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9	BEFORE THE BOARD OF PHARMACY		
10	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
11	In the Matter of the Accusation Against:	ase No. 3084	
12	JAE Y. PARK, doing busines as		
13	220, 11, 2200 = 2, 00	CCUSATION	
14	Los Angeles, CA 90019 JAE Y. PARK, Pharmacist-in-Charge		
15	Original Pharmacy Permit No. PHY 44525		•
16	JAE YOUNG PARK, also known as		
17	JAE Y. PARK. 1501 Emerald Lane Diamond Bar, CA 91765		
18	Original Pharmacist No. RPH 44773		
19	Respondents.		
20	Respondents.		.*
21	Complainant alleges:	· · · · · · · · · · · · · · · · · · ·	
22	<u>PARTIES</u>		
23	1. Virginia Herold ("Complainant")	brings this Accusation solely	in her
24	official capacity as the Executive Officer of the Board of Pharmacy ("Board"), Department of		
25	Consumer Affairs.	· .	<u>-</u>
26	2. On or about August 22, 1991, the Board issued Original Pharmacist		
27	License No. 44773 to Jae Young Park, also known as Jae Y. Park, ("Respondent Park"). The		
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"(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs.

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

#### 7. Section 4113 of the Code states:

"(a) Every pharmacy shall designate a pharmacist-in-charge and within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated.

- (b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."
  - 8. Section 4070 of the Code states:
- "(a) Except as provided in Section 4019 and subdivision (b), an oral or an electronic data transmission prescription as defined in subdivision (c) of Section 4040 shall as soon as practicable be reduced to writing by the pharmacist and shall be filled by, or under the direction of, the pharmacist. The pharmacist need not reduce to writing the address, telephone number, license classification, federal registry number of the prescriber or the address of the patient or patients if the information is readily retrievable in the pharmacy."
  - 9. Health and Safety Code section 11153, states, in pertinent part:
- "(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or

habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use."

- 10. California Code of Regulations, title 16, section 1716.2 states:
- "(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:
  - (1) The date of preparation.
- (2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.
- (3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
  - (4) The signature or initials of the pharmacist performing the compounding.
- (5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.
  - (6) The name(s) of the manufacturer(s) of the raw materials.
  - (7) The quantity in units of finished products or grams of raw materials.
  - (8) The package size and the number of units prepared."
  - 11. California Code of Regulations, title 16, section 1717, states:
- "(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

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"Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

"(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself.

"All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing.

"Chart orders as defined in Section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.

- "(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code Section 4005."
- 12. California Code of Regulations, title 16, section 1717.4, subdivision (h), states:

"Any person who transmits, maintains or receives any prescription or prescription refill, orally, in writing or electronically, shall ensure the security, integrity, authenticity, and confidentiality of the prescription and any information contained therein."

- 13. California Code of Regulations, title 16, section 1761 states:
- "(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.
- (b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose."

- 14. California Code of Regulations, title 16, section 1793.7, states, in pertinent part:
- "(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.
- (d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures."
- 15. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.
- 16. Section 125.3 of the Code provides, 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.

#### CONTROLLED SUBSTANCES/DANGEROUS DRUGS

- A. "Codeine" is a Schedule II controlled substance, as defined by Health and Safety Code section 11055, and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.
- B. "Klonopin" is the brand name for Clonazepam. It is a Schedule IV controlled substance, as defined in Health and Safety Code section 11057, and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.
- C. "Phenergan with Codeine" is the brand name for Promethazine with Codeine. It is a Schedule V controlled substance, as defined in Health and Safety Code section 11058, and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.

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- D. "Tylenol with Codeine #3" is the brand name for Acetaminiphen 300mg with Codeine 30mg. It is a Schedule III controlled substance, as defined in Health and Safety Code section 11056, and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.
- E. "Valium" is the brand name for Diazepam. It is a Schedule IV controlled substance, as defined in Health and Safety Code section 11057, and is categorized as a "dangerous drug" pursuant to Business and Professions Code section 4022.
- F. "Antibiotics" generally are categorized as "dangerous drugs" pursuant to Business and Professions Code section 4022.

