional 280 prescriptions, 9,930ml, and 1,986 vials. This caused the compounded drug product to be produced in a manner whereby it may have been contaminated or may have been rendered injurious to health.

[2] Drug products are manufactured for a certain use such as dietary or pharmaceutical. This is sometimes referred to as the "grade" of the product, i.e. "dietary grade" or "pharmaceutical grade" when a product has no use specified, it is considered to be ungraded and not manufactured to any known specification.

FIFTH CAUSE FOR DISCIPLINE

(Offering for Sale an Adulterated Drug)

83. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for failing to follow laws, rules, and regulations governing the practice of pharmacy, specifically Code section 4169, subdivision (a)(2), and Health and Safety Code sections 111250, 111255, and 111295, by dispensing adulterated drugs, specifically DMPS Sodium PF, which was a non-sterile to sterile injection compounded with an ungraded chemical. This was true at least for lot number 021820022@2, which was dispensed into California between February 22, and November 1, 2022, pursuant to 58 prescriptions, for a total of 2,080ml, or 408 vials. This is also likely to be true for an additional 280 prescriptions, 9,930ml, and 1,986 vials.

SIXTH CAUSE FOR DISCIPLINE

(Furnishing a Dangerous Drug Without a Prescription)

84. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for failing to follow laws, rules, and regulations governing the practice of pharmacy, specifically Code section 4059, subdivision (a), in that between September 28, 2021 and August 11, 2022, Respondent dispensed and furnished 11 prescriptions for dangerous drugs that were invalid in that the prescriber was not authorized to prescribe at the time due to her license being in inactive status.

SEVENTH CAUSE FOR DISCIPLINE

(Failing to Perform Compliant End Product Sterility)

85. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for failing to follow laws, rules, and regulations governing the practice of pharmacy, specifically Regulations section 1751.7, subdivision (e)(1), which requires that batch-produced sterile drug preparations shall be subject to USP chapter 71 compliant and pyrogens testing, and shall be quarantined until the testing confirms sterility. Respondent Pharmacy failed to use USP 71 compliant sterility testing, instead using "Scan RDI" a non-USP 71 compliant sterility test. Respondent Pharmacy dispensed at least 33,120ml, 1,104 vials, and 173

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prescriptions of glutathione from lot 02082022@2 into California from approximately February 23, 2022, to March 3, 2022.

EIGHTH CAUSE FOR DISCIPLINE

(Failing to Supervise Non-Licensed Personnel)

86. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for failing to follow laws, rules, and regulations governing the practice of pharmacy, specifically Regulations section 1793.3, subdivisions (a) and (b), which states that non-licensed personnel may type prescription labels or otherwise enter prescription information into a computer record system but the responsibility for the non-licensed personnel's accuracy and the information entered by them lies with the registered pharmacist supervising such non-licensed personnel. Respondent Pharmacy had untrained and unlicensed staff performing duties in unlicensed locations, including a location outside of the United States. The unlicensed, unsupervised staff was responsible for order processing and review, billing, complaint handling, and adverse drug reaction reporting.

NINTH CAUSE FOR DISCIPLINE

(Failing to Have Compliant Quality Assurance Program)

87. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for failing to follow laws, rules, and regulations governing the practice of pharmacy, specifically Regulations section 1711, subdivision (e), which requires licensees to have a robust quality assurance program to advance error prevention, investigate errors, and assess the systems that led to the error so that the systems can be corrected. Respondent Pharmacy failed to do appropriate investigation or data collection, and analysis, failed to determine the cause of medication errors, and failed to attempt to ensure that errors did not recur.

TENTH CAUSE FOR DISCIPLINE

(Unlicensed Personnel Acting as Pharmacist)

88. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for failing to follow laws, rules, and regulations governing the practice of pharmacy, specifically Regulations section 1793.1, which states that only a pharmacist or intern

pharmacist being supervised by a pharmacist may receive new prescription drug orders orally, consult with the patient or patient's agent regarding a prescription or medical information contained in the patient's records, identify, evaluate, and interpret a prescription, interpret clinical data in the patient's medical records, consult with any prescriber, nurse, or other health care professional, supervise the packaging of drugs and check the packaging procedure and product, exercise professional judgment. Respondent Pharmacy allowed unlicensed personnel to process prescription drug orders, review any holds on orders that could delay the processing of the prescription, update and change the patient's information regarding where the drug would be shipped, verify multiple orders by a patient and merge such orders together, open orders, verify HIPAA protocols, access all prescriptions on file, select the prescription to be refilled, and release the prescription to the pharmacy, open a new order on a patient's profile, access the patient's profile, the prescriber's office profile, send refill requests, process refill requests, investigate reasons for replacement prescriptions to be sent, consulting with the patient, pharmacist, and prescriber as needed, fills out complaint forms, create a new order, select the order for dispensing, and release the order to the pharmacy to fill the replacement. Many of these activities require professional judgment in the identification, evaluation, and interpretation of prescriptions.

DECEMBER 21, 2022, INVESTIGATION REPORT (CI 2022 98212)

89. On or about November 10, 2022, the Board was notified of a recall initiated by Respondent Pharmacy for two lots of Timolol-Latanoprost (0.5/0.005)% P-F, an investigation by Board Inspector C.A. therefore ensued.

90. Timolol-Latanoprost (0.5/0.005)% P-F is indicated for the treatment of glaucoma and ocular hypertension, and reduces intraocular pressure (fluid within the eye), it is a dangerous drug pursuant to Code section 4022, but it is not a controlled substance.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Support Beyond Use Date)

91. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for violating laws, rules, and regulations governing the practice of pharmacy, specifically Regulations section 1735.2, subdivision (i), which states that every compounded drug

preparation shall be given a beyond use date (BUD) after which the compounded drug should not be used, stored, transported, or delivered. For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by a method suitability test, a container closure integrity test, and stability studies. Respondent Pharmacy dispensed and delivered to patients sterile compounded Timolol-Latanoprost (0.5/0.005)% P-F with a BUD of 150 days without having a method suitability test, a container closure integrity test, or stability studies. This is true for at least two lots, with 71 prescriptions and 385 ml, but it is expected to also be true for 5 lots, 176 orders, and 975 ml.

TWELFTH CAUSE FOR DISCIPLINE

(Failing to Perform Compliant End Product Sterility Testing)

92. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for failing to follow laws, rules, and regulations governing the practice of pharmacy, specifically Regulations section 1751.7, subdivision (e)(1), which requires that batch-produced sterile drug preparations shall be subject to USP chapter 71 compliant and pyrogens testing, and shall be quarantined until the testing confirms sterility. Between approximately January 1, 2022, and December 12, 2022, Respondent Pharmacy released batch-produced sterile drug preparations of Timolol-Latanoprost (0.5/0.005)% P-F without documented end product testing for sterility. This is true for at least two lots, with 71 prescriptions and 385ml, but it is expected to also be true for 5 lots, 176 orders, and 975ml.

FEBRUARY 7, 2024, INVESTIGATION REPORT (CI 2023 100479)

93. From July 2023 through the date of the Investigation Report, Respondent Outsourcer reported numerous complaints from their patients as to the products compounded by Respondent Outsourcer and dispensed to these patients. An investigation ensued and Inspector P.P-S. was assigned to investigate.

94. Most of the drug products complained of were manufactured by Respondent Outsourcer and dispensed by Respondent Pharmacy.

95. Multiple patients complained that various batches and different types of eye drops caused pain in their eyes and had other side effects including burning, stinging, dry eyes,

insomnia, headache, or a bad taste in the mouth. At least one patient had three different lots of Respondent Outsourcer's eye drops and only experienced these side effects with one of the three.

