

1 PATRIC HOOPER (State Bar No. 57343)
HOOPER, LUNDY & BOOKMAN, P.C.
2 1875 Century Park East, Suite 1600
Los Angeles, California 90067-2517
3 Telephone: (310) 551-8111
Facsimile: (310) 551-8181
4 E-Mail: phooper@health-law.com
5 Attorneys for Riverside Pharmacy &
Compounding Shop; Eunhye Parke; Taeryong
6 Park

FILED
Superior Court of California
County of Los Angeles

MAR 01 2016

Sherril A. ... Officer/Clerk
By J. DeLuna, Deputy
Jennifer De Luna

7
8 SUPERIOR COURT OF THE STATE OF CALIFORNIA
9 COUNTY OF LOS ANGELES, CENTRAL DISTRICT
10

11 RIVERSIDE PHARMACY &
COMPOUNDING SHOP; EUNHYE PARK;
12 and TAERYONG PARK,

Case No. **BS160781**

**[PROPOSED] ORDER STAYING
ADMINISTRATIVE DECISION**

13 Petitioners,

14 vs.

Date: March 1, 2016
Time: 8:30 a.m.
Dept.: 85 or 86

15 CALIFORNIA STATE BOARD OF
PHARMACY,

Trial Date: None Set

16 Respondent.
17

18
19 Petitioners' application for stay of the administrative decision came on regularly for
20 hearing on March 1, 2016, in Department 85, the Honorable JAMA CHAFFERT, Judge
21 Presiding. Petitioners were represented by Patric Hooper of Hooper, Lundy & Bookman, P.C, and
22 Zachary Fanselow, Deputy Attorney General, appeared on behalf of the Respondent California
23 State Board of Pharmacy ("Board").

24 After reviewing and considering the moving and opposing papers and having heard and
25 considered oral argument, and good cause appearing therefor,

26 IT IS ORDERED that Respondent Board stay the operation of its February 16, 2016
27 decision in question in this lawsuit pending the outcome of this administrative mandate
28 proceeding.

HOOPER, LUNDY & BOOKMAN, P.C.
1875 CENTURY PARK EAST, SUITE 1600
LOS ANGELES, CALIFORNIA 90067-2517
TEL: (310) 551-8111 • FAX: (310) 551-8181

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

IT IS SO ORDERED.

DATED: 3/1, 2016

*π to comply w/ all conditions of probation
other than 90 day suspension during
pendency of case.*

J. Chaffet

Judge of the Superior Court

HOOPER, LUNDY & BOOKMAN, P.C.
1875 CENTURY PARK EAST, SUITE 1600
LOS ANGELES, CALIFORNIA 90067-2517
TEL: (310) 551-8111 • FAX: (310) 551-8181

**BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the Accusation Against¹:

**RIVERSIDE PHARMACY &
COMPOUNDING SHOP**

Original Pharmacy Permit No. PHY 46371;

EUNHYE PARK

Pharmacist license No. RPH 48602;

and

TAERYONG PARK

Pharmacy Technician Registration No. TCH
32183,

Respondents.

Case No. 4774

OAH No. 2014010558

DECISION AFTER RECONSIDERATION

Administrative Law Judge (ALJ) Angela Villegas, Office of Administrative Hearings, heard this matter on February 4 and 5, 2015, in Los Angeles, California. Deputy Attorney General Sydney Mehringer represented Complainant. Respondents Eunhye Park and Taeryong Park were present. Respondents Eunhye Park, Taeryong Park and Riverside Pharmacy & Compounding Shop were represented by attorney Patric Hooper. The matter was submitted to the ALJ on February 5, 2015.

The ALJ issued her Proposed Decision on February 12, 2015. The Proposed Decision was submitted to the Board of Pharmacy ("Board"). The Board adopted said proposed decision to become effective on April 10, 2015. On March 25, 2015, Complainant filed a Petition for Reconsideration. On April 8, 2015, the Board granted Reconsideration of its decision, staying the effective date.

On May 26, 2015, the Board issued an Order Fixing Date for Submission of Argument, requiring submissions by June 25, 2015. Written argument was timely received from both parties.

¹ The November 4, 2013, Accusation in this matter was also filed against Respondent Rebecca M. Schneringer (TCH 96891). Respondent Schneringer, however, failed to respond to the Accusation and her license was revoked by Default Decision effective March 10, 2014.

The entire record, including written arguments, the transcript and exhibits from the hearing having been read and considered, the Board, pursuant to Government Code section 11521, issues the following decision:

AMENDMENT OF THE SUPPLEMENTAL ACCUSATION

At the hearing, Complainant amended the Supplemental Accusation as follows:

1. At page 9, paragraph 64, line 7, the reference to California Code of Regulations, title 16, section 1793.7, subdivision (c), was deleted and replaced with a reference to California Code of Regulations, title 16, section 1735.2, subdivision (d).
2. At page 11, paragraph 71, line 22, the reference to California Code of Regulations, title 16, section 1711, subdivision (j), was deleted and replaced with a reference to California Code of Regulations, title 16, subdivision (d).

SEALING OF PRIVATE MEDICAL INFORMATION

After the hearing, it was discovered that Exhibit 4, pages 132 and 133, consisted of a prescription drug history for Respondent Taeryong Park. Neither this medical information nor Mr. Park's identifying information could be redacted without destroying the evidentiary value of the cited pages. Accordingly, the ALJ ordered the pages to be sealed.

FACTUAL FINDINGS

1. Complainant Virginia Herold, Executive Officer of the California State Board of Pharmacy, Department of Consumer Affairs (Board), filed the Accusation, including its supplements and amendments, in her official capacity.
2. Respondent Eunhye Park (PIC Park) holds pharmacist license number RPH 48602, issued by the Board on March 12, 1996, and scheduled to expire May 31, 2015, unless renewed. PIC Park's license has no history of discipline.
3. Respondent Taeryong Park (Technician Park) holds pharmacy technician registration number TCH 32183, issued by the Board on January 27, 2000, and scheduled to expire December 31, 2015, unless renewed. Technician Park's registration has no history of discipline.
4. Respondent Riverside Pharmacy & Compounding Shop (the Pharmacy) is the name under which Riverside Park Pharmacy, Inc., does business. The Pharmacy operates under pharmacy permit number PHY 46371, which the Board issued to Riverside Park Pharmacy, Inc. on May 8, 2003, and which is scheduled to expire May 1, 2015, unless renewed. Respondents PIC Park and Technician Park, who are wife and husband, have owned the Pharmacy since 2003, and also own Riverside Park Pharmacy, Inc. PIC Park is the Pharmacy's pharmacist-in-charge (PIC) and has been since the permit was issued. The Pharmacy's permit has no history of discipline. Approximately 10 percent of the Pharmacy's business is preparing compounded medications.

5. In 2010 and 2011, the Pharmacy employed pharmacy technician Rebecca Schneringer (see footnote 1) on a part-time basis. Schneringer also worked at other pharmacies at the time. The board investigated Schneringer on suspicion that she had diverted pharmaceuticals from her employers. As part of that investigation, former Board inspector Valerie Knight inspected the Pharmacy on June 7, 2011. The June 7, 2011, inspection revealed the following conditions.

a. For the years 2005, 2007, and 2011, the only controlled substance inventories that had been performed were for Schedule II controlled substances. No inventories for Schedule III, IV, or V controlled substances had been performed during those years. For the year 2009, no controlled substance inventory had been performed at all. At the hearing, PIC Park explained that her work at the Pharmacy keeps her very busy, and she must prioritize her tasks. She determined that taking inventory was a relatively low-priority task, and consequently overlooked it, except for the Schedule II inventories in 2005, 2007, and 2011.

b. One prescription label failed to include a physical description of the medication being dispensed. Instead the physical description appeared in the patient monograph. At the hearing, PIC Park explained that occasionally the Pharmacy's computer software produces an anomalous label that fails to include all of the necessary information, but that she usually catches and corrects the anomaly when she reviews the label before providing the medication to the patient. This time, she acknowledged, she failed to catch the anomaly. Nevertheless, she testified credibly that the Pharmacy's prescription labels normally include complete information.

c. The Pharmacy's written policies and procedures regarding employee theft and/or impairment were not comprehensive, and did not require notification to the Board within 30 days of such an occurrence (or the discovery thereof). Instead, the policies and procedures were labeled, "Reporting Suspected Fraud, Waste and Abuse" (Exhibit 4), and did not address the issue of employee impairment. Moreover, the policies referenced only Medicare Part D, and not any aspect of California pharmacy law.

d. Technician Park possessed a key to the Pharmacy, and the key was not kept in a tamper-evident container.

e. The Pharmacy's permit was, and had been since the Pharmacy's previous inspection in 2003, displayed at the back of the Pharmacy, where it could not be clearly read by members of the public. Despite the 2003 inspector's recommendation that the permit be moved to a more prominent location, it had not been moved.

f. The Pharmacy had only a brief written job description for pharmacy technicians and lacked documentation of comprehensive policies and procedures governing pharmacy technicians.

g. For each drug compounded, the pharmacy did not have a master formula; did not identify the pharmacist reviewing the final product; did not document the quantity of each component used in compounding the product; did not document the manufacturer and lot

number of each component used; did not document the equipment used; did not document the expiration date of the final product; and did not document the amount compounded.

6. The notice of violation inspector Knight provided to Respondents (Exhibit 4) did not note compounding violations, and inspector Knight's inspection report (Exhibit 7) did not expressly cite regulations governing compounding. Nevertheless, the inspection report did note, "Pharmacy compounds topical and oral caps / solutions for dispensing to patients. Inaccurate records kept, RPH not verify and document technician compounding. ... Pharmacy records of compounded items does [sic] not include any information of manufacturer used, expiration date, lot #, etc. ... PIC Park does not indicate verification of the compounding record that she checked the finished product[.]" (*Id.*)

7. During inspector Knight's visit, she saw Technician Park place a topical syringe into a satchel, and asked him about it. He admitted the syringe contained a compounded preparation of testosterone with lipoderm cream. Technician Park explained to inspector Knight (and testified at the hearing) that he had prepared the cream for a patient, and had some left over. He became curious as to the effects of the testosterone and wanted to try it on himself, which he did for two or three days, until inspector Knight discovered the syringe. If Technician Park liked the effects, his plan was to ask his own doctor for a prescription for the same testosterone preparation. This explanation was credible and forthright, but Technician Park's sincere expression of his rationale does not alter the nature of his misconduct. Although he accepted responsibility for his conduct without hesitation, his acceptance is considered in light of the fact that the inspector saw him take the syringe. Technician Park also claimed he was testing the preparation for quality, but self-testing of compounded products was an unreasonable and unsafe quality control method. His acceptance also does not recognize or diminish the grave nature of the wrongdoing.

8. Inspector Knight also conducted a zero-based audit² of four controlled substances, including hydrocodone/acetaminophen 10/325 tablets (meaning each tablet contained 10 mg of hydrocodone and 325 mg of acetaminophen), which Schneringer was suspected of diverting. Inspector Knight's audit showed a deficit of 2,578 hydrocodone/acetaminophen 10/325 tablets over the period from June 8, 2010, to June 7, 2011. (Exhibit 4.) On July 31, 2012, inspector Knight notified PIC Park of the audit's findings, and instructed her to report the loss to the Board and the federal Drug Enforcement Administration, which PIC Park did on approximately August 2, 2012. (Exhibit 4.)

9. PIC Park testified that she was "shocked" at the large number of missing hydrocodone/acetaminophen 10/325 tablets, and did not believe Schneringer could have stolen so many, because the Pharmacy employed security measures, including two cameras and a policy of always having at least two people on duty. In 2013, PIC Park performed her own count of hydrocodone/acetaminophen tablets from the period from June 18, 2010, to June 7, 2011. (Exhibit C.) PIC Park's comparison report is dated December 16, 2013. PIC Park's count compared the number of tablets dispensed during the relevant period with the number of tablets

² According to inspector Knight's investigation report (Exhibit 4), a zero based audit assumes a starting quantity of zero of the item being counted.

purchased during that period, and showed that the Pharmacy had dispensed approximately 3,000 more such tablets than it had purchased during the relevant period, such that there was no shortage.

10. The result of inspector Knight's audit, showing a shortage, was more reliable than that of PIC Park's count, showing a surplus. Even setting aside the 10 day discrepancy in the periods covered by the two reviews, PIC Park's count, unlike inspector Knight's audit, was not limited to hydrocodone/acetaminophen 10/325 tablets, and did not account for stock on hand. (Exhibit C; testimony of Eunhye Park.) Moreover, inspector Knight's audit showed stock on hand of 401 hydrocodone/acetaminophen 10/325 tablets, making it very unlikely that the Pharmacy could have dispensed nearly 3,000 more such tablets than it acquired over the period of a year.

11. After inspector Knight's visit, PIC Park performed inventories of Schedule III, IV, and V controlled substances, provided revised written policies regarding employee theft or impairment, and moved the Pharmacy's permit to a location where it could be read by members of the public.

12. On August 21, 2013, investigating a complaint from a Pharmacy patient, Board inspector Valerie Sakamura inspected the Pharmacy again. On January 22, 2013, the Pharmacy had incorrectly filled the patient's prescription. The prescription was for 60 Percocet tablets: specifically, oxycodone/acetaminophen 7.5/325 (meaning 7.5 mg oxycodone and 325 mg acetaminophen), but the Pharmacy instead dispensed 60 tablets of oxycodone/acetaminophen 7.5/500 (meaning each tablet contained 175 mg more acetaminophen than had been prescribed). PIC Park caught the error on the same day it was made, but the medication had already been delivered to the patient. PIC Park telephoned the patient, but the patient did not answer the phone, and PIC Park left a message. The following day, the patient returned the call and was provided with the correct medication.

13. PIC Park did not document the January 22, 2013, error. She did not have, and could not produce to inspector Sakamura, a written quality assurance policy to document, investigate, and prevent errors. PIC Park explained to inspector Sakamura that, instead, she would simply discuss any errors that occurred, because "the patients are like family[.]" (Exhibit 5.) After inspector Sakamura's visit, PIC Park provided a written quality assurance plan setting forth a procedure to deal with errors, which required, among other things, documentation of the error. (Exhibit 13.)

14. While conducting the inspection on August 21, 2013, inspector Sakamura observed a closed door leading to the Pharmacy's compounding room. When inspector Sakamura entered the compounding room, she saw Technician Park and another pharmacy technician, Alvina Sumbatyan, compounding medications. PIC Park acknowledged, both to inspector Sakamura during the inspection and at the hearing, that, at that time, she often trusted Technician Park to oversee the compounding himself, because he had been educated as a pharmacist, and had worked as a pharmacist in South Korea, before the couple relocated to the

United States, and was trained in compounding techniques.³ Technician Park confirmed that he trained and oversaw technician Sumbatyan in compounding.

15. The Pharmacy's documentation of its compounding, and the Pharmacy's compounding practices as observed by inspector Sakamura, did not include pharmacist review of every final compounded product, and did not include documentation of the quantity of each component used in producing a final product, the manufacturer and lot number of each component, the equipment used, the expiration date of the final product or its components, or the final amount produced. In addition, although master formulae existed for many compounded products, those formulae had handwritten alterations that varied from the original formulae. The Pharmacy did not provide inspector Sakamura with written policies and procedures for its compounding functions, did not produce documentation that compounding staff (other than Technician Park) had received training in compounding, did not produce a written quality assurance plan for compounded items, and did not produce a compounding self-assessment.

16. On duty at the time of inspector Sakamura's visit were not only Technician Park and technician Sumbatyan, but also a third pharmacy technician, Kathryn Brenny, who was filling prescriptions and transferring medications into bottles. Meanwhile, the only pharmacist on duty at the time was PIC Park. At the hearing, PIC Park testified she had believed, at the time, that technician Brenny was actually a student, rather than a pharmacy technician, but PIC Park acknowledged that Brenny had already graduated from pharmacy technician school. None of the pharmacy technicians was wearing an identification badge.

17. Inspector Sakamura reviewed the Pharmacy's written policies and procedures concerning employee theft and/or impairment, and felt they were inadequate, because they did not explain what the Pharmacy would do if employee theft or impairment occurred (Exhibits 5 and 9; testimony of Valerie Sakamura), and instead merely parroted statutory and/or regulatory language. The evidence did not disclose the content of the Pharmacy's theft and/or impairment policies and procedures at the time of inspector Sakamura's visit. Exhibit 8 contained a photograph of those policies and procedures, but the text was not legible.

18. After inspector Sakamura's visit, PIC Park provided her with a revised theft and/or impairment policy, specifying, among other things, that the Pharmacy would report instances of theft and/or impairment to the Board within 14 days; immediately remove any impaired employee from service; and investigate, discipline and/or terminate any employee discovered to have engaged in theft. (Exhibit 13.)

