

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

In the Matter of the Accusation Against:

**PARK WEST PHARMACY, INC.;**  
**MARGARITA KAZARIAN, OWNER,**  
Pharmacy Permit No. PHY 46623,

and

**JERRY A. WHITTEMORE,**  
Pharmacist License No. RPH 21221,

Respondents.

Case No. 5378

OAH No. 2015051032

**DECISION AFTER REJECTION OF PROPOSED DECISION**

Thomas Y. Lucero, Administrative Law Judge (ALJ), Office of Administrative Hearings, State of California, heard these consolidated matters<sup>1</sup> on December 1, 2, and 3, 2015, in Los Angeles. This decision relates to the accusation against respondents Park West Pharmacy, Inc., Margarita Kazarian, and Jerry A. Whittemore, board case number 5378. Complainant was represented by William D. Gardner, Deputy Attorney General. Respondents, Park West Pharmacy, Inc., Margarita Kazarian, and Jerry A. Whittemore, were represented by Paul. L. Cass, attorney at law.

Oral and documentary evidence was received. The record was closed and the matter was submitted to the ALJ for decision on December 18, 2015. The ALJ issued his Proposed Decision on December 30, 2015.

On March 11, 2016, pursuant to section 11517 of the Government Code, the California State Board of Pharmacy (“Board”) issued an Order rejecting the December 30, 2015, Proposed Decision of the ALJ in the above-entitled matter. On May 13, 2016, the Board issued an Order reflecting that the transcript had been received, but that respondent’s exhibits had been omitted from the record. The parties were asked to coordinate their responses to provide stipulated copies of the exhibits. Both parties submitted exhibits; the submitted exhibits were compared and a

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<sup>1</sup> For purposes of the hearing, this matter was consolidated with the Matter of the Accusation against Kenneth Road Pharmacy, Inc., Margarita Kazarian, Owner, and Robert S. Lipp, board case number 5377.

proposed resolution for completing the record was offered, along with an opportunity to object. In the absence of objection from either party, the record was completed as proposed.

The deadline for submission of written argument was set for May 31, 2016. Timely argument was received from both parties. On June 28, 2016, the Board issued an Order Extending Time for Issuance of the Decision After Rejection.

The Board, having reviewed and considered the entire record, including the transcript, exhibits and written argument, now issues this decision.

## FACTUAL FINDINGS

1. The accusation was brought by Virginia K. Herold in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs, State of California. Each respondent filed a timely request for hearing.

### *Licenses*

2. On May 28, 2004, the Board issued permit no. PHY 46623 to respondent Park West Pharmacy, Inc. (Park West), which operates a pharmacy in West Hills, California. The permit is set to expire on May 1, 2016.

3. On April 3, 1992, the Board issued Margarita Kazarian original pharmacist license no. RPH 45273, which the Board revoked on November 18, 2014. (Exhibit 3.)

4. The revocation of Ms. Kazarian's license does not "deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee...." (Business and Professions Code section 4300.1)

5. On July 25, 1959, the Board issued respondent Jerry A. Whittemore original pharmacist license no. RPH 21221, which was set to expire on January 31, 2016, unless renewed.

6. Starting May 28, 2004, Ms. Kazarian was President of Park West and owned all of its stock. On November 30, 2015, Ms. Kazarian closed escrow on an agreement to sell all stock in Park West and to resign from being any sort of officer of the company, as described in more detail below.<sup>2</sup>

7. From October 29, 2007, to June 18, 2014, Ms. Kazarian was the PIC at Park West. Since June 18, 2014, Mr. Whittemore has been the PIC.

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<sup>2</sup> Escrow instructions and escrow-related documents, such as documentation of due diligence, were not in evidence.

### *Pharmacy Sale Agreement*

8. Following revocation of her pharmacist license, Ms. Kazarian sought to sell Park West. She had a few purchase offers. Until the day before the hearing, each prospective purchaser withdrew.

9. The pharmacy does substantial business. The dollar amount of annual sales is in the low seven figures. Expenses are high. Rent payments for the pharmacy's premises is in excess of \$5,000 per month. The pharmacy's drug inventory is valued in the six figures. Four people work there. Daily operations require a great deal of care, attention, and training, in order to keep operations in compliance with pharmacy laws. These laws are exacting and detailed in order to ensure public safety in the dispensing of dangerous drugs. A purchaser would require substantial means, financial and pharmacy-related, to consider purchasing the pharmacy.

10. Escrow with respect to a written agreement for the purchase and sale of Park West closed on November 30, 2015. The named purchaser was Julia Perez, who holds pharmacy technician license, no. TCH 25887. She is currently employed at a pharmacy operated by Kenneth Road Pharmacy, Inc., which for several years has been owned by Ms. Kazarian. Ms. Perez was previously employed for approximately 10 years by another pharmacy, now closed, also owned by Ms. Kazarian.

A. Under the purchase agreement, Ms. Perez is to pay Ms. Kazarian \$520,000. Of that fee, \$400,000 is allocated to corporate stock and business assets. Inventory was separately valued at \$120,000. Under a promissory note, Ms. Perez is to make payment in 48 monthly installments of \$10,000, including interest at four percent, from January 1, 2016 through December 1, 2019. The debt may be repaid sooner without penalty. (Exhibit A.)

B. There was a virtually identical agreement relating to the purchase and sale of another pharmacy, Kenneth Road Pharmacy, Inc. (Kenneth Road), also owned by Ms. Kazarian. Escrow as to that agreement also closed November 30, 2015, and differed from the agreement relating to Park West in no significant way, except that different dollar figures were used. (Exhibit B.)<sup>3</sup>

11. The agreement references the Board's regulation of pharmacies:

Contingencies: Parties are unaware of any rules or regulations that would prevent the transfer of stock and Corporate ownership from Seller to Buyer prior to the Board of Pharmacy approval. However, if such requirement do exists [sic], then the change in Corporate stock ownership shall be effective upon receiving such approval.

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<sup>3</sup> Exhibit A relates to Park West, Exhibit B to Kenneth Road, except that, apparently by inadvertence, Articles of Incorporation and Bylaws were switched, so that Kenneth Road's are found in Exhibit A, Park West's in Exhibit B.

“Board of Pharmacy approval” is not defined in the agreements. Ms. Perez testified to her understanding that in order to operate the pharmacies, she must obtain Board approval of the Community Pharmacy Permit Application she submitted with respect to each pharmacy on December 1, 2015. (Exhibits A and B.) At the time of the bearing, the Board had not yet acted on the applications.

12. The agreement had no substantial information regarding past or projected business operations of the pharmacy. There are no detailed profit projections or budgets. There is no detailed list of corporate assets. There are no dollar figures regarding salaries, inventory costs, or other details regarding liabilities. Ms. Perez had no collateral to pledge. Her promissory note has a provision, section 8, regarding collateral, but it is boilerplate designed for a corporation, rather than an individual. The provision bears no relationship to Ms. Perez’s situation:

The assets of Maker [Ms. Perez] and each of its subsidiaries (the “Collateral”), whether wholly owned or otherwise, and whether currently existing or not, shall serve as collateral and guarantee for Maker's obligations under this Agreement, excluding the Corporation [Park West]. Maker agrees to properly use and maintain the Collateral and maintain insurance of a type and in amounts agreeable to Payee [Ms. Kazarian]. ...

13. Ms. Perez had no substantial capital with which to purchase a pharmacy. She does not own property against which she could borrow funds in order to finance the purchase of a business. For over a decade, virtually all of her income has been her annual salary as a pharmacy technician employed by a corporation owned and controlled by Ms. Kazarian. Ms. Perez plan to pay for the purchase of Kenneth Road and Park West from profits the pharmacies are projected to generate.

14. Despite the provisions for complete transfer of corporate assets under the agreements, Ms. Kazarian continues to have signing authority on bank accounts in the names of Park West and Kenneth Road. With this authority, she has signed checks, for payroll and rent, on Park West’s corporate account since the November 30, 2015 close of escrow. She has no other duties or involvement in pharmacy operations.

#### *Investigation*

15. There were three Board investigators of Park West. Sarah Bayley, Pharm.D., took the lead with her investigation on November 25, 2013. She worked for some years in retail pharmacy. She has been an inspector for the Board since 2000. The other two investigators were Sejal Desai, Pharm.D., and Karla Retherford-Parreira, Pharm.D. Ms. Desai and Ms. Retherford-Parreira were present at a follow-up investigation on December 11, 2014. Ms. Bayley investigated further on December 12, 2014. Their reports of the investigation discuss several drugs that were examined. The drugs are available to patients only with a prescription, and thus are dangerous drugs within the meaning of Business and Professions Code section 4022, subdivision (c).

