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

In the Matter of the Petition for Early Termination of Probation:

EUN JOO GAK, RPH 54146; GAKS PHARMACY, LLC, dba Balboa Pharmacy, PHY 51136, Petitioners

Agency Case No. 6514

OAH No. 2024030291

DECISION

This matter was heard by a quorum of the Disciplinary Petition Committee (Committee) of the Board of Pharmacy (Board) under Business and Professions Code section 4309, subdivision (c), by videoconference on March 13, 2024. Administrative Law Judge Alan R. Alvord, Office of Administrative Hearings, State of California, presided, assisted, and advised the Committee in the conduct of the hearing under Government Code section 11517, subdivision (b)(1).

Kristina Jarvis, Deputy Attorney General, Office of the Attorney General, Department of Justice, appeared under Government section 11522.

Eun Joo Gak, RPh, petitioner (Petitioner Gak), represented herself and petitioner Gaks Pharmacy, LLC, dba Balboa Pharmacy.

Oral and documentary evidence was received. The record was closed, and the matter was submitted for decision on March 13, 2024.

FACTUAL FINDINGS

License History and Jurisdictional Matters

- 1. The Board issued Pharmacist License No. RPH 54146 to Eun Joo Gak on October 15, 2002. The license is in full force and effect and will expire on December 31, 2025.
- 2. The Board issued Pharmacy Permit No. PHY 51136 to Gaks Pharmacy, LLC, to do business as Balboa Pharmacy on November 2, 2012. Eun Joo Gak has been a member of Gaks Pharmacy, LLC, since November 2, 2012. As of June 1, 2021, Kyu Yoon Cho, RPH 48207, has been the Pharmacist-in-Charge (PIC).
- 3. Petitioners submitted a petition for early termination of probation to the Board on September 11, 2023. The Board set the matter for hearing before the Committee, sent notice of the hearing, and petitioners stipulated to electronic recording of the hearing. Petitioners have completed two years of probation and are eligible to petition for early termination.

Accusation and Stipulation for Probation

4. The Board's Executive Officer issued an accusation on November 14, 2019. The accusation followed an online complaint the Board received in August 2017

that petitioners were selling dangerous drugs without a prescription, possessed misbranded drugs, and provided unauthorized prescription take-back services. A Board inspector conducted an inspection of the pharmacy in February 2018. The inspector found boxes from Korea containing ketoprofen and flurbiprofen for sale in the over-the-counter area of the pharmacy. In the active drug supply area, the inspector found boxes from Korea containing flubendazole and 12 misbranded vials with medication inside next to stock bottles of aspirin.

- 5. Petitioner Gak explained to the inspector that ketoprofen, flurbiprofen, and flubendazole were sold over the counter in Korea so petitioners also sold them over the counter. The supplier petitioners used for the drugs, Natural Wholefood Korea, Inc., was not licensed by California or the U.S. Food and Drug Administration in the supply chain and was suspended from business in California by the Franchise Tax Board.
- 6. The inspector also observed: petitioners' automated pouch packaging device did not properly label medication cells; the pharmacy's storage room contained a box with returned previously dispensed prescription containers with medication inside from other pharmacies that were not stored in a proper receptacle for prescription take-back-services; petitioners were not registered with the Drug Enforcement Agency as a collector and did not notify the Board of take-back services.
- 7. The Board received another complaint in August 2018 that petitioners were dispensing controlled substances based on illegitimate prescriptions. In October 2018, a Board inspection showed the Controlled Substance Utilization Review and Evaluation System (CURES) data indicated trends of dispensing controlled substances with irregularities and red flags of illegitimacy. A review of petitioners' records showed

petitioners dispensed controlled substances after ignoring, or not being aware of, as required, objective factors that indicated possible irregularity, illegitimacy, or abuse.

8. On January 25, 2021, petitioners stipulated to and accepted revocation stayed and five years of probation with terms and conditions including regular reporting, retaining an independent consultant pharmacist, remedial education, volunteering with a community service program, a donation of \$10,000 to a nonprofit drug addiction treatment organization, and payment of enforcement costs of \$17,500. Petitioner Gak was required to take remedial education and an ethics course. The decision and order adopting the stipulation became effective May 12, 2021.