96. Respondent Outsourcer failed to investigate these patient complaints, informed the patients that these were known and expected side effects, and failed to test any retained product or have patients return the complained-about product for additional testing.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Investigate Complaints of Adverse Drug Reactions)

97. Respondent Outsourcer is subject to disciplinary action pursuant to Code sections 4301, subdivisions (j) and (o), and 4129.2, for violating laws regulating dangerous drugs and for failing to follow laws, rules, and regulations governing the practice of pharmacy, by failing to comply with CGMP when compounding, in conjunction with 21 C.F.R. section 211.22, subdivision (a), setting forth the responsibilities of the quality control unit. The circumstances are as follows:

98. Respondent Outsourcer did not fully investigate customer or patient complaints of experiencing adverse drug reactions. At minimum 12 complaints were not fully investigated, numbers 2023363, 2023439, 2023458, 2023520, 2023559, 2023573, ADE 23-011, ADE 23-019, ADE 23-025, ADE 23-032, ADE 23-057, and ADE 23-074. No retained samples were tested to ensure release specifications and no investigations were done to ensure compliance with CGMP.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Review Production Records)

99. Respondent Outsourcer is subject to disciplinary action pursuant to Code sections 4301, subdivisions (j) and (o), and 4129.2, for violating laws regulating dangerous drugs and for failing to follow laws, rules, and regulations governing the practice of pharmacy, by failing to comply with CGMP when compounding, in conjunction with 21 C.F.R. section 211.192, production record review which required Respondent Outsourcer to have a quality control unit that reviewed and approved all drug product production and control records to determine compliance with all policies and procedures before a batch is released or distributed, and any

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failure of the drug product to meet specifications shall be thoroughly investigated. The circumstances are as follows:

100. Respondent Outsourcer did not fully investigate customer or patient complaints of experiencing adverse drug reactions. At minimum 12 complaints were not fully investigated, numbers 2023363, 2023439, 2023458, 2023520, 2023559, 2023573, ADE 23-011, ADE 23-019, ADE 23-025, ADE 23-032, ADE 23-057, and ADE 23-074. No retained samples were tested to ensure release specifications and no investigations were done to ensure compliance with CGMP.

FIFTEENTH CAUSE FOR DISCIPLINE

(Failure to Test Reserved or Retained Samples)

101. Respondent Outsourcer is subject to disciplinary action pursuant to Code sections 4301, subdivisions (j) and (o), and 4129.2, for violating laws regulating dangerous drugs and for failing to follow laws, rules, and regulations governing the practice of pharmacy, by failing to comply with CGMP when compounding, in conjunction with 21 C.F.R. section 211.170, subdivision (a), which states that an appropriately identified reserve sample that is representative of each lot in each shipment of each active ingredient shall be retained with at least twice the quantity necessary for all tests required to determine whether the product's labeled claim met its established specifications, except for sterility and pyrogen testing. The circumstances are as follows:

102. Respondent Outsourcer did not fully investigate customer or patient complaints of experiencing adverse drug reactions. At minimum 12 complaints were not fully investigated, numbers 2023363, 2023439, 2023458, 2023520, 2023559, 2023573, ADE 23-011, ADE 23-019, ADE 23-025, ADE 23-032, ADE 23-057, and ADE 23-074. No retained samples were tested to ensure release specifications and no investigations were done to ensure compliance with CGMP.

SIXTEENTH CAUSE FOR DISCIPLINE

(Responsibilities of Quality Control Unit)

103. Respondent Outsourcer is subject to disciplinary action pursuant to Code sections 4301, subdivisions (j) and (o), and 4129.2, for violating laws regulating dangerous drugs and for failing to follow laws, rules, and regulations governing the practice of pharmacy, by failing to

comply with CGMP when compounding, in conjunction with 21 C.F.R. section 211.22, subdivision (a), which states that there shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to ensure that no errors have occurred or that all errors are thoroughly investigated. The circumstances are as follows:

104. Respondent Outsourcer did not fully investigate customer or patient complaints of experiencing adverse drug reactions. At minimum 12 complaints were not fully investigated, numbers 2023363, 2023439, 2023458, 2023520, 2023559, 2023573, ADE 23-011, ADE 23-019, ADE 23-025, ADE 23-032, ADE 23-057, and ADE 23-074. No retained samples were tested for any of the batches involved to ensure release specifications and investigations to ensure compliance to CGMP were not performed. The quality control unit did not have control or authority over investigations of adverse drug reactions.

JUNE 7, 2024, INVESTIGATION REPORT (CI 2023 103406)

105. On or about December 14, 2023, the Board was notified of a complaint that had been made to Respondent Outsourcer by a prescriber who had dispensed Respondent Outsourcer's eyedrops Klarity-Cyclosporine 0.1% known as "Klarity-C" to a patient, only for the eyedrops to grow mold in the cap within two weeks. An investigation by Board Inspector P.P.S. therefore ensued.

106. Klarity-C is indicated for use in patients with dry eyes and increases tear production it is a dangerous drug pursuant to Code section 4022, but it is not a controlled substance.

107. Board Inspector P.P.S. found that Respondent Outsourcer had compounded the Klarity-C in question, and Respondent Pharmacy had shipped it to the prescriber who then provided it to the patient. The patient had the eyedrops for approximately 2 weeks and stored it properly, but when the patient opened the bottle for the first time, they discovered that there was mold in the cap.

108. Respondent Outsourcer decided that the patient may have lied about not using the product and that mold may have been introduced by improper use, and therefore the only

corrective action Respondent Outsourcer took regarding this compliant was to add a direction to the label directing patients to ensure there was no residual product on the tip of the eyedrop dispenser before replacing the cap.

109. The FDA also conducted an inspection and investigation and stated that Respondent Outsourcer had received more than 1,000 complaints regarding their eyedrops and failed to do complete and robust quality assurance investigations.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to Have Robust Quality Control)

110. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, failure to comply with regulations of the board and with cGMP applicable to outsourcing facilities. Specifically, Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (c), failing to have a quality control unit with the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product. Respondent Outsourcer provided a bottle of Klarity-C to a patient that had mold in the lid of the container, thus, the quality control unit failed to ensure the purity of the product.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to Have Appropriate Written Procedures)

111. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, failure to comply with regulations of the board and with cGMP applicable to outsourcing facilities. Specifically, Respondent Outsourcer violated Federal Regulations section 211.113, control of microbiological contamination of drug products purporting to be sterile, subdivision (b), having appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile. Respondent Outsourcer provided a bottle of purportedly sterile Klarity-C to a patient, which had mold in the lid of the container. The procedures to prevent contamination of this lot of Klarity-C were not effective.

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NINETEENTH CAUSE FOR DISCIPLINE

(Failure to Perform Thorough Investigation)

112. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, failure to comply with regulations of the board and with cGMP applicable to outsourcing facilities. Specifically, Respondent Outsourcer violated Federal Regulations section 211.192, failing to perform a thorough investigation after a patient reported that a bottle of Klairty-C which had been unopened and properly stored had grown mold in the cap prior to use. The investigation was superficial, discounted information provided by the patient, made unsupported assumptions, and failed to take into account 61 other patient complaints regarding the container closure system used for this medication.

JUNE 26, 2024, INVESTIGATION REPORT (CI 2023 101540)

113. On or about August 11, 2023, the Board was notified of a recall initiated by Respondent Pharmacy for two lots of Moxifloaxacin-Bromfenac sterile ophthalmic solution 0.5%-0.075% (MB), due to the discovery of sub-potent Bromfenac levels in retention samples. An investigation by Board Inspector M.V. therefore ensued.

114. MB is indicated for use in the management of bacterial eye infections and inflammation post cataract surgery, it is a dangerous drug pursuant to Code section 4022, but it is not a controlled substance.

115. Respondent Outsourcer initiated the recall on August 9, 2023. The first attempts by Respondent Outsourcer to contact prescribers occurred by telephone six (6) days later on August 15, 2023. Respondent Outsourcer's policies and procedures state that all prescribers are to be notified promptly of the recall in writing. At the time of Board Inspector M.V.'s inspection on or about September 14, 2023, six (6) prescribers not yet been sent notification of the recall in writing.

