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

In the Matter of the Accusation Against:

PDB, INC. DBA PILL BOX DRUG, PATRICK PAEK HWANG, PRESIDENT, SECRETARY, PHARMACIST-IN-CHARGE, Pharmacy Permit No. PHY 43286

Respondent.

Agency Case No. 7835

OAH No. 2024080397

DECISION AND ORDER

The attached Stipulated Surrender of License and 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 November 6, 2024.

It is so ORDERED on October 7, 2024.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
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NANCY A. KAISER
Supervising Deputy Attorney General
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Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **PDB, INC. DBA PILL BOX DRUG, PATRICK PAEK HWANG, PRESIDENT, SECRETARY, PHARMACIST-IN-CHARGE** **165 Palos Verdes Blvd** **Redondo Beach, CA 90277** **Pharmacy Permit No. PHY 432286** Respondent.	Case No. 7835 OAH No. 2024080397 **STIPULATED SURRENDER OF LICENSE AND ORDER**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren ("Complainant") is the Executive Officer of the Board of Pharmacy ("Board"). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Stephen D. Svetich, Deputy Attorney General.

2. Respondent PDB, Inc., doing business as Pill Box Drug ("Respondent") is represented in this proceeding by attorney Tony J. Park, whose address is: California Pharmacy Lawyers, 9090 Irvine Center Drive, Irvine, CA 92618-4658.

3. On or about April 25, 2003, the Board issued Pharmacy Permit Number PHY 43286 to Respondent. At all times relevant to the allegations alleged herein, Patrick Paek Hwang ("PIC Hwang") was the President, Secretary, and Pharmacist-in-Charge of Respondent. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2025, unless renewed. On June 14, 2024, Complainant filed a Petition for Interim Suspension Order seeking the suspension of Respondent's Pharmacy Permit. On July 18, 2024, the Office of Administrative Hearings issued an order pursuant to Business and Professions Code section 494 suspending Respondent's Pharmacy Permit pending a full administrative determination on the allegations raised in an Accusation. Pursuant to that order, Respondent's Pharmacy Permit is currently suspended.

JURISDICTION

4. Accusation No. 7835 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 August 1, 2024. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 7835 is attached as **Exhibit A** and incorporated by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 7835. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.

6. 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.

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

CULPABILITY

8. Respondent admits the truth of each and every charge and allegation in Accusation No. 7835, agrees that cause exists for discipline, and hereby surrenders its Pharmacy Permit No. PHY 432286 for the Board's formal acceptance.

9. Respondent understands that by signing this stipulation, it enables the Board to issue an order accepting the surrender of its Pharmacy Permit without further process.

CONTINGENCY

10. This stipulation shall be subject to approval by the Board. Respondent understands and agrees that counsel for Complainant and the staff of the Board may communicate directly with the Board regarding this stipulation and surrender, 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 Surrender 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.

11. The parties understand and agree that Portable Document Format ("PDF") and facsimile copies of this Stipulated Surrender of License and Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

12. This Stipulated Surrender of License and 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 Surrender of License and 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.

13. 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 Order:

ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 432286, issued to Respondent PDB, Inc. doing business as Pill Box Drug, Patrick Paek Hwang, President, Secretary, and Pharmacist-in-Charge, is surrendered and accepted by the Board. However, the surrender will be stayed for a period of 180 days from the effective date of the Order adopting this Stipulated Surrender, by which time the pharmacy shall be sold or closed. The parties agree that the interim suspension issued July 18, 2024, shall remain in place through the entirety of the stay of the surrender.

1. In the event that Respondent's pharmacy is not sold within 180 days from the effective date of this decision, Respondent shall, within ten (10) days of the lapse of six months from the effective date, arrange for the destruction of, the transfer to, sale of, or storage in a facility licensed and approved by the Board, all controlled substances and dangerous drugs and/or dangerous devices. Respondent shall further arrange for the transfer of all records of acquisition and disposition of dangerous drugs to premises licensed and approved by the Board. Respondent shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to Board guidelines.