Petition for Early Termination of Probation

PROBATION COMPLIANCE

9. The petition and staff review showed petitioners have complied with all probationary terms, have made all required reports to the Board, paid the costs of enforcement in full, paid all probation monitoring costs, completed the community service requirement, paid \$10,000 to a nonprofit drug addiction program, completed required remedial education, ethics course, and retained an independent consultant pharmacist.

REFERENCE LETTERS

10. Raffi Svadjian, RPh., is the probationary consultant pharmacist for petitioners. Svadjian wrote that Petitioner Gak has demonstrated her knowledge of, respect for, and compliance with all aspects of pharmacy laws and regulations. She has cooperated and complied with all aspects of probation requirements. During Svadjian's visits to the pharmacy, petitioner discussed recent changes to the law and

practice requirements. Svadjian observed that Petitioner Gak is abreast of upcoming changes and has readied the pharmacy for changes. Svadjian has not found any instance of deviation from lawful pharmacy practice during his visits.

- 11. Kyu Yoon Cho, RPh., is the current PIC for petitioner pharmacy. Cho has worked with Petitioner Gak during pharmacy hours and sat with her in meetings with the consulting pharmacist. During the meetings, petitioner was "very active and always had lots of questions." Cho reported finding no sign or evidence of questionable products of foreign origin, no prescription vials or packaging pouches from other pharmacies, no misbranded drugs, and no hint of improper prescription take-back service activities in the over-the-counter area, dispensing area, office, and storage area. Petitioner has "cleaned up the whole pharmacy." Cho did manual inventory counts every three months and checked against petitioner's record, finding no discrepancies. Cho has observed Petitioner Gak screen patients and ask corresponding responsibility questions to physicians about narcotic prescription orders, and inquire about proper medical purpose, quantity, dosage, directions, and drug interactions.
- 12. Julie Kim, Pharm.D., USC School of Pharmacy, has watched Petitioner Gak for many years and worked with petitioner as a member of the executive committee of the California Korean American Pharmacist Association. Petitioner has gained respect of colleagues with her selfless service to the community and provided updated legal, regulatory, and clinical updates. Petitioner is a trustworthy and respectful individual as a person and as a pharmacist. She creates a family-like environment for patients to feel welcome and taken care of.
- 13. A customer and friend of Petitioner Gak wrote that petitioner and the pharmacy are an excellent asset to the community that provide professional and respectful service and care for patient safety.

PETITIONER GAK'S TESTIMONY

- 14. Petitioner Gak took responsibility for the conduct that led to discipline. She acknowledged that she purchased Korean over the counter products that required a prescription in the U.S., that she pre-filled bottles of aspirin without proper labeling, accepted expired medications without following the steps for prescription take-backs, and that she filled prescriptions without performing her corresponding responsibility to check for legitimate patient purposes. She testified that she now checks CURES, confirms a physician patient relationship, looks for irregularities, and makes inquiries.
- 15. Petitioner testified that she was naïve in believing she was ready to open her own pharmacy. She was trying to please older Korean patients who requested products that were sold over the counter in Korea. A customer said she had expired medications and did not know what to do with them and petitioner wanted to accommodate the customer, so she accepted the take-backs. She accepted responsibility for failing to check that a prescription was required for these drugs and for not following the steps to take back prescriptions.

LEGAL CONCLUSIONS

- 1. A pharmacist or permit holder whose license or permit has been placed on probation for a period of three years or more may petition the Board for early termination of probation after at least two years have passed since the effective date of such discipline. (Bus. & Prof. Code, § 4309, subd. (a)(2).)
- 2. More than two years have passed since petitioners' probation period started. Thus, the petition is timely.

