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7
8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:

Case No. 3853

11 **VALLEY PHARMACY**
12 **1082 E. El Camino Real, # 2**
Sunnyvale, CA 94087
13 **Pharmacy License No. PHY 43889**

A C C U S A T I O N

14 **and**

15 **YEON HYANG KIM**
16 **7740 Obsidian Court**
Cupertino, CA 95014
17 **Pharmacist License No. RPH 44940**

18 Respondents.

19 Complainant alleges:

20 **PARTIES**

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

23 2. On or about October 23, 1998, the Board of Pharmacy issued Pharmacy License No.
24 PHY 43889 to Yeon Hyang Kim dba Valley Pharmacy (Respondent Valley). The records of the
25 Board of Pharmacy show that Yeon Hyang Kim is and has been the Individual Licensed Owner
26 of Respondent Valley since on or about October 23, 1998, and has also served as Pharmacist in
27 Charge since on or about that date. The License was in full force and effect at all times relevant
28 to the charges brought herein and will expire on October 1, 2011, unless renewed.

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

5 9. Section 4113, subdivision (b) of the Code states:

6 “The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state
7 and federal laws and regulations pertaining to the practice of pharmacy.”

8 10. Section 4169, subdivision (a)(4) of the Code provides, in pertinent part, that a person
9 or entity may not purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the
10 beyond use date [also known as expiration date] on the label.

11 11. Section 4342, subdivision (a) of the Code provides, in pertinent part, that the Board of
12 Pharmacy may exercise its discretion to institute any action provided by law that is necessary to
13 prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and
14 tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia
15 or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic
16 Law (Part 5 [commencing with section 109875] of Division 104 of the Health and Safety Code).

17 12. California Code of Regulations, title 16, section 1714, subdivision (b) provides that
18 each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment
19 so that drugs are safely and properly prepared, maintained, secured and distributed.

20 13. California Code of Regulations, title 16, section 1715, subdivision (a) requires that
21 the pharmacist-in-charge of each pharmacy shall complete a self-assessment of the pharmacy's
22 compliance with federal and state pharmacy law before July 1 of every odd-numbered year, and
23 subdivision (d) requires that each self-assessment shall be kept for three years after completion.

24 14. California Code of Regulations, title 16, section 1716.2, subdivision (a) provides that
25 where a pharmacy compounds for future furnishing upon receipt of a prescription, the pharmacy
26 shall maintain records that include, but are not limited to: the date of preparation; lot numbers;
27 the expiration date of the finished product; the signature or initials of the pharmacist performing
28 the compounding; a formula for the compounded product; and other pertinent information.

1 15. Health and Safety Code section 11165 provides, in pertinent part, for establishment
2 and maintenance of a Controlled Substance Utilization Review and Evaluation System (CURES)
3 for the electronic monitoring of prescribing and dispensing of Schedule II, III, and IV controlled
4 substances, and requires, in pertinent part, that for each prescription for a Schedule II, III, or IV
5 controlled substance, the dispensing pharmacy or clinic transmit a report with certain information
6 on the patient, prescriber, controlled substance, and prescription, to the California Department of
7 Justice, on a weekly basis in a format prescribed by the California Department of Justice.¹

8 16. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
9 administrative law judge to direct a licensee found to have committed a violation of the licensing
10 act to pay a sum not to exceed its reasonable costs of investigation and enforcement.

11 CONTROLLED SUBSTANCES / DANGEROUS DRUGS

12 17. Section 4021 of the Code states:

13 “‘Controlled substance’ means any substance listed in Chapter 2 (commencing with Section
14 11053) of Division 10 of the Health and Safety Code.”

15 18. Section 4022 of the Code states, in pertinent part:

16 “‘Dangerous drug’ or ‘dangerous device’ means any drug or device unsafe for self use,
17 except veterinary drugs that are labeled as such, and includes the following:

18 “(a) Any drug that bears the legend: ‘Caution: federal law prohibits dispensing without
19 prescription,’ ‘Rx only,’ or words of similar import.

20 “(c) Any other drug or device that by federal or state law can be lawfully dispensed only on
21 prescription or furnished pursuant to Section 4006.”

22 19. **Procardia** is a brand name for **nifedipine**, a dangerous drug as designated by
23 Business and Professions Code section 4022. It is a drug used to treat hypertension.

24 20. **Paxil** is a brand name for **paroxetine**, a dangerous drug as designated by Business
25 and Professions Code section 4022. It is a drug used to treat depression.

26
27 ¹ Health and Safety Code section 11165 was first amended to impose CURES reporting
28 requirements effective January 1, 2005. As of that date prescriptions for Schedule II and III drugs
had to be reported. Effective January 1, 2007, Schedule IV prescriptions also had to be reported.

1 FACTUAL BACKGROUND

2 21. On or about October 15, 2003, Respondent Valley was the subject of an inspection by
3 Board Inspector(s). Respondent Kim participated in that inspection as pharmacist-in-charge. The
4 inspection revealed deficiencies that were discussed with Respondent Kim, including that:

- 5 a. No pharmacy self-assessment had been completed and/or retained in pharmacy files;
6 b. Numerous expired medications were found in the pharmacy's active inventory; and
7 c. The pharmacy had pre-packaged liquids and tablets in unlabeled containers without
8 any record of drugs pre-packaged for future use, expiration date(s), etc.

