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

11 In the Matter of the Accusation Against:

Case No. 5536

12 **RALEY'S CORP. dba RALEY'S**
13 **PHARMACY #247**
14 **1842 Fort Jones Street**
Yreka, CA 96097

ACCUSATION

15 **Original Permit Number PHY 30855**

16 **and**

17 **RALEY'S HOLDING COMPANY dba**
18 **RALEY'S PHARMACY #247**
1842 Fort Jones Street, Yreka, CA 96097
19 **Yreka, CA 96097**

20 **Original Permit Number PHY 53495**

21 **and**

22 **RUSSELL DEAN SANDERS**
23 **P.O. Box 9**
Grenada, CA 96038-0009

24 **Original Pharmacist License No. RPH 30311**

25 Respondents.

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1 Complainant alleges:

2 **PARTIES**

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

5 2. On or about November 1, 1984, the Board of Pharmacy issued Original Permit
6 Number PHY 30855 to Raley's Corp. dba Raley's Pharmacy #247 (Respondent Raley's). The
7 Original Permit was in full force and effect at all times relevant to the charges brought herein,
8 however it was canceled on May 20, 2015 pursuant to a change of ownership and has not been
9 renewed.

10 3. On or about May 19, 2015, the Board of Pharmacy issued Original Permit Number
11 PHY 53495 to Raley's Holding Company dba Raley's Pharmacy #247 (Respondent Raley's).
12 The Original Permit is in full force and effect and will expire on May 1, 2016, unless renewed.

13 4. On or about June 22, 1976, the Board of Pharmacy issued Original Pharmacist
14 License Number RPH 30311 to Russell Dean Sanders (Respondent Sanders). Respondent
15 Sanders was the Pharmacist-in-Charge of Respondent Raley's from May 3, 1990 through January
16 18, 2014. The Original Pharmacist License was in full force and effect at all times relevant to the
17 charges brought herein, however it expired on September 30, 2014, and has not been renewed.

18 **JURISDICTION**

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

22 6. Code section 4300.1 states:

23 The expiration, cancellation, forfeiture, or suspension of a board-issued
24 license by operation of law or by order or decision of the board or a court of law, the
25 placement of a license on a retired status, or the voluntary surrender of a license by a
26 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.

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1 **BUSINESS AND PROFESSIONS CODE**

2 7. Code section 4301 states, in pertinent part:

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

7 (d) The clearly excessive furnishing of controlled substances in violation
8 of subdivision (a) of Section 11153 of the Health and Safety Code. . . .

8 8. Code section 4081 states:

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

20 (b) The owner, officer, and partner of a pharmacy, wholesaler, third-party
21 logistics provider, or veterinary food-animal drug retailer shall be jointly responsible,
22 with the pharmacist-in-charge, responsible manager, or designated representative-in-
23 charge, for maintaining the records and inventory described in this section.

24 (c) The pharmacist-in-charge, responsible manager, or designated
25 representative-in-charge shall not be criminally responsible for acts of the owner,
26 officer, partner, or employee that violate this section and of which the pharmacist-in-
27 charge, responsible manager, or designated representative-in-charge had no
28 knowledge, or in which he or she did not knowingly participate.

29 **HEALTH AND SAFETY CODE**

30 9. Health and Safety Code section 11153 states, in pertinent part:

31 (a) A prescription for a controlled substance shall only be issued for a
32 legitimate medical purpose by an individual practitioner acting in the usual course of
33 his or her professional practice. The responsibility for the proper prescribing and
34 dispensing of controlled substances is upon the prescribing practitioner, but a
35 corresponding responsibility rests with the pharmacist who fills the prescription.
36 Except as authorized by this division, the following are not legal prescriptions: (1) an
37 order purporting to be a prescription which is issued not in the usual course of
38 professional treatment or in legitimate and authorized research; or (2) an order for an
39 addict or habitual user of controlled substances, which is issued not in the course of
40 professional treatment or as part of an authorized narcotic treatment program, for the
41 purpose of providing the user with controlled substances, sufficient to keep him or her
42 comfortable by maintaining customary use.

1 **CALIFORNIA CODE OF REGULATIONS**

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

3 ...

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

8 ...

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

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

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

18 "The controlled substances inventories required by Title 21, CFR, Section
19 1304 shall be available for inspection upon request for at least 3 years after the date of
20 the inventory."

