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

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| In the Matter of the Accusation Against:<br><br>**KENNETH ROAD PHARMACY, INC., MARGARITA KAZARIAN**, Owner,<br>Pharmacy Permit No. PHY 50214,<br><br>And<br><br>**ROBERT S. LIPP,**<br>Pharmacist License No. RPH 32284,<br><br>Respondents. | Case No. 5377<br><br>OAH No. 2015051030 |

## DECISION AFTER REJECTION OF PROPOSED DECISION

Thomas Y. Lucero, Administrative Law Judge (ALJ), Office of Administrative Hearings, State of California, heard these consolidated matters on December 1, 2, and 3, 2015, in Los Angeles[1]. This decision pertains to the accusation against respondents Kenneth Road Pharmacy, Inc., Margarita Kazarian, and Robert S. Lipp, board case number 5377.

Complainant was represented by William D. Gardner, Deputy Attorney General. Respondents, Kenneth Road Pharmacy, Inc., Margarita Kazarian, and Robert S. Lipp, were represented by Paul. L. Cass, attorney at law. Oral and documentary evidence was received. The record was closed and the matter was submitted 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 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.

[1] For purposes of the hearing, this matter was consolidated with the *Matter of the Accusation against Park West Pharmacy, Inc., Margarita Kazarian, Owner (PHY 46623), and Jerry A. Whittemore (RPH 21221),* board case number 5378, OAH No. 2015051032.

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. A. 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.

B. The accusation in this matter was amended by interlineation so that the reference to "paragraphs 18 and 19," which appears twice on page 7, at line 20 and lines 26 through 27, was amended to "paragraphs 31 and 32," and the reference to "paragraphs 20 and 21," which appears twice on page 8, at lines 8 and 15, was amended to "paragraphs 33 and 34."

*Licenses*

2. On May 4, 2010, the Board issued permit no. PHY 50214 to respondent Kenneth Road Pharmacy, Inc. (Kenneth Road), which operates a pharmacy in Glendale, 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 which any investigation of, or action or disciplinary proceeding against, the licensee...." (Business and Professions Code section 4300.1)

5. On August 9, 1978, the Board issued respondent Robert S. Lipp original pharmacist license no. RPH 32284, which was set to expire on April 30, 2016, unless renewed.

6. Since May 4, 2010, Mr. Lipp has been the Pharmacist-in-Charge (PJC) at Kenneth Road.

7. Starting May 4, 2010, Ms. Kazarian was the 100 percent shareholder, Director, Chief Executive Officer, President; Secretary, and Treasurer of Kenneth Road. On November 30, 2015, the day before the hearing, Ms. Kazarian closed escrow on an agreement to sell all stock in Kenneth Road and to resign from being any sort of officer of the company, as described in more detail below.

*Pharmacy Sale Agreement*

8. Following revocation of her pharmacist license, Ms. Kazarian sought to sell Kenneth Road. 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 are in excess of $5,000 per month. The pharmacy's drug inventory is valued in the six figures. Six 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 Kenneth Road closed on November 30, 2015.[2] The named purchaser was Julia Perez, who holds pharmacy technician license, no. TCH 25887. She is currently employed at Kenneth Road. She was previously employed for over a decade by another pharmacy, now closed, also owned by Ms. Kazarian.

A. Under the purchase agreement, Ms. Perez is to pay Ms. Kazarian $825,000. Of the purchase price, $575,000 is allocated to corporate stock and business assets. Inventory was separately valued at $250,000. Under a promissory note, Ms. Perez is to make payment in 48 monthly installments of $20,000, including interest at four percent, from January 1, 2016 through December 1, 2019. The debt may be repaid sooner without penalty. (Exhibit B.)

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

11. The agreement 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.

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[2] Escrow instructions and escrow-related documents, such as documentation of due diligence, were not in evidence.

[3] 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. 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.

13. 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 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 [Kenneth Road]. Maker agrees to properly use and maintain the Collateral and maintain insurance of a type and in amounts agreeable to Payee [Ms. Kazarian]. ...

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 Kenneth Road and Park West. With this authority, she has signed checks on Kenneth Road's corporate account since the November 30, 2015, for payroll and payment of rent. She has no other duties or involvement in pharmacy operations.

