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7  
8 **BEFORE THE**  
**BOARD OF PHARMACY**  
9 **DEPARTMENT OF CONSUMER AFFAIRS**  
**STATE OF CALIFORNIA**

10 In the Matter of the Accusation Against:

Case No. 5978

11 **GRABO UNITED INC. DBA CT**  
12 **PHARMACY, ROBERT YU-MING SHEN,**  
13 **YUNG PO WONG**  
14 **709 N. Hill St., #23**  
**Los Angeles, CA 90012**

**A C C U S A T I O N**

15 **Pharmacy Permit No. PHY 46522**

16 **YUNG PO WONG**  
17 **18462 Nottingham Lane**  
**Rowland Heights, CA 91748**

18 **Pharmacist License No. RPH 46920**

19 **ROBERT SHEN**  
20 **1854 Rancho Hills Drive**  
**Chino Hills, CA 91709**

21 **Chief Executive Officer No. TCH 34**

22 Respondents.

23 Complainant alleges:

24 **PARTIES**

25 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity  
26 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.  
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2. On or about September 23, 2003, the Board of Pharmacy issued Pharmacy Permit Number PHY 46522 to Grabo United Inc. dba CT Pharmacy, Robert Yu-Ming Shen (Respondent Pharmacy). The Pharmacy Permit was canceled on May 26, 2016 due to a discontinuance of business effective April 14, 2016.

3. On March 8, 1994, the Board issued Pharmacist License Number RPH 46920 to Yung Po Wong ("Respondent PIC"). The Pharmacist License was in force at all times relevant to this Accusation's charges and will expire on August 31, 2019 unless renewed. This license is presently inactive.

4. On September 12, 1992, The Board issued Pharmacy Technician Registration Number TCH 34 to Robert Shen (Respondent Shen). The Pharmacy Technician License was in force at all times relevant to this Accusation's charges and expired on July 31, 2016.

## JURISDICTION

5. 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.

6. **Section 4300** of the Code provides, in pertinent part, that every license issued by the Board is subject to discipline, including suspension or revocation.

7. **Section 4300.1 of the Code states:**

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

8. **Section 4302** of the Code states:

“The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.”

**STATUTORY PROVISIONS**

9. **Section 4081, subdivision (a)** of the Code states:

“All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.”

10. **Section 4101, subdivision (a)** of the Code states:

“A pharmacist may take charge of and act as the pharmacist-in-charge of a pharmacy upon application by the pharmacy and approval by the board. A pharmacist-in-charge who ceases to act as the pharmacist-in-charge of the pharmacy shall notify the board in writing within 30 days of the date of that change in status.”

11. **Section 4160, subdivision (a)** of the Code states:

“A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.”

12. **Section 4169, subdivision (a)** of the Code states:

“A person or entity shall not do any of the following:

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

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

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

4 (4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the  
5 beyond use date on the label.

6 (5) Fail to maintain records of the acquisition or disposition of dangerous drugs or  
7 dangerous devices for at least three years.”

8 13. **Section 4301, subdivision (o)** of the Code states:

9 “The board shall take action against any holder of a license who is guilty of unprofessional  
10 conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is  
11 not limited to, Violating or attempting to violate, directly or indirectly, or assisting in or abetting  
12 the violation of or conspiring to violate any provision or term of this chapter or of the applicable  
13 federal and state laws and regulations governing pharmacy, including regulations established by  
14 the board or by any other state or federal regulatory agency.”

15 14. **Section 4307(a)** provides:

16 “Any person who has been denied a license or whose license has been revoked or is  
17 under suspension, or who has failed to renew his or her license while it was under suspension, or  
18 who has been a manager, administrator, owner, member, officer, director, associate, partner, or  
19 any other person with management or control of any partnership, corporation, trust, firm, or  
20 association whose application for a license has been denied or revoked, is under suspension or  
21 has been placed on probation, and while acting as the manager, administrator, owner, member,  
22 officer, director, associate, partner, or any other person with management or control had  
23 knowledge of or knowingly participated in any conduct for which the license was denied,  
24 revoked, suspended, or placed on probation, shall be prohibited from serving as a manager,  
25 administrator, owner, member, officer, director, associate, partner, or in any other position with  
26 management or control of a licensee.”

27 15. **Section 11161.5 of Health & Safety Code** provides:  
28

1       “(a) Prescription forms for controlled substance prescriptions shall be obtained from  
2 security printers approved by the Department of Justice.

3       (b) The department may approve security printer applications after the applicant has  
4 provided the following information:

5               (1) Name, address, and telephone number of the applicant.

6               (2) Policies and procedures of the applicant for verifying the identity of the prescriber  
7 ordering controlled substance prescription forms.

8               (3) Policies and procedures of the applicant for verifying delivery of controlled  
9 substance prescription forms to prescribers.

10              (4) (A) The location, names, and titles of the applicant’s agent for service of process  
11 in this state; all principal corporate officers, if any; all managing general partners, if any; and any  
12 individual owner, partner, corporate officer, manager, agent, representative, employee, or  
13 subcontractor of the applicant who has direct access to, or management or control of, controlled  
14 substance prescription forms.