21 **CODE OF FEDERAL REGULATIONS**

22 12. Code of Federal Regulations, title 21, section 1306.04 states, in pertinent part:

23 (a) A prescription for a controlled substance to be effective must be
24 issued for a legitimate medical purpose by an individual practitioner acting in the
25 usual course of his professional practice. The responsibility for the proper
26 prescribing and dispensing of controlled substances is upon the prescribing
27 practitioner, but a corresponding responsibility rests with the pharmacist who fills the
28 prescription. An order purporting to be a prescription issued not in the usual course
of professional treatment or in legitimate and authorized research is not a prescription
within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the
person knowingly filling such a purported prescription, as well as the person issuing
it, shall be subject to the penalties provided for violations of the provisions of law
relating to controlled substances.

COST RECOVERY

13. Code section 125.3 provides, in pertinent part, that a 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 **CONTROLLED SUBSTANCES**

2 14. "Hydrocodone w/APAP" (hydrocodone with acetaminophen tablets) is a
3 semisynthetic narcotic analgesic, a dangerous drug as defined in Code section 4022, a Schedule
4 III controlled substance and narcotic as defined by section 11056(e) of the Health and Safety
5 Code, and a Schedule III controlled substance as defined by section 1308.13(e) of Title 21 of the
6 Code of Federal Regulations.

7 15. "Carisoprodol" is a muscle-relaxant and sedative. It is a dangerous drug as defined in
8 Code section 4022 and a schedule IV controlled substance as defined by section 1308.14(c)(6) of
9 Title 21 of the Code of Federal Regulations.

10 16. "Oxycodone" with acetaminophen and oxycodone with aspirin both contain
11 oxycodone, a white odorless crystalline powder derived from the opium alkaloid, thebaine.
12 Oxycodone is a semisynthetic narcotic analgesic with multiple actions qualitatively similar to
13 those of morphine. It is a dangerous drug as defined in Code section 4022, a schedule II
14 controlled substance and narcotic as defined by section 11055(b)(1)(M) of the Health and Safety
15 Code, and a Schedule II controlled substance as defined by section 1308.12(b)(1) of Title 21 of
16 the Code of Federal Regulations.

17 **BACKGROUND**

18 **Events occurring in 2013**

19 17. On or about September 24, 2013, the Board received a complaint alleging that during
20 a two-month period, Respondent Sanders, as the Pharmacist-in-Charge of Respondent Raley's,
21 failed to consider red-flag warnings and dispensed controlled substances to over eight people
22 from a physician 450 miles away in Fresno, Dr. J. F.

23 18. In response to the complaint, Board Inspector K. R.-P. ("Inspector") requested
24 CURES¹ reports for Dr. J. F. (from January 1, 2012 through October 10, 2013) and Respondent
25 Raley's (from January 1 through October 10, 2013).

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27 ¹ CURES is a database containing information on Schedule II through IV controlled
28 substances dispensed in California. It is a valuable investigative, preventive, and educational tool
for the healthcare community, regulatory boards, and law enforcement.

1 19. The Inspector reviewed the CURES reports and selected the following patients which
2 had prescriptions written by Dr. J. F.: A. F., B. B., D. W., E. N., E. B., J. N., S. W., and D. M.
3 The Inspector requested various information from Respondents Raley's and Sanders regarding
4 prescriptions that had been issued to these patients from January 1, 2011 through November 4,
5 2013. When Sanders responded to the request, he admitted filling the referenced prescriptions
6 from May 18 through July 22, 2013. Sanders admitted there were oddities in the prescriptions in
7 that they were issued from Dr. J. F., in Fresno, for patients residing in Weed, California (which is
8 400 miles from Dr. J. F.'s office and twenty-four miles from Raley's). Sanders also admitted that
9 all of the prescriptions were brought in by a "caregiver," R. B., who picked up prescriptions for
10 six of the seven patients. Sanders further admitted that all seven patients paid cash for their
11 prescriptions; no third-party insurance was billed.

12 20. According to prescription documents provided by Respondent Raley's, Raley's filled
13 a total of twenty-two prescriptions written by Dr. J. F. between January 1 and October 10, 2013.
14 The Inspector confirmed twenty prescriptions with CURES data reports from Dr. J. F. and
15 Raley's.

