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8	Attorneys for Complainant	
9		RE THE PHARMACY
10	DEPARTMENT OF C	CONSUMER AFFAIRS CALIFORNIA
11		
11	In the Matter of the First Amended Accusation	Case No. 5102
	Against:	FIRST AMENDED
13	PHARMACIA CORPORATION d.b.a. 1800 SULLIVAN PHARMACY	ACCUSATION
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	
17	Pharmacy Permit No. PHY 18784	
18	and	
19	RANDALL W. TONELLI	
20	14 Golden Ridge Court San Mateo, CA 94402	
21		
22	Pharmacist License No. RPH 24318	
23	Respondents.	
24	Complainant alleges:	
25	PAR	TIES
26	1. Virginia Herold (Complainant) bring	s this First Amended Accusation solely in her
27	official capacity as the Executive Officer of the I	Board of Pharmacy, Department of Consumer
28	Affairs.	
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	(1800 SULLIVAN PHARMACY & RANI	DALL W. TONELLI) FIRST AMENDED ACCUSATION

2. On or about July 29, 1985, the Board of Pharmacy issued Pharmacy Permit Number 1 PHY 18784 to Pharmacia Corporation doing business as 1800 Sullivan Pharmacy (Respondent 2 3 Pharmacy), with William M. Tonelli as President, Elsie Tonelli as Vice President, and Randall W. Tonelli as Secretary and Pharmacist-in-Charge. The permit was in full force and effect at all 4 times relevant to the charges brought in this Accusation and will expire on February 1, 2017, 5 unless renewed. 6 3. On or about October 29, 1965, the Board of Pharmacy issued Pharmacist License 7 Number RPH 24318 to Randall W. Tonelli (Respondent Pharmacist). The license was in full 8 9 force and effective at all times relevant to the charges brought in this Accusation, and will expire on February 20, 2017, unless renewed. 1011 JURISDICTION 4. This First Amended Accusation is brought before the Board of Pharmacy (Board), 12 13 Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated. 14 15 5. Section 4300 of the Code states, in pertinent part: "(a) Every license issued may be suspended or revoked. 16 "(b) The board shall discipline the holder of any license issued by the board, whose default 17 has been entered or whose case has been heard by the board and found guilty, by any of the 18 following methods: 19 20 "(1) Suspending judgment. "(2) Placing him or her upon probation. 2122 "(3) Suspending his or her right to practice for a period not exceeding one year. "(4) Revoking his or her license. 23 "(5) Taking any other action in relation to disciplining him or her as the board in its 24 discretion may deem proper. 25 26 27 "(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board 28 2

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

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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."

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

"Any person who has been denied a license or whose license has been revoked or is 11 under suspension, or who has failed to renew his or her license while it was under suspension, or 12 who has been a manager, administrator, owner member, officer, director, associate, or partner of 13 any partnership, corporation, firm, or association whose application for a license has been denied 14 or revoked, is under suspension or has been placed on probation, and while acting as the manger, 15 administrator, owner, member, officer, director, associate, or partner had knowledge or 16 17 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, 18 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.

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

24

STATUTORY AND REGULATORY PROVISIONS

8. Section 4061 of the Code states, in pertinent part:
"(a) No manufacturer's sales representative shall distribute any dangerous drug or
dangerous device as a complimentary sample without the written request of a physician, dentist,
podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7...."

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Section 4081 of the Code states, in pertinent part:

1	2. Section 4001 of the Code states, in portment 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	"(1) 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 conductA 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	
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	(1800 SULLIVAN PHARMACY & RANDALL W. TONELLI) FIRST AMENDED ACCUSATION	ſ

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

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

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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.

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

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

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

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

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COST RECOVERY PROVISION

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

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
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1 premises to fill prescriptions for Rotacare patients.

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Criminal Conviction

21. On or about July 11, 2016, in United States of America v. Randall Tonelli, United 3 States District Court, Northern District of California, Case No. CR-1600072-001 TEH, 4 Respondent Pharmacist pled guilty to and was convicted of committing the following offenses 5 6 between January of 2010 and on or about August 16, 2012; (1) knowingly offer to sell or trade a prescription drug sample (21 U.S.C. §§ 331(t), 333(b)(1)(B), and 353(c)); and (2) misbranding 7 drugs while held for sale with the intent to defraud or mislead (21 U.S.C. §§ 331(k) and 8 9 333(a)(2)). Respondent Pharmacist was sentenced to five years of probation and was ordered to forfeit \$884,809.21 and his Board of Pharmacy License Number 24318 to the United States. 10 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)) 22. 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 15 unprofessional conduct by maintaining an unsecured pharmacy (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1714, subds. (b), (d)). Respondents failed to maintain effective 16 17 control of the security of the prescription department against theft or loss of controlled substances. In a Board audit for the period of May 25, 2009, to May 9, 2011, Respondents could 18 not account for the loss of approximately 1,976 dosage units of hydrocodone/apap, as follows: 19 20 494 dosage units of hydrocodone/apap 7.5 mg/750 mg; 1,452 dosage units of hydrocodone/apap 10 mg/325 mg; and 30 dosage units of hydrocodone/apap 10 mg/500 mg. 21 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) 23. Respondent Pharmacy has subjected its pharmacy permit to discipline and 24 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 7 (1800 SULLIVAN PHARMACY & RANDALL W. TONELLI) FIRST AMENDED ACCUSATION