19. To address inspector Sakamura's concerns with regard to compounding practices and documentation, the Pharmacy procured "PK" software, produced by Professional Compounding Centers of America (PCCA), to help document and track compounded medications. Inspector Sakamura's testimony acknowledged that the PK software, if properly used, could correct the recordkeeping issues she observed.

³ Technician Park explained that he tried to become licensed as a pharmacist in California, but was unable to pass one of the tests, which required a written essay.

20. At the hearing, respondents also produced a PCCA Standard Operating Procedures (SOP) manual (Exhibit E), setting forth comprehensive policies and procedures for compounding, which Respondents claimed they followed at the Pharmacy. Although Respondents had the PCCA SOP manual at the time of inspector Sakamura's inspection, they stated that they did not think to show it to her during or after her visit.

21. The PCCA SOP manual contains blanks for the pharmacist to note when each policy was reviewed and implemented; none of those blanks were filled in. Moreover, approximately half of the SOPs set forth in the PCCA SOP manual contain blank charts or other forms for use in documenting various compounding procedures, quality control, patient surveys, and the like. No documentation was produced at the hearing showing that the Pharmacy actually used any of those forms in carrying out its compounding functions. Hence, Respondents' contention that they followed the PCCA SOP manual was dubious, at best. Moreover, at the time of inspector Sakamura's visit, Respondents undisputedly documented their compounding simply by affixing a sticker containing patients' prescription information to the paper setting forth the compounding formula. That practice does not comport with any of the PCCA SOPs set forth in the manual. Accordingly, the evidence did not show that Respondents followed the procedures set forth in the PCCA SOP manual at the time of inspector Sakamura's visit.

22. After inspector Sakamura's visit, the pharmacy did begin preparing detailed compounding worksheets for each compounded product, but one such worksheet (Exhibit 16) reflected that Respondents did not note the exact quantity of each component used, as opposed to the quantity called for by the formula. In addition, the worksheet set forth an erroneous expiration date for the final product, which was later than the expiration date of one of the components.

23. PIC Park apologized for the Pharmacy's shortcomings and her own failure to achieve full compliance with pharmacy laws and regulations. Both PIC Park and Technician Park work full-time, or more than full-time, in the Pharmacy. In addition to Technician Park's technician duties, he also oversees and performs the Pharmacy's maintenance and cleaning, its non-pharmacy business and paperwork, and even delivers medications when other delivery personnel are not available. Indeed, Technician Park's non-technician duties absorb more of his time than do his technician duties.

24. The Board's reasonable costs of investigation and enforcement in this matter total \$16,823.70. This is \$3,585.30 less than the \$20,409 sought by Complainant.

a. The amounts set forth in Complaint's certifications of costs (Exhibit 3) are reasonable as to the hours spent, and hourly rates charged by, inspector Sakamura, supervisor Joan Coyne, Deputy Attorney General Sydney M. Mehringer, and other professionals and paraprofessionals in the Attorney General's Office. The large number of violations identified, the repeated and technical nature of some of them, the follow-up involved, and the detailed nature of the pleadings and proof in this matter made it necessary for substantial time to be spent in the investigation and prosecution of this case.

b. For the same reasons, inspector Knight's hourly rate was reasonable, as was the number of hours inspector Knight spent on travel and investigation, which were limited to the hours Knight spent in connection with her inspection and investigation of Respondents.

c. The 92.5 hours inspector Knight spent on report preparation, however, must be discounted to reflect the fact that inspector Knight's investigation report (Exhibit 4) deals not only with Respondents, but also with seven other persons and entities that were part of the investigation into Schneringer's activities. Approximately 62 percent of inspector Knight's investigation report is devoted to Respondents; approximately 38 percent of the report addresses other persons and entities. Accordingly, the 92.5 hours claimed for report preparation will be discounted by 38 percent (35.12 hours), so that 57.35 hours will be allowed as Complainant's reasonable cost of report preparation by inspector Knight. At inspector Knight's hourly rate of \$102, the amount allowed for the preparation of her report is \$5,849.70.

d. In sum, the costs allowed are \$1,734 for inspector Sakamura; \$9,011.70 for inspector Knight; \$153 for supervisor Coyne; and \$5,925 for the Deputy Attorney General. These amounts total \$16,823.70.

LEGAL CONCLUSIONS

1. In an action seeking disciplinary action against a professional license, including a pharmacist's license, the governing agency bears the burden of establishing cause for discipline by clear and convincing evidence to a reasonable certainty. (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 855-857.). This is because a professional license represents the licensee's fulfillment of extensive education, training, and testing requirements; the licensee has an extremely strong interest in retaining the license that she has expended so much effort in obtaining. To establish cause for discipline for an occupational non-professional license, however, cause for discipline need only be established by the *preponderance of the evidence* standard. (*Imports Performance v Dept. of Consumer Affairs, Bur. Of Automotive Repair* (2011) 201 Cal.App.4th 911, 916-917; *San Benito Foods v. Veneman* (1996) 50 Cal.App.4th 1889; *Mann v. Dep't of Motor Vehicles* (1999) 76 Cal. App. 4th 312, 319, 90 Cal. Rptr. 2d 277, 282.) Although the standards of proof are different for the various licenses, each violation found below was established by clear and convincing evidence to a reasonable certainty.

2. Pursuant to section 4001.1 of the Business and Professions Code,

Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

3. Pharmacy law also requires that public protection must take priority over rehabilitation and, where evidence of rehabilitation and public protection are in conflict, public protection shall take precedence. (Bus. & Prof. Code, § 4313.) This decision is made in

accordance with the Board's statutory duty to prevent harm to consumers including, but not limited to, prevent types of misconduct found here that can result in serious harm to consumers.

4. Complainant established cause to discipline PIC Park's license, technician Park's registration and the Pharmacy's permit, on grounds that PIC Park, Technician Park and the Pharmacy engaged in unprofessional conduct.⁴ The Pharmacy is responsible for the unprofessional conduct of PIC Park, who in turn is responsible for the Pharmacy's and its staff's adherence to applicable laws and regulations. (Bus. & Prof. Code, §§ 4036.5, 4113.)

5. Technician Park engaged in unprofessional conduct as alleged in Accusation for Causes of Discipline (CFDs) 15 through 17, by possessing and furnishing to himself a controlled substance not prescribed for him: namely, the testosterone with lipoderm cream. (Factual Finding 7.) (Bus. & Prof. Code, §§ 4301, subd. (o), 4059, and 4060; Health & Saf. Code, §§ 11056, subd. (f)(30), 11170, 11350, subd. (a).) Technician Park's conduct violated the cited laws and regulations. (Bus. & Prof. Code, § 4301, subd. (j).)

6. As of June 7, 2011, PIC Park, and by extension the Pharmacy, had engaged in unprofessional conduct in the following ways:

a. Failing to conduct timely biennial inventories of Schedule III, IV, and V controlled substances during 2005, 2007, and 2011, and failing to conduct any controlled substance inventory at all in 2009. (Factual Finding 5.) (Bus. & Prof. Code, §§ 4301, subds. (j) and (o), 4081, subd. (b); 21 C.F.R. §1304.11(c); 16 C.C.R. (Regulation) § 1718.) (Accusation CFDs 6 and 14.)

b. Failing to include on a patient label the physical description of the medication being dispensed. (Factual Finding 5.) (Bus. & Prof. Code, §§ 4301, subd. (o), 4076, subd. (a)(11)(A).) (Accusation CFD 7.)

c. Failing to have sufficient written policies and procedures regarding employee theft and/or impairment. (Factual Finding 5.) (Bus. & Prof. Code, §§ 4301, subd. (o), 4104, subds. (a) and (b).) (Accusation CFD 8.)

d. Allowing Technician Park to possess a key to the Pharmacy, not in a tamper evident container. (Factual Finding 5.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1714, subds. (d) and (e).) (Accusation CFD 9.)

e. Posting the Pharmacy's permit near the back of the Pharmacy, where it could not be clearly read by members of the public. (Factual Finding 5.) (Bus. & Prof. Code, §§ 4301, subd. (o), 4058.) (Accusation CFD 10.)

⁴ Although the Accusation and Supplemental Accusation set forth numerous, separately-pled causes for discipline, each of them is grounded in unprofessional conduct pursuant to Business and Professions Code section 4301.

f. Failing to have comprehensive written job descriptions and policies and procedures governing pharmacy technicians. (Factual Finding 5.) (Bus. & Prof. Code, §§ 4301, subd. (o); Regulation §1793.7, subd. (d).) (Accusation CFD 11.)

g. Failing to have master formulae for compounded drugs; failing to identify the pharmacist reviewing the final product; failing to document the quantity of each component used in compounding the product; failing to document the manufacturer and lot number of each component used; failing to document the expiration date of the final product; and failing to document the amount compounded.⁵ (Factual Finding 5.) (Bus. & Prof. Code, §§ 4301, subd. (o); Regulation § 1735.3, subd. (a).) (Accusation CFD 12.) Respondents contended that inspector Knight failed to put them on notice of violations (Factual finding 6), but that contention was not persuasive. Whether inspector Knight did or did not provide such notice was irrelevant to the existence of the violation or to Respondents' obligation to comply with the laws and regulations governing compounding.

h. Failing to secure and account for a controlled substance: namely, 2,578 hydrocodone/acetaminophen 10/325 tablets over the course of the year preceding inspector Knight's visit. (Factual Findings 8-10.) (Bus. & Prof. Code, § 4301, subd. (o); Health & Saf. Code §§ 11055, subd. (b)(1)(I), 11056, subd. (e)(4); Regulation §§1714, subd. (b), 1718.) (Accusation CFDs 5 and 14.)

7. As of August 21, 2013, PIC Park, and by extension the Pharmacy, and engaged in unprofessional conduct in the following ways:

a. Incorrectly filling a patient's prescription on January 22, 2013. (Factual Finding 12.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1716.) (Supplemental Accusation CFD 30.)

b. Failing to document the above error, and failing to have a quality assurance policy in place – and available for review – to document, investigate, and prevent errors. (Factual Finding 13.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1716.) (Supplemental Accusation CFD 30.)

c. Failing to provide direct pharmacist supervision and oversight of compounding functions carried out by pharmacy technicians. (Factual Finding 14 and 15.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1793.7, subd. (a).) (Supplemental Accusation CFD 19.)

d. Failing to provide documentation showing that pharmacy technician Alvina Sumbatyan, who performed compounding tasks, had received training in compounding techniques. (Factual Finding 15.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1735.7, subd. (a).) (Supplemental Accusation CFD 25.)

⁵ The Accusation (par 39(a)(5)) alleges that it was also a violation for the Pharmacy not to document the equipment used in compounding, but the Regulation cited sets forth no such requirement.

e. Failing to have written policies and procedures governing compounding functions. (Factual Finding 15.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1735.5.) Although the evidence showed that Respondents possessed the PCCA SOP manual produced at the hearing on or before August 21, 2013 (Factual Findings 21 and 22), the evidence did not establish that the policies and procedures set forth in the PCCA SOP manual had been reviewed or implemented by that date. (Factual Finding 21.) (Supplemental Accusation CFD 24.)

f. Failing to have a written quality assurance plan for compounded items. (Factual Finding 15.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1735.8.) (Supplemental Accusation CFD 26.)

g. Failing to perform a timely compounding self-assessment. (Factual Finding 15.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1735.2, subd. (j).) (Supplemental Accusation CFD 27.)

h. Failing to have unaltered master formulae for compounded drugs; identify the pharmacist reviewing the final product; document the quantity of each component used in compounding the product; document the manufacturer and lot number of each component used; document the expiration date of the final product; and document the amount compounded.⁶ (Bus. & Prof. Code, § 4301, subd. (o); Regulation §§ 1735.2, subd. (d), 1735.3, subd.(a).) (Supplemental Accusation CFDs 22 and 23.)

i. Having three pharmacy technicians working when only one pharmacist was on duty, exceeding the allowed pharmacist-to-technician ratio. (Factual Finding 16.) (Bus. & Prof. Code, §§ 4301, subd. (o), 4115, subd. (f)(1).) (Supplemental Accusation CFD 28.)

j. Failing to require pharmacy technicians to wear identification badges. (Factual Finding 16.) (Bus. & Prof. Code, §§ 4301, subd. (o); Regulation § 1793.7, subd. (c).) (Supplemental Accusation CFD 21.)

8. Complainant did not establish unprofessional conduct based on the inadequacy of the Pharmacy's policies and procedures for employee theft and/or impairment on August 21, 2013. ((Bus. & Prof. Code, §§ 4301, subd. (o); 4104, subs. (a) and (b).) The evidence presented did not include the actual text of the Pharmacy's theft and/or impairment policies and procedures – at least not in a legible form. (Factual Finding 17.) All that was presented was inspector Sakamura's opinion that the policies and procedures were deficient. (*Id.*) Without the actual text of the policies and procedures, it was not possible to determine the validity of inspector Sakamura's opinion. Consequently, Supplemental Accusation CFD 18 was not substantiated.

9. Respondents conceded that discipline was warranted. There are a large number of violations, and some of them are of an extremely serious and of a particularly persistent nature. The Board's disciplinary guidelines (Guidelines) categorize violations by degree of seriousness,

⁶ The Supplemental Accusation (pars. 65(a)(5)) alleges that it was also a violation for the Pharmacy not to document the equipment used in compounding, but the cited Regulations set forth no such requirement. Rather, Regulation section 1735.2, subdivision (d), requires that a master formula specify the equipment *to be used*.

with Category I encompassing relatively minor violations (Guidelines at pp 6 and 68); Category II encompassing “violations with a serious potential for harm” or “involv[ing] greater disregard for pharmacy law and public safety” (Guidelines at pp. 11 and 73); and Category III encompassing knowing or willful violations “pertaining to dispensing or distributing dangerous drugs or controlled substances[.]” as well as “drug shortages[.]” (Guidelines at pp. 15 and 77.)

10. The violations established in this case fall under all three categories (Guidelines at pp. 6-15 and 68-79), except that the compounding documentation violations and the violation of Regulations 1711 (setting forth the requirement of a quality assurance policy) are not classified under any category. Under the Guidelines, for violations not identified under a particularly category, “the appropriate penalty ... may be best derived by comparison to any analogous violation(s) that are included.” (Guidelines at p. 5.) The violations of compounding documentation regulations and of Regulations 1711 fit under Category II, because they concern documenting pharmacy practices and attempting to prevent and facilitate correction of errors. As such, these violations involve “a serious potential for harm” because they could result in injury to a patient, and “involve greater disregard for pharmacy law and public safety” than violations of merely administrative requirements. (Guidelines at pp. 11 and 73.) Here, the failure to supervise compounding and knowingly permitting technicians to practice unsupervised by a pharmacist, however, fits best under Category III because unlicensed persons were knowingly allowed to perform the duties of a pharmacist. (See Bus. & Prof. Code §§ 4328, 4330, & 4331; Guidelines, p. 16 & 75.)

11. Under the Guidelines, the existence of multiple violations means that “the appropriate penalty shall increase[.]” (Guidelines at p. 5.) Moreover, where violations have occurred “in more than one category, the minimum and maximum penalties shall be those recommended in the highest category.” (*Id.*) In this case, since some of Respondents’ violations are within Category III (Legal Conclusion 7), the discipline to be accorded must be evaluated as set forth under Category III.

12. For Category III violations, the maximum discipline is outright revocation, and the minimum discipline is revocation, stayed, with 90 days actual suspension, and three to five years’ probation, with standard terms and conditions and option terms and conditions “as appropriate.” (Guidelines at pp. 15, 44, and 77.) The Guidelines recommend “[a] minimum five-year probation period ... where self-administration or diversion of controlled substances is involved.” (Guidelines at pp. 5, 43, and 67.) And for pharmacy technicians, the Guidelines provide that “revocation is typically the appropriate penalty when grounds for discipline are found to exist.” (Guidelines at p. 43.)

13. Deviation from the Guidelines’ recommended discipline is appropriate where “the facts of the particular case warrant[.]” (Regulation § 1760.) In this case, deviation from the Guidelines is not appropriate for the reasons that follow.

14. Respondents’ violations of laws and regulations governing drug and pharmacy security, and compounding, had the potential to seriously harm both Pharmacy customers and the public at large. (Factual Findings 5, 7-10, 14, and 15.) (Guidelines at p. 3, (1) and (2).) Likewise, the Pharmacy’s and PIC Park’s incorrect filling of the Percocet prescription (Factual

Finding 12) had the potential to harm the person for whom the medication was prescribed. (Guidelines at p. 3, (2).) In addition, Respondents' violations were numerous (Factual Findings 5-17) and several persisted over the course of inspections more than two years apart. The misconduct is significantly aggravated by the fact that Board inspectors provided counseling, warnings, and follow-up over a lengthy period of time. (*Id.*) (Guidelines at p.3, (4) and (5).) Despite Respondents' representations that they will follow compounding practices and procedures in the future, Respondents failed to demonstrate that they were following their own corrective actions, as demonstrated by its presentation of a manual with pre-purchased forms reflecting the blanks indicating it had not been used. (Factual Finding 20-21.) Respondents' statements, even if sincerely expressed, that they regret the prior misconduct and plan to correct in the future, it is contradicted by failures to demonstrate such remorse by their actions.