*Investigation*

15. Sarah Bayley, Pharm.D., worked for some years in retail pharmacy. She has been an inspector for the Board since 2000. She testified to leading the investigation of Kenneth Road during two visits, on November 26, 2013 and December 11, 2014. Mr. Lipp was present and cooperative on both visits. Ms. Bayley's Investigation Report, Exhibit 18, discusses several drugs she 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). The report summarizes several irregularities Ms. Bayley found.

A. Small color variations among pills[4] were found in several bottles with these drugs: Diovan, Cymbalta, Crestor, Afeditab, and Namenda[5]. One pill's coating was slightly chipped. Inspector Bayley showed Mr. Lipp the pills in one such container and he agreed that they varied in color. Mr. Lipp could see the chipping on one pill only with a magnifying glass.

B. There were imprint variations. Imprints are characters manufacturers stamp on pills. The pills' variations in the darkness of the imprints were found in one bottle each of these drugs: acorvastatin, Aciphex, Afeditab, Crestor, Cymbalta, and moxifloxacin. Ms. Bayley saw on the moxifloxacin pills that the imprints were worn and difficult to read. On some pills imprints varied along with a pill's color, so that some imprints and the color surrounding them varied from other pills in darkness or color saturation. In the bottle of atorvastatin pills, as shown by the photograph in Exhibit 26, the imprints of two different manufacturers were found.

C. As indicated in Exhibits 22 and 23, some bottles were overfilled. That is, the manufacturer's label indicated that a full bottle contained a specified number of pills, but when counted the pills were more than the specified number. Mr. Lipp helped to count the pills. The overfills were:

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| Diovan: | one bottle with 120 pills, instead of 90 per the label |
| Crestor: | one bottle with 92 pills, instead of 90 per the label |
| fenofibrate: | one bottle with 108 pills, instead of 90 per the label |
| Trilipix: | one bottle with 125 pills, instead of 90 per the label |
| Trilipix: | one bottle with 124 pills, instead of 90 per the label. |

D. Seals on one bottle each of Notriptyline and Lyrica were broken, though the bottles had the correct number of pills according to manufacturers' labels.

16. Exhibits 25 and 26 include photographs of some of the pill conditions discussed in the Investigation Report. The photographs were taken by Ms. Bayley with her cell phone camera under whatever ambient indoor light was available at the pharmacy. Some color and imprint variations to which Ms. Bayley testified are evident in the photographs; some are not.

17. Ms. Bayley testified that the irregularities she observed indicate misbranding and adulteration.

A. As a rule, color variations are not seen in pills sealed in a single bottle by the manufacturer. 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.

B. Imprint variations, like color variations, indicate that pills come from different bottles. Pills with imprints that are difficult to read or with chipping are older than those that do not display these variations or they have been handled more roughly than others in the bottle. She testified that the inference is that the pharmacy may have allowed exposure of such pills to impurities and adulteration.

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[4] The term "pill" used in this Proposed Decision is interchangeable with similar terms, such as capsules and tablets, to which the Board's evidence at times refers.

[5] Trade names are capitalized, generic drug's names are not.

C. 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[6].

D. 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.

18. Mr. Lipp testified that pills from different bottles may be mixed by accident. A prescription may call for dispensing 30 pills. The person filling such a prescription finds an open bottle of the drug and believes mistakenly that it contains fewer than 30 pills. The person therefore opens a second bottle and mixes in the pills from the first bottle before dispensing 30 pills. That leaves the second bottle not just with mixed pills, but also overfilled. Mr. Lipp acknowledged that such an accident should not happen under good pharmacy practice.

19. At the December 12, 2014, investigation, Mr. Lipp gave Ms. Bayley another explanation for overfilled bottles. He said that his staff may have simply combined the contents of different bottles into one. Ms. Bayley stated that that was an unacceptable practice. Mr. Lipp agreed. (Exhibit 23.)

20. Ms. Bayley sent the contents of several bottles she took from Kenneth Road during her investigation to the Federal Drug Administration (FDA) for testing, to discover whether the drug might be adulterated, counterfeit, or otherwise illegal. The FDA has not issued the results of any tests or examination of the drugs. Some weeks after she sent the drugs, Ms. Bayley asked the FDA when testing might be performed, but obtained no useful information.

