

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

In the Matter of the Accusation Against:

Case No. 5102

**PHARMACIA CORPORATION d.b.a
1800 SULLIVAN PHARMACY
William M. Tonelli, President
Elsie Tonelli, Vice President
Randall W. Tonelli, Secretary and
Pharmacist-in-Charge
1800 Sullivan Avenue, Suite 102
Daly City, CA 94015**

Pharmacy Permit No. PHY 18784

and

**RANDALL W. TONELLI
14 Golden Ridge Court
San Mateo, CA 94402**

Pharmacist License No. RPH 24318

Respondents.

DECISION AND ORDER

The attached Stipulated Surrender of License and 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 December 22, 2016.

It is so ORDERED on November 22, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

1 KAMALA D. HARRIS
Attorney General of California
2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 ASPASIA A. PAPAVALASSILOU
Deputy Attorney General
4 State Bar No. 196360
1515 Clay Street, 20th Floor
5 P.O. Box 70550
Oakland, CA 94612-0550
6 Telephone: (510) 879-0818
Facsimile: (510) 622-2270
7 E-mail: Aspasia.Papavassiliou@doj.ca.gov
Attorneys for Complainant

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

11 In the Matter of the First Amended Accusation
12 Against:

Case No. 5102

13 **PHARMACIA CORPORATION d.b.a.**
1800 SULLIVAN PHARMACY
14 **William M. Tonelli, President**
Elsie Tonelli, Vice President
15 **Randall W. Tonelli, Secretary and**
Pharmacist-in-Charge
16 **1800 Sullivan Avenue, Suite 102**
Daly City, CA 94015

**STIPULATED SURRENDER OF
LICENSE AND ORDER**

17 **Pharmacy Permit No. PHY 18784**

18 and

19 **RANDALL W. TONELLI**
20 **14 Golden Ridge Court**
San Mateo, CA 94402

21 **Pharmacist License No. RPH 24318**

22 Respondents.
23

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. Virginia Herold (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 Kamala D. Harris, Attorney General of the State of California, by Aspasia A. Papavassiliou,
2 Deputy Attorney General.

3 2. Respondents 1800 Sullivan Pharmacy and Randall W. Tonelli are represented in this
4 proceeding by attorney Alexander M. Medina, whose address is 983 Reserve Drive, Roseville,
5 CA 95678.

6 3. On or about July 29, 1985, the Board of Pharmacy issued Pharmacy Permit Number
7 PHY 18784 to Pharmacia Corporation doing business as 1800 Sullivan Pharmacy (Respondent
8 Pharmacy), with William M. Tonelli as President, Elsie Tonelli as Vice President, and Randall W.
9 Tonelli as Secretary and Pharmacist-in-Charge. The permit will expire on February 1, 2017,
10 unless renewed.

11 4. On or about October 29, 1965, the Board of Pharmacy issued Pharmacist License
12 Number RPH 24318 to Randall W. Tonelli (Respondent Pharmacist). The license will expire on
13 February 20, 2017, unless renewed.

14 JURISDICTION

15 5. The First Amended Accusation in Case No. 5102 was filed before the Board and is
16 currently pending against Respondents. The original Accusation and all other statutorily required
17 documents were properly served on Respondent on June 2, 2016. Respondents timely filed their
18 Notice of Defense contesting the Accusation. A copy of the First Amended Accusation is
19 attached as Exhibit A and incorporated by reference.

20 ADVISEMENT AND WAIVERS

21 6. Respondent Pharmacist, individually and on behalf of Respondent Pharmacy, has
22 carefully read, fully discussed with counsel, and understands the charges and allegations in the
23 First Amended Accusation, Case No. 5102, and has also carefully read, fully discussed with
24 counsel, and understands the effects of this Stipulated Surrender of License and Order.

25 7. Respondents are fully aware of their legal rights in this matter, including the right to a
26 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine
27 the witnesses against them; the right to present evidence and to testify on their own behalf; the
28 right to the issuance of subpoenas to compel the attendance of witnesses and the production of

1 documents; the right to reconsideration and court review of an adverse decision; and all other
2 rights accorded by the California Administrative Procedure Act and other applicable laws.