## FIRST CAUSE FOR DISCIPLINE

## (Failure to Reduce to Writing Orally Transmitted Prescriptions)

Respondents are subject to discipline pursuant to Code sections 4300, 4301, subdivision (o), 4070, subdivision (a), and 4113, in conjunction with California Code of Regulations, title 16, sections 1717, subdivision (c), and 1717.4, subdivision (h), in that Respondent Park repeatedly took receipt of orally transmitted prescriptions in a spiral notebook, which contained the patient's name, drug and quantity of the drug to be filled. Further, Respondent Park failed to reduce the complete prescription to writing until after the prescription was dispensed. Specifically, during an inspection of Respondent Forum Drug on May 5, 2006, a Board inspector observed Respondent Park writing orally transmitted prescriptions containing only patient names, drugs, and quantities to be dispensed, in a spiral notebook after speaking with a physician, as well as filling the prescription prior to reducing the telephoned prescriptions to a proper telephone prescription form. Further, Respondent Park failed to provide the Board inspector with telephone prescription forms corresponding to all of the telephoned prescription notes contained in the spiral notebook.

#### SECOND CAUSE FOR DISCIPLINE

# (Requirements of Employing Pharmacy Technicians)

18. Respondents are subject to discipline pursuant to Code sections 4300, 4301, subdivision (o), and 4113, in conjunction with California of Regulations, title 16, section

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1793.7, subdivisions (c) and (d), in that Respondents employed a pharmacy technician and failed to develop a job description, written policies and procedures, and name tags for the technicians. Specifically, during an inspection of Respondent Forum Drug on May 5, 2006, a Board inspector observed a pharmacy technician filling prescriptions without a name tag to identify herself as a pharmacy technician. When Respondent Park was asked to provide a copy of Respondents' policies and procedures and job description for the position of pharmacy technician, Respondent Park stated they did not exist.

#### THIRD CAUSE FOR DISCIPLINE

#### (Erroneous and Uncertain Prescriptions)

19. Respondents are subject to discipline pursuant to Code sections 4300 4301, subdivision (o), and 4113, in conjunction with California Code of Regulations, title 16, section 1761, subdivisions (a) and/or (b), in that Respondents dispensed erroneous and uncertain prescriptions, and/or, prescriptions that Respondents should have known were not for a legitimate medical purpose, as follows:

- a. <u>Phenergan with Codeine</u>: In or between May 5, 2003 and May 5, 2006, Respondents dispensed Phenergan with Codeine to at least six patients, including, but not limited to, Patients E.B., C.F., I.G., O.M., J. S., and H.W., as a long-term therapy for the treatment of productive cough associated with chronic bronchitis. Respondents failed to question whether Phenergen with Codeine was the appropriate treatment, as Phenergan with Codeine is indicated for the temporary relief of cough and is not recommended for habitual use, or for the treatment of productive cough associated with chronic bronchitis. The circumstances include the following:
- i. In or between May 5, 2003 and May 5, 2006, Respondents filled prescriptions for Phenergan with Codeine for Patient E.B. at least 35 times, Patient C.F. at least

<sup>1.</sup> All Patients are referred to by their first and last initial to protect patient privacy. All patient names will be released upon the receipt of a proper request for discovery in this matter from the Respondent. In addition, the majority of the prescriptions filled for the listed patients, as well as the majority of Respondents' customers, were patients of physician M. Apusen.

35 times, Patient I.G. at least 33 times, Patient O. M. at least 32 times, Patient J.S. at least 28 times, and Patient H.W. at least 37 times.

- ii. Additionally, in or between March 1, 2006 and April 27, 2006, Respondents dispensed prescriptions for Phenergen with Codeine 604 of 719 patient visits, or eighty-four percent (84%) of the patient visits to Respondent Forum Drug.
- iii. A review of Respondents' patient profiles revealed that prescriptions for Phenergen with Codeine were consistently dispensed in the same amount of 360ml, or 12 ounces, and consistently calculated as a 22 day supply. Additionally, the patient profiles revealed that prescriptions for Phenergen with Codeine were filled consistently approximately 30 days apart. This pattern is not consistent with normal pharmacy settings. Refills for Phenergen with Codeine are not routinely filled 30 days apart, as Phenergen with Codeine is prescribed on as needed basis.
- b. <u>Clonazepam/Diazepam:</u> In or between May 5, 2003 and May 5, 2006, Respondents dispensed maximum dosages of Clonazepam and Diazepam, two benodiazepines representing duplicate therapy, concurrently to at least four patients, including, but not limited to, Patients E.B., C.F., J. S., and H.W.
- c. <u>Acetaminophen with Codeine:</u> In or between May 5, 2003 and May 5, 2006, Respondents dispensed Acetaminophen with Codeine #3 to at least five patients, including, but not limited to, Patients E.B., C.F., I.G., O.M., and J. S., for the treatment of degenerative joint disease. Respondents failed to question whether the use other therapies was appropriate, as the use of codeine is not recommended for patients with degenerative joint disease.
- d. Antibiotics: In or between May 5, 2003 and May 5, 2006, Respondents dispensed prescriptions for the long-term use of antibiotics for the treatment of chronic bronchitis to at least five patients, including, but not limited to, Patients C.F., I.G., O.M., J. S., and H.W. Respondents failed to question whether other treatments were appropriate, as the long term, prophylactic use of antibiotics in patients is not appropriate.
- e. <u>Spiral Notebook:</u> Respondents filled uncertain prescriptions, in that

