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9		RE THE				
10	DEPARTMENT OF C	PHARMACY CONSUMER AFFAIRS				
11	STATE OF CALIFORNIA					
12	In the Matter of the Accusation Against:	Case No. 5694				
13	LAURA MICHELLE DAWLY					
14	17152 Century Plant Rd. Apple Valley, CA 92307	ACCUSATION				
15	Pharmacist License No. RPH 55947					
16	Respondent.					
17						
18	Complainant alleges:					
19	<u>PARTIES</u>					
20	1. Virginia Herold (Complainant) bring	s this Accusation solely in her official capacity				
21	as the Executive Officer of the Board of Pharmac	cy, Department of Consumer Affairs.				
22	2. On or about August 5, 2004, the Boa	rd of Pharmacy issued Pharmacist License				
23	Number RPH 55947 to Laura Michelle Dawly (R	Respondent). From on or about March 8, 2011 to				
24	on or about January 14, 2015, and from on or abo	out May 21, 2015, to the present, Respondent has				
25	been the pharmacist-in-charge of Rite Aid Pharm	acy #6514, located at 16120 Bear Valley Road,				
26	Victorville, CA 92395 ("Rite Aid Pharmacy"). T	he Pharmacist License was in full force and				
27	effect at all times relevant to the charges brought	herein and will expire on December 31, 2017,				
28	unless renewed.					
- 11	1					

#### **JURISDICTION**

3. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

# **STATUTORY PROVISIONS**

- 4. Section 4300 states, in part, that "[e]very license issued may be suspended or revoked."
  - 5. 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."

6. Section 4301 of the Code states, in part, that:

"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 [the Pharmacy Law, Bus. & Prof. Code, § 4000, et seq.) 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."

1	7. Section 4022 of the Code states, in part, that:
2	"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in
3	humans or animals, and includes the following:
4	"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without
5	prescription," "Rx only," or words of similar import.
6	•••
7	"(c) Any other drug or device that by federal or state law can be lawfully dispensed only o
8	prescription or furnished pursuant to Section 4006."

- on
  - 8. Section 4076 of the Code states, in part, that:
- "(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:
  - (2) The directions for the use of the drug."
  - Section 4169 of the Code states, in part, that: 9.
  - "(a) A person or entity shall not do any of the following:
- (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code."
  - Section 4342 of the Code states: 10.
- "(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).
- (b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4321 and 4336,"

### **HEALTH AND SAFETY CODE**

11. Health and Safety Code 11172 states: "No person shall antedate or postdate a prescription."

## **REGULATORY PROVISIONS**

- 12. California Code of Regulations, title 16, section 1711, states, in part, that:
- "(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.
- "(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716.

  Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.
- (d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.
- (f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created."
  - 13. California Code of Regulations, title 16, section 1716, states, in part, that:
- "Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code."

### COST RECOVERY

14. Section 125.3 of the Code states, in 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.

# 15. DRUG CLASSIFICATIONS

ethylphenidate	Per Bus. & Prof. Code, § 4022 Yes	Substance Per Health & Safety Code (HSC) Yes HSC §	Use
ethylphenidate		Code (HSC) Yes	ADHD
ethylphenidate	Yes	Yes	ADHD
ethylphenidate	Yes	I	ADHD
		HSC §	
		11055(d)(6)	1.
ethylphenidate	Yes	Yes	ADHD
₹		HSC §	
		11055(d)(6)	
ythromycin	Yes	No	Antibiotic
riamterene/HCTZ	Yes	No	Hypertension
	ythromycin	·	ythromycin Yes No

# FIRST CAUSE FOR DISCIPLINE

## (Variation from Prescription)

- 16. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating California Code of Regulations, title 16, section 1716, in that Respondent deviated from the requirements of a prescription without the prior consent of the prescriber. The circumstances are as follows:
- 17. On or about January 30, 2014, while working at Rite Aid Pharmacy, Respondent incorrectly processed and verified a prescription as methylphenidate 5mg Rx #320772 to patient MD, instead of the prescribed methylphenidate ER 54mg. On or about February 5, 2014, another pharmacist at Rite Aid Pharmacy corrected the error and dispensed methylphenidate ER 54mg Rx #323796 to patient MD.

18. On or about February 17, 2014, while working at Rite Aid Pharmacy, Respondent incorrectly dispensed a prescription for erythromycin 250mg Rx #326326 for patient TF instead of the prescribed patient EF. On or about February 18, 2014, another pharmacist at Rite Aid Pharmacy corrected the error and dispensed erythromycin 250mg Rx #326641 for patient EF.