3 8. Respondents voluntarily, knowingly, and intelligently waive and give up each and
4 every right set forth above.

5 CULPABILITY

6 9. Respondents understand that the charges and allegations in the First Amended
7 Accusation, Case No. 5102, if proven at a hearing, constitute cause for imposing discipline upon
8 their pharmacy permit and pharmacist license.

9 10. For the purpose of resolving the First Amended Accusation without the expense and
10 uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could
11 establish a factual basis for the charges in the First Amended Accusation and that those charges
12 constitute cause for discipline. Respondents hereby give up their right to contest that cause for
13 discipline exists based on those charges.

14 11. Respondents understand that by signing this stipulation, they enable the Board to
15 issue an order accepting the surrender of their pharmacy permit and pharmacist license without
16 further process.

17 RESERVATION

18 12. The admissions made by Respondents in this stipulation are only for the purposes of
19 this proceeding, or any other proceedings in which the Board of Pharmacy or other professional
20 licensing agency is involved, and shall not be admissible in any other criminal or civil
21 proceeding.

22 CONTINGENCY

23 13. This stipulation shall be subject to approval by the Board. Respondents understand
24 and agree that counsel for Complainant and the staff of the Board may communicate directly with
25 the Board regarding this stipulation and surrender, without notice to or participation by
26 Respondents or their counsel. By signing the stipulation, Respondents understand and agree that
27 they may not withdraw their agreement or seek to rescind the stipulation prior to the time the
28 Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and

1 Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for
2 this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall
3 not be disqualified from further action by having considered this matter.

4 14. The parties understand and agree that Portable Document Format (PDF) and facsimile
5 copies of this Stipulated Surrender of License and Order, including Portable Document Format
6 (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

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

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

15 **ORDER**

16 IT IS HEREBY ORDERED that the following licenses are surrendered and accepted by the
17 Board of Pharmacy: 1) Pharmacy Permit No. PHY 18784, issued to Pharmacia Corporation doing
18 business as 1800 Sullivan Pharmacy (Respondent Pharmacy) and Pharmacist License No. RPH
19 24318, issued to Randall W. Tonelli (Respondent Pharmacist).

20 1. The surrenders of Respondents' pharmacy permit and pharmacist license and the
21 acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline
22 against Respondents. This stipulation constitutes a record of the discipline and shall become a
23 part of Respondents' license histories with the Board of Pharmacy.

24 2. Respondents shall lose all rights and privileges as a pharmacy and pharmacist in
25 California as of the effective date of the Board's Decision and Order.

26 3. Respondents shall cause to be delivered to the Board their pocket licenses and, if
27 issued, their wall certificates, on or before the effective date of the Decision and Order.

28 4. If Respondents ever apply for licensure or petition for reinstatement in the State of

1 California, the Board shall treat the matter as a new application for licensure. Respondents must
2 comply with all the laws, regulations and procedures for licensure in effect at the time the
3 application or petition is filed, and all of the charges and allegations contained in the First
4 Amended Accusation, Case No. 5102, shall be deemed to be true, correct and admitted by
5 Respondents when the Board determines whether to grant or deny the application. Respondents
6 shall satisfy all requirements applicable to that license as of the date the application is submitted
7 to the Board and Respondents are required to report their surrenders as a disciplinary action. For
8 Respondent Pharmacist, the requirements include, but are not limited to, taking and passing the
9 California Licensure Examination prior to the issuance of a new license.

10 5. Respondent Pharmacist shall pay the agency its costs of investigation and
11 enforcement in the amount of \$13,922.00 prior to issuance of a new or reinstated license.

12 6. If Respondents should ever apply or reapply for a new license or certification, or
13 petition for reinstatement of a license, by any other health care licensing agency in the State of
14 California, all of the charges and allegations contained in the First Amended Accusation, Case
15 No. 5102, shall be deemed to be true, correct, and admitted by Respondent for the purpose of any
16 Statement of Issues or any other proceeding seeking to deny or restrict licensure.

