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

In the Matter of the Accusation Against:

AGAPI PHARMACY, INC. DBA AGAPI PHARMACY, ASMIK AYRAPETYAN, PRESIDENT AND PHARMACIST-IN-CHARGE,

Permit No. PHY 47114,

and

ASMIK AYRAPETYAN,

Pharmacist License No. RPH 51512,

Respondents.

Agency Case No. 6924

OAH No. 2021020709

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on December 8, 2021.

It is so ORDERED on November 8, 2021.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Seung W. Oh, Pharm.D.
Board President

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PROPOSED DECISION

Ji-Lan Zang, Administrative Law Judge, Office of Administrative Hearings, State of California, heard this matter by videoconference on September 1 and 2, 2021, in Los Angeles, California.

Heather Vo, Deputy Attorney General, represented Anne Sodergren (complainant), Executive Officer, Board of Pharmacy (Board), Department of Consumer Affairs.

Herbert L. Weinberg, Attorney at Law, represented Agapi Pharmacy, Inc., doing business as Agapi Pharmacy (Agapi Pharmacy), and Asmik Ayrapetyan (respondent), 100 percent shareholder, President, and Pharmacist-In-Charge (PIC) of Agapi Pharmacy, who appeared.

Oral and documentary evidence was received. The record was closed and the matter was submitted for decision on September 2, 2021.

FACTUAL FINDINGS

Jurisdictional Matters

1. On March 15, 2005, the Board issued Pharmacy Permit Number 47114 to Agapi Pharmacy, with respondent as its President, 100 percent shareholder, and PIC. This pharmacy permit was in full force and effect at all times relevant to this matter and will expire on March 1, 2022, unless renewed.

2. On March 31, 2005, the Board issued Pharmacist License Number RPH 51512 to respondent. This pharmacist license was in full force and effect at all times relevant to this matter and will expire on March 31, 2022, unless renewed.

3. Neither Agapi Pharmacy nor respondent has a prior history of discipline with the Board.

4. On December 29, 2020, complainant filed the Accusation in her official capacity. Respondent timely filed a Notice of Defense and a Request for Hearing. This hearing ensued.

The September 18, 2019 Inspection

5. On September 18, 2019, Board Inspector Anna Brodsky conducted an inspection of Agapi Pharmacy. Inspector Brodsky received her undergraduate degree from the University of Arizona and her Doctor of Pharmacy degree from the University of Southern California. She has practiced as a licensed pharmacist since 2010, and she has worked in retail pharmacies, skilled nursing facilities, and specialty pharmacies. Inspector Brodsky has worked as a Board Inspector since July 2019.

6. Agapi Pharmacy is located inside the SuperKing Supermarket in a residential part of the City of Glendale. Present during this initial inspection were respondent and Pharmacy Technician Vahe Avakian (TCH Avakian), who is also respondent's son.

FOREIGN MEDICATIONS FOR SALE

7. During the inspection, Inspector Brodsky noticed packages of prescription medications and over-the-counter (OTC) medications with writing in the Russian language. Because she is a native Russian speaker, Inspector Brodsky was able to read the Russian writing on the packages. She found the following foreign drugs on the active drug inventory shelves at Agapi Pharmacy:

- One packet of nine sachets of Catafast;
- One tube of Diclofenac gel;

- Three tubes of Ftorocort;
- Six tubes of Heparin ointment;
- One 20-tablet pack of Ketorolac;
- Six tubes of Levomekol;
- 10-tablet packs of Levomycetin (exact quantity not established by the record);
- Two tubes of Lioton cream;
- Three tubes of Lorinden C cream;
- One tube of Metrogil Denta;
- 13 20-tablet packs of Nitrofurantoin 100 mg;
- Four 20-tablet packs of Nitrofurantoin 50 mg;
- Three 10-tablet packs of Nystatin;
- 500 tablets of Senade;
- Six tubes of Sinaflan; and
- Nine 10-tablet packs of Tylenol 325 mg;

8. Of these drugs, Catafast, Diclofenac gel, Ftorocort, Nitrofurantoin, Ketorolac, Nystatin, and Sinaflan are all dangerous drugs pursuant to Business and

Professions Code section 4022[1] and are prohibited without a prescription in the United States (U.S.). Furthermore, Diclofenac gel and Ketorolac sold in the U.S. must carry a boxed warning, also known as black box warning. Black box warning is a warning that appears on the package insert for certain prescription drugs, which, according to Food and Drug Administration (FDA) specifications, is formatted with a box or border around the text. The black box warning is the strongest warning that the FDA requires, and it indicates that the drug carries a significant risk of serious or even life-threatening adverse effects. However, the Diclofenac gel and Ketorolac on Agapi Pharmacy's shelves did not carry such warnings.

9. Furthermore, Inspector Brodsky determined that several medications are not approved in the U.S. For example, heparin, sold in ointment form at Agapi Pharmacy, is not approved in the U.S. The FDA requires heparin to be dispensed only as an intravenous (IV) injection by prescription. Chloramphenicol and Methyluracil, the active ingredients in Levomekol, are not approved by the FDA in ointment form; they are only approved as IV injections. Levomycetin, as an oral dose, was discontinued in the U.S. in 1991 due to the side effect of aplastic anemia; its active ingredient, Chloramphenicol, is only approved as an IV injection. Lioton cream, sold as a topical gel at Agapi Pharmacy, is available in the U.S. only as an IV injection. Flumethasone,

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[1] Business and Professions Code section 4022 defines dangerous drug as any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import, or any other drug that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Business and Professions Code section 4006. (Bus. & Prof. Code, § 4022, subds. (a) & (c).)

the active ingredient in Lorinden C, is only approved as a bulk ingredient for veterinary compounding. Metrogil Denta was sold at Agapi Pharmacy as a topical oral gel. However, its active ingredients are metronidazole, which is approved in the U.S. only as an oral tablet or for vaginal use, and chlorhexidine, which is approved only as an oral rinse.

