

**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;**

**Pharmacy Permit No. PHY 30023**

**and**

**JERRY DON OSWALD;**

**Pharmacist License No. RPH 31903**

**Respondents**

**OAH No. 2019100053**

**Agency Case No. 6160**

**DECISION AND ORDER**

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.



This Decision shall become effective at 5:00 p.m. on October 8, 2020.

It is so ORDERED on September 8, 2020.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Greg M. Lippe", written in a cursive style.

By

Greg Lippe  
Board President



1 XAVIER BECERRA  
Attorney General of California  
2 JAMES M. LEDAKIS  
Supervising Deputy Attorney General  
3 DANIEL J. CROSS  
Deputy Attorney General  
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*Attorneys for Complainant*  
8

9 **BEFORE THE**  
10 **BOARD OF PHARMACY**  
11 **DEPARTMENT OF CONSUMER AFFAIRS**  
12 **STATE OF CALIFORNIA**

13 In the Matter of the First Amended Accusation  
Against:

14 **TUSTIN COMMUNITY PHARMACY,**  
15 **INC. DBA TUSTIN COMMUNITY**  
16 **PHARMACY**  
13400 Newport Avenue  
Tustin, CA 92680

17 **Pharmacy Permit No. PHY 30023,**  
18 **and**

19 **JERRY DON OSWALD**  
20 **13400 Newport Avenue**  
Tustin, CA 92780

21 **Pharmacist License No. RPH 31903,**

22 Respondents.  
23

Case No. 6160

OAH No. 2019100053

**STIPULATED SETTLEMENT AND  
DISCIPLINARY ORDER**

24 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-  
25 entitled proceedings that the following matters are true:

26 **PARTIES**

27 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy  
28 (Board). She brought this action solely in her official capacity and is represented in this matter by



1 Xavier Becerra, Attorney General of the State of California, by Daniel J. Cross, Deputy Attorney  
2 General.

3 2. Respondents Jerry Don Oswald (Respondent Oswald) and Tustin Community  
4 Pharmacy, Inc., dba Tustin Community Pharmacy (Respondent Pharmacy), are represented in this  
5 proceeding by Luis Andre P. Vizcocho, R.Ph., J.D. of California Pharmacy Lawyers, located at  
6 55 Cetus, 1<sup>st</sup> Floor, Irvine, CA 92618.

7 3. On June 1, 1983, the Board issued Pharmacy Permit Number PHY 30023 to  
8 Respondent Pharmacy. The Pharmacy Permit was in full force and effect at all times relevant to  
9 the charges brought herein. The Pharmacy Permit expired on June 24, 2016, and has not been  
10 renewed.

11 4. On July 31, 1978, the Board issued Pharmacist License Number RPH 31903 to  
12 Respondent Oswald. Respondent Oswald was the Pharmacist in Charge (PIC) of Respondent  
13 Pharmacy from April 4, 1985 to July 21, 2016, when the Pharmacy's permit was cancelled.  
14 Respondent Oswald's Pharmacist License was in full force and effect at all times relevant to the  
15 charges brought herein and will expire on August 31, 2020, if not renewed.

#### 16 **JURISDICTION**

17 5. First Amended Accusation Number 6160 was filed before the Board, and is currently  
18 pending against Respondents. First Amended Accusation, the original Accusation, and all other  
19 statutorily required documents were properly served on Respondents. Respondents timely filed  
20 their Notice of Defense contesting the Accusation.

21 6. A copy of First Amended Accusation Number 6160 is attached as exhibit A and  
22 incorporated herein by reference.

#### 23 **ADVISEMENT AND WAIVERS**

24 7. Respondents have carefully read, fully discussed with counsel, and understand the  
25 charges and allegations in First Amended Accusation Number 6160. Respondents have also  
26 carefully read, fully discussed with counsel, and understand the effects of this Stipulated  
27 Settlement and Disciplinary Order.

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8. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each right set forth above.

## CULPABILITY

10. Respondents understand and agree that the charges and allegations in First Amended Accusation Number 6160, if proven at a hearing, constitute cause for imposing discipline upon their Pharmacy Permit and Pharmacist License.

11. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondents agree that at a hearing Complainant could establish a factual basis for the charges in the First Amended Accusation. Respondents hereby gives up their right to contest those charges.

12. Respondents agree that their Pharmacy Permit and Pharmacist License are subject to discipline and agree to be bound by the Board's disciplinary terms as set forth in the Disciplinary Order below.

