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

In the Matter of the Accusation Against**:** **UNITED PHARMACY,** **PAMELA GUMBS, OWNER** 2929 Telegraph Ave. Berkeley, CA 94705 **Original Permit No. PHY 48413;** **PAMELA GUMBS** 2971 Florida St. Oakland, CA 94602 **Pharmacist No. RPH 29485;** Respondents.	Case No. 6318 **A C C U S A T I O N**

PARTIES

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

2. On October 5, 2007, the Board issued Original Permit Number PHY 48413 to United Pharmacy (Respondent United Pharmacy), with owner Pamela Gumbs as Pharmacist-in-Charge (PIC). The Original Permit was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on October 1, 2021, unless renewed.

3. On May 27, 1975, the Board issued Registered Pharmacist License Number RPH 29485 to Pamela Gumbs (Respondent Gumbs). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on

April 30, 2022, unless renewed. At all times relevant to the charges in this Accusation against her, Respondent Gumbs functioned as the PIC at Respondent United Pharmacy.

JURISDICTION

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

5. Code section 4011 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.].

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

7. Code section 4300.1 provides:

> 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. Code section 4307, subdivision (a) provides:

> 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.

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STATUTORY PROVISIONS

9. Code section 4022 states:

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

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

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

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

10. Code section 4076, subdivision (a) states, in relevant part, that a pharmacist shall not dispense any prescription drug except in a container that meets the requirements of state and federal law, and is correctly labeled with the quantity of the drug or drugs dispensed.

11. Code section 4077 states, in relevant part, that except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

12. Code section 4081 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.

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

13. Code section 4105 states:

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

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

14. Code section 4113, subdivision (c) states: "The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

15. Code section 4301 states, in relevant part:

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

. . .

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

. . .

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

16. Code section 4306.5 states, in relevant part, that unprofessional conduct for a pharmacist may include the following:

(a) acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the Board.

(b) acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

(c) acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

17. Code section 4332 states:

"Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor."

18. Code section 4342, subdivision (a) states:

"(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States 155 Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 404 of the Health and Safety Code).

19. Health and Safety Code section 11162.1 states, in relevant part:

(a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall

appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermochromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:

1–24

25–49

50–74

75–100

101–150

151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.

(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.

(11) The date of origin of the prescription.

(12) A check box indicating the prescriber's order not to substitute.

(13) An identifying number assigned to the approved security printer by the Department of Justice.

(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

20. Health and Safety Code section 11153, subdivision (a), states:

A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of 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.

21. Health and Safety Code section 11164 states, in relevant part:

"Except as provided in section 11167, no 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."

22. Health and Safety Code section 111255 states, in relevant part, that 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 where it may have been rendered injurious to health.

23. Health and Safety Code section 111295 states, in relevant part, that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated.

REGULATORY PROVISIONS

24. Code of Federal Regulations, title 21, section 1301.76, subdivision (b), states:

"(b) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. . . ."

25. Code of Federal Regulations, title 21, section 1304.04, states, in relevant 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."

26. Code of Federal Regulations, title 21, section 1304.11, states, in relevant part:

> (a) *General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.
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> . . .
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> c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two year of the previous biennial inventory date.

27. Code of Regulations, title 16, section 1707.3 states, in relevant part, that prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

28. Code of Regulations, title 16, section 1714, subdivision (b) states: "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."

29. Code of Regulations, title 16, section 1715.6 states that the owner shall report to the Board within 30 days of discovery of any loss of controlled substances, including their amounts and strengths.

30. 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."

31. Code of Regulations, title 16, section 1718.1 states, in relevant part, that all prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21, Code of Federal Regulations, section 211.137 are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor, pharmacy, or other persons authorized to dispense such drugs in California.

32. Code of Regulations, title 16, section 1735.2 states, in relevant part:

> (e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:
>
> (1) Active ingredients to be used.
>
> . . .
>
> (3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.
>
> (4) Inactive ingredients to be used.
>
> . . .
>
> (i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

. . .