10. Inspector Brodsky found many of these medications with price tags on the Agapi Pharmacy Shelf. For example, a 10-tablet packet of Levomycetin had a price tag of $5.99. (Ex. 6, AGO 83.) A packet of Nitrofurantoin 50 mg had a price tag of $4.99. (*Id.* at AGO 89.) She asked respondent about the purpose of stocking these foreign medications, and respondent stated that the foreign medications were for sale to her walk-in Armenian and Russian patients. Inspector Brodsky also asked respondent about the wholesaler from whom the pharmacy purchased the foreign prescription and OTC medications. Respondent answered that she purchased the foreign medications from a supplier called Phyto Lab. Inspector Brodsky requested to review the invoices from Phyto Lab, and respondent produced two pages of Phyto Lab invoices. (Ex. 7.) However, these Phyto Lab invoices only show Agapi Pharmacy's purchases of herbal supplements, but not its purchase of OTC and prescription drugs. Additionally, based on a license search performed by Inspector Brodsky, Phyto Lab is not a wholesaler or a pharmacy licensed by the Board to sell medications in California.

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FAILURE TO COMPLETE THE COMMUNITY PHARMACY SELF-ASSESSMENT

11. During the inspection, Inspector Brodsky also requested to review the most recent Community Pharmacy Self-Assessment (Self-Assessment)[2] completed by respondent as the PIC of Agapi Pharmacy. Respondent was not able to produce a Self-Assessment completed after June 3, 2005. When Inspector Brodsky asked respondent if she completed a more recent Self-Assessment, respondent answered that the last Self-Assessment she completed was on June 3, 2005.

INSPECTION REPORT AND ORDER OF CORRECTION

12. At the end of this initial inspection, Inspector Brodsky asked respondent to remove the foreign medications from her pharmacy. Using the computer and printer she brought to the inspection, Inspector Brodsky also typed and printed an Inspection Report dated the same date. (Ex. 5.) A portion of the Inspection Report entitled "Discussion" read, in part:

> • CCR 1715 Self-Assessment of a Pharmacy by the [PIC]. Pharmacy does not have current self- assessment. Last [Self-Assessment] 06/05/2005.
>
> FDCA 11440/BPC 4169 (a) (2) Manufacture or sale of misbranded drug or device/ Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably

[2] California Code of Regulations, title 16, section 1715, requires the PIC of each pharmacy to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law before July 1 of every odd-numbered year.

should have known were adulterated. . . . pharmacy has foreign medications and OTCs on the shelf.

(*Id*. at AGO 74.)

13. Inspector Brodsky reviewed the Inspection Report with respondent, who signed the Inspection Report after declaring that "I have reviewed, discussed, and understand and received a copy of this form." (Ex. 5, AGO 75.)

14. Inspector Brodsky also issued an Order of Correction dated September 18, 2019. This Order of Correction notified Agapi Pharmacy that it violated laws governing the practice of pharmacy, including Business and Professions Code section 4169, subdivision (a)(2), prohibiting the purchase or transfer of dangerous drugs that are known, or reasonably should have been known, to be adulterated. In support of this violation, the Order of Correction stated, "pharmacy has foreign drugs on the shelf." (Ex. 5, AGO 76.) Respondent also signed this Order of Correction after declaring that "I have reviewed, discussed, and understand and received a copy of this form." (*Id*. at AGO 77.)

RESPONDENT'S COMPLETION OF THE 2019 SELF-ASSESSMENT

15. On October 1, 2019, respondent emailed to Inspector Brodsky, a copy of her completed 2019 Self-Assessment. (Ex. 11.)

The October 30, 2019 Inspection

FOREIGN MEDICATIONS FOR SALE

16. On October 30, 2019, Inspector Brodsky returned to Agapi Pharmacy to conduct a follow-up inspection. Respondent, TCH Avakian, and Pharmacy Technician

Saryana Samoylova (TCH Samoylova) were present to assist with the inspection. During this inspection, Inspector Brodsky observed packages with Russian writing on the active inventory and storage room shelves. Specifically, she found the following foreign OTC and prescription drugs:

- 30 tablets and eight boxes of Aspirin 500 mg;
- 11 20-tablet packs of Analgin
- 10 10-tablet packs of Analgin
- Six 10-tablet packs of Furacilin
- 13 10-tablet packs of Furazolidone
- One 10-tablet pack of Ketorolac
- Five 30-tablet packs of Nimesil
- 10 20-tablet packs of Streptocid
- 14 tablets of Vicasol

17. Of these drugs, Ketorolac is a dangerous drug pursuant to Business and Professions Code section 4022 and is prohibited without a prescription in the U.S. In addition, many of these foreign drugs found on Agapi Pharmacy's shelves are prescription medications that are not approved by the FDA. For example, Analgin was withdrawn from the U.S. market in 1977 due to serious blood-related toxicity. Furacilin was also withdrawn from the U.S. market due to mutagenic/carcinogenic properties. Furazolidone is only approved by the FDA as a bulk ingredient for veterinary compounding. Nimesil was removed from the U.S. market to due liver toxicity.

Streptocid is not approved by the FDA because it has been supplanted by other modern antibiotics. Vicasol is also not approved by the FDA because its active ingredient, Menadlone, is banned due to potential toxicity for human use.

18. Inspector Brodsky again found many of these medications with price tags on the Agapi Pharmacy shelf. For example, a packet of Analgin had a price tag of $4.99. (Ex. 6, AGO 122.) A packet of Vicasol had a price tag of $4.99. (*Id*. at AGO 118.) When Inspector Brodsky asked respondent about the purpose of stocking these foreign medications, respondent stated she sold these medications to Armenian tourists. Respondent also claimed that some of the medications were for personal use. She reported that the Nimesil was for her husband's use, and the Vicasol, a coagulant, was used to treat her son's hemorrhoids. When asked how long she had been selling these medications at Agapi Pharmacy, respondent answered that she had done so since the inception of Agapi Pharmacy in 2005. According to respondent, TCH Smoylova ordered these medications from Phyto Lab and Russia Shoppe in New York.

