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

In the Matter of the Accusation Against: **RELIABLE DRUG** 801 Irving Street San Francisco, CA 94122 **Original Permit No. PHY 46431,** and **SAM C.H. CHING,** **a.k.a. SAM CHING** **a.k.a. SAMUEL C. CHING** 801 Irving Street San Francisco, CA 94122 **Original Pharmacist License No. RPH 20273** Respondents.	Case No. 5406

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 July 1, 2016.

It is so ORDERED on June 21, 2016.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
Amy Gutierrez, Pharm.D.
Board President

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In the Matter of the Accusation Against: **RELIABLE DRUG** 801 Irving Street San Francisco, CA 94122 **Pharmacy Permit No. PHY 46431,** and **SAM C.H. CHING** **a.k.a. SAM CHING** **a.k.a. SAMUEL C. CHING** 801 Irving Street San Francisco, CA 94122 **Pharmacist License No. RPH 20273** Respondents.	Case No. 5406 **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. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Aspasia A. Papavassiliou, Deputy Attorney General.

2. Respondents Reliable Drug and Sam C.H. Ching, also known as Sam Ching and Samuel C. Ching (Respondents), are represented in this proceeding by attorney Natalia Mazina, whose address is Kelly, Hockel and Klein PC, 44 Montgomery Street, Suite 1500, San Francisco, CA 94104-4601.

3. On or about August 19, 2003, the Board of Pharmacy issued Pharmacy Permit No. PHY 46431 to Reliable Drug (Respondent Reliable Drug). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought in Accusation No. 5406 and will expire on August 1, 2016, unless renewed.

4. On or about April 20, 1957, the Board of Pharmacy issued Pharmacist License Number RPH 20273 to Sam C.H. Ching, also known as Sam Ching, and also known as Samuel C. Ching (Respondent Ching). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on February 28, 2018, unless renewed.

5. Respondent Ching is and was, at all times relevant to the charges brought in this Accusation, the Pharmacist-in-Charge (PIC) of Respondent Reliable Drug.

JURISDICTION

6. Accusation No. 5406 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on March 17, 2016. Respondents timely filed their Notice of Defense contesting the Accusation. A copy of Accusation No. 5406 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in Accusation No. 5406. Respondents also have carefully read, fully discussed with counsel, and understand the effects of this Stipulated Surrender of License and Order.

8. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel, at

its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their 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.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

10. Respondents admit the truth of each and every charge and allegation in Accusation No. 5406, agree that cause exists for discipline and hereby surrender their Pharmacy Permit No. PHY 46431 and Pharmacist License No. RPH 20273 for the Board's formal acceptance.

11. Respondents understand that signing this stipulation enables the Board to issue an order accepting the surrender of their Pharmacy Permit and Pharmacist License without further process.

RESERVATION

12. The admissions made by Respondents in this stipulation are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their 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.

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

15. 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.

16. 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 46431, issued to Respondent Reliable Drug, and Pharmacist License No. RPH 20273, issued to Respondent Sam C. H. Ching, are surrendered and accepted by the Board of Pharmacy.

1. The surrender of Respondents' Pharmacy Permit and Pharmacist License and the acceptance of the surrendered licenses by the Board shall constitute the imposition of discipline against Respondents. This stipulation constitutes a record of the discipline and shall become a part of Respondents' license history with the Board of Pharmacy.

2. Respondent Sam C. H. Ching shall lose all rights and privileges as a pharmacist in California as of the effective date of the Board's Decision and Order.

3. The surrender of Respondent Reliable Drug's pharmacy permit is stayed until July 1, 2016, to allow for the sale of the pharmacy. Respondent shall lose all rights and privileges as a pharmacy effective July 1, 2016. Before then, Respondent Reliable Drug must engage an independent consultant, approved in advance by the Board or its designee, to conduct weekly audits of the pharmacy's operations until such time as the sale is complete and a new license is

issued. The independent consultant must be a licensed pharmacist who does not have a pending Accusation filed against them and who is not on probation with the Board. Failure to have such a consultant in place is cause for Reliable Drug's pharmacy permit to be deemed surrendered immediately.