2. In the event that Respondent's pharmacy is not sold within 180 days from the effective date of this decision, Respondent shall also, within ten (10) days of the lapse of six months from the effective date, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to ongoing patients, Respondent shall provide a copy of the written notice to the Board. "Ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the prior ninety days.

3. The surrender of Respondent's Pharmacy Permit and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

4. Respondent shall lose all rights and privileges as a pharmacy in California as of the effective date of the Board's Decision and Order.

5. Respondent shall relinquish its pharmacy permit, and any indicia of licensure issued by the Board, including but not limited to wall and renewal license certificates, within five (5) days of the lapse of 180 days from the effective date of this decision.

6. Respondent understands and agrees that if it ever file an application for licensure of a licensed premises or a petition for reinstatement in the State of California, the Board shall treat the application or petition as a new application for licensure.

7. Respondent may not reapply for any license from the Board for three (3) years from the effective date of this decision. Respondent stipulates that should it apply for any license from the Board on or after the effective date of this decision, all allegations set forth in Accusation No. 7835 shall be deemed to be true, correct and admitted by the applicant when the Board determines whether to grant or deny an application.

8. If Respondent applies for any license from the Board, it shall satisfy all requirements applicable to that license as of the date the application is submitted to the Board.

9. If Respondent ever applies or reapplies for a license or certification by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation No. 7835 shall be deemed to be true, correct, and admitted by them for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

10. Respondent shall pay the Board its costs of investigation and enforcement in the amount of $17,653.50 prior to applying for a new or reinstated license.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will

have on my Pharmacy Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

PDB, INC. DBA PILL BOX DRUG,
PATRICK PAEK HWANG, PRESIDENT,
SECRETARY, PHARMACIST-IN-CHARGE
Respondent

I have read and fully discussed with Respondent PDB, Inc., doing business as Pill Box Drug, Patrick Paek Hwang, President, Secretary, Pharmacist-in-Charge, the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: _____

TONY J. PARK
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
NANCY A. KAISER
Supervising Deputy Attorney General

STEPHEN D. SVETICH
Deputy Attorney General
Attorneys for Complainant

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have on my Pharmacy Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 8/21/2024

DocuSigned by:
Patrick Paek Hwang
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PDB, INC. DBA PILL BOX DRUG,
PATRICK PAEK HWANG, PRESIDENT,
SECRETARY, PHARMACIST-IN-CHARGE
Respondent

I have read and fully discussed with Respondent PDB, Inc., doing business as Pill Box Drug, Patrick Paek Hwang, President, Secretary, Pharmacist-in-Charge, the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: 8/21/2024

DocuSigned by:
Tony J. Park
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TONY J. PARK
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: August 22, 2024

Respectfully submitted,

ROB BONTA
Attorney General of California
NANCY A. KAISER
Supervising Deputy Attorney General

STEPHEN D. SVETICH
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 7835

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Attorneys for Complainant

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

In the Matter of the Accusation Against:	Case No. 7835
PDB, INC., DBA PILL BOX DRUG, PATRICK PAEK HWANG, PRESIDENT, SECRETARY, PHARMACIST-IN-CHARGE **165 Palos Verdes Blvd.,** **Redondo Beach, CA 90277**	**ACCUSATION**
Pharmacy Permit No. PHY 43286, Respondent.	

PARTIES

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

2. On or about April 25, 2003, the Board issued Pharmacy Permit Number PHY 43286 to PDB, Inc., doing business as Pill Box Drug ("Respondent"). At all times relevant to the allegations alleged herein, Patrick Paek Hwang ("PIC Hwang") was the President, Secretary, and Pharmacist-in-Charge of Respondent. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2025, unless renewed. On

June 14, 2024, Complainant filed a Petition for Interim Suspension Order seeking the suspension of Respondent's Pharmacy Permit. On July 18, 2024, the Office of Administrative Hearings issued an order pursuant to Business and Professions Code section 494 suspending Respondent's Pharmacy Permit pending a full administrative determination on the allegations raised in the Petition for Interim Suspension Order. Pursuant to that order, Respondent's Pharmacy Permit is currently suspended.

