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

In the Matter of the Accusation Against**:** **Tustin Community Pharmacy, Inc.** **Dba Tustin Community Pharmacy** **13400 Newport Avenue** **Tustin, CA 92680** **Original Permit No. PHY 30023** **And** **Jerry Don Oswald** **13400 Newport Ave.** **Tustin, CA 92780** **Pharmacist License No. RPH 31903** Respondents.	Case No. 6160 **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about June 1, 1983, the Board of Pharmacy issued Pharmacy Permit Number PHY 30023 to Tustin Community Pharmacy, Inc. dba Tustin Community Pharmacy. The

Original Permit was in full force and effect at all times relevant to the charges brought herein. The Pharmacy discontinued business on June 24, 2016 and the license has been cancelled.

3. On or about July 31, 1978, the Board of Pharmacy issued Pharmacist License No. RPH 31903 to Jerry Don Oswald, who was the Pharmacist in Charge (PIC) of Respondent Tustin Pharmacy from April 4, 1985 to July 21, 2016, when the Pharmacy's permit was cancelled. PIC Oswald's Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2018, if not renewed.

JURISDICTION

4. 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.

5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

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.

STATUTORY AUTHORITY

8. 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.

9. Section 4033, subdivision (a)(1) of the Code defines the term "manufacturer" as "every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer."

10. Section 4036.5 of the Code states:

"Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

11. Section 4059 of the Code states:

(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.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7., or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

. . . .

12. Section 4105 of the Code states:

(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises

for a period of three years from the date of making.

(d)(1) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the responsible manager, or the designated representative on duty or the designated representative-3PL on duty if the designated representative-in-charge or responsible manager is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board may, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

13. Section 4113, subdivision (c) of the Code states: "The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

14. Section 4169 of the Code states:

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

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

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

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

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

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

. . . .

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

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

. . . .

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

. . . .

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

. . . .

16. Section 4307(a) of the Code states that:

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, 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 manger, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge 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 manger, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

17. Health and Safety Code section 111330 provides that any drug or device is misbranded if its labeling is false or misleading in any particular.

18. Health and Safety Code section 111430 provides that a drug or device is misbranded if it was manufactured in an establishment not duly registered with the Secretary of Health, Education, and Welfare of the United States.

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

20. Health and Safety Code section 111445 provides that it is unlawful for any person to misbrand any drug or device.

21. Health and Safety Code section 111450 provides that it is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

22. Health and Safety Code section 111615 provides that no person shall manufacture any drug or device in this state unless he or she has a valid license from the Department of Public Health.

REGULATORY PROVISIONS[1]

23. Title 16, California Code of Regulations, section 1735, subdivisions (a) and (c) states in pertinent part:

> (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
>
> (1) Altering the dosage form or delivery system of a drug
>
> (2) Altering the strength of a drug
>
> (3) Combining components or active ingredients
>
> (4) Preparing a drug product from chemicals or bulk drug substances
>
> …
>
> (c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.

[1] The Board's compounding regulations were amended, effective January 1, 2017. The regulations cited in this Accusation refer to the regulations in effect at the time of the violations alleged herein.

24. Title 16, California Code of Regulations, section 1735.2 provides:

(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

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

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

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

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

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

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

(4) Inactive ingredients to be used.

(5) Process and/or procedure used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other

components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

25. Title 16, California Code of Regulations, section 1735.3 states:

(a) For each compounded drug product, the pharmacy records shall include:

(1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia—National Formulary (USP-NF) (35th

Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

(7) A pharmacy assigned reference or lot number for the compounded drug product.

(8) The expiration date of the final compounded drug product.

(9) The quantity or amount of drug product compounded.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

26. Title 16, California Code of Regulations, section 1735.4, subdivision (b) states:

A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

27. Title 16, California Code of Regulations, section 1735.5 states:

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedures manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedures manual

(2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product;

(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on those procedures as part of the staff training and competency evaluation process.

(4) Documentation of the methodology used to test integrity, potency, quality,

and labeled strength of compounded drug products.