116. At some point after performing validation studies in 2019 and before making batch numbers 21OCT025, 22JUL006, and 22DC047, beginning in or around October 2021,

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Respondent Outsourcer switched manufacturers of the Bromfenac active pharmaceutical ingredient (API) but failed to re-validate their compounding practices upon making that change.

117. Approximately 240 units of MB were shipped to California after confirmed sub-potent stability results for the Bromfenac were received by Respondent Outsourcer.

118. On or about September 21, 2023, Respondent Outsourcer notified the Board of another recall, this one for Tropicamide-Proparacaine-Phenylephrine-Ketorolac 1%-0.5%-2.5%-0.5% ophthalmic solutions (M4), due to a stability deviation which did not support the BUD of 270 days given to this product.

119. M4 is indicated for use to dilate the pupil and numb the eye, primarily for eye exams and procedures. It also can help reduce pain and inflammation associated with eye surgery.

120. In addition to the lack of stability of M4 to support the BUD, Respondent Outsourcer discovered that Ketorolac in this product was sub-potent after 180 days of shelf life.

121. Respondent Outsourcer stated that the Keterolac level in this product was tested at 241 days as 92.8% potent; however, this testing was actually done at 211 days.

122. At least six shipments of M4 were shipped to California after the sub-potent Keterolac was determined by Respondent Outsourcer, including one shipment 21 days after the determination. This is approximately 1,092 units.

123. On or about October 4, 2023, the Board received notification of another recall initiated by Respondent Outsourcer, this one for Epinephrine-Lidocaine 0.25 mg/mL-0.75 mg/mL ophthalmic injections (Epi-Lido) due to a quality complaint regarding a color-change and potential sub-potency of epinephrine levels in one lot.

124. Epi-Lido is indicated for use to cause temporary numbness or loss of feeling for certain medical procedures. This helps the patient experience less pain during minor medical procedures.

125. Respondent Outsourcer did not provide written notification of the recall of Epi-Lido within ten business days of the recall being enacted, as required by Respondent Outsourcer's policies and procedures.

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126. At least 30 vials of Epi-Lido were provided to Respondent Outsourcer's marketing team, which then provided them as samples to prescribers. These prescribers then would have either used or provided them to patients. Respondent Outsourcer did not provide any notice of the Epi-Lido recall to any of these prescribers or their patients.

127. Respondent Outsourcer received at least four complaints from four different states about the same lot of Epi-Lido within approximately a seven week time span.

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to Maintain Potency Through BUD)

128. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Specifically, Respondent Outsourcer violated Federal Regulation 211.22, subdivision (c), by failing to have a quality control unit with the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product and allowed at least four lots of MB, two lots of M4, and one lot of Epi-Lido that were compounded by Respondent Outsourcer and sent to prescribers and patients that were sub-potent, as set forth in paragraphs 113 through 127, above.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Follow Recall Policies and Procedures)

129. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Specifically, Respondent Outsourcer violated Federal Regulation 211.22, subdivision (d), by failing to follow their own policies and procedures regarding recalls as set forth in paragraphs 113 through 127, above.

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TWENTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Have Appropriate Recall Policies and Procedures)

130. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Specifically, Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (d), and section 211.150, subdivision (b), by failing to have or follow written procedures for distributing drug products including a system by which the distribution of each lot of drug product can be readily determined in order to facilitate its recall, if necessary. Respondent Outsourcer failed to have written policies and procedures for distributing products through sales representatives for demonstration or evaluation purposes, and did not have any written procedure for recalling the products distributed in this manner.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Failure to Re-Validate Process to Ensure Potency)

131. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Specifically, Respondent Outsourcer violated Federal Regulation 211.22, subdivision (c), by failing to re-validate the manufacturing process for MB after a change in manufacturer for the Bromfenac API in order to ensure the potency was maintained through the BUD.

TWENTY-FOURTH CAUSE FOR DISCIPLINE

(Inappropriate Assignment of BUD)

132. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Specifically, Respondent Outsourcer violated Federal Regulations section 211.137, subdivision (a), and section 211.166 by assigning a 150 day BUD to M4 products without having stability data to support it.

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TWENTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Follow Stability Program Procedures)

133. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Specifically, Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (c), and section 211.166, subdivision (a) by failing to have Respondent Outsourcer's quality control unit comply with its own policies and procedures and follow-up on results of stability testing in accordance with Respondent Outsourcer's Stability Program.

TWENTY-SIXTH CAUSE FOR DISCIPLINE

(Failure to Complete Investigations in a Timely Manner)

134. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Specifically, Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (c), in that Respondent Outsourcer failed to complete its investigations on the MB and M4 stability potency failures in a timely manner which resulted in undue risk to the patients. Both of these products were shipped to California patients while Respondent Outsourcer's investigation into these failures remained open.

TWENTY-SEVENTH CAUSE FOR DISCIPLINE

(Sale of Adulterated Drugs)

135. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Health and Safety Code section 111285 and 111295, in that Respondent manufactured, sold, delivered, held, or offered for sale adulterated drugs. Specifically, Respondent Outsourcer sold and shipped to California patients at least 54 units of M4 after out-of-specification potency results from Lot 21AUG049 were confirmed.

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136. On or about the week of September 11, 2023, Board inspectors were scheduled to do an on-site non-resident outsourcing facility inspection at Respondent Outsourcer's facility. Due to this scheduled inspection, on or about August 2, 2023, Board inspectors began requesting documents from Respondent Outsourcer.

137. Prior to the inspection, on or about January 11, 2023, a cease and desist order had been issued by the Board to Respondent Outsourcer, due to Respondent Outsourcer's utilization of an unlicensed call center owned by a company named "Pro Outsourcing" located in Tijuana, Mexico.

138. On or about September 8, 2023, a Board inspector accessed Respondent Outsourcer's website and Respondent Outsourcer's online chat with a representative with the name "Angela" whose location showed in the chat as Tijuana, Mexico. When the Board inspector inquired as to where "Angela" was located, she stated she was located in California, not Mexico, and that location showing was "an IT error." Shortly thereafter, "Angela's" location was no longer present in the chat log. An individual named Angela Zuniga has been listed as being an employee of "Pro Outsourcing" since at least 2019.

139. During the on-site inspection in September 2023, Board inspectors observe that Respondent Outsourcer had multiple violations of federal regulations and California pharmacy law relating to cleanliness, training of employees, maintenance of equipment, recordkeeping, testing, and updating policies and procedures.

140. On or about August 9, 2023, Respondent Outsourcer made the decision to recall a sterile compounded product moxifloxacin – bromfenac sterile ophthalmic solution 0.5%/0.075%. However, Respondent Outsourcer failed to notify all of the prescribers in writing, and some of the purported notices were inconsistent with the recall procedures in Respondent Outsourcer's own policies and procedures, for example instead of all of the information necessary, some notices were a simple email with information requesting return logistics rather than full written notification.

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TWENTY-EIGHTH CAUSE FOR DISCIPLINE

(Failure to Adequately Maintain or Clean Equipment)

141. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.67, subdivision (a), by failing to adequately maintain or clean equipment. During the inspection in September 2023, Board inspectors observed that the autoclave was found to have a brown residue inside the inner chamber and the stir bars had visual and apparent filth and degradation.

TWENTY-NINTH CAUSE FOR DISCIPLINE

(Failure to Adequately Calibrate and Maintain Balances/Scales)

142. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Specifically, Respondent Outsourcer violated Federal Regulations section 211.67, subdivision (a), by failing to maintain and adequately calibrate balances used for weighing ingredients. During the inspection in September 2023, Board inspectors observed that balances were out of calibration and in a poor state of repair with residue and a black and brown filth visually apparent.

THIRTIETH CAUSE FOR DISCIPLINE

(Failure to Follow Policies and Procedures)

143. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Specifically, Respondent Outsourcer violated Federal Regulations section 211.67, subdivision (b), by failing to follow Respondent Outsourcer's own procedure *Preventative Maintenance and Instrument Calibration* which requires removal of nonworking or non-calibrated equipment, and for the Quality Unit to have oversight of the program. However, during the inspection in September

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2023, SCL-002 was not adequately calibrated or removed from service until such calibration could be accomplished.

THIRTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Ensure Proper Execution of Recall Procedures)

144. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Specifically, Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (c), because Respondent Outsourcer decided to recall moxifloaxin bromfenac sterile ophthalmic solution 0.5%/0.075% on or about August 9, 2023, and at the time of inspection on September 12, 2023, all consignees of the medication had not yet been notified. Respondent Outsourcer's Quality Unit failed to ensure proper execution of the recall procedure which required Respondent Outsourcer to promptly notify all affected prescribers of the recall in writing. Some of the prescribers did not receive written notice of the recall for more than 30 calendar days, and some received incomplete notification which did not contain all intended messaging.

THIRTY-SECOND CAUSE FOR DISCIPLINE

(Failure of Quality Control Unit to Control Procedures)

145. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (c), because Respondent Outsourcer failed to imbue its quality control unit with the authority, education, and training to ensure a sate of control. Examples include, but are not limited to the following:

a. Refrigeration units 011 and 012 were observed to be utilized outside their validated state. These units were loaded in capacities or configurations not validated and outside of the original equipment manufacturer's operating limits.

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b. The use of utensils such as stir bars were not adequately validated. The durability and cleanability of the items which undergo multiple cleaning treatments and thermocycles were not adequately validated for their intended use.

c. Respondent Outsourcer's staff failed to follow approved procedure, and the root cause, or causes, of the failure were not fully addressed through an investigation and remediation process. As an example, staff were found to have violated the data integrity policy relating to the use of the bubble point machine, but no retraining or evaluation of the training program was done as part of the corrective actions.

d. The Quality Control Unit failed to maintain adequate oversight of the actions of contracted customer services representatives impersonating Respondent Outsourcer's staff. The Quality Control Unit failed to terminate Respondent Outsourcer's relationship with Pro Outsourcing once Respondent Outsourcer was notified that continuing to utilize Pro Outsourcing in the manner in which they were contracted was a violation of California law. Additionally, the Quality Control Unit failed to have adequate oversight of training and the performance of the contract employees for critical processes such as the intake of customer complaints and adverse drug reactions.

THIRTY-THIRD CAUSE FOR DISCIPLINE

(Failure to have Adequate Environmental Monitoring)

146. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.42, subdivision (c)(10)(iv), because Respondent Outsourcer had an inadequate environmental monitoring program. Specifically, the active viable air sampling was not performed during each production shift. For example, one lot was compounded and filled over three calendar days, 14,960 vials were distributed from this batch, including 600 vials to California, and only one active viable air sample was taken and evaluated. Respondent Outsourcer also failed to investigate similar scenarios for other batches which may have had similar deficiencies in environmental monitoring.

THIRTY-FOURTH CAUSE FOR DISCIPLINE

(Failure to Perform Yield Calculations and Investigation Rejections)

147. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.103, because Respondent Outsourcer failed to determine actual yields and percentages of theoretical yields at the conclusion of each appropriate manufacturing phase, processing, packaging, and holding. For example, lot # 23FEB018 was a 1100 unit batch for which only 737 units were produced, with 258 units being rejected during filling, and 107 units being rejected during packaging and labeling due to leaking. Yet, despite this high rejection rate, Respondent Outsourcer failed to do any investigation to determine the causes of, and any modification that could be attempted to resolve these rejection rates.

THIRTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Implement Corrective Actions and Perform Endotoxin Testing)

148. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.84, subdivision (a), because Respondent Outsourcer failed to complete endotoxin testing on all incoming lots of bulk drug substances. This failure had been identified at the Board's prior inspection and Respondent Outsourcer committed to a corrective action plan to resolve the issue by testing all lots. At the time of this inspection, a year later, Respondent Outsourcer was still not compliant.

THIRTY-SIXTH CAUSE FOR DISCIPLINE

(Failure to have Adequate User Controls and Ensure Data Integrity)

149. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.68, subdivision (b), because Respondent Outsourcer had

multiple assets, including the bubble point testing machine and autoclave, which were found to have inadequate user controls and Respondent Outsourcer failed to ensure data integrity. For example, lot # 23FEB018 was found to have inaccurate bubble point records without any explanation. Additionally, original records, the raw data, from the bubble point machine were not regularly reviewed by the Quality Control Unit.

THIRTY-SEVENTH CAUSE FOR DISCIPLINE

(Failure to Establish Scientifically Sound and Appropriate Specification Standards)

150. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.160, subdivision (b), because Respondent Outsourcer utilized inappropriate excessive endotoxin specifications for an ophthalmic injectable product, and Respondent Outsourcer failed to ensure their testing conformed to USP<771> requirements. Additionally, other tests within USP<771> such as osmolality/osmolarity were not performed.

THIRTY-EIGHTH CAUSE FOR DISCIPLINE

(Failure to Have and Follow an Adequate Stability Program)

151. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.166, subdivision (a), because Respondent Outsourcer failed to have and fully follow an appropriate and adequate written testing program designed to assess the stability characteristics of drug products. Examples include, but are not limited to the following:

152. The stability studies for emulsions and/or suspensions were not adequately conducted to demonstrate uniform redispersability/resuspendability. Additionally, particle size distribution testing and evaluation had not been performed on relevant products during stability studies prior to commercialization.

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153. The stability studies for Fortisite[3] did not include adequate evaluation of antimicrobial effectiveness testing to support the product's shelf-life prior to commercialization. The antimicrobial effectiveness testing had only been performed at the start of the stability study.

154. The stability studies for product formulation LD072, vancomycin 2.5% sterile ophthalmic solution, did not have antimicrobial effectiveness testing beyond the initial timepoint 0 and was not evaluated to support the product's labeled expiry of 180 days.

155. The commercialization of Fortisite lots 22NOV035 and 22NOV036 did not follow the stability program requirements. There was not an adequate number of passing product validation batches, and there had not been a sufficient quantity of real time and accelerated data collected and reviewed.

THIRTY-NINTH CAUSE FOR DISCIPLINE

(Failure to Adequately Train Compounding Staff)

156. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.125, subdivision (a), because Respondent Outsourcer failed to properly train employees or failed to ensure that employees were properly utilizing their training and experience to perform their assigned functions. Specifically, during inspection, examples observed included, but are not limited to, the following:

157. Operators performing bubble point testing for Lot 23FEB018 were found to not accurately document the actual performance of the bubble point test as required.

158. Customer service representatives contracted through Pro Outsourcing failed to accurately document information related to complaints files and the Quality Unit failed to conduct an adequate review or provide adequate explanation of the inaccurate records prior to approval.

159. An expiration of 180 days was placed on the product Fortisite for which three (3) months of accelerated and long-term data was not collected and evaluated. Additionally, three (3) successful process validations batches had not been completed as required prior to

[3] Fortisite is an eyedrop consisting of tobramycin 1.5% and vancomycin 5%.

commercialization. This is a failure of the Quality Control Unit to follow Respondent Outsourcer's own policies and procedures.

FORTIETH CAUSE FOR DISCIPLINE

(Falsely Representing the Existence or Non-Existence of Facts)

160. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivision (g), for knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts. During the course of the inspection and investigation, Board inspectors were provided materially false statements by Respondent Outsourcer as follows:

161. On or about October 9, 2023, Respondent Outsourcer provided a written statement confirming that the balances and scales utilized in its facility would undergo preventative maintenance monthly. It was later discovered that this work was only being scheduled every three months. BAL-005 received maintenance on February 28, 2024, and did not receive subsequent maintenance until May 28, 2024.

162. On or about October 9, 2023, Respondent Outsourcer provided a written statement confirming that BAL-005 had been cleaned on or about September 12, 2023; however, the written records show the work was actually completed on October 4, 2023. This was five days before Respondent Outsourcer provided the October 9, 2023, written statement, so this statement was false at the time it was made.