## RESERVATION

13. The admissions made by Respondents herein are only for the purposes of this proceeding, or any other proceedings in which the Board or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

## CONTINGENCY

14. This stipulation shall be subject to approval by the Board. Respondents understand and agree that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by



1 Respondents or their counsel. By signing the stipulation, Respondents understand and agree that  
2 they may not withdraw their agreement or seek to rescind the stipulation prior to the time the  
3 Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and  
4 Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for  
5 this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall  
6 not be disqualified from further action by having considered this matter.

7 15. The parties understand and agree that Portable Document Format (PDF) and facsimile  
8 copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile  
9 signatures thereto, shall have the same force and effect as the originals.

10 16. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an  
11 integrated writing representing the complete, final, and exclusive embodiment of their agreement.  
12 It supersedes any prior or contemporaneous agreements, understandings, discussions,  
13 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary  
14 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a  
15 writing executed by an authorized representative of each party.

16 17. In consideration of the foregoing admissions and stipulations, the parties agree that  
17 the Board may, without further notice or formal proceeding, issue and enter the following  
18 Disciplinary Order:

19 **DISCIPLINARY ORDER**

20 **Discipline as to Respondent Pharmacy:**

21 IT IS HEREBY ORDERED that Pharmacy Permit Number PHY 30023 issued to  
22 Respondent Pharmacy is surrendered and accepted by the Board.

23 1. The surrender of Respondent Pharmacy's Pharmacy Permit and the acceptance of the  
24 surrendered permit by the Board shall constitute the imposition of discipline against Respondent  
25 Pharmacy. This stipulation constitutes a record of the discipline and shall become a part of  
26 Respondent Pharmacy's license history with the Board.

27 2. Respondent Pharmacy shall lose all rights and privileges as a pharmacy in California  
28 as of the effective date of the Board's Decision and Order.



1           3.     Respondent Pharmacy shall cause its wall certificate to be delivered to the Board on  
2 or before the effective date of the Decision and Order.

3           4.     If Respondent Pharmacy ever applies for licensure or petitions for reinstatement in  
4 the State of California, the Board shall treat it as a new application for licensure. Respondent  
5 Pharmacy must comply with all the laws, regulations, and procedures for licensure in effect at the  
6 time the application or petition is filed, and all of the charges and allegations contained in First  
7 Amended Accusation Number 6160 shall be deemed to be true, correct, and admitted by  
8 Respondent Pharmacy when the Board determines whether to grant or deny the application or  
9 petition.

10          5.     Respondent Pharmacy shall pay the agency its costs of investigation and enforcement  
11 in the amount of \$12,236.75 prior to issuance of a new or reinstated license.

12          6.     If Respondent Pharmacy should ever apply or reapply for a new license or  
13 certification, or petition for reinstatement of a license, by any other health care licensing agency  
14 in the State of California, all of the charges and allegations contained in First Amended  
15 Accusation Number 6160 shall be deemed to be true, correct, and admitted by Respondent  
16 Pharmacy for the purpose of any Statement of Issues or any other proceeding seeking to deny or  
17 restrict licensure.

18     **Discipline as to Respondent Oswald:**

19           IT IS HEREBY ORDERED that Pharmacist License Number RPH 31903 issued to  
20 Respondent Oswald is revoked. However, the revocation is stayed and Respondent Oswald is  
21 placed on probation for three years on the following terms and conditions.

22           1.     **Obey All Laws**

23           Respondent Oswald shall obey all state and federal laws and regulations.

24           Respondent Oswald shall report any of the following occurrences to the Board, in writing,  
25 within 72 hours of such occurrence:

- 26           •     an arrest or issuance of a criminal complaint for violation of any provision of the  
27                 Pharmacy Law, state and federal food and drug laws, or state and federal controlled  
28                 substances laws;



- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal

criminal proceeding to any criminal complaint, information or indictment;

a conviction of any crime; or

the filing of a disciplinary pleading, issuance of a citation, or initiation of another

administrative action filed by any state or federal agency that involves Respondent

Oswald's pharmacy license, is related to the practice of pharmacy, or is related to the

manufacturing, obtaining, handling, distributing, billing, or charging for any drug,

device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

## **2. Report to the Board**

Respondent Oswald shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed.