4. If the pharmacy is not sold by July 1, 2016, Respondent Reliable Drug, within ten (10) days of that effective date of the surrender, arrange for the destruction of, the transfer to, sale of or storage in a facility licensed by the board of all controlled substances and dangerous drugs and devices. Respondent shall further provide written proof of such disposition and submit a completed Discontinuance of Business form according to board guidelines.

5. If the pharmacy is not expected to be sold by July 1, 2016, Respondent Reliable Drug shall also, by that date, arrange for the continuation of care for ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

6. Respondents shall cause to be delivered to the Board any pocket license or wall certificate on or before the effective date of the surrender.

7. If Respondents every apply for licensure or petition for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondents must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 5406 shall be deemed to be true, correct and admitted by Respondents when the Board determines whether to grant or deny the application or petition.

8. Respondent Sam C.H. Ching shall pay the agency its costs of investigation and enforcement in the amount of $22,377.50 prior to issuance of a new or reinstated license.

9. If Respondents should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation, No. 5406 shall be deemed to be true, correct, and admitted by Respondents for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.

10. Respondents shall not apply to the Board for licensure or petition for reinstatement for three years from the effective date of the Board's Decision and Order.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Natalia Mazina. I understand the stipulation and the effect it will have on my Pharmacy Permit and Pharmacist License. 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: June 2, 2016

Sam Ching on behalf of RELIABLE DRUG;
SAM C.H. CHING
Respondents

I have read and fully discussed with Respondents Reliable Drug and Sam C.H. Ching the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

DATED: 6.1.16

NATALIA MAZINA
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: 6/3/2016

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
DIANN SOKOLOFF
Supervising Deputy Attorney General

ASPASIA A. PAPAVASSILIOU
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5406

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BEFORE THE
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In the Matter of the Accusation Against: **RELIABLE DRUG** 801 Irving Street San Francisco, CA 94122 **Pharmacy Permit No. PHY 46431,** and **SAM C. H. CHING** **a.k.a. SAM CHING** **a.k.a. SAMUEL C. CHING** 801 Irving Street San Francisco, CA 94122 **Pharmacist License No. RPH 20273** Respondents.	Case No. 5406 **ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about August 19, 2003, the Board of Pharmacy issued Pharmacy Permit Number PHY 46431 to Reliable Drug (Respondent Reliable Drug). The Pharmacy Permit was in

full force and effect at all times relevant to the charges brought in this Accusation and will expire on August 1, 2016, unless renewed.

3. On or about August 9, 2003, the Board of Pharmacy issued Pharmacist License Number RPH 20273 to Sam C.H. Ching, also known as Sam Ching, and also known as Samuel C. Ching (Respondent Ching). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on February 28, 2018, unless renewed.

4. Respondent Ching is and was, at all times relevant to the charges brought in this Accusation, the Pharmacist-in-Charge (PIC) of Respondent Reliable Drug.

JURISDICTION

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

6. Section 4300 of the Code states, in pertinent part:

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

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

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

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

"(4) Revoking his or her license.

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

. . .

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

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

7. Section 4300.1 of the Code states:

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

STATUTORY AND REGULATORY PROVISIONS

8. Section 4078 of the Code states, in pertinent part:

"(b) . . . [A] person may label a prescription, or a prescriber may direct that a prescription be labeled, with information about the drug that is false under either of the following circumstances:

. . .

(2) If, in the medical judgment of the prescriber, the labeling is appropriate for the proper treatment of the patient.

"(c) The furnisher of a prescription labeled pursuant to subdivision (b) shall make, and retain for three years from the date of making, a record stating the manner in which the information on the prescription label varies from the actual drug in the container and documenting the order of the prescriber to so label the container. The prescriber shall make, and retain for at least three years, a record of his or her order to so label the container."