163. On or about November 22, 2023, Respondent Outsourcer provided a written statement committing to providing an update by the end of December 2023 relating to data collected or maintained by its vendor Pro Outsourcing. No update was provided as promised until inquiry during an onsite investigation on June 13, 2024.

164. On or about February 10, 2023, Respondent Outsourcer provided a written statement asserting that all call center employees were trained on procedure SOP CLR-GEN-IPG-002. However, Respondent Outsourcer was unable to provide training records for call center employees contracted from Pro Outsourcing.

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165. On or about February 10, 2023, Respondent Outsourcer provided a written statement confirming that the use of Pro Outsourcing call center employees was anticipated to end by March 31, 2023. However, Respondent Outsourcer failed to discontinue the services of Pro Outsourcing until the first day of the Board's renewal inspection, and inquiry by the Board's inspector on September 12, 2023.

FORTY-FIRST CAUSE FOR DISCIPLINE

(Aiding and Abetting Violations of Pharmacy Law)

166. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for aiding and abetting the violation of California law. Respondent Outsourcer contracted with customer service vendor Pro Outsourcing, with call centers located in Tijuana, Mexico, which were not licensed by the Board, to provide customer services to Respondent Outsourcer's customers. On or about January 11, 2023, the Board issued a cease and desist letter to Pro Outsourcing, notifying the company that it was in violation of California law. A copy of this letter was provided to Respondent Outsourcer. Despite this notice, Respondent Outsourcer continued to contract with Pro Outsourcing, allowing Pro Outsourcing employees to do at least the following tasks:

a. Access patient profiles with personal health information to facility the dispensing of a drug.

b. Receive product quality complaints and fail to report quality complaints as procedurally required.

c. Provide consultation and clinical advice consistent with the duties of a pharmacist.

FORTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Adequately Investigate Product Complaints)

167. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.198, subdivisions (a) and (b), because Respondent

Outsourcer failed to have training or maintain training records for staff members employed by contract vendor Pro Outsourcing who routinely engaged in product complaint and adverse reaction reporting intake. Additionally, the Quality Control Unit failed to adequately ensure all complaints and adverse reactions were properly record or review. Examples include, but are not limited to, the following:

a. Complaint record 2023133 had multiple documentation errors which were not fully explained or rectified prior to the complaint being closed. Additionally, an investigation was not extended to review situations with similar discrepancies.

b. A product quality complaint of mold was received for Klarity-C Lot# 22DEC021 on July 17, 2023, Respondent Outsourcer failed to complete an investigation related to this complaint.

FORTY-THIRD CAUSE FOR DISCIPLINE

(Failure to Ensure Contract Vendor Complied with State and Federal Law)

168. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (d), because Respondent Outsourcer failed to ensure its contract vendor, Pro Outsourcing, followed state and federal regulations. Examples include, but are not limited to, the following:

a. Respondent Outsourcer either did not have, or could not provide, any written assurances that protected health information of patients that was generated, maintained, or accessed by Respondent Outsourcer's contract vendor was or is being held in a safe and secure manner. Upon the dissolution of the business relationship, Respondent Outsourcer either did not have, or could not provide, any written assurances that such records were either returned to Respondent Outsourcer or were securely destroyed.

b. Respondent Outsourcer failed to ensure the discontinuation of services by contract vendor Pro Outsourcing upon receipt of the Board's cease and desist order issued on or about January 11, 2023. Services were not discontinued until approximately September 12, 2023.

Additionally, email for Pro Outsourcing employees through Respondent Outsourcer remained active until at least June 13, 2024.

FORTY-FOURTH CAUSE FOR DISCIPLINE

(Sale of Adulterated Drugs)

169. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), for failing to comply with pharmacy laws and regulations. Respondent Outsourcer violated Code section 4169, subdivision (a)(2), when it purchased, traded, sold, or transferred dangerous drugs that it knew, or should have known, were adulterated. Specifically, Respondent Outsourcer failed to adequately investigate failures to the predefined specifications for their product Fortisite. Respondent Outsourcer failed to adequately and fully investigate the failures of the subvisible particulates, and repeated testing were not scientifically justified and lacked rationale. Additionally, the supportive visual inspection procedures were inadequate and did not provide assurances that the product was essentially free of visible particulates. Finally, Respondent Outsourcer's release of Fortisite did not follow their own stability procedures effective at the time of release.

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170. On or about February 21, 2024, an on-site nonresident sterile compounding pharmacy inspection was conducted at Respondent Pharmacy's facility. Records were requested from Respondent Pharmacy prior to the actual on-site inspection. Board inspector S.P. conducted the inspection and reviewed the records provided by Respondent Pharmacy.

171. On or about November 1, 2022, the United States Pharmacopeia (USP) updated chapters relating to compounding both sterile and non-sterile drug products, among others. The revision and update process took several years, and the pharmaceutical industry engaged in sterile and non-sterile compounding was vocal and active in participation in the process to update these chapters. Pharmacies compounding either sterile or non-sterile drug products were required to begin complying with these updated chapters of USP-NF on or about November 1, 2022, which became enforceable on or about November 1, 2023.

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172. Board inspector S.P. reviewed batches of the following sterile compounded drug products:

a. Timolol-Brimonidine tartrate-Dorzolamide-Bimatoprost PF, ophthalmic (0.5/0.15/2/0.01%) solution, an eye drop.

b. Timolol-Brimonidine tartrate-Dorzolamide PF opthalmic (0.5/0.15/2%) solution, an eye drop.

c. Cyclosporine-Loteprednol etabonate in Klarity PF opthalmic (0.1 %-0.2%) suspension, an eye drop.

d. Loteprednol etabonate in Klarity PF opthalmic (0.5%) suspension, an eye drop.

FORTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Support Beyond Use Date)

173. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), for failing to comply with Code section 4126.8, by failing to compound drug preparations for furnishing, distribution, and use in this state, pursuant to the standards established in the pharmacy compounding chapters of the current version of the USP-NF, including relevant testing and quality assurances. Specifically, USP-NF requirements state that without terminal sterilization, the beyond use date for such compounds is 60 days after compounding, when stored at room temperature. Respondent Pharmacy compounded sterile drug preparations, eye drops, and did not perform terminal sterilization, yet assigned beyond use dates of 180 days, when stored at room temperature. This was true at least for lot numbers 01042024@2, 01052024@1, 12112023@2, and 12192023@1.

FORTY-SIXTH CAUSE FOR DISCIPLINE

(Exceeded Maximum Batch Size)

174. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), for failing to comply with Code section 4126.8, by failing to compound drug preparations for furnishing, distribution, and use in this state, pursuant to the standards established in the pharmacy compounding chapters of the current version of the USP-NF, including relevant testing and quality assurances. Specifically, USP-NF requirements state that

the maximum batch size for all compounded sterile products requiring sterility testing must be limited to 250 final yield units. Respondent Pharmacy compounded batches far in excess of this limit, as follows:

a. Timolol-Bnmonidine tartrate-Dorzolamide-Bimatoprost PF ophthalmic (0.5/0.15/2/0.01%) solution, lot #01042024@2, with a batch yield of 1100.

b. Timolol-Brimonidine tartrate-Dorzolamide PF opthalmic (0.5/0.15/2)% solution lot #01052024@1, with a batch yield of 1080.

c. Cyclosporine-Loteprednol etabonate in Klarity PF ophthalmic (0.1 %-0.2%) suspension lot #l2112023@2, with a batch yield of 506.

d. Loteprednol etabonate in Klarity PF opthalmic (0.5%) suspension lot #l2192023@1, with a batch yield of 994.