21. 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 that, because Kenneth Road (and Park West) were owned by Ms. Kazarian, respondents were in violation of the law against a licensee's ownership by a

[6] 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.*

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.

22. As indicated in Exhibit 4, the complainant incurred reasonable prosecution costs of $9,560. In addition, the complainant claims costs of investigation totaling $15,900. The investigation costs are excessive. The complainant's investigation of Kenneth Road was very similar to that of Park West. The investigation of Park West included issues relating to drug compounding that were not issues at Kenneth Road. The costs claimed for the investigation of Park West are $4,293.50. No details were provided that would help to account for the large discrepancy between the two claims for investigation costs. In the circumstances, the costs for the investigation of Kenneth Road should be reduced to a figure comparable and somewhat less than that relating to Park West, that is, $4,000. Thus reasonable costs for prosecution and investigation total $13,560.

## LEGAL CONCLUSIONS

1. Pharmacies and pharmacists must be licensed by the Board of Pharmacy. The Board of Pharmacy 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 of Pharmacy 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.4th 911, 916-917; *San Benito Foods v Veneman* (1996) 50 Cal.App.4th 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 permitholder or service by certified mail, return receipt requested, at the permitholder'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 permitholder 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 Kenneth Road. 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 13.

B. Ms. Kazarian's handling of payroll and lease payments after the November 30, 2015, close of escrow, as indicated in Finding 14, constitutes improper ongoing management and control. In consequence of the revocation of Ms. Kazarian's license, she and Kenneth Road 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 Kenneth Road by reason of Ms. Kazarian's improper ownership. Under section 4301, subdivision (o), both Kenneth Road and Ms. Kazarian are in violation of the prohibition in section 4307 on her management of the pharmacies. The appropriate consequence of these violations is revocation.

12. Ms. Kazarian and Kenneth Road 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 provided respondents statutory notice. The petition was written. It was sent to Kenneth Road's address of record. It referred to the revocation of Ms. Kazarian's license and the resulting impropriety of her owning Kenneth Road under Business

and Professions Code section 4307 and 4308. 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 of Kenneth Road's pharmacy permit is appropriate in these circumstances.

*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 Kenneth Road and the PIC, Mr. Lipp, based on Factual Findings 15-17, in that the evidence established that drugs at Kenneth Road 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 Kenneth Road and the PIC, Mr. Lipp, 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. At least one bottle 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 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 means a label affirmatively stating that the pills had a particular expiration date, when that could not be demonstrated, is misleading.

C. When pills were mixed from different bottles and were overfilled, 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).

E. Broken seals, in this case, were not shown to be the equivalent of labeling that was false or misleading.

24. The Board is entitled to recover its reasonable costs from Kenneth Road for investigation and prosecution of this matter, pursuant to Business and Professions Code section 125.3, in the sum of $13,560 by reason of Finding 22.

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

26. Cause exists for discipline, however, revocation of the license of respondent Robert S. Lipp is not warranted. Mr. Lipp's violations of law were minor, but still warrant actual discipline because of the condition of the pills found, as well as the number of overfilled bottles and the quantities by which bottle was overfilled, suggests that this was not an accident, but rather a practice that he regularly allowed in the pharmacy. Mr. Lipp was, however, cooperative in the Board's investigation. Considering these factors, and all pertinent factors set out in California Code of Regulations, title 16, section 1775.2, public reproval is the appropriate level of discipline against his license.

## ORDER

1. Pharmacy permit number PHY 50214, issued to respondent, Kenneth Road 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, Kenneth Road Pharmacy, Inc., shall pay the Board's costs of investigation and prosecution in the amount of $13,560, in such manner as the Board may direct.

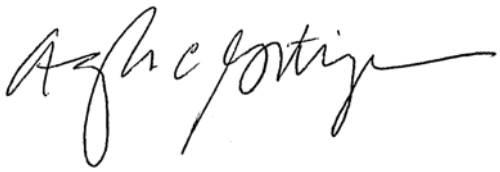
3. The accusation against respondent, Margarita Kazarian, is upheld only in so far as she is liable, jointly and severally, for payment of the Board's costs of investigation and prosecution in the amount of $13,560.