17 7. Respondents shall not apply to the Board for licensure or petition for reinstatement
18 for at least three years after the effective date of the Board's Decision and Order.

19 ACCEPTANCE

20 I have carefully read the above Stipulated Surrender of License and Order and have fully
21 discussed it with my attorney, Alexander M. Medina. I understand the stipulation and the effect it
22 will have on my pharmacist license and pharmacy permit. I enter into this Stipulated Surrender of
23 License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the
24 Decision and Order of the Board of Pharmacy.

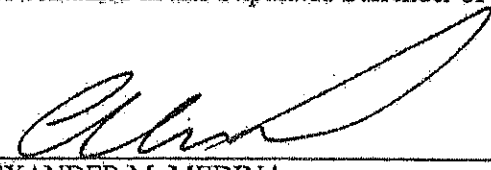
25 DATED: 10/7/16

26 Randall W. Tonelli
27 RANDALL W. TONELLI, individually and on
28 behalf of PHARMACIA CORPORATION d.b.a
1800 SULLIVAN PHARMACY
Respondents

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I have read and fully discussed with Respondent Randall W. Tonelli, individually and in his capacity as an officer of Respondent Pharmacia Corporation doing business as 1800 Sullivan Pharmacy, the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: October 14, 2016

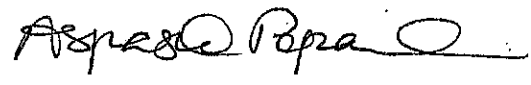

ALEXANDER M. MEDINA
Attorney for Respondents

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: October 13, 2016

Respectfully submitted,
KAMALA D. HARRIS
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General


ASPASIA A. PAPANASSILIOU
Deputy Attorney General
Attorneys for Complainant

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Exhibit A
First Amended Accusation No. 5102

1 KAMALA D. HARRIS
Attorney General of California
2 DIANN SOKOLOFF
Supervising Deputy Attorney General
3 ASPASIA A. PAPAVALSILIOU
Deputy Attorney General
4 State Bar No. 196360
1515 Clay Street, 20th Floor
5 P.O. Box 70550
Oakland, CA 94612-0550
6 Telephone: (510) 622-2199
Facsimile: (510) 622-2270
7 E-mail: Aspasia.Papavassiliou@doj.ca.gov
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17 **Pharmacy Permit No. PHY 18784**

18 and

19 **RANDALL W. TONELLI**
20 **14 Golden Ridge Court**
San Mateo, CA 94402

21 **Pharmacist License No. RPH 24318**

22 Respondents.
23

Case No. 5102

FIRST AMENDED
ACCUSATION

24 Complainant alleges:

25 PARTIES

26 1. Virginia Herold (Complainant) brings this First Amended Accusation solely in her
27 official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer
28 Affairs.

1 shall have all the powers granted therein. The action shall be final, except that the propriety of
2 the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of
3 Civil Procedure."

4 6. Section 4300.1 of the Code states:

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

10 7. Section 4307 (a) of the Code states:

11 "Any person who has been denied a license or whose license has been revoked or is
12 under suspension, or who has failed to renew his or her license while it was under suspension, or
13 who has been a manager, administrator, owner member, officer, director, associate, or partner of
14 any partnership, corporation, firm, or association whose application for a license has been denied
15 or revoked, is under suspension or has been placed on probation, and while acting as the manger,
16 administrator, owner, member, officer, director, associate, or partner had knowledge or
17 knowingly participated in any conduct for which the license was denied, revoked, suspended, or
18 placed on probation, shall be prohibited from serving as a manger, administrator, owner, member,
19 officer, director, associate, or partner of a licensee as follows:

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

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

24 STATUTORY AND REGULATORY PROVISIONS

25 8. Section 4061 of the Code states, in pertinent part:

26 "(a) No manufacturer's sales representative shall distribute any dangerous drug or
27 dangerous device as a complimentary sample without the written request of a physician, dentist,
28 podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7...."