9. Section 4081, subdivision (a), of the Code states, in pertinent part:

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

10. Section 4301 of the Code states, 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 procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . .

"(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."

11. Section 4342, subdivision (a), of the Code states:

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

12. Health and Safety Code section 11164 states, in pertinent 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 and shall meet the following requirements:

. . .

"(b)(1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. . ."

13. Health and Safety Code section 11165, subdivision (d) states:

"For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription."

14. Health and Safety Code section 111400 states that any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

15. Title 21 of the Code of Federal Regulations, part 1304.22, paragraph (c), states:

"*Records for dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription must also comply with §1304.26."

16. Title 21 of the Code of Federal Regulations, part 1305.22, paragraph (g), states:

"When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."

17. California Code of Regulations, title 16, section 1707.1, states, in pertinent part:

"(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.

(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours:

. . .

(B) For each prescription dispensed by the pharmacy:

(1) The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed..."

18. California Code of Regulations, title 16, section 1714, states, 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."

19. California Code of Regulations, title 16, section 1735.2, subdivision (h), states:

"Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

20. California Code of Regulations, title 16, section 1735.3, subdivision (a)(6), states that for each compounded drug product, the pharmacy records shall include the manufacturer, expiration date and lot number of each component.

21. California Code of Regulations, title 16, section 1735.4, subdivision (a), states that in addition to the labeling information required under Business and Professions Code section 4076,

the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).

COST RECOVERY PROVISION

22. 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.

FACTUAL BACKGROUND

23. From on or about March 26, 2014, to on or about January 20, 2015, the Board conducted four inspections of Reliable Drug, Respondents' pharmacy located at 801 Irving Street in San Francisco. Board inspectors found numerous violations, as summarized below.

First Inspection

24. On or about March 26, 2014, Respondents had expired medications in the pharmacy's active drug inventory. In addition, the pharmacy and compounding area were messy and cluttered, and there were multiple spots of powder residue of various colors on the compounding scale and compounding counter. (Respondent Ching was not at the pharmacy that day so the inspection was more limited than a typical inspection.)

Second Inspection

25. On or about June 18, 2014, Respondents still had expired medications in the active drug inventory. In addition, DEA-222 forms for ordering controlled substances were not being properly endorsed or fully executed; there was incorrect labeling of compounded drugs (e.g., labels of two prescriptions did not contain the generic names of the principal active ingredients); patient medication profile records were inaccurate (e.g., the dispensing record for one prescription indicated 90 grams of medication dispensed but Respondent Ching indicated that 120 grams had been dispensed, as prescribed); and a compounded drug was labeled as "fluoxymesterone" when the ingredient used to compound it was testosterone instead of androstenedione (Respondent Ching stated that he had been unable to obtain androstenedione so was using testosterone instead).

Third Inspection

26. On or about July 2, 2014, a review of compounding worksheets for the prior six months showed that approximately 190 of approximately 300 compounded drug products were made with expired ingredients or with ingredients that would expire too soon, i.e. before the expiration date designated by Respondents for the compounded product. In addition, multiple compounding worksheets showed drugs compounded with ingredients that had no documented manufacturer lot number or expiration date.

Fourth Inspection

27. On or about January 20, 2015, Respondents were dispensing the unapproved drug domperidone without authorization from the Food and Drug Administration. On or about January 15, 2015, a Board inspector notified Respondents that they could not legally dispense domperidone but Respondents dispensed domperidone on January 16, 2015, and again on January 20, 2015.[1] In addition, Respondents' compounding worksheets still showed deficiencies in that four of eight worksheets reviewed were missing the manufacturer name, lot number, or expiration date of an ingredient. Finally, Respondent Ching stated that he simply "threw away" expired drugs including morphine and cocaine.