16. The investigators' written reports are Exhibits 7, 8, 9, 11, and 12. There are minor inconsistencies. For instance, Ms. Bayley's December 14, 2014 report, Exhibit 7, which includes a summary of Ms. Desai's findings, indicates that a bottle of Crestor<sup>4</sup> is packaged by the manufacturer with 100 pills,<sup>5</sup> whereas Ms. Desai indicates in her December 15, 2014 report, Exhibit 8, that the packaging is 90 pills. Exhibit 7 does not mention an overfilled bottle of Lexapro, though the overfill is described in Exhibit 8.

17. The three investigators testified to several violations of pharmacy law:

A. Overfills, bottles with more pills than indicated on the label, were found as follows:

Cymbalta:	one bottle with 161 pills, instead of 90 per the label
digoxin:	one bottle with 120 pills, instead of 100 per the label
Crestor:	one bottle with 105 pills, instead of 100 per the label
Lexapro:	one bottle with 105 pills, instead of 100 per the label

There was no explanation of how the overfills happened.

B. There were slight variations among the imprints on pills in the overfilled bottle of Cymbalta noted above. Imprints are characters manufacturers stamp on pills. Some of the imprints are a little darker than others. There were also small color variations among these pills. The variations are illustrated in a photograph in Exhibit 16. The photograph was taken by Ms. Desai with her cell phone camera.

C. Seals on one bottle of Levitra pills and three bottles of Lexipro pills were broken. The bottles had the correct number of pills according to manufacturers' labels.

D. A pharmacist technician, Lisa Tollison, took back 13 prescription drugs and one over-the-counter drug which had been dispensed to a patient who died before using them. The patient had been a customer of the pharmacy for some 10 years. The customer's son asked that Park West take charge of the drugs' destruction. Ms. Tollison explained that normally' the pharmacy did not take back drugs, but she made an exception in this instance, in order to be accommodating. She did not inform Mr. Whittemore. Park West had no acquisition or inventory records for the returned drugs.

E. Ms. Tollison was unable to provide a compounding self-assessment by the PIC, Mr. Whittemore, as Ms. Bayley requested. During Ms. Bayley's investigation, Ms. Tollison attempted to telephone Mr. Whittemore to ask about the assessment, but did not reach him. Mr. Whittemore was required to prepare the assessment no later than July 18, 2014, within 30 days after he became PIC. Ms. Bayley thus found that Mr. Whittemore had not complied with California Code of Regulations, title 16, section 1735.2, subdivision (g).

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<sup>4</sup> Trade names are capitalized, generic drugs' names are not.

<sup>5</sup> The term "pills" used in this Proposed Decision is interchangeable with similar terms, such as capsules and tablets, to which the Board's evidence at times refers.

F. The pharmacy's manual of policies and procedures for drug compounding was incomplete. At the December 11, 2014, inspection, the manual was out of compliance with the following sections of California Code of Regulations, title 16, in that it lacked a plan for: (i) recall of drugs, required by section 1735.5; (ii) training of staff, required by section 1735.7; and (iii) quality assurance, required by section 1735.8.

18. On December 17, 2014, Ms. Tollison faxed the Board a compounding self-assessment signed by Mr. Whittemore. By that time, however, Park West had stopped compounding drugs. It had last done compounding on November 18, 2014. Before that, the pharmacy compounded drugs approximately two times per month.

19. Ms. Bayley testified that the color and imprint variations in the Cymbalta pills observed at Park West indicate misbranding and adulteration.

A. As a rule, color and imprint variations are not seen in pills sealed in a single bottle by the manufacturer. Like overfilling, the variations signify the pills cannot be matched to information on the manufacturer's label, they must be considered misbranded and possibly adulterated.

B. Overfilling a bottle and mixing pills from more than one bottle destroys a pharmacist's ability to match pills to important information on labels. Ms. Bayley testified that overfills are another indication of misbranding and possible adulteration. It makes it difficult if not impossible for the pharmacist, pharmacy inspector, or a consumer to be able to identify things like the origin of the pills or the expiration date, since at least some of the pills in the bottle were not placed in that bottle by the manufacturer, but by the pharmacy. Identifying the origin of the pills is essential to determine legitimacy of the pills (to avoid counterfeit pills), to determine the expiration date, and, if there is ever a recall, to determine the manufacturer and lot number to prevent a consumer from taking recalled medications. Federal law now even requires that, for certain medications, all packages (of every size) going into or out of a pharmacy be labeled with such detailed information for similar reasons<sup>6</sup>.

C. Breaking a bottle's seal is not common practice unless the pharmacy has removed pills for dispensing to patients. Dispensing pills would leave fewer pills in the bottle than indicated on its label. Bottles with broken seals and the same number of pills as shown on the label indicate, in Ms. Bayley's opinion, that the pharmacy is either using pills improperly or is careless in opening bottles for no purpose related to good pharmacy practice.

20. On January 16, 2015, the Board filed a Petition for Interim Suspension Order (petition). The petition alleged, among other things, the November 18, 2014, revocation of Ms. Kazarian's license and that, because Park West (and Kenneth Road) were owned by

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<sup>6</sup> The Drug Quality and Security Act (DQSA), was signed into law on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act, outlines a system to identify and trace certain prescription drugs as they are distributed in the United States, to better enable verification of the legitimacy of the drug product identifier down to the package level, enhance detection and notification of illegitimate products in the drug supply chain, and facilitate more efficient recalls of drug products. 21 U.S.C. 581, *et seq.*

Ms. Kazarian, respondents were in violation of the law against a licensee's ownership by a person whose license the Board was revoked. Denial of the petition was served on February 18, 2015, and was based on an alleged failure by the Board to send written notice that Ms. Kazarian had 30 days to find a buyer or otherwise dispose of her interest in the pharmacy.

21. As indicated in Exhibit 4, the Board incurred reasonable prosecution costs of \$9,900 and reasonable investigation costs of \$4,293, for a total of \$14,193.

## LEGAL CONCLUSIONS

1. Pharmacies and pharmacists must be licensed by the Board. The Board has as its highest priority the protection of the public. Every pharmacy must have a "pharmacist-in-charge," an individual licensed by the board, who is responsible for a pharmacy's compliance with all state and federal laws.

2. The Board is guided by a statute that mandates that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public must be paramount. (Bus. & Prof. Code, § 4001.1.)

3. The Board has the burden of proof.

A. The standard of proof against the pharmacy's license, which is not a "professional" license in that there are not extensive education, training and testing requirements to obtain such licensure. Since it is a nonprofessional license, complainant must establish cause for discipline against a pharmacy license by demonstrating cause for discipline by a preponderance of the evidence. (*Imports Performance v Dept. of Consumer Affairs, Bur. Of Automotive Repair* (2011) 201 Cal.App.4<sup>th</sup> 911, 916-917; *San Benito Foods v Veneman* (1996) 50 Cal.App.4<sup>th</sup> 1889.)

B. The standard of proof to discipline a professional licensee, such as a pharmacist's, must be "clear and convincing." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) The evidence must be so clear as to leave no substantial doubt and strong enough to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478, 487.)

C. In this matter, clear and convincing evidence establishes each violation found with respect to both licensees.

### *Improper Ownership*

4. Business and Professions Code section 4301 provides in part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct... Unprofessional conduct shall include, but is not limited to, any of the following: [¶] ...[¶]

(j) The violation of any of the statutes of this state, of 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.

5. Business and Professions Code section 4302 provides:

The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.

6. Business and Professions Code section 4307 provides:

Any person...whose license has been revoked ... shall be prohibited from serving as a manager, administrator, owner, ... officer, [or] director ... of a licensee ...

7. Business and Professions Code section 4308 provides:

Whenever a person is prohibited from serving as a manager, administrator, owner, ...officer, [or] director... of a licensee as provided by Section 4307, the board shall, in each case where it has that information, notify in writing each licensee for whom the person is a manger, administrator, owner,...officer, [or] director...of the prohibition. The board shall send the notification to the licensee's address of record. The licensee shall have 30 days from the date that the notice is sent to remove and replace the prohibited person and, where appropriate, file a change of permit to reflect that change.

8. Business and Professions Code section 4110 provides in pertinent part:

(a)... A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. ... The board may, by regulation, determine the circumstance under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be required *in* an amount established by the



board as specified in subdivision (a) of Section 4400. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permit holder or service by certified mail, return receipt requested, at the permit holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permit holder be deemed to have a vested property right or interest in the permit.