15              (B) A report containing this information shall be made on an annual basis and  
16 within 30 days after any change of office, principal corporate officers, managing general partner,  
17 or of any person described in subparagraph (A).

18              (5) (A) A signed statement indicating whether the applicant, any principal corporate  
19 officer, any managing general partner, or any individual owner, partner, corporate officer,  
20 manager, agent, representative, employee, or subcontractor of the applicant who has direct access  
21 to, or management or control of, controlled substance prescription forms, has ever been convicted  
22 of, or pled no contest to, a violation of any law of a foreign country, the United States, or any  
23 state, or of any local ordinance.

24              (B) The department shall provide the applicant and any individual owner, partner,  
25 corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who  
26 has direct access to, or management or control of, controlled substance prescription forms, with  
27 the means and direction to provide fingerprints and related information, in a manner specified by  
28

1 the department, for the purpose of completing state, federal, or foreign criminal background  
2 checks.

3 (C) Any applicant described in subdivision (b) shall submit his or her fingerprint  
4 images and related information to the department, for the purpose of the department obtaining  
5 information as to the existence and nature of a record of state, federal, or foreign level convictions  
6 and state, federal, or foreign level arrests for which the department establishes that the applicant  
7 was released on bail or on his or her own recognizance pending trial, as described in subdivision  
8 (l) of Section 11105 of the Penal Code. Requests for federal level criminal offender record  
9 information received by the department pursuant to this section shall be forwarded to the Federal  
10 Bureau of Investigation by the department.

11 (D) The department shall assess against each security printer applicant a fee  
12 determined by the department to be sufficient to cover all processing, maintenance, and  
13 investigative costs generated from or associated with completing state, federal, or foreign  
14 background checks and inspections of security printers pursuant to this section with respect to  
15 that applicant; the fee shall be paid by the applicant at the time he or she submits the security  
16 printer application, fingerprints, and related information to the department.

17 (E) The department shall retain fingerprint impressions and related information  
18 for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.

### 19 20 **CALIFORNIA CODE OF REGULATIONS**

21 16. California Code of Regulations, title 16, **section 1714, subdivision (b)**, states:

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

26 17. California Code of Regulations, title 16, **section 1715** states:

27 "(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section  
28 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's

1 compliance with federal and state pharmacy law. The assessment shall be performed before July 1  
2 of every odd-numbered year. The primary purpose of the self-assessment is to promote  
3 compliance through self-examination and education.

4 ...

5 (d) Each self-assessment shall be kept on file in the pharmacy for three years after it is  
6 performed."

7 18. California Code of Regulations, title 16, **section 1718** states:

8 "Current Inventory" as used in Sections 4081 and 4332 of the Business and Professions  
9 Code shall be considered to include complete accountability for all dangerous drugs handled by  
10 every licensee enumerated in Sections 4081 and 4332. The controlled substances inventories  
11 required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least  
12 3 years after the date of the inventory."

13 19. California Code of Regulations, title 16, **section 1718.1** states:

14 "All prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21,  
15 Code of Federal Regulations, section 211.137 are deemed to have expired and may not be  
16 manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor,  
17 pharmacist, pharmacy or other persons authorized to dispense such drugs in California."

18 **CODE OF FEDERAL REGULATIONS**

19 20. Title 21 of Code of Federal Regulations section 1304.11 states:

20 ...

21 "(b) Initial inventory date. Every person required to keep records shall take an inventory of  
22 all stocks of controlled substances on hand on the date he/she first engages in the manufacture,  
23 distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this  
24 section as applicable. In the event a person commences business with no controlled substances on  
25 hand, he/she shall record this fact as the initial inventory.

26 (c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a  
27 new inventory of all stocks of controlled substances on hand at least every two years. The  
28

1 biennial inventory may be taken on any date which is within two years of the previous biennial  
2 inventory date.”

3 21. Title 21 of Code of Federal Regulations section 1364.03 states:

4 ” (a) A prescription for a controlled substance may be issued only by an individual  
5 practitioner who is:

6 (1) authorized to prescribe controlled substances by the jurisdiction in which he is  
7 licensed to practice his profession and

8 (2) either registered or exempted from registration pursuant to Secs. 1301.22(c) and  
9 1301.23 of this chapter.

10 (b) A prescription issued by an individual practitioner may be communicated to a  
11 pharmacist by an employee or agent of the individual practitioner.

#### 12 **CONTROLLED SUBSTANCES AND DANGEROUS DRUGS**

13 22. **Phenergan/Codeine Syrup**, also known as promethazine/codeine syrup, is a  
14 Schedule V controlled substance under Health and Safety Code section 11058, subdivision (c)(1)  
15 and is a dangerous drug under Business and Professions Code section 4022. This combination  
16 medication is used to treat symptoms caused by the common cold, flu, allergies, or other  
17 breathing illnesses (e.g., sinusitis, bronchitis). Codeine is an opioid cough suppressant  
18 (antitussive) that affects a certain part of the brain, reducing the urge to cough.