1 9. Section 4081 of the Code states, in pertinent part:

2 "(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs
3 or dangerous devices shall be at all times during business hours open to inspection by authorized
4 officers of the law, and shall be preserved for at least three years from the date of making. A
5 current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary
6 food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,
7 institution, or establishment holding a currently valid and unrevoked certificate, license, permit,
8 registration, or exemption under Division 2 (commencing with Section 1200) of the Health and
9 Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and
10 Institutions Code who maintains a stock of dangerous drugs or dangerous devices."

11 10. Section 4301 of the Code states, in pertinent part:

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

15 ...

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

18 ...

19 "(l) The conviction of a crime substantially related to the qualifications, functions, and
20 duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13
21 (commencing with Section 801) of Title 21 of the United States Code regulating controlled
22 substances or of a violation of the statutes of this state regulating controlled substances or
23 dangerous drugs shall be conclusive evidence of unprofessional conduct....A plea or verdict of
24 guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the
25 meaning of this provision. The board may take action when the time for appeal has elapsed, or the
26 judgment of conviction has been affirmed on appeal or when an order granting probation is made
27 suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of
28 the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not

1 guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or
2 indictment.

3 ...

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

8 11. California Code of Regulations, title 16, section 1714, states, in pertinent part:

9 "(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and
10 equipment so that drugs are safely and properly prepared, maintained, secured and distributed.
11 The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice
12 of pharmacy.

13 ...

14 "(d) Each pharmacist while on duty shall be responsible for the security of the prescription
15 department, including provisions for effective control against theft or diversion of dangerous
16 drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy
17 where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist "

18 12. California Code of Regulations, title 16, section 1718, states:

19 "'Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions
20 Code shall be considered to include complete accountability for all dangerous drugs handled by
21 every licensee enumerated in Sections 4081 and 4332.

22 "The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
23 available for inspection upon request for at least 3 years after the date of the inventory."

24 COST RECOVERY PROVISION

25 13. Section 125.3 of the Code states, in pertinent part, that the Board may request the
26 administrative law judge to direct a licentiate found to have committed a violation or violations of
27 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
28 enforcement of the case.

1 DRUG

2 14. The drug combination of hydrocodone with acetaminophen (apap) is a Schedule III
3 controlled substance under Health and Safety Code section 11056, subd. (e)(4), and a dangerous
4 drug under Business and Professions Code section 4022.

5 FACTUAL BACKGROUND

6 Board Investigation

7 15. Board staff conducted an investigation involving Respondent Pharmacy regarding its
8 handling of controlled substances and its alleged obtaining of pharmaceutical drug samples.

9 *Controlled Substances*

10 16. On or about April 8, 2011, the Board received a complaint from pharmaceutical
11 company the ParMed Pharmaceuticals, Inc. (ParMed) about ParMed's suspension of controlled
12 substance sales to Respondent Pharmacy. ParMed alleged that it blocked Respondent Pharmacy
13 due to its refusal to permit a "Quality & Regulatory Anti-Diversion visit" from ParMed.

14 17. As a result of the complaint, a Board inspector conducted an audit of the period from
15 May 25, 2009 to May 9, 2011, and found that Respondent Pharmacy had a loss of approximately
16 1,976 dosage units of hydrocodone/apap and an overage of approximately 2,798 dosage units of
17 hydrocodone/apap.

18 *Drug Samples*

19 18. On or about December 9, 2011, the United States Food and Drug Administration
20 (FDA) provided information to Board staff about the FDA's investigation of a complaint from the
21 pharmaceutical company Merck that Respondent Pharmacy was receiving large bags of various
22 samples of pharmaceutical drugs, such as cholesterol and blood pressure medications.

23 19. On or about August 15, 2012, a Board inspector visited Respondent Pharmacy and
24 found various pharmaceutical drug samples on the inventory shelves and also within boxes and
25 bags in a small alcove section of the pharmacy.

26 20. On or about August 16, 2012, in an interview with FDA agents, Respondent
27 Pharmacist stated that the Respondent Pharmacy received pharmaceutical drug samples from
28 Rotacare, a charity and clinic for uninsured, low-income patients, and maintained them on the

1 premises to fill prescriptions for Rotacare patients.