4. Respondent, Robert S. Lipp, pharmacist license number RPH 32284, is hereby publicly reproved. Respondent is required to report this reproval 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 _____
Amy Gutierrez, Pharm.D.
Board President

BEFORE THE
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| In the Matter of the Accusation Against:<br><br>KENNETH ROAD PHARMACY, INC.:<br>MARGARITA KAZARIAN, OWNER,<br>Pharmacy Permit No. PHY 50214,<br><br>and<br><br>ROBERT S. LIPP,<br>Pharmacist License No. RPH 32284,<br><br>Respondents.<br><br>In the Matter of the Accusation Against:<br><br>PARK WEST PHARMACY, INC.:<br>MARGARITA KAZARIAN, OWNER,<br>Pharmacy Permit No. PHY 46623,<br><br>and<br><br>JERRY A. WHITTEMORE,<br>Pharmacist License No. RPH 21221,<br><br>Respondents. | Case Nos. 5377<br>5378<br><br>OAH Nos. 2015051030<br>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[1] 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 13th day of May, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

[1] Complainant's admitted exhibits are part of the record.

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

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|---|---|
| In the Matter of the Accusation Against:<br><br>KENNETH ROAD PHARMACY, INC.:<br>MARGARITA KAZARIAN, OWNER,<br>Pharmacy Permit No. PHY 50214,<br><br>and<br><br>ROBERT S. LIPP,<br>Pharmacist License No. RPH 32284,<br><br>Respondents.<br><br>In the Matter of the Accusation Against:<br><br>PARK WEST PHARMACY, INC.:<br>MARGARITA KAZARIAN, OWNER,<br>Pharmacy Permit No. PHY 46623,<br><br>and<br><br>JERRY A. WHITTEMORE,<br>Pharmacist License No. RPH 21221,<br><br>Respondents. | Case No. 5377<br><br>OAH No. 2015051030 |

**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

By 

Amy Gutierrez, Pharm.D.
Board President

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

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|---|---|
| In the Matter of the Accusation Against:<br><br>KENNETH ROAD PHARMACY, INC.;<br>MARGARITA KAZARIAN, OWNER,<br>Pharmacy Permit No. PHY 50214,<br><br>and<br><br>ROBERT S. LIPP,<br>Pharmacist License No. RPH 32284,<br><br>Respondents. | Case Nos. 5377<br>5378<br><br>OAH Nos. 2015051030<br>2015051032 |
| In the Matter of the Accusation Against:<br><br>PARK WEST PHARMACY, INC.;<br>MARGARITA KAZARIAN, OWNER,<br>Pharmacy Permit No. PHY 46623,<br><br>and<br><br>JERRY A. WHITTEMORE,<br>Pharmacist License No. RPH 21221,<br><br>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 Kenneth Road Pharmacy, Inc., Margarita Kazarian, and Robert S. Lipp, case number 5377.

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

Respondents, Kenneth Road Pharmacy, Inc., Margarita Kazarian, and Robert S. Lipp, were represented by Paul L. Cass, attorney at law.

The accusation in this matter was amended by interlineation so that the reference to "paragraphs 18 and 19," which appears twice on page 7, at line 20 and lines 26 through 27, was amended to "paragraphs 31 and 32," and the reference to "paragraphs 20 and 21," which appears twice on page 8, at lines 8 and 15, was amended to "paragraphs 33 and 34."

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 prosecution of and investigation in 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 4, 2010, the Board issued permit no. PHY 50214 to respondent Kenneth Road Pharmacy, Inc. (Kenneth Road), which operates a pharmacy in Glendale, 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 August 9, 1978, the Board issued respondent Robert S. Lipp original pharmacist license no. RPH 32284, which is set to expire on April 30, 2016.

6. Since May 4, 2010, Mr. Lipp has been the Pharmacist-in-Charge (PIC) at Kenneth Road.

7. Starting May 4, 2010, Ms. Kazarian was the 100 percent shareholder, Director, Chief Executive Officer, President, Secretary, and Treasurer of Kenneth Road. On November 30, 2015, the day before the hearing, Ms. Kazarian closed escrow on an agreement to sell all stock in Kenneth Road and to resign from being any sort of officer of the company, as described in more detail below.