JURISDICTION

3. This Accusation is brought before the Board, under the authority of the following laws. All section references are to the Business and Professions Code ("Code") unless otherwise indicated.

4. 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 & Safety Code, § 11000 et seq.].

5. Code section 4300, subdivision (a), provides that every license issued by the Board may be suspended or revoked.

6. Code section 4300.1 provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, 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.

7. Section 4302 of the Code states, "[t]he board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee."

8. Section 4307 of the Code states:

> (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.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308 , may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

9. Business and Professions Code section 4076.6 provides, in pertinent part:

(a) Upon the request of a patient or patient's representative, a dispenser shall provide translated directions for use, which shall be printed on the prescription container, label, or on a supplemental document. If translated directions for use appear on a prescription container or label, the English-language version of the

may appear on other areas of the label outside the patient-centered area. When it is not possible for the English-language directions for use to appear on the container or label, it shall be provided on a supplemental document.

. . . .

10. Section 4081 of the Code states:

(a) All records of manufacture and of sale, acquisition, 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, pharmacy, veterinary food-animal drug retailer, 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.

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

. . . .

11. Business and Professions Code section 4084 provides, in pertinent part:

(a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated, misbranded, or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.

(b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated, misbranded, or counterfeit, a board inspector shall remove the tag or other marking.

(c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.

(d) For the purposes of this article, "counterfeit" shall have the meaning defined in Section 109905 of the Health and Safety Code.

(e) For the purposes of this article, "adulterated" shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(f) For the purposes of this article, "misbranded" shall have the meaning Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

12. Business and Professions Code section 4169 provides, in pertinent part:

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

. . . .

(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.

. . . .

13. Business and Professions Code section 4301 provides, in pertinent part:

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

. . . .

(b) Incompetence.

(c) Gross negligence.

. . . .

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

. . . .

(*o*) Violating or attempting to violate, directly or indirectly, or assisting in or

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.

. . . .

14. Health and Safety Code section 111250 provides, in pertinent part:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

15. Health and Safety Code section 111255 provides, in pertinent part:

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

16. Health and Safety Code section 111295 provides, in pertinent part:

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

17. Health and Safety Code section 111330 provides, in pertinent part:

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

18. Health and Safety Code section 111335 provides, in pertinent part:

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

19. Health and Safety Code section 111440 provides, in pertinent part:

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

REGULATORY PROVISIONS

20. California Code of Regulations, title 16, section 1707.2 provides, in pertinent part:

. . . .

(b)(1) When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail or delivery), a pharmacy shall ensure that:

(A) the patient receives written notice of his or her right to request consultation;

(B) the patient receives written notice of the hours of availability and the telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record; and

(C) a pharmacist shall be available (i) to speak to the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week.

. . . .

21. California Code of Regulations, title 16, section 1707.5 provides, in pertinent part:

. . . .

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

. . . .

22. California Code of Regulations, title 16, section 1714 provides, in pertinent part:

. . . .

(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes.

. . . .

23. California Code of Regulations, title 16, section 1715.65 provides, in pertinent part:

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory activities and prepare inventory reconciliation reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g), inventory reconciliation reports shall be prepared on the following ongoing basis:

(1) For federal Schedule II controlled substances, at least once every three months.

(2) For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months:

(A) Alprazolam, 1 milligram/unit.

(B) Alprazolam, 2 milligrams/unit.

(C) Tramadol, 50 milligrams/unit.

(D) Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.