- 3. The petition may be heard by the Board sitting with an administrative law judge, or a committee of the Board sitting with an administrative law judge. Where the petition is heard by a committee of the Board, the decision shall be subject to review by the Board under Government Code section 11517. (Bus. & Prof. Code, § 4309, subd. (c).)
- 4. Petitioner bears the burden of proving by clear and convincing evidence that early termination of probation is appropriate. (*Flanzer v. Bd. of Dental Examiners* (1990) 220 Cal.App.3d 1392, 1398; *Hippard v. State Bar* (1989) 49 Cal.3d 1084, 1091–1092.) When evaluating the Petition, the Board may consider: (1) all of the petitioner's activities since the disciplinary action; (2) the offense for which the petitioner was disciplined; (3) the petitioner's activities during the time the license was in good standing; (4) the petitioner's documented rehabilitative efforts; and (5) the petitioner's general reputation for truth and professional ability. (Bus. & Prof. Code, § 4309, subd. (d).)
- 5. The evidence established that petitioner has engaged in extensive rehabilitation through probation, education and community service. She has worked closely with a new PIC and consulting pharmacist to improve practices. She's shown that she performs corresponding responsibilities and has a system for keeping up to date with legal, regulatory, and clinical changes. She has learned that she must strike a balance between helping patients and complying with the legal and regulatory requirements. The evidence showed that public protection no longer requires petitioner's license to be on probation.

ORDER

On May 24, 2024, the Board of Pharmacy, Department of Consumer Affairs, adopted the attached Decision, which reflects the Committee's recommendation, as its own. The petitions for early termination of probation of Eun Joo Gak, Pharmacist License No. RPH 54146, and Gaks Pharmacy, LLC, dba Balboa Pharmacy, Pharmacy Permit No. PHY 51136, are GRANTED.

This decision shall become effective at 5:00 p.m. on July 3, 2024.

It is so ORDERED on June 3, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

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Seung W. Oh, Pharm.D. Board President

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

In the Matter of the Accusation Against:

GAKS PHARMACY, LLC dba BALBOA PHARMACY, Pharmacy Permit No. 51136;

and

EUN JOO GAK, Pharmacist License No. RPH 54146,

Respondents

Agency Case No. 6514

OAH No. 2020080664

DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on May 12, 2021.

It is so ORDERED on April 12, 2021.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

Ay n. Ligge

By

Greg Lippe Board President

1	Xavier Becerra		
2	Attorney General of California ARMANDO ZAMBRANO		
3	Supervising Deputy Attorney General NANCY A. KAISER		
4	Deputy Attorney General State Bar No. 192083		
5	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013		
6	Telephone: (213) 269-6320 Facsimile: (916) 731-2126		
7	Attorneys for Complainant		
8	BEFOR	E THE	
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS		
10	STATE OF CALLEODNIA		
11			
12	In the Matter of the Accusation Against:	Case No. 6514	
13	GAKS PHARMACY, LLC DBA BALBOA	OAH No. 2020080664	
14	PHARMACY 10700 Balboa Blvd. #101		
15	Granada Hills, CA 91344	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO GAKS	
16	Pharmacy Permit No. PHY 51136,	PHARMACY, LLC DBA BALBOA PHARMACY ONLY	
17	and		
18 19	EUN JOO GAK 10700 Balboa Blvd. #101 Granada Hills, CA 91344		
20	Pharmacist License No. RPH 54146		
21	Respondents.		
22			
23	IT IS HERERY STIDI II ATED AND AGD	EED by and between the parties to the above-	
24	entitled proceedings that the following matters are		
25	PART		
26		Executive Officer of the Board of Pharmacy	
27	(Board). She brought this action solely in her offi	•	
28	(Source). She orought this decion solery in her only	colar capacity and is represented in this matter by	
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	STIPULATED SETTLEMENT (BALBOA PHARMACY)(6514)		

Xavier Becerra, Attorney General of the State of California, by Nancy A. Kaiser, Deputy Attorney General.

- 2. Respondent Gaks Pharmacy, LLC dba Balboa Pharmacy (Respondent) is represented in this proceeding by attorney Andre P. Vizcocho, R.PH, J.D., whose address is: 55 Cetus, 1st Floor, Irvine, CA 92618.
- 3. On or about November 2, 2012, the Board of Pharmacy (Board) issued Pharmacy Permit No. PHY 51136 to Gaks Pharmacy, LLC dba Balboa Pharmacy (Respondent). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 6514, and will expire on November 1, 2021, unless renewed.