9. Upon revocation of her license, it became improper for Ms. Kazarian to own or operate a pharmacy, including Park West. She was thus in violation of Business and Professions Code section 4307.

10. The transaction between Ms. Kazarian and Ms. Perez was not a bona fide sale.

A. As a long-time employee of Ms. Kazarian's pharmacies with insufficient capital, Ms. Perez did not have the means to negotiate an arm's-length transaction. Many aspects of the purchase and sale agreement so indicate, as indicated in Finding 12.

B. Ms. Kazarian's handling payroll and lease payments after the November 30, 2015, close of escrow, as indicated in Finding 13, constitutes improper ongoing management and control. In consequence of the revocation of Ms. Kazarian's license, she and Park West were required by Business and Professions Code section 4308 to remove and replace Ms. Kazarian, not only as owner of the corporation, but also as manager of the pharmacy. Respondents have failed to comply.

11. Cause exists to discipline Park West by reason of Ms. Kazarian's improper ownership. Under Business and Professions Code section 4301, subdivision (o), both Park West and Ms. Kazarian are in violation of the prohibition in section 4307 on her management of the pharmacies.

12. Ms. Kazarian and Park West argued they have not been provided written notice such as to trigger the 30-day period set out in section 4308 for Ms. Kazarian's relinquishing ownership. The argument is not persuasive. The proceedings initiated by the Board's January 16, 2015, petition, as indicated in Finding 21, provided respondents statutory notice. That the petition included other matter does not detract its functioning as proper notice under section 4308.

13. Incorporated by reference in California Code of Regulations, title 16, section 1760, are the Board's Disciplinary Guidelines. The guidelines state that a corporation's violation of Business and Professions Code section 4302 is subject to Category II discipline, including revocation. Revocation is appropriate here.

*Adulteration*

14. Business and Professions Code section 4113, subdivision (c), provides:

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.

15. Business and Professions Code section 4156 provides in pertinent part:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

16. Health and Safety Code section 111255 provides:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

17. Health and Safety Code section 111295 provides:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

18. Health and Safety Code section 111305 provides:

It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any [such] drug or device.

19. Cause exists to discipline the license of Park West and the PIC, Mr. Whittemore, based on Factual Findings 15-19, in that the evidence established that drugs at Park West were adulterated. The irregularities in pills, in their color and imprints, and the overfills indicate that the drugs were adulterated within the meaning of Health and Safety Code section 111255. The drugs were "*packed, or held under conditions* whereby [they] *may have been contaminated* with filth, or whereby [they] *may have been rendered injurious to health.*" [Emphasis added.] The drugs' expiration date, lot number and manufacturer information was not available for at least some of the pills in the over filled bottles; it is not sufficient to speculate about such information. Health and Safety Code section 111255 does not require that the drugs were *actually* contaminated with filth or *actually* injurious to health to find them to be adulterated; it is sufficient that they were handled in a manner where there "may have been" potential risk to a consumer.

*Misbranding*

20. Health and Safety Code section 111330 provides that “Any drug or device is misbranded if its labeling is false or misleading in any particular.”

21. Health and Safety Code section 111340 provides:

Any drug or device is misbranded unless it bears a label containing all of the following information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380.

22. Health and Safety Code section 111440 provides that “It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.”

23. Cause exists to discipline the license of Park West and the PIC, Mr. Whittemore, based on possession of misbranded drugs.

A. Mixing pills from different bottles of the same drug was shown to be misleading regarding the quantity of drugs in bottles at the pharmacy.

B. If pills from an older bottle lost potency, but the loss was concealed by the pharmacy’s mixing them with pills from a newer bottle, that poses a risk to the consumer. The fact that there were more pills than should be in the bottle, and that there is no way to tell where the pills came from. A label affirmatively stating that the pills had a particular expiration date, when that expiration date could not be demonstrated, is misleading. In addition, the representation that the pills are from the same lot number cannot be demonstrated.

C. When pills mixed from different bottles caused an overfill, the labeling on the overfilled bottle is not the “accurate statement of the quantity of the contents” as required by Health and Safety Code section 111340, subdivision (b).

D. In this particular case, the pills with irregularities, in color, imprints, and chipping, were not shown to violate Health and Safety Code section 111340, subdivision (b).

E. In this particular case, the broken seals were not shown to be false or misleading. The bottles were properly labeled, containing the correct type and number of pills according to the manufacturer’s label.

*Acquisition and Inventory Records*

24. Business and Professions Code section 4081 provides in pertinent part:

(a) All records of ... acquisition, [or] receipt ... of dangerous drugs ... shall be at all times during business hours open to inspection by authorized officers of the law .... A current inventory shall be kept by every ... pharmacy ... holding a currently valid and unrevoked ... permit ....

(b) The owner ... of a pharmacy ... shall be jointly responsible, with the pharmacist-in-charge ... for maintaining the records ... described in this section.

25. Cause exists to discipline the permit of Park West and the license of Mr. Whittemore in that the pharmacy, contrary to Business and Professions Code section 4081, subdivision (a), failed to have proper acquisition and inventory records for 14 drugs returned to the pharmacy, as indicated in Finding 17D. Under Business and Professions Code section 4081, subdivision (b), they are jointly responsible for the missing records.

26. Ms. Tollison took back drugs in this one instance. She intended to help the bereaved son of a long-time customer by destroying the drugs at his request. She neglected to record her conduct.

*Drug Compounding Self-Assessment*

27. California Code of Regulations, title 16, section 1735.2, subdivision (j), provides in pertinent part:

Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board . . . . The applicable sections of the self-assessment shall subsequently be completed . . . within 30 days of the start of a new pharmacist-in-charge . . . . The primary purpose of the self-assessment is to promote compliance through self-examination and education.

28. Cause exists to discipline the license of Mr. Whittemore for his failure, as indicated in Finding 17E, to prepare a drug compounding self-assessment by July 18, 2014. As indicated in Finding 18, his self-assessment should have been available for four months, until November 18, 2014, when the pharmacy stopped compounding drugs.

29. The pharmacy did little compounding, about two times per month, as indicated in Finding 18. There was no evidence that Mr. Whittemore or the pharmacy were likely to cause harm because of the pharmacy's compounding activity. On its own, the lack of a self-assessment is not an egregious violation of the Board's regulations.

*Compounding Policies and Procedures*

30. California Code of Regulations, title 16, section 1735.5 provides:

(a) Any pharmacy engaged in compounding shall maintain 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. [¶] ... [¶]

(c) The policy and procedure manual shall include the following[:] [¶] ... [¶]

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

31. Cause exists to discipline the permit of Park West and the license of Mr. Whittemore for their failure, as indicated in Finding 17F, to document a plan for recall of certain dispensed drugs, as required by California Code of Regulations, title 16, section 1735.5, subsection (c)(2).

32. The failure to document a plan for drug recall is a relatively minor violation of the Board's regulations. Such plans apply to compounded drugs. As noted above, respondents did little compounding, about two times per month. They stopped compounding altogether in November 2014, as indicated in Finding 18. Mr. Whittemore was responsible for a plan for four months only, from July 18, 2014, when he became PIC, until November 18, 2014, when the pharmacy stopped compounding.

33. The Board is entitled to recover from Park West its reasonable costs for investigation and prosecution of this matter, pursuant to Business and Professions Code section 125.3, in the sum of \$14,193, by reason of Finding 21.

34. The Board has previously imposed the maximum discipline, revocation against the pharmacist license of respondent, Margarita Kazarian, so that no further discipline against that license is warranted, except that she should be jointly and severally liable with Park West, as its owner, for payment of the Board's costs of investigation and prosecution.

35. Mr. Whittemore is responsible for the lack of required documentation of different kinds during four months of 2014, as indicated in Conclusions 23, 24, 26, 27, 29, and 30. Discipline is appropriate because of the potential risk to consumers posed by the pharmacy's practices; revocation is, however, not warranted. Mr. Whittemore's violations were not egregious. Considering these factors, and all pertinent factors set out in California Code of Regulations, title 16, section 1775.2, public reproof is the appropriate level of discipline against his license.

ORDER

1. The pharmacy permit, number PHY 46623, issued to respondent Park West Pharmacy, Inc., owned by Margarita Kazarian, is revoked.

Respondent owner shall, by the effective date of this decision, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent owner shall provide written proof of such disposition, submit a completed Discontinuance of Business form and return the wall and renewal license to the board within five days of disposition.

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.

2. Respondent, Park West Pharmacy, Inc., shall pay the Board's costs of investigation and prosecution in the amount of \$14,193, in such manner as the Board may direct.