(3)(A) For any controlled substance not covered by paragraph (1) or (2), an inventory reconciliation report shall be prepared for identified controlled substances lost no later than three months after discovery of the reportable loss of that controlled substance. This report shall be completed if the loss is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of that controlled substance before the loss was discovered through the date of discovery. At a minimum, a reportable loss is as specified in section 1715.6, or any pattern(s) of loss(es) identified by the pharmacist in charge, as defined by the pharmacy's policies and procedures. A reportable loss shall require an inventory reconciliation report for each pattern of loss identified.

(B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions sufficient to identify loss of controlled substances. The functions sufficient to identify loss outside of the inventory reconciliation process shall be identified within the pharmacy's policies and procedures.

(b) The pharmacist-in-charge of a pharmacy or consulting pharmacist for a clinic shall review all inventory activities performed and inventory reconciliation reports prepared pursuant to this section, and establish and maintain secure methods to prevent losses of federal controlled substances. Written policies and procedures shall be developed for performing the inventory activities and preparing the inventory

reconciliation reports required by this section.

(c) An inventory reconciliation report prepared pursuant to this section shall include all of the following:

(1) A physical count, not an estimate, of all quantities of each federal controlled substance covered by the report that the pharmacy or clinic has in inventory, except as provided in subdivision (h). The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section. An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);

(2) A review of all acquisitions and dispositions of each federal controlled substance covered by the report since the last inventory reconciliation report covering that controlled substance;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) Identification of all records used to compile the report, which shall be maintained in the pharmacy or clinic pursuant to subdivision (e)(2);

(5) Identification of each individual involved in preparing the report; and

(6) Possible causes of overages.

. . . .

24. California Code of Regulations, title 16, section 1717.5 provides, in pertinent part:

(a) A pharmacy may offer a program to automatically refill prescriptions provided the pharmacy complies with this section.

(1) The pharmacy shall have written policies and procedures describing the program, which shall set forth, at a minimum, how the pharmacy will comply with this section.

(2) Before a patient enrolls, the pharmacy shall provide a written or electronic notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program. The patient or patient's agent shall enroll by written, online, or electronic informed consent to participate in the program for each new prescription wherein there is a change in the prescription medication, strength, dosage form, or directions for use.

. . . .

25. California Code of Regulations, title 16, section 1718, states:

"Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory.

26. California Code of Regulations, title 16, section 1746.4 provides, in pertinent part:

(a) A pharmacist initiating and/or administering any vaccine pursuant to section 4052 or 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

. . . .

(2) Basic life support certification.

. . . .

27. California Code of Regulations, title 16, section 1764 provides, in pertinent part:

No pharmacist shall exhibit, discuss, or reveal the contents of any prescription, the therapeutic effect thereof, the nature, extent, or degree of illness suffered by any patient or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist serving the patient, or a person duly authorized by law to receive such information.

28. Code of Federal Regulations, title 21, section 1304.04 provides, in pertinent part:

. . . .

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

. . . .

(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed,

letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances. However, if a pharmacy employs a computer application for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

. . . .

COST RECOVERY

29. 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.

DRUG DEFINITIONS

30. The drugs at issue in this matter are defined in Table 1, below:

TABLE 1

BRAND NAME	GENERIC NAME	DANGEROUS DRUG PER B & PC 4022	CONTROLLED SUBSTANCE PER H & SC	INDICATIONS FOR USE
Keppra	levetiracetam	yes	no	Seizure
Tapazole	methimazole	yes	no	Hyperthyroidism
AndroGel	testosterone	yes	yes	Testosterone replacement
Dotti Transdermal (patch)	Estradiol patch	yes	no	Menopause symptoms
Baytril	enrofloxacin	yes	no	Bacterial infection
Ativan	lorazepam	yes	yes	Anxiety
Pepcid	famotidine	yes	no	Heartburn

FACTUAL ALLEGATIONS

31. Respondent operates a retail pharmacy that dispenses an average of 100 prescriptions per day, with approximately 80% as refills and 20% as new prescriptions. Respondent's facility is normally staffed with two pharmacists and one clerk. The two pharmacists are PIC Hwang and his daughter, Emily Hwang, RPH 84218 ("RPH Hwang"). PIC Hwang compounds an average of 30 prescriptions per day, with approximately 70% of the prescriptions compounded for veterinary use and approximately 30% of the prescriptions compounded for human use.