JURISDICTION

- 4. Accusation No. 6514 was filed before the Board, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on November 25, 2019. Respondent timely filed its Notice of Defense contesting the Accusation.
- 5. A copy of Accusation No. 6514 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 6514. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 7. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- Respondent admits the truth of each and every charge and allegation in Accusation
 No. 6514.
- 10. Respondent agrees that its Pharmacy Permit is subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

- 11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.
- 13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

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14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 51136 issued to Respondent Gaks Pharmacy, LLC dba Balboa Pharmacy is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions:

1. **Definition: Respondent**

For the purposes of these terms and conditions, "Respondent" shall refer to Gaks Pharmacy, LLC dba Balboa Pharmacy. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, members, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by Respondent to or before the Board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

2. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws;
- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment;
- a conviction of any crime; or
- discipline, citation, or other administrative action filed by any state or federal agency
 which involves Respondent's pharmacy permit or which is related to the practice of
 pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging

for any dangerous drug, and/or dangerous device or controlled substance.

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

3. Report to the Board

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

4. Interview with the Board

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

Respondent shall timely cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of the probation, including but not limited to: timely responses to requests for information by Board staff; timely compliance with directives from Board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

6. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent shall pay to the Board its costs of investigation and prosecution in the amount of \$17,500. Respondent and Respondent Eun Joo Gak shall be jointly and severally liable for payment of said costs.

Respondent shall be permitted to pay these costs in a payment plan approved by the Board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation. There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

7. Probation Monitoring Costs

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

8. Status of License

Respondent shall, at all times while on probation, maintain current pharmacy permit with the Board. Failure to maintain current licensure shall be considered a violation of probation.

If Respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

9. License Surrender While on Probation/Suspension

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

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

Respondent further stipulates that it shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. Sale or Discontinuance of Business

During the period of probation, should Respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to Respondent, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the Board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

11. Notice to Employees

Respondent shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent shall submit written notification to the Board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to timely provide such notification to employees, or to timely submit such notification to the Board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

12. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in Respondent or Respondent's stock, and all of its officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and

regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. Premises Open for Business

Respondent shall remain open and engaged in its ordinary business as a [insert license type] in California for a minimum of 120 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent is informed otherwise in writing by the Board or its designee. If Respondent is not open and engaged in its ordinary business as a pharmacy for a minimum of 120 hours in any calendar month, for any reason (including vacation), Respondent shall notify the Board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours Respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which Respondent will resume business as required. Respondent shall further notify the Board in writing with ten (10) days following the next calendar month during which Respondent is open and engaged in its ordinary business as a pharmacy in California for a minimum of 120 hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

14. Posted Notice of Probation

Respondent shall prominently post a probation notice provided by the Board or its designee in a place conspicuous to and readable by the public within two (2) days of receipt thereof from the Board or its designee. Failure to timely post such notice, or to maintain the posting during the entire period of probation, shall be considered a violation of probation.

Respondent shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

15. Violation of Probation

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

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

16. Completion of Probation

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

17. Community Services Program

Within sixty (60) days of the effective date of this decision, Respondent shall submit to the Board or its designee, for prior approval, a community service program in which Respondent shall provide free health-care related services to a community or charitable facility or agency for at least four (4) hours per month for the first three (3) months of probation. Respondent shall also make a \$10,000 donation to nonprofit organization that distributes naloxone or provides services for the treatment of drug addiction. The \$10,000 may be paid in installments, so long as the full amount is paid no later than one (1) year prior to the end date of probation.

Within thirty (30) days of Board approval thereof, Respondent shall submit documentation to the Board demonstrating commencement of the community service program. Respondent shall report on progress with the community service program in the quarterly reports.

Failure to timely submit, commence, or comply with the program shall be considered a violation of probation.

18. No Additional Ownership or Management of Licensed Premises

Respondent shall not acquire any additional ownership, legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, associate, partner or any business, firm, partnership, or corporation currently or hereinafter licensed by the Board except as approved by the Board or its designee. Violations of this restriction shall be considered a violation of probation.