19. After her conversation with respondent, Inspector Brodsky interviewed TCH Samoylova, who confirmed that she places the orders for the foreign medications by telephone with Russian Shoppe and Phyto Lab. TCH Samoylova stated that she unpacks the orders and puts the products on the shelves, but she did not keep any invoices.

20. At the end of the inspection, respondent wrote a statement, dated October 30, 2019, under penalty of perjury, as follows:

Russian medication New York

Phyto Lab

> Russia Shopp[e]
>
> We are order herbal [illegible] for 13 years and OTC like aspirin for Russia from Armenia tourists and OTC aspirin (for mixing) and temperature.

(Ex. 9)

21. Respondent also signed an Inspection Report dated the same date, in which she agreed to provide certain documents, including "all and any acquisition records from Russian Shoppe of Russian medications (10/30/2016 through 10/30/2019)" to Inspector Brodsky by November 13, 2019. (Ex. 8, AGO 135.) This Inspection Report also noted that "[Inspector Brodsky] instructed [respondent] to remove all foreign prescription medications from her pharmacy." (*Id.* at AGO 134.)

RUSSIAN SHOPPE INVOICES

22. On November 9, 2019, respondent emailed Inspector Brodsky invoices from Phyto Lab and Russian Shoppe. However, these invoices only contained Agapi Pharmacy's orders for herbal supplements and creams, but did not contain orders for the Russian medications Inspector Brodsky found at the pharmacy.

23. The invoices provided by respondent showed that Russian Shoppe's parent company is Altarica Inc. Based on a license search performed by Inspector Brodsky, neither Russian Shoppe nor Altarica Inc. are wholesalers or pharmacies licensed by the Board to sell medications in California.

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The February 13, 2020 Inspection

24. On February 13, 2020, Inspector Brodsky returned to Agapi Pharmacy to conduct another follow-up inspection. During this inspection, Inspector Brodsky found foreign OTC medications, including Senade and Faringocept on the active drug inventory shelf and in the storage room shelves. Inspector Brodsky asked respondent for proof of destruction of the foreign prescription drugs found during the previous inspections. Respondent stated that she disposed those medications into the trashcan at the SuperKing supermarket, which was later taken away by a waste management company. Inspector Brodsky instructed respondent to destroy the Senade and Faringocept with a reverse distributor.[3]

25. On March 27, 2020, respondent emailed Inspector Brodsky a certificate from RX Reverse Distributors, Inc., showing that the Senade and Faringocept were destroyed.

Testimony of Inspector Brodsky

26. At the hearing, Inspector Brodsky testified credibly regarding the various violations she found during her inspections of Agapi Phamarcy, which are summarized below.

[3] A reverse distributor is a company that receives controlled substances from a pharmacy for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent, or, where necessary, processing such substances or arranging for processing such substances for disposal. (21 C.F.R. § 1300.01.)

DANGEROUS DRUGS

27. Many of the foreign drugs found in Agapi Pharmacy, such as Catafast, Ketorolac, Nystatin, and Sinaflan, are prescription drugs that are dangerous drugs within the meaning of Business and Professions Code section 4022. According to Inspector Brodsky, the U.S. utilizes a tracking system to ensure the legitimacy and safety of dangerous drugs that are purchased and dispensed. To begin with, a pharmacist may purchase these types of medications from only licensed wholesalers or pharmacies. When dispensing a prescription medication, a pharmacist types the prescription into a computer, and each medication dispensed is assigned a prescription number. The computer also generates a label containing important information, including the name of the prescriber, the date of the prescription, and the expiration date of the drug. The pharmacist retrieves the medication and affixes the label on the medication to be dispensed. For new prescriptions, a pharmacist must consult with the patient, and if there are any issues with medication, the pharmacist may call the prescriber. Although the patient may pay for the medication either by cash or insurance, all prescription drugs sold are tracked by the computer system.

28. In this case, Agapi Pharmacy purchased prescription, dangerous drugs from Phyto Lab and Russian Shoppe, neither of whom are wholesalers or pharmacies licensed to sell drugs in California. Although respondent stated that she sold prescription drugs to Russian and Armenian patients, she did not produce any prescription records for these drugs. According to Inspector Brodsky, Agapi pharmacy, by purchasing and furnishing these dangerous drugs outside of this tracking system, imperils patients' health because patients must be evaluated in the event of an adverse reaction to a drug.

MISBRANDED DRUGS

29. Agapi Pharmacy had in its stock multiple foreign drugs. Some of these foreign drugs are medications that may be purchased in the U.S. only by prescription. Other medications are not approved by the FDA. All these drugs are misbranded. In particular, Diclofenac gel and Ketorolac sold in the U.S. must carry a black box warning, but the Russian-made versions of these medications found at Agapi Pharmacy did not carry such warnings. In another example, during the October 13, 2019 inspection, Vicasol was found on the shelves of Agapi Pharmacy. Vicasol is an alternative to the FDA-approved medication, Mephyton. However, Vicasol's active ingredient, Menadlone, is banned by the FDA, due to its toxicity to human beings. Mephyton is expensive and sells for approximately $45 per tablet in the U.S., but Agapi Pharmacy sells the Russian version as a cheap alternative. Although respondent told Inspector Brodsky that the Vicasol was used to treat her son's hemorrhoids, Vicasol is a coagulant that is used to treat blood disorder, not as a first-step therapy for hemorrhoids.