15. In addition, some of the violations were so serious and reflected flagrant disregard of laws and regulations known to Respondents, and warrant serious consequences even without counseling or warnings. These violations included the Pharmacy's failure to keep track of its controlled substances – both by physically losing over 2,500 hydrocodone/acetaminophen 10/325 tablets (Factual Findings 8 – 10) and by failing to conduct required biennial inventories (Factual Finding 5); Technician Park's possession and use of the leftover testosterone cream he had prepared for a patient (Factual Finding 7); and PIC Park's failure to properly supervise technicians working for her (Factual Findings 5, 6, 14-16). (Guidelines at p. 3, (6).) Indeed, Technician Park's possession and use of the testosterone cream can only be viewed as an intentional violation, and his characterization of his conduct as a type of quality assurance is so unreasonable, it reaches the absurd. (Factual Finding 7.) (Guideline at p. 3, (14).) Technician Park's reasons for taking the medication, even if sincere, do not mitigate the consequence of his knowing and risky misconduct. Furthermore, to the extent Respondents' practices at the Pharmacy were driven by the press of business (Factual Findings 5 and 23), it stands to reason that Respondents engage in them for economic reasons: i.e., for a perceived or actual financial benefit. (Guidelines at p. 3, (15).)

16. Respondents presented some evidence that, despite their numerous and repeated violations, they have tried to improve their practices and bring themselves into compliance. (Factual Findings 5, 11, 13, 17, and 19 – 22.) (Guidelines at p. 3, (8) and (9).) The violations occurred between one-and-a-half and three-and-a-half years ago (Factual Findings 5 – 17) (Guidelines at p. 3, (13), and some limited progress has been made. (Factual Findings 5 – 22.)

a. PIC Park apologized for the Pharmacy's violations (Factual Finding 23), but she did so in the context of facing discipline against her license. In addition, as noted above, Respondents expressed a willingness to come into compliance in the past, but their conduct demonstrates a failure to execute on their willingness. (Factual Findings 5, 13, 15, and 17-22; Legal Conclusions 4, 6, and 7.)

b. Technician Park readily admitted his wrong doing with regard to the testosterone (Factual Finding 7), but his candor is considered in context: he was seen with the syringe by the inspector. In addition, as noted above, although he admitted wrong doing and expressed an apology, he defended and attempted to minimize his misconduct by suggesting that his actions were a form of quality control. His failure to take complete responsibility for his

actions reflects that he understands neither the significance of his misconduct nor carries genuine remorse for his conduct. (See *Seide v. Committee of Bar Examiners* (1989) 49 Cal.3d 933, 940; *Pacheco v. State Bar* (1987) 43 Cal.3d 1041, 1058 (acknowledging and accepting responsibility for wrongdoing are critical to rehabilitation).)

17. a. The foregoing combination of aggravating and mitigating circumstances (Guidelines at p. 3, (7) and (8)) shows that probation is not appropriate for Technician Park. Outright revocation of Technician Park's registration is necessary to protect the public. (Bus. & Prof. Code, §§ 4001.1, 4313.) There are no terms of probation the Board can impose sufficient to protect the public.

b. Technician Park, a former pharmacist (in South Korea) (Factual Finding 14), possesses knowledge and training exceeding that of the usual pharmacy technician. (See Guidelines at p. 43 ("Pharmacy technicians are issued a license based on minimal education, training requirements or certification.") Technician Park's conduct cannot be excused by any special knowledge he possesses; in fact, it is worse because he should have known better. He is not a licensed pharmacist in California, but even if he had been, his deliberate conduct in taking medication not prescribed for him was unacceptable.

18. Probation "[t]erms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation." (Guidelines at pp. 5 and 43.) In this case, the standard terms of probation will be imposed against Respondents PIC Park and the Pharmacy and optional terms will be included as appropriate.

19. A suspension will be ordered against Respondents PIC Park and the Pharmacy. It will allow a break from the usual press of business for respondents to reflect on, and rectify where possible, as well as to convey the significance of the misconduct.

20. An optional term of probation prohibiting ownership of licensed premises will be imposed against PIC Park only as to the acquisition of new interests in licensed premises.

21. PIC Park will be allowed to serve as the pharmacist-in-charge, but only at her own, existing pharmacy. PIC Park's need for remediation and oversight in her role as pharmacist-in-charge and supervisor of pharmacy technicians will also be met through the optional term of probation requiring her and the Pharmacy to employ an independent consultant.

22. In addition, PIC Park will be required to obtain remedial education in pharmacy inventory control, pharmacy management, and pharmacy documentation requirements, in order to help her achieve improvement in these areas, which have been persistently substandard. (Factual Findings 5 – 17.) Likewise, since self-assessment and inventory control were areas in which violations occurred (*id.*), PIC Park's probation will include an optional term requiring self-assessment, and PIC Park's and the Pharmacy's probation terms will include maintenance of a separate file for information regarding the acquisition and disposition of controlled substances, and periodic provision of inventory information to the Board.

23. Complainant established entitlement to reasonable costs of investigation and enforcement in this case, in the amount of \$16,823.70. (Factual Finding 24.) (Bus. & Prof. Code § 125.3, subd. (a).)

ORDER

Pharmacist license number RPH 48602, issued to Respondent Eunhye Park, is revoked. The revocation, however, is stayed and Respondent is placed on probation for five years upon terms and conditions 1 through 21 below.

Pharmacy permit number PHY 46371, issued to Respondent Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop (Respondent Riverside Pharmacy), is revoked. The revocation, however, is stayed and Respondent is placed on probation for five years upon terms and conditions 1 through 9 and 22 through 30 below.

Pharmacy Technician registration number TCH 32183, issued to Taeryong Park, is revoked. Respondent Taeryong Park shall be jointly and severally liable with the other respondents to pay the Board its costs of investigation and prosecution in the amount of \$16,823.70.

Terms of Probation Applicable to Both Respondent Eunhye Park and Respondent Riverside Pharmacy

1. Obey All Laws

Respondents shall obey all state and federal laws and regulations. Respondents shall report any of the following occurrences to the Board, in writing, within 72 hours of such occurrence:

- a. An arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- b. A plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- c. A conviction of any crime; and
- d. Discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Each Respondent shall report to the Board quarterly, on a schedule as directed by the Board or its designee. Each respondent's report shall be made either in person or in writing, as directed. Among other requirements, Respondents shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, each Respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Each Respondent shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondents' compliance with the terms and conditions of probation. Failure to cooperate shall be considered a violation of probation.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondents Eunhye Park and Respondent Riverside Pharmacy shall pay to the Board its costs of investigation and prosecution in the amount of \$16,823.70. Respondents shall be jointly and severally liable to pay this amount, and shall make said payments according to a plan to be approved by the Board or its designee. There shall be no deviation from the payment schedule without prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

6. Probation Monitoring Costs

Respondents shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Respondents shall be jointly and severally liable to pay this amount. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. Status of License

Each Respondent shall, at all times while on probation, maintain an active, current license (including registration or permit) with the Board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation. If a Respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication, that Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. Violation of Probation

If a Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over that Respondent, and probation shall automatically be extended as to that Respondent, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If a Respondent violates probation in any respect, the Board, after giving that Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against a Respondent during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

9. Completion of Probation

Upon written notice by the Board or its designee indicating successful completion of a Respondent's probation, that Respondent's license will be fully restored.

Additional Terms of Probation Applicable to Respondent Eunhye Park

10. Suspension

As part of probation, Respondent Eunhye Park is suspended from practice as a pharmacist for 90 days beginning on the effective date of this decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or any other distributor of drugs that is licensed by the board, or any manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances. During this suspension, respondent shall not engage in any activity that requires the professional judgment of and/or licensure as a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacturing, distributing, wholesaling, or retailing of dangerous drugs and/or dangerous devices or controlled substances. Failure to comply with this suspension shall be considered a violation of probation.

During the period of suspension, respondent shall not leave California for any period exceeding ten (10) days, regardless of purpose (including vacation). Any such absence in excess of ten (10) days during the period of suspension shall be considered a violation of probation, and shall toll the suspension, i.e., the suspension shall be extended by one day for

each day over ten (10) days respondent is absent from California. During any such period of tolling of suspension, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is notified otherwise in writing by the board or its designee. Respondent shall notify the board or its designee in writing within ten (10) days of any departure from California, for any period, and shall further notify the board or its designee in writing within ten (10) days of return. Failure to timely provide such notification(s) shall be considered a violation of probation. Upon such departure and return, respondent shall not resume practice until notified by the board or its designee that the period of suspension has been satisfactorily completed.

11. Consultant for Owner or Pharmacist in Charge

During the period of probation, Respondent Eunhye Park shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the board.

Respondent may be a pharmacist-in-charge, however, during any such period, Respondent shall retain an independent consultant at her own expense who shall be responsible for reviewing pharmacy operations on a quarterly basis for compliance by Respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by Respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the Board, whose name shall be submitted to the Board or its designee, for prior approval, within 30 days of the effective date of this decision. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy other than Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop.

12. Remedial Education

Within ninety (90) days of the effective date of this decision, Respondent Eunhye Park shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to pharmacy inventory control, pharmacy management, including supervision, and pharmacy documentation requirements. The program of remedial education shall consist of at least 10 hours, which shall be completed within one year at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes for pharmacists.

Failure to timely submit for approval or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee. Following the completion of each course, the board or its designee may require the respondent, at her own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation.

Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

13. No New Ownership of Licensed Premises

Respondent Eunhye Park shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

14. Separate File of Controlled Substance Records

Respondent Eunhye Park shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

15. Report of Controlled Substances

Respondent Eunhye Park shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board or its designee may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board or its designee. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the reporting period as determined by the board or its designee. Failure to timely prepare or submit such reports shall be considered a violation of probation.

16. Continuing Education

Respondent Eunhye Park shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

17. Notice to Employers

During the period of probation, Respondent Eunhye Park shall notify all present and prospective employers, other than Riverside Park Pharmacy, Inc., of the decision in this case and the terms, conditions and restrictions imposed on Respondent by this decision, as follows:

- a. Within 15 days of Respondent undertaking any new employment, Respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4774, and terms and conditions imposed thereby.

It shall be Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

- b. If Respondent works for or is employed by or through a pharmacy employment service, Respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in case number 4774 before commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.
- c. Within 15 days of Respondent undertaking any new employment by or through a pharmacy employment service, Respondent shall cause his direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 4774 and the terms and conditions imposed thereby.

It shall be Respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board. Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the Board shall be considered a violation of probation. "Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether Respondent is an employee, independent contractor or volunteer.

18. No Supervision of Interns or Serving as a Consultant

During the period of probation, Respondent Eunhye Park shall not supervise any intern pharmacist or serve as a consultant, unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

19. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent Eunhye Park shall notify the Board in writing within 10 days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the Board in writing within 10 days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the Board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

20. Tolling of Probation

Except during periods of suspension, Respondent Eunhye Park shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, Respondent must nonetheless comply with all terms and conditions of probation.

Should Respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, Respondent must notify the Board in writing within 10 days of the cessation of practice, and must further notify the Board in writing within 10 days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding 36 months.

"Cessation of practice" means any calendar month during which Respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 *et seq.* "Resumption of practice" means any calendar month during which Respondent is practicing as a pharmacist for at least 80 hours as a pharmacist as defined by Business and Professions Code section 4000 *et seq.*

21. License Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent Eunhye Park cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his or her license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his or her pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

Additional Terms and Conditions of Probation Applicable to Respondent Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop

22. Suspension

Pharmacy permit number PHY 46371, issued to Respondent Riverside Park Pharmacy, Inc., to operate Riverside Pharmacy & Compounding Shop (Respondent Riverside Pharmacy), is suspended for a period of 90 days, beginning on the effective date of this decision. During the period of suspension, Respondent shall cease all pharmacy operations. Failure to comply with this suspension shall be considered a violation of probation.

23. Posted Notice of Suspension

Respondent Riverside Pharmacy shall prominently post a suspension notice provided by the Board in a place conspicuous and readable to the public. The suspension notice shall remain

posted during the entire period of suspension ordered by this decision. Respondent shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the closure of the licensed entity.

24. Notice to Employees

Respondent Riverside Pharmacy shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation. "Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

25. Owners and Officers: Knowledge of the Law

Respondent Riverside Pharmacy shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

26. Separate File of Controlled Substance Records

Respondent Riverside Pharmacy shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

27. Report of Controlled Substances

Respondent Riverside Pharmacy shall submit quarterly reports to the board detailing the total acquisition and disposition of such controlled substances as the board may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) or acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the board. The report shall be delivered or mailed to the board no later than ten (10) days following the end of the

reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

28. Consultant for Owner or Pharmacist in Charge

In the event Respondent Eunhye Park ceases to act as pharmacist-in-charge, Respondent Riverside Pharmacy shall independently retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a quarterly basis for compliance by Respondent with state and federal laws and regulations governing the practice of pharmacy. The consultant shall be a pharmacist licensed by and not on probation with the Board, whose name shall be submitted to the Board or its designee, for prior approval, within 30 days of the effective date of this decision. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

29. Posted Notice of Probation

Respondent Riverside Pharmacy shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation. Respondent shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity. Failure to post such notice shall be considered a violation of probation.

30. Surrender License Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent Riverside Pharmacy discontinue business, respondent may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer. Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent owner must further stipulate that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

This Decision shall become effective on March 17, 2016.

It is so ORDERED on February 16, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

**BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the Accusation Against:

**RIVERSIDE PHARMACY &
COMPOUNDING SHOP; EUNHYE PARK**
Pharmacy Permit No. PHY 46371,

EUNHYE PARK
Pharmacist License No. RPH 48602,

TAERYONG PARK
Pharmacy Technician Registration No. TCH 32183,

and

REBECCA M. SCHNERINGER
Pharmacy Technician Registration No. TCH 96891

Respondents.

Case No. 4774

OAH No. 2014010558

**ORDER GRANTING
PETITION FOR
RECONSIDERATION AND STAY
OF EXECUTION OF THE
EFFECTIVE DATE OF DECISION
AND ORDER AS TO RIVERSIDE
PHARMACY & COMPOUNDING
SHOP, EUNHYE PARK, and
TAERYONG PARK ONLY**

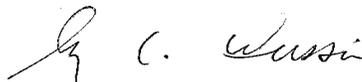
Complainant having requested reconsideration of the decision in the above-entitled matter, and good cause appearing, IT IS HEREBY ORDERED:

- (1) That reconsideration be, and is, hereby granted, said reconsideration to be solely on the issue whether to require an actual 90 day suspension for Respondent Riverside Pharmacy and Compounding Shop; 90 day suspension for Respondent PIC Eunhye park; and either revoke or impose more stringent discipline against Taeryong Park's pharmacy technician registration.
- (2) That the parties will be notified of the date for submission of any written argument they may wish to submit when the transcript of the above-mentioned hearing becomes available; and;
- (3) The Decision of the Board in this matter issued on March 11, 2015, is hereby stayed until the Board renders its decision on reconsideration.

The board itself will decide the case upon the record, including the exhibits and written argument of the parties, without taking additional evidence.

IT IS SO ORDERED this 8th day of April, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

STANLEY C. WEISSER, Board President

**BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the Accusation Against:

RIVERSIDE PHARMACY &
COMPOUNDING SHOP; EUNHYE PARK
Pharmacy Permit No. PHY 46371,

EUNHYE PARK
Pharmacist License No. RPH 48602,

REBECCA M. SCHNERINGER
Pharmacy Technician Registration No. TCH
96891,

and

TAERYONG PARK
Pharmacy Technician Registration No. TCH 32183

Respondents.

Case No. 4774

OAH No. 2014010558

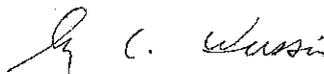
DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on April 10, 2015.

It is so ORDERED on March 11, 2015.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

STAN C. WEISSER, Board President

BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:

RIVERSIDE PHARMACY &
COMPOUNDING SHOP; EUNHYE PARK
Pharmacy Permit No. PHY 46371,

EUNHYE PARK
Pharmacist License No. RPH 48602,

REBECCA M. SCHNERINGER
Pharmacy Technician Registration No. TCH
96891,

and

TAERYONG PARK
Pharmacy Technician Registration No. TCH
32183

Respondents.