Inspection on April 24, 2024

32. On April 24, 2024, two Board inspectors conducted a routine inspection at Respondent's facility. PIC Hwang was present to assist the Board's inspectors during the inspection. The inspectors conducted a full review of Respondent's practices, including its handling of outdated drugs and nonsterile compounding practices. Respondent did not have a

compounding self-assessment, a biennial Drug Enforcement Agency ("DEA") inventory, or a quarterly Schedule II Inventory Reconciliation for the Board's inspectors to review.

33. An inspector observed numerous problems with Respondent's compounding practices. PIC Hwang, Respondent's only compounding pharmacist, had not completed an annual competency or validation since 2000, even though it is required annually. Respondent does not have equipment calibration for compounding equipment, does not monitor ambient room temperature, and does not have cleaning records, all of which are requirements. PIC Hwang had not performed the required annual reviews of Respondent's compounding policies and procedures. PIC Hwang last sent out a sample Compounded Non-Sterile Preparation ("CNSP") for quality assurance testing approximately ten years ago, even though such testing is required annually. Respondent's compounding prescription labels failed to state, "compounded by" or any information notifying the consumer it was compounded, as required. Respondent did not maintain compounding records for prescriptions compounded, as required.

34. An inspector observed numerous compounded medications without necessary labels which contain necessary information – the date of preparation, the Beyond Use Date ("BUD"), or the drug/contents in the containers. There were over 20 containers with compounded preparation(s) inside which did not bear a label of any kind. There was a plastic bag labeled as "levetiracetam 30mg/0.1mL" containing prefilled syringes, but the individual syringes were not labeled with any information. Exacerbating this failure, Respondent did not maintain any compounding record(s) for the drugs in these syringes. Inspectors also observed over 50 plastic bags labeled as "methimazole 1.25 mg/0.1mL," along with other concentration strengths, with lot numbers and expiration dates indicating they expired on December 22, 2022, over a year before the inspection. Again, Respondent did not maintain any compounding record(s) for the drugs in these bags.

35. Overall, the facility was extremely dirty, disorganized, cluttered, and in a state of disrepair. It was not in an appropriate condition for compounding drugs. There were numerous staff food products (hot sauce and bagel seasoning) and cleaning products stored on the shelf adjacent to the active compounding drug inventory. Both sinks in the pharmacy appeared dirty,

cluttered, and in a state of disrepair, and none of the sinks were suitable to use for pharmaceutical purposes.

36. At the conclusion of the inspection, the Board issued Respondent an Order of Correction for the following violations observed during the inspection on April 24, 2024:

a. ***Violation of California Code of Regulations, title 16, section 1714(b):*** Respondent did not monitor daily refrigerator temperatures to ensure drugs, including vaccines, are safely and properly maintained. During the inspection, Respondent's refrigerator temperature was approximately 51-53 degrees Fahrenheit, which is dangerously above the normal range of 36-46 degrees Fahrenheit.

b. ***Violation of California Code of Regulations, title 16, section 1715.65(c):*** Respondent did not perform the required quarterly Schedule II inventory reconciliation. It only had a perpetual Schedule II inventory count.

c. ***Violation of California Code of Regulations, title 16, section 1707.2(b)(1):*** Respondent did not provide a written notice of the patient's right to request consultation for prescriptions which are delivered.

d. ***Violation of Business and Professions Code section 4076.6, subdivision (a):*** When translated directions, not in English, were present on the prescription container label, the English language versions were not available either on the container, label or on a supplemental document provided to the patient.

e. ***Violation of California Code of Regulations, title 16, section 1764:*** Patient prescription labels were in general trash and waste bins.

f. ***Violation of California Code of Regulations, title 16, section 1707.5(d):*** Respondent did not have policies and procedures in place for interpretive services.

g. ***Violation of California Code of Regulations, title 16, section 1717.5(a)(2):*** Respondent did not provide a written or electronic notice summarizing its automatic refill program and did not obtain patient consent for enrollment for each prescription.

h. ***Violation of Code of Federal Regulations, title 21, section 1304.04(h)(1):*** Invoice records for Schedule II drugs were not stored separately from all other invoice records.