2 Criminal Conviction

3 21. On or about July 11, 2016, in *United States of America v. Randall Tonelli*, United
4 States District Court, Northern District of California, Case No. CR-1600072-001 TEH,
5 Respondent Pharmacist pled guilty to and was convicted of committing the following offenses
6 between January of 2010 and on or about August 16, 2012: (1) knowingly offer to sell or trade a
7 prescription drug sample (21 U.S.C. §§ 331(t), 333(b)(1)(B), and 353(c)); and (2) misbranding
8 drugs while held for sale with the intent to defraud or mislead (21 U.S.C. §§ 331(k) and
9 333(a)(2)). Respondent Pharmacist was sentenced to five years of probation and was ordered to
10 forfeit \$884,809.21 and his Board of Pharmacy License Number 24318 to the United States.

11 FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Unsecured Pharmacy)

12 (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1714, subds. (b), (d))

13 22. Respondent Pharmacy has subjected its pharmacy permit to discipline and
14 Respondent Pharmacist has subjected his pharmacist license to discipline because they engaged in
15 unprofessional conduct by maintaining an unsecured pharmacy (Bus. & Prof. Code, § 4301, subd.
16 (o); Cal. Code Regs., tit. 16, § 1714, subds. (b), (d)). Respondents failed to maintain effective
17 control of the security of the prescription department against theft or loss of controlled
18 substances. In a Board audit for the period of May 25, 2009, to May 9, 2011, Respondents could
19 not account for the loss of approximately 1,976 dosage units of hydrocodone/apap, as follows:
20 494 dosage units of hydrocodone/apap 7.5 mg/750 mg; 1,452 dosage units of hydrocodone/apap
21 10 mg/325 mg; and 30 dosage units of hydrocodone/apap 10 mg/500 mg.

22 SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Failure to Maintain Current Inventory)

23 (Bus. & Prof. Code, §§ 4301, subds.(j), (o), and 4081 subd. (a); Cal. Code Regs., tit. 16, § 1718)

24 23. Respondent Pharmacy has subjected its pharmacy permit to discipline and
25 Respondent Pharmacist has subjected his pharmacist license to discipline because they engaged in
26 unprofessional conduct by failing to maintain current inventory (Bus. & Prof. Code, §§ 4301,
27 subds.(j), (o), and 4081 subd. (a); Cal. Code Regs., tit. 16, § 1718). Respondents failed to
28 maintain complete accountability of all controlled substances. In a Board audit for the period of

1 May 25, 2009, to May 9, 2011, Respondents could not account for the loss of approximately
2 1,976 dosage units of hydrocodone/apap, as follows: 494 dosage units of hydrocodone/apap 7.5
3 mg/750 mg; 1,452 dosage units of hydrocodone/apap 10 mg/325 mg; and 30 dosage units of
4 hydrocodone/apap 10 mg/500 mg. In addition, Respondents could not account for an overage of
5 approximately 2,798 dosage units of hydrocodone/apap, as follows: 2,268 dosage units of
6 hydrocodone/apap 5 mg/500 mg; 126 dosage units of hydrocodone/apap 5mg/325 mg; 225
7 dosage units of hydrocodone/apap 7.5 mg/325 mg; 4 dosage units of hydrocodone/apap 7.5
8 mg/500 mg; and 175 dosage units of hydrocodone/apap 10 mg/650 mg.

9 THIRD CAUSE FOR DISCIPLINE

10 (Unprofessional Conduct: Obtaining and Possessing Drug Samples)
11 (Bus. & Prof. Code, §§ 4301, subd. (o) and 4061, subd. (a))

12 24. Respondent Pharmacy has subjected its pharmacy permit to discipline and
13 Respondent Pharmacist has subjected his pharmacist license to discipline because they engaged in
14 unprofessional conduct by obtaining and possessing pharmaceutical drug samples (Bus. & Prof.
15 Code, §§ 4301, subd. (o) and 4061, subd. (a).) The circumstances are described in paragraphs 18-
16 22, above.