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 10	THIRD CAUSE FOR DISCIPLINE (Unprofessional Conduct: Obtaining and Possessing Drug Samples) (Bus. & Prof. Code, §§ 4301, subd. (o) and 4061, subd. (a))
11	24. Respondent Pharmacy has subjected its pharmacy permit to discipline and
12	Respondent Pharmacist has subjected his pharmacist license to discipline because they engaged in
13	unprofessional conduct by obtaining and possessing pharmaceutical drug samples (Bus. & Prof.
14	Code, §§ 4301, subd. (o) and 4061, subd. (a).) The circumstances are described in paragraphs 18-
15	22, above.
16 17	FOURTH CAUSE FOR DISCIPLINE (Unprofessional Conduct: Violation of Law Regarding Controlled Substances) (Bus. & Prof. Code, § 4301, subd. (j))
18	25. Respondent Pharmacy has subjected its pharmacy permit to discipline and
19	Respondent Pharmacist has subjected his pharmacist license to discipline because Respondent
20	Pharmacist violated a law regarding controlled substances (Bus. & Prof. Code, § 4301, subd. (j)).
21	The circumstances are described in paragraphs 18-22, above.
22 23	FIFTH CAUSE FOR DISCIPLINE (Unprofessional Conduct: Substantially Related Conviction) (Bus. & Prof. Code, § 4301, subd. (1))
24	26. Respondent Pharmacy has subjected its pharmacy permit to discipline and
25	Respondent Pharmacist has subjected his pharmacist license to discipline because Respondent
26	Pharmacist was convicted of a criminal offense substantially related to the practice of pharmacy
27	(Bus. & Prof. Code, § 4301, subd. (1)). The circumstances are described in paragraphs 18-22,
28	above.
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	(1800 SULLIVAN PHARMACY & RANDALL W. TONELLI) FIRST AMENDED ACCUSATION

1	SIXTH CAUSE FOR DISCIPLINE (Unprofessional Conduct: Violation of Pharmacy Law)
2	(Bus. & Prof. Code, § 4301, subd. (o))
3	27. Respondent Pharmacy has subjected its pharmacy permit to discipline and
4	Respondent Pharmacist has subjected his pharmacist license to discipline because Respondent
5	Pharmacist violated a law pertaining to pharmacy (Bus. & Prof. Code, § 4301, subd. (o)). The
6	circumstances are described in paragraphs 18-22, above.
7	OTHER MATTERS
8	28. Pursuant to section 4307, if discipline is imposed on Pharmacy Permit Number PHY
9	18784, issued to Pharmaca Corporation doing business as 1800 Sullivan Pharmacy, then William
10	M. Tonelli, Elise Tonelli, and Randall W. Tonelli, if they had knowledge of or knowingly
11	participated in any conduct for which the licensee was disciplined, shall be prohibited from
12	serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
13	licensee for five years if Pharmacy Permit Number PHY 18784 is placed on probation or, if it is
14	revoked, until the pharmacy permit is reinstated.
15	PRAYER
16	WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this
17	First Amended Accusation, and that following the hearing, the Board of Pharmacy issue a
18	decision:
19	1. Revoking or suspending Pharmacy Permit Number PHY 18784, issued to Pharmacia
20	Corporation doing business as 1800 Sullivan Pharmacy;
21	2. Revoking or suspending Pharmacist License Number RPH 24318, issued to Randall
22	W. Tonelli;
23	3. Prohibiting William M. Tonelli from serving as a manager, administrator, owner,
24	member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
25	Number PHY 18784 is placed on probation or, if it is revoked, until the pharmacy permit is
26	reinstated;
27	4. Prohibiting Elsie Tonelli from serving as a manager, administrator, owner, member,
28	officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number
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	(1800 SULLIVAN PHARMACY & RANDALL W. TONELLI) FIRST AMENDED ACCUSATION

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

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

10 DATED: 9/8/16 11

7.