Case No. 4774

OAH No. 2014010558

PROPOSED DECISION

Administrative Law Judge Angela Villegas, State of California, Office of Administrative Hearings, heard this matter on February 4 and 5, 2015, in Los Angeles, California.

Sydney M. Mehringer, Deputy Attorney General, represented Complainant.

Respondents Eunhye Park and Taeryong Park were present. Respondents Eunhye Park, Taeryong Park, and Riverside Pharmacy & Compounding Shop were represented by attorney Patric Hooper.¹

¹ Respondent Rebecca M. Schneringer did not file a notice of defense and did not appear at the hearing in this matter. According to the Supplemental Accusation (para. 47, fn. 1), the Board issued a default decision revoking Respondent Schneringer's pharmacy technical registration, effective March 10, 2014.

Evidence was received, and the matter was submitted for decision, on February 5, 2015.

AMENDMENT OF THE SUPPLEMENTAL ACCUSATION

At the hearing, Complainant amended the Supplemental Accusation as follows:

1. At page 9, paragraph 64, line 7, the reference to California Code of Regulations, title 16, section 1793.7, subdivision (c), was deleted and replaced with a reference to California Code of Regulations, title 16, section 1735.2, subdivision (d).
2. At page 11, paragraph 71, line 22, the reference to California Code of Regulations, title 16, section 1711, subdivision (j), was deleted and replaced with a reference to California Code of Regulations, title 16, section 1711, subdivision (d).

SEALING OF PRIVATE MEDICAL INFORMATION

After the hearing, it was discovered that Exhibit 4, pages 132 and 133, consisted of a prescription drug history for Respondent Taeryong Park. Neither this medical information nor Mr. Park's identifying information could be redacted without destroying the evidentiary value of the cited pages. Accordingly, the pages were ordered sealed.

FACTUAL FINDINGS

1. Complainant Virginia Herold, Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board), filed the Accusation and Supplemental Accusation in her official capacity.
2. Respondent Eunhye Park (PIC Park) holds pharmacist license number RPH 48602, issued by the Board on March 12, 1996, and scheduled to expire May 31, 2015, unless renewed. PIC Park's license has no history of discipline.
3. Respondent Taeryong Park (Technician Park) holds pharmacy technician registration number TCH 32183, issued by the Board on January 27, 2000, and scheduled to expire December 31, 2015, unless renewed. Technician Park's registration has no history of discipline.
4. Respondent Riverside Pharmacy & Compounding Shop (the Pharmacy) is the name under which Riverside Park Pharmacy, Inc., does business. The Pharmacy operates under pharmacy permit number PHY 46371, which the Board issued to Riverside Park Pharmacy, Inc. on May 8, 2003, and which is scheduled to expire May 1, 2015, unless renewed. Respondents Taeryong Park and Eunhye Park, who are husband and wife, have

owned the Pharmacy since 2003, and also own Riverside Park Pharmacy, Inc. PIC Park is the Pharmacy's pharmacist-in-charge, and has been since the permit was issued. The Pharmacy's permit has no history of discipline. Approximately 10 percent of the Pharmacy's business is preparing compounded medications.

5. In 2010 and 2011, the Pharmacy employed pharmacy technician Rebecca Schneringer (see fn. 1) on a part-time basis. Schneringer also worked at other pharmacies at that time. The Board investigated Schneringer on suspicion that she had diverted pharmaceuticals from her employers. As part of that investigation, former Board inspector Valerie Knight inspected the Pharmacy on June 7, 2011. The June 7, 2011 inspection revealed the following conditions.

(a) For the years 2005, 2007, and 2011, the only controlled substance inventories that had been performed were for Schedule II controlled substances. No inventories for Schedule III, IV, or V controlled substances had been performed during those years. For the year 2009, no controlled substance inventory had been performed at all. At the hearing, PIC Park explained that her work at the Pharmacy keeps her very busy, and she must prioritize her tasks. She determined that taking inventory was a relatively low-priority task, and consequently overlooked it, except for the Schedule II inventories in 2005, 2007, and 2011.

(b) One prescription label failed to include a physical description of the medication being dispensed. Instead, the physical description appeared in the patient monograph. At the hearing, PIC Park explained that occasionally, the Pharmacy's computer software produces an anomalous label that fails to include all of the necessary information, but that she usually catches and corrects the anomaly when she reviews the label before providing the medication to the patient. This time, she acknowledged, she failed to catch the anomaly. Nevertheless, she testified credibly that the Pharmacy's prescription labels normally include complete information.

(c) The Pharmacy's written policies and procedures regarding employee theft and/or impairment were not comprehensive, and did not require notification to the Board within 30 days of such an occurrence (or the discovery thereof). Instead, the policies and procedures were labeled, "Reporting Suspected Fraud, Waste and Abuse" (Exhibit 4), and did not address the issue of employee impairment. Moreover, the policies referenced only Medicare Part D, and not any aspect of California pharmacy law.

(d) Technician Park possessed a key to the Pharmacy, and the key was not kept in a tamper-evident container.

(e) The Pharmacy's permit was, and had been since the Pharmacy's previous inspection in 2003, displayed at the back of the Pharmacy, where it could not be clearly read by members of the public. Despite the 2003 inspector's recommendation that the permit be moved to a more prominent location, it had not been moved.

(f) The Pharmacy had only a brief written job description for pharmacy technicians, and lacked documentation of comprehensive policies and procedures governing pharmacy technicians.

(g) For each drug compounded, the Pharmacy did not have a master formula; did not identify the pharmacist reviewing the final product; did not document the quantity of each component used in compounding the product; did not document the manufacturer and lot number of each component used; did not document the equipment used; did not document the expiration date of the final product; and did not document the amount compounded.

6. The notice of violation inspector Knight provided to Respondents (Exhibit 4) did not note compounding violations, and inspector Knight's inspection report (Exhibit 7) did not expressly cite regulations governing compounding. Nevertheless, the inspection report did note, "Pharmacy compounds topical and oral caps / solutions for dispensing to patients. Inaccurate records kept, RPH not verify and document technician compounding. . . . Pharmacy records of compounded items does [*sic*] not include any information of manufacturer used, expiration date, lot #, etc. . . . PIC Park does not indicate verification of the compounding record that she checked the finished product[.]" (*Id.*)

7. During inspector Knight's visit, she saw Technician Park place a topical syringe into a satchel, and asked him about it. He admitted the syringe contained a compounded preparation of testosterone with lipoderm cream. Technician Park explained to inspector Knight (and testified at the hearing) that he had prepared the cream for a patient, and had some left over. He became curious as to the effects of the testosterone and wanted to try it on himself, which he did for two or three days, until inspector Knight discovered the syringe. If Technician Park liked the effects, his plan was to ask his own doctor for a prescription for the same testosterone preparation. This explanation was credible and forthright, and Technician Part accepted responsibility for his conduct without hesitation. Technician Park also claimed he was testing the preparation for quality, but self-testing of compounded products was an unreasonable quality control method.

8. Inspector Knight also conducted a zero-based audit² of four controlled substances, including hydrocodone/acetaminophen 10/325 tablets (meaning each tablet contained 10 mg of hydrocodone and 325 mg of acetaminophen), which Schneringer was suspected of diverting. Inspector Knight's audit showed a deficit of 2,578 hydrocodone/acetaminophen 10/325 tablets over the period from June 8, 2010 to June 7, 2011. (Exhibit 4.) On July 31, 2012, inspector Knight notified PIC Park of the audit's findings, and instructed her to report the loss to the Board and the federal Drug Enforcement Administration, which PIC Park did on approximately August 2, 2012. (Exhibit 4.)

² According to Inspector Knight's investigation report (Exhibit 4), a zero-based audit assumes a starting quantity of zero of the item being counted.

9. PIC Park was “shocked” (testimony of Eunhye Park) at the large number of missing hydrocodone/acetaminophen 10/325 tablets, and did not believe Schneringer could have stolen so many, because the Pharmacy employed security measures, including two cameras and a policy of always having at least two people on duty. Accordingly, in 2013, PIC Park performed her own count of hydrocodone/acetaminophen tablets from the period from June 18, 2010 to June 7, 2011. (Exhibit C.) PIC Park’s count compared the number of tablets dispensed during the relevant period with the number of tablets purchased during that period, and showed that the Pharmacy had dispensed approximately 3,000 more such tablets than it had purchased during the relevant period, such that there was no shortage.

10. The result of inspector Knight’s audit, showing a shortage, was more reliable than that of PIC Park’s count, showing a surplus. Even setting aside the 10-day discrepancy in the periods covered by the two reviews, PIC Park’s count, unlike inspector Knight’s audit, was not limited to hydrocodone/acetaminophen 10/325 tablets, and did not account for stock on hand. (Exhibit C; testimony of Eunhye Park.) Moreover, inspector Knight’s audit showed stock on hand of 401 hydrocodone/acetaminophen 10/325 tablets, making it very unlikely that the Pharmacy could have dispensed nearly 3,000 more such tablets than it acquired over the period of a year.

11. After inspector Knight’s visit, PIC Park performed inventories of Schedule III, IV, and V controlled substances, provided revised written policies regarding employee theft and/or impairment, and moved the Pharmacy’s permit to a location where it could be read by members of the public.

12. On August 21, 2013, investigating a complaint from a Pharmacy patient, Board inspector Valerie Sakamura inspected the Pharmacy again. On January 22, 2013, the Pharmacy had incorrectly filled the patient’s prescription. The prescription was for 60 Percocet tablets: specifically, oxycodone/acetaminophen 7.5/325 (meaning 7.5 mg oxycodone and 325 mg acetaminophen), but the Pharmacy instead dispensed 60 tablets of oxycodone/acetaminophen 7.5/500 (meaning each tablet contained 175 mg more acetaminophen than had been prescribed). PIC Park caught the error on the same day it was made, but the medication had already been delivered to the patient. PIC Park telephoned the patient, but the patient did not answer the phone, and PIC Park left a message. The following day, the patient returned the call and was provided with the correct medication.

13. PIC Park did not document the January 22, 2013 error. She did not have, and could not produce to inspector Sakamura, a written quality assurance policy to document, investigate, and prevent errors. PIC Park explained to inspector Sakamura that, instead, she would simply discuss any errors that occurred, because “the patients are like family[.]” (Exhibit 5.) After inspector Sakamura’s visit, PIC Park provided a written quality assurance plan setting forth a procedure to deal with errors, which required, among other things, documentation of the error. (Exhibit 13.)

///
///

14. While conducting the inspection on August 21, 2013, inspector Sakamura observed a closed door leading to the Pharmacy's compounding room. When inspector Sakamura entered the compounding room, she saw Technician Park and another pharmacy technician, Alvina Sumbatyan, compounding medications. Since the door to the compounding room had been closed, PIC Park could not have directly seen the technicians while they compounded medications. PIC Park acknowledged, both to inspector Sakamura and at the hearing, that at that time, she often trusted Technician Park to oversee the compounding himself, because he had been educated as a pharmacist, and had worked as a pharmacist in South Korea, before the couple relocated to the United States, and was well-trained in compounding techniques.³ Technician Park confirmed that he trained and oversaw technician Sumbatyan in compounding.

15. The Pharmacy's documentation of its compounding, and the Pharmacy's compounding practices as observed by inspector Sakamura, did not include pharmacist review of every final compounded product, and did not include documentation of the quantity of each component used in producing a final product, the manufacturer and lot number of each component, the equipment used, the expiration date of the final product or its components, or the final amount produced. In addition, although master formulae existed for many compounded products, those formulae had handwritten alterations that varied from the original formulae. The Pharmacy did not provide inspector Sakamura with written policies and procedures for its compounding functions, did not produce documentation that compounding staff (other than Technician Park) had received training in compounding, did not produce a written quality assurance plan for compounded items, and did not produce a compounding self-assessment.

16. On duty at the time of inspector Sakamura's visit were not only Technician Park and technician Sumbatyan, but also a third pharmacy technician, Kathryn Brenny, who was filling prescriptions and transferring medications into bottles. Meanwhile, the only pharmacist on duty at that time was PIC Park. At the hearing, PIC Park testified she had believed, at the time, that technician Brenny was actually a student, rather than a pharmacy technician, but PIC Park acknowledged that Brenny had already graduated from pharmacy technician school. None of the pharmacy technicians was wearing an identification badge.

17. Inspector Sakamura reviewed the Pharmacy's written policies and procedures concerning employee theft and/or impairment, and felt they were inadequate, because they did not explain what the Pharmacy would do if employee theft or impairment occurred (Exhibits 5 and 9; testimony of Valerie Sakamura), and instead merely parroted statutory and/or regulatory language. The evidence did not disclose the content of the Pharmacy's theft and/or impairment policies and procedures at the time of inspector Sakamura's visit. Exhibit 8 contained a photograph of those policies and procedures, but the text was not legible.

³ Technician Park tried to become licensed as a pharmacist in California, but was unable to pass one of the tests, which required a written essay.

18. After inspector Sakamura's visit, PIC Park provided her with a revised theft and/or impairment policy, specifying, among other things, that the Pharmacy would report instances of theft and/or impairment to the Board within 14 days; immediately remove any impaired employee from service; and investigate, discipline and/or terminate any employee discovered to have engaged in theft. (Exhibit 13.)

19. To address inspector Sakamura's concerns with regard to compounding practices and documentation, the Pharmacy procured "PK" software, produced by Professional Compounding Centers of America (PCCA), to help document and track compounded medications. Inspector Sakamura's testimony acknowledged that the PK software, if properly used, could correct the recordkeeping issues she observed.

20. At the hearing, Respondents also produced a PCCA Standard Operating Procedures (SOP) manual (Exhibit E), setting forth comprehensive policies and procedures for compounding, which Respondents claimed they followed at the Pharmacy. Although Respondents had the PCCA SOP manual at the time of inspector Sakamura's inspection, they did not think to show it to her during or after her visit.

21. The PCCA SOP manual contains blanks for the pharmacist to note when each policy was reviewed and implemented; none of those blanks were filled in. Moreover, approximately half of the SOPs set forth in the PCCA SOP manual contain blank charts or other forms for use in documenting various compounding procedures, quality control, patient surveys, and the like. No documentation was produced at the hearing showing that the Pharmacy actually used any of those forms in carrying out its compounding functions. Hence, Respondents' contention that they followed the PCCA SOP manual was dubious. Moreover, at the time of inspector Sakamura's visit, Respondents undisputedly documented their compounding simply by affixing a sticker containing patients' prescription information to the paper setting forth the compounding formula. That practice would not comport with any of the PCCA SOPs set forth in the manual. Accordingly, the evidence did not show that Respondents followed the procedures set forth in the PCCA SOP manual at the time of inspector Sakamura's visit.

22. After inspector Sakamura's visit, the Pharmacy did begin preparing detailed compounding worksheets for each compounded product, but one such worksheet (Exhibit 16) reflected that Respondents did not note the exact quantity of each component used, as opposed to the quantity called for by the formula. In addition, the worksheet set forth an erroneous expiration date for the final product, which was later than the expiration date of one of the components.

23. PIC Park apologized for the Pharmacy's shortcomings and her own failure to achieve full compliance with pharmacy laws and regulations. Both PIC Park and Technician Park work full-time, or more than full-time, in the Pharmacy. In addition to Technician Park's technician duties, he also oversees and performs the Pharmacy's maintenance and

cleaning, its non-pharmacy business and paperwork, and even delivers medications when other delivery personnel are not available. Indeed, Technician Park's non-technician duties absorb more of his time than do his technician duties.

24. The Board's reasonable costs of investigation and enforcement in this matter total \$16,823.70. This is \$3,585.30 less than the \$20,409 sought by Complainant.

(a) The amounts set forth in Complainant's certifications of costs (Exhibit 3) are reasonable as to the hours spent, and hourly rates charged by, inspector Sakamura, supervisor Joan Coyne, Deputy Attorney General Sydney M. Mehringer, and other professionals and paraprofessionals in the Attorney General's office. The large number of violations identified, the repeated and technical nature of some of them, the follow-up involved, and the detailed nature of the pleadings and proof in this matter made it necessary for substantial time to be spent in the investigation and prosecution of this case.

(b) For the same reasons, inspector Knight's hourly rate was reasonable, as was the number of hours inspector Knight spent on travel and investigation, which were limited to the hours Knight spent in connection with her inspection and investigation of Respondents.

(c) The 92.5 hours inspector Knight spent on report preparation, however, must be discounted to reflect the fact that inspector Knight's investigation report (Exhibit 4) deals not only with Respondents, but also with seven other persons and entities that were part of the investigation into Schneringer's activities. Approximately 62 percent of inspector Knight's investigation report is devoted to Respondents; approximately 38 percent of the report addresses other persons and entities. Accordingly, the 92.5 hours claimed for report preparation will be discounted by 38 percent (35.15 hours), so that 57.35 hours will be allowed as Complainant's reasonable cost of report preparation by inspector Knight. At inspector Knight's hourly rate of \$102, the amount allowed for the preparation of her report is \$5,849.70.