17 FOURTH CAUSE FOR DISCIPLINE

18 (Unprofessional Conduct: Violation of Law Regarding Controlled Substances)
19 (Bus. & Prof. Code, § 4301, subd. (j))

20 25. Respondent Pharmacy has subjected its pharmacy permit to discipline and
21 Respondent Pharmacist has subjected his pharmacist license to discipline because Respondent
22 Pharmacist violated a law regarding controlled substances (Bus. & Prof. Code, § 4301, subd. (j)).
23 The circumstances are described in paragraphs 18-22, above.

24 FIFTH CAUSE FOR DISCIPLINE

25 (Unprofessional Conduct: Substantially Related Conviction)
26 (Bus. & Prof. Code, § 4301, subd. (l))

27 26. Respondent Pharmacy has subjected its pharmacy permit to discipline and
28 Respondent Pharmacist has subjected his pharmacist license to discipline because Respondent
29 Pharmacist was convicted of a criminal offense substantially related to the practice of pharmacy
(Bus. & Prof. Code, § 4301, subd. (l)). The circumstances are described in paragraphs 18-22,
above.

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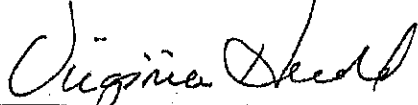
PHY 18784 is placed on probation or, if it is revoked, until the pharmacy permit is reinstated;

5. Prohibiting Randall W. Tonelli from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 18784 is placed on probation or, if it is revoked, until the pharmacy permit is reinstated;

6. Ordering Pharmaca Corporation doing business as 1800 Sullivan Pharmacy and Randall W. Tonelli to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, under Business and Professions Code section 125.3;

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

DATED: 9/8/16



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

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1 KAMALA D. HARRIS
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2 DIANN SOKOLOFF
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4 State Bar No. 196360
1515 Clay Street, 20th Floor
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A C C U S A T I O N

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18 and

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22 Respondents.

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24 Complainant alleges:

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26 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as
27 the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

1 shall have all the powers granted therein. The action shall be final, except that the propriety of the
2 action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil
3 Procedure."

4 6. Section 4300.1 of the Code states:

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

10 STATUTORY AND REGULATORY PROVISIONS

11 7. Section 4301 of the Code states, in pertinent part:

12 "The board shall take action against any holder of a license who is guilty of unprofessional
13 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

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

15 ...

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

18 ...

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

23 8. Section 4061 of the Code states, in pertinent part:

24 "(a) No manufacturer's sales representative shall distribute any dangerous drug or dangerous
25 device as a complimentary sample without the written request of a physician, dentist, podiatrist,
26 optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7...."

27

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1 9. Section 4081 of the Code states, in pertinent part:

2 "(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or
3 dangerous devices shall be at all times during business hours open to inspection by authorized
4 officers of the law, and shall be preserved for at least three years from the date of making. A
5 current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary
6 food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,
7 institution, or establishment holding a currently valid and unrevoked certificate, license, permit,
8 registration, or exemption under Division 2 (commencing with Section 1200) of the Health and
9 Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and
10 Institutions Code who maintains a stock of dangerous drugs or dangerous devices."

11 10. Section 4307 (a) of the Code states:

12 "Any person who has been denied a license or whose license has been revoked or is
13 under suspension, or who has failed to renew his or her license while it was under suspension, or
14 who has been a manager, administrator, owner member, officer, director, associate, or partner of
15 any partnership, corporation, firm, or association whose application for a license has been denied
16 or revoked, is under suspension or has been placed on probation, and while acting as the manger,
17 administrator, owner, member, officer, director, associate, or partner had knowledge or knowingly
18 participated in any conduct for which the license was denied, revoked, suspended, or placed on
19 probation, shall be prohibited from serving as a manger, administrator, owner, member, officer,
20 director, associate, or partner of a licensee as follows:

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

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

25 11. California Code of Regulations, title 16, section 1714, states, in pertinent part:

26 "(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and
27 equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The
28

1 pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of
2 pharmacy.

3 . . .