Among other requirements, Respondent Oswald shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

## **3. Interview with the Board**

Upon receipt of reasonable prior notice, Respondent Oswald shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

## **4. Cooperate with Board Staff**

Respondent Oswald shall timely cooperate with the board's inspection program and with the Board's monitoring and investigation of Respondent Oswald's compliance with the terms and



1 conditions of probation, including but not limited to: timely responses to requests for information  
2 by Board staff; timely compliance with directives from Board staff regarding requirements of any  
3 term or condition of probation; and timely completion of documentation pertaining to a term or  
4 condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5 **5. Continuing Education**

6 Respondent Oswald shall provide evidence of efforts to maintain skill and knowledge as a  
7 pharmacist as directed by the Board or its designee.

8 **6. Reporting of Employment and Notice to Employers**

9 During the period of probation, Respondent Oswald shall notify all present and prospective  
10 employers of the decision in case number 6160 and the terms, conditions and restrictions imposed  
11 on Respondent Oswald by the decision, as follows:

12 Within 30 days of the effective date of this decision, and within 10 days of undertaking any  
13 new employment, Respondent Oswald shall report to the Board in writing the name, physical  
14 address, and mailing address of each of his employer(s), and the name(s) and telephone  
15 number(s) of all of his direct supervisor(s), as well as any pharmacist(s)-in-charge, designated  
16 representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work  
17 schedule, if known. Respondent Oswald shall also include the reason(s) for leaving the prior  
18 employment. Respondent Oswald shall sign and return to the Board a written consent authorizing  
19 the Board or its designee to communicate with all of Respondent Oswald's employer(s) and  
20 supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the Board  
21 or its designee, concerning Respondent Oswald's work status, performance, and monitoring.  
22 Failure to comply with the requirements or deadlines of this condition shall be considered a  
23 violation of probation.

24 Within 30 days of the effective date of this decision, and within 15 days of Respondent  
25 Oswald undertaking any new employment, Respondent Oswald shall cause (a) his direct  
26 supervisor, (b) his pharmacist-in-charge, designated representative-in-charge, responsible  
27 manager, or other compliance supervisor, and (c) the owner or owner representative of his  
28 employer, to report to the Board in writing acknowledging that the listed individual(s) has/have



1 read the decision in case number 6160, and terms and conditions imposed thereby. If one person  
2 serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It  
3 shall be the Respondent Oswald's responsibility to ensure that these acknowledgment(s) are  
4 timely submitted to the Board. In the event of a change in the person(s) serving the role(s)  
5 described in (a), (b), or (c) during the term of probation, Respondent Oswald shall cause the  
6 person(s) taking over the role(s) to report to the Board in writing within 15 days of the change  
7 acknowledging that he or she has read the decision in case number 6160, and the terms and  
8 conditions imposed thereby.

9 If Respondent Oswald works for or is employed by or through an employment service,  
10 Respondent Oswald must notify the person(s) described in (a), (b), and (c) above at every entity  
11 licensed by the Board of the decision in case number 6160, and the terms and conditions imposed  
12 thereby in advance of Respondent Oswald commencing work at such licensed entity. A record of  
13 this notification must be provided to the Board upon request.

14 Furthermore, within 30 days of the effective date of this decision, and within 15 days of  
15 undertaking any new employment by or through an employment service, Respondent Oswald  
16 shall cause the person(s) described in (a), (b), and (c) above at the employment service to report  
17 to the Board in writing acknowledging that he or she has read the decision in case number 6160,  
18 and the terms and conditions imposed thereby. It shall be Respondent Oswald's responsibility to  
19 ensure that these acknowledgment(s) are timely submitted to the Board.

20 Failure to timely notify present or prospective employer(s) or failure to cause the identified  
21 person(s) with that/those employer(s) to submit timely written acknowledgments to the Board  
22 shall be considered a violation of probation.

23 "Employment" within the meaning of this provision includes any full-time, part-time,  
24 temporary, relief, or employment/management service position as a Licensed Pharmacist, or any  
25 position for which a Pharmacist License is a requirement or criterion for employment, whether  
26 Respondent Oswald is an employee, independent contractor or volunteer.

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1           **7. Notification of Change(s) in Name, Address(es), or Phone Number(s)**

2           Respondent Oswald shall further notify the Board in writing within 10 days of any change  
3 in name, residence address, mailing address, e-mail address or phone number.

4           Failure to timely notify the Board of any change in employer, name, address, or phone  
5 number shall be considered a violation of probation.