(d) In sum, the costs allowed are \$1,734 for inspector Sakamura; \$9,011.70 for inspector Knight; \$153 for supervisor Coyne; and \$5,925 for the Deputy Attorney General. These amounts total \$16,823.70.

LEGAL CONCLUSIONS

1. Complainant established cause to discipline PIC Park's license, Technician Park's registration, and the Pharmacy's permit, on grounds that PIC Park, Technician Park, and the Pharmacy engaged in unprofessional conduct.⁴ The Pharmacy is responsible for the

⁴ Although the Accusation and Supplemental Accusation set forth numerous, separately-pled causes for discipline, each of them is grounded in unprofessional conduct pursuant to Business and Professions Code section 4301.

unprofessional conduct of PIC Park, who in turn is responsible for the Pharmacy's and its staff's adherence to applicable laws and regulations. (Bus. & Prof. Code, §§ 4036.5; 4113.)

2. Technician Park engaged in unprofessional conduct as alleged in Accusation Causes for Discipline (CFDs) 15 through 17, by possessing and furnishing to himself a controlled substance not prescribed for him: namely, the testosterone with lipoderm cream. (Factual Finding 7.) (Bus. & Prof. Code, §§ 4301, subd. (o); 4059; and 4060; Health & Saf. Code, §§ 11056, subd. (f)(30); 11170; 11350, subd. (a).) Technician Park's conduct violated the cited laws and regulations. (Bus. & Prof. Code, § 4301, subd. (j).)

3. As of June 7, 2011, PIC Park, and by extension the Pharmacy, had engaged in unprofessional conduct in the following ways.

(a) Failing to conduct timely biennial inventories of Schedule III, IV, and V controlled substances during 2005, 2007, and 2011, and failing to conduct any controlled substance inventory at all in 2009. (Factual Finding 5.) (Bus. & Prof. Code, §§ 4301, subds. (j) and (o); 4081, subd. (b); 21 C.F.R. § 1304.11(c); Cal. Code Regs., tit. 16 (Regulation), § 1718.) (Cf. Accusation CFDs 6 and 14.)

(b) Failing to include on a patient label the physical description of the medication being dispensed. (Factual Finding 5.) (Bus. & Prof. Code, §§ 4301, subd. (o); 4076, subd. (a)(11)(A).) (Cf. Accusation CFD 7.)

(c) Failing to have sufficient written policies and procedures regarding employee theft and/or impairment. (Factual Finding 5.) (Bus. & Prof. Code, §§ 4301, subd. (o); 4104, subds. (a) and (b).) (Cf. Accusation CFD 8.)

(d) Allowing Technician Park to possess a key to the Pharmacy, not in a tamper-evident container. (Factual Finding 5.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1714, subds. (d) and (e).) (Cf. Accusation CFD 9.)

(e) Posting the Pharmacy's permit near the back of the Pharmacy, where it could not be clearly read by members of the public. (Factual Finding 5.) (Bus. & Prof. Code, §§ 4301, subd. (o); 4058.) (Cf. Accusation CFD10.)

(f) Failing to have comprehensive written job descriptions and policies and procedures governing pharmacy technicians. (Factual Finding 5.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1793.7, subd. (d).) (Cf. Accusation CFD 11.)

(g) Failing to have master formulae for compounded drugs; failing to identify the pharmacist reviewing the final product; failing to document the quantity of each component used in compounding the product; failing to document the manufacturer and lot number of each component used; failing to document the expiration date of the final product;

and failing to document the amount compounded.⁵ (Factual Finding 5.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1735.3, subd. (a).) (Cf. Accusation CFD 12.) Respondents contended that inspector Knight failed put them on notice of violations (Factual Finding 6), but that contention was not persuasive. Whether inspector Knight did or did not provide such notice was irrelevant to the existence of the violation or to Respondents' obligation to comply with the laws and regulations governing compounding.

(h) Failing to secure and account for a controlled substance: namely, 2,578 hydrocodone/acetaminophen 10/325 tablets over the course of the year preceding inspector Knight's visit. (Factual Findings 8 – 10.) (Bus. & Prof. Code, § 4301, subd. (o); Health & Saf. Code, §§ 11055, subd. (b)(1)(I); 11056, subd. (e)(4); Regulation §§ 1714, subd. (b); 1718.) (Cf. Accusation CFDs 5 and 14.)

4. As of August 21, 2013, PIC Park, and by extension the Pharmacy, had engaged in unprofessional conduct in the following ways.

(a) Incorrectly filling a patient's prescription on January 22, 2013. (Factual Finding 12.) (Bus. & Prof. Code, §4301, subd. (o); Regulation § 1716.) (Cf. Supplemental Accusation CFD 30.)

(b) Failing to document the above error, and failing to have a quality assurance policy in place—and available for review—to document, investigate, and prevent errors. (Factual Finding 13.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1711, subds. (c)(1), (d), and (e).) (Cf. Supplemental Accusation CFDs 20 and 29.)

(c) Failing to provide direct pharmacist supervision and oversight of compounding functions carried out by pharmacy technicians. (Factual Findings 14 and 15.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1793.7, subd. (a).) (Cf. Supplemental Accusation CFD 19.)

(d) Failing to provide documentation showing that pharmacy technician Alvina Sumbatyan, who performed compounding tasks, had received training in compounding techniques. (Factual Finding 15.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1735.7.) (Cf. Supplemental Accusation CFD 25.)

(e) Failing to have written policies and procedures governing compounding functions. (Factual Finding 15.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1735.5.) Although the evidence showed that Respondents possessed the PCCA SOP manual produced at the hearing on or before August 21, 2013 (Factual Findings 21 and

⁵ The Accusation (para. 39(a)(5)) alleges that it was also a violation for the Pharmacy not to document the equipment used in compounding, but the cited Regulation cited sets forth no such requirement.

22), the evidence did not establish that the policies and procedures set forth in the PCCA SOP manual had been reviewed or implemented by that date. (Factual Finding 21.) (Cf. Supplemental Accusation CFD 24.)

(f) Failing to have a written quality assurance plan for compounded items. (Factual Finding 15.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1735.8.) (Cf. Supplemental Accusation CFD 26.)

(g) Failing to perform a timely compounding self-assessment. (Factual Finding 15.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1735.2, subd. (j).) (Cf. Supplemental Accusation CFD 27.)

(h) Failing to have unaltered master formulae for compounded drugs; identify the pharmacist reviewing the final product; document the quantity of each component used in compounding the product; document the manufacturer and lot number of each component used; document the expiration date of the final product; and document the amount compounded.⁶ (Factual Finding 15.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation §§ 1735.2, subd. (d), 1735.3, subd. (a).) (Cf. Supplemental Accusation CFDs 22 and 23.)

(i) Having three pharmacy technicians working when only one pharmacist was on duty, exceeding the allowed pharmacist-to-technician ratio. (Factual Finding 16.) (Bus. & Prof. Code, §§ 4301, subd. (o); 4115, subd. (f)(1).) (Cf. Supplemental Accusation CFD 28.)

(j) Failing to require pharmacy technicians to wear identification badges. (Factual Finding 16.) (Bus. & Prof. Code, § 4301, subd. (o); Regulation § 1793.7, subd. (c).) (Cf. Supplemental Accusation CFD 21.)

5. Complainant did not establish unprofessional conduct based on the inadequacy of the Pharmacy's policies and procedures for employee theft and/or impairment on August 21, 2013. (Bus. & Prof. Code, §§ 4301, subd. (o); 4104, subds. (a) and (b).) The evidence presented did not include the actual text of the Pharmacy's theft and/or impairment policies and procedures—at least, not in a legible form. (Factual Finding 17.) All that was presented was inspector Sakamura's opinion that the policies and procedures were deficient. (*Id.*) Without the actual text of the policies and procedures, it was not possible to determine the validity of inspector Sakamura's opinion. Consequently, Supplemental Accusation CFD 18 was not substantiated.

⁶ The Supplemental Accusation (para. 65(a)(5)) alleges that it was also a violation for the Pharmacy not to document the equipment used in compounding, but the cited Regulations set forth no such requirement. Rather, Regulation section 1735.2, subdivision (d), requires that a master formula specify the equipment *to be* used.

6. Respondents' showing was not sufficient to dispense with discipline altogether—indeed, Respondents conceded that discipline was warranted. Despite the large number of violations, and the serious and persistent nature of some of them, the appropriate discipline in this case is probation for all Respondents. The Board's disciplinary guidelines (Guidelines) categorize violations by degree of seriousness, with Category I encompassing relatively minor violations (Guidelines at pp. 6 and 68); Category II encompassing "violations with a serious potential for harm" or "involv[ing] greater disregard for pharmacy law and public safety" (Guidelines at pp. 11 and 73); and Category III encompassing knowing or willful violations "pertaining to dispensing or distributing dangerous drugs or controlled substances[.]" as well as "drug shortages[.]" (Guidelines at pp. 15 and 77.)

7. The violations established in this case fall under all three categories (Guidelines at pp. 6 – 15 and 68 – 79), except that the compounding violations and the violation of Regulation 1711 (setting forth the requirement of a quality assurance policy) are not classified under any category. Under the Guidelines, for violations not identified under a particular category, "the appropriate penalty . . . may be best derived by comparison to any analogous violation(s) that are included." (Guidelines at p. 5.) The violations of compounding regulations and of Regulation 1711 fit best under Category II, because they primarily concern documenting pharmacy practices and attempting to prevent and facilitate correction of errors. As such, these violations involve "a serious potential for harm" because they could result in injury to a patient, and "involve greater disregard for pharmacy law and public safety" than violations of merely administrative requirements. (Guidelines at pp. 11 and 73.)

8. Under the Guidelines, the existence of multiple violations means that "the appropriate penalty shall increase[.]" (Guidelines at p. 5.) Moreover, where violations have occurred "in more than one category, the minimum and maximum penalties shall be those recommended in the highest category." (*Id.*) In this case, since some of Respondents' violations are within Category III (cf. Legal Conclusion 7), the discipline to be accorded must be evaluated as set forth under Category III.

9. For Category III violations, the maximum discipline is outright revocation, and the minimum discipline is revocation, stayed, with 90 days actual suspension, and three to five years' probation, with standard terms and conditions and optional terms and conditions "as appropriate." (Guidelines at pp. 15, 44, and 77.) The Guidelines recommend "[a] minimum five-year probation period . . . where self-administration or diversion of controlled substances is involved." (Guidelines at pp. 5, 43, and 67.) And for pharmacy technicians, the Guidelines provide that "revocation is typically the appropriate penalty when grounds for discipline are found to exist." (Guidelines at p. 43.)

10. Deviation from the Guidelines' recommended discipline is appropriate where "the facts of the particular case warrant[.]" (Regulation § 1760.) In this case, deviation from the Guidelines is appropriate to the extent the Guidelines would call for the outright revocation of Technician Park's registration, for the reasons that follow.

11. Respondents' violations of laws and regulations governing drug and pharmacy security, and compounding, had the potential to harm both Pharmacy customers and the public at large. (Factual Findings 5, 7 – 10, 14, and 15.) (Guidelines at p. 3, (1) and (2).) Likewise, the Pharmacy's and PIC Park's incorrect filling of the Percocet prescription (Factual Finding 12) had the potential to harm the person for whom the medication was prescribed. (Guidelines at p. 3, (2).) In addition, Respondents' violations were numerous (Factual Findings 5 – 17) and several persisted over the course of inspections more than two years apart, despite counseling, warnings, and follow-up. (*Id.*) (Guidelines at p. 3, (4) and (5).)

12. In addition, some of the violations were serious and reflected disregard of laws and regulations known to Respondents, even without counseling or warnings. These violations included the Pharmacy's failure to keep track of its controlled substances—both by physically losing over 2,500 hydrocodone/acetaminophen 10/325 tablets (Factual Findings 8 – 10) and by failing to conduct required biennial inventories (Factual Finding 5)—and Technician Park's possession and use of the leftover testosterone cream he had prepared for a patient (Factual Finding 7). (Guidelines at p. 3, (6).) Indeed, Technician Park's possession and use of the testosterone cream can only be viewed as an intentional violation. (Factual Finding 7.) (Guidelines at p. 3, (14).) Furthermore, to the extent Respondents' practices at the Pharmacy were driven by the press of business (Factual Findings 5 and 23), it stands to reason that Respondents engaged in them for economic reasons: i.e., for a perceived or actual financial benefit. (Guidelines at p. 3, (15).)

13. On the other hand, Respondents presented evidence that, despite their numerous and repeated violations, they have tried to improve their practices and bring themselves into compliance. (Factual Findings 5, 11, 13, 17, and 19 – 22.) (Guidelines at p. 3, (8) and (9).) The violations occurred between one-and-a-half and three-and-a-half years ago (Factual Findings 5 – 17) (Guidelines at p. 3, (13)), and though not all of the violations have been fully corrected, progress has been made. (Factual Findings 5 – 22.) PIC Park apologized for the Pharmacy's violations (Factual Finding 23), and Technician Park readily admitted his wrongdoing with regard to the testosterone (Factual Finding 7). These actions bespeak an acceptance of responsibility on Respondents' part and a desire to rectify their problems. (See *Seide v. Committee of Bar Examiners* (1989) 49 Cal.3d 933, 940; *Pacheco v. State Bar* (1987) 43 Cal.3d 1041, 1058 (acknowledging and accepting responsibility for wrongdoing are critical to rehabilitation).)

14. (a) The foregoing combination of aggravating and mitigating circumstances (Guidelines at p. 3, (7) and (8)) shows that probation is appropriate for all Respondents, even Technician Park. Outright revocation of Technician Park's registration would be unduly punitive, and is not necessary to protect the public. (See *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856 (purpose of license discipline is to protect the public, not punish).)

///
///

(b) Technician Park, a former pharmacist (in South Korea) (Factual Finding 14), possesses knowledge and training far exceeding that of the usual pharmacy technician. (See Guidelines at p. 43 (“Pharmacy technicians are issued a license based on minimal education, training requirements or certification.”).) This does not excuse Technician Park’s conduct, but does suggest he has much to contribute to the proper functioning of the Pharmacy and in assisting PIC Park, if afforded an opportunity for probationary registration. Likewise, his understanding that his conduct was wrong and ready admission of it (Factual Finding 7) indicate he will not likely engage in similar conduct in the future.

(c) Moreover, Technician Park undisputedly has more knowledge of, and training in, compounding than the Pharmacy’s other compounding technician (Factual Finding 14), such that improving the Pharmacy’s compounding practices will likely require Technician Park’s involvement. Consequently, under the unique circumstances of this case, outright revocation of Technician Park’s registration would be inappropriate. For the same reason, Technician Park will not be required to obtain certification prior to resuming work, which is usually a standard term of probation for pharmacy technicians. (Guidelines at p. 46.) (Regulation § 1760.)

15. Probation “[t]erms and conditions are imposed to provide consumer protection and to allow the probationer to demonstrate rehabilitation.” (Guidelines at pp. 5 and 43.) In this case, the standard terms of probation will be imposed, except where they would be counterproductive, and optional terms will be included as appropriate.

16. Actual suspension will not be ordered. Although a period of actual suspension of the Pharmacy’s permit to operate might assist Respondents in finding time, away from the press of business, to reflect on and rectify some of the Pharmacy’s shortcomings, suspension was not shown to be necessary to protect the public, and would be unduly punitive, considering that the Pharmacy is the joint business of both PIC Park and Technician Park, at which they both work full-time. (Factual Findings 4 and 23.) Instead, a stayed 90-day suspension of the Pharmacy’s permit to operate will be imposed.

17. Likewise, requiring Respondents Park to divest from the Pharmacy would deprive them of the investment that has provided them with their full-time work and income since 2003 (Factual Findings 4 and 23), and consequently would also work a punishment not shown to be necessary for the protection of the public. Accordingly, optional terms of probation prohibiting ownership of licensed premises will be imposed only as to the acquisition of new interests in licensed premises.

18. The same is true for an order prohibiting PIC Park from serving as the pharmacist-in-charge at her own Pharmacy, practicing without direct supervision, or supervising ancillary personnel, including pharmacy technicians. PIC Park’s need for remediation and oversight in her role as pharmacist-in-charge and supervisor of pharmacy technicians will be met through the optional term of probation requiring her (and the Pharmacy) to employ an independent consultant.