(F) For water-containing topical/dermal and mucosal liquid and semi-solid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation…

33. Code of Regulations, title 16, section 1735.3 states, in relevant part, that for each compounded drug preparation, pharmacy records shall include a compounding log, consisting of a single document, that provides the expiration date, manufacturer, and lot number of each component.

34. Code of Regulations, title 16, section 1735.7 states, in relevant part:

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.

35. Code of Regulations, title 16, section 1735.8 states, in relevant part:

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.

36. Code of Regulations, title 16, section 1761 states, in relevant part:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity, or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose."

COST RECOVERY

37. 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.

DRUGS

38. Alprazolam, also known by the trade name Xanax, is a Schedule IV controlled substance under Health and Safety Code section 11057, subdivision (d)(1), and a dangerous drug under Business and Professions Code section 4022. It is used to treat anxiety.

39. Ativan, also known by the brand name lorazepam, is a Schedule IV controlled substance under Health and Safety Code section 11057, subdivision (d)(16) and a dangerous drug under Business and Professions Code section 4022. It is used to treat anxiety.

40. Buprenorphine/Naloxone, also known as Suboxone, is a Schedule V controlled substance under Health and Safety Code section 11058, subdivision (d), and a dangerous drug under Business and Professions Code section 4022. It is used to treat anxiety.

41. Carisoprodol, also known by the brand name Soma, is a Schedule IV controlled

substance under Title 21, Code of Federal Regulations, section 1308.14, subdivision (c)(4) and a dangerous drug under Business and Professions Code section 4022. It is used as a muscle relaxant.

42. Clonazepam, also known by the brand name Klonopin, is a Schedule IV controlled substance under Health and Safety Code section 11057, subdivision (d)(7), and a dangerous drug under Business and Professions Code section 4022. It is used for anxiety.

43. Desyrel, also known by the generic name trazodone is a dangerous drug under Business and Professions Code section 4022. It is an antidepressant.

44. Hydrocodone/acetaminophen, also known by the brand name Norco, is a Schedule II controlled substance under Health and Safety Code section 11055, subdivision (b)(1)(I), and Title 21 CFR, section l308.12, subdivision (b)(1)(vi), and a dangerous drug under Business and Professions Code section 4022. It is used for pain management.

45. Lioresal, also known by the generic name baclofen, is a dangerous drug under Business and Professions Code section 4022. It is used to treat muscle spasms.

46. Neurontin, also known by the generic name gabapentin, is a dangerous drug under Business and Professions Code section 4022. It is used to treat seizures and neuropathic pain.

47. Promethazine with Codeine, also known by the brand name Phenergan with Codeine, is a Schedule V controlled substance under Health and Safety Code section 11058, subdivision (c)(1), and a dangerous drug under Business and Professions Code section 4022. It is used to treat cold or allergy symptoms and includes an opioid cough medicine, which may be habit forming.

48. Zolpidem, also known by the brand name Ambien, is a Schedule IV controlled substance under Health and Safety Code section 11057, subdivision (d)(32), and a dangerous drug under Business and Professions Code section 4022. It is used to treat insomnia.

FACTUAL BACKGROUND

49. On or about July 17, 2019, patient JW filed a complaint with the Board against Respondent Pharmacy due to repeated errors with JW's prescription orders filled at Respondent

Pharmacy. JW received her medications from Respondent Pharmacy in "bubble packs."[1] On multiple occasions in the years leading up to her complaint with the Board, JW's bubble packs were missing medications. Despite bringing the errors to Respondent Pharmacy's attention, the errors continued. On one occasion, JW experienced withdrawal symptoms because Respondent Pharmacy failed to include the drug clonazepam in her bubble pack. On another occasion, a packaging oversight attributed to Respondent Pharmacy led to JW taking more of the drug lorazepam than prescribed.