The invoice records for Schedule II drugs were comingled with invoice records for all other drugs.

i. ***Violation of Code of Federal Regulations, title 21, section 1304.04(h)(4):*** Prescriptions for Schedule III, IV, and V drugs were not readily retrievable. Respondent did not stamp these prescriptions with a red "C" on the face of the prescription or otherwise maintain them in a manner electronically such that they are distinguishable from other drugs in Respondent's recordkeeping system.

j. ***Violation of California Code of Regulations, title 16, section 1717.5(a)(1):*** Respondent did not have written policies and procedures regarding its automatic refill program.

k. ***Violation of California Code of Regulations, title 16, section 1746.4(b)(2):*** Respondent's two pharmacists (including PIC Hwang) did not have current Basic Life Support ("BLS") certification.

37. On May 1, 2024, the Board issued to Respondent a Notice of Violation informing Respondent to "not engage in compounding until in compliance with compounding regulations." The Notice of Violation noted the following violations observed during the inspection on April 24, 2024:

a. ***Violation of California Code of Regulations, title 16, section 1714(b):*** Respondent's facilities, space, fixtures, and equipment were not maintained to ensure drugs are safely and properly prepared, maintained, secured, and distributed.

b. ***Violation of California Code of Regulations, title 16, section 1714(c):*** Respondent's pharmacy, fixtures, and equipment were not maintained in a clean and orderly condition. The sink used for pharmaceutical purposes was dirty, uncleaned, and used for food items.

c. ***Violation of Business and Professions Code section 4169, subdivision (a)(3):*** Respondent maintained many dangerous drugs that had false and misleading labels. For example, BUDs were not correct or extended without support, and expiration dates/ lot numbers were not accurate.

d. ***Violation of Business and Professions Code section 4169, subdivision (a)(2):*** Respondent produced, prepared, packed, or held many dangerous drugs under conditions whereby they may have been contaminated with filth. For example, CNSPs were produced, prepared, packed, or held in unsanitary conditions.

Inspection on May 6, 2024

38. On May 6, 2024, four Board inspectors returned to Respondent's pharmacy to conduct a second inspection at the pharmacy and embargo dangerous drugs and devices suspected to be adulterated[1] or misbranded,[2] pursuant to Business and Professions Code section 4084.

39. During this inspection, Respondent's pharmacy remained in a disorganized and cluttered state. It was again in a state that was not an appropriate condition for compounding drugs. Despite the poor condition of Respondent's pharmacy, the Board's inspectors observed evidence that Respondent was still compounding in violation of Pharmacy Law even after Respondent received the Board's notice dated May 1, 2024. PIC Hwang also admitted to improperly compounding hazardous drugs (cyclosporine ophthalmic eye drops for dogs) without a sterile compounding environment approximately six to seven years prior to the Board's inspection.

40. The Board's inspectors also observed several other violations of pharmacy law during their inspection. In Respondent's will call area, there was a receipt for a prescription dated April 30, 2024, for testosterone 3 mg/gram cream that was stapled to a bag containing Dotti Transdermal, not testosterone, ready to be dispensed to a patient. Inspectors also observed three prescription bottles dispensed by other pharmacies with expired medications. RPH Hwang admitted to a Board inspector that patients sometimes brought prescriptions dispensed by other pharmacies for Respondent to use them to compound their prescriptions, even though that practice is not legally permissible.