FIRST CAUSE FOR DISCIPLINE
(Failure to Meet Operational Standards)
(Cal. Code Regs., tit. 16, § 1714, subd. (c))

28. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents failed to meet operational standards in that they failed to maintain the pharmacy, equipment, or fixtures in a clean and orderly condition (Cal. Code Regs., tit. 16, § 1714, subd. (c)). On or about June 18, 2014, Board inspectors observed that the pharmacy and compounding area were messy and

[1] Domperidone, in countries where it is approved, is primarily used to stimulate gastric emptying or to treat nausea, but it is sometimes also used to increase lactation. On or about June 7, 2004, the FDA issued a public warning that distributing any domperidone-containing products is illegal and that the drug's risk of heart problems and sudden death outweigh any potential to healthily lactating women. Only patients with certain gastrointestinal conditions may be treated with domperidone and only following approval of an investigational new drug application.

cluttered, and there were multiple spots of powder residue of various colors on the compounding scale and compounding counter.

SECOND CAUSE FOR DISCIPLINE
(False or Misleading Label on Prescription)
(Bus. & Prof. Code, § 4078, subds. (b)(2) and (c))

29. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents falsely or misleadingly labeled a prescription without documentation of medical justification for the false labeling (Bus. & Prof. Code, § 4078, subds. (b)(2) and (c)). On or about June 18, 2014, Board inspectors discovered that on or about May 14, 2014, and again on or about June 9, 2014, Respondents had compounded batches of "fluoxymesterone" capsules with the active ingredient testosterone instead of androstenedione. The capsules were stored in the pharmacy and dispensed to multiple patients. Respondents were unable to provided documentation that there was a doctor's order for the misleading labels.

THIRD CAUSE FOR DISCIPLINE
(Incomplete Records of Compounded Drug Products)
(Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(6))

30. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents' records for each compounded drug product failed to include the manufacturer, expiration date, and lot number of each component (Cal. Code Regs., tit. 16, § 1735.3, subd. (a)(6)). On or about July 2, 2014, a review of worksheets for drugs compounded in the prior six months showed that in approximately 50 of 329 of the compounded drugs, Respondents failed to note the manufacturer, lot number, or expiration date of one or more components.

FOURTH CAUSE FOR DISCIPLINE
(Incomplete Labeling of Compounded Drugs)
(Cal. Code Regs., tit. 16, § 1735.4, subd. (a))

31. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents failed to include the generic name(s) of the principal active ingredient(s) on labels of their compounded drugs. On or about June 18, 2014, Board inspectors observed that labels for two prescriptions

(one for "E2 1.5/E3 2.0/P4 80 mg Oil," dated June 11, 2014, and one for "Cushing's Ointment," dated May 29, 2014) did not contain the generic names of the principal active ingredients.

FIFTH CAUSE FOR DISCIPLINE
(Failure to Properly Complete DEA Forms 222)
(21 C.F.R. 1305.22)

32. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents failed to create a record of the quantity and date of receipt of certain controlled substances, as required by DEA Form 222 (21 C.F.R. 1305.22). On or about March 26, 2014, and June 18, 2014, a Board inspector observed that Respondents had failed to properly record the quantity of each Schedule II controlled substance received and the date the drug was received.

SIXTH CAUSE FOR DISCIPLINE
(Drugs Lacking Quality and Strength)
(Bus. & Prof. Code, § 4342)

33. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents were selling drugs lacking quality and strength (Bus. & Prof. Code, § 4342). During Board inspections on or about March 26, 2014, and June 18, 2014, inspectors noted numerous expired drugs and compounding ingredients in the active drug inventory. In addition, according to Respondents' compounding work sheets dated January 7, 2014, through June 24, 2014, approximately 190 of approximately 300 compounded drug products were made with expired ingredients or with ingredients that would expire before the expiration dates designated by Respondents.