ACQUISITION RECORDS AND INVENTORY

30. A pharmacy is required to maintain it records of acquisition and disposition for three years. During the September 18 and October 30, 2019 inspections, respondent told Inspector Brodsky that she obtained the Russian prescription drugs from Phyto Lab and Russian Shoppe. However, the invoices respondent provided to Inspector Brodsky showed only purchases of herbal supplements and creams. TCH Samoylova also admitted to Inspector Brodsky that she placed orders through Russian Shoppe, but she did not keep any of the invoices. Agapi Pharmacy never produced any invoices showing its purchases of the foreign prescription drugs to Inspector Brodsky.

SELF-ASSESSMENT

31. At the hearing, Inspector Brodsky testified that the primary purpose of the Self-Assessment is to promote compliance through self-examination and education. She described the Self-Assessment as the "bible of pharmacy practice" because it is the primary tool for a PIC to stay up to date with both state and federal pharmacy laws and regulations. Inspector Brodsky noted that the Self-Assessment is also easily accessible and searchable on the Board's website. However, as of the September 18, 2019 Inspection, respondent had not completed any Self-Assessment since June 2005.

Respondent's Testimony

32. Respondent was born in Iran and grew up in Armenia. She obtained her Doctor of Pharmacy degree from Yerevan State Medical University in Armenia. Respondent began her career in Armenia, but she has practiced as a pharmacist in California for 21 years. Respondent initially worked in retail pharmacy, until she purchased and became the PIC of Agapi Pharmacy in 2005.

33. At the hearing, respondent averred that she did not completed the Self-Assessment from June 2005 to October 2019 because she was "busy and forgot" (her words).

34. Respondent testified that Agapi Pharmacy has carried Russian-labeled herbal supplements, shampoos, and OTC drugs since its inception in 2005. In 2016, Agapi Pharmacy began carrying Russian-labeled dangerous drugs because Armenian and Russian tourists requested them. Respondent stated that she purchased the Russian-labeled dangerous drugs through the internet from Phyto Lab and Russian Shoppe. Respondent did not present any documentation showing that she sold any of

the foreign dangerous drugs found at Agapi Pharmacy to consumers pursuant to legitimate prescriptions.

35. Respondent offered several different explanations for carrying the Russian-labeled dangerous drugs at Agapi Pharmacy. Respondent at first asserted that she did not know it was unlawful to sell the foreign dangerous drugs without a prescription because such practices were allowed in Armenia, where she received her pharmaceutical education. Respondent maintained that many other pharmacies located in the same area as Agapi Pharmacy also sold the same foreign dangerous drugs without a prescription. Respondent later contradicted herself and claimed that she did not dispense many of the foreign dangerous drugs. She reported that the Catafast was from a patient who left it at Agapi Pharmacy; that the Ketorolac was for her personal use; that the Nemisil was for her husband's personal use; that the Vicasol was for her son's personal use as a treatment for hemorrhoids; and that the Furazolidone and the Nitrofurantoin was ordered by TCH Samoylova by mistake.

36. Respondent also claimed that after the initial, September 18, 2019 inspection, Inspector Brodsky did not tell her to remove all foreign dangerous drugs. Respondent testified that Inspector Brodsky told her the presence of the foreign dangerous drugs was "out of her jurisdiction" and that respondent could do "whatever [she] wanted with it" (respondent's words). Respondent further claimed that Inspector Brodsky pressured her to sign the October 13, 2019 statement in which respondent admitted that she purchased drugs from Phyto Lab and Russian Shoppe for 13 years. Respondent asserted her belief that Phyto Lab and Russian Shoppe are legitimate wholesalers because they have a New Jersey business license.

37. Respondent admitted at the hearing that she did not know Nemisil was removed from the U.S. market due to liver toxicity; that Analgin was withdrawn due to

blood toxicity; that Levomycetin in the tablet form was withdrawn due to the side effect of aplastic anemia; that Furazolidone is not approved by the FDA for human use; and that Vicasol's active ingredient, Menadlone, is banned by the FDA for its toxicity.

38. Much of respondent's testimony was dishonest and disingenuous. Her explanation that many of the foreign dangerous drugs are for personal use is implausible, given the drugs were found in Agapi Pharmacy's active drug inventory shelves and bore price tags. In particular, respondent's claim that the Vicasol was for her son's treatment of hemorrhoids is contradicted by Inspector Brodsky's credible testimony that Vicasol is a coagulant for treating blood disorders; it is not a first-step therapy for treating hemorrhoids. Furthermore, respondent's testimony that Inspector Brodsky failed to instruct her to remove the foreign dangerous drugs from Agapi Pharmacy after the September 18, 2019 inspection is not credible. Inspector Brodsky, in her Inspection Report and Order of Correction dated the same date, informed respondent of Agapi Pharmacy's violations of the Board's laws and regulations regarding carrying the misbranded, foreign OTC and dangerous drugs on its shelves.

39. Respondent stated she no longer carries any foreign dangerous drugs at Agapi Pharmacy, and she wishes to retain her licenses because Agapi Pharmacy is her family's sole source of income.

40. Respondent also submitted three letters of support from friends and colleagues who describe her as an exemplary healthcare professional.

Costs

41. Complainant submitted evidence of the costs of investigation and enforcement of this matter, summarized as follows: 67.25 hours of legal services at rates ranging from $205 to $220 per hour for a subtotal of $16,763.75; and 99.5 hours

of investigative services at rates ranging from $121 to $127 per hour for a subtotal of $12,075.50. The total costs of investigation and enforcement of this matter are $28,839.25. These costs are reasonable. Agapi Pharmacy and respondent did not present any evidence regarding their ability to pay recovery costs.