  Respondent Park wrote orally transmitted prescriptions as notes in a spiral notebook, which only

contained the name of the patient, the drug prescribed and the quantity to be dispensed.

Respondent Park would later reduce to actual prescription to a telephone prescription form.

- i. Specifically, during an inspection of Respondent Forum Drug on May 5, 2006, Respondent Park was observed writing notes regarding prescriptions in a spiral notebook while on the telephone with a physician. The notes in the spiral notebook failed to contain information regarding whether refills were authorized, the directions for the prescription's use, and the name of the prescribing physician. Respondent Park stated that when Dr. M. Apusen called in a prescription, he would write notes in the spiral notebook, and when he had time, he would reduce the full prescription to a telephone prescription form.
- ii. When asked to provide the telephone prescription forms for the current week, Respondent Park provided only some prescriptions, to which he added directions and the prescribing physician's name. Further, it was determined that some orally transmitted prescriptions were not properly reduced to telephone prescription forms before the prescriptions were dispensed, as was required.

#### FOURTH CAUSE FOR DISCIPLINE

(Excessive Furnishing of Controlled Substances)

20. Respondents are subject to discipline pursuant to Code sections 4300, 4301, subdivisions (d) and (j), and 4113, in conjunction with Health and Safety Code section 11153, subdivision (a), in that Respondents furnished excessive amounts of controlled substances not for a legitimate medical purpose, as discussed in paragraph 19, subparagraphs (a), (b) and (c), above, which are herein incorporated by reference as set forth in full.

#### FIFTH CAUSE FOR DISCIPLINE

(Gross Negligence and Incompetence)

21. Respondents are subject to discipline pursuant to Code sections 4300, 4301, subdivisions (b), and/or, (c), and 4113, in that Respondents committed gross negligence, and/or, incompetence, by filling erroneous and uncertain prescriptions, and by furnishing excessive amounts of controlled substances, and/or, dangerous drugs, as more fully discussed in paragraph 19, subparagraphs (a), (b), (c) and (d), and paragraph 20, above.

#### SIXTH CAUSE FOR DISCIPLINE

(Failure to Record Lot Numbers and Expiration Dates)

22. Respondents are subject to discipline pursuant to Code sections 4300, 4301, subdivision (o), and 4113, in conjunction with California Code of Regulations, title 16, section 1716.2, in that Respondents failed to record the lot numbers and expiration dates for drugs that were pre-packaged for records for future dispensing (a.k.a. pre-pack log). <sup>2</sup>/
Specifically, during an inspection of Respondent Forum Drug on May 5, 2006, a Board inspector determined that Respondents dispensed pre-packed medications. A review of Respondent's pre-pack log revealed that Respondents mainly pre-packaged pain medications and antibiotics.

Further review of the pre-pack log revealed that Respondents did not record the lot numbers and expiration dates of the medications that were pre-packed.

## SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

23. Respondents are subject to discipline pursuant to Code sections 4300, 4301, and 4113, in that Respondents committed unprofessional conduct, as more fully discussed in paragraph 17 through 22, above.

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<sup>2.</sup> Respondents were issued a Correction Order on or about January 10, 2003, regarding Respondents' requirement to record lot numbers and expiration dates on the pre-pack log.

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#### **PRAYER**

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

- 1. Revoking or suspending Pharmacy Permit No. 44525, issued to Forum Drug; Jae Young Park;
- 2. Revoking or suspending Pharmacist License No. 44773, issued to Jae Young Park;
- 3. Ordering Jae Young Park and Forum Drug to pay the Board of Pharmacy, Department of Consumer Affairs the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;
  - 4. Taking such other and further action as deemed necessary and proper.

DATED: 12/1/08

VIRĢINIA HEROLI

Executive Officer

Board of Pharmacy State of California

Complainant