50. On or about November 7, 2019, a Board Inspector employed by the Board of Pharmacy reviewed some of the bubble packs JW kept in storage[2]. The inspector found that on multiple, separate occasions, JW's bubble packs contained an amount of tablets or capsules different from the amount indicated on the label. The inspector found that on February 15 and March 1[3] prescription drug trazodone, 50 mg, was missing from the bubble pack, despite being listed on the label. On May 25, June 29, July 4, July 11, July 20, July 23, July 24, and July 25, the prescription drug gabapentin, 400 mg, was missing from the bubble pack, despite being listed on the label. On July 20, July 23, July 24, and July 25, the prescription drug baclofen, 20 mg, was missing from the bubble pack, despite being listed on the label.

51. The inspector also identified the following observations related to the packaging of the drugs: First, the prescription numbers and complete dates were not listed on the individual "bubbles." Also, it was not possible to decipher how many days' supply each bubble pack was dispensed for. Finally, there were no initials indicating which pharmacist checked the blister card pack to ensure the correct medications were placed into each "bubble."

52. Previously, on or about June 8, 2017, a Board Inspector employed by the Board of Pharmacy conducted an in-person inspection of Respondent Pharmacy. The inspection was prompted by some irregularities identified in an audit of Respondent Pharmacy's records. The following pharmacy violations, which occurred between April 1, 2014 and July 27, 2017, were

[1] Bubble packs are also known as "blister pack cards."

[2] It was not possible, based on the information supplied on the bubble packs, to establish the representative years. However, months and dates were identified, and are relied on here.

identified by the Board Inspector, and represent a compilation of findings from the June 8, 2017 in-person inspection, and the inspector's subsequent review of Respondent Pharmacy's records spanning the dates of April 1, 2014 to July 27, 2017:

53. Between April 1, 2014 and July 27, 2017, Respondent Pharmacy routinely early refilled prescriptions for controlled substances to patients before existing supplies were exhausted. More specifically, between April 1, 2014 and July 27, 2017, Respondent Pharmacy filled approximately 180 prescriptions five days or more before previous prescription supplies were exhausted, and some prescriptions were early refilled multiple times. As a result of these practices, approximately 5,000 tablets or capsules of controlled substances were early supplied to patients between April 1, 2014 and July 27, 2017, in violation of pharmacy law. Additionally, Respondent Pharmacy's failure to review records contributed to Respondent Pharmacy refilling prescriptions early.

54. Between October 31, 2013, and June 13, 2017, Respondent Pharmacy failed to properly and timely dispose of expired drugs, and also failed to store expired drugs separately from non-expired drugs. More specifically, Respondent Pharmacy stored over 180 bottles and packages of expired drugs dating back to 2013 intermingled with non-expired drugs in its active stock. Additionally, on June 8, 2017, the Board inspector confirmed during an in-person inspection that inadequate safeguards were in place to safely and reliably prevent the non-expired drugs from being dispensed to patients.

55. During the month of August, 2015, Respondent Pharmacy was robbed. Respondent Pharmacy failed to timely report controlled substance losses, including theft of Hydrocodone, to the Drug Enforcement Agency (DEA) and the Board. Additionally, Respondent Pharmacy failed to maintain accurate, up to date controlled substance inventory information and also failed to update documentation of its inventory every two years, as required by Title 21 Code of Federal Regulations, Part 1304, Section 11, and Business and Professions Code section 4081. (21 CFR 1304.11; Bus. & Prof. Code § 4081). As a result, Respondent Pharmacy could not adequately respond to Board inquiries about the stolen inventory, because Respondent Pharmacy was unable to produce accurate documentation identifying the quantities and kinds of controlled substances

that were stolen during the August, 2015 robbery. Respondent Pharmacy also failed to adequately maintain disposition records of controlled substances and dangerous drugs.

56. On or about May 26, 2017, Respondent Pharmacy violated pharmacy law when it compounded 600 grams of .2 percent Nitroglycerin ointment and packaged it into individual 30 gram vials without first preparing a master formula which included all active and inactive ingredients.