LEGAL CONCLUSIONS

Burden and Standard of Proof

1. Agapi Pharmacy's pharmacy permit is a nonprofessional license because it does not require the extensive educational, training, or testing requirements as does a professional license. (See *Mann v. Department of Motor Vehicles* (1999) 76 Cal.App.4th 312, 319; *San Benito Foods v. Veneman* (1996) 50 Cal.App.4th 1889, 1894.) An applicant for a pharmacy permit need not be a pharmacist; instead, the applicant must designate a PIC with the requisite education, training, and licensure. (Bus. & Prof. Code, §§ 4110, subd. (a), 4113, subd. (a).) To impose discipline on Agapi Pharmacy's nonprofessional pharmacy permit, complainant must prove cause for discipline by a preponderance of the evidence, which is a lower standard of proof than clear and convincing evidence. (*Imports Performance v. Department of Consumer Affairs, Bureau of Automotive Repair* (2011) 201 Cal.App.4th 911, 916–917; Evid. Code, §115.) "'Preponderance of the evidence means evidence that has more convincing force than that opposed to it.' [citations omitted] . . . . The sole focus of the legal definition of 'preponderance' in the phrase 'preponderance of the evidence' is on the *quality* of the evidence. The *quantity* of evidence presented by each side is irrelevant." (*Glage v. Hawes Firearms Co.* (1990) 226 Cal.App.3d 314, 324–325, emphasis in original.)

2. However, respondent's pharmacist license is a professional license. (Bus. & Prof. Code § 4050; *Murphy v. E.R. Squibb & Sons, Inc.* (1985) 40 Cal.3d 672, 678-679.) To impose discipline on a professional license, complainant must prove cause for discipline by clear and convincing evidence to a reasonable certainty. (*Sternberg v. California State Board of Pharmacy* (2015) 239 Cal.App.4th 1159, 1171; *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856.) Clear and convincing evidence requires proof that is so clear as to leave no substantial doubt and that is sufficiently strong to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478, 487.)

Causes for Discipline

3. Business and Professions Code sections 4059, subdivision (a), and 4126.5, subdivision (a)(5), prohibit the furnishing of dangerous drugs without a lawful prescription from a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor. Therefore, cause exists to discipline Agapi Pharmacy and respondent for violating Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with Business and Professions Code sections 4059, subdivision (a), and 4126.5, subdivision (a)(5). Agapi Pharmacy and respondent sold dangerous drugs over the counter without a prescription to consumers. (Factual Findings 5 to 25, 27 to 28, and 34 to 38.)

4. Business and Professions Code section 4169, subdivision (a)(1), provides that a person or entity shall not "purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy." Therefore, cause exists to discipline Agapi Pharmacy and respondent for violating Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction

with Business and Professions Code section 4169, subdivision (a)(1). Agapi Pharmacy and respondent purchased and stored dangerous from Russian Shoppe and Phyto Lab, which are not licensed in California as a pharmacy or wholesaler. (Factual Findings 5 to 25, 27 to 28, and 34 to 38.)

5. Business and Professions Code section 4169, subdivision (a)(3), prohibits the "[p]urchase, trade, sell[ing], or transfer [of] dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code." Health and Safety Code section 111335 provides that "[a]ny drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)." Health and Safety Code section 111397, subdivision (a), provides that "[a]ny foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded." Therefore, cause exists to discipline Agapi Pharmacy and respondent for violating Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with Business and Professions Code section 4169, subdivision (a)(3), and Health and Safety Code sections 111335 and 111397, subdivision (a). Agapi Pharmacy and respondent purchased, traded, sold, and/or transferred drugs that they knew or reasonably should have known were misbranded. Agapi Pharmacy carried foreign dangerous drugs that were obtained outside of the licensed supply chain regulated by the Board, and some of the drugs were not approved by the FDA. (Factual Findings 5 to 25, 29, and 34 to 38.)

6. Business and Professions Code section 4342, subdivision (a), grants authority to the Board to institute actions that are necessary to prevent the sales of

drugs that violate the California Food Drug and Cosmetics Law set forth at Health and Safety Code section 109875 et seq. Health and Safety Code section 111440 states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded." Therefore, cause exists to discipline Agapi Pharmacy and respondent for violating Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with Business and Professions Code section 4342, subdivision (a), and Health and Safety Code section 111440. Agapi Pharmacy and respondent were in possession of misbranded foreign dangerous drugs for sale to consumers. (Factual Findings 5 to 25, 29, and 34 to 38.)

7. Business and Professions Code section 4333, subdivision (a), requires a pharmacy to maintain all filled prescriptions on the premises and available for inspection for at least three years. Business and Professions Code section 4081, subdivision (a), requires a pharmacy to maintain all records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs on the premises and available for inspection for at least three years. Business and Professions Code section 4105, subdivision (a), requires an entity licensed by the Board to retain all records or other documentation of the acquisition and disposition of dangerous drugs on the licensed premises in a readily retrievable form. Therefore, cause exists to discipline Agapi Pharmacy and respondent for violating Business and Professions Code section 4301, subdivisions (j) and (o), in conjunction with Business and Professions Code sections 4333, subdivision (a), 4081, subdivision (a), and 4105, subdivision (a). Agapi Pharmacy and respondent did not maintain records of acquisition and disposition of drugs for retrieval during the September 18, 2019 and October 30, 2019 inspections. (Factual Findings 5 to 25, 30, and 34 to 38.)

8. California Code of Regulations, title 16, section 1715, requires the PIC of each pharmacy to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law before July 1 of every odd-numbered year. Therefore, cause exists to discipline Agapi Pharmacy and respondent for violating Business and Professions Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1715. Between June 2005 and October 2019, respondent did not complete a Self-Assessment. (Factual Findings 11 to 15, 31, and 33.)

Level of Discipline

9. The Board's Disciplinary Guidelines (Rev. 2/2017) (Guidelines) describe categories of violations and recommended penalties. Most of the violations involved in this case, such as dispensing or furnishing without valid prescription, violations of laws governing dangerous drugs, and purchasing, trading, selling, or transferring misbranded dangerous drugs constitute Category III violations. (*Id.* at p. 8.) For Category III violations, the minimum recommended penalty is revocation stayed, 90 days of actual suspension, and three to five years' probation. The maximum recommended penalty is revocation. (*Id.* at p. 7.)