*Pharmacy Sale Agreement*

8. Following revocation of her pharmacist license, Ms. Kazarian sought to sell Kenneth Road. 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. Six 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 Kenneth Road closed on November 30, 2015.[1] The named purchaser was Julia Perez, who holds pharmacy technician license, no. TCH 25887. She is currently employed at Kenneth Road. She was previously employed for over a decade by another pharmacy, now closed, also owned by Ms. Kazarian.

A. Under the purchase agreement, Ms. Perez is to pay Ms. Kazarian $825,000. $575,000 is allocated to corporate stock and business assets. Inventory was separately valued at $250,000. Under a promissory note, Ms. Perez is to make payment in 48 monthly installments of $20,000, including interest at four percent, from January 1, 2016 through December 1, 2019. The debt may be repaid sooner without penalty. (Exhibit B.)

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

[1] Escrow instructions and escrow-related documents, such as documentation of due diligence, were not in evidence.

agreement relating to Kenneth Road in no significant way, except that different dollar figures were used. (Exhibit A.)[2]

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. 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.

13. 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 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 [Kenneth Road]. Maker agrees to properly use and maintain the Collateral and maintain insurance of a type and in amounts agreeable to Payee [Ms. Kazarian]. . . .

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

[2] 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.

of Kenneth Road and Park West. With this authority, she has signed checks on Kenneth Road's corporate account since the November 30, 2015 for payroll payment of rent. She has no other duties or involvement in pharmacy operations.

*Investigation*

15. Sarah Bayley, Pharm.D., worked for some years in retail pharmacy. She has been an inspector for the Board since 2000. She testified to leading the investigation of Kenneth Road during two visits, on November 26, 2013 and December 11, 2014. Mr. Lipp was present and cooperative on both visits. Ms. Bayley's Investigation Report, Exhibit 18, discusses several drugs she 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). The report summarizes several irregularities Ms. Bayley found.

A. Small color variations among pills[3] were found in several bottles with these drugs: Diovan, Cymbalta, Crestor, Afeditab, and Namenda.[4] One pill's coating was slightly chipped. Investigator Bayley showed Mr. Lipp the pills in one such container and he agreed that they varied in color. Mr. Lipp could see the chipping on one pill only with a magnifying glass.

B. There were imprint variations. Imprints are characters manufacturers stamp on pills. The pills' variations in the darkness of the imprints were found in one bottle each of these drugs: atorvastatin, Aciphex, Afeditab, Crestor, Cymbalta, and moxifloxacin. Ms. Bayley saw on the moxifloxacin pills that the imprints were worn and difficult to read. On some pills, imprints varied along with a pill's color, so that some imprints and the color surrounding them varied from other pills in darkness or color saturation. In the bottle of atorvastatin pills, as shown by the photograph in Exhibit 26, the imprints of two different manufacturers were found.

C. As indicated in Exhibits 22 and 23, some bottles were overfilled. That is, the manufacturer's label indicated that a full bottle contained a specified number of pills, but when counted the pills were more than the specified number. Mr. Lipp helped to count the pills. The overfills were:

| | |
|---|---|
| Diovan: | one bottle with 120 pills, instead of 90 per the label |
| Crestor: | one bottle with 92 pills, instead of 90 per the label |
| fenofibrate: | one bottle with 108 pills, instead of 90 per the label |
| Trilipix: | one bottle with 125 pills, instead of 90 per the label |

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[3] 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.

[4] Trade names are capitalized, generic drugs' names are not.

Trilipix: one bottle with 124 pills, instead of 90 per the label.

D. Seals on one bottle each of Notriptyline and Lyrica were broken, though the bottles had the correct number of pills according to manufacturers' labels.

16. Exhibits 25 and 26 include photographs of some of the pill conditions discussed in the Investigation Report. The photographs were taken by Ms. Bayley with her cell phone camera under whatever ambient indoor light was available at the pharmacy. Some color and imprint variations to which Ms. Bayley testified are evident in the photographs; some are not.

17. Ms. Bayley testified that the irregularities she observed indicate misbranding and adulteration.

A. As a rule, color variations are not seen in pills sealed in a single bottle by the manufacturer. 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.