# SECOND CAUSE FOR DISCIPLINE

# (Dispensing Dangerous Drug in Incorrectly Labeled Container)

- 19. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating section 4076, subdivision (a)(2) of the Code, and California Code of Regulations, title 16, section 1716, for dispensing a dangerous drug in an incorrectly labeled container. The circumstances are as follows:
- 20. On or about April 5, 2013, while working at Rite Aid Pharmacy, Respondent dispensed triamterene/HCTZ 37.5/25 as Rx #262434 to patient RB, which was incorrectly labeled with directions to "take one capsule by mouth once daily one capsule by mouth twice daily," instead of the prescribed directions to "take one capsule daily." On or about April 19, 2013, Respondent corrected the error and processed and verified patient RB's prescription under a new prescription number of Rx #270129.

#### THIRD CAUSE FOR DISCIPLINE

# (Quality Assurance Program)

- 21. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating California Code of Regulations, title 16, 1711, subdivisions (d) and (f), for failure to complete quality assurance reports for all reported medication errors. The circumstances are as follows:
- 22. On or about January 6, 2015, a Board inspection of Rite Aid Pharmacy revealed that, while Respondent was the pharmacist-in-charge, Rite Aid Pharmacy did not complete quality assurance reports for all reported medication errors, as follows:
- a. On or about March 8, 2013, and on or about April 5, 2013, patient RB's triamterene/ HCTZ 37.5/25 Rx #262434 was dispensed with the incorrect directions. On or about April 19,

2013, the error was corrected, but there was no quality assurance report of this medication error available when requested on January 6, 2015.

- b. On or about January 30, 2014, patient MD's methylphenidate ER 54mg prescription was incorrectly dispensed as methylphenidate 5mg Rx #320772. On or about February 5, 2014, the error was corrected, but there was no quality assurance report of this medication error available when requested by the Board on January 6, 2015.
- c. On or about February 17, 2014, patient EF's erythromycin 250mg was incorrectly dispensed to TF as erythromycin 250mg Rx #326326. On or about February 18, 2014, the error was corrected, but there was no quality assurance report of this medication error available when requested by the Board on January 6, 2015.

Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 16 through 20 above, as though set forth in full herein.

# FOURTH CAUSE FOR DISCIPLINE

# (Postdating Prescription Prohibited)

- 23. Respondent is subject to disciplinary action under section 4301, subdivisions (j) and (o), of the Code, for violating Health and Safety Code 11172, in that on or about September 26, 2013, Respondent dispensed a post-dated prescription. The circumstances are as follows:
- 24. On September 26, 2013, Rite Aid Pharmacy received a postdated prescription, dated September 29, 2013, for morphine sulfate ER 60mg and morphine sulfate IR 30mg for patient WK. On September 26, 2013, while working at Rite Aid Pharmacy, Respondent dispensed both morphine sulfate ER 60mg Rx #298354 and morphine sulfate IR 30mg Rx #298355 to patient WK.

#### FIFTH CAUSE FOR DISCIPLINE

# (Sales of Preparations or Drugs Lacking Quality or Strength)

25. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating sections 4342 and 4169, subdivision (a)(2), of the Code, for dispensing dangerous drugs that she knew or reasonably should have known were adulterated. The circumstances are as follows:

26. On or about January 30, 2014, while Respondent was the pharmacist-in-charge, patient MD's methylphenidate 5mg Rx #320772 was incorrectly dispensed, and methylphenidate 5mg Rx #320772 medication bottle containing 84 of the 90 dispensed tablets was returned to the pharmacy on February 5, 2014. The methylphenidate 5mg Rx #320772 medication bottle was commingled with the pharmacy's active drug stock and the contents of the returned medication bottle of methylphenidate 5mg were dispensed to another patient. Specifically, on or about May 12, 2014, while Respondent was the pharmacist-in-charge, 60 of patient MD's returned methylphenidate 5mg tablets were used to dispense a prescription for methylphenidate 5mg Rx #344319 to patient MH.

## **PRAYER**

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

- 1. Revoking or suspending Pharmacist License Number RPH 55947, issued to Laura Michelle Dawly;
- 2. Ordering Laura Michelle Dawly to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;
  - 3. Taking such other and further action as deemed necessary and proper.

DATED: \_/0/10/16

VIRGINIA HEROLD Executive Officer

Board of Pharmacy

Department of Consumer Affairs

State of California Complainant

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