19 23. **Symbicort**, also known as budesonide/formoterol inhaler is a dangerous drug under  
20 Business and Professions Code section 4022. It is used to treat asthma or chronic obstructive  
21 pulmonary disease (COPD).

22 24. **Linzess**, also known as linaclotide, is a dangerous drug under Business and  
23 Professions Code section 4022. It is used to treat chronic constipation or irritable bowel  
24 syndrome.

25 25. **Invokana**, also known as canagliflozin is a dangerous drug under Business and  
26 Professions Code section 4022. It is used to treat type II diabetes.

27 26. **Spiriva Handihaler**, also known as tiotropium capsules for inhalation is a dangerous  
28 drug under Business and Professions Code section 4022. It is used to treat COPD.

27. **Ranexa**, also known as ranolazine is a dangerous drug under Business and Professions Code section 4022. It is used to treat chronic chest pain.

28. **Creon**, also known as Pancrelipase is a dangerous drug under Business and Professions Code section 4022. It is used to treat pancreatic enzyme insufficiency

29. **Crestor**, also known as rosuvastatin is a dangerous drug under Business and Professions Code section 4022. It is used to treat high cholesterol.

30. **Voltaren gel**, also known as diclofenac topical gel is a dangerous drug under Business and Professions Code section 4022. It is used as an anti-inflammatory.

## COST RECOVERY

31. **Section 125.3** of the Business and Professions Code states, in pertinent part, that the Board may request the administrative law judge to direct a licensee 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.

**SEPTEMBER 25, 2015 INSPECTION**

32. On September 25, 2015, the Board's Inspector conducted an inspection at Respondent Pharmacy. Respondent PIC was present and assisted in the inspection. Respondent Pharmacy was an independent pharmacy in a retail plaza. Respondent PIC explained that Respondent Pharmacy filled about 200-300 prescriptions per day and did not offer immunizations, compounding, or delivery. The Board's Inspector asked to review a current Community Pharmacy Self-Assessment. The most recent self-assessment Respondent PIC located was dated either May 31, 2001 or May 31, 2005. The date was difficult to read. The revision date on the Self-Assessment form was "1/05."

33. The Board's Inspector asked Respondent PIC to provide the most recent inventory of controlled substances, required to be completed every two years by the Drug Enforcement Administration (DEA). However, Respondent PIC was unable to locate any DEA Biennial Inventories of controlled substances. The Board's Inspector requested a copy of the Respondent Pharmacy's written policy and procedures to address quality assurance and employee theft and diversion. Respondent PIC provided Respondent Pharmacy's Quality Assurance Policy and

1 Procedure. However, he did not have any quality assurance reviews on file and explained there  
2 were no recent incidents requiring a quality assurance review. Respondent PIC explained that he  
3 did not have a policy and procedure to address theft, diversion, or impairment of licensed  
4 employees.

5 34. The Board's Inspector asked Respondent PIC if Respondent Pharmacy was able to  
6 provide interpretive services to patients with limited English proficiency. The Board's Inspector  
7 did not see a notice of availability of interpretive services posted in the pharmacy. Respondent  
8 PIC could not produce a policy and procedure regarding interpretive services or any  
9 documentation to show the pharmacy was registered with a translation service. He explained that  
10 the pharmacy's typical practice was to have pharmacy staff members translate for patients who  
11 did not speak and understand English. The Board's Inspector explained Respondent Pharmacy  
12 was required to have interpretive services available, post a notice of availability of interpretive  
13 services, and maintain a written policy and procedure to address the provision of interpretive  
14 services.

15 35. The Board's Inspector noticed several pads containing blank prescription form for  
16 H.C.W., MD. The prescription pads were on a storage shelf and in a stack next to the computer  
17 used for typing and processing prescriptions. Dr. H.C.W.'s address on the pads was listed as,  
18 "709 N. Hill Street, Suite 19, Los Angeles, CA 90012." Respondent PIC stated that Dr.  
19 H.C.W.'s office was located in the same retail plaza as Respondent Pharmacy. Respondent PIC  
20 told the Board's Inspector he ordered the prescription forms for Dr. H.C.W. as a professional  
21 courtesy. Respondent PIC said he did not charge Dr. H.C.W. for the prescription forms.  
22 Respondent PIC provided an invoice from Hildebrand Printing. The invoice was dated April 1,  
23 2014. The invoice showed Respondent Pharmacy ordered 120 prescription pads with Dr.  
24 H.C.W.'s information and paid \$346.62. The Board's Inspector asked Respondent PIC why the  
25 prescription forms were in the pharmacy rather than at Dr. H.C.W.'s office. Respondent PIC  
26 initially stated the prescription forms were to be used as examples in the event Dr. H.C.W.  
27 wanted Respondent Pharmacy to reorder prescription forms. Later in the inspection, Respondent  
28

1 PIC stated that the pharmacy staff sometimes filled out prescription documents for Dr. H.C.W. to  
2 sign.

3 36. The Board's Inspector collected and took pictures of the 10 "pads" of prescription  
4 forms with Dr. H.C.W.'s preprinted name and address, and told Respondent PIC security  
5 prescription documents must be delivered directly from the security printer to the prescriber. The  
6 Board's Inspector asked Respondent PIC to show her where Respondent Pharmacy stored  
7 wholesaler invoices for purchases of dangerous drugs. Respondent PIC offered to show her a  
8 sample of Respondent Pharmacy's invoices, and explained he took invoices to his accountant's  
9 office and therefore all wholesaler invoices for the previous three years were not in the pharmacy  
10 at the time. He further stated that Respondent Pharmacy did not officially store records off-site,  
11 rather the records were only temporarily out of the pharmacy.