19. In addition, PIC Park will be required to obtain remedial education in pharmacy inventory control, pharmacy management, and pharmacy documentation requirements, in order to help her achieve improvement in these areas, which have been persistently substandard. (Factual Findings 5 – 17.) Likewise, since self-assessment and inventory control were areas in which violations occurred (*id.*), PIC Park's probation will include an optional term requiring self-assessment, and PIC Park's and the Pharmacy's probation terms will include maintenance of a separate file for information regarding the acquisition and disposition of controlled substances, and periodic provision of inventory information to the Board.

20. Complainant urged that the optional term of probation requiring abstinence from alcohol and controlled substances be imposed against Technician Park. That term will not be imposed. Although Technician Park's use of testosterone that was not prescribed for him (Factual Finding 7) was a serious violation, it appears to have been a one-time instance of malfeasance, and there was no showing that Technician Park has a drug or alcohol habit or addiction, such that he must be specifically prohibited from using alcohol or prescription drugs.

21. Complainant established entitlement to the reasonable costs of investigation and enforcement in this case, in the amount of \$16,823.70. (Factual Finding 24.) (Bus. & Prof. Code § 125.3, subd. (a).)

ORDER

Pharmacist license number RPH 48602, issued to Respondent Eunhye Park, is revoked; however, the revocation is stayed and Respondent is placed on probation for five years upon terms and conditions 1 through 10 and 11 through 21, below.

Pharmacy technician registration number TCH 32183, issued to Respondent Taeryong Park, is revoked; however, the revocation is stayed and Respondent is placed on probation for five years upon terms and conditions 1 through 10 and 22 through 25, below.

Pharmacy permit number PHY 46371, issued to Respondent Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop, is revoked; however, the revocation is stayed and Respondent is placed on probation for five years upon terms and conditions 1 through 10 and 26 through 32, below.

Terms and Conditions Applicable to All Respondents

1. Obey All Laws.

Respondents shall obey all state and federal laws and regulations. Respondents shall report any of the following occurrences to the Board, in writing, within 72 hours of such occurrence:

- an arrest of any Respondent, or issuance of a criminal complaint against any Respondent, for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea by any Respondent of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, indictment, or information;
- conviction of any Respondent of any crime;
- discipline, citation, or other administrative action filed by any state or federal agency which involves any Respondent's pharmacist license, pharmacy technician registration, and/or pharmacy permit, or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device, or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board.

Each Respondent shall report to the Board quarterly, on a schedule as directed by the Board or its designee. Each Respondent's report shall be made either in person or in writing, as directed. Among other requirements, Respondents shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

3. Interview with the Board.

Upon receipt of reasonable prior notice, each Respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff.

Each Respondent shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondents' compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. Reimbursement of Board Costs.

As a condition precedent to successful completion of probation, Respondents shall pay to the Board its costs of investigation and prosecution in the amount of \$16,823.70. Respondents shall be jointly and severally liable to pay this amount, and shall make said payments according to a plan to be approved by the Board or its designee. There shall be no deviation from the payment schedule without prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

6. Probation Monitoring Costs.

Respondents shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Respondents shall be jointly and severally liable to pay such costs. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. Status of License.

Each Respondent shall, at all times while on probation, maintain an active, current license, registration, and/or pharmacy permit, as applicable, with the Board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license, registration, and/or permit shall be considered a violation of probation. If any Respondent's license, registration, and/or permit expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication, that Respondent's license, registration, and/or permit shall be subject to all terms and conditions of this probation not previously satisfied.

8. License Surrender While on Probation/Suspension.

Following the effective date of this decision, should any Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, that Respondent may tender his, her, or its license, registration, and/or permit to the Board for surrender. The Board or its designee shall have discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, registration, and/or permit, the surrendering Respondent will no longer be subject to the terms and conditions of probation. Any surrender pursuant to this paragraph constitutes a record of discipline and shall become a part of the surrendering Respondent's license history with the Board.

Upon acceptance of the surrender, the surrendering Respondent shall relinquish his, her, or its pocket and wall license, registration documentation, and/or permit, as applicable, to the Board within 10 days of notification by the Board that the surrender has been accepted. The surrendering Respondent may not reapply for any license, registration, and/or permit from the Board for three years from the effective date of the surrender. The surrendering Respondent shall meet all requirements applicable to the license, registration, and/or permit sought as of the date of application to the Board, including any outstanding costs.

9. Violation of Probation.

If any Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over that Respondent, and probation shall automatically be extended as to that Respondent, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose any stayed penalty.

If any Respondent violates probation in any respect, the Board, after giving that Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed as against that Respondent. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license, registration, and/or permit, as applicable.

If a petition to revoke probation or an accusation is filed against any Respondent during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended as to that Respondent, until the petition to revoke probation or accusation is heard and decided.

10. Completion of Probation.

Upon written notice by the Board or its designee indicating successful completion of probation, the license, registration, and/or permit of each Respondent so notified will be fully restored.

Additional Terms and Conditions Applicable to Respondent Eunhye Park

11. Continuing Education.

Respondent Eunhye Park shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

12. Notice to Employers.

During the period of probation, Respondent Eunhye Park shall notify all present and prospective employers, other than Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop, of the decision in case number 4774 and the terms, conditions and restrictions imposed on her by the decision, as follows:

• Within 15 days of Respondent undertaking any new employment, Respondent shall cause her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4774, and terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

- If Respondent works for or is employed by or through a pharmacy employment service, Respondent must notify her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in case number 4774 before commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

- Within 15 days of Respondent undertaking any new employment by or through a pharmacy employment service, Respondent shall cause her direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 4774 and the terms and conditions imposed thereby.

It shall be Respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board. Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the Board shall be considered a violation of probation. "Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether Respondent is an employee, independent contractor or volunteer.

13. No Supervision of Interns or Serving as a Consultant.

During the period of probation, Respondent Eunhye Park shall not supervise any intern pharmacist or serve as a consultant, unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

14. Consultant for Owner or Pharmacist-In-Charge.

During the period of probation, Respondent Eunhye Park shall not supervise any intern pharmacist or serve as a consultant to any entity licensed by the Board, as set forth in paragraph 13. Respondent may be a pharmacist-in-charge. However, if during the period of probation Respondent serves as a pharmacist-in-charge, Respondent shall retain an independent consultant at her own expense who shall be responsible for reviewing pharmacy operations on a quarterly basis for compliance by Respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by Respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the Board, whose name shall be submitted to the Board or its designee, for prior approval, within 30 days of the effective date of this decision. Respondent shall not be a pharmacist-in-charge at more than one pharmacy or at any pharmacy other than Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

15. Notification of a Change in Name, Residence Address, Mailing Address or Employment.

Respondent Eunhye Park shall notify the Board in writing within 10 days of any change of employment. The notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the Board in writing within 10 days of a change in name, residence address, mailing address, or phone number. Failure to timely notify the Board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

16. Tolling of Probation.

Except during periods of suspension, if any, Respondent Eunhye Park shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, Respondent must nonetheless comply with all terms and conditions of probation. Should Respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, Respondent must notify the Board in writing within 10 days of the cessation of practice, and must further notify the Board in writing within 10 days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation. It is a violation of probation for Respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding 36 months. "Cessation of practice" means any calendar month during which Respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which Respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

17. Remedial Education.

Within 90 days of the effective date of this decision, Respondent Eunhye Park shall submit to the Board or its designee, for prior approval, an appropriate program of remedial education related to pharmacy inventory control, pharmacy management, and pharmacy documentation requirements. The program of remedial education shall consist of at least 10 hours, which shall be completed within one year at Respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education courses used for license renewal purposes. Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the Board, is provided to the Board or its designee.

Following the completion of each course, the Board or its designee may require Respondent, at her own expense, to take an approved examination to test Respondent's knowledge of the course. If Respondent does not achieve a passing score on the

examination, this failure shall be considered a violation of probation. Any such examination failure shall require Respondent to take another course approved by the Board in the same subject area.

18. Pharmacy Self-Assessment Mechanism.

Within the first year of probation, Respondent Eunhye Park shall complete the Pharmacist Self-Assessment Mechanism (PSAM) examination provided by the National Association of Boards of Pharmacy (NABP). Respondent shall submit a record of completion to the Board demonstrating she has completed this examination. Respondent shall bear all costs for the examination. Continuing education hours received for this examination shall not be used as part of the required continuing education hours for renewal purposes. Failure to timely complete the PSAM or submit documentation thereof shall be considered a violation of probation. Respondent shall waive any rights to confidentiality and provide examination results to the Board or its designee.

19. No New Ownership of Licensed Premises.

Respondent Eunhye Park shall not acquire any new ownership, legal or beneficial interest, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the Board. If Respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the Board, Respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

20. Separate File of Records.

Respondent Eunhye Park shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

21. Report of Controlled Substances.

Respondent Eunhye Park shall submit quarterly reports to the Board detailing the total acquisition and disposition of such controlled substances as the Board may direct. Respondent shall specify the manner of disposition (e.g., by prescription, due to burglary, etc.) and acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the Board. The report shall be delivered or mailed to the Board no later than 10 days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

///

///

///

Additional Terms and Conditions of Probation Applicable to Respondent Taeryong Park

22. Notice to Employers.

During the period of probation, Respondent Taeryong Park shall notify all present and prospective employers, other than Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop, of the decision in case number 4774 and the terms, conditions and restrictions imposed on him by the decision, as follows:

- Within 15 days of Respondent undertaking any new employment, Respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4774 and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgement(s) to the Board.

- If Respondent works for or is employed by or through a pharmacy employment service, Respondent must notify his direct supervisor, pharmacist-in-charge and owner at every pharmacy of the terms and conditions of the decision in case number 4774 in advance of Respondent commencing work at each pharmacy. A record of this notification must be provided to the Board upon request.

- Within 15 days of Respondent undertaking any new employment by or through a pharmacy employment service, Respondent shall cause his direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 4774 and the terms and conditions imposed thereby.

It shall be Respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board. Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgements to the Board shall be considered a violation of probation. "Employment" within the meaning of this provision shall include any full-time, part-time, temporary or relief service or pharmacy management service as a pharmacy technician or in any position for which a pharmacy technician license is a requirement or criterion for employment, whether Respondent is considered an employee, independent contractor or volunteer.

23. Notification of a Change in Name, Residence Address, Mailing Address or Employment.

Respondent Taeryong Park shall notify the Board in writing within 10 days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the Board in writing within 10 days of a change in name, residence address and mailing address, or phone number. Failure to timely notify the Board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

24. Tolling of Probation.

Except during periods of suspension, if any, Respondent Taeryong Park shall, at all times while on probation, be employed as a pharmacy technician in California for a minimum of 25 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, Respondent must nonetheless comply with all terms and conditions of probation. Should Respondent, regardless of residency, for any reason (including vacation) cease working as a pharmacy technician for a minimum of 25 hours per calendar month in California, Respondent must notify the Board in writing within 10 days of cessation of work and must further notify the Board in writing within 10 days of the resumption of work. Any failure to provide such notification(s) shall be considered a violation of probation. It is a violation of probation for Respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding 36 months. "Cessation of work" means calendar month during which Respondent is not working for at least 25 hours as a pharmacy technician, as defined in Business and Professions Code section 4115. "Resumption of work" means any calendar month during which Respondent is working as a pharmacy technician for at least 25 hours as a pharmacy technician as defined by Business and Professions Code section 4115.

25. No New Ownership of Licensed Premises.

Respondent Taeryong Park shall not acquire any new ownership, legal or beneficial interest, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the Board. If Respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the Board, Respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective of this decision. Violation of this restriction shall be considered a violation of probation.

Additional Terms and Conditions of Probation Applicable to Respondent Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop

26. Suspension.

Pharmacy permit number PHY 46371, issued to Respondent Riverside Park Pharmacy, Inc. to operate Riverside Pharmacy & Compounding Shop, is suspended for a period of 90 days. During the period of suspension, Respondent shall cease all pharmacy operations. Failure to comply with this suspension shall be considered a violation of probation. Provided, however, the suspension is stayed for so long as Respondent Riverside Park Pharmacy, Inc. complies with the terms and conditions of probation as set forth in this order.

///
///

27. Notice to Employees.

Respondent Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop, shall, on or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent shall submit written notification to the Board, within 15 days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the Board shall be considered a violation of probation. "Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

28. Owners and Officers: Knowledge of the Law.

Respondent Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop, shall provide, within 30 days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of 10 percent or more of the interest in Respondent or Respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

29. Posted Notice of Probation.

Respondent Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop, shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation. Respondent shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity. Failure to post such notice shall be considered a violation of probation.

30. Separate File of Records.

Respondent Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop, shall maintain and make available for inspection a separate file of all records pertaining to the acquisition or disposition of all controlled substances. Failure to maintain such file or make it available for inspection shall be considered a violation of probation.

31. Report of Controlled Substances.

Respondent Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop, shall submit quarterly reports to the Board detailing the total acquisition and disposition of such controlled substances as the Board may direct. Respondent shall

specify the manner of disposition (e.g., by prescription, due to burglary, etc.) and acquisition (e.g., from a manufacturer, from another retailer, etc.) of such controlled substances. Respondent shall report on a quarterly basis or as directed by the Board. The report shall be delivered or mailed to the Board no later than 10 days following the end of the reporting period. Failure to timely prepare or submit such reports shall be considered a violation of probation.

32. Posted Notice of Suspension.

During any period of actual suspension, Respondent Riverside Park Pharmacy, Inc., doing business as Riverside Pharmacy & Compounding Shop, shall prominently post a suspension notice provided by the Board in a place conspicuous and readable to the public. The suspension notice shall remain posted during the entire period of suspension ordered by this decision. Respondent shall not, directly or indirectly, engage in any conduct or make any statement, orally, electronically or in writing, which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the closure of the licensed entity. The suspension notice need not be posted during any period during which suspension is stayed.

Dated: February 12, 2015


Angela Villegas
Administrative Law Judge
Office of Administrative Hearings

1 KAMALA D. HARRIS
Attorney General of California
2 MARC D. GREENBAUM
Supervising Deputy Attorney General
3 SYDNEY M. MEHRINGER
Deputy Attorney General
4 State Bar No. 245282
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 897-2537
6 Facsimile: (213) 897-2804
E-mail: Sydney.Mehringer@doj.ca.gov
7 *Attorneys for Complainant*

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

11 In the Matter of the Accusation Against:

Case No. 4774

12 **RIVERSIDE PHARMACY &**
13 **COMPOUNDING SHOP; EUNHYE PARK**
14 **11655 Riverside Dr.**
15 **North Hollywood, CA 91602**

OAH No. 2014010558

SUPPLEMENTAL ACCUSATION

16 **Pharmacy Permit No. PHY 46371,**

17 **EUNHYE PARK**
18 **12344 Moorpark St, #3**
19 **Studio City, CA 91605**

20 **Pharmacist License No. RPH 48602,**

21 **REBECCA M. SCHNERINGER**
22 **1792 Alyso St.**
23 **Simi Valley, CA 93065**

24 **Pharmacy Technician Registration No. TCH**
25 **96891,**

26 **and**

27 **TAERYONG PARK**
28 **12344 Moorpark St., #3**
Studio City, CA 91604

Pharmacy Technician Registration No. TCH
32183

Respondents.

1 Complainant alleges:

2 **PARTIES**

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

6 45. On or about May 8, 2003, the Board of Pharmacy issued Pharmacy Permit Number
7 PHY 46371 to Riverside Pharmacy & Compounding Shop ("Respondent Riverside Pharmacy")
8 with Eunhye (Grace) Park as the Pharmacist-in-Charge. The Pharmacy Permit was in full force
9 and effect at all times relevant to the charges brought herein and will expire on May 1, 2014,
10 unless renewed.

11 46. On or about March 12, 1996, the Board of Pharmacy issued Pharmacist License
12 Number RPH 48602 to Eunhye Park ("Respondent PIC Park"). The Pharmacist License was in
13 full force and effect at all times relevant to the charges brought herein and will expire on May 31,
14 2015, unless renewed.

15 47. Paragraphs 7 through 43 of Accusation 4774 are hereby incorporated by reference as
16 though fully set forth herein.¹

17 **JURISDICTION**

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

21 **STATUTES AND REGULATIONS**

22 49. Section 4104, subdivision (b) of the Code states:
23
24
25

26 ¹ Effective March 10, 2014, Respondent Rebecca Schneringer's Pharmacy Technician
27 Registration No. TCH 96891 was revoked. The Supplemental Accusation does not allege any
28 new causes for discipline against Respondent Schneringer. Likewise, this Supplemental
Accusation does not allege any new causes for discipline against Respondent Taeryong (Tyler)
Park, Pharmacy Technician Registration Number TCH 32183.

1 "(b) Every pharmacy shall have written policies and procedures for addressing chemical,
2 mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among
3 licensed individuals employed by or with the pharmacy."