FORTY-SEVENTH CAUSE FOR DISCIPLINE

(Failure to Support Beyond Use Date)

175. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), for failing to comply with Code section 4126.8, by failing to compound drug preparations for furnishing, distribution, and use in this state, pursuant to the standards established in the pharmacy compounding chapters of the current version of the USP-NF, including relevant testing and quality assurances. Specifically, Respondent Pharmacy compounded sterile drug preparations, eye drops, in multi-dose containers, and labeled them to indicate that once opened, they must be discarded after 28 days when stored at room temperature. However, Respondent Pharmacy had failed to perform or pass antimicrobial testing in accordance with USP 51, as required by USP 797, section 14.5. This was true for at least the following:

a. Timolol-Bnmonidine tartrate-Dorzolamide-Bimatoprost PF ophthalmic (0.5/0.15/2/0.01%) solution, lot #01042024@2, with a beyond use date of 180 days.

b. Timolol-Brimonidine tartrate-Dorzolamide PF opthalmic (0.5/0.15/2)% solution lot #01052024@1, with a beyond use date of 180 days.

c. Cyclosporine-Loteprednol etabonate in Klarity PF ophthalmic (0.1 %-0.2%) suspension lot #l2112023@2, with a beyond use date of 180 days.

d. Loteprednol etabonate in Klarity PF opthalmic (0.5%) suspension lot #l2192023@1, with a beyond use date of 180 days.

FORTY-EIGHTH CAUSE FOR DISCIPLINE

(Non-Pharmacist Staff Performing Pharmacist Duties)

176. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivision (o), for violating laws, rules, and regulations governing the practice of pharmacy, when Respondent Pharmacy failed to comply with Regulations section 1793.1, duties of a pharmacist. Specifically, Respondent Pharmacy had non-pharmacist staff performing pharmacist responsibilities when, for at least four California consumers, unlicensed non-pharmacist staff consulted with patients about their prescriptions, both before and after dispensing, identified and discussed prescriptions on medication profiles, offered alternative medication recommendations and quantities to patients, and offered consultation on medication storage. Additionally, between at least January 2, 2023, and May 31, 2023, after a cease and desist letter was issued to Respondent Pharmacist's subcontractor Pro Outsourcing, continued to identify and discuss prescriptions with patients.

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177. On or about April 3, 2024, a supervising pharmacist at Respondent Outsourcer emailed the Board to provide notification of multiple voluntary recalls of compounded sterile drug products. The recalled drugs were two lots of epinephrine/lidocaine, an ophthalmic injection, and one lot of prednisolone/moxifloxacin/bromfenac, an ophthalmic solution. The reason for both recalls was that testing indicated that the drugs would become subpotent prior to their expiration dates.

178. On or about May 7, 2024, the same supervising pharmacist at Respondent Outsourcer emailed the Board again to provide notice of additional voluntary recalls. The recall for epinephrine/lidocaine was expanded to include ten new lot numbers, again due to subpotent epinepherine, and the recall for prednisolone/moxifloxacin/bromfenac was expanded to include one additional lot, this time due to observations made by the FDA during an inspection. In addition, Respondent Outsourcer also recalled the drugs Klarity-C (cyclosporine 0.1%) an

ophthalmic solution, two additional lots of epinephrine-lidocaine, dexamethasone/moxifloaxacin, dexamethasone/moxifloaxacin/ketorolac, and two different strengths of moxifloaxacin, all in response to observations made by the FDA during their inspection.

179. On or about June 13, 2024, Board inspectors J.W. and J.F. conducted an onside investigation and Respondent Outsourcer's facility. The purpose of this inspection was to investigate these recalls, as well as complaints received by the Board as documented in investigation number CI 2023 102402, paragraphs 136 through 169, above.

180. On or about August 13-15, 2024, Board inspectors J.W. and J.F. were scheduled to and did conduct an onsite nonresident outsourcing facility inspection at Respondent Outsourcer's facility. Due to this scheduled inspection, on or about June 21, 2024, Board inspectors began requesting and reviewing documents from Respondent Outsourcer.

181. During the onsite inspection in August 2024, Board inspectors observed that Respondent Outsourcer had multiple violations of federal regulations, cGMP, and California pharmacy law relating to cleanliness, training of employees, maintenance of equipment, recordkeeping, testing, and updating policies and procedures.

FORTY-NINTH CAUSE FOR DISCIPLINE

(Failure to Adequately Validate or Utilize Equipment)

182. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (c), when it failed to adequately validate refrigeration units for their intended purpose to store materials at refrigeration of 2-8C. Additionally, units which were previously validated were utilized in ways for which the validation did not support or did not have adequate documentation to support. For example, units were loaded in configurations which were not supported by validation as well as loaded in configurations not permitted by procedure. Specifically, the performance validation for RF-012 and RF-007 was incomplete and the load patterns of the units were not defined in their qualification.

FIFTIETH CAUSE FOR DISCIPLINE

(Failure to Adequately Maintain or Clean Equipment)

183. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (c), by having inadequate procedures and validations to support the maintenance of cold chain of drug product which required refrigeration. For example, during an annual inspection it was observed there was inadequate cold chain validation to support Respondent Outsourcer's cold chain distribution and the procedure which governed cold chain shipping was not fully followed. There was inadequate evidence Respondent Outsourcer maintains product at its label claim storage condition through its manufacture, packaging, holding, and distribution.

FIFTY-FIRST CAUSE FOR DISCIPLINE

(Producing, Preparing, Packing, Holding Adulterated Drugs)

184. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Health and Safety Code section 111255, in that Respondent produced, prepared, packed, or held a drug under circumstances or conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. Respondent Outsourcer failed to provide adequate assurances the product is maintained at its label claim temperature through its shipment and distribution process. Product recalls have been required for instances where drug product such as epinephrine/lidocaine was found to be sub-potent due to inadequate maintenance of cold chain storage.

FIFTY-SECOND CAUSE FOR DISCIPLINE

(Sale of Adulterated Drugs)

185. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Health and Safety Code section 111285 and 111295, in that Respondent manufactured, sold, delivered, held, or offered for sale adulterated drugs. Specifically, Respondent Outsourcer observed stability failures of their product

epinephrine/lidocaine on or about July 20, 2022, from their contract laboratory at the 90-day timepoint of their stability study. Additional lots of this product continued to be produced and distributed with 360 day expiration dates until on or about April 3, 2024, when Respondent Outsourcer finally began recalling the product. Respondent Outsourcer's decision to change the expiration date for these drug products from 360 days to 180 days was not justified, nor was the eventual expiration date change to 150 days, since the failure occurred in testing at 90 days.

FIFTY-THIRD CAUSE FOR DISCIPLINE

(Sale of Misbranded Drugs)

186. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), for failing to comply with pharmacy laws and regulations. Respondent Outsourcer violated Code section 4169, subdivision (a)(s), when it purchased, traded, sold, or transferred dangerous drugs that it knew, or should have known, were misbranded. Specifically, Respondent Outsourcer observed stability failures of their product epinephrine/lidocaine on or about July 20, 2022, from their contract laboratory at the 90-day timepoint of their stability study. Additional lots of this product continued to be produced and distributed with 360 day expiration dates until on or about April 3, 2024, when Respondent Outsourcer finally began recalling the product. Respondent Outsourcer's decision to change the expiration date for these drug products from 360 days to 180 days was not justified, nor was the eventual expiration date change to 150 days, since the failure occurred in testing at 90 days.

FIFTY-FOURTH CAUSE FOR DISCIPLINE

(Failure to Have or Properly Utilize Personnel to Remedy Failing Test Results)

187. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.25, subdivision (c), when it failed to ensure that it's Quality Control Unit investigate and take action in a timely manner when the product epinephrine/lidocaine failed stability testing. Respondent Outsourcer observed the first stability

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failures in July 2022, but failed to take any corrective action and continued to sell and dispense adulterated and misbranded products to consumers until at least April 3, 2024.

FIFTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Adequately Examine Label Claims and Stability Results)

188. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (c), when it failed to ensure that it's Quality Control Unit adequately evaluate the final label claims and stability results when assigning a product expiration date to its epinephrine/lidocaine drug product of 360 days, then 180 days, and then 150 days, when the data showed the product was only valid for 90 days.