SEVENTH CAUSE FOR DISCIPLINE
(Failure to Maintain Medication Profiles/Patient Medication Records)
(Cal. Code Regs., tit. 16, § 1707.1, subd. (a)(1)(B))

34. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents failed to maintain an accurate patient medication record the quantity of medication dispensed (Cal. Code Regs., tit. 16, § 1707.1, subd. (a)(1)(B)). During an inspection on or about June 18, 2014, Board inspectors observed that prescription records showed that on May 29, 2014, Rx #411415 (containing a Scheduled II controlled drug) was dispensed to a patient with a quantity of 90 gm

but the compounding worksheet showed, and Respondent Ching stated, that an actual quantity of 120 gm was dispensed to the patient.

EIGHTH CAUSE FOR DISCIPLINE
(Failure to Comply with Requirements Regarding Expiration Dates for Compounded Drugs)
(Cal. Code Regs., tit. 16, § 1735.2, subd. (h))

35. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents failed to designate appropriate expiration dates for their compounded drugs, in that the "beyond use date" of compounded drugs shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging (Cal. Code Regs., tit. 16, § 1735.2, subd. (h)). According to Respondents' compounding work sheets dated January 7, 2014, through June 24, 2014, approximately 227 compounded drug products were made with expired ingredients or with ingredients that would expire before the expiration dates designated by Respondents.

NINTH CAUSE FOR DISCIPLINE
(Dispensing Controlled Substance Without Proper Form or Verification)
(Health and Safety Code, § 11164, subds. (a) and (b)(1))

36. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents dispensed a controlled substance when the prescription was written on a form that was not compliant with the requirements for a controlled substance prescription form, and Respondents were unable to provide any documentation that the order had been confirmed verbally with the prescriber. On or about June 18, 2014, Board inspectors observed that Rx #411415, dated May 27, 2014, for a compounded drug containing the controlled substance ketamine, was written on a non-compliant prescription form and Respondents were unable to provide documentation of verbal confirmation of the prescription.

TENTH CAUSE FOR DISCIPLINE
(Failure to Comply with CURES)
(Health and Saf. Code, § 11165, subd. (d))

37. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and

Respondent Ching has subjected his pharmacist license to discipline, because Respondents failed to comply with the Controlled Substance Utilization Review and Evaluation System (Health and Saf. Code, § 11165, subd. (d)). On or about January 2, 2014 to on or about May 30, 2014, Respondents failed to report to the Department of Justice the required dispensing information for approximately 89 compounded prescriptions containing the Schedule III controlled substances ketamine or testosterone.

ELEVENTH CAUSE FOR DISCIPLINE
(Dispensing Misbranded Drugs)
(Health and Saf. Code, § 111400)

38. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents dispensed misbranded drugs in that any drug is misbranded if it is dangerous to health when used as recommended or suggested in its labeling (Health and Saf. Code, § 111400). From on or about April 1, 2013, to on or about May 30, 2014, Respondents dispensed approximately 53 prescriptions that were compounded from the unapproved drug, domperidone. According to the United States Food and Drug Administration, domperidone was not an approved drug and drug products containing domperidone violated the Federal Food, Drug, and Cosmetic Act. In addition, on or about January 15, 2015, a Board inspector notified Respondents that they could not legally dispense domperidone but Respondents dispensed domperidone on January 16, 2015, and again on January 20, 2015.

TWELFTH CAUSE FOR DISCIPLINE
(Failure to Maintain Operational Standards and Security)
(Cal. Code Regs., tit. 16, § 1714, subd. (b))

39. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents failed to maintain, secure, and distribute drugs safely and properly (Cal. Code Regs., tit. 16, § 1714, subd. (b)). On or about January 20, 2015, Respondent Ching admitted to a Board inspector that he disposed numerous drugs, including morphine and cocaine, by simply throwing them away.

THIRTEENTH CAUSE FOR DISCIPLINE
(Failure to Maintain Records of Dangerous Drugs)
(Bus. & Prof. Code, § 4081, subd. (a))

40. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents failed to maintain disposition records for dangerous drugs for three years (Bus. & Prof. Code, § 4081). On or about January 20, 2015, Respondent Ching admitted to a Board inspector that he had recently (within the last six months) disposed numerous dangerous drugs, including morphine and cocaine, by throwing them away without keeping records of their disposition.