Consultant Pharmacist Review of Pharmacy Operations

During the period of probation, Respondent shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent with state and federal laws and regulations governing the practice of pharmacy. The consultant shall be a pharmacist licensed by and not on probation with the Board and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. During the period of probation, the Board or its designee retains the discretion to reduce the frequency of the pharmacist consultant's review of Respondent's operations. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation.

20. **Statement of Acknowledgement**

Respondent shall provide a written statement acknowledging that Respondent's owner is aware of the potential impact of probation from payers and an acknowledgement of such potential impact.

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1	<u>ACCEPTANCE</u>	
2	I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully	
3	discussed it with my attorney, Andre P. Vizcocho, R.PH, J.D. I understand the stipulation and the	
4	effect it will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary	
5	Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order	
6	of the Board of Pharmacy.	
7		
8	DATED:	
9	By: Eun Joo Gak, Owner GAKS PHARMACY, LLC DBA BALBOA	
10	PHARMACY Respondent	
11	I have read and fully discussed with Respondent Eun Joo Gak, Owner of Respondent Gaks	
12	Pharmacy, LLC dba Balboa Pharmacy, the terms and conditions and other matters contained in	
13	the above Stipulated Settlement and Disciplinary Order. I approve its form and content.	
14	DATED:	
15	ANDRE P. VIZCOCHO, R.PH, J.D. Attorney for Respondent	
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STIPULATED SETTLEMENT (BALBOA PHARMACY)(6514)

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Luis Andre P. Vizcocho, R.PH, J.D. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

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DATED:

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By: Eun Joo Gak, Owner

GAKS PHARMACY, LLC DBA BALBOA

PHARMACY Respondent

I have read and fully discussed with Respondent Eun Joo Gak, Owner of Respondent Gaks Pharmacy, LLC dba Balboa Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED:

1 25 21

LUIS ANDRE P. VIZCOCHO, R.PH, J.D.

Attorney for Respondent

1		ACCEPTANCE	
2	I have carefully read the abov	ve Stipulated Settlement and Disciplinary Orde	er and have fully
3	discussed it with my attorney, Luis	Andre P. Vizcocho, R.PH, J.D. I understand	the stipulation
4	and the effect it will have on my Ph	harmacy Permit. I enter into this Stipulated Ser	ttlement and
5	Disciplinary Order voluntarily, kno	owingly, and intelligently, and agree to be boun	nd by the
6	Decision and Order of the Board of	f Pharmacy.	
7			
8	DATED:		
9		By: Eun Joo Gak, Owner GAKS PHARMACY, LLC DBA BALE	BOA
10		PHARMACY Respondent	
11	I have read and fully discusse	ed with Respondent Eun Joo Gak, Owner of R	espondent Gaks
12	Pharmacy, LLC dba Balboa Pharm	acy, the terms and conditions and other matter	rs contained in
13	the above Stipulated Settlement and	d Disciplinary Order. I approve its form and o	content.
14	DATED: January 25, 2021	Multi	
15		LUIS ANDRE P. VIZCOCHO, R.PH, J Attorney for Respondent	.D.
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1	ENDORSEMENT			
2	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully			
3	submitted for consideration by the Bo	submitted for consideration by the Board of Pharmacy.		
4	DATED:	Respectfully submitted,		
5		Xavier Becerra		
6 7		Attorney General of California ARMANDO ZAMBRANO Supervising Deputy Attorney General		
8				
9		Nancy A. Kaiser		
10		NANCY A. KAISER Deputy Attorney General Attorneys for Complainant		
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STIPULATED SETTLEMENT (BALBOA PHARMACY)(6514)

ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy. Respectfully submitted, XAVIER BECERRA Attorney General of California ARMANDO ZAMBRANO Supervising Deputy Attorney General Deputy Attorney General Attorneys for Complainant LA2018601968 63880313 2.docx