12 37. The Board's Inspector discussed Business and Professions Code Section 4105 in  
13 reference with all of the records or other documentation of the acquisition and disposition of  
14 dangerous drugs and dangerous devices. The Board's Inspector located and reviewed invoices  
15 from the wholesalers, and collected a sample of invoices from each wholesaler. She further  
16 located invoices from ESP Medical Inc., and searched for ESP Medical Inc.'s wholesaler license  
17 on the Board of Pharmacy's website and determined ESP Medical Inc. did not have a current  
18 wholesaler license, and that E S P Services' wholesaler license was revoked by stipulation on  
19 September 17, 2012. She collected 45 invoices for sales from ESP Medical Inc. dated after  
20 September 17, 2012.

21 38. The Board's Inspector discussed ESP Medical Inc. with Respondent PIC who stated  
22 that he had verified ESP Medical Inc.'s California wholesaler license previously, and produced a  
23 printout of the Board of Pharmacy's website entry for E S P Services. Respondent PIC explained  
24 that he had not ordered from ESP Medical Inc. recently and didn't believe any medications from  
25 ESP Medical Inc. would still be in the pharmacy's stock. The Board's Inspector spot checked  
26 Respondent Pharmacy's inventory stock of drugs listed on ESP Medical Inc.'s invoices, and did  
27 not find any medications from the lot numbers listed on ESP Medical Inc.'s invoices. She noticed  
28 a large box of empty pharmacy dispensing vials with labels from other pharmacies, and asked

1 Respondent PIC why Respondent Pharmacy had these vials. Respondent PIC explained that his  
2 patients bring old pharmacy bottles to the Respondent Pharmacy and he recycles them as a  
3 courtesy, and he added that he did not receive medications from patients, only empty bottles.

4 39. The Board's Inspector also noticed Respondent Pharmacy's stock of empty pharmacy  
5 vials and caps for prescription filling was varied, and asked Respondent PIC if he reused the  
6 pharmacy vials he collected from patients to dispense prescriptions. Respondent PIC stated he  
7 did not. The Board's Inspector discussed California Code of Regulations Section 1717, and  
8 Respondent PIC reiterated that Respondent Pharmacy only dispensed medications in new  
9 prescription vials.

10 40. The Board's Inspector observed many expired medications in the pharmacy.  
11 Respondent PIC explained these medications were separated from the pharmacy's inventory and  
12 would be sent to a reverse distributor. She noted that Respondent Pharmacy had three shelves,  
13 labeled for expired medications, containing expired medications, that there were two additional  
14 boxes containing expired medications, that there was also a small bag containing Diovan and  
15 valsartan bottles (a portion of these bottles were expired), and she observed several boxes  
16 containing prescription samples. These boxes were along the back wall of the pharmacy,  
17 separated from the pharmacy's drug inventory.

18 41. The Board's Inspector asked Respondent PIC why drug samples were stored in the  
19 pharmacy. Respondent PIC stated sometimes the samples were, "sent to the pharmacy" and  
20 sometimes physicians would provide the samples to the pharmacy for disposal. Respondent PIC  
21 explained that he did not dispense drug samples and intended to send the samples in the pharmacy  
22 to a reverse distributor. The boxes of samples included the following: (1) one box containing 11  
23 packages of Edarbi 80 mg; (2) one box containing Amitiza, Bystolic, Spiriva, Flomax, and  
24 Farziga samples; (3) one box containing Anoro and Breo samples; (4) one box containing Luvena  
25 samples; (5) one box containing Invokana and Jalyn samples; (6) one box containing Flovent  
26 HFA 44mcg and 110 mcg inhaler, Symbicort inhaler, Spiriva Handihaler, Tudorza Pressair,  
27 Advair HFA 115/21, and Asmanex 220 samples; (7) one box containing Exelon patch and Soma  
28

1 250 mg samples along with other expired medications; (8) one box containing Oseni 25/30,  
2 Oseni 25/15, Nesina, Linzess 145 and 290, Onglyza, and Pradaxa samples.