16 21. A review of the patient profiles from the CURES report, selected by the Inspector,
17 which had prescriptions written by Dr. J. F. and filled by Respondent Raley's between May 18
18 and July 22, 2013, revealed the following: (1) all seven of the patients received oxycodone 30 mg
19 (2) six of the seven patients received hydrocodone/apap 10/325mg; (3) six of the seven patients
20 received carisoprodol 350mg; (4) two of the seven patients received meloxicam 15mg; (5) two of
21 the seven patients received ibuprofen 800mg; (6) one of the seven patients received alprazolam
22 2mg; and (7) two of the seven patients received methadone 10mg. Every prescription presented
23 was filled and picked up.

24 **Events occurring in 2014**

25 22. On or about September 11, 2014, Respondent Raley's provided the Board with a copy
26 of Report of Theft or Loss of Controlled Substances DEA Form 106 stating that a Pharmacy
27 Clerk had been terminated for theft of hydrocodone/apap 10mg/325mg on or about September 6,

28 2014.

23. On or about October 22, 2014, the Board received an audit summary from Respondent Raley's regarding the amount of loss/theft of hydrocodone/apap. The audit summary indicated the following:

	<u>Count at Last Inventory</u>	<u>Purchases</u>	<u>Dispensed RXs</u>	<u>Returns/ Destruction</u>	<u>Actual Inventory 10/9/14 COB</u>	<u>Variance</u>
<u>DRUG</u>						
hc/apap 10/325	6,368	118,421	121,888	0	564	-2,337
hc/apap 5/300	432	700	913	0	160	-59
hc/apap 5/500	1,667	57,900	59,102	0	0	-465
hc/apap 7.5/500	1,240	0	120	1,120	0	0
hc/apap 7.5/325	120	1,720	1,590	0	230	-20
hc/apap 5/325	624	10,170	10,715	0	0	-79

24. Board Inspector J. W. reviewed the audit summary and discovered several discrepancies with the identification of the reported drug loss. J. W. subsequently requested a corrected or updated audit summary.

25. On or about February 9, 2015, the Board received an updated audit summary from Respondent Raley's. The audit summary indicated the following:

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	<u>Count at Last Inventory</u>	<u>Purchases</u>	<u>Dispensed RXs</u>	<u>Returns/ Destruction</u>	<u>Actual Inventory 10/9/14 COB</u>	<u>Variance</u>	
3	<u>DRUG</u>						
4	hc/apap 10/325	6,368	118,421	121,888	0	564	-2,337
6	hc/apap 5/300	432	700	913	0	160	-59
8	hc/apap 5/325	1,667	57,900	59,102	0	0	-465
10	hc/apap 5/500	1,240	0	120	1,120	0	0
11	hc/apap 7.5/500	120	1,720	1,590	0	230	20
13	hc/apap 7.5/325	624	10,170	10,715	0	0	-79

14 26. On or about February 17, 2015, Board Inspector J. W. obtained Respondent Raley's
15 DEA inventory for 2014 and DEA inventory of hydrocodone/apap products from October 6, 2014
16 (a snapshot showing inventory for that day).

17 27. On or about February 19, 2015, Respondent Raley's Pharmacist-in-Charge provided
18 Board Inspector J. W. with Raley's perpetual inventory log sheets for several hydrocodone/apap
19 products from October 6-20, 2015.

20 28. Using the DEA inventories and Respondent Raley's perpetual inventory log sheets,
21 Board Inspector J. W. reviewed Raley's updated audit summary and discovered a discrepancy in
22 the identification of the reported drug loss. Specifically, J. W. noted that 564 dosage units were
23 reported as ending inventory by Raley's for hydrocodone/apap 10mg/325mg, however the
24 perpetual inventory logs revealed that ending inventory was 156 dosage units. J. W. calculated
25 the following numbers for beginning and ending inventory as follows:

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	<u>DEA Inventory 1/17/14 (BOB)</u>	<u>Perpetual Log Inventory 10/9/14 (COB)</u>
1		
2	<u>DRUG</u>	
3	hc/apap 10/325	6,368 156
4	hc/apap 5/300	374 160
5		
6	hc/apap 5/325	1,667 0
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8	hc/apap 5/500	1,240 0
9		
10	hc/apap 7.5/500	120 230
11	hc/apap 7.5/325	624 0
12		