10. The Guidelines specify that, in determining whether the minimum, maximum, or an intermediate penalty is to be imposed in a given case, the following factors should be considered: (1) actual or potential harm to the public; (2) actual or potential harm to any consumer; (3) prior disciplinary record; (4) prior warnings; (5) number and or variety of current violations; (6) the nature and severity of the act(s) or offense(s), or crime(s); (7) aggravating evidence; (8) mitigating evidence; (9) rehabilitation evidence; (10) compliance with terms of any criminal sentence, parole, or probation; (11) overall criminal record; (12) if applicable, evidence of dismissal proceedings pursuant to section 1203.4 of the Penal Code; (13) the time that has

elapsed since commission of the act(s) or offenses(s); (14) whether the conduct was intentional or negligent; (15) financial benefit to the respondent from the misconduct; (16) other licenses held by the respondent and license history of those licenses; and (17) Uniform Standards Regarding Substance-Abusing Healing Arts Licensees. (*Id.* at p. 3.)

11. Although there was no evidence of actual harm, the potential harm to the public from Agapi Pharmacy and respondent's violations was significant. By respondent's own admission, Agapi Pharmacy has sold foreign dangerous drugs since at least 2016, and there is no documentation to show that these drugs were sold pursuant to legitimate prescriptions. Many of the foreign dangerous drugs found on Agapi Pharmacy shelves were also either withdrawn from the U.S. market due to toxicity or not approved by the FDA for human use. Furthermore, between June 2005 and October 2019, respondent did not complete any Self-Assessment, when, as Inspector Brodsky noted in her testimony, the Self-Assessment is one of the most important tools for a pharmacist to stay up to date with both state and federal pharmacy laws and regulations.

12. Neither Agapi Pharmacy nor respondent has a prior record of discipline. However, Agapi Pharmacy and respondent had warnings about the deficiencies in their pharmacy practice after Inspector Brodsky's initial inspection on September 18, 2019. On that same date, Inspector Brodsky issued an Inspection Report and Order of Correction regarding the pharmacy law violations she had found. Respondent signed the Inspection Report and Order of Correction indicating that she had reviewed, discussed, and understood the contents of these documents. Inspector Brodsky also instructed respondent to remove all foreign drugs from Agapi Pharmacy. Yet, when

Inspector Brodsky returned for her second inspection on October 30, 2019, more foreign dangerous medications were found on Agapi Pharmacy's shelves.

13. In total, complainant established six separate causes for discipline. All the violations, including furnishing dangerous drugs without a prescription, purchasing and selling misbranded drugs, and failure to complete a Self-Assessment since 2005, are extremely serious in nature. Agapi Pharmacy and respondent's misconduct also are not remote in time because Inspector Brodsky found foreign, misbranded OTC drugs at Agapi Pharmacy during her third inspection on February 13, 2020. The duration of the misconduct is also long, given that Agapi Pharmacy stocked foreign OTC drugs since 2005 and foreign dangerous drugs since at least 2016. Although respondent claimed ignorance of the Pharmacy Laws due to her education in Armenia, licensees are charged with knowledge of the Board's laws and regulations. Given these factors, it can only be inferred that respondent's conduct is intentional, rather than negligent, even though there is little evidence that respondent and Agapi Pharmacy financially benefitted from the misconduct. Most significantly, respondent presented scant evidence of rehabilitation, other than three character reference letters. At the hearing, respondent was less than candid in her testimony, and she blamed others, including TCH Samoylova, for the wrongdoing, when respondent, as the PIC, is responsible for the pharmacy's adherence to federal and state laws and regulations.[4]

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[4] Other factors under the Guidelines for determining the appropriate level of discipline are not applicable in this case and therefore are not discussed.

14. The Guidelines state, "[t]hese categories assume a single violation. For multiple violations, the appropriate penalty shall increase accordingly." (Guidelines, p. 5.) The Guidelines also provide:

> Category IV discipline (revocation) is recommended for the most serious violations of laws or regulations pertaining to pharmacy and/or to the dispensing or distributing of dangerous drugs and/or dangerous devices or controlled substances. Violations in this category may include:
>
> [¶] . . . .[¶]
>
> repeated or serious example(s) of conduct described in Category I, Category II, or Category III.

(*Id.* at p. 8.)

15. In light of the foregoing, respondent and Agapi Pharmacy's violations are deemed repeated and serious examples of Category III conduct. As a result, protection of the public health, safety, and welfare requires the revocation of Agapi Pharmacy's pharmacy permit and respondent's pharmacist license.

16. Because the discipline imposed on Agapi Pharmacy's pharmacy permit is revocation, pursuant to Business and Professions Code section 4307, respondent, as the manager of Agapi Pharmacy who had knowledge of and knowingly participated in the conduct for which Agapi Pharmacy is disciplined, shall be prohibited from serving as the manager, administrator, owner, member, officer, director, associate, or partner of a Board licensee, until the pharmacy permit is reinstated.

Costs

17. Under Business and Professions Code section 125.3, the Board may recover costs "not to exceed the reasonable costs of the investigation and enforcement" of this matter. As set forth in Factual Finding 41, the costs claimed are $28,839.25. These costs are reasonable. Agapi Pharmacy and respondent did not present any evidence to warrant a reduction in costs.

18. Given the nature of the order below, it would be unnecessarily punitive to require Agapi Pharmacy and respondent to pay the Board's costs at this time. However, it is reasonable to require Agapi Pharmacy and respondent to pay the Board's costs upon the reinstatement of Agapi Pharmacy's pharmacy permit and/or respondent's pharmacist license.