6           **8. Restrictions on Supervision and Oversight of Licensed Facilities**

7           During the period of probation, Respondent Oswald shall not supervise any intern  
8 pharmacist or serve as a consultant to any entity licensed by the Board. Respondent may be a  
9 pharmacist-in-charge, designated representative-in-charge, responsible manager, or other  
10 compliance supervisor of Tustin Pharmacy, Pharmacy Permit Number 53356 (Tustin Pharmacy),  
11 but only if Respondent Oswald or Tustin Pharmacy retains, at his expense, an independent  
12 consultant who shall be responsible for conducting an on-site physical inspection to review the  
13 operations of Tustin Pharmacy on a monthly basis for compliance by Respondent Oswald and  
14 Tustin Pharmacy with state and federal laws and regulations governing the practice of pharmacy,  
15 and compliance by Respondent Oswald with the obligations of his supervisory position. During  
16 the period of probation, the Board or its designee retains the discretion to reduce the frequency  
17 and form of inspection and the pharmacist consultant's review. The consultant shall be a  
18 pharmacist licensed by and not on probation with the Board, who has been approved by the Board  
19 or its designee to serve in this position. Respondent Oswald shall submit the name of the  
20 proposed consultant to the Board or its designee for approval within 30 days of the effective date  
21 of the decision. Assumption of any unauthorized supervision responsibilities shall be considered  
22 a violation of probation. In addition, failure to timely seek approval for, timely retain, or ensure  
23 timely reporting by the consultant shall be considered a violation of probation.

24           **9. Reimbursement of Board Costs**

25           As a condition precedent to successful completion of probation, Respondent Oswald shall  
26 pay to the Board its costs of investigation and prosecution in the amount of \$8,000.00.  
27 Respondent Oswald shall be permitted to pay these costs in a payment plan approved by the  
28 Board or its designee, so long as full payment is completed no later than 1 year prior to the end



1 date of probation. There shall be no deviation from this schedule absent prior written approval by  
2 the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a  
3 violation of probation.

4 **10. Probation Monitoring Costs**

5 Respondent Oswald shall pay any costs associated with probation monitoring as determined  
6 by the Board each year of probation. Such costs shall be payable to the Board on a schedule as  
7 directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed  
8 shall be considered a violation of probation.

9 **11. Status of License**

10 Respondent Oswald shall, at all times while on probation, maintain active, current licensure  
11 with the Board, including any period during which suspension or probation is tolled. Failure to  
12 maintain active, current licensure shall be considered a violation of probation.

13 If Respondent Oswald's license expires or is cancelled by operation of law or otherwise at  
14 any time during the period of probation, including any extensions thereof due to tolling or  
15 otherwise, upon renewal or reapplication Respondent Oswald's license shall be subject to all  
16 terms and conditions of this probation not previously satisfied.

17 **12. License Surrender While on Probation**

18 Following the effective date of this decision, should Respondent Oswald cease practice due  
19 to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,  
20 Respondent Oswald may relinquish his Pharmacist License, including any indicia of licensure  
21 issued by the Board, along with a request to surrender the license. The Board or its designee shall  
22 have the discretion whether to accept the surrender or take any other action it deems appropriate  
23 and reasonable. Upon formal acceptance of the surrender of the license, Respondent Oswald will  
24 no longer be subject to the terms and conditions of probation. The surrender will constitute a  
25 record of discipline and shall become a part of the Respondent Oswald's license history with the  
26 Board.

27 Upon acceptance of the surrender, Respondent Oswald shall relinquish his pocket and wall  
28 license, including any indicia of licensure not previously provided to the Board, within 10 days of



notification by the Board that the surrender is accepted. Respondent Oswald may not reapply for any license from the Board for three years from the effective date of the surrender. Respondent Oswald shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

**13. Practice Requirement – Extension of Probation**

Except during periods of suspension, Respondent Oswald shall, at all times while on probation, be employed as a Licensed Pharmacist in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent Oswald must nonetheless comply with all terms and conditions of probation, unless he receives a waiver in writing from the Board or its designee.

If Respondent Oswald does not practice as a Licensed Pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), he shall notify the Board in writing within 10 days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent Oswald will resume practice at the required level. Respondent Oswald shall further notify the Board in writing within 10 days following the next calendar month during which Respondent Oswald practices as a Licensed Pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent Oswald's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The Board or its designee may post a notice of the extended probation period on its website.