Exhibit A

Accusation No. 6514

1	XAVIER BECERRA		
2	Attorney General of California DAVID E. BRICE Supermising Deputy Attorney Congress		
3	Supervising Deputy Attorney General JEFF STONE Deputy Attorney Congress		
4	Deputy Attorney General State Bar No. 155190		
5	1300 I Street, Suite 125 P.O. Box 944255 Sogramento, CA 04244 2550		
6	Sacramento, CA 94244-2550 Telephone: (916) 210-7726 Faccinities (916) 227-8642		
7	Facsimile: (916) 327-8643 Attorneys for Complainant		
8			
9	BEFORE THE BOARD OF PHARMACY		
10	DEPARTMENT OF CO STATE OF C		
11		1	
12	In the Matter of the Accusation Against:	Case No. 6514	
13	GAKS PHARMACY, LLC DBA BALBOA PHARMACY; EUN JOO GAK, MEMBER	ACCUSATION	
14	AND PHARMACIST-IN-CHARGE 10700 Balboa Blvd., #101		
15	Granada Hills, CA 91344		
16	Pharmacy Permit No. PHY 51136,		
17	and		
18	EUN JOO GAK 10700 Balboa Blvd., #101 Granada Hills, CA 91344		
19	Pharmacist License No. RPH 54146		
20			
21	Respondents.		
22			
23	Complainant alleges:		
24	PAR		
25		s this Accusation solely in her official capacity	
26	as the Interim Executive Office of the Board of Pl	harmacy (Board), Department of Consumer	
27	Affairs.		
28			
	1		

7. 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.

. . .

8. Section 4307, subdivision (a), of the Code states, in pertinent part:

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 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.

STATUTORY PROVISIONS

- 9. Section 4059(a) of the Code states, in pertinent 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 pertinent 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, 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.

his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

19. Section 11164 of the Health and Safety Code states, in pertinent part:

[N]o person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

- (a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision(b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:
- (1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.
- 20. Section 111335 of the Health and Safety Code states, in pertinent part, that any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290).

21. Section 111397 of the Health & Saf. Code states, in pertinent 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.
- (b) Any foreign dangerous drug that is imported lawfully under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or pursuant to an announcement by the United States Food and Drug Administration of the exercise of enforcement discretion for instances including, but not limited to, clinical research purposes, drug shortages development of countermeasures against chemical, biological, radiological, and nuclear terrorism agents, or pandemic influenza preparedness and response is not misbranded.

22. Section 111440 of the Health & Saf. Code states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

REGULATORY PROVISIONS

23. CCR, title 16, section 1776 states:

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board may offer, under the requirements in this article, specified prescription drug take-back services through collection receptacles and/or mail back envelopes or packages to provide options for the public to discard unwanted, unused or outdated prescription drugs. Each entity must comply with regulations of the federal Drug Enforcement Administration (DEA) and this article.

Only California-licensed pharmacies, hospitals/clinics with onsite pharmacies, and drug distributors (licensed wholesalers and third-party logistics providers) who are registered with the DEA as collectors and licensed in good standing with the board may host a pharmaceutical take-back receptacle as authorized under this article.

COST RECOVERY

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

DRUG CLASSIFICATIONS

- 25. Flurbiprofen, used for pain, is a dangerous drug pursuant to Code section 4022, and sold under the brand name Efvex, is a formulation not approved by the Food and Drug Administration in the United States.
- 26. Ketoprofen, used for pain, is a dangerous drug pursuant to Code section 4022, and sold under the brand name Ketotop, is a formulation not approved by the Food and Drug Administration for use in the United States.
- 27. Flubendazole, an anthelmintic used to kill parasites, sold under the brand name Zelcom, is not approved for human use in the United States.
- 28. Alprazolam and Clonazepam, benzodiazepines used to treat anxiety and panic disorders, sold under the brand names Xanax and Klonopin, are Schedule IV controlled

substances under Health & Saf. Code section 11057, subdivision (d)(1) and (7), and dangerous drugs pursuant to Code section 4022.

- 29. Ibuprofen, used for pain and inflammation, sold under the brand name Motrin, is a dangerous drug pursuant to Code section 4022.
- 30. Oxycodone, used for pain, is a Schedule II controlled substance under Health & Saf. Code section 11055, subdivision (b)(1)(M) and a dangerous drug pursuant to Code section 4022.
- 31. Hydrocodone, used for pain, is a Schedule II controlled substance under Health & Saf. Code section 11056(e)(5), and a dangerous drug pursuant to Code section 4022.