ORDER

1. Pharmacy Permit Number PHY 47114, issued to Agapi Pharmacy, Inc. doing business as Agapi Pharmacy, is revoked. Respondent Asmik Ayrapetyan, 100 percent shareholder and President of Agapi Pharmacy, 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 Ayrapetyan shall provide written proof of such disposition, submit a completed Discontinuance of Business form, and return the wall and renewal licenses to the Board within five days of disposition.

2. Respondent Asmik Ayrapetyan is prohibited from serving as the manager, administer, owner, member, officer, associate, or partner of a licensee until Pharmacy Permit Number PHY 47114 is reinstated.

3. Pharmacist License Number RPH 51512, issued to respondent Asmik Ayrapetyan is revoked. Respondent Ayrapetyan shall relinquish her wall license and pocket renewal license to the Board within 10 days of the effective date of this decision. Respondent Ayrapetyan may not reapply or petition the Board for reinstatement of her revoked license for three years from the effective date of this decision.

4. As a condition precedent to reinstatement of Agapi Pharmacy's pharmacy permit and/or respondent Asmik Ayrapetyan's pharmacist license, respondents Agapi Pharmacy and Ayrapetyan shall reimburse the Board for its costs of investigation and prosecution in the amount of $28,839.25. Said amount shall be paid in full prior to the reinstatement of Agapi Pharmacy's pharmacy permit and/or respondent Ayrapetyan's pharmacist license, unless otherwise ordered by the Board.

DATE: 10/01/2021

Ji-Lan Zang

JI-LAN ZANG

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**:** **AGAPI PHARMACY INC., dba AGAPI PHARMACY** **ASMIK AYRAPETYAN, President and Pharmacist-in-Charge** 6501 San Fernando Rd., #K Glendale, CA 91201 Permit No. PHY 47114 **And** **ASMIK AYRAPETYAN** 1246 Idlewood Rd. Glendale, CA 91202 Pharmacist License No. RPH 51512 Respondents.	Case No. 6924 **ACCUSATION**

PARTIES

1. Anne Sodergren (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 March 15, 2005, the Board of Pharmacy issued Permit Number PHY 47114 to Agapi Pharmacy Inc., dba Agapi Pharmacy; Asmik Ayrapetyan as President

(Respondent Agapi Pharmacy). The Permit was in full force and effect at all times relevant to the charges brought herein and will expire on March 1, 2021, unless renewed.

3. On or about March 31, 2000, the Board of Pharmacy issued Pharmacist License Number RPH 51512 to Asmik Ayrapetyan (Respondent Ayrapetyan). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on March 31, 2022, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), 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 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health and Safety Code, § 11000 et seq.].

6. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.

STATUTORY AND REGULATORY PROVISIONS

7. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self use in humans or animals, and includes the following:

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

(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

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

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8. Section 4052.2 of the Code states, in relevant part:

….

"(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

….

(4) Except for procedures or functions provided by a health care facility, a licensed correctional clinic, as defined in Section 4187, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours."

….

9. Section 4059 of the Code states in relevant part:

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

….

10. Section 4081 of the Code states in relevant part:

"(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility,

physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

….

11. Section 4105 of the Code states in relevant part:

"(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

….

12. Section 4113 of the Code states in relevant part:

….

"(c) 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. Section 4126.5 of the Code states in relevant part:

"(a) A pharmacy may furnish dangerous drugs only to the following:

….

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law."

….

///

14. Section 4169 of the Code states in relevant part:

"(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."

….

15. Section 4300 of the Code states in relevant part:

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

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

(1) Suspending judgment.

(2) Placing him or her upon probation.

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

(4) Revoking his or her license.

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

….

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of

the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

16. 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.”

17. Section 4301 of the Code states in relevant part:

"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.”

….

18. Section 4307 of the Code states in relevant 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, partner, or any other person with management or control of any partnership, corporation, trust, 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, partner, or any other person with management or control 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, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

….

19. Section 4333 of the Code states in relevant part:

"(a) All prescriptions filled by a pharmacy and all other records required by Section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. In cases where the pharmacy discontinues business, these records shall be maintained in a board-licensed facility for at least three years."

….

20. Section 4342 of the Code states in relevant part:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

….

Health and Safety Code

21. Section 111335 of the Health and Safety Code states:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

22. Section 111397 of the Health and Safety Code states in relevant part:

"(a) Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded."

….

23. Section 111440 of the Health and Safety Code states in relevant part:

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

California Code of Regulations

24. California Code of Regulations, title 16, section 1715, states in relevant part:

"(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

COST RECOVERY

25. 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

INSPECTION #1 – SEPTEMBER 18, 2019

26. On September 18, 2019, a Board inspection was conducted at Agapi Pharmacy located at 6501 San Fernando Dr. #K, Glendale, California 91201. Present were Respondent Asmik Ayrapetyan and Pharmacy Technician Vahe Avakian. During the inspection, Board Inspector A.B. observed prescription medications and over-the-counter medications packages

written in Russian. When questioned about the Russian-labeled prescription medications, Respondent Ayrapetyan stated that the medications were sold to her Armenian and Russian patients. Respondent Ayrapetyan stated that she received shipments of Russian-labeled medications and supplements from a supplier named Phyto Lab. An inspection of the storage room located next to the office area revealed boxes of herbal supplements, over-the-counter and prescription medications, all contained Russian labels.

27. Respondent Ayrapetyan was asked to produce a current pharmacy Self-Assessment Form, which she was not able to do.

28. At the conclusion of the inspection, Respondent Ayrapetyan was ordered to remove the Russian-labeled medications from her pharmacy. The Board inspection revealed violations of pharmacy law including possessing and distributing misbranded products, using a non-licensed wholesaler, lack of record keeping and lack of current Self-Assessment form.