4 "(d) Each pharmacist while on duty shall be responsible for the security of the prescription
5 department, including provisions for effective control against theft or diversion of dangerous drugs
6 and devices, and records for such drugs and devices. Possession of a key to the pharmacy where
7 dangerous drugs and controlled substances are stored shall be restricted to a pharmacist "

8 12. California Code of Regulations, title 16, section 1718, states:

9 "Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions
10 Code shall be considered to include complete accountability for all dangerous drugs handled by
11 every licensee enumerated in Sections 4081 and 4332.

12 "The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
13 available for inspection upon request for at least 3 years after the date of the inventory."

14 COST RECOVERY PROVISION

15 13. Section 125.3 of the Code states, in pertinent part, that the Board may request the
16 administrative law judge to direct a licentiate found to have committed a violation or violations of
17 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
18 enforcement of the case.

19 DRUG

20 14. The drug combination of hydrocodone with acetaminophen (apap) is a Schedule III
21 controlled substance under Health and Safety Code section 11056, subd. (e)(4), and a dangerous
22 drug under Business and Professions Code section 4022.

23 FACTUAL BACKGROUND

24 15. Board staff conducted an investigation involving Respondent Pharmacy regarding (1)
25 its handling of controlled substances and (2) its alleged obtaining of pharmaceutical drug samples.

26 *Controlled Substances*

27 16. On or about April 8, 2011, the Board received a complaint from pharmaceutical
28 company the ParMed Pharmaceuticals, Inc. (ParMed) about ParMed's suspension of controlled

1 substance sales to Respondent Pharmacy. ParMed alleged that it blocked Respondent Pharmacy
2 due to its refusal to permit a "Quality & Regulatory Anti-Diversion visit" from ParMed.

3 17. As a result of the complaint, a Board inspector conducted an audit of the period from
4 May 25, 2009 to May 9, 2011, and found that Respondent Pharmacy had a loss of approximately
5 1,976 dosage units of hydrocodone/apap and an overage of approximately 2,798 dosage units of
6 hydrocodone/apap.

7 *Drug Samples*

8 18. On or about December 9, 2011, the United States Food and Drug Administration
9 (FDA) provided information to Board staff about the FDA's investigation of a complaint from the
10 pharmaceutical company Merck that Respondent Pharmacy was receiving large bags of various
11 samples of pharmaceutical drugs, such as cholesterol and blood pressure medications.

12 19. On or about August 15, 2012, a Board inspector visited Respondent Pharmacy and
13 found various pharmaceutical drug samples on the inventory shelves and also within boxes and
14 bags in a small alcove section of the pharmacy.

15 20. On or about August 16, 2012, in an interview with FDA agents, Respondent
16 Pharmacist admitted that the Respondent Pharmacy received pharmaceutical drug samples from
17 Rotacare, a charity and clinic for uninsured, low-income patients, and maintained them on the
18 premises to fill prescriptions for Rotacare patients.

19 FIRST CAUSE FOR DISCIPLINE

20 (Unprofessional Conduct: Unsecured Pharmacy)

21 (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1714, subds. (b), (d))

22 21. Respondent Pharmacy has subjected its pharmacy permit to discipline and Respondent
23 Pharmacist has subjected his pharmacist license to discipline because they engaged in
24 unprofessional conduct by maintaining an unsecured pharmacy (Bus. & Prof. Code, § 4301, subd.
25 (o); Cal. Code Regs., tit. 16, § 1714, subds. (b), (d)). Respondents failed to maintain effective
26 control of the security of the prescription department against theft or loss of controlled substances.
27 In a Board audit for the period of May 25, 2009, to May 9, 2011, Respondents could not account
28 for the loss of approximately 1,976 dosage units of hydrocodone/apap, as follows: 494 dosage

1 units of hydrocodone/apap 7.5 mg/750 mg; 1,452 dosage units of hydrocodone/apap 10 mg/325
2 mg; and 30 dosage units of hydrocodone/apap 10 mg/500 mg.