4 50. Section 4115 of the Code states, in pertinent part:

5

6 "(f)

7 "(1) A pharmacy with only one pharmacist shall have no more than one pharmacy
8 technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians
9 performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed
10 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to
11 Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a
12 licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2),
13 an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a
14 person receiving treatment in a facility operated by the State Department of State Hospitals, the
15 State Department of Developmental Services, or the Department of Veterans Affairs. . . ."

16 51. California Code of Regulations, title 16, section 1711 states, in pertinent part:

17

18 "(c)(1) Each quality assurance program shall be managed in accordance with written
19 policies and procedures maintained in the pharmacy in an immediately retrievable form.

20

21 "(d) Each pharmacy shall use the findings of its quality assurance program to develop
22 pharmacy systems and workflow processes designed to prevent medication errors. An
23 investigation of each medication error shall commence as soon as is reasonably possible, but no
24 later than 2 business days from the date the medication error is discovered. All medication errors
25 discovered shall be subject to a quality assurance review. . . ."

26 52. California Code of Regulations, title 16, section 1716 states, in pertinent part:

27

28

1 "Pharmacists shall not deviate from the requirements of a prescription except upon the prior
2 consent of the prescriber or to select the drug product in accordance with Section 4073 of the
3 Business and Professions Code.

4 "Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-
5 accepted pharmaceutical practice in the compounding or dispensing of a prescription."

6 53. California Code of Regulations, title 16, section 1735.2 states, in pertinent part:

7

8 "(d) A drug product shall not be compounded until the pharmacy has first prepared a written
9 master formula record that includes at least the following elements:

10 "(1) Active ingredients to be used.

11 "(2) Equipment to be used.

12 "(3) Expiration dating requirements.

13 "(4) Inactive ingredients to be used.

14 "(5) Process and/or procedure used to prepare the drug.

15 "(6) Quality reviews required at each step in preparation of the drug.

16 "(7) Post-compounding process or procedures required, if any.

17

18 "(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-
19 charge shall complete a self-assessment for compounding pharmacies developed by the board.
20 (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy
21 Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section
22 applicable to all compounding, and a second section applicable to sterile injectable compounding.
23 The first section must be completed by the pharmacist-in-charge before any compounding is
24 performed in the pharmacy. The second section must be completed by the pharmacist-in-charge
25 before any sterile injectable compounding is performed in the pharmacy. The applicable sections
26 of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year,
27 within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a
28

1 new pharmacy license. The primary purpose of the self-assessment is to promote compliance
2 through self-examination and education."

3 54. California Code of Regulations, title 16, section 1735.5 states:

4 "(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure
5 manual for compounding that establishes procurement procedures, methodologies for the
6 formulation and compounding of drugs, facilities and equipment cleaning, maintenance,
7 operation, and other standard operating procedures related to compounding.

8 "(b) The policy and procedure manual shall be reviewed on an annual basis by the
9 pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

10 "(c) The policy and procedure manual shall include the following:

11 "(1) Procedures for notifying staff assigned to compounding duties of any changes in
12 processes or to the policy and procedure manual.

13 "(2) Documentation of a plan for recall of a dispensed compounded drug product
14 where subsequent verification demonstrates the potential for adverse effects with continued use of
15 a compounded drug product.

16 "(3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting
17 equipment used in compounding, and for training on these procedures as part of the staff training
18 and competency evaluation process.

19 "(4) Documentation of the methodology used to test integrity, potency, quality, and
20 labeled strength of compounded drug products.

21 "(5) Documentation of the methodology used to determine appropriate expiration
22 dates for compounded drug products."

23 55. California Code of Regulations, title 16, section 1735.3 states, in pertinent part:

24 "(a) For each compounded drug product, the pharmacy records shall include:

25 "(1) The master formula record.

26 "(2) The date the drug product was compounded.

27 "(3) The identity of the pharmacy personnel who compounded the drug product.

28 "(4) The identity of the pharmacist reviewing the final drug product.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

"(5) The quantity of each component used in compounding the drug product.

"(6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia--National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

"(7) A pharmacy assigned reference or lot number for the compounded drug product.

"(8) The expiration date of the final compounded drug product.

"(9) The quantity or amount of drug product compounded. . . ."

56. California Code of Regulations, title 16, section 1735.7 states:

"(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

"(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

"(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product."

57. California Code of Regulations, title 16, section 1735.8 states:

"(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.

"(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

1 "(e) The quality assurance plan shall include written standards for qualitative and
2 quantitative integrity, potency, quality, and labeled strength analysis of compounded drug
3 products. All qualitative and quantitative analysis reports for compounded drug products shall be
4 retained by the pharmacy and collated with the compounding record and master formula.

5 "(d) The quality assurance plan shall include a written procedure for scheduled action in the
6 event any compounded drug product is ever discovered to be below minimum standards for
7 integrity, potency, quality, or labeled strength."

8 58. California Code of Regulations, title 16, section 1793.7 states, in pertinent part:

9 "(a) Except as otherwise provided in section 1793.8, any function performed by a pharmacy
10 technician in connection with the dispensing of a prescription, including repackaging from bulk
11 and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist.
12 Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a
13 correctional facility, the pharmacist shall indicate verification of the prescription by initialing the
14 prescription label before the medication is provided to the patient.

15
16 "(c) A pharmacy technician must wear identification clearly identifying him or her as a
17 pharmacy technician. . . ."

18 **CONTROLLED SUBSTANCE/DANGEROUS DRUG**

19 59. Percocet, a brand name for the combination of oxycodone and acetaminophen, is a
20 Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision
21 (b)(1)(M), and is categorized as a dangerous drug according to Code section 4022.

22 **EIGHTEENTH CAUSE FOR DISCIPLINE**

23 **(Theft/Impairment Policy and Procedure)**

24 60. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
25 action under Code sections 4104, subdivision (b) and 4301, subdivision (o) on the grounds of
26 unprofessional conduct in that on or about August 21, 2013, Respondent Riverside Pharmacy and
27 Respondent PIC Park violated the Pharmacy Law by failing to have in place proper written
28 policies and procedures regarding theft, diversion, or self-use of dangerous drugs, and employee

1 impairment. During an inspection of Respondent Riverside Pharmacy on August 21, 2013,
2 Respondent Riverside Pharmacy had in place procedures regarding theft, diversion, or self-use of
3 dangerous drugs, and employee impairment, however the procedures were inadequate because
4 they did not address what the pharmacy would do in the case of theft or impairment.

5 **NINETEENTH CAUSE FOR DISCIPLINE**

6 **(Inadequate Technician Oversight for Compounded Items)**

7 61. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
8 action under Code section 4301, subdivision (o) and California Code of Regulations, title 16,
9 section 1793.7, subdivision (a) on the grounds of unprofessional conduct in that on or about
10 August 21, 2013, Respondent Riverside Pharmacy and Respondent PIC Park violated the
11 Pharmacy Law by failing to have a pharmacist check (i.e. verify and document in writing) the
12 functions performed by pharmacy technicians in connection with the dispensing of prescriptions.

13 **TWENTIETH CAUSE FOR DISCIPLINE**

14 **(Quality Assurance Policy and Procedure Not Available During Inspection)**

15 62. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
16 action under Code section 4301, subdivision (o) and California Code of Regulations, title 16,
17 section 1711, subdivision (c)(1) on the grounds of unprofessional conduct in that on or about
18 August 21, 2013, Respondent Riverside Pharmacy and Respondent PIC Park violated the
19 Pharmacy Law by failing to provide a Quality Assurance Policy to the Board Inspector at the time
20 of the inspection on August 21, 2013 and by failing to document that on or about January 22,
21 2013, Respondent Riverside Pharmacy dispensed the incorrect dosage of Percocet to a patient.

22 **TWENTY FIRST CAUSE FOR DISCIPLINE**

23 **(Pharmacy Technicians Without Name Badges)**

24 63. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
25 action under Code section 4301, subdivision (o) and California Code of Regulations, title 16,
26 section 1793.7, subdivision (c) on the grounds of unprofessional conduct in that on or about
27 August 21, 2013, Respondent Riverside Pharmacy and Respondent PIC Park violated the
28

1 Pharmacy Law by not requiring pharmacy technicians working in the pharmacy to wear badges
2 identifying themselves as pharmacy technicians.

3 **TWENTY SECOND CAUSE FOR DISCIPLINE**

4 **(Pharmacy Compounding Non-Sterile Items with No Master Formula)**

5 64. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
6 action under Code section 4301, subdivision (o) and California Code of Regulations, title 16,
7 section 1793.7, subdivision (o) on the grounds of unprofessional conduct in that on or about
8 August 21, 2013, Respondent Riverside Pharmacy and Respondent PIC Park violated the
9 Pharmacy Law by failing to have a proper master formula for compounded drugs. Respondent
10 Riverside Pharmacy had binders of general recipes that did not clearly state the process or
11 procedure used to prepare the drugs, did not have any quality reviews, and did not have a clear
12 system for expiration dating.

13 **TWENTY THIRD CAUSE FOR DISCIPLINE**

14 **(Record of Compounded Drug Products)**

15 65. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
16 action under Code section 4301, subdivision (o) and California Code of Regulations, title 16,
17 section 1735.3, subdivision (a) on the grounds of unprofessional conduct in that on or about
18 August 21, 2013, Respondent Riverside Pharmacy and Respondent PIC Park violated the
19 Pharmacy Law by failing to have by not having adequate records regarding compounded drugs.
20 The circumstances are as follows:

21 (a) On or about August 21, 2013, during an inspection of Respondent Riverside
22 Pharmacy, a Board inspector noted that for each compounded drug product, Respondent Riverside
23 Pharmacy did not have: (1) a master formula record; (2) the identity of the pharmacist viewing the
24 final drug product; (3) the quantity of each component used in compounding the drug product; (4)
25 the manufacturer and lot number of each component used in compounding the drug product; (5)
26 the equipment used in compounding the drug product; (6) the expiration date of the final
27 compounded drug product; and (7) and quantity or amount of the drug product compounded.

28 ///

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

TWENTY FOURTH CAUSE FOR DISCIPLINE

(Compounding Policies and Procedures Not Available)

66. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary action under Code section 4301, subdivision (o) and California Code of Regulations, title 16, section 1735.5 on the grounds of unprofessional conduct in that on or about August 21, 2013, Respondent Riverside Pharmacy and Respondent PIC Park violated the Pharmacy Law by failing to have a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

TWENTY FIFTH CAUSE FOR DISCIPLINE

(No Training of Compounding Staff)

67. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary action under Code section 4301, subdivision (o) and California Code of Regulations, title 16, section 1735.7 on the grounds of unprofessional conduct in that on or about August 21, 2013, Respondent Riverside Pharmacy and Respondent PIC Park violated the Pharmacy Law by failing to provide documentation that its pharmacy technicians possessed the skills and training to perform their duties related to compounding and by failing to provide documentation that its pharmacy technicians were evaluated for on-going competency.

TWENTY SIXTH CAUSE FOR DISCIPLINE

(No Quality Assurance Policy for Compounded Items)

68. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary action under Code section 4301, subdivision (o) and California Code of Regulations, title 16, section 1735.8 on the grounds of unprofessional conduct in that on or about August 21, 2013, Respondent Riverside Pharmacy and Respondent PIC Park violated the Pharmacy Law by failing to have a written quality assurance plan for compounded drugs.

///
///

1 **TWENTY SEVENTH CAUSE FOR DISCIPLINE**

2 **(No Compounding Self-Assessment)**

3 69. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
4 action under Code section 4301, subdivision (o) and California Code of Regulations, title 16,
5 section 1735.2, subdivision (j) on the grounds of unprofessional conduct in that on or about
6 August 21, 2013, Respondent Riverside Pharmacy and Respondent PIC Park violated the
7 Pharmacy Law by failing to have a completed self-assessment form. The Board-approved form is
8 required to be completed every other year.

9 **TWENTY EIGHTH CAUSE FOR DISCIPLINE**

10 **(Pharmacist: Technician Ratio)**

11 70. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
12 action under Code section 4115, subdivision (f)(1) and Code section 4301, subdivision (o) on the
13 grounds of unprofessional conduct in that on or about August 21, 2013, Respondent Riverside
14 Pharmacy and Respondent PIC Park violated the Pharmacy Law by failing to have the proper ratio
15 of pharmacists to pharmacy technicians. In a retail pharmacy setting, the ratio is one pharmacist
16 for one pharmacy technician. On August 21, 2013, there was one pharmacist (Respondent PIC
17 Park) and three pharmacy technicians working at Respondent Riverside Pharmacy.

18 **TWENTY NINTH CAUSE FOR DISCIPLINE**

19 **(Failure to Document Error in Quality Assurance)**

20 71. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
21 action under Code section 4301, subdivision (o) and California Code of Regulations, title 16,
22 section 1711, subdivision (j) on the grounds of unprofessional conduct in that on or about August
23 21, 2013, Respondent Riverside Pharmacy and Respondent PIC Park violated the Pharmacy Law
24 by generally failing to document errors in the quality assurance system and specifically failing to
25 document an error on January 22, 2013 when prescription number 640387, which was written for
26 oxycodone/acetaminophen 7.5/325 #60, was dispensed as oxycodone/acetaminophen 7.5/500 #60.

27 ///

28 ///

1 KAMALA D. HARRIS
Attorney General of California
2 KAREN B. CHAPPELLE
Supervising Deputy Attorney General
3 SYDNEY M. MEHRINGER
Deputy Attorney General
4 State Bar No. 245282
300 So. Spring Street, Suite 1702
5 Los Angeles, CA 90013
Telephone: (213) 897-2537
6 Facsimile: (213) 897-2804
E-mail: Sydney.Mehringer@doj.ca.gov
7 Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 4774

12 **RIVERSIDE PHARMACY &**
COMPOUNDING SHOP; EUNHYE PARK
13 **11655 Riverside Dr.**
14 **North Hollywood, CA 91602**

A C C U S A T I O N

15 **Pharmacy Permit No. PHY 46371,**

16 **EUNHYE PARK**
12344 Moorpark Street, #3
Studio City, CA 91604

17 **Pharmacist License No. RPH 48602,**

18 **TAERYONG PARK**
19 **12344 Moorpark St. #3**
20 **Studio City, CA 91604**

21 **Pharmacy Technician Registration No. TCH**
32183,

22 **and**

23 **REBECCA M. SCHNERINGER**
24 **1792 Alviso St.**
Simi Valley, CA 93065

25 **Pharmacy Technician Registration No. TCH**
26 **96891**

27 Respondents.

28

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 May 8, 2003, the Board of Pharmacy issued Pharmacy Permit Number
6 PHY 46371 to Riverside Pharmacy & Compounding Shop ("Respondent Riverside Pharmacy")
7 with Eunhye (Grace) Park as the Pharmacist-in-Charge. The Pharmacy Permit was in full force
8 and effect at all times relevant to the charges brought herein and will expire on May 1, 2014,
9 unless renewed.

10 3. On or about March 12, 1996, the Board of Pharmacy issued Pharmacist License
11 Number RPH 48602 to Eunhye Park ("Respondent PIC Park"). The Pharmacist License was in
12 full force and effect at all times relevant to the charges brought herein and will expire on May 31,
13 2015, unless renewed.

14 4. On or about February 27, 2000, the Board of Pharmacy issued Pharmacy Technician
15 Registration Number TCH 32183 to Respondent Taeryong (Tyler) Park ("Respondent TCH
16 Park"). The Pharmacy Technician Registration was in full force and effect at all times relevant to
17 the charges brought herein and will expire on December 31, 2013, unless renewed.

18 5. On or about March 30, 2010, the Board of Pharmacy issued Pharmacy Technician
19 Registration Number TCH 96891 to Respondent Rebecca M. Schneringer ("Respondent TCH
20 Schneringer). The Pharmacy Technician Registration was in full force and effect at all times
21 relevant to the charges brought herein. The license expired on April 30, 2013, has not been
22 renewed, and is canceled.

23 **JURISDICTION**

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

27 7. Section 4300.1 of the Code states:
28

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

6 8. Section 4300 of the Code states, in pertinent part:

7 "(a) Every license issued may be suspended or revoked.

8 "(b) The board shall discipline the holder of any license issued by the board, whose default
9 has been entered or whose case has been heard by the board and found guilty, by any of the
10 following methods:

11 "(1) Suspending judgment.

12 "(2) Placing him or her upon probation.

13 "(3) Suspending his or her right to practice for a period not exceeding one year.

14 "(4) Revoking his or her license.

15 "(5) Taking any other action in relation to disciplining him or her as the board in its
16 discretion may deem proper.

17 "(e) The proceedings under this article shall be conducted in accordance with Chapter 5
18 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board
19 shall have all the powers granted therein. The action shall be final, except that the propriety of the
20 action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil
21 Procedure."