INSPECTION #2 - OCTOBER 30, 2019

29. A follow-up inspection was performed on or about October 30, 2019 at Agapi Pharmacy by Board Inspector A.B. and two inspectors from the Los Angeles County Health Authority Law Enforcement Task Force. Respondent Ayrapetyan assisted with the inspection. The facts and circumstances of the inspection are as follows:

30. During the inspection, Board Inspector A.B. observed Russian-labeled medications on the same shelves as she had observed at the previous inspection on September 18, 2019. All the packages contained Russian labels on the prescription medications, over-the-counter medications, and herbal supplements on the pharmacy shelves.

31. Respondent Ayrapetyan stated that the Russian-labeled medications and supplements came from RussianShoppe and Phyto Lab. She stated that she sold the Russian-labeled prescription medications to Armenian tourists and customers who asked for the medications and has done so since opening her business.

32. RussianShoppe and Phyto Lab are online entities and do not hold any licenses with the Board and do not have a wholesale license.

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33. Board Inspector A.B. also observed several additional boxes of Russian-labeled prescription medications on shelves in the pharmacy's storage room

34. At the conclusion of the inspection, Respondent Ayrapetyan was again instructed to remove all Russian-labeled medications from her pharmacy.

FIRST CAUSE FOR DISCIPLINE

(Furnishing Dangerous Drugs Prohibited Without a Prescription)

35. Respondent Agapi Pharmacy and Respondent Ayrapetyan are subject to disciplinary action for violating Business and Professions Code section 4301(j) and (o), in conjunction with 4059(a) and 4126.5(a)(5), in that the pharmacy sold dangerous drugs over the counter without a prescription to consumers. Complainant refers to and by this reference incorporates allegations of paragraphs 26 through 34 above as though fully set forth.

SECOND CAUSE FOR DISCIPLINE

(Purchasing and Storing Dangerous Drugs from Unlicensed Entities)

36. Respondent Agapi Pharmacy and Respondent Ayrapetyan are subject to disciplinary action for violating Business and Professions Code section 4301(j) and (o), in conjunction with 4169(a)(1), in that Respondents purchased and stored dangerous from entities, RussianShoppe and Phyto Lab, which are not licensed in California as a pharmacy or wholesaler. Complainant refers to and by this reference incorporates allegations of paragraphs 26 through 34 as though fully set forth.

THIRD CAUSE FOR DISCIPLINE

(Purchase, Trade, Sell, or Transfer Misbranded Drugs)

37. Respondent Agapi Pharmacy and Respondent Ayrapetyan are subject to disciplinary action for violating Business and Professions Code section 4301(j) and (o), in conjunction with 4169(a)(3), and Health and Safety Code sections 111335 and 111397(a), in that Respondents purchased, traded, sold, and or transferred drugs that Respondents knew or reasonably should have known were misbranded. Complainant refers to and by this reference incorporates allegations of paragraphs 26 through 34 as though fully set forth.

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FOURTH CAUSE FOR DISCIPLINE

(Possession of Misbranded Drugs)

38. Respondent Agapi Pharmacy and Respondent Ayrapetyan are subject to disciplinary action for violating Business and Professions Code section 4301(j) and (o), in conjunction with 4342(a), and Health and Safety Code section 111440, in that the pharmacy was in possession of dangerous drugs in the storage room and on the shelves for consumers to purchase. Complainant refers to and by this reference incorporates allegations of paragraphs 26 through 34 above as though fully set forth.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Acquisition Records and Inventory)

39. Respondent Agapi Pharmacy and Respondent Ayrapetyan are subject to disciplinary action for violating Business and Professions Code section 4301(j) and (o), in conjunction with 4333(a), 4081(a), and 4105(a), in that the pharmacy was unable to provide records of acquisition of dangerous drugs and disposition of dangerous drugs when requested by the Board. Complainant refers to and by this reference incorporates allegations of paragraphs 26 through 34 above as though fully set forth.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Complete Self-Assessment Form)

40. Respondent Agapi Pharmacy and Respondent Ayrapetyan are subject to disciplinary action for violating Business and Professions Code section 4301(o), in conjunction with California Code of Regulations, title 16, section 1715, in that a Board inspection conducted on September 18, 2019, revealed that the pharmacy did not maintain a self-assessment form since June 3, 2005. Complainant refers to and by this reference incorporates allegations of paragraph 26 through 34 above as though fully set forth.

OTHER MATTERS

41. Pursuant to Business and Professions Code section 4307, if Pharmacy Permit Number PHY 47114 or Pharmacist License Number RPH 51512 is disciplined as part of the Board's Decision, then Asmik Ayrapetyan shall be prohibited from serving as a manager, administrator,

owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee for a period (1) not to exceed five years if either Pharmacy Permit Number PHY 47114 or Pharmacist License Number RPH 51512 is placed on probation as part of the Board's decision, or (2) until said licenses are reinstated if they are revoked as part of the Board's decision.

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 Permit Number PHY 47114, issued to Agapi Pharmacy Inc. dba Agapi Pharmacy; Asmik Ayrapetyan, as President;

2. Revoking or suspending Pharmacist License Number RPH 51512, issued to Asmik Ayrapetyan;

3. Prohibiting Agapi Pharmacy Inc. dba Agapi Pharmacy; Asmik Ayrapetyan, as President from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Permit Number PHY 47114 is placed on probation or until Permit Number PHY 47114 is reinstated if Permit Number PHY 47114 issued to Agapi Pharmacy Inc. dba Agapi Pharmacy; Asmik Ayrapetyan, as President is revoked;

4. Prohibiting Asmik Ayrapetyan from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 51512 is placed on probation or until Pharmacist License Number RPH 51512 is reinstated if Pharmacist License Number RPH 51512 issued to Asmik Ayrapetyan is revoked;

5. Ordering Agapi Pharmacy and Asmik Ayrapetyan 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; and,

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

DATED: 12/29/2020

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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