B. Imprint variations, like color variations, indicate that pills come from different bottles. Pills with imprints that are difficult to read or with chipping are older than those that do not display these variations or they have been handled more roughly than others in the bottle. She testified that the inference is that the pharmacy may have allowed exposure of such pills to impurities and adulteration.

C. Overfilling a bottle, like mixing pills from more than one bottle, destroys a pharmacist's ability to match pills to quantity information on labels.

D. 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.

18. Mr. Lipp testified that pills from different bottles may be mixed by accident. A prescription may call for dispensing 30 pills. The person filling such a prescription finds an open bottle of the drug and believes mistakenly that it contains fewer than 30 pills. The person therefore opens a second bottle and mixes in the pills from the first bottle before dispensing 30 pills. That leaves the second bottle not just with mixed pills, but also overfilled. Mr. Lipp acknowledged that such an accident should not happen under good pharmacy practice.

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19. At the December 12, 2014 investigation, Mr. Lipp gave Ms. Bayley another explanation for overfilled bottles. He said that his staff may have simply combined the contents of different bottles into one. Ms. Bayley stated that that was an unacceptable practice. Mr. Lipp agreed. (Exhibit 23.)

20. Ms. Bayley sent the contents of several bottles she took from Kenneth Road during her investigation to the Federal Drug Administration (FDA) for testing, to discover whether the drugs might be adulterated, counterfeit, or otherwise illegal. The FDA has not issued the results of any tests or examination of the drugs. Some weeks after she sent the drugs, Ms. Bayley asked the FDA when testing might be performed, but obtained no useful information.

21. 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 that, because Kenneth Road (and Park West) 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.

22. As indicated in Exhibit 4, the Board incurred reasonable prosecution costs of $9,560. In addition, the Board claims costs of investigation totaling $15,900. The investigation costs are excessive. The Board's investigation of Kenneth Road was very similar to that of Park West. The investigation of Park West included issues relating to drug compounding that were not issues at Kenneth Road. The costs claimed for the investigation of Park West are $4,293.50. No details were provided that would help to account for the large discrepancy between the two claims for investigation costs. In the circumstances, the costs for the investigation of Kenneth Road should be reduced to a figure comparable and somewhat less than that relating to Park West, that is, $4,000. Thus reasonable costs for prosecution and investigation total $13,560.

## 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 Kenneth Road.

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*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.

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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 permitholder or service by certified mail, return receipt requested, at the permitholder'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 permitholder 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 Kenneth Road. 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 indicated in Finding 13.

B. Ms. Kazarian's handling payroll and lease payments after the November 30, 2015 close of escrow, as indicated in Finding 14, constitutes improper ongoing management and control. In consequence of the revocation of Ms. Kazarian's license, she and Kenneth Road 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 Kenneth Road by reason of Ms. Kazarian's improper ownership. Under section 4301, subdivision (o), both Kenneth Road and Ms. Kazarian are in violation of the prohibition in section 4307 on her management of the pharmacies.

10. Ms. Kazarian and Kenneth Road 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 provided respondents statutory notice. The petition was written. It was sent to Kenneth Road's address of record. It referred to the revocation of Ms. Kazarian's license and the resulting impropriety of her owning Kenneth Road under Business and Professions Code section 4307 and 4308. 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, including revocation. Revocation of Kenneth Road's pharmacy permit is appropriate in these circumstances.

*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.

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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 Kenneth Road were adulterated.

A. The irregularities in pills, in their color and imprints, which Ms. Bayley observed at Kenneth Road, were 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.

B. Likewise 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 foreign elements or the like.

C. The results of testing of the pharmacy's drugs by the FDA, which might or might not indicate adulteration, were not available at the time of hearing.

*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 license of Kenneth Road and the PIC, Mr. Lipp, 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 further 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 any other 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, given that no injury or danger was shown to result or likely to result, the overfilling was a minor violation.

D. Pills with irregularities, in color, imprints, and chipping, were not shown to cause injury or danger. In these circumstances, they are 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.

22. The Board is entitled to recover its reasonable costs from Kenneth Road for investigation and prosecution of this matter, pursuant to Business and Professions Code section 125.3, in the sum of 13,560 by reason of Finding 22.

23. 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 Kenneth Road for payment of the Board's costs of investigation and prosecution.