57. On or about May 26, 2017, Respondent Pharmacy violated pharmacy law when it compounded 600 grams of .2 percent Nitroglycerin ointment using a purified water base and packaged it with an expiration date of 188 days, instead of 30 days for water-containing topical/dermal and mucosal liquid and semi-solid formulations. (Cal. Code of Regs. § 1735.2.) Additionally, the compounding log for the product did not list the expiration dates or lot numbers of the ingredients used, thus the Board of Pharmacy concluded that no true beyond use date for the end-product could be properly determined.

58. On or about May 26, 2017, Respondent Pharmacy violated pharmacy law when it compounded 600 grams of .2 percent Nitroglycerin without maintaining a compounding log which included the manufacturer, expiration date, and lot number of each component.

59. On June 8, 2017, Board of Pharmacy inspectors could not locate and Respondent did not offer required documentation substantiating that pharmacy personnel were trained to properly and accurately perform their assigned responsibilities specific to compounding. Respondent Pharmacy did not have an ongoing competency evaluation process in place, as required, for compounding personnel.

60. On or about May 26, 2017, Respondent Pharmacy violated pharmacy law by failing to have a quality assurance plan in place to verify, monitor, and review the compounding process. Respondent Pharmacy also lacked a plan to ensure qualitative and quantitative analysis of compound drug preparations.

61. On June 8, 2017, Board of Pharmacy investigators determined that between April 1, 2014 and July 27, 2017, Respondent Pharmacy dispensed prescriptions for the following controlled substances, and in each case failed to comply with controlled substance prescription

requirements and security features: Promethazine/Codeine (240 prescriptions), Hydrocodone/APAP (300 prescriptions), Alprazolam (90 prescriptions), Diazepam (180 prescriptions). The documented violations included, but were not limited to: failing to include the required watermark printed on the backside of the prescription blank; failing to include the required quantity check off boxes on each prescription form (from 1-24 to 151 and over); failing to include the required statement printed on the bottom of the prescription that states, "Prescription is void if the number of drugs prescribed is not noted); A check box indicating the prescriber's order not to substitute; and failing to include an identifying number assigned by the Department of Justice to the approved security printer.

62. On or about December 20, 2016, while employed as a pharmacist at Respondent Pharmacy, Respondent Cho verified a prescription for Hydrocodone/APAP to be dispensed even though the prescription document was missing several features required for controlled substance security forms.

63. On October 6, 2016 and January 10, 2017, while employed as a pharmacist at Respondent Pharmacy, Respondent Gebremichael verified prescriptions to be dispensed for Diazepam and Hydrocodone even though the prescription documents lacked required safety features. One of the prescription documents presented with irregularities commonly seen in illegitimate prescriptions, including cash payment and out of area prescriber.

64. On June 30, 2015 and January 2, 2017, while employed as a pharmacist at Respondent Pharmacy, Respondent Bacon verified prescriptions to be dispensed for Alprazolam and Hydrocodone/APAP even though the prescription documents were missing several features required for controlled substance security forms.

65. On June 8, 2017, Board of Pharmacy investigators determined that between April 1, 2014 and July 27, 2017, Respondent Pharmacy dispensed approximately 180 controlled substance prescriptions that contained irregularities and omissions. The irregularities, which are commonly seen in illegitimate prescriptions, included cash payments, out of area patients and prescribers, and omissions of several required security features.

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FIRST CAUSE FOR DISCIPLINE

(Operational Standards Failure Related to Housing of Expired Drugs)

66. Respondent Pharmacy has subjected its pharmacy permit to disciplinary action, and Respondent Pharmacist Gumbs has subjected her pharmacist license to disciplinary action, because Respondents stored expired drugs intermingled with their active stock of drugs, which were held for sale, in violation of California Code of Regulations section 1714, subdivision (b), and Health and Safety Code sections 111255 and 111295. The circumstances are set forth in paragraph 54, above.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Controlled Substance Inventories)

67. Respondent Pharmacy has subjected its pharmacy permit to disciplinary action, and Respondent Pharmacist Gumbs has subjected her pharmacist license to disciplinary action, because Respondents failed to complete and maintain required controlled substance inventories, in violation of California Code of Regulations section 1718, and Code of Federal Regulations, Title 21, section 1304.11, subdivisions (a) and (c). The circumstances are set forth in paragraph 55 above.