3 42. The Board's Inspector noticed many unlabeled amber pharmacy vials containing  
4 medication in Respondent Pharmacy's inventory. Some of the bottles were rubber-banded to  
5 manufacturers' bottles. Some of the bottles were in boxes labeled with the drug name and other  
6 bottles were next to manufacturers' bottles on the shelves. She also observed a large box  
7 containing both empty unlabeled amber vials and unlabeled amber vials containing white tablets.  
8 Respondent PIC stated that all the tablets were atorvastatin. The Board's Inspector explained to  
9 the Respondent Respondent PIC that medications in the pharmacy's inventory for dispensing  
10 should be labeled with the drug name and strength, National Drug Code (NDC) number, lot  
11 number, and expiration date. Respondent PIC explained that the unlabeled or partially labeled  
12 bottles were on the shelves because Respondent Pharmacy staff sometimes pre-counted  
13 commonly dispensed quantities of commonly dispensed medications. Respondent PIC stated that  
14 he would instruct the staff to fully label any pre-counted bottles in the future.

15 43. The Board's Inspector observed a bottle of medication in inventory which had a  
16 partial label which was not consistent with the label of Respondent Pharmacy. It appeared the  
17 medication had been previously dispensed by another pharmacy. Respondent PIC stated he did  
18 not know how this bottle ended up in inventory at Respondent Pharmacy, explained that he  
19 understood Respondent Pharmacy could not receive medications from patients and dispense  
20 them, and stated that he would dispose of this medication.

21 44. The Board's Inspector reviewed completed prescription documents for Schedule III-  
22 V controlled substances which were comingled with prescription documents for non-controlled  
23 substances. She did not see unusual or obviously excessive prescriptions for  
24 promethazine/codeine syrup. The Board's Inspector informed Respondent PIC that she planned  
25 to conduct an audit of promethazine/codeine. She asked Respondent PIC to provide records of  
26 disposition for promethazine/codeine. Respondent PIC printed dispensing records for  
27 promethazine/codeine syrup from October 1, 2013 to December 31, 2013 and from January 1,  
28 2014 to September 24, 2015.

1       45. The Board's Inspector asked Respondent PIC to count Respondent Pharmacy's  
2 current inventory of promethazine/codeine syrup and record it on a Stock-on-Hand Form. She  
3 asked Pharmacy Technician S.C. to check if there were any prescriptions for  
4 promethazine/codeine syrup currently in process, and TCH S.C. printed a daily dispensing report  
5 and confirmed Respondent Pharmacy had not processed any prescriptions for  
6 promethazine/codeine syrup that day.

7       46. The Board's Inspector asked when Respondent Pharmacy last received a wholesaler  
8 order. Respondent PIC stated that the most recent order was received the previous day, August  
9 24, 2015, and he completed the count.

10       47. At the end of the inspection, The Board's Inspector reviewed the inspection report  
11 with Respondent PIC, and she included requests for the following items in the inspection report:  
12 (a) front page and signature page of a completed self-assessment; (b) completed DEA Biennial  
13 Inventory; (c) written statement regarding CT Pharmacy's purchasing of prescription forms for  
14 Dr. H.C.W.; (d) documentation showing unlabeled drugs, expired drugs, and sample drugs were  
15 sent to a reverse distributor; (e) written policies and procedures for the provision of interpretive  
16 services, and theft or impairment of licensed employees.

17       48. The Board's Inspector also issued written notices to the Respondents.

18                               **OCTOBER 15, 2015 INSPECTION**

19       49. On October 15, 2015, the Board's Inspector conducted a follow-up inspection at the  
20 Respondent Pharmacy. Respondent PIC was not in the pharmacy, however, the pharmacist A.L.  
21 was present. During the inspection, the pharmacy owner, Respondent Shen arrived and assisted in  
22 the inspection as well. Details of the inspection included but were not limited to the following:

23       50. The Board's Inspector requested a Microsoft Excel file containing complete  
24 dispensing records for Respondent Pharmacy from October 14, 2012 to October 14, 2015. She  
25 stated she wished to conduct an audit of selected non-controlled substances. She explained the  
26 audit to the pharmacist RPH A.L. and the technician S.C. and told them she needed to determine  
27 the pharmacy's current on-hand quantities of the following medications: Symbicort 160/4.5,  
28 Creon 24000 units, Spiriva Handihaler, Crestor 10 mg, Voltaren gel, Ranexa 500 mg, Invokana

1 100 mg, and Linzess 145 mcg. S.C. printed a daily dispensing report and reviewed the  
2 prescriptions currently in process on the pharmacy's counter, and identified prescriptions on the  
3 daily dispensing report which had been processed but not yet filled. A.L. and S.C. counted  
4 Respondent Pharmacy's current on-hand quantities of the medications above. S.C. filled out a  
5 Stock-on-Hand form and A.L. signed to attest to its accuracy.

6 51. The Board's Inspector located and collected 25 additional invoices from ESP  
7 Medical, Inc., and located and collected invoices from HD Smith/Smart Source, LLC Wholesale  
8 Supply, and TopRx. She reviewed several "books" or files of completed prescription documents  
9 and identified several prescriptions for controlled substances written by Dr. H.W. who was the  
10 physician whose blank prescription forms were found at Respondent Pharmacy during the  
11 inspection on September 25, 2015. She left instructions for the Respondent PIC to review the  
12 prescription documents and determine if body of the prescription documents were filled out by a  
13 pharmacy staff member, a staff member of Dr. H.C.W.'s, or Dr. H.C.W. himself.