24. Revocation of the license of respondent, Robert S. Lipp is not warranted. It was not established that his conduct as a PIC endangers public health, safety, or welfare. Mr. Lipp's violations of law were minor. He was cooperative in the Board's investigation. Considering these factors, and all pertinent factors set out in California Code of Regulations, title 16, section 1775.2, a citation and fine are appropriate.

## ORDER

1. The pharmacy permit, number PHY 50214, of respondent, Kenneth Road Pharmacy, Inc., is revoked.

2. Respondent, Kenneth Road Pharmacy, Inc., shall pay the Board's costs of investigation and prosecution in the amount of $13,560, 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 $13,560.

4. The accusation against respondent, Robert S. Lipp, pharmacist license number RPH 32284, 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

THOMAS Y. LUCERO
Administrative Law Judge
Office of Administrative Hearings

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

| | |
|---|---|
| In the Matter of the Accusation Against:<br><br>**KENNETH ROAD PHARMACY, INC.;**<br>**MARGARITA KAZARIAN, OWNER**<br>**1400 W. Kenneth Road**<br>**Glendale, CA 91201**<br>**Pharmacy Permit No. PHY 50214**<br><br>**and**<br><br>**ROBERT S. LIPP**<br>**9332 Crystal View Dr.**<br>**Tujunga, CA 91042**<br>**Pharmacist License No. RPH 32284**<br><br>Respondents. | Case No. 5377<br><br>**A C C U S A T I O N** |

Complainant alleges:

## PARTIES

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

2. On or about May 4, 2010, the Board of Pharmacy issued Pharmacy Permit Number PHY 50214 to Kenneth Road Pharmacy, Inc.; Margarita Kazarian, sole owner, corporate officer and director. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on May 1, 2016, unless renewed.

3. On or about August 9, 1978, the Board issued Pharmacist License No. RPH 32284 to Robert S. Lipp. The pharmacist license will expire on April 30, 2016, unless renewed. Robert S. Lipp has been the pharmacist-in-charge ("PIC") of Kenneth Road Pharmacy, Inc. since May 4, 2010, and at all times relevant to the charges brought herein.

**JURISDICTION**

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

5. Section 4300.1 of the Code states:

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

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

7. Section 4011 of the Code states:

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

**CALIFORNIA PHARMACY LAW**

8. Section 4113, subdivision (c), states that "[t]he 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."

9. Section 4301 of the Code states:

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

. . .

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

. . .

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

10. Section 4302 provides that "[t]he 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."

. . .

11. Section 4307 provides in pertinent part:

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

**CALIFORNIA HEALTH AND SAFETY CODE**

12. Section 111255 of the Health and Safety Code 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."

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13. Section 111295 of the Health and Safety Code provides:

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

14. Section 111305 of the Health and Safety Code 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 drug or device."

15. Section 111330 of the of the Health and Safety Code provides:

"Any drug or device is misbranded if its labeling is false or misleading in any particular."

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

17. Section 111390 of the Health and Safety Code provides:

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

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

19. Section 111440 of the Health and Safety Code provides:

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

**COST RECOVERY**

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

**DANGEROUS DRUGS**

21. Aciphex is a prescription medication used to treat acid reflux. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

22. Afeditab is a prescription blood pressure medication. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

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

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

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

26. Diovan is a prescription blood pressure medication. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

27. Fenofibrate is a prescription medication used to lower cholesterol and triglyceride levels in the blood. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

28. Moxifloxacin is a prescription antibiotic. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

29. Namenda is a prescription medication used to treat patients with dementia and memory loss related to Alzheimer's disease. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

30. Trilipix is a prescription medication used to lower cholesterol and triglyceride levels in the blood. It is classified as a dangerous drug pursuant to Business and Professions Code section 4022.