22 STATUTORY PROVISIONS

23 9. Section 4036.5 of the Code states:

24 "'Pharmacist-in-charge' means a pharmacist proposed by a pharmacy and approved by the
25 board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all
26 state and federal laws and regulations pertaining to the practice of pharmacy."

27 10. Section 4058 of the Code states:

28

1 "Every person holding a license issued under this chapter to operate a premises shall display
2 the original license and current renewal license upon the licensed premises in a place where it
3 may be clearly read by the public."

4 11. Section 4059, subdivision (a) of the Code states:

5 "(a) A person may not furnish any dangerous drug, except upon the prescription of a
6 physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section
7 3640.7. A person may not furnish any dangerous device, except upon the prescription of a
8 physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section
9 3640.7."

10 12. Section 4060 of the Code states:

11 "No person shall possess any controlled substance, except that furnished to a person upon
12 the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor
13 pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified
14 nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, or a
15 physician assistant pursuant to Section 3502.1, or naturopathic doctor pursuant to Section 3640.5,
16 or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of
17 subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not
18 apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy,
19 pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified
20 nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly
21 labeled with the name and address of the supplier or producer.

22 "Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a
23 physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and
24 devices."

25 13. Section 4076 of the Code states, in pertinent part:

26 "(a) A pharmacist shall not dispense any prescription except in a container that meets the
27 requirements of state and federal law and is correctly labeled with all of the following:

28 ///

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

"(11)

"(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

"(i) Prescriptions dispensed by a veterinarian.

"(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

"(iii) Dispensed medications for which no physical description exists in any commercially available database.

"(B) This paragraph applies to outpatient pharmacies only.

"(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

"(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph."

14. 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.

"(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section. . . ."

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

15. Section 4104 of the Code states, in pertinent part:

"(a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

"(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy. . . . "

16. Section 4301 of the Code states:

"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:

....

"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

....

"(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

....

"(i) 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.

....

1 "(b) Initial inventory date. Every person required to keep records shall take an inventory of
2 all stocks of controlled substances on hand on the date he/she first engages in the manufacture,
3 distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this
4 section as applicable. In the event a person commences business with no controlled substances on
5 hand, he/she shall record this fact as the initial inventory.

6 "(c) After the initial inventory is taken, the registrant shall take a new inventory of all stocks
7 of controlled substances on hand at least every two years. The biennial inventory may be taken on
8 any date which is within two years of the previous biennial inventory date. . . ."

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

10

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

15

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

20 "(e) The pharmacy owner, the building owner or manager, or a family member of a
21 pharmacist owner (but not more than one of the aforementioned) may possess a key to the
22 pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key
23 to a pharmacist or 2) providing access in case of emergency. An emergency would include fire,
24 flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that
25 the pharmacist may readily determine whether the key has been removed from the container. . . ."

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

27

28

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

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

6 23. California Code of Regulations, title 16, section 1735.3, subdivision (a) states:

7 "(a) For each compounded drug product, the pharmacy records shall include:

8 "(1) The master formula record.

9 "(2) The date the drug product was compounded.

10 "(3) The identity of the pharmacy personnel who compounded the drug product.

11 "(4) The identity of the pharmacist reviewing the final drug product.

12 "(5) The quantity of each component used in compounding the drug product.

13 "(6) The manufacturer, expiration date and lot number of each component. If the
14 manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.
15 Exempt from the requirements in this paragraph are sterile products compounded on a one-time
16 basis for administration within seventy-two (72) hours and stored in accordance with standards
17 for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia--National
18 Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference,
19 to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

20 "(7) A pharmacy assigned reference or lot number for the compounded drug product.

21 "(8) The expiration date of the final compounded drug product.

22 "(9) The quantity or amount of drug product compounded."

23 24. California Code of Regulations, title 16, section 1793.7, subdivision (d) states:

24 "(d) Any pharmacy employing or using a pharmacy technician shall develop a job
25 description and written policies and procedures adequate to ensure compliance with the
26 provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time
27 of making, records adequate to establish compliance with these sections and written policies and
28 procedures."

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

CONTROLLED SUBSTANCES/DANGEROUS DRUGS

25. Hydrocodone/APAP is a combination of hydrocodone and acetaminophen is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (e)(4) and is a dangerous drug pursuant to Business and Professions Code section 4022.

26. Testosterone is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (f)(30) and is a dangerous drug pursuant to Business and Professions Code section 4022.

COST RECOVERY

27. 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.

FIRST CAUSE FOR DISCIPLINE

(Commission of Dishonest Act)

28. Respondent TCH Schneringer is subject to disciplinary action under Code section 4301, subdivision (f) on the grounds of unprofessional conduct in that Respondent TCH Schneringer committed a dishonest act when on or about June 25, 2010, she took hydrocodone/APAP from The Prescription Center, a pharmacy where she was employed. The circumstances are as follows:

(a) On or about June 25, 2010, while working at The Prescription Center as a registered pharmacy technician, another registered pharmacy technician observed Respondent TCH Schneringer putting something in her purse. A relief pharmacist heard shaking pills in Respondent TCH Schneringer's purse and the pharmacist asked Respondent TCH Schneringer to open her purse. The Pharmacist-in-Charge seized a sealed 500 size bottle of hydrocodone/APAP 10-325. Respondent TCH Schneringer did not have a prescription for this drug.

///
///
///

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

SECOND CAUSE FOR DISCIPLINE

(Furnishing Controlled Substance without a Prescription)

29. Respondent TCH Schneringer is subject to disciplinary action under Code sections 4059 and 4301, subdivision (o) on the grounds of unprofessional conduct in that on or about June 25, 2010 Respondent TCH Schneringer violated the Pharmacy Law when she unlawfully furnished to herself a 500 size bottle of hydrocodone/APAP for which she did not have a prescription. Complainant incorporates by reference Paragraph 28, subparagraph (a), as though fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Possession of a Controlled Substance)

30. Respondent TCH Schneringer is subject to disciplinary action under Code sections 4060 and 4301, subdivision (o) on the grounds of unprofessional conduct in that on or about June 25, 2010, Respondent TCH Schneringer violated the Pharmacy Law by possessing a controlled substance, to wit, hydrocodone/APAP, without a prescription. Complainant incorporates by reference Paragraph 28, subparagraph (a), as though fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Violation of State Statues Regulating Controlled Substances)

31. Respondent TCH Schneringer is subject to disciplinary action under Code section 4301, subdivision (j) and Health and Safety Code sections 11350, subdivision (a) and 11170 on the grounds of unprofessional conduct in that on or about June 25, 2010, Respondent TCH Schneringer violated California rules regulating controlled substances when she unlawfully possessed and self-furnished hydrocodone/APAP without a prescription. Complainant incorporates by reference Paragraph 28, subparagraph (a), as though fully set forth herein.

FIFTH CAUSE FOR DISCIPLINE

(Pharmacy Drug Security)

32. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1714, subdivision (b), in that Respondent Riverside Pharmacy and

1 Respondent PIC Park violated the Pharmacy Law by failing to maintain Respondent Riverside
2 Pharmacy in such a manner so that drugs are safely and properly maintained and secured. The
3 circumstances are as follows:

4 (a) On or about June 7, 2011, a Board inspector conducted a routine inspection of
5 Respondent Riverside Pharmacy which was where Respondent TCH Schneringer was working at
6 the time.

7 (b) The Board inspector conducted a "zero-based" audit on five controlled
8 substances for a one year period from June 8, 2010 to June 7, 2011. Based on the audit, from
9 June 8, 2010 to June 7, 2011, Respondent Riverside Pharmacy and Respondent PIC Park failed to
10 maintain and secure approximately 2,578 tablets of hydrocodone/APAP.

11 **SIXTH CAUSE FOR DISCIPLINE**

12 **(DEA Inventory)**

13 33. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
14 action under Code sections 4301, subdivisions (j) and (o), in conjunction with Code of Federal
15 Regulations, title 21, section 1304.11, subdivisions (c) and (h)(1) and (h)(3) and California Code
16 of Regulations, title 16, section 1718, on the grounds of unprofessional conduct in that
17 Respondent Riverside Pharmacy and Respondent PIC Park violated federal and state rules and
18 regulations by failing to maintain a proper DEA inventory of controlled substances. The
19 circumstances are as follows:

20 (a) On or about June 7, 2011, during an inspection of Respondent Riverside
21 Pharmacy, a Board inspector found that only Schedule II controlled substance inventories had
22 been taken for 2005, 2007, and 2011. No Schedule III, IV, or V controlled substance inventories
23 had been taken. No 2009 DEA inventory was taken for any type of controlled substance.

24 **SEVENTH CAUSE FOR DISCIPLINE**

25 **(Tablet Identification on Patient Medication Container Label)**

26 34. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
27 action under Code sections 4076, subdivision (a)(11)(A) and 4301, subdivision (o) on the grounds
28 of unprofessional conduct in that on or about June 7, 2011, Respondent Riverside Pharmacy and

1 Respondent PIC Park violated the Pharmacy Law by having the physical description of certain
2 dispensed medication on the patient monograph and not as part of the label on the container.

3 **EIGHTH CAUSE FOR DISCIPLINE**

4 **(Theft/Impairment Policy and Procedure)**

5 35. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
6 action under Code sections 4104, subdivisions (a) and (b) and 4301, subdivision (o) on the
7 grounds of unprofessional conduct in that on or about June 7, 2011, Respondent Riverside
8 Pharmacy and Respondent PIC Park violated the Pharmacy Law by failing to have in place proper
9 written policies and procedures regarding theft, diversion, or self-use of dangerous drugs, and
10 employee impairment.

11 **NINTH CAUSE FOR DISCIPLINE**

12 **(Key to Pharmacy)**

13 36. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
14 action under Code section 4301, subdivision (o), in conjunction with California Code of
15 Regulations, title 16, section 1714, subdivisions (d) and (e), on the grounds of unprofessional
16 conduct in that on or about June 7, 2011, Respondent Riverside Pharmacy and Respondent PIC
17 Park violated the Pharmacy Law by allowing Respondent TCH Park, the co-owner of Respondent
18 Riverside Pharmacy and a registered pharmacy technician – not a pharmacist, to have possession
19 of a key to Respondent Riverside Pharmacy that was not in a tamper-evident container.

20 **TENTH CAUSE FOR DISCIPLINE**

21 **(Pharmacy Permit Not Readable to Public)**

22 37. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
23 action under Code sections 4058 and 4301, subdivision (o) on the grounds of unprofessional
24 conduct in that on or about June 7, 2011, Respondent Riverside Pharmacy and Respondent PIC
25 Park violated the Pharmacy Law by failing to display the original pharmacy permit and renewal
26 permit in a place where it was clearly readable to the public. The circumstances are as follows:
27
28

1 (a) On or about August 5, 2003, during an inspection of Respondent Riverside
2 Pharmacy, a Board inspector noted "Recommend moving pharmacy permit to location where
3 public can read it. Currently in back of pharmacy high on shelf."

4 (b) On or about June 7, 2011, during an inspection of Respondent Riverside
5 Pharmacy, a Board inspector noted that the pharmacy permits were still located in the back of the
6 pharmacy and high on a shelf.

7 **ELEVENTH CAUSE FOR DISCIPLINE**

8 **(Pharmacy Technician Written Policies and Procedures)**

9 38. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
10 action under Code section 4301, subdivision (o), in conjunction with California Code of
11 Regulations, title 16, section 1793.7, subdivision (d), on the grounds of unprofessional conduct in
12 that on or about June 7, 2011, Respondent Riverside Pharmacy and Respondent PIC Park violated
13 the Pharmacy Law by failing to have adequate written policies and procedures regarding the
14 employment of pharmacy technicians.

15 **TWELFTH CAUSE FOR DISCIPLINE**

16 **(Records of Compounded Drug Products)**

17 39. Respondent Riverside Pharmacy and Respondent PIC Park are subject to disciplinary
18 action under Code section 4301, subdivision (o), in conjunction with California Code of
19 Regulations, title 16, section 1735.3, subdivision (a), on the grounds of unprofessional conduct in
20 that on or about June 7, 2011, Respondent Riverside Pharmacy and Respondent PIC Park violated
21 the Pharmacy Law by not having adequate records regarding compounded drugs. The
22 circumstances are as follows:

23 (a) On or about June 7, 2011, during an inspection of Respondent Riverside
24 Pharmacy, a Board inspector noted that for each compounded drug product, Respondent Riverside
25 Pharmacy did not have: (1) a master formula record; (2) the identity of the pharmacist viewing the
26 final drug product; (3) the quantity of each component used in compounding the drug product; (4)
27 the manufacturer and lot number of each component used in compounding the drug product; (5)
28

1 the equipment used in compounding the drug product; (6) the expiration date of the final
2 compounded drug product; and (7) and quantity or amount of the drug product compounded.

3 **FOURTEENTH CAUSE FOR DISCIPLINE**

4 **(Failure to Maintain Records)**

5 40. Respondent PIC Park is subject to disciplinary action under Code sections 4081,
6 subdivision (b) and 4301, subdivision (o), in conjunction with California Code of Regulations,
7 title 16, section 1718, on the grounds of unprofessional conduct in that Respondent PIC Park
8 violated the Pharmacy Law by failing to maintain accurate records and complete accountability of
9 approximately 2,578 tablets of hydrocodone/APAP between June 8, 2010 to June 7, 2011.

10 Complainant incorporates by reference Paragraph 32 subparagraph (b), as though fully set forth
11 herein.

12 **FIFTEENTH CAUSE FOR DISCIPLINE**

13 **(Furnishing Controlled Substance without a Prescription)**

14 41. Respondent TCH Park is subject to disciplinary action under Code sections 4059 and
15 4301, subdivision (o) on the grounds of unprofessional conduct in that on or about June 7, 2011
16 Respondent TCH Park violated the Pharmacy Law when he unlawfully furnished to himself
17 approximately 30 ml of testosterone 15% with lipoderm. The circumstances are as follows:

18 (a) On or about June 7, 2011 during an inspection of Respondent Riverside
19 Pharmacy, a Board inspector observed Respondent TCH Park place an amber syringe in his
20 leather valise in the back office of the pharmacy. The inspector instructed Respondent TCH Park
21 to pull the item out of the valise and she collected the amber syringe. When questioned regarding
22 the contents of the syringe, Respondent TCH Park admitted that it contained testosterone with
23 lipoderm. Respondent TCH Park had made the medication for a customer and he admitted to
24 keeping the leftover medication to use on himself.

25 **SIXTEENTH CAUSE FOR DISCIPLINE**

26 **(Possession of a Controlled Substance without a Prescription)**

27 42. Respondent TCH Park is subject to disciplinary action under Code sections 4060 and
28 4301, subdivision (o) on the grounds of unprofessional conduct in that on or about June 7, 2011

1 Respondent TCH Park violated the Pharmacy Law by possessing a controlled substance, to wit,
2 testosterone, without a prescription. Complainant incorporates by reference Paragraph 41,
3 subparagraph (a), as though fully set forth herein.

4 **SEVENTEENTH CAUSE FOR DISCIPLINE**

5 **(Violation of State Statues Regulating Controlled Substances)**

6 43. Respondent TCH Park is subject to disciplinary action under Code section 4301,
7 subdivision (j) and Health and Safety Code sections 11350, subdivision (a) and 11170 on the
8 grounds of unprofessional conduct in that on or about June 7, 2011, Respondent TCH Park
9 violated California rules regulating controlled substances when he unlawfully possessed and self-
10 furnished testosterone without a prescription. Complainant incorporates by reference Paragraph
11 41, subparagraph (a), as though fully set forth herein.

12 **PRAYER**

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

15 1. Revoking or suspending Pharmacy Permit Number PHY 46371, issued to Riverside
16 Pharmacy & Compounding Shop with Eunhye Park as the Pharmacist-in-Charge;

17 2. Revoking or suspending Pharmacist License Number RPH 48602, issued to Eunhye
18 Park;

19 3. Revoking or suspending Pharmacy Technician Registration Number TCH 32183,
20 issued to Taeryong Park;

21 4. Revoking or suspending Pharmacy Technician Registration Number TCH 96891,
22 issued to Rebecca M. Schneringer;

23 5. Ordering Riverside Pharmacy & Compounding Shop, Eunhye Park, Taeryong Park,
24 and Rebecca M. Schneringer to pay the Board of Pharmacy the reasonable costs of the
25 investigation and enforcement of this case, pursuant to Business and Professions Code section
26 125.3; and

27 ///

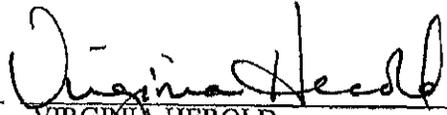
28 ///

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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

DATED:

11/4/13



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

LA2013510075
51379268.doc