FACTUAL BACKGROUND

- 32. On or about August 24, 2017, the Board received an online complaint that Respondents were selling dangerous drugs without prescriptions, had possession of misbranded drugs, and provided unauthorized prescription take-back services.
- 33. On or about February 7, 2018, a Board inspector conducted an inspection of Respondent Balboa Pharmacy in Granada Hills, with Respondent Gak, Pharmacist-In-Charge, present.
- 34. During the February 7, 2018 inspection, in the over-the-counter area of Respondent Balboa Pharmacy, the Board inspector found boxes from Korea containing Ketoprofen (sold as Ketotop) and Flurbiprofen (sold as Efvex). In the active drug supply area of Respondent Balboa Pharmacy, the Board inspector found boxes from Korea containing Flubendazole (sold as Zelcom). The active drug supply at Respondent Balboa Pharmacy also revealed 12 misbranded vials with medication inside located next to stock bottles of aspirin.
- 35. During the February 7, 2018 inspection, Respondent Gak stated that the Ketoprofen, Flurbiprofen, and Flubendazole were supplied to Respondents by Natural Wholefood Korea, Inc. and that since the drugs were sold over the counter in Korea, there were sold over the counter at Respondent Balboa Pharmacy. Natural Wholefood Korea, Inc. is not in the licensed supply chain regulated by the United States Food and Drug Administration (FDA), the Board, or State Department of Public Health (DPH) and is suspended from business by the Franchise Tax Board.

- 36. During the February 7, 2018 inspection, Respondent Balboa Pharmacy also had a JVM Automated Pouch Packaging Device with medication cells that were not properly labeled; they contained medication name, strength, and manufacturer, but did not include medication lot numbers and expiration dates.
- 37. During the February 7, 2018 inspection, Respondent Balboa Pharmacy's storage room contained a box with returned previously dispensed prescription containers with medications inside them. The previously dispensed containers were labeled with numerous different pharmacies. Respondent Gak did not have a proper receptacle for Prescription Take-Back Services, was not registered with the Drug Enforcement Agency as a collector, and did not notify the Board of such activity.
- 38. On or about August 16, 2018, the Board received a complaint from an anonymous healthcare provider that Respondents Balboa Pharmacy and Gak may have been providing prescriptions for controlled substances that were not legitimate. On or about October 22, 2018, a Board inspection was performed at Respondent Balboa Pharmacy, with Respondent Gak, PIC, present. A Board inspector reviewed documentation relating to Respondents' prescription activity between October 22, 2015, and October 22, 2018, compiled through the Controlled Substance Utilization Review and Evaluation System (CURES), part of California's Prescription Drug Monitoring Program. Review of the CURES report indicated trends of dispensing controlled substances with irregularities and red flags of illegitimacy. Respondents also provided the Board inspector with their electronic dispensing records for the time period October 22, 2015, through October 22, 2018.
- 39. The October 22, 2018 inspection and review of records and data showed that Respondents dispensed controlled substances after ignoring, or not being aware of as required, objective factors that were irregular from medically legitimate prescriptions. Prescriptions exhibited objective factors of illegitimacy, irregularity, and abuse, including, but not limited to:
 - cash payment percentages beyond the regular amount seen by Respondents; uniformity of treatment with the same drugs and doses used by three particular prescribers;

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FOURTH CAUSE FOR DISCIPLINE

(Holding a Misbranded Drug)

43. Respondent Balboa Pharmacy and Respondent Gak, as Pharmacist-In-Charge, are subject to disciplinary action under Code section 4342(a) and Health & Saf. Code section 111440, in that they sold, offered for sale, delivered or held pharmaceutical preparations and drugs that were misbranded. The circumstances are set forth in paragraph 36 above.

