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1 2 3 4 5 6 7 8 9	BOARD O DEPARTMENT OF	ORE THE F PHARMACY F CONSUMER AFFAIRS F CALIFORNIA
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11	In the Matter of the Accusation Against:	Case No. 3430
12	JOHN MICHAEL PUCCINELLI 22477 Santa Paula Ave.	ACCUSATION
13	Cupertino, CA 95014 Pharmacist License No. RPH 26552	·
14	and	
15	SAVCO GENERIC DRUGS	
16	2101 Forest Avenue, No. 122	
17	San Jose, CA 95128 Pharmacy Permit No. PHY 32506	
18	Responde	ents.
19		
20	Complainant alleges:	
21	<u><u>P</u><u>A</u></u>	ARTIES
22		ings this Accusation solely in her official capacity
23	as the Executive Officer of the Board of Pharm	nacy, Department of Consumer Affairs.
24	2. On or about July 16, 1970, the Boa	ard of Pharmacy issued Pharmacist License
25	Number RPH 26552 to John Michael Puccinel	lli (Respondent Puccinelli). The Pharmacist
26	License was in full force and effect at all times	s relevant to the charges brought herein and will
27	expire on March 31, 2011, unless renewed.	
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1	3. On or about December 3, 1985, the Board of Pharmacy issued Pharmacy Permit No.
2	PHY 32506 to Savco Generic Drugs (Respondent Savco), with James W. Junker, RPH 24929 as
3	President of the company, Lloyd Ando as Vice President, and Ron Sakamoto as Secretary. The
4	Savco Pharmacy Permit was in full force and effect at all times relevant to the charges brought
5	herein and will expire on December 1, 2009, unless renewed.
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7	JURISDICTION
8	4. This Accusation is brought before the Board of Pharmacy (Board), Department of
9	Consumer Affairs, under the authority of the following laws. All section references are to the
10	Business and Professions Code unless otherwise indicated.
11	5. Section 4300(a) of the Code provides that every license issued by the Board may be
12	suspended or revoked.
13	6. Section 4301 of the Code states:
14	"The board shall take action against any holder of a license who is guilty of unprofessional
15	conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.
16	Unprofessional conduct shall include, but is not limited to, any of the following:
17	
18	"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or
19	corruption, whether the act is committed in the course of relations as a licensee or otherwise, and
20	whether the act is a felony or misdemeanor or not.
21	•••
22	"(j) The violation of any of the statutes of this state, or any other state, or of the United
23	States regulating controlled substances and dangerous drugs.
24	
25	"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
26	violation of or conspiring to violate any provision or term of this chapter or of the applicable
27	federal and state laws and regulations governing pharmacy, including regulations established by
28	the board or by any other state or federal regulatory agency."
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2	7. Section 4081 of the Code states:
3	"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs
4	or dangerous devices shall be at all times during business hours open to inspection by authorized
5	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 pharmacy who maintains a stock of dangerous
6	drugs or dangerous devices.
7	
8	"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal
9	drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-
10	charge, for maintaining the records and inventory described in this section.
11	"(c) The pharmacist-in-charge or representative-in-charge shall not be criminally
12	responsible for acts of the owner, officer, partner, or employee that violate this section and of
13	which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or
14	she did not knowingly participate."
15	8. Section 4104(b) of the Code states:
16	"Every pharmacy shall have written policies and procedures for addressing chemical,
17	mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among
18	licensed individuals employed by or with the pharmacy."
19	9. Section 4105 of the Code states:
20	"(a) All records or other documentation of the acquisition and disposition of dangerous
21	drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed
22	premises in a readily retrievable form.
23	"(b) The licensee may remove the original records or documentation from the licensed
24	premises on a temporary basis for license-related purposes. However, a duplicate set of those
25	records or other documentation shall be retained on the licensed premises.
26	"(c) The records required by this section shall be retained on the licensed premises for a
27	period of three years from the date of making.
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"(d) Any records that are maintained electronically shall be maintained so that the
pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the
case of a veterinary food-animal drug retailer or wholesaler, the designated representative on
duty, shall, at all times during which the licensed premises are open for business, be able to
produce a hard copy and electronic copy of all records of acquisition or disposition or other drug
or dispensing-related records maintained electronically.