3. The accusation against respondent, Margarita Kazarian, is upheld only in so far as she is liable, jointly and severally, with Park West for payment of the Board's costs of investigation and prosecution in the amount of \$14,193.

4. Respondent, Jerry A. Whittemore, pharmacist license number RPH 21221, is hereby publicly reproved. Respondent is required to report this reproof as a disciplinary action.

This Decision shall become effective at 5:00 pm on August 29, 2016.

It is so ORDERED on July 29, 2016.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA



By

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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:

KENNETH ROAD PHARMACY, INC.:  
MARGARITA KAZARIAN, OWNER,  
Pharmacy Permit No. PHY 50214,

and

ROBERT S. LIPP,  
Pharmacist License No. RPH 32284,

Respondents.

In the Matter of the Accusation Against:

PARK WEST PHARMACY, INC.:  
MARGARITA KAZARIAN, OWNER,  
Pharmacy Permit No. PHY 46623,

and

JERRY A. WHITTEMORE,  
Pharmacist License No. RPH 21221,

Respondents.

Case Nos. 5377

5378

OAH Nos. 2015051030

2015051032

**ORDER SETTING DATES FOR  
SUBMISSION OF WRITTEN ARGUMENT AND  
COMPLETION OF ADMINISTRATIVE RECORD**

Pursuant to section 11517 of the Government Code, the California State Board of Pharmacy (hereinafter "board") rejected the Proposed Decisions of the administrative law judge in the above matters by Orders dated March 11, 2016. The transcript of the hearing in the above-entitled matter having now become available, the parties are hereby notified of the opportunity to submit written arguments in accordance with the Order Rejecting Proposed Decision.

The matters were consolidated at hearing and so this order applies to both cases.

The parties may submit any argument they wish based on the existing record in this matter, making citations thereto.

Although no new evidence may be submitted, the parties are asked to provide copies of respondent's exhibits as noted below.

In addition to written argument, because the board's record does not contain any of respondent's exhibits<sup>1</sup> from the hearing that occurred on December 1, 2 and 3, 2015, the parties may submit the most accurate copy of respondent's exhibits entered into evidence at hearing. A copy of the Exhibit List is attached to this Order. Accordingly,

1. On or before **May 26, 2016**, the parties shall file a coordinated response to the board with stipulated copies of those exhibits that respondent entered into evidence during the administrative hearing. In the event the parties do not stipulate to all admitted exhibits, each party shall provide its representation of copies of the exhibits to the board, and each other by the same date. Each party shall have until **June 1, 2016**, to file objections to the other parties' filing.
2. On or before **May 31, 2016**, any desired written argument shall be filed with the Board of Pharmacy, 1625 N. Market Blvd, Suite N-219, Sacramento, California 95834.

IT IS SO ORDERED this 13<sup>th</sup> day of May, 2016.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA



By

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Amy Gutierrez, Pharm.D.  
Board President

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<sup>1</sup> Complainant's admitted exhibits are part of the record.



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Respondents.

Case No. 5378

OAH No. 2015051032

**ORDER REJECTING PROPOSED DECISION**

Pursuant to section 11517 of the Government Code, the Proposed Decision of the Administrative Law Judge in the above-entitled matter is rejected. The California State Board of Pharmacy (hereinafter "board") will decide the case upon the record, including the transcript(s) of the hearing, and upon such written argument as the parties may wish to submit.

Although the right to argue is not limited, the board is particularly interested in arguments directed to the questions of whether the allegations were appropriately evaluated and whether the discipline is appropriate.

The parties will be notified of the date for submission of such argument when the transcript of the above-mentioned hearing becomes available.

It is so ORDERED on March 11, 2016.

BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA

A handwritten signature in black ink, appearing to read "Amy Gutierrez", written in a cursive style.

By

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Amy Gutierrez, Pharm.D.  
Board President

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and

JERRY A. WHITTEMORE,  
Pharmacist License No. RPH 21221,

Respondents.

**PROPOSED DECISION**

Thomas Y. Lucero, Administrative Law Judge, Office of Administrative Hearings, State of California, heard these consolidated matters on December 1, 2, and 3, 2015, in Los Angeles. This proposed decision is rendered with respect to the accusation against respondents Park West Pharmacy, Inc., Margarita Kazarian, and James A. Whittemore, case number 5378.

Complainant was represented by William D. Gardner, Deputy Attorney General.

Respondents, Park West Pharmacy, Inc., Margarita Kazarian, and James A. Whittemore, were represented by Paul L. Cass, attorney at law.

Oral and documentary evidence was received. The record was left open so that by December 9, 2015, complainant could submit a brief regarding admissibility of certain exhibits, to which respondents could respond by no later than December 18, 2015. The briefs were timely submitted and marked for identification, complainant's as Exhibit 29, respondent's as Exhibit I. Complainant's brief argued that certifications in Exhibit 4, of the costs of investigation and prosecution of this matter, were properly admitted into evidence. Respondents' brief withdrew their objections to Exhibit 4 and it was admitted. Complainant's brief also addressed Exhibit 5, a November 18, 2014 decision and order regarding Margarita Kazarian and Adams Square Pharmacy. A relevance objection was sustained at the hearing. Complainant argued for reconsideration. After reconsideration, the ruling stands. Exhibit 5 was not admitted into evidence.

The record was closed and the matter was submitted for decision on December 18, 2015.

#### FACTUAL FINDINGS

1. The accusation was brought by Virginia K. Herold in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs, State of California. Each respondent filed a timely request for hearing.

##### *Licenses*

2. On May 28, 2004, the Board issued permit no. PHY 46623 to respondent Park West Pharmacy, Inc. (Park West), which operates a pharmacy in West Hills, California. The permit is set to expire on May 1, 2016.

3. On April 3, 1992, the Board issued Margarita Kazarian original pharmacist license no. RPH 45273, which the Board revoked on November 18, 2014. (Exhibit 3.)

4. The revocation of Ms. Kazarian's license does not "deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee . . . ." (Business and Professions Code section 4300.1.)

5. On July 25, 1959, the Board issued respondent Jerry A. Whittemore original pharmacist license no. RPH 21221, which is set to expire on January 31, 2016.

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6. Starting May 28, 2004, Ms. Kazarian was President of Park West and owned all of its stock. On November 30, 2015, Ms. Kazarian closed escrow on an agreement to sell all stock in Park West and to resign from being any sort of officer of the company, as described in more detail below.<sup>1</sup>

7. From October 29, 2007 to June 18, 2014, Ms. Kazarian was the PIC at Park West. Since June 18, 2014, Mr. Whittemore has been the PIC.

*Pharmacy Sale Agreement*

8. Following revocation of her pharmacist license, Ms. Kazarian sought to sell Park West. She had a few purchase offers. Until the day before the hearing, each prospective purchaser withdrew.

9. The pharmacy does substantial business. The dollar amount of annual sales is in the low seven figures. Expenses are high. Rent for the pharmacy's premises is in excess of \$5,000 per month. The pharmacy's drug inventory is valued in the six figures. Four people work at the pharmacy. Daily operations require a great deal of care, attention, and training, in order to keep operations in compliance with pharmacy laws. These laws are exacting and detailed in order to ensure public safety in the dispensing of dangerous drugs. A purchaser would require substantial means, financial and pharmacy-related, to consider purchasing the pharmacy.

10. Escrow with respect to a written agreement for the purchase and sale of Park West closed on November 30, 2015. The named purchaser was Julia Perez, who holds a pharmacy technician license, no. TCH 25887. She is currently employed at a pharmacy operated by Kenneth Road Pharmacy, Inc., which for several years has been owned by Ms. Kazarian. Ms. Perez was previously employed for approximately 10 years by another pharmacy, now closed, also owned by Ms. Kazarian.

A. Under the purchase agreement, Ms. Perez is to pay Ms. Kazarian \$520,000. \$400,000 is allocated to corporate stock and business assets. Inventory was separately valued at \$120,000. Under a promissory note, Ms. Perez is to make payment in 48 monthly installments of \$10,000, including interest at four percent, from January 1, 2016 through December 1, 2019. The debt may be repaid sooner without penalty. (Exhibit A.)

B. There was a virtually identical agreement relating to the purchase and sale of another pharmacy, Kenneth Road Pharmacy, Inc. (Kenneth Road), owned by Ms. Kazarian. Escrow as to that agreement also closed on November 30, 201, and differed from the

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<sup>1</sup> Escrow instructions and escrow-related documents, such as documentation of due diligence, were not in evidence.

agreement relating to Park West in no significant way, except that different dollar figures were used. (Exhibit B.)<sup>2</sup>

11. The agreements reference the Board's regulation of pharmacies:

Contingencies: Parties are unaware of any rules or regulations that would prevent the transfer of stock and Corporate ownership from Seller to Buyer prior to the Board of Pharmacy approval. However, if such requirement do exists [sic], then the change in Corporate stock ownership shall be effective upon receiving such approval.