13 29. Board Inspector J. W. revised Respondent Raley's updated audit summary, using 374
14 dosage units for the beginning inventory for hydrocodone/apap 5mg/300mg, and 156 dosage units
15 for the ending inventory for hydrocodone/apap 10mg/325mg, and generated the following audit
16 summary:

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	<u>Count at Last Inventory</u>	<u>Purchases</u>	<u>Dispensed RXs</u>	<u>Returns/ Destruction</u>	<u>Actual Inventory 10/9/14 COB</u>	<u>Variance</u>	
3	<u>DRUG</u>						
4	hc/apap 10/325	6,368	118,421	121,888	0	156	-2,745
6	hc/apap 5/300	374	700	913	0	160	-1
8	hc/apap 5/325	1,667	57,900	59,102	0	0	-465
10	hc/apap 5/500	1,240	0	120	1,120	0	0
11	hc/apap 7.5/500	120	1,720	1,590	0	230	0
13	hc/apap 7.5/325	624	10,170	10,715	0	0	-79

30. Based upon Board Inspector J. W.'s corrected audit summary for Respondent Raley's, Raley's failed to account for the loss of approximately 2,745 dosage units of hydrocodone/apap 10mg/325mg, one dosage unit of hydrocodone/apap 5mg/300mg, 465 dosage units of hydrocodone/apap 5mg/325mg, and seventy-nine dosage units of hydrocodone/apap 7.5mg/325 mg.

RESPONDENT RALEY'S

FIRST CAUSE FOR DISCIPLINE

(Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation)

31. Respondent Raley's is subject to disciplinary action under Code section 4301(d), by and through Health and Safety Code section 11153(a) and Code of Federal Regulations, title 21, section 1306.04(a), in that Raley's, by and through its pharmacist employees, excessively furnished controlled substances without a legitimate medical purpose to seven patients between May 18 and July 22, 2013. The facts and circumstances are described with more particularity in paragraphs 17-21, above.

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SECOND CAUSE FOR DISCIPLINE

(Unsecured Pharmacy)

32. Respondent Raley's is subject to disciplinary action under California Code of Regulations, section 1714(b), in that Raley's facilities, space, fixtures, and equipment were not maintained so that drugs were safely and properly maintained, secured, and distributed, when a pharmacy clerk employed by Raley's stole hydrocodone/apap 10mg/325mg on or before September 6, 2014. The circumstances are described with more particularity in paragraph 22, above.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Current Inventory)

33. Respondent Raley's is subject to disciplinary action under Code section 4081(a), and California Code of Regulations, title 16, section 1718, in that Raley's, by and through its pharmacist employees, failed to keep an accurate controlled substance current inventory for at least three years after the date of the inventory, as alleged above in paragraphs 22-30.

RESPONDENT SANDERS

FOURTH CAUSE FOR DISCIPLINE

(Responsibility for Legitimacy of Prescription; Corresponding Responsibility of Pharmacist; Knowing Violation)

34. Respondent Sanders is subject to disciplinary action under Code section 4301(d), by and through Health and Safety Code section 11153(a) and Code of Federal Regulations, title 21, section 1306.04(a), in that Sanders, as the Pharmacist-in-Charge of Respondent Raley's, allowed the excessive furnishing of controlled substances by Raley's pharmacist employees without a legitimate medical purpose to seven patients between May 18 and July 22, 2013. The facts and circumstances are described with more particularity in paragraphs 17-21, above.

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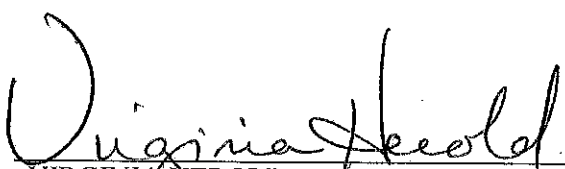
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PRAYER

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 Original Permit Number PHY 30855, issued to Raley's Corp. dba Raley's Pharmacy #247;
2. Revoking or suspending Original Permit Number PHY 53495, issued to Raley's Holding Company dba Raley's Pharmacy #247;
3. Revoking or suspending Original Pharmacist License Number RPH 30311, issued to Russell Dean Sanders;
4. Ordering Raley's Corp. dba Raley's Pharmacy # 247, Raley's Holding Company dba Raley's Pharmacy #247, and Russell Dean Sanders 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; and
5. Taking such other and further action as deemed necessary and proper.

DATED: 2/20/16



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

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