(5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

COSTS

28. 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.

FACTS

29. Respondent Tustin Pharmacy operated on Newport Avenue in Tustin California from 1983 to some time in 2016, when its license expired and was cancelled. PIC Oswald was the Pharmacist in Charge of the Pharmacy from 1985 until it closed.

30. On August 6, 2014, Pharmacy Board inspectors conducted a routine inspection of Respondent Tustin Pharmacy. At the time of the inspection, the pharmacy was under common ownership between PIC Oswald and another pharmacist, MR. PIC Oswald was present for the inspection. Tustin Pharmacy had a Drug Manufacturer License from the California Department of Public Health, License #41379, with an expiration date of June 16, 2015 and the pharmacy had a United States Postal Service station contracted inside of it.

31. During the routine inspection, it was noted that controlled substance invoices were commingled with non-controlled substance invoices. The inspector ordered a correction for the invoices to be separated.

32. PIC Oswald reported that the pharmacy performed very little simple compounding. However, the inspector located a prepared mouthwash on the shelf labeled: Ben/Dec/Xyl2%/MAAL AA SOL Mfg: COMPOUND. When asked for the records for the preparation of the compound, PIC Oswald produced a composition note book. In the book was 1 page of entries for 6 items compounded by the pharmacy.[2]

[2] There were 6 entries in this log on the following dates: 6/24/no year; 6/26/2014; 7/7/2014; 7/30/2014; and 8/6/no year. The entries did not suffice as a compounding log or master formula, as they only contained the Rx number, ingredients, ingredient manufacturer lot numbers, ingredient expiration dates; and a date. There were no

(continued…)

33. PIC Oswald stated he had been compounding simple items in this manner since at least 1990, but the majority of compounding was completed by Healthcare Pharmacy. [3] PIC Oswald admitted that he had not completed a compounding self-assessment.

34. Two products compounded by Healthcare Pharmacy for Tustin Pharmacy patients were located at Tustin Pharmacy during the inspection, C4645940 Testosterone 100mg/gm cream for patient WL and C4646403 Testosterone 4mg/gm cream for patient MM. The prescriptions were labeled with Healthcare Pharmacy labels, including Healthcare Pharmacy's phone number and address. An additional highlighted label can be seen on the prescriptions stating "REFILLS: (714) 731-1344". This phone number is to Respondent Tustin Pharmacy, not Healthcare Pharmacy.[4]

35. Tustin Pharmacy also received non-patient specific compounds from Healthcare Pharmacy. Healthcare Pharmacy sent a specific compounded dry socket soothing gel to Tustin Pharmacy. The soothing gel, Keflex, and Vicodin were repackaged for a dental office. Board inspectors located a sample order form dated 7/29/14 from the dentist's office to Tustin Pharmacy. The prescriber was Dr. CT, and the preprinted form had a variety of medications (including controlled substances) the prescriber could order repackaged by the pharmacy.

36. The Inspectors also located copies of prescriptions in the back of the pharmacy dated between April 30, 2012 and May 16, 2014. These prescriptions were for three large volume

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names of the person compounding and verifying the compound, the quantity of each component used was missing, and the total quantity of the compound produced was missing.

[3] Healthcare Pharmacy, Original Permit PHY 35296, was owned in part by PIC Oswald and in part by Pharmacist MR. Healthcare Pharmacy is not and has never been an establishment duly registered as a manufacturer with the Secretary of Health, Education and Welfare of the United States or licensed with the California Department of Public Health as a manufacturer. An inspection of Healthcare Pharmacy had alerted the Board that Healthcare Pharmacy was compounding non-patient specific dental soothing gel and sending it to Respondent Tustin Pharmacy.