"Board of Pharmacy approval" is not defined in the agreements. Ms. Perez testified to her understanding that in order to operate the pharmacies, she must obtain Board approval of the Community Pharmacy Permit Application she submitted with respect to each pharmacy on December 1, 2015. (Exhibits A and B.) At the time of the hearing, the Board had not yet acted on the applications.

12. The agreement has no substantial information regarding past or projected business operations of the pharmacy. There are no detailed profit projections or budgets. There is no detailed list of corporate assets. There are no dollar figures regarding salaries, inventory costs, or other details regarding liabilities. Ms. Perez had no collateral to pledge. Her promissory note has a provision, section 8, regarding collateral, but it is boilerplate designed for a corporation, rather than an individual. The provision bears no relationship to Ms. Perez's situation:

The assets of Maker [Ms. Perez] and each of its subsidiaries (the "Collateral"), whether wholly owned or otherwise, and whether currently existing or not, shall serve as collateral and guarantee for Maker's obligations under this Agreement, excluding the Corporation [Park West]. Maker agrees to properly use and maintain the Collateral and maintain insurance of a type and in amounts agreeable to Payee [Ms. Kazarian]. . . .

13. Ms. Perez had no substantial capital with which to purchase a pharmacy. She does not own property against which she could borrow funds in order to finance the purchase of a business. For over a decade, virtually all of her income has been her annual salary as a pharmacy technician employed by a corporation owned and controlled by Ms. Kazarian. Ms. Perez plans to pay for the purchase of Kenneth Road and Park West from profits the pharmacies are projected to generate.

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<sup>2</sup> Exhibit A relates to Park West, Exhibit B to Kenneth Road, except that, apparently by inadvertence, Articles of Incorporation and Bylaws were switched, so that Kenneth Road's are found in Exhibit A, Park West's in Exhibit B.

14. Despite the provisions for complete transfer of corporate assets under the agreements, Ms. Kazarian continues to have signing authority on bank accounts in the names of Park West and Kenneth Road. With this authority, she has signed checks, for payroll and rent, on Park West's corporate account since the November 30, 2015 close of escrow. She has no other duties or involvement in pharmacy operations.

### *Investigation*

15. There were three Board investigators of Park West. Sarah Bayley, Pharm.D., took the lead with her investigation on November 25, 2013. She worked for some years in retail pharmacy. She has been an inspector for the Board since 2000. The other two investigators were Sejal Desai, Pharm.D., and Karla Retherford-Parreira, Pharm.D. Ms. Desai and Ms. Retherford-Parreira were present at a follow-up investigation on December 11, 2014. Ms. Bayley investigated further on December 12, 2014. Their reports of the investigation discuss several drugs that were examined. The drugs are available to patients only with a prescription, and thus are dangerous drugs within the meaning of Business and Professions Code section 4022, subdivision (c).

16. The investigators' written reports are Exhibits 7, 8, 9, 11, and 12. There are minor inconsistencies. For instance, Ms. Bayley's December 14, 2014 report, Exhibit 7, which includes a summary of Ms. Desai's findings, indicates that a bottle of Crestor<sup>3</sup> is packaged by the manufacturer with 100 pills,<sup>4</sup> whereas Ms. Desai indicates in her December 15, 2014 report, Exhibit 8, that the packaging is 90 pills. Exhibit 7 does not mention an overfilled bottle of Lexapro, though the overfill is described in Exhibit 8.

17. The three investigators testified to several violations of pharmacy law:

A. Overfills, bottles with more pills than indicated on the label, were found as follows:

Cymbalta:	one bottle with 161 pills, instead of 90 per the label
digoxin:	one bottle with 120 pills, instead of 100 per the label
Crestor:	one bottle with 105 pills, instead of 100 per the label
Lexapro:	one bottle with 105 pills, instead of 100 per the label

There was no explanation of how the overfills happened. There was no evidence that overfills caused harm to consumers or the public.

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<sup>3</sup> Trade names are capitalized, generic drugs' names are not.

<sup>4</sup> The term "pills" used in this Proposed Decision is interchangeable with similar terms, such as capsules and tablets, to which the Board's evidence at times refers.

B. There were slight variations among the imprints on pills in the overfilled bottle of Cymbalta noted above. Imprints are characters manufacturers stamp on pills. Some of the imprints are a little darker than others. There were also small color variations among these pills. The variations are illustrated in a photograph in Exhibit 16. The photograph was taken by Ms. Desai with her cell phone camera.

C. Seals on one bottle of Levitra pills and three bottles of Lexipro pills were broken. The bottles had the correct number of pills according to manufacturers' labels.

D. A pharmacist technician, Lisa Tollison, took back 13 prescription drugs and one over-the-counter drug which had been dispensed to a patient who died before using them. The patient had been a customer of the pharmacy for some 10 years. The customer's son asked that Park West take charge of the drugs' destruction. Ms. Tollison explained that normally the pharmacy did not take back drugs, but she made an exception in this instance, in order to be accommodating. She did not inform Mr. Whittemore. Park West had no acquisition or inventory records for the returned drugs.

E. Ms. Tollison was unable to provide a compounding self-assessment by the PIC, Mr. Whittemore, as Ms. Bayley requested. During Ms. Bayley's investigation, Ms. Tollison attempted to telephone Mr. Whittemore to ask about the assessment, but did not reach him. Mr. Whittemore was required to prepare the assessment no later than July 18, 2014, within 30 days after he became PIC. Ms. Bayley thus found that Mr. Whittemore had not complied with California Code of Regulations, title 16, section 1735.2, subdivision (j).

F. The pharmacy's manual of policies and procedures for drug compounding was incomplete. At the December 11, 2014 inspection, the manual was out of compliance with the following sections of California Code of Regulations, title 16, in that it lacked a plan for: (i) recall of drugs, required by section 1735.5; (ii) training of staff, required by section 1735.7; and (iii) quality assurance, required by section 1735.8.

18. On December 17, 2014, Ms. Tollison faxed the Board a compounding self-assessment signed by Mr. Whittemore. By that time, however, Park West had stopped compounding drugs. It had last done compounding on November 18, 2014. Before that, the pharmacy compounded drugs approximately two times per month.

19. Ms. Bayley testified that the color and imprint variations in the Cymbalta pills observed at Park West indicate misbranding and adulteration.

A. As a rule, color and imprint variations are not seen in pills sealed in a single bottle by the manufacturer. Like overfilling, the variations signify the pills are from more than one bottle and have been mixed by the pharmacy. She said that if pills cannot be matched to information on the manufacturer's label, they must be considered misbranded and possibly adulterated.



B. Overfilling a bottle and mixing pills from more than one bottle destroys a pharmacist's ability to match pills to information on labels. She testified that overfills are another indication of misbranding and possible adulteration.

C. Breaking a bottle's seal is not common practice unless the pharmacy has removed pills for dispensing to patients. Dispensing pills would leave fewer pills in the bottle than indicated on its label. Bottles with broken seals and the same number of pills as shown on the label indicate, in Ms. Bayley's opinion, that the pharmacy is either using pills improperly or is careless in opening bottles for no purpose related to good pharmacy practice.

20. On January 16, 2015, the Board filed a Petition for Interim Suspension Order (petition). The petition alleged, among other things, the November 18, 2014 revocation of Ms. Kazarian's license and that, because Park West (and Kenneth Road) were owned by Ms. Kazarian, respondents were in violation of the law against a licensee's ownership by a person whose license the Board has revoked. Denial of the petition was served on February 18, 2015, and was based on an alleged failure by the Board to send written notice that Ms. Kazarian had 30 days to find a buyer or otherwise dispose of her interest in the pharmacy.

21. As indicated in Exhibit 4, the Board incurred reasonable prosecution costs of \$9,900 and reasonable investigation costs of \$4,293, for a total of \$14,193.

## LEGAL CONCLUSIONS

1. The Board has the burden of proof. Its evidence must be "clear and convincing." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) The evidence must be so clear as to leave no substantial doubt and strong enough to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478, 487.) The Board met this standard with respect to improper ownership of Park West.

### *Improper Ownership*

2. Business and Professions Code section 4301 provides in part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct . . . . Unprofessional conduct shall include, but is not limited to, any of the following: [¶] . . . [¶]

(j) The violation of any of the statutes of this state, of 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.