**14. Remedial Education**

Within 60 days of the effective date of this decision, and once each year of probation, Respondent Oswald shall complete a six-hour course in Compounding, including both USP 795 and USP 800 training. The courses shall be completed at Respondent Oswald's own expense.



1 All remedial education shall be in addition to, and shall not be credited toward, continuing  
2 education (CE) courses used for license renewal purposes for pharmacists.

3 Failure to timely complete the courses shall be considered a violation of probation. The  
4 period of probation will be automatically extended until such courses are successfully completed  
5 and written proof, in a form acceptable to the Board, is provided to the Board or its designee.

6 Following the completion of the course each year, the Board or its designee may require  
7 Respondent Oswald, at his own expense, to take an approved examination to test his knowledge  
8 of the course. If Respondent Oswald does not achieve a passing score on the examination that  
9 course shall not count towards satisfaction of this term and he shall take another course approved  
10 by the Board in the same subject area.

#### 11 **15. Ethics Course**

12 Within 60 days of the effective date of this decision, Respondent Oswald shall enroll in a  
13 course in ethics, at his own expense, approved in advance by the Board or its designee that  
14 complies with Title 16 of the California Code of Regulations, section 1773.5. Respondent  
15 Oswald shall provide proof of enrollment upon request. Within five days of completion,  
16 Respondent Oswald shall submit a copy of the certificate of completion to the Board or its  
17 designee. Failure to timely enroll in an approved ethics course, to initiate the course during the  
18 first year of probation, to successfully complete it before the end of the second year of probation,  
19 or to timely submit proof of completion to the Board or its designee, shall be considered a  
20 violation of probation.

#### 21 **16. No Additional Ownership or Management of Licensed Premises**

22 Respondent Oswald shall not acquire any new ownership, legal or beneficial interest, nor  
23 serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any  
24 additional business, firm, partnership, or corporation licensed by the Board. If Respondent  
25 Oswald currently owns or has any legal or beneficial interest in, or serves as a manager,  
26 administrator, member, officer, director, trustee, associate, or partner of any business, firm,  
27 partnership, or corporation currently or hereinafter licensed by the Board, Respondent Oswald  
28 may continue to serve in such capacity or hold that interest, but only to the extent of that position



1 or interest as of the effective date of this decision. Violation of this restriction shall be considered  
2 a violation of probation.

3 **17. Violation of Probation**

4 If Respondent Oswald has not complied with any term or condition of probation, the Board  
5 shall have continuing jurisdiction over respondent, and the Board shall provide notice to  
6 Respondent Oswald that probation shall automatically be extended, until all terms and conditions  
7 have been satisfied or the board has taken other action as deemed appropriate to treat the failure  
8 to comply as a violation of probation, to terminate probation, and to impose the penalty that was  
9 stayed. The Board or its designee may post a notice of the extended probation period on its  
10 website.

11 If Respondent Oswald violates probation in any respect, the board, after giving Respondent  
12 Oswald notice and an opportunity to be heard, may revoke probation and carry out the  
13 disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed  
14 against Respondent Oswald during probation, or the preparation of an accusation or petition to  
15 revoke probation is requested from the Office of the Attorney General, the Board shall have  
16 continuing jurisdiction and the period of probation shall be automatically extended until the  
17 petition to revoke probation or accusation is heard and decided.

18 **18. Completion of Probation**

19 Upon written notice by the Board or its designee indicating successful completion of  
20 probation, Respondent Oswald's license will be fully restored.

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**ACCEPTANCE**

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Luis Andre P. Vizcocho, R.Ph., J.D. of California Pharmacy Lawyers. I understand the stipulation and the effect it will have on my Pharmacy Permit and Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: \_\_\_\_\_

\_\_\_\_\_  
JERRY DON OSWALD  
*Respondent*

DATED: \_\_\_\_\_

\_\_\_\_\_  
TUSTIN COMMUNITY PHARMACY, INC., DBA  
TUSTIN COMMUNITY PHARMACY  
*Respondent*

I have read and fully discussed with Respondents Jerry Don Oswald and Tustin Community Pharmacy, Inc., dba Tustin Community Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: \_\_\_\_\_

\_\_\_\_\_  
Luis Andre P. Vizcocho, R.Ph., J.D.,  
California Pharmacy Lawyers  
*Attorney for Respondent*



ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Luis Andre P. Vizcocho, R.Ph., J.D. of California Pharmacy Lawyers. I understand the stipulation and the effect it will have on my Pharmacy Permit and Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED:

07-06-20



JERRY DON OSWALD  
*Respondent*

DATED:

07-06-20



TUSTIN COMMUNITY PHARMACY, INC., DBA  
TUSTIN COMMUNITY PHARMACY  
*Respondent*

I have read and fully discussed with Respondents Jerry Don Oswald and Tustin Community Pharmacy, Inc., dba Tustin Community Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED:

Luis Andre P. Vizcocho, R.Ph., J.D.,  
California Pharmacy Lawyers  
*Attorney for Respondent*



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ACCEPTANCE

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DATED: \_\_\_\_\_

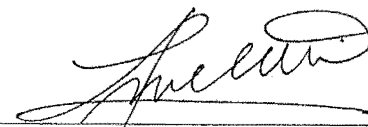
JERRY DON OSWALD  
*Respondent*

DATED: \_\_\_\_\_

TUSTIN COMMUNITY PHARMACY, INC., DBA  
TUSTIN COMMUNITY PHARMACY  
*Respondent*

I have read and fully discussed with Respondents Jerry Don Oswald and Tustin Community Pharmacy, Inc., dba Tustin Community Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: July 10, 2020

  
Luis Andre P. Vizcocho, R.Ph., J.D.,  
California Pharmacy Lawyers  
*Attorney for Respondent*



**ENDORSEMENT**

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: \_\_\_\_\_

Respectfully submitted,

XAVIER BECERRA  
Attorney General of California  
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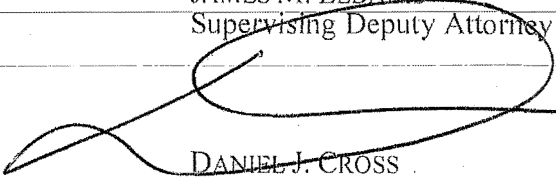
**ENDORSEMENT**

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

DATED: 7/13/20

Respectfully submitted,

XAVIER BECERRA  
Attorney General of California  
JAMES M. LEDAKIS  
Supervising Deputy Attorney General



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## **Exhibit A**

**First Amended Accusation Number 6160**



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8  
9 **BEFORE THE**  
**BOARD OF PHARMACY**  
10 **DEPARTMENT OF CONSUMER AFFAIRS**  
**STATE OF CALIFORNIA**

11 In the Matter of the Accusation Against:

Case No. 6160

12 **Tustin Community Pharmacy, Inc.**  
13 **Db a Tustin Community Pharmacy**  
14 **13400 Newport Avenue**  
**Tustin, CA 92680**

**FIRST AMENDED ACCUSATION**

15 **Original Permit No. PHY 30023**

16 **And**

17 **Jerry Don Oswald**  
18 **13400 Newport Ave.**  
**Tustin, CA 92780**

19 **Pharmacist License No. RPH 31903**

20 Respondents.

21  
22 Complainant alleges:

23 **PARTIES**

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

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



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

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

### 8 JURISDICTION

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

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

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

17 7. Section 4300.1 of the Code states:

18 The expiration, cancellation, forfeiture, or suspension of a board-issued  
19 license by operation of law or by order or decision of the board or a court of law,  
20 the placement of a license on a retired status, or the voluntary surrender of a  
21 license by a licensee shall not deprive the board of jurisdiction to commence or  
22 proceed with any investigation of, or action or disciplinary proceeding against, the  
23 licensee or to render a decision suspending or revoking the license.

### 24 STATUTORY AUTHORITY

25 8. Section 4022 of the Code states:

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

28 (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.



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

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

5 . . . .

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

7 The board shall take action against any holder of a license who is guilty of  
8 unprofessional conduct or whose license has been issued by mistake.

9 Unprofessional conduct shall include, but is not limited to, any of the following:

10 . . . .

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

13 . . . .

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

19 . . . .

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

21 Any person who has been denied a license or whose license has been revoked  
22 or is under suspension, or who has failed to renew his or her license while it was  
23 under suspension, or who has been a manager, administrator, owner member, officer,  
24 director, associate, partner, or any other person with management or control of any  
25 partnership, corporation, firm, or association whose application for a license has been  
26 denied or revoked, is under suspension or has been placed on probation, and while  
27 acting as the manger, administrator, owner, member, officer, director, associate,  
28 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 17. Health and Safety Code section 111330 provides that any drug or device is  
18 misbranded if its labeling is false or misleading in any particular.