[1] The definition of an "adulterated drug" is contained in Health and Safety Code sections 111250 and 111255, cited above in the section titled, "Statutory Provisions."

[2] The definition of a "misbranded drug" is contained in Health and Safety Code sections 111330 and 111335, cited above in the section titled, "Statutory Provisions."

41. PIC Hwang was dishonest with the Board's inspectors regarding the disposition of expired medications discovered during the inspection on April 24, 2024. After PIC Hwang told the inspectors expired API containers and expired and mislabeled compounded preparations were in sealed cardboard boxes waiting to be picked up by a reverse distributor, the Board's inspectors found them hidden in the second floor storage room in a filing cabinet.

42. The Board commenced the embargo process because it had probable cause to believe there were numerous dangerous drugs or dangerous devices that were adulterated and misbranded. The Board embargoed the contents located in the HD compounding room, the non-HD compounding hood and surrounding area, inventory stock, stock refrigerator, will call area/will call refrigerator, and the storage area on the second level. All embargoed items were placed in cardboard boxes and/or sealed in their original bulk container and placed in the HD compounding room, the non-HD compounding hood, and inside the drug refrigerator.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct, Adulterated Drugs)

43. Respondent is subject to disciplinary action pursuant to Code sections 4301, subdivision (j), and 4169, subdivision (a)(2), in conjunction with Health and Safety Code sections 111250, 111255, and 111295, in that as of the Board's inspections on April 24, 2024, and May 6, 2024, Respondent produced, prepared, packed, or held dangerous drugs under conditions whereby they may have been contaminated with filth. Complainant refers to and by this reference incorporates the allegations set forth above in paragraphs 30 through 42, inclusive, as though set forth fully herein.

SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct, Misbranded Drugs)

44. Respondent is subject to disciplinary action pursuant to Code sections 4301, subdivision (j), and 4169, subdivision (a)(3), in conjunction with Health and Safety Code sections 111330, 111335, and 111440, in that as of the Board's inspections on April 24, 2024, and May 6, 2024, Respondent maintained dangerous drugs that had false and misleading labels. Complainant

refers to and by this reference incorporates the allegations set forth above in paragraphs 30 through 42, inclusive, as though set forth fully herein.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct, Failure to Make Available English Translations of Prescription Instructions)

45. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), in that Respondent violated Code section 4076.6, subdivision (a), in that as of the Board's inspection on April 24, 2024, Respondent failed to make available to patients the English language versions of non-English directions present on a prescription labels. Complainant refers to and by this reference incorporates the allegations set forth above in paragraphs 30 through 42, inclusive, as though set forth fully herein.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct, Violating California Regulations Applicable to Pharmacy)

46. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivision (o), in that Respondent violated the following provisions of title 16 of the California Code of Regulations:

i. Section 1714(b): As of the Board's inspection on April 24, 2024, Respondent did not monitor daily refrigerator temperatures to ensure drugs, including vaccines, are safely and properly maintained. During the inspection, Respondent's refrigerator temperature was approximately 51-53 degrees Fahrenheit, which is dangerously above the normal range of 36-46 degrees Fahrenheit.

ii. Section 1715.65(c): As of the Board's inspection on April 24, 2024, Respondent had not performed the required quarterly Schedule II inventory reconciliation. Respondent only has a perpetual Schedule II inventory count.

iii. Section 1707.2(b)(1): As of the Board's inspection on April 24, 2024, Respondent did not provide a written notice of the patient's right to request consultation for prescriptions which are delivered.

iv. Section 1764: As of the Board's inspection on April 24, 2024, Respondent failed to maintain the confidentiality of private patient healthcare information by disposing of patient prescription labels in general trash and waste bins.

v. Section 1707.5(d): As of the Board's inspection on April 24, 2024, Respondent did not have policies and procedures in place for interpretive services.

vi. Section 1717.5(a)(2): As of the Board's inspection on April 24, 2024, Respondent did not provide a written or electronic notice summarizing its automatic refill program and does not obtain patient consent for enrollment for each prescription.