3. Business and Professions Code section 4302 provides:

The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.

4. Business and Professions Code section 4307 provides:

Any person . . . whose license has been revoked . . . shall be prohibited from serving as a manager, administrator, owner, . . . officer, [or] director . . . of a licensee . . . .

5. Business and Professions Code section 4308 provides:

Whenever a person is prohibited from serving as a manager, administrator, owner, . . . officer, [or] director . . . of a licensee as provided by Section 4307, the board shall, in each case where it has that information, notify in writing each licensee for whom the person is a manager, administrator, owner, . . . officer, [or] director . . . of the prohibition. The board shall send the notification to the licensee's address of record. The licensee shall have 30 days from the date that the notice is sent to remove and replace the prohibited person and, where appropriate, file a change of permit to reflect that change.

6. Business and Professions Code section 4110 provides in pertinent part:

(a) . . . A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. . . . The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be required in an amount established by the board as specified in subdivision (a) of Section 4400. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was

issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permit holder or service by certified mail, return receipt requested, at the permit holder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permit holder be deemed to have a vested property right or interest in the permit.

7. Upon revocation of her license, it became improper for Ms. Kazarian to own or operate a pharmacy, including Park West. She was thus in violation of Business and Professions Code section 4307.

8. The transaction between Ms. Kazarian and Ms. Perez was not a bona fide sale.

A. As a long-time employee of Ms. Kazarian's pharmacies with insufficient capital, Ms. Perez did not have the means to negotiate an arm's-length transaction. Many aspects of the purchase and sale agreement so indicate, as noted above in Finding 12.

B. Ms. Kazarian's handling payroll and lease payments after the November 30, 2015 close of escrow, as indicated in Finding 13, constitutes improper ongoing management and control. In consequence of the revocation of Ms. Kazarian's license, she and Park West were required by Business and Professions Code section 4308 to remove and replace Ms. Kazarian, not only as owner of the corporation, but also as manager of the pharmacy. Respondents have failed to comply.

9. Cause exists to discipline Park West's pharmacy permit by reason of Ms. Kazarian's improper ownership. Under section 4301, subdivision (o), both Park West and Ms. Kazarian are in violation of the prohibition in section 4307 on her management of the pharmacy.

10. Ms. Kazarian and Park West argued they have not been provided written notice such as to trigger the 30-day period set out in section 4308 for Ms. Kazarian's relinquishing ownership. The argument is not persuasive. The proceedings initiated by the Board's January 16, 2015 petition, as indicated in Finding 21, provided respondents statutory notice. That the petition included other matter does not detract from its functioning as proper notice under section 4308.

11. Incorporated by reference in California Code of Regulations, title 16, section 1760, are the Board's Disciplinary Guidelines. The guidelines state that a corporation's violation of Business and Professions Code section 4302 is subject to Category II discipline, which may include revocation. Revocation is appropriate here.

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*Adulteration*

12. Business and Professions Code section 4113, subdivision (c), provides:

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.

13. Business and Professions Code section 4156 provides in pertinent part:

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

14. Health and Safety Code section 111255 provides:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

15. Health and Safety Code section 111295 provides:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

16. Health and Safety Code section 111305 provides:

It is unlawful for any person to receive in commerce any drug or device that is adulterated or to deliver or proffer for delivery any [such] drug or device.

17. The evidence did not establish that drugs at Park West were adulterated.

A. The irregularities in Cymbalta pills, in their color and imprints, which Ms. Desai photographed at Park West, were slight, and not shown to be the equivalent of drugs "contaminated with filth" or "injurious to health" within the meaning of Health and Safety Code section 111255. Ms. Bayley's opinion that such variations could be indications of adulteration was not supported by facts.

B. Conditions at the pharmacy were not shown to have resulted in drugs that were contaminated with filth or rendered injurious to health. There was no evidence, for instance, that pills were left in the open or otherwise exposed to sources of contamination.

*Misbranding*

18. Health and Safety Code section 111330 provides that "Any drug or device is misbranded if its labeling is false or misleading in any particular."

19. Health and Safety Code section 111340 provides:

Any drug or device is misbranded unless it bears a label containing all of the following information:

- (a) The name and place of business of the manufacturer, packer, or distributor.
- (b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

Reasonable variations from the requirements of subdivision (b) shall be permitted. Requirements for placement and prominence of the information and exemptions as to small packages shall be established in accordance with regulations adopted pursuant to Section 110380.

20. Health and Safety Code section 111440 provides that "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

21. Cause exists to discipline the permit of Park West and the license of the PIC, Mr. Whittemore, based on possession of misbranded drugs.

A. Mixing pills from different bottles of the same drug was shown to be misleading regarding the quantity of drugs in bottles at the pharmacy. There was no evidence, however, that the pills in such bottles did not accurately state the name and place of business of a single manufacturer, in accordance with Health and Safety Code section 111340, subdivision (a).

B. If pills from an older bottle lost potency, but the loss was concealed by the pharmacy's mixing them with pills from a newer bottle, that might be evidence of false or misleading labeling. There was no such evidence. There was no evidence indicating that mixing pills resulted in labeling that falsified the efficacy of the drugs to be dispensed from such bottles or was misleading in another significant way.

C. When pills mixed from different bottles caused an overfill, the labeling on the overfilled bottle is not the "accurate statement of the quantity of the contents" as required by Health and Safety Code section 111340, subdivision (b). However, no injury or danger was shown to result or likely to result from the overfilled bottles. There were few overfills. Under these circumstances, the overfilling was a minor violation.

D. Pills with variations in color and imprints were not shown to cause injury or danger. The variations were slight and few, observed in one bottle of Cymbalta. Under these circumstances, they were permitted reasonable variations from the requirements of Health and Safety Code section 111340, subdivision (b).

E. Broken seals were not shown to be the equivalent of labeling that was false or misleading. The bottles were properly labeled, containing the correct type and number of pills according to the manufacturer's label.

#### *Acquisition and Inventory Records*

22. Business and Professions Code section 4081 provides in pertinent part:

(a) All records of . . . acquisition, [or] receipt . . . of dangerous drugs . . . shall be at all times during business hours open to inspection by authorized officers of the law . . . . A current inventory shall be kept by every . . . pharmacy . . . holding a currently valid and unrevoked . . . permit . . . .

(b) The owner . . . of a pharmacy . . . shall be jointly responsible, with the pharmacist-in-charge . . . for maintaining the records . . . described in this section.

23. Cause exists to discipline the permit of Park West and the license of Mr. Whittemore in that the pharmacy, contrary to Business and Professions Code section 4081, subdivisions (a), failed to have proper acquisition and inventory records for 14 drugs returned to the pharmacy, as indicated in Finding 17D. Under Business and Professions Code section 4081, subdivision (b), they are jointly responsible for the missing records.

24. The missing records are a minor violation of law. Ms. Tollison took back drugs in this one instance. She intended to help the bereaved son of a long-time customer by destroying the drugs at his request. She neglected to record her conduct. There was no evidence that the lack of records or the returned drugs were likely to cause harm to a consumer or the public.

#### *Drug Compounding Self-Assessment*

25. California Code of Regulations, title 16, section 1735.2, subdivision (j), provides in pertinent part:

Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. . . . The applicable sections of the self-assessment shall subsequently be completed . . . within 30 days of the start of a new pharmacist-in-charge . . . . The primary purpose of the self-assessment is to promote compliance through self-examination and education.

26. Cause exists to discipline the license of Mr. Whittemore for his failure, as indicated in Finding 17E, to prepare a drug compounding self-assessment by July 18, 2014. As indicated in Finding 18, his self-assessment should have been available for four months, until November 18, 2014, when the pharmacy stopped compounding drugs.

27. The lack of a self-assessment is a minor violation of the Board's regulations. The pharmacy did little compounding, about two times per month, as indicated in Finding 18. There was no evidence that Mr. Whittemore or the pharmacy were likely to cause harm because of the pharmacy's compounding activity.

*Compounding Policies and Procedures*

28. California Code of Regulations, title 16, section 1735.5 provides:

(a) Any pharmacy engaged in compounding shall maintain 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. [¶] . . . [¶]

(c) The policy and procedure manual shall include the following[:] [¶] . . . [¶]

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

29. Cause exists to discipline the permit of Park West and the license of Mr. Whittemore for their failure, as indicated in Finding 17F, to document a plan for recall of certain dispensed drugs, as required by California Code of Regulations, title 16, section 1735.5, subsection (c)(2).