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

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

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

11. California Code of Regulations, title 16, section 1715.6, states:

24 "The owner shall report to the Board within thirty (30) days of discovery of any loss of the
25 controlled substances, including their amounts and strengths."

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1	12. California Code of Regulations, title 16, section 1718, states:
2	"Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions
3	Code shall be considered to include complete accountability for all dangerous drugs handled by
4	every licensee enumerated in Sections 4081 and 4332.
5	"The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
6	available for inspection upon request for at least 3 years after the date of the inventory."
7	13. California Health and Safety Code section 11208 states:
8	"In a prosecution under this division, proof that a defendant received or has had in his
9	possession at any time a greater amount of controlled substances than is accounted for by any
10	record required by law or that the amount of controlled substances possessed by the defendant is a
11	lesser amount than is accounted for by any record required by law is prima facie evidence of
12	guilt."
13	14. Section 125.3 of the Code states, in pertinent part, that the Board may request the
14	administrative law judge to direct a licentiate found to have committed a violation or violations of
15	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
16	enforcement of the case.
17	15. Section 118, subdivision (b), of the Code provides that the expiration of a license
18	shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period
19	within which the license may be renewed, restored, reissued or reinstated.
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21	CONTROLLED SUBSTANCES/DANGEROUS DRUGS
22	16. Section 4022 of the Code states:
23	"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in
24	humans or animals, and includes the following:
25	"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without
26	prescription," "Rx only," or words of similar import.
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1	"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale
2	by or on the order of a," "Rx only," or words of similar import, the blank to be filled
3	in with the designation of the practitioner licensed to use or order use of the device.
4	"(c) Any other drug or device that by federal or state law can be lawfully dispensed only on
5	prescription or furnished pursuant to Section 4006."
6	17. Vicodin, Lortab, Lorcet, and Norco are brand names for compounds of varying
7	dosages of acetaminophen and hydrocodone bitartrate, also known as Hydrocodone-APAP, a
8	Schedule III controlled substance as designated by Health and Safety Code section 11056(e)(4)
9	and a dangerous drug as designated by Business and Professions Code section 4022, used for pain
10	relief.
11	
12	FACTUAL BACKGROUND
13	18. Respondent John Puccinelli was the Pharmacist-in-Charge (PIC) employed by and
14	responsible for Respondent Savco, at 2101 Forest Avenue, No. 122 in San Jose, California, from
15	August 21, 2006 until February 10, 2009.
16	19. On or about October 2, 2008, Respondent Puccinelli discovered that Aimee Riaski, an
17	employee of Respondent Savco, had pilfered a large quantity of the controlled substance
18	Hydrocodone/APAP. On or about January 29, 2009, Respondent Puccinelli reported to the Board
19	theft or loss of 16,000 tablets of Hydrocodone-APAP 10/500, and 142,500 tablets of
20	Hydrocodone-APAP 10/325 from Respondent Savco, due to employee pilferage.
21	20. Further internal controlled substance audits conducted at Respondent Savco for the
22	periods April 30, 2007 to May 14, 2009 and April 30, 2005 to May 14, 2009 substantiated a total
23	shortage (acquisitions greater than dispositions) as follows:
24	Hydrocodone/APAP 10/325: 135,771 tablets missing;
25	Hydrocodone/APAP 10/500: 16,740 tablets missing;
26	Hydrocodone/APAP 5/500: 24,775 tablets missing; and
27	Hydrocodone/APAP 7.5/750: 7,393 tablets missing.
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1	21. Respondent Savco did not have written policies and procedures on theft, diversion or
2	self-use in place at the time of the employee pilferage. Respondent Savco also failed to have in
3	place an effective control on the security of controlled substances, and failed to adequately
4	maintain inventory of controlled substances.
5	