vii. Section 1304.04(h)(1): As of the Board's inspection on April 24, 2024, Respondent failed to store invoice records for Schedule II drugs separately from all other invoice records. The invoice records for Schedule II drugs were comingled with invoice records for all other drugs.

viii. Section 1304.04(h)(4): As of the Board's inspection on April 24, 2024, Respondent's prescription records for Schedule III, IV, and V drugs are not readily retrievable. Respondent did not maintain these records in a manner such that they are distinguishable from records for other drugs.

ix. Section 1717.5(a)(1): As of the Board's inspection on April 24, 2024, Respondent did not have written policies and procedures regarding its automatic refill program.

x. Section 1746.4(b)(2): As of the Board's inspection on April 24, 2024, Respondent's two pharmacists (PIC Hwang and Pharmacist Hwang) did not have current BLS certification but were administering vaccines to patients.

xi. Section 1714(b): As of the Board's inspections on April 24, 2024, and May 6, 2024, Respondent's facilities, space, fixtures, and equipment were not maintained to ensure drugs are safely and properly prepared, maintained, secured, and distributed.

xii. Section 1714(c): As of the Board's inspections on April 24, 2024, and May 6, 2024, Respondent's pharmacy, fixtures, and equipment were not maintained in a clean and orderly condition. The sink for pharmaceutical purposes was dirty, uncleaned, and used for food items.

Complainant refers to and by this reference incorporates the allegations set forth above in paragraphs 30 through 42, inclusive, as though set forth fully herein.

DISCIPLINE CONSIDERATIONS

47. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges that on or about July 24, 2020, in a prior action, the Board issued Citation Number CI 2018 82230 to Respondent for violating Business and Professions Code sections 4081, subdivision (a) and 4169, subdivision (a)(5) [Failure to Maintain Records of Dangerous Drugs and Devices]; Business and Professions Code section 4342, subdivision (a), and Health and Safety Code sections 111440 and 111295 [Adulterated Drugs]; California Code of Regulations, title 16, sections 1714(c) [Failure to Maintain Fixtures and Equipment in a Sanitary and Orderly Condition]; and 1735.3(a)(2)(F) [Failure to Maintain Compounding Records]. The Board ordered Respondent to pay a civil penalty of $3,000. That Citation is now final.

48. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges that on or about May 28, 2020, in a prior action, the Board issued Citation Number CI 2018 83492 to Respondent for violating California Code of Regulations, title 16, sections 1714(c) [Variation from Prescription]. There was no civil penalty imposed. That Citation is now final.

OTHER MATTERS

49. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 43286, issued to PDB, Inc., doing business as Pill Box Drug, PDB, Inc. 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 43286 is placed on probation or until Pharmacy Permit Number 43286 is reinstated if it is revoked.

50. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 43286, issued to PDB, Inc., doing business as Pill Box Drug, while Patrick Paek Hwang was the Pharmacist-in-Charge, then Patrick Paek Hwang 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 43286, issued to PDB, Inc., doing business as Pill Box Drug, is placed on probation or until 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:

1. Revoking or suspending Pharmacy Permit Number PHY 43286, issued to PDB, Inc., doing business as Pill Box Drug;

2. Prohibiting PDB, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43286 is placed on probation or until Pharmacy Permit Number PHY 43286 is reinstated if Pharmacy Permit Number PHY 43286 issued to PDB, Inc., doing business as Pill Box Drug, is revoked;

3. Prohibiting Patrick Paek Hwang from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43286 is placed on probation or until Pharmacy Permit Number PHY 43286 is reinstated if Pharmacy Permit Number PHY 43286 issued to PDB, Inc., doing business as Pill Box Drug, is revoked;

4. Ordering PDB, Inc. 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, if placed on probation, the costs of probation monitoring; and,

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

DATED: 8/1/2024

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2024.08.01 09:56:34 -07'00'

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

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