30. The failure to document a plan for drug recall is a relatively minor violation of the Board's regulations. Such plans apply to compounded drugs. As noted above, respondents did little compounding, about two times per month. They stopped compounding altogether in November 2014, as indicated in Finding 18. Mr. Whittemore was responsible for a plan for four months only, from July 18, 2014, when he became PIC, until November 18, 2014, when the pharmacy stopped compounding.

31. The Board is entitled to recover from Park West its reasonable costs for investigation and prosecution of this matter, pursuant to Business and Professions Code section 125.3, in the sum of \$14,193 by reason of Finding 21.

32. The Board has previously imposed the maximum discipline, revocation, against the license of respondent, Margarita Kazarian, so that no further discipline against

her is warranted, except that she should be jointly and severally liable with Park West for payment of the Board's costs of investigation and prosecution.

33. Mr. Whittemore is responsible for the lack of required documentation of different kinds during four months of 2014, as indicated in Conclusions 23, 24, 26, 27, 29, and 30. Revocation is not warranted. Mr. Whittemore's violations were minor. There was no evidence that any violation was willful. Considering these factors, and all pertinent factors set out in California Code of Regulations, title 16, section 1775.2, a citation and fine are warranted.

### ORDER

1. Pharmacy permit number PHY 46623, issued to respondent Park West Pharmacy, Inc., is revoked.

2. Respondent, Park West Pharmacy, Inc., shall pay the Board's costs of investigation and prosecution in the amount of \$14,193, in such manner as the Board may direct.

3. The accusation against respondent, Margarita Kazarian, is upheld only in so far as she is liable, jointly and severally, for payment of the Board's costs of investigation and prosecution in the amount of \$14,193.

3. The accusation against respondent, James A. Whittemore, pharmacist license number RPH 21221, is reduced to a citation. Respondent shall pay a fine of \$750 at such time and on such terms as the Board may direct.

Dated: December 30, 2015

DocuSigned by:

Thomas Lucero

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THOMAS Y. LUCERO  
Administrative Law Judge  
Office of Administrative Hearings



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7

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

10 In the Matter of the Accusation Against:

Case No. 5378

11 **PARK WEST PHARMACY, INC.;**  
12 **MARGARITA KAZARIAN, OWNER**  
13 **7230 Medical Center Drive, #106**  
14 **West Hills, CA 91307-4003**  
**Pharmacy Permit No. PHY 46623**

**A C C U S A T I O N**

15 and

16 **JERRY A. WHITTEMORE**  
17 **3300 Shelby Dr.**  
**Los Angeles, CA 90034**  
**Pharmacist License No. RPH 21221**

18 Respondents.

19  
20 Complainant alleges:

21 **PARTIES**

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

24 2. On or about May 28, 2004, the Board of Pharmacy issued Pharmacy Permit Number  
25 PHY 46623 to Park West Pharmacy, Inc.; Margarita Kazarian, sole owner, corporate officer and  
26 director. The Pharmacy Permit was in full force and effect at all times relevant to the charges  
27 brought herein and will expire on May 1, 2016, unless renewed.

28 ///

1 3. On or about July 25, 1959, the Board issued Pharmacist License No. RPH 21221 to  
2 Jerry A. Whittemore. The pharmacist license will expire on January 31, 2016, unless renewed.  
3 Respondent Whittemore has been the pharmacist-in-charge ("PIC") of Park West Pharmacy, Inc.  
4 since June 18, 2014, and at all times relevant to the charges brought herein.

5 **JURISDICTION**

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

9 5. Section 4300.1 of the Code states:

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

15 6. Section 4300 of the Code states that "[e]very license issued may be suspended or  
16 revoked."

17 7. Section 4011 of the Code states:

18 "The board shall administer and enforce this chapter and the Uniform Controlled  
19 Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code)."

20 **CALIFORNIA PHARMACY LAW**

21 8. Section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be  
22 responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining  
23 to the practice of pharmacy."

24 9. Section 4301 of the Code states:

25 "The board shall take action against any holder of a license who is guilty of unprofessional  
26 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.  
27 Unprofessional conduct shall include, but is not limited to, any of the following:  
28

...

1       "(j) The violation of any of the statutes of this state, or any other state, or of the United  
2 States regulating controlled substances and dangerous drugs.

3       ...

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

8       10.       Section 4302 provides that "[t]he board may deny, suspend, or revoke any license  
9 of a corporation where conditions exist in relation to any person holding 10 percent or more of the  
10 corporate stock of the corporation, or where conditions exist in relation to any officer or director  
11 of the corporation that would constitute grounds for disciplinary action against a licensee."

12       ...

13       11.       Section 4307 provides in pertinent part:

14       "(a) Any person who has been denied a license or whose license has been revoked or is  
15 under suspension, or who has failed to renew his or her license while it was under suspension, or  
16 who has been a manager, administrator, owner, member, officer, director, associate, or partner of  
17 any partnership, corporation, firm, or association whose application for a license has been denied  
18 or revoked, is under suspension or has been placed on probation, and while acting as the manager,  
19 administrator, owner, member, officer, director, associate, or partner had knowledge of or  
20 knowingly participated in any conduct for which the license was denied, revoked, suspended, or  
21 placed on probation, shall be prohibited from serving as a manager, administrator, owner,  
22 member, officer, director, associate, or partner of a licensee . . . ."

23       12.       Section 4081 of the Code states:

24       "(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs  
25 or dangerous devices shall be at all times during business hours open to inspection by authorized  
26 officers of the law, and shall be preserved for at least three years from the date of making. A  
27 current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary  
28 food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,

1 institution, or establishment holding a currently valid and unrevoked certificate, license, permit,  
2 registration, or exemption under Division 2 (commencing with Section 1200) of the Health and  
3 Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and  
4 Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

8 13. California Code of Regulations, title 16, section 1735.2, subdivision (j), provides:

9 "Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-  
10 charge shall complete a self-assessment for compounding pharmacies developed by the board.  
11 (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy  
12 Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) That form contains a first section  
13 applicable to all compounding, and a second section applicable to sterile injectable compounding.  
14 The first section must be completed by the pharmacist-in-charge before any compounding is  
15 performed in the pharmacy. The second section must be completed by the pharmacist-in-charge  
16 before any sterile injectable compounding is performed in the pharmacy. The applicable sections  
17 of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year,  
18 within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a  
19 new pharmacy license. The primary purpose of the self-assessment is to promote compliance  
20 through self-examination and education."

21 14. California Code of Regulations, title 16, section 1735.5 provides:.,

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

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

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

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

3 2) Documentation of a plan for recall of a dispensed compounded drug product where  
4 subsequent verification demonstrates the potential for adverse effects with continued use of  
5 a compounded drug product.

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

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

11 (5) Documentation of the methodology used to determine appropriate expiration dates  
12 for compounded drug products.”

13 **CALIFORNIA HEALTH AND SAFETY CODE**

14 15. Section 111255 of the Health and Safety Code provides:

15 “Any drug or device is adulterated if it has been produced, prepared, packed, or held under  
16 conditions whereby it may have been contaminated with filth, or whereby it may have been  
17 rendered injurious to health.”

18 16. Section 111295 of the Health and Safety Code provides:

19 “It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug  
20 or device that is adulterated.”

21 17. Section 111305 of the Health and Safety Code provides:

22 “It is unlawful for any person to receive in commerce any drug or device that is adulterated  
23 or to deliver or proffer for delivery any drug or device.”

24 18. Section 111330 of the of the Health and Safety Code provides:

25 “Any drug or device is misbranded if its labeling is false or misleading in any particular.”

26 19. Section 111340, subdivision (b), provides that a drug is misbranded unless it bears a  
27 label containing “[a]n accurate statement of the quantity of the contents in terms of weight,  
28 measure, or numerical count.”

1 20. Section 111390 of the Health and Safety Code provides:

2 "Any drug or device is misbranded if its container is so made, formed, or filled as to be  
3 misleading."

4 ~~21. Section 111395, subdivision (c) of the Health and Safety Code provides that a drug is~~  
5 ~~misbranded if "[t]he contents of the original package have been, wholly or partly, removed and~~  
6 ~~replaced with other material in the package."~~

7 22. Section 111440 of the Health and Safety Code provides:

8 "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug  
9 or device that is misbranded."

10 **DANGEROUS DRUGS**

11 23. Crestor is a prescription medication used to lower cholesterol and triglyceride levels  
12 in the blood. It is classified as a dangerous drug pursuant to Business and Professions Code  
13 section 4022.

14 24. Cymbalta is a prescription antidepressant medication. It is classified as a dangerous  
15 drug pursuant to Business and Professions Code section 4022.