[4] PIC Oswald reported that Healthcare Pharmacy completed the majority of the compounding for Tustin Pharmacy. If Tustin Pharmacy received a prescription for a compounded medication, the prescription was sent over to Healthcare Pharmacy via a driver. Healthcare Pharmacy would then compound the medication, and assign a prescription number specific to Healthcare Pharmacy. The medication would then be sent to Tustin Pharmacy for pickup by the patient. Any prescription refills were maintained by Healthcare Pharmacy, and if the patient called Tustin Pharmacy for a refill, Tustin Pharmacy would call Healthcare Pharmacy and ask for the refill for the patient. The patient had the option to pick up the medication at Tustin Pharmacy or at Healthcare Pharmacy. Tustin Pharmacy and Healthcare Pharmacy did not share a common electronic file and the prescription was not entered into the Tustin Pharmacy computer system at all if it is compounded by Healthcare Pharmacy. Health care Pharmacy kept records on the compounded medication. Patients paid Tustin pharmacy for the medications that were compounded at Healthcare Pharmacy.

compounded creams prescriptions which were compounded at Friendly Hills United Drug and Healthcare Pharmacy: Amitriptyline 4%/ Dextromethorphan 10% /Tramadol 20% (ADT); Capsaicin 0.0375%/ Menthol 10%/ Camphor 2.5%/ Tramadol 20% (Capflex); and Flurbiprofen 25%/Diclofenac 10% (Flurbi). The prescriptions were check boxes for the cream, with a Friendly Hills United Drugs header across the top. There were prescription labels with Friendly Hills United Drugs on the prescriptions as well.

37. PIC Oswald reported that Friendly Hills United Drugs and Healthcare Pharmacy sent compounded drugs to Tustin Pharmacy because the pharmacy has a special "Zebra" Printer, which allowed them to rapidly label the medications. PIC Oswald explained the USPS satellite office at the pharmacy was used to mail these medications to either the patient or the doctor's office. PIC Oswald told the inspectors that the compounded creams came to him in sealed boxes when they were already labeled patient specific and Tustin Pharmacy just added postage and shipped the box. When the compounded creams were going to doctor's offices for office use, the creams were labeled at Tustin Pharmacy, then packaged and mailed. PIC Oswald admitted he did not know what was inside the boxes he labeled and/or shipped, but he assumed it was the compounded cream(s).

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Complete Compounding Self-Assessment)

38. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that Respondents failed to perform a compounding self assessment prior to compounding medications at the pharmacy, in violation of CCR 1735.2(j), as set forth in paragraphs 29-37 above, which are incorporated herein by this reference. PIC Oswald admitted that he had not completed a compounding self-assessment prior to compounding medications at Tustin Pharmacy.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Create Complete Master Formula Prior to Compounding Medication)

39. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that Respondents failed to create complete a master formula prior to compounding medication, in violation of CCR 1735.2(d), as set forth in paragraphs 29-37

above, which are incorporated herein by this reference. PIC Oswald had not created complete master formulas prior to compounding the medications that he compounded at Tustin Pharmacy.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Failure to Keep Complete Compounding Records)

40. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that Respondents failed to maintain complete compounding records, in violation of CCR 1735.3(a) and (d), as set forth in paragraphs 29-37 above, which are incorporated herein by this reference. PIC Oswald did not utilize a complete compounding record. The compounding records also lacked the amount of each ingredient used, the amount of the compound prepared, and the drug's expiration date.

FOURTH CAUSE FOR DISCIPLINE
(Unprofessional Conduct – Failure to Maintain Records For Medications Received from Healthcare Pharmacy)

41. Respondents are subject to disciplinary action for unprofessional conduct under Code section 4301, subsection (o), in that Respondents failed to receive or maintain appropriate acquisition records of dangerous drugs received from Healthcare Pharmacy, in violation of Code section 4059 and 4105(a), as set forth in paragraphs 29-37 above which are incorporated herein by this reference.