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

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

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

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

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

#### 14 **REGULATORY PROVISIONS<sup>1</sup>**

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

17 (a) "Compounding" means any of the following activities occurring in a  
18 licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to  
a prescription:

19 (1) Altering the dosage form or delivery system of a drug

20 (2) Altering the strength of a drug

21 (3) Combining components or active ingredients

22 (4) Preparing a drug product from chemicals or bulk drug substances

23 ...

24 (c) "Compounding" does not include, except in small quantities under limited  
25 circumstances as justified by a specific, documented, medical need, preparation of a  
26 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.

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27 <sup>1</sup> The Board's compounding regulations were amended, effective January 1, 2017. The  
28 regulations cited in this Accusation refer to the regulations in effect at the time of the violations  
alleged herein.



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

2                   (a) Except as specified in (b) and (c), no drug preparation shall be  
3 compounded prior to receipt by a pharmacy of a valid prescription for an individual  
4 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.

5                   (b) A pharmacy may prepare and store a limited quantity of a  
6 compounded drug product in advance of receipt of a patient-specific prescription  
7 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.

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

10                   (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

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

13                   (3) for any individual prescriber and for all prescribers taken as a whole,  
14 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.

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

17                   (1) Active ingredients to be used.

18                   (2) Equipment to be used.

19                   (3) Expiration dating requirements.

20                   (4) Inactive ingredients to be used.

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

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

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

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

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

28                   (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 licensee found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

### **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.<sup>2</sup>

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<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup>

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.

<sup>3</sup> 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.

<sup>4</sup> 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. Healthcare Pharmacy kept records on the compounded medication. Patients paid Tustin pharmacy for the medications that were compounded at Healthcare Pharmacy.



1 compounded creams prescriptions which were compounded at Friendly Hills United Drug and  
2 Healthcare Pharmacy: Amitriptyline 4%/ Dextromethorphan 10% /Tramadol 20% (ADT); Capsaicin  
3 0.0375%/ Menthol 10%/ Camphor 2.5%/ Tramadol 20% (Capflex); and Flurbiprofen 25%/Diclofenac  
4 10% (Flurbi). The prescriptions were check boxes for the cream, with a Friendly Hills United Drugs  
5 header across the top. There were prescription labels with Friendly Hills United Drugs on the  
6 prescriptions as well.

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

#### 16 **FIRST CAUSE FOR DISCIPLINE**

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

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

#### 24 **SECOND CAUSE FOR DISCIPLINE**

##### 25 **(Unprofessional Conduct – Failure to Create Complete Master Formula 26 Prior to Compounding Medication)**

27 39. Respondents are subject to disciplinary action for unprofessional conduct under Code  
28 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



1 considered misbranded. Receiving, holding, and relabeling medications compounded by  
2 Healthcare Pharmacy is a violation of Health and Safety Code sections 111440, 111445, and  
3 111450.

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

9 c. Tustin Pharmacy was receiving, holding, and selling medications compounded  
10 by Healthcare Pharmacy, including prescription numbers (1) C4645940 Testosterone 100mg/gm  
11 cream for patient WL and (2) C4646403 Testosterone 4mg/gm cream for patient MM which were  
12 located at the pharmacy during the inspection.

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

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

#### 18 **SIXTH CAUSE FOR DISCIPLINE**

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

20 43. Respondents are subject to disciplinary action under Code sections 4301(j) and (o),  
21 for violating statutes regulating controlled substances and dangerous drugs and state laws  
22 governing pharmacy, in that Respondents delivered or proffered for delivery misbranded drugs,  
23 as defined by Health & Safety Code section 111330 and 111430 in violation of Health and Safety  
24 Code section 111450, as set forth in paragraphs 29-37, which are incorporated herein by  
25 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,



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

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

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

14 6. Ordering Tustin Community Pharmacy, Inc. doing business as Tustin Community  
15 Pharmacy and Jerry Don Oswald to pay the Board of Pharmacy the reasonable costs of the  
16 investigation and enforcement of this case, pursuant to Business and Professions Code section  
17 125.3; and,

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

19  
20 DATED: February 17, 2020



21 ANNE SODERGREN  
22 Executive Officer  
23 Board of Pharmacy  
24 Department of Consumer Affairs  
State of California  
*Complainant*

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