FIFTH CAUSE FOR DISCIPLINE

(Unauthorized Prescription Drug Take-Back Services)

44. Respondent Balboa Pharmacy and Respondent Gak, as Pharmacist-In-Charge, are subject to disciplinary action under CCR, title 16, section 1776, by and through Code section 4301(o), in that they provided prescription take-back services without complying with that article and the regulations of the DEA. The circumstances are set forth in paragraph 37 above.

SIXTH CAUSE FOR DISCIPLINE

(Corresponding Responsibility for Legitimacy of Prescription)

- 45. Respondent Balboa Pharmacy and Respondent Gak, as Pharmacist-In-Charge, are subject to disciplinary action under Health and Safety Code section 11153 and 16 CCR 1761, by and through Code sections 4301(o) and 4113, in that they failed to fulfill their corresponding responsibility to ensure the proper prescribing and dispensing of controlled substances. The circumstances are as follows:
- 46. On or about October 22, 2018, and during further investigation which reviewed dispensing data and records from October 22, 2015 to October 22, 2018, it was found that Respondents dispensed excessive controlled substances prescriptions with irregularities and red flags of abuse without ensuring the prescriptions were issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.

 Respondents dispensed controlled substances after ignoring, or not being aware of, objective factors which were irregular from medically legitimate prescriptions. The objective factors of illegitimacy, irregularity, and abuse are set forth more fully in paragraphs 38 and 39 above.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

47. Respondent Balboa Pharmacy and Respondent Gak, as Pharmacist-In-Charge, are subject to disciplinary action under Code sections 4301, subdivisions (a), (d), (j) and (o) and 4113, in that they committed unprofessional conduct by operating in a grossly negligent manner, violating laws and regulations governing the practice of pharmacy, violating laws and regulations regulating controlled substances, and clearly excessive furnishing of controlled substances without the exercise of its corresponding responsibility to only dispense medically legitimate prescriptions. Respondents' conduct constituted gross negligence by operating in violation of the laws and regulations intended to ensure the safe practice of pharmacy and the safe distribution of controlled substances. Respondents operated in a manner that was gross deviation from the standard of safe pharmacy practice, and which could cause harm to patients or other persons. The circumstances are set forth in paragraphs 32 through 39 above.

OTHER MATTERS

- 48. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 51136, issued to Gaks Pharmacy, LLC dba Balboa Pharmacy, then Gaks Pharmacy, LLC dba Balboa Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51136 is placed on probation or until Pharmacy Permit Number PHY 51136 is reinstated if it is revoked.
- 49. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 51136, issued to Gaks Pharmacy, LLC dba Balboa Pharmacy, while Respondent Eun Joo Gak has been an officer and owner and had knowledge of or knowingly participated in any conduct for which the license was disciplined, then Respondent Eun Joo Gak shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51136 is placed on probation or until Pharmacy Permit Number PHY 51136 is reinstated if it is revoked.

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50. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 54146, issued to Respondent Eun Joo Gak, then Respondent Eun Joo Gak shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 54146 is placed on probation or until pharmacist License Number RPH 54146 is reinstated if it is revoked.

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:

- Revoking or suspending Pharmacy Permit Number PHY 51136, issued to Gaks
 Pharmacy, LLC dba Balboa Pharmacy;
- Revoking or suspending Pharmacy License Number RPH 54146, issued to Eun Joo
 Gak;
- 3. Prohibiting Gaks Pharmacy, LLC dba Balboa Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51136 is placed on probation or until Pharmacy Permit Number PHY 51136 is reinstated if it is revoked;
- 4. Prohibiting Eun Joo Gak from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 51136 is placed on probation or until Pharmacy Permit Number PHY 51136 is reinstated if it is revoked;
- 5. Prohibiting Eun Joo Gak from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 54146 is placed on probation or until Pharmacist License Number RPH 54146 is reinstated if it is revoked;
- 6. Ordering Gaks Pharmacy, LLC dba Balboa Pharmacy and Eun Joo Gak 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,

1	7. Taking such other and further action as deemed necessary and proper.
2	
3	DATED: November 14, 2019
4	ANNE SODERGREN
5	Interim Executive Officer Board of Pharmacy
6	Board of Pharmacy Department of Consumer Affairs State of California
7	Complainant
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