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Mislabeling and Selling Misbranded Drugs)

42. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating statutes regulating controlled substances and dangerous drugs and state laws governing pharmacy, in that Respondents mislabeled and sold misbranded drugs, as defined by Health & Safety Code sections 111330, 111430, 111440, 111445, and 111450. These violations are set forth in paragraphs 29-37, which are incorporated herein by reference, and as follows.

a. Healthcare Pharmacy was manufacturing medication, but was not a licensed manufacturer. Because Healthcare Pharmacy was not a licensed manufacturer, products produced at Healthcare Pharmacy but not sold to the ultimate consumer at Healthcare Pharmacy were

considered misbranded. Receiving, holding, and relabeling medications compounded by Healthcare Pharmacy is a violation of Health and Safety Code sections 111440, 111445, and 111450.

b. It was also a violation to sell medications compounded at Healthcare Pharmacy but sent to Tustin Pharmacy for relabeling or for patient pickup, including the testosterone cream and the dental socket soothing gel being received by the pharmacy that was non-patient specific. Tustin Pharmacy may not lawfully receive, hold, misbrand, or sell drugs manufactured from establishments that were not duly registered.

c. Tustin Pharmacy was receiving, holding, and selling medications compounded by Healthcare Pharmacy, including prescription numbers (1) C4645940 Testosterone lOOmg/gm cream for patient WL and (2) C4646403 Testosterone 4mg/gm cream for patient MM which were located at the pharmacy during the inspection.

d. Tustin Pharmacy was also receiving misbranded compounded medications from Healthcare Pharmacy, relabeling them, and selling them to a dentist's office. This is a violation of Business and Professions Code 4169(a)(3) for selling or transferring misbranded medication.

e. Tustin Pharmacy's manufacturing/repackaging license does not allow Tustin Pharmacy to receive, repackage, and subsequently sell misbranded medications.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Delivered or Proffered for Delivery Misbranded Drugs)

43. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating statutes regulating controlled substances and dangerous drugs and state laws governing pharmacy, in that Respondents delivered or proffered for delivery misbranded drugs, as defined by Health & Safety Code section 111330 and 111430 in violation of Health and Safety Code section 111450, as set forth in paragraphs 29-37, which are incorporated herein by reference.

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OTHER MATTERS

44. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 30023 issued to Tustin Community Pharmacy, Inc. doing business as Tustin Community Pharmacy, Tustin Community Pharmacy, Inc, doing business as Tustin Community Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 30023 is placed on probation or until Pharmacy Permit Number PHY 30023 is reinstated if it is revoked.

45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 30023 issued to Tustin Community Pharmacy, Inc. doing business as Tustin Community Pharmacy while Jerry Don Oswald has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Jerry Don Oswald shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 30023 is placed on probation or until Pharmacy Permit Number PHY 30023 is reinstated if it is revoked.

46. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 31903 issued to Jerry Don Oswald, Jerry Don Oswald shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 30023 is placed on probation or until Pharmacist License Number RPH 30023 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 Pharmacy Permit Number PHY 30023, issued to Tustin Community Pharmacy, Inc. dba Tustin Community Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 31903, issued to Jerry Don Oswald;

3. Prohibiting Tustin Community Pharmacy, Inc. doing business as Tustin Community Pharmacy, from serving as a manager, administrator, owner, member, officer, director, associate,

or partner of a licensee for five years if Pharmacy Permit Number PHY 30023 is placed on probation or until Pharmacy Permit Number PHY 30023 is reinstated if Pharmacy Permit Number PHY 30023 issued to Tustin Community Pharmacy, Inc. doing business as Tustin Community Pharmacy is revoked;

4. Prohibiting Jerry Don Oswald from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 30023 is placed on probation or until Pharmacy Permit Number PHY 30023 is reinstated if Pharmacy Permit Number PHY 30023 issued to Tustin Community Pharmacy, Inc. doing business as Tustin Community Pharmacy is revoked;

5. Prohibiting Jerry Don Oswald from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 31903 is placed on probation or until Pharmacist License Number RPH 31903 is reinstated if Pharmacist License Number RPH 31903 issued to Jerry Don Oswald is revoked;

6. Ordering Tustin Community Pharmacy, Inc. doing business as Tustin Community Pharmacy and Jerry Don Oswald 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,

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

DATED: February 17, 2020

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

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