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

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(1800 SULLIVAN PHARMACY & RANDALL W. TONELLI) FIRST AMENDED ACCUSATION

1 2 3 4 5 6 7 8 9 10	BOARD OF DEPARTMENT OF C	RE THE PHARMACY CONSUMER AFFAIRS CALIFORNIA
11	In the Matter of the Accusation Against:	Case No. 5102
12 13 14 15 16 17 18 19 20 21 21 22 23	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.	
24	Complainant alleges:	
25	PAR	TIES
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.
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		(1800 SULLIVAN PHARMÁCY) ACCUSATION

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1	2. On or about July 29, 1985, the Board of Pharmacy issued Pharmacy Permit Number
2	PHY 18784 to Pharmacia Corporation doing business as 1800 Sullivan Pharmacy (Respondent
3	Pharmacy), with William M. Tonelli as President, Elsie Tonelli as Vice President, and Randall W.
4	Tonelli as Secretary and Pharmacist-in-Charge. The permit was in full force and effect at all times
5.	relevant to the charges brought in this Accusation and will expire on February 1, 2017, unless
- 6	renewed.
7	3. On or about October 29, 1965, the Board of Pharmacy issued Pharmacist License
8	Number RPH 24318 to Randall W. Tonelli (Respondent Pharmacist). The license was in full force
9.	and effective at all times relevant to the charges brought in this Accusation, and will expire on
10	February 20, 2017, unless renewed.
· 11.	JURISDICTION
12	4. This Accusation is brought before the Board of Pharmacy (Board), Department of
13	Consumer Affairs, under the authority of the following laws. All section references are to the
14	Business and Professions Code unless otherwise indicated.
15	5. Section 4300 of the Code states, in pertinent part:
16	"(a) Every license issued may be suspended or revoked.
17	"(b) The board shall discipline the holder of any license issued by the board, whose default
18	has been entered or whose case has been heard by the board and found guilty, by any of the
19	following methods:
20	"(1) Suspending judgment.
21	"(2) Placing him or her upon probation.
22	"(3) Suspending his or her right to practice for a period not exceeding one year.
23	"(4) Revoking his or her license.
24	"(5) Taking any other action in relation to disciplining him or her as the board in its
25	discretion may deem proper.
26	
27	"(e) The proceedings under this article shall be conducted in accordance with Chapter 5
28	(commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board
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	(1800 SULLIVAN PHARMACY) ACCUSATION

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

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Section 4300.1 of the Code states:

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

STATUTORY AND REGULATORY PROVISIONS

Section 4301 of the Code states, in pertinent part:

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

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

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

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

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

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Section 4081 of the Code states, in pertinent part:

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

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

"Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, or partner 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, or partner 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."

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

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

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

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

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

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

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

COST RECOVERY PROVISION

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

<u>DRUG</u>

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

FACTUAL BACKGROUND

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

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

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

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

Drug Samples

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

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

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

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Unsecured Pharmacy)
(Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1714, subds. (b), (d))
21. Respondent Pharmacy has subjected its pharmacy permit to discipline and Respondent
Pharmacist has subjected his pharmacist license to discipline because they engaged in
unprofessional conduct by maintaining an unsecured pharmacy (Bus. & Prof. Code, § 4301, subd.
(o); Cal. Code Regs., tit. 16, § 1714, subds. (b), (d)). Respondents failed to maintain effective
control of the security of the prescription department against theft or loss of controlled substances.
In a Board audit for the period of May 25, 2009, to May 9, 2011, Respondents could not account
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
4	(Unprofessional Conduct: Failure to Maintain Current Inventory) (Bus. & Prof. Code, §§ 4301, subds.(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	subds.(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 19	<u>THIRD CAUSE FOR DISCIPLINE</u> (Unprofessional Conduct: Obtaining and Possessing Drug Samples) (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
	7
	(1800 SULLIVAN PHARMACY) ACCUSATION

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

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<u>PRAYER</u>

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

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

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

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

Prohibiting Elsie Tonelli from serving as a manager, administrator, owner, member, 4. 16 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 1718784 is placed on probation or, if it is revoked, until the pharmacy permit is reinstated; 18

Prohibiting Randall W. Tonelli from serving as a manager, administrator, owner, 5. 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;

Ordering Pharmaca Corporation doing business as 1800 Sullivan Pharmacy and 6. 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;

Taking such other and further action as deemed necessary and proper. 7. Ŵ 5 k2/16 DATED: VIRGINIĂ HEROLD Executive Officer Board of Pharmacy Department of Consumer Affairs State of California Complainant SF2014902158 90520597.doc (1800 SULLIVAN PHARMACY) ACCUSATION