THIRD CAUSE FOR DISCIPLINE

(Failure to Report Loss of Controlled Substances to the Board and DEA)

68. Respondent Pharmacy has subjected its pharmacy license to disciplinary action, and Respondent Pharmacist Gumbs has subjected her pharmacist license to disciplinary action, because Respondents failed to comply with requirements related to reporting the loss of controlled substances to the Board and the Drug Enforcement Administration (DEA), in violation of California Code of Regulations, title 16, section 1715.6. and Code of Federal Regulations, Title 21, section 1301.76, subdivision (b). The circumstances are described in paragraph 55, above.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain or Produce Required Drug Records)

69. Respondent Pharmacy has subjected its pharmacy license to disciplinary action, and Respondent Pharmacist Gumbs has subjected her pharmacist license to disciplinary action,

because Respondents failed to maintain an accurate current inventory and all records of the disposition of drugs stolen during the theft of Respondent Pharmacy in August 2015, in violation of Code sections 4332, 4081, subdivision (a), 4105, subdivisions (a) and (c), and California Code of Regulations section 1718. The circumstances are described in paragraph 55, above.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Properly Prepare Compounding Master Formula)

70. Respondent Pharmacy has subjected its pharmacy permit to disciplinary action and Respondent Pharmacist Gumbs has subjected her pharmacist license to disciplinary, because on May 26, 2017, Respondents compounded a drug without first preparing a master formula, which included all active and inactive ingredients, in violation of California Code of Regulations section 1735.2, subdivision (e)(1)(3). The circumstances are described in paragraph 56, above.

SIXTH CAUSE FOR DISCIPLINE

(Beyond Use Dating of Compounding Drugs)

71. Respondent Pharmacy has subjected its pharmacy permit to disciplinary action and Respondent Pharmacist Gumbs has subjected her pharmacist license to disciplinary action, because on or about May 26, 2017, Respondents compounded 600 grams of .2 percent Nitroglycerin ointment using a purified water base and packaged it with an expiration date of 188 days, in violation of California Code of Regulations, section 1735.2, subdivision (i)(1)(F). The circumstances are described in paragraph 57, above.

SEVENTH CAUSE FOR DISCIPLINE

(Recordkeeping Errors - Compounded Drug Preparations)

72. Respondent Pharmacy has subjected its pharmacy permit to disciplinary action and Respondent Pharmacist Gumbs has subjected her pharmacist license to disciplinary action, in that Respondents compounded drug preparations without maintaining a compounding record which documented the manufacturer, expiration date, and lot number of each component, in violation of California Code of Regulations section 1735.3, subdivision (a)(2)(F). The circumstances are described in paragraph 58, above.

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EIGHTH CAUSE FOR DISCIPLINE

(Training of Compounding Staff and Corresponding Records)

73. Respondent Pharmacy has subjected its pharmacy license to disciplinary action, in violation of California Code of Regulations section 1735.7, subdivisions (a), (b) and (c), because on May 26, 2017, Respondent failed to provide documentation substantiating that pharmacy personnel were trained to properly and accurately perform their assigned responsibilities in violation of subdivision (a) of section 1735.7; failed to provide investigators with an ongoing competency evaluation process for personnel involved in compounding in violation of subdivision (b) of section 1735.7; and failed to demonstrate knowledge of processes and procedures used in compounding, in violation of subdivision (c) of section 1735.7. The circumstances are further explained in paragraphs 56-60, above.