## BACKGROUND

31. Respondent Kenneth Road Pharmacy, Inc. ("Kenneth Road" or "Respondent") is a corporate entity that holds a pharmacy permit issued by the Board. Kenneth Road is solely owned by Margarita Kazarian ("Kazarian"). Kazarian also serves as Kenneth Road's sole

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corporate officer and director. Kazarian is a former pharmacist whose license was revoked by the Board in an order effective November 18, 2014.[1]

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

**INSPECTION OF KENNETH ROAD**

33. On November 26, 2013, the Board conducted an inspection of Kenneth Road, during which Board inspectors discovered violations of law involving misbranded and adulterated drugs. Specifically, Board inspectors documented multiple instances in which manufacturer containers found on Kenneth Road's shelves contained tablets that bore no actual relation to the container or the identifying information contained thereon, including: (1) a 90-tablet manufacturer bottle of Diovan that contained 120 tablets; (2) a 90-tablet manufacturer bottle of Crestor that contained 92 tablets; (3) an open manufacturer bottle of Aciphex containing tablets that were not uniform and exhibited imprint variations; (4) an open manufacturer bottle of Namenda containing tablets that exhibited color variations; (5) an open manufacturer bottle of Cymbalta containing tablets that exhibited both color and imprint variations; and (6) an open manufacturer bottle of Afeditab containing tablets that exhibited variations in color and imprint. In addition, the inspectors found an amber vial containing 206 tablets with a handwritten label reading "Atorvastatin 20 mg Exp

[1] *In the Matter of the Accusation Against Adams Square Pharmacy; Margarita Kazarian, et al.* (Case No. 5189; OAH No. 2014050753).

09/14." that contained a mixture of two different generic versions of atorvastatin (brand name "Lipitor"), one manufactured by the Apotex corporation and one manufactured by Mylan Pharmaceuticals.

34. On December 11, 2014, the Board conducted another inspection of Kenneth Road, which revealed additional violations of law involving misbranded and adulterated drugs. Specifically, Board inspectors again documented multiple instances in which manufacturer containers found on Kenneth Road's shelves contained tablets that bore no actual relation to the container or the identifying information contained thereon, including: (1) an open 90-tablet manufacturer bottle of Trilipix 135 mg that contained 125 tablets; (2) another open 90-tablet manufacturer bottle of Trilipix 135 mg that contained 124 tablets; (3) an open 90-tablet manufacturer bottle of fenofibrate 145 mg that contained 108 tablets; (4) and an open manufacturer container of moxifloxacin 400 mg that contained tablets that were not uniform and exhibited different degrees of age and wear.

**FIRST CAUSE FOR DISCIPLINE**

**(Prohibited Corporate Ownership and Governance )**

35. Respondent Kenneth Road is subject to disciplinary action under section 4301, subdivision (o), in conjunction with section 4307, subdivision (a), in that Kenneth Road is operating with an owner, officer and/or director who is prohibited from serving in any one of those capacities. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 18 and 19, inclusive, as though set forth fully herein.

**SECOND CAUSE FOR DISCIPLINE**

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

36. Respondent Kenneth Road is subject to disciplinary action under section 4302 in that a corporate officer, director and/or person holding 10 percent or more of Kenneth Road's corporate stock engaged in conduct that constitutes grounds for disciplinary action. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 16 and 17, inclusive, as though set forth fully herein.

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## THIRD CAUSE FOR DISCIPLINE

**(Adulterated Drugs)**

37. Respondent Kenneth Road and respondent Lipp (collectively, "Respondents") are subject to disciplinary action under section 4301, subdivision (j), in conjunction with section 4113, subdivision (c), and Heath and Safety Code sections 111255, 111295 and 111305 in that Respondents received adulterated drugs in commerce and/or held or offered adulterated drugs for sale. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 20 and 21, inclusive, as though set forth fully herein.

## FOURTH CAUSE FOR DISCIPLINE

**(Misbranded Drugs)**

38. Respondents are subject to disciplinary action under section 4301, subdivision (j), in conjunction with Heath and Safety Code sections 111330, 111340, subdivision (b), 111390, 111395, subdivision (c), and 111440 in that Respondents held and/or offered for sale misbranded drugs. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 20 and 21, inclusive, as though set forth fully herein.

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**PRAYER**

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

1. Revoking or suspending Pharmacy Permit Number PHY 50214, issued to Kenneth Road Pharmacy, Inc.;

2. Revoking or suspending Pharmacist License No. RPH 32284, issued to Robert S. Lipp;

3. Ordering Kenneth Road Pharmacy, Inc. and Robert S. Lipp to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

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

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

DATED: 4/24/15

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

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