FIFTY-SIXTH CAUSE FOR DISCIPLINE

(Failure to Have or Properly Utilize Personnel to Remedy Failing Test Results)

189. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.25, subdivision (c), when it failed to ensure that it's Quality Control Unit investigate and take action in a timely manner when the product prednisolone/moxifloxacin/bromfenac failed stability testing. Respondent Outsourcer observed the first stability failures on or about September 21, 2023, indicating that the product's stability did not last past 180 days, but failed to take any corrective action and continued to sell and dispense adulterated and misbranded products to consumers until at least April 10, 2024.

FIFTY-SEVENTH CAUSE FOR DISCIPLINE

(Failure to Follow Written Sampling Procedures)

190. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.160, subdivision (b), when it re-tested at least twice, the

prednisolone/moxifloxacin/bromfenac product that had failed stability testing. There was inadequate documentation or justification for resampling. The subsequent investigation and recall event was therefore delayed and not performed in a timely fashion.

FIFTY-EIGHTH CAUSE FOR DISCIPLINE

(Failure to Follow Test Results)

191. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (c), when it invalidated an initial failing sterility test result provided by its independent contract laboratory and released lot 23NOV008 following a repeated sterility test. There was inadequate justification for the invalidation of the original test results and the contract laboratory determined there was insufficient evidence to invalidate the original test results.

FIFTY-NINTH CAUSE FOR DISCIPLINE

(Failure to Have Adequate Visual Inspection Procedures)

192. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (c), when it had inadequate visual inspection procedures, and failed to require an investigation when critical defects were found during the 100% visual inspection process. Likewise, no investigation was required if the 100% visual inspection failed and the 200% visual inspection and subsequent AQL sampling was passing.

SIXTIETH CAUSE FOR DISCIPLINE

(Failure to Evaluate Visual Inspection Operators)

193. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer

violated Federal Regulations section 211.192, when it failed to evaluate the visual inspection operators ability to successfully remove defective units over multiple inspection events, and failed to evaluate the risk of glass recovered in defective units prior to releasing the batch. For example, lot 24JAN004 failed its visual inspection twice, and a particulate in the product was identified as glass. Additionally, this lot exhibited critical defects of 3% which exceeded the threshold limit of 1%.

SIXTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Evaluate Distributed Products)

194. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.192, when it failed to thoroughly evaluate epinephrine/lidocaine product that had been distributed prior to the recall on or about April 3, 2024.

SIXTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Ensure Properly Trained Employees)

195. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.25, subdivision (a), when it failed to ensure that each employee engaged in the manufacture, processing, packing, or holding of drug products had the education, training, and experience to enable that employee to perform the assigned functions. Some examples include but are not limited to the following:

a. Aseptic operators failed to follow the required procedures which required operators to reject units which had their HEPA filtered airflow disrupted during production. There were incomplete assurances operators consistently complied to the procedure. This resulted in a drug product recall due to “human error”.

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b. Bubble point testing operators failed to follow procedure which limited the number of times a filter may be tested or retested. There were multiple batches in which the filter was tested beyond the allowable limits. This resulted in a drug product recall.

c. There was a failure to follow procedure in regard to the use and storage of drug and other products within refrigeration units. During inspection it was observed multiple refrigeration units to be improperly loaded inconsistent with the procedural requirements.

SIXTY-THIRD CAUSE FOR DISCIPLINE

(Failure to Ensure Employees Followed Policies and Procedures)

196. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.68, subdivision (b), when it failed to ensure that each employee who performed the bubble point verification test on sterilizing filters followed the required procedure. Instead, employees repeatedly tested filters beyond the allowable limits. The Quality Control Unit failed to have adequate oversight over the control of the bubble point machine, and failed to provide routine review of the complete testing records prior to the release and distribution of batches.

SIXTY-FOURTH CAUSE FOR DISCIPLINE

(Failure to Ensure Properly Trained Employees)

197. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.25, subdivision (a), when it failed to ensure that each employee engaged in performing visual inspections of finished drug product had been trained and qualified to perform such inspection with sufficient scope and rigor. Visual inspection employees were not required to demonstrate their proficiency in identifying types of particulates including critical defects prior to performing the visual inspections on commercial batches.

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SIXTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Ensure Properly Trained Employees)

198. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (c), when it failed to ensure that the visual inspection program was adequate. Respondent Outsourcer had been notified by multiple inspections of deficiencies which were not fully resolved. As an example, the program failed to require investigation in scenarios in which an insanitary condition may exist, such as in the presence of extrinsic particulates or multiple intrinsic or extrinsic particulates within a single container.

SIXTY-SIXTH CAUSE FOR DISCIPLINE

(Failure to Ensure Properly Trained Employees)

199. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.25, subdivision (a), when it failed to ensure that each employee engaged in the manufacture, processing, packing, or holding of drug products had the education, training, and experience to enable that employee to perform the assigned functions. Specifically, employees who were performing release testing pursuant to USP<790> relating to destructive visual inspection testing did not have adequate training and qualifications. As an example, the training records for employee C.W. did not demonstrate the employee's ability to identify the required particulates consistent with visual inspection or their ability to decipher color differences that may exist within a product.

SIXTY-SEVENTH CAUSE FOR DISCIPLINE

(Failure to Have and Follow Appropriate Written Procedures)

200. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to

comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.113, subdivision (b), when it failed to establish and follow appropriate written procedures, designed to prevent microbiological contamination of sterile drug products. Specifically, Respondent Outsourcer failed to have adequate environmental monitoring sampling plans, and personnel monitoring program. Examples include the following:

a. The selection of surface samples was not adequately justified and did not incorporate critical processing equipment such as automated filling lines (Flexicon-30 and DARA) where aseptic interventions occur. For example, the filling bowl container product contact dropper tips did not have adequate monitoring.

b. The monitoring of a single site within the restricted access barrier DARA filling line was not justified and not representative of the filling process and interventions which occur on the unit.

c. Personnel who perform aseptic operations within the RABS unit of the DARA filling machine did not have sampling commensurate to their risk to the operation and the samples collected were not evaluated based on the risk they represented. For example, personnel fully enter the ISO-5 space at least during set up as well as enter or partially enter the RABS during the filling process. The sample specifications collected for the chest and forehead samples were set at action levels of 6 colony forming units (CFUs). Microbial recoveries potentially attributed to the ISO-5 space may not always require an investigation into their impact on the batch.

SIXTY-EIGHTH CAUSE FOR DISCIPLINE

(Failure to Adequately Evaluate Container Closure System)

201. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.166, subdivision (a), when it failed to adequately evaluate the drug and drug product container closure system in its worst-case storage orientation. Respondent Outsourcer also misapplied other stability study designs such as the misapplication of

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matrixing or bracketing where multiple drug products and strengths were proposed to be studied under reduced study designs without justification.

SIXTY-NINTH CAUSE FOR DISCIPLINE

(Failure to Adequately Evaluate Active Pharmaceutical Ingredients)

202. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.84, subdivision (d)(2), when it failed to adequately evaluate active pharmaceutical ingredients for microbial bioburden at appropriate intervals prior to use in compounding. Additionally, the active pharmaceutical ingredient glycerin utilized in Respondent Outsourcer's product Klarity was sourced from a manufacturer that is not registered with the FDA as required.

SEVENTIETH CAUSE FOR DISCIPLINE

(Failure to Ensure Drug Products have Proper Strength, Quality, Purity)

203. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.100, subdivision (a), when it failed to ensure that drug products have the identity, strength, quality, and purity they purport or are represented to possess. Specifically, procedures which required containers to be wrapped in foil in an effort to protect the product from light were not fully followed and easily allowed for light penetration. The failure to completely wrap the containers also failed to comply with Respondent Outsourcer's procedures which required the operator to "completely wrap the bottle with aluminum foil". These products are labile to light exposure.

SEVENTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Promptly Investigate and Perform Risk Assessment)

204. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (b), for failing to

comply with regulations of the board and cGMP relating to outsourcing. Respondent Outsourcer violated Federal Regulations section 211.22, subdivision (a), when it failed to promptly investigate a failed aseptic process validation media fill for lot 24MAR031, for the DARA filling line. The investigation was opened late, was past due at the time of inspection, and an associated risk assessment was not performed to justify ongoing use of the DARA filling line. All processes and operators involved in the failed media fill continued without modification or demonstration of qualifications.

SEVENTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Promptly Notify Board of Disciplinary or Other Action)

205. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), along with Code section 4129.2, subdivision (e)(1), for failing to notify the Board within 10 days of any other state, or the FDA, taking any disciplinary or other action. Respondent Outsourcer failed to notify the Board that on or about April 16, 2021, the Arkansas State Board of Pharmacy denied Respondent Outsourcer's application for a nonresident outsourcing license in that state.

SEVENTY-THIRD CAUSE FOR DISCIPLINE

(Knowingly Making or Signing Any False Statement)

206. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivision (g), for knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts. Specifically, Respondent Outsourcer provided information that was false to the FDA and to the Board in relation to the recall of Klarity-C on or about May 7, 2024. Respondent Outsourcer stated that all of the distribution of this drug product was to physicians, when in fact, approximately 85% of the distribution went to Respondent Pharmacy.

SEVENTY-FOURTH CAUSE FOR DISCIPLINE

(Acts Involving Moral Turpitude, Fraud, Deceit, or Curruption)

207. Respondent Outsourcer is subject to disciplinary action pursuant to Code section 4301, subdivision (f), for committing any act involving moral turpitude, dishonesty, fraud, deceit,

or corruption. Specifically, Respondent Outsourcer sustained a media fill failure for lot 24MAR031, and as of the inspection in August 2024, an investigation and risk assessment had not been completed. Two of Respondent Outsourcer's personnel in charge of the Quality Control Unit informed Board inspectors that they could maintain sterility assurances because they had already completed the risk assessment and determined the production process was still validated. This information was false and these two personnel later admitted they had neither seen, nor reviewed the uncompleted risk assessment at the time they made those assurances.

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208. On or about February 13, 2025, an onsite nonresident sterile compounding pharmacy inspection was conducted at Respondent Pharmacy's facility. Records were requested from Respondent Pharmacy prior to the actual on-site inspection.

209. Board inspector J.S. conducted the inspection and reviewed the records provided by Respondent Pharmacy.

210. Board inspector J.S. requested Respondent Pharmacy provide records for three sterile compounding preparations prior to the inspection. Respondent Pharmacy provided said records. The three preparations were all eye drops; Azithromycin PF in Klarity 1% solution, cyclosporine-loteprednol etabonate in Klarity PF 0.1%/0.2% suspension, and loteprednol etabonate in Klarity PF (0.5%) suspension.

211. The acronym "PF" in the three eye drops named above indicates the eye drops are "preservative free." All three of these eye drops bore labels indicating that they were dispensed in multi-dose bottles. Without additional testing, multi-dose bottles are only appropriate for compounded sterile preparations which contain preservatives. Single-dose bottles may be preservative free. Respondent Pharmacy's records show that all three of these compounded sterile preparations were prepared without preservatives and without additional testing, yet were dispensed in multi-dose bottles.

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SEVENTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Support Beyond Use Date)

212. Respondent Pharmacy is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), for failing to comply with Code section 4126.8, by failing to compound drug preparations for furnishing, distribution, and use in this state, pursuant to the standards established in the pharmacy compounding chapters of the current version of the USP-NF, including relevant testing and quality assurances. Specifically, Respondent Pharmacy compounded sterile drug preparations, eye drops, in multi-dose containers, and labeled them to indicate that once opened, they must be discarded after 28 days when stored at room temperature. However, Respondent Pharmacy had failed to perform or pass antimicrobial testing in accordance with USP 51, as required by USP 797, section 14.5.

DISCIPLINE CONSIDERATIONS

213. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that on or about October 15, 2021, in a prior action, the Board of Pharmacy issued Citation Number CI 2021 93270, and ordered Respondent to pay $750.00 due to out of state disciplinary action. Specifically, on January 28, 2020, the Maine State Board of Pharmacy issued a reprimand, an order to cease and desist shipping pharmaceutical drugs into Maine until validly licensed, and a $10,750.00 fine due to the pharmacy's failure to notify the Maine Board of Pharmacy of a change of location, and making approximately 105 separate shipments of prescription drugs from its new, unlicensed location, between February 11, 2019, and April 29, 2019. That Citation is now final.

214. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that on or about October 15, 2021, in a prior action, the Board of Pharmacy issued Citation Number CI 2021 93271, and ordered Respondent to pay $750.00 due to out of state disciplinary action. Specifically, on May 3, 2019, the New Jersey State Board of Pharmacy issued a $2,000.00 fine based on violations of New Jersey State Pharmacy Law observed during an inspection, including failure to conduct environmental testing and failure to

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maintain clean and orderly conditions in the sterile compounding cleanroom. That Citation is now final.

215. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that on or about April 22, 2020, the Alabama State Board of Pharmacy issued a Statement of Charges and Notice of Hearing to Respondent Pharmacy based on findings resulting from an inspection on May 1, 2017, by the New Jersey State Board of Pharmacy, as well as the out of state discipline from the Maine State Board of Pharmacy set forth above in paragraph 90. On or about June 14, 2022, Respondent Pharmacy entered into a Consent Order with the Alabama State Board of Pharmacy whereby Respondent Pharmacy agreed to pay a $50,000.00 administrative fine, and be prohibited from dispensing to Alabama patients any drug product compounded by or received from any 503(b) outsourcing facilities.

OTHER MATTERS

216. Pursuant to Code section 4307, if discipline is imposed against Nonresident Outsourcing Facility Permit number NSF 133, issued to Harrow Health Inc., DBA Imprimis NJOF LLC, John Phillip Saharek, President, Then Harrow Health Inc. and John Phillip Saharek shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Outsourcing Facility Permit number NSF 133 is placed on probation or until it is reinstated if it is revoked.

217. Pursuant to Code section 4307, if discipline is imposed against Nonresident Pharmacy Permit number NRP 2062 or Nonresident Sterile Compounding Pharmacy Permit number NSC 101151, issued to Harrow Health Inc., DBA Imprimis Rx, John Phillip Saharek, President, Then Harrow Health Inc. and John Phillip Saharek shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Outsourcing Facility Permit number NSF 133 is placed on probation or until it 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 Nonresident Outsourcing Facility Permit number NSF 133, issued to Harrow Health Inc. dba Imprimis NJOF LLC; John Phillip Saharek, President;

2. Revoking or suspending Nonresident Pharmacy Permit number NRP 2062, issued to Harrow Health Inc. dba ImprimisRx; John Phillip Saharek, President;

3. Revoking or suspending Nonresident Sterile Compounding Pharmacy Permit number NSC 101151, issued to Harrow Health Inc. dba ImprimisRx; John Phillip Saharek, President;

4. Prohibiting the owners and managers of Respondent Nonresident Outsourcing Facility Permit Number NSF 133, issued to Harrow Health Inc. dba Imprimis NJOF LLC; John Phillip Saharek, President, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Outsourcing Facility Permit number NSF 133 is placed on probation or until it is reinstated if revoked;

5. Prohibiting the owners and managers of Respondent Nonresident Pharmacy Permit Number NRP 2062, issued to Harrow Health Inc. dba ImprimisRx; John Phillip Saharek, President, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Pharmacy Permit number NRP 2062 is placed on probation or until it is reinstated if revoked;

6. Prohibiting the owners and managers of Respondent Nonresident Sterile Compounding Pharmacy Permit Number NSC 101151, issued to Harrow Health Inc. dba ImprimisRx; John Phillip Saharek, President, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Sterile Compounding Pharmacy Permit number NSC 101151 is placed on probation or until it is reinstated if revoked;

7. Ordering Harrow Health Inc. dba Imprimis NJOF LLC; John Phillip Saharek, President, and Harrow Health Inc. dba ImprimisRx; John Phillip Saharek, President 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,

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

DATED: 8/14/2025

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2025.08.14 16:07:05 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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