6	CAUSES FOR DISCIPLINE AS TO RESPONDENT PUCCINELLI
7	FIRST CAUSE FOR DISCIPLINE
8	(Failure to Maintain Security of Controlled Substances)
9	22. Respondent Puccinelli is subject to disciplinary action under sections 4301(j) and/or
10	(o) of the Code, section 11208 of the Health and Safety Code, and/or California Code of
11	Regulations, title 16, section 1714, subdivision (d), in that, as described in paragraphs 18-20
5 12	above, Respondent Puccinelli failed to maintain the security of the controlled substances
13	received, dispensed and/or otherwise handled therein.
14	SECOND CAUSE FOR DISCIPLINE
15	(Failure to Maintain Current Inventory of Controlled Substances)
16	23. Respondent Puccinelli is subject to disciplinary action under sections 4301(j) and/or
17	(o) of the Code, section 11208 of the Health and Safety Code, and/or California Code of
18	Regulations, title 16, section 1718, in that, as described in paragraphs 18-20 above, Respondent
19	Puccinelli failed to maintain an accurate and complete inventory of controlled substances
20	received, dispensed and/or otherwise handled therein.
21	THIRD CAUSE FOR DISCIPLINE
22	(Failure to Maintain Policies and Procedures)
23	24. Respondent Puccinelli is subject to disciplinary action under sections 4301(j) and/or
24	(o), and/or 4104(b) of the Code, in that, as described in paragraph 21 above, Respondent
25	Puccinelli failed to have written policies and procedures on theft/diversion or self-use in place.
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1	CAUSES FOR DISCIPLINE AS TO RESPONDENT SAVCO
2	FOURTH CAUSE FOR DISCIPLINE
3	(Failure to Maintain Security of Controlled Substances)
4	25. Respondent Savco is subject to disciplinary action under sections 4301(j) and/or (o),
5	and 4081 of the Code, section 11208 of the Health and Safety Code, and/or California Code of
6	Regulations, title 16, section 1714, subdivision (b), in that, as described in paragraphs 18-20
7	above, Respondent Savco failed to maintain the security of the controlled substances received,
8	dispensed and/or otherwise handled therein.
9	FIFTH CAUSE FOR DISCIPLINE
10	(Failure to Maintain Accurate Controlled Substances Inventory)
11	26. Respondent Savco is subject to disciplinary action under sections 4301(j) and/or (o),
12	and 4081 of the Code, section 11208 of the Health and Safety Code, and/or California Code of
13	Regulations, title 16, section 1718 in that, as described in paragraphs 18-20 above, Respondent
. 14	Savco failed to maintain an accurate and complete inventory of controlled substances received,
. 15	dispensed and/or otherwise handled therein.
16	SIXTH CAUSE FOR DISCIPLINE
17	(Failure to Maintain Policies and Procedures)
18	27. Respondent Savco is subject to disciplinary action under sections 4301(j) and/or (o),
19	and 4104(b) of the Code, in that, as described in paragraph 21 above, Respondent Savco failed to
20	have written policies and procedures on theft/diversion or self-use in place.
21	SEVENTH CAUSE FOR DISCIPLINE
22	(Failure to Report Drug Loss)
23	28. Respondent Savco is subject to disciplinary action under sections 4301(j) and/or (o),
24	and California Code of Regulations, title 16, section 1715.6, in that, as described in paragraphs
25	18-20 above, Respondent Savco failed to report the loss of controlled substances to the Board
26	within 30 days.
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1	PRAYER
2	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
3	and that following the hearing, the Board of Pharmacy issue a decision:
4	1. Revoking or suspending Pharmacist License Number RPH 26552, issued to John
5	Michael Puccinelli (Respondent Puccinelli);
6	2. Revoking or suspending Pharmacy Permit Number PHY 32506, issued to Respondent
7	Savco Generic Drugs (Respondent Savco);
8	3. Forbidding Respondent Puccinelli and Savco owners and officers (James W. Junker,
9	Lloyd Ando, and Ron Sakamoto) from serving as a manager, administrator, owner, member,
10	officer, director, associate, or partner of Respondent Savco or of any other Board licensee,
11	pursuant to Business and Professions Code section 4307;
12	4. Ordering John Michael Puccinelli and Savco Generic Drugs jointly and severally to
13	pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,
14	pursuant to Business and Professions Code section 125.3;
15	5. Taking such other and further action as deemed necessary and proper.
16	
17	DATED: 12/8/09 Jurginia Levol
18	VIRGINIA HEROLD Executive Officer
19	Board of Pharmacy Department of Consumer Affairs
20	State of California Complainant
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