NINTH CAUSE FOR DISCIPLINE

(Compounding Quality Assurance)

74. Respondent Pharmacy has subjected its pharmacy permit to disciplinary action, and Respondent Pharmacist Gumbs has subjected her pharmacist license to disciplinary action in violation of California Code of Regulations section 1735.8, subdivisions (a), (b), (c) and (d), because on May 26, 2017, Respondents failed to have a quality assurance plan to verify, monitor, and review the compounding process, and a plan to ensure qualitative and quantitative analysis of compound drug preparations. The circumstances are described in paragraphs 60, above.

TENTH CAUSE FOR DISCIPLINE

(Controlled Substance Prescription Requirements)

75. Respondent Pharmacy has subjected its pharmacy permit to disciplinary action, and Respondent Pharmacist Gumbs has subjected her pharmacist license to disciplinary action, because between the dates of February 28, 2015 and March 9, 2017, Respondents dispensed 10 controlled substance prescriptions using prescription forms which were missing required security features, in violation of Health & Safety Code sections 11162.1 & 11164 and California Code of Regulations, title 16, section 1761, subdivisions (a) and (b). The circumstances are described in paragraphs 61-65, above.

ELEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct: Corresponding Responsibility, Irregular Prescriptions)

76. Respondent Pharmacy has subjected its pharmacy permit to disciplinary action, and Respondent Pharmacist Gumbs has subjected her pharmacist license to disciplinary action under Code sections 4301, subdivision (d), (j), and (o), in that Respondents dispensed 10 controlled substances despite invalid security forms with red flags for illegitimacy, and 180 controlled prescriptions more than five days before previously dispensed supplies were exhausted, in violation of Health and Safety Code section 11153, subdivision (a), Code section 4306.5, subdivisions (a), (b), and (c), and California Code of Regulations section 1761, subdivisions (a) and (b). The circumstances are described in paragraph 53, and 61-65, above.

TWELFTH CAUSE FOR DISCIPLINE

(Prescription Container Errors – Labeling)

77. Respondent Pharmacy has subjected its pharmacy permit to discipline and Respondent Pharmacist Gumbs has subjected her pharmacist license to discipline in violation of Business and Professions Code section 4076, subdivision (a)(8) because Respondents repeatedly dispensed drugs in mislabeled containers which included an incorrect quantity of dispensed drugs. The circumstances are described in paragraphs 49-51, above.

OTHER MATTERS

78. Under Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 48413 issued to United Pharmacy, then United 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 48413 is placed on probation or until Pharmacy Permit Number PHY 48413 is reinstated if it is revoked.

79. Under Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 48413 issued to United Pharmacy, while Pamela Gumbs has been an officer and owner and had knowledge of, or knowingly participated, in any conduct for which the licensee was disciplined, then Pamela Gumbs 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 48413 is placed on probation or until Pharmacy Permit Number PHY 48413 is reinstated if it is revoked.

80. Under Code section 4307, if discipline is imposed on Pharmacist License Number RPH 29485 issued to Pamela Gumbs, then Pamela Gumbs 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 29485 is placed on probation or until Pharmacist License Number RPH 29485 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:

1. Revoking or suspending Pharmacy Permit Number PHY 48413, issued to United Pharmacy;

2. Revoking or suspending Pharmacy License Number RPH 29485, issued to Pamela Gumbs;

3. Prohibiting United 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 48413 is placed on probation or until Pharmacy Permit Number PHY 48413 issued to United Pharmacy is reinstated if it is revoked;

4. Prohibiting Pamela Gumbs from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 48413 is placed on probation or until Pharmacy Permit Number PHY 48413 issued to United Pharmacy, Inc. is reinstated if it is revoked;

5. Prohibiting Pamela Gumbs from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy License Number RPH 29485 is placed on probation or until Pharmacy License Number RPH 29485 issued to Pamela Gumbs is reinstated if it is revoked;

6. Ordering Respondents 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,

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

DATED: 8/23/2021

Signature on File

Anne Sodergren
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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