3 SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Failure to Maintain Current Inventory)

4 (Bus. & Prof. Code, §§ 4301, subs.(j), (o), and 4081 subd. (a); Cal. Code Regs., tit. 16, § 1718)

5 22. Respondent Pharmacy has subjected its pharmacy permit to discipline and Respondent
6 Pharmacist has subjected his pharmacist license to discipline because they engaged in
7 unprofessional conduct by failing to maintain current inventory (Bus. & Prof. Code, §§ 4301,
8 subs.(j), (o), and 4081 subd. (a); Cal. Code Regs., tit. 16, § 1718). Respondents failed to
9 maintain complete accountability of all controlled substances. In a Board audit for the period of
10 May 25, 2009, to May 9, 2011, Respondents could not account for the loss of approximately
11 1,976 dosage units of hydrocodone/apap, as follows: 494 dosage units of hydrocodone/apap 7.5
12 mg/750 mg; 1,452 dosage units of hydrocodone/apap 10 mg/325 mg; and 30 dosage units of
13 hydrocodone/apap 10 mg/500 mg. In addition, Respondents could not account for an overage of
14 approximately 2,798 dosage units of hydrocodone/apap, as follows: 2,268 dosage units of
15 hydrocodone/apap 5 mg/500 mg; 126 dosage units of hydrocodone/apap 5mg/325 mg; 225 dosage
16 units of hydrocodone/apap 7.5 mg/325 mg; 4 dosage units of hydrocodone/apap 7.5 mg/500 mg;
17 and 175 dosage units of hydrocodone/apap 10 mg/650 mg.

18 THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Obtaining and Possessing Drug Samples)

19 (Bus. & Prof. Code, §§ 4301, subd. (o) and 4061, subd. (a))

20 23. Respondent Pharmacy has subjected its pharmacy permit to discipline and Respondent
21 Pharmacist has subjected his pharmacist license to discipline because they engaged in
22 unprofessional conduct by obtaining and possessing pharmaceutical drug samples (Bus. & Prof.
23 Code, §§ 4301, subd. (o) and 4061, subd. (a).) The circumstances are described in paragraphs 18-
24 20, above.

25 OTHER MATTERS

26 24. Pursuant to section 4307, if discipline is imposed on Pharmacy Permit Number PHY
27 18784, issued to Pharmaca Corporation doing business as 1800 Sullivan Pharmacy, then William
28 M. Tonelli, Elise Tonelli, and Randall W. Tonelli, if they had knowledge of or knowingly

1 participated in any conduct for which the licensee was disciplined, shall be prohibited from serving
2 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee
3 for five years if Pharmacy Permit Number PHY 18784 is placed on probation or, if it is revoked,
4 until the pharmacy permit is reinstated.

5 PRAYER

6 WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this
7 Accusation, and that following the hearing, the Board of Pharmacy issue a decision:

8 1. Revoking or suspending Pharmacy Permit Number PHY 18784, issued to Pharmacia
9 Corporation doing business as 1800 Sullivan Pharmacy;

10 2. Revoking or suspending Pharmacist License Number RPH 24318, issued to Randall
11 W. Tonelli;

12 3. Prohibiting William M. Tonelli from serving as a manager, administrator, owner,
13 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
14 Number PHY 18784 is placed on probation or, if it is revoked, until the pharmacy permit is
15 reinstated;

16 4. Prohibiting Elsie Tonelli from serving as a manager, administrator, owner, member,
17 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY
18 18784 is placed on probation or, if it is revoked, until the pharmacy permit is reinstated;

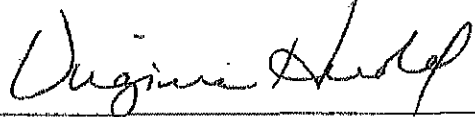
19 5. Prohibiting Randall W. Tonelli from serving as a manager, administrator, owner,
20 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
21 Number PHY 18784 is placed on probation or, if it is revoked, until the pharmacy permit is
22 reinstated;

23 6. Ordering Pharmaca Corporation doing business as 1800 Sullivan Pharmacy and
24 Randall W. Tonelli to pay the Board of Pharmacy the reasonable costs of the investigation and
25 enforcement of this case, under Business and Professions Code section 125.3;

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

DATED: 5/22/16



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

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