16 25. Digoxin is a prescription medication used to treat atrial fibrillation and related heart  
17 rhythm problems. It is classified as a dangerous drug pursuant to Business and Professions Code  
18 section 4022.

19 26. Lexapro is a prescription antidepressant medication. It is classified as a dangerous  
20 drug pursuant to Business and Professions Code section 4022.

21 **COST RECOVERY**

22 27. Section 125.3 of the Code states, in pertinent part, that the Board may request the  
23 administrative law judge to direct a licensee found to have committed a violation or violations of  
24 the licensing act to pay a sum not to exceed the reasonable costs of the investigation and  
25 enforcement of the case.

26 ///

27 ///

28 ///

1 **BACKGROUND**

2 28. Respondent Park West Pharmacy, Inc. ("Park West" or "Respondent") is a corporate  
3 entity that holds a pharmacy permit issued by the Board. Park West is solely owned by Margarita  
4 Kazarian ("Kazarian"). Kazarian also serves as Park West's sole corporate officer and director.  
5 Kazarian is a former pharmacist whose license was revoked by the Board in an order effective  
6 November 18, 2014.<sup>1</sup> Kazarian served as the PIC of Park West from October 2007 to June 2014.

7 29. The revocation of Kazarian's pharmacist license resulted from numerous violations of  
8 state and federal law while doing business as Adams Square Pharmacy ("Adams Square").  
9 Among other things, those violations included selling and/or holding for sale counterfeit drugs,  
10 adulterated drugs and misbranded drugs, engaging in dishonest acts and subverting the Board's  
11 investigation into that misconduct. Specifically, the Board's case showed that Adams Square  
12 obtained a variety of pharmaceutical tablets, including counterfeit product, from unknown sources  
13 and then placed those medications inside authentic manufacturer containers which bore lot  
14 numbers and expiration dates that had no actual relation to the tablets themselves. Adams  
15 Square's pharmacy permit and Kazarian's pharmacist license were both revoked by the Board as  
16 a result of these and other violations.

17 **INSPECTIONS OF PARK WEST**

18 30. On November 15, 2013, the Board conducted an inspection of Park West, during  
19 which Board inspectors found that Park West was engaged in drug compounding activities  
20 without completing a compounding self-assessment or maintaining policies and procedures for  
21 compounding as required by state law. Thereafter, on December 11 and 12, 2014, the Board  
22 conducted additional inspections of Park West, during which Board inspectors found that Park  
23 West continued to be engaged in drug compounding activities in violation of state law in that its  
24 compounding policies and procedures were incomplete and it had not completed a compounding  
25 self-assessment following a change in the designation of its PIC. During the December 2014

26 \_\_\_\_\_  
27 <sup>1</sup> *In the Matter of the Accusation Against Adams Square Pharmacy; Margarita Kazarian, et al.*  
28 (Case No. 5189; OAH No. 2014050753).

1 inspections, the Board also discovered a variety of additional violations of law involving  
2 misbranded and adulterated drugs. Specifically, Board inspectors documented multiple instances  
3 in which manufacturer containers found on Park West's shelves contained tablets that bore no  
4 actual relation to the container or the identifying information contained thereon, including: (1) a  
5 60-capsule manufacturer bottle of Cymbalta 20 mg that contained 161 capsules, many of which  
6 exhibited color and imprint variations; (2) a 100-tablet manufacturer bottle of Digoxin 125 mcg  
7 that contained 120 capsules; (3) a 90-tablet manufacturer bottle of Crestor 5 mg that contained  
8 105 tablets; and (4) a 100-tablet manufacturer bottle of Lexapro 10 mg that contained 105 tablets.

9 **FIRST CAUSE FOR DISCIPLINE**

10 **(Prohibited Corporate Ownership and Governance)**

11 31. Respondent Park West is subject to disciplinary action under section 4301,  
12 subdivision (o), in conjunction with section 4307, subdivision (a), in that Park West is operating  
13 with an owner, officer and/or director who is prohibited from serving in any one of those  
14 capacities. Complainant refers to, and by this reference incorporates, the allegations set forth  
15 above in paragraphs 28 and 29, inclusive, as though set forth fully herein.

16 **SECOND CAUSE FOR DISCIPLINE**

17 **(Misconduct by Owner and/or Corporate Officer)**

18 32. Respondent Park West is subject to disciplinary action under section 4302 in that a  
19 corporate officer, director and/or person holding 10 percent or more of Park West's corporate  
20 stock engaged in conduct that constitutes grounds for disciplinary action. Complainant refers to,  
21 and by this reference incorporates, the allegations set forth above in paragraphs 28 and 29,  
22 inclusive, as though set forth fully herein.

23 **THIRD CAUSE FOR DISCIPLINE**

24 **(Adulterated Drugs)**

25 33. Respondent Park West and respondent Whittemore (collectively, "Respondents") are  
26 subject to disciplinary action under section 4301, subdivision (j), in conjunction with section  
27 4113, subdivision (c), and Health and Safety Code sections 111255, 111295 and 111305, in that  
28 Respondents received adulterated drugs in commerce and/or held or offered adulterated drugs for



1 sale. Complainant refers to, and by this reference incorporates, the allegations set forth above in  
2 paragraph 30, inclusive, as though set forth fully herein.

3 **FOURTH CAUSE FOR DISCIPLINE**

4 **(Misbranded Drugs)**

5 34. Respondents are subject to disciplinary action under section 4301, subdivision (j), in  
6 conjunction with section 4113, subdivision (c), and Health and Safety Code sections 111330,  
7 111340, subdivision (b), 111390, 111395, subdivision (c), and 111440 in that Respondents held  
8 and/or offered for sale misbranded drugs. Complainant refers to, and by this reference  
9 incorporates, the allegations set forth above in paragraph 30, inclusive, as though set forth fully  
10 herein.

11 **FIFTH CAUSE FOR DISCIPLINE**

12 **(Acquisition & Inventory Records Violation)**

13 35. Respondents are subject to disciplinary action under section 4301, subdivision (o), in  
14 conjunction with section 4113, subdivision (c), in that Respondents failed to maintain acquisition  
15 and inventory records in compliance with section 4081. Complainant refers to, and by this  
16 reference incorporates, the allegations set forth above in paragraph 30, inclusive, as though set  
17 forth fully herein.

18 **SIXTH CAUSE FOR DISCIPLINE**

19 **(Drug Compounding Self-Assessment Violation)**

20 36. Respondents are subject to disciplinary action under section 4301, subdivision (o), in  
21 conjunction with California Code of Regulations, title 16, section 1735.2, subdivision (j), in that  
22 Respondent engaged in drug compounding activities without completing a compounding self-  
23 assessment as required by state law. Complainant refers to, and by this reference incorporates,  
24 the allegations set forth above in paragraph 30, inclusive, as though set forth fully herein.

25 **SEVENTH CAUSE FOR DISCIPLINE**

26 **(Drug Compounding Policy & Procedures Violation)**

27 37. Respondents are subject to disciplinary action under section 4301, subdivision (o), in  
28 conjunction with California Code of Regulations, title 16, section 1735.5, in that Respondent

1 engaged in drug compounding activities without having drug compounding policies and  
2 procedures in place as required by state law. Complainant refers to, and by this reference  
3 incorporates, the allegations set forth above in paragraph 30, inclusive, as though set forth fully  
4 herein.

5 **PRAYER**

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

8 1. Revoking or suspending Pharmacy Permit Number PHY 46623, issued to Park West  
9 Pharmacy, Inc.;

10 2. Revoking or suspending Pharmacist License No. RPH 21221, issued to Jerry A.  
11 Whittemore;

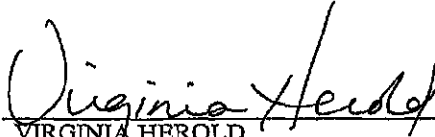
12 3. Ordering Park West Pharmacy, Inc. and Jerry A. Whittemore to pay the Board of  
13 Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to  
14 Business and Professions Code section 125.3;

15 4. Ordering that Margarita Kazarian is prohibited from serving as a manager,  
16 administrator, owner, member, officer, director, associate, or partner of a licensed pharmacy  
17 pursuant to Business and Professions Code section 4307;

18 5. Ordering that any transfer of Park West Pharmacy Inc.'s pharmaceutical inventory be  
19 subject to Board oversight and that any misbranded, adulterated or otherwise illicit  
20 pharmaceuticals contained in that inventory be destroyed;

21 6. Taking such other and further action as deemed necessary and proper.  
22

23  
24 DATED: 4/24/15

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

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