FOURTEENTH CAUSE FOR DISCIPLINE
(Failure to Maintain Required Records of Disposal of Controlled Substances)
(21 C.F.R. 1304.22 (c))

41. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents failed to maintain records of their disposal of controlled substances (21 C.F.R. 1304.22(c)). Respondents were required to maintain controlled substance disposal records including the date and manner of disposal; the name, address, and registration number of the person to whom the drugs were distributed; and the quantity disposed. On or about January 20, 2015, Respondent Ching admitted to a Board inspector that he had disposed numerous controlled substances, including morphine and cocaine, by simply throwing them away, without maintaining records of their disposition.

FIFTEEENTH CAUSE FOR DISCIPLINE
(Unprofessional Conduct: Violation of Laws or Regulations Related to Pharmacy)
(Bus. & Prof. Code, § 4301, subd. (o))

42. Respondent Reliable Drug has subjected its pharmacy permit to discipline, and Respondent Ching has subjected his pharmacist license to discipline, because Respondents committed unprofessional conduct by violating laws or regulations governing pharmacy (Bus. & Prof. Code, § 4301, subd. (o)). The circumstances are set forth in paragraphs 28 through 42, above.

DISCIPLINE CONSIDERATIONS

43. To determine the degree of discipline, if any, to be imposed on Respondents, Complainant alleges that the Board has issued the following prior citations, which are now final.

A. On or about February 8, 2011, Respondent Pharmacy was issued Citation Number CI 2009 44550 for dispensing a prescription containing a significant error (Cal. Code Regs., tit. 16, subd. (a)) and deviating from the requirements of a prescription (Cal. Code Regs., tit. 16, § 1716). The circumstances of the violation are that on or about August 14, 2008, a staff member of the pharmacy furnished Lovastatin to patient JR, when the drug was prescribed, labeled, and intended for patient MB.

B. On or about February 8, 2011, Respondent Ching, as PIC of Respondent Pharmacy, was issued Citation Number CI 2010 47011 for dispensing a prescription containing a significant error (Cal. Code Regs., tit. 16, subd. (a)) and deviating from the requirements of a prescription (Cal. Code Regs., tit. 16, § 1716). The circumstances of the violation were that on or about August 14, 2008, a staff member of the pharmacy furnished Lovastatin to patient JR, when the drug was prescribed, labeled, and intended for patient MB.

C. On or about April 22, 2010, Respondent Ching, as PIC of Respondent Pharmacy, was issued a citation for the following violations discovered during a Board inspection conducted on or about November 4, 2008:

(1) Expired Drugs and Compounding Ingredients in Dispensable Inventory (Bus. & Prof. Code, § 4342) due to multiple expired drugs found in the dispensable inventory;

(2) Compounded Medications Labeled with Expiration Dates beyond 180 Days (Cal. Code Regs., tit. 16, 1716.2, subd. (a)(3)) due to three compounded medications in the will call area labeled with expiration dates beyond 180 days from the dates of preparation;

(3) Misbranded Drugs (Health and Saf. Code, § 111330) due to medications compounded with expired ingredients and therefore having false expiration dates on the consumer labels;

(4) Failure to Establish Theft/Impairment of Licensed Employee Policies and Procedures (Bus. & Prof. Code, § 4104) due to not having written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals; and

(5) Failure to Develop Technician Job Description (Cal. Code Regs., tit. 16, § 1793.7, subd. (d)) due to employing a pharmacy technician without having a job description with written polices and procedures.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 46431, issued to Reliable Drug;

2. Revoking or suspending Pharmacist License Number RPH 20273, issued to Sam C. H. Ching, also known as Sam Ching and also known as Samuel C. Ching;

3. Ordering Reliable Drug and Sam C. H. Ching to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, under Business and Professions Code section 125.3;

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

DATED: 3/16/16

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

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