9 22. On or about September 26, 2006, Respondent Valley was the subject of an inspection
10 by Board Inspector(s). Respondent Kim participated in that inspection as pharmacist-in-charge.
11 The inspection revealed deficiencies that were discussed with Respondent Kim, including that:

- 12 a. The pharmacy self-assessment in the pharmacy records was dated October 16, 2003,
13 and was more than two years old – the self-assessment due by July 1, 2005 was not performed;
14 b. Numerous expired medications were found in the pharmacy's active inventory; and
15 c. The pharmacy had failed to transmit any data to CURES for Schedule III controlled
16 substance prescriptions that had been filled on various dates in 2006.

17 23. On or about June 25, 2010, Respondent Valley was again the subject of an inspection
18 by Board Inspector(s). Respondent Kim participated in that inspection as pharmacist-in-charge.
19 The inspection revealed deficiencies that were discussed with Respondent Kim, including that:

- 20 a. The pharmacy self-assessment in the pharmacy records was dated June 30, 2007, and
21 was more than two years old – the self-assessment due by July 1, 2009 was not performed;
22 b. Numerous expired medications were found in the pharmacy's active inventory;
23 c. On at least three occasions the pharmacy dispensed medications to patients on dates
24 that were beyond the expiration/beyond use dates on the medication labels – **Nifedipine** ER 90mg
25 tablets with a labeled expiration date of January 1, 2010 were dispensed to a patient on or about
26 May 4, 2010, and **Paroxetine** 10mg tablets with a labeled expiration date of November 30, 2009
27 were dispensed to a patient on or about January 12, 2010 and/or February 18, 2010;

28 ///

1 d. The pharmacy had pre-packaged liquids and tablets in unlabeled containers without
2 any record of drugs pre-packaged for future use, expiration date(s), etc.; and

3 e. The pharmacy had not transmitted any dispensing data to CURES for Schedule III
4 and IV controlled substances that were dispensed between January 1, 2009 and June 25, 2010.

5 **CAUSES FOR DISCIPLINE, AS TO BOTH RESPONDENTS**

6 FIRST CAUSE FOR DISCIPLINE

7 (Failure to Complete Timely Pharmacy Self-Assessment)

8 24. Respondent Valley and Respondent Kim are each and severally subject to discipline
9 under section(s) 4301, 4301(j), 4301(o), and/or 4113(b) of the Code, and/or California Code of
10 Regulations, title 16, section 1715(a), in that as described in paragraph 23 above, in the period
11 prior to June 25, 2010, Respondent(s) failed to complete a timely pharmacy self-assessment.

12 SECOND CAUSE FOR DISCIPLINE

13 (Expired Drugs in Active Inventory)

14 25. Respondent Valley and Respondent Kim are each and severally subject to discipline
15 under section(s) 4301, 4301(j), 4301(o), 4113(b), and/or 4342 of the Code, and/or California
16 Code of Regulations, title 16, section 1714(b), in that as described in paragraph 23 above, in the
17 period prior to June 25, 2010, expired medications were commingled with the active inventory.

18 THIRD CAUSE FOR DISCIPLINE

19 (Dispensing Expired Drugs to Patients)

20 26. Respondent Valley and Respondent Kim are each and severally subject to discipline
21 under section(s) 4301, 4301(j), 4301(o), and/or 4169(a)(4) of the Code, in that as described in
22 paragraph 23 above, on at least three occasions the pharmacy dispensed medications to patients
23 on dates that were beyond the expiration/beyond use dates on the medication labels.

24 FOURTH CAUSE FOR DISCIPLINE

25 (Failure to Keep Records of Unlabeled Pre-Packaged Drugs)

26 27. Respondent Valley and Respondent Kim are each and severally subject to discipline
27 under section(s) 4301, 4301(j), 4301(o), and/or 4113(b) of the Code, and/or California Code of
28 Regulations, title 16, section 1716.2(a), in that as described in paragraph 23 above, in the period

1 prior to June 25, 2010 Respondent(s) compounded and/or pre-packaged medications for future
2 furnishing without keeping records of such activities, including expiration date(s), etc.

3 FIFTH CAUSE FOR DISCIPLINE

4 (Failure to Report Controlled Substance Prescriptions to CURES)

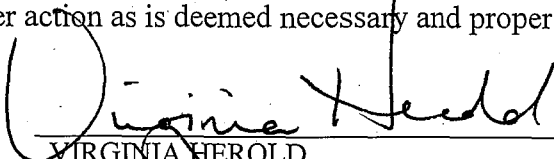
5 28. Respondent Valley and Respondent Kim are each and severally subject to discipline
6 under section(s) 4301, 4301(j), 4301(o), and/or 4113(b) of the Code, and/or Health and Safety
7 Code section 11165, in that as described in paragraph 23 above, in the period prior to June 25,
8 2010, the pharmacy had not transmitted any dispensing data to CURES for Schedule III and IV
9 controlled substances that were dispensed between January 1, 2009 and June 25, 2010.

10
11 PRAYER

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

- 14 1. Revoking or suspending Pharmacy License No. PHY 43889, issued to Yeon Hyang
15 Kim dba Valley Pharmacy (Respondent Valley);
- 16 2. Revoking or suspending Pharmacist License No. RPH 44940, issued to Yeon Hyang
17 Kim (Respondent Kim);
- 18 3. Ordering Respondent Valley and Respondent Kim (Respondents) to be jointly and
19 severally responsible to pay the Board of Pharmacy the reasonable costs of the investigation and
20 enforcement of this case, pursuant to Business and Professions Code section 125.3;
- 21 4. Taking such other and further action as is deemed necessary and proper.

22
23 DATED: 3/4/11


24 VIRGINIA HEROLD
25 Executive Officer
26 Board of Pharmacy
27 Department of Consumer Affairs
28 State of California
Complainant

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