14 52. The Board's Inspector interviewed Respondent Shen about his interactions with ESP  
15 Medical, Inc. by asking how he placed orders with ESP Medical, Inc. Respondent Shen  
16 explained that ESP Medical, Inc. would call the pharmacy to ask if they would like to place an  
17 order. If the pharmacy wished to place an order, they would do so over the phone. The Board's  
18 Inspector asked Respondent Shen how ESP Medical, Inc. provided the orders to CT Pharmacy.  
19 Respondent Shen explained orders were delivered to the pharmacy by a driver. The Board's  
20 Inspector asked how Respondent Shen paid ESP Medical, Inc. for the orders. Respondent Shen  
21 explained he paid by check and handed the checks to the delivery driver when the orders were  
22 dropped off. The Board's Inspector asked if Respondent Shen had any contact information for  
23 ESP Medical Inc. or its representatives other than the phone number and address listed on the  
24 invoice. Respondent Shen stated he had no knowledge of any other address, phone number,  
25 email, or website associated with ESP Medical, Inc. The Board's Inspector left instructions for  
26 Respondent PIC to provide any information he could regarding Respondent Pharmacy's most  
27 recent purchases from ESP Medical, Inc. including payment information and any methods of  
28

1 contact used for ESP Medical, Inc. in 2013 and 2014. At the end of the inspection, the Board's  
2 Inspector reviewed the inspection report with A.L. and issued an official receipt.

3 **RESPONDENT PHARMACY'S INSPECTION RESPONSE**

4 53. Respondent Pharmacy provided the following documents: an Excel spreadsheet  
5 containing all prescriptions filled by Respondent Pharmacy from October 14, 2012 to October 14,  
6 2015; (b) a letter from Respondent PIC addressing the deficiencies noted in the inspections with  
7 an inventory of controlled substances dated October 6, 2015, the front page and signature page of  
8 a Community Pharmacy Self-Assessment dated October 6, 2015. Regarding Respondent  
9 Pharmacy's ordering from ESP Medical Inc. or E S P Services, Respondent PIC stated  
10 Respondent Pharmacy had verified E S P Services, "held a clear wholesaler license on September  
11 10, 2012." He attached a printout of the Board of Pharmacy's license verification page showing  
12 E S P Services held an active wholesaler license in California on 09/10/2012.

13 54. Regarding retention of records of dangerous drugs and devices on the premises,  
14 Respondent PIC wrote, "During the September 25, 2015 inspection the pharmacy staff was  
15 unable to immediately locate some records of acquisition of dangerous drugs. The records in  
16 question were merely set aside for the purposes of conducting a financial review of the purchases  
17 and were subsequently located in a separate area of the pharmacy. Please note that the records in  
18 question were never removed from the licensed premises." This statement contradicted  
19 Respondent PIC's verbal statements during the inspection on September 25, 2015. When asked  
20 to review Respondent Pharmacy's invoices showing purchases from wholesalers, Pharmacist  
21 Wong told the Board's Inspector that a portion of these invoice were unavailable because  
22 Respondent Pharmacy gave the invoices to an accountant.

23 55. Respondent PIC attached a "Theft, Diversion and Impairment" policy and procedure  
24 for CT Pharmacy effective October 1, 2015, a "Translation Services" policy and procedure along  
25 with the "Point to your Language" sign available on the Board of Pharmacy's website.

26 56. Regarding Dr. H.C.W.'s prescription forms found in Respondent Pharmacy,  
27 Respondent PIC wrote, "As a courtesy to local prescriber, Respondent Pharmacy assisted with  
28 placing orders for, and arranged for delivery of, secure prescription forms to Dr. H.C.W.", and

1 attached a statement from Dr. H.C.W. stating that the prescription pad purchasing order is placed  
2 by Respondent Pharmacy and the prescriptions is not for free, that the prescription pad delivered  
3 to pharmacy just for convenience, and that the pharmacy staffs are always available to help to  
4 receive the orders, and that Respondent Pharmacy will bill the clinic for total what Dr. H.C.W.  
5 owes each month which is including the medication orders for clinic use. This statement  
6 contradicted Respondent PIC's statements during the inspection on September 25, 2016.  
7 Respondent PIC stated he did not charge Dr. H.C.W. for the prescription documents and provided  
8 them free of charge as a, "professional courtesy."

9 57. Respondent PIC stated that all items identified during the inspection on September  
10 25, 2016 were returned to Rx Reverse Distributors Inc., and attached a job sheet from Rx Reverse  
11 Distributors Inc. and FedEx labels for shipments from CT Pharmacy to Rx Reverse Distributors  
12 Inc.

13 58. Regarding the request for Respondent PIC to review prescription documents from Dr.  
14 H.C.W. and determine if a pharmacy staff member wrote the body of the prescription or if Dr.  
15 H.C.W. or his agent wrote the body of the prescription, Respondent PIC stated he found no  
16 indication that any of CT Pharmacy staff members filled out any information in the body of the  
17 prescription, and attached another statement from Dr. H.C.W. stating that some of the  
18 prescriptions that he prescribed for patients was not his handwriting because he will have his  
19 nurse next to him write it out for him and Dr. H.C.W. will sign it off, which explains why the  
20 handwritings are different. Dr. H.C.W. wrote that the only nurse is C.T.L. aka C.O. who worked  
21 for him for more than 36 years. This statement contradicted Respondent PIC's statements during  
22 the inspection on September 25, 2015 when Respondent PIC told the Board's Inspector that  
23 pharmacy staff members sometimes wrote out prescriptions for Dr. H.C.W. to sign.

#### 24 AUDITS

25 59. The Board's Inspector gathered the information necessary to conduct an audit of  
26 promethazine/codeine syrup and the non-controlled substances she selected during the inspection  
27 on October 15, 2015.

60. CTMP, Inc. provided the requested records and certification. However, CTMP, Inc. was unable to provide pedigrees or DSCSA Transaction Histories for the majority of its sales to Respondent Pharmacy. Additionally, the Board's Inspector was informed that CTMP, Inc. ordered dangerous drugs from an unlicensed entity.

61. Colossal Health provided the requested records and certification, however, it did not provide any Pedigrees or DSCSA Transaction Histories. The Board's Inspector's attempted to contact Colossal Health regarding this request and Colossal Health's failed to produce pedigrees or DSCSA Transaction Histories for sales to the Respondent Pharmacy.

62. The Board's Inspector requested and received certified records of sales of the audit medications to the Respondent Pharmacy from Cardinal Health, Anda, Smart Source, Associated Pharmacies Inc., Valley Wholesale Drug Co., TopRx, and LLC Wholesale Supply. She was unable to contact ESP Medical Inc./E S P Services. During the inspections on September 25, 2015 and October 15, 2015, she collected all the invoices from ESP Medical Inc./E S P Services she was able to find.

#### PROMETHAZINE/CODEINE AUDIT

63. The table below contains Respondent Pharmacy's acquisitions of promethazine/codeine during the audit period.

| Promethazine/codeine syrup quantity ordered from 01/02/2014 to 09/25/2015 |                   |
|---------------------------------------------------------------------------|-------------------|
| Wholesaler                                                                | Amount Ordered    |
| Cardinal Health                                                           | 524,084 mL        |
| Anda                                                                      | 0                 |
| Smart Source                                                              | 1,419 mL          |
| Colossal Health                                                           | 0                 |
| CTMP, Inc.                                                                | 0                 |
| E S P                                                                     | 0                 |
| Drogueria de la Villa                                                     | 0                 |
| Associated Pharmacies Inc.                                                | 0                 |
| Valley Wholesale Drug Co.                                                 | 5,676 mL          |
| TopRx                                                                     | 0                 |
| LLC Wholesale Supply                                                      | 0                 |
| <b>Total</b>                                                              | <b>531,179 mL</b> |

| Drug Name and Strength | Estimated Initial Amount | Amount Ordered WLS (A) | Total Amount (T+A)=T | Amount Dispensed (D) 1/2/14 to 9/25/15 | Amount to be Account ed for (T-D) | Stock on Hand (S) Date: 9/25/15 | Amount Over S ≥ T-D | Amount Short S ≤ T-D |
|------------------------|--------------------------|------------------------|----------------------|----------------------------------------|-----------------------------------|---------------------------------|---------------------|----------------------|
|------------------------|--------------------------|------------------------|----------------------|----------------------------------------|-----------------------------------|---------------------------------|---------------------|----------------------|

|                                      |      |            |         |            |            |          |  |            |
|--------------------------------------|------|------------|---------|------------|------------|----------|--|------------|
| Promethazine/codeine 6.25-5 mg/10 mL | 0 mL | 531,179 mL | 531,179 | 367,432 mL | 163,747 mL | 8,041 mL |  | 155,706 mL |
|--------------------------------------|------|------------|---------|------------|------------|----------|--|------------|

64. The Board's Inspector determined the shortage of 155,706 mL of promethazine/codeine syrup between 01/02/2014 and 09/25/2015 was significant.

**RESPONDENT PHARMACY'S ORDERING FROM E S P SERVICES/ ESP MEDICAL INC.**

65. After reviewing the invoices from E S P Medical, Inc. collected at the Respondent Pharmacy, the Board Inspector collected 71 invoices in total as summarized below:

| Date       | Invoice Number | Total Price |
|------------|----------------|-------------|
| 4/7/2014   | 10-7380        | 7626.69     |
| 3/4/2014   | 10-7127        | 7769.70     |
| 2/3/2014   | 10-6969        | 9329.67     |
| 1/27/2014  | 10-6912        | 8858.88     |
| 1/17/2014  | 10-6850        | 9391.68     |
| 12/30/2013 | 10-6738        | 16233.30    |
| 12/13/2013 | 10-6622        | 7857.08     |
| 12/9/2013  | 10-5689        | 8992.63     |
| 12/4/2013  | 10-6560        | 9315.09     |
| 11/27/2013 | 10-6516        | 9655.99     |
| 11/7/2013  | 10-6380        | 9641.27     |
| 11/1/2013  | 10-6348        | 8758.38     |
| 10/30/2013 | 10-6327        | 7767.90     |
| 10/24/2013 | 10-6279        | 6129.92     |
| 10/14/2013 | 10-6219        | 22272.35    |
| 10/8/2013  | 10-6177        | 14196.96    |

|    |           |         |          |
|----|-----------|---------|----------|
| 1  | 10/4/2013 | 10-6157 | 8998.19  |
| 2  | 9/16/2013 | 10-6056 | 9968.58  |
| 3  | 9/12/2013 | 10-6038 | 8997.39  |
| 4  | 9/10/2013 | 10-6003 | 24115.93 |
| 5  | 9/6/2013  | 10-5976 | 9312.19  |
| 6  | 8/28/2013 | 10-5917 | 12505.08 |
| 7  | 8/19/2013 | 10-5849 | 9605.96  |
| 8  | 8/13/2013 | 10-5805 | 8307.38  |
| 9  | 8/1/2013  | 10-5697 | 8835.18  |
| 10 | 7/27/2013 | 10-5669 | 9639.99  |
| 11 | 7/24/2013 | 10-5635 | 8914.88  |
| 12 | 7/8/2013  | 10-5493 | 15977.99 |
| 13 | 7/2/2013  | 10-5476 | 9327.36  |
| 14 | 6/26/2013 | 10-5444 | 6953.98  |
| 15 | 6/21/2013 | 10-5399 | 8920.98  |
| 16 | 5/23/2013 | 10-5186 | 16466.75 |
| 17 | 5/3/2013  | 10-5095 | 8983.08  |
| 18 | 4/30/2013 | 10-5078 | 19897.89 |
| 19 | 4/26/2013 | 10-5040 | 6961.08  |
| 20 | 4/11/2013 | 10-4921 | 16890.80 |
| 21 | 4/8/2013  | 10-4889 | 9224.39  |
| 22 | 4/4/2013  | 10-4862 | 8985.88  |
| 23 | 4/1/2013  | 10-4837 | 9672.69  |
| 24 | 3/19/2013 | 10-4753 | 9271.90  |
| 25 | 3/12/2013 | 10-4669 | 7207.29  |
| 26 | 2/19/2013 | 10-4528 | 9359.99  |
| 27 | 2/13/2013 | 10-4477 | 7896.10  |
| 28 |           |         |          |

|    |            |         |          |
|----|------------|---------|----------|
| 1  | 2/9/2013   | 10-4449 | 8966.63  |
| 2  | 2/6/2013   | 10-4417 | 8838.17  |
| 3  | 2/2/2013   | 10-4393 | 7799.58  |
| 4  | 1/30/2013  | 10-4363 | 7964.89  |
| 5  | 1/25/2013  | 10-4339 | 8968.26  |
| 6  | 1/21/2013  | 10-4309 | 9200.69  |
| 7  | 1/9/2013   | 10-4241 | 9438.74  |
| 8  | 1/4/2013   | 10-4205 | 8979.69  |
| 9  | 12/17/2012 | 10-4099 | 12073.80 |
| 10 | 12/6/2012  | 10-4057 | 6621.91  |
| 11 | 12/3/2012  | 10-4030 | 6981.89  |
| 12 | 11/29/2012 | 10-4011 | 8930.25  |
| 13 | 11/23/2012 | 10-3972 | 7919.68  |
| 14 | 11/15/2012 | 10-3931 | 9393.60  |
| 15 | 11/12/2012 | 10-3902 | 6139.08  |
| 16 | 11/7/2012  | 10-3871 | 6687.28  |
| 17 | 11/3/2012  | 10-3851 | 8992.78  |
| 18 | 10/31/2012 | 10-3833 | 9662.35  |
| 19 | 10/26/2012 | 10-3816 | 9480.09  |
| 20 | 10/18/2012 | 10-3755 | 6377.88  |
| 21 | 10/15/2012 | 10-3727 | 9533.30  |
| 22 | 10/8/2012  | 10-3698 | 10785.29 |
| 23 | 10/4/2012  | 10-3683 | 9305.69  |
| 24 | 10/1/2012  | 10-3665 | 9491.15  |
| 25 | 9/27/2012  | 10-3647 | 20195.58 |
| 26 | 9/25/2012  | 10-3628 | 8917.97  |
| 27 | 9/21/2012  | 10-3609 | 9762.68  |
| 28 |            |         |          |

|   |              |                     |
|---|--------------|---------------------|
| 1 | <b>Total</b> | <b>\$711,402.68</b> |
|---|--------------|---------------------|

2        65. The invoices were dated between September 21, 2012 and April 7, 2014 and included  
3 purchases totaling \$711,402.68. The total packages (bottles, inhalers, tubes, etc.) Respondent  
4 Pharmacy ordered from ESP Medical Inc. on the 71 invoices the Board Inspector collected are  
5 listed as follows:

|    |                         |                              |
|----|-------------------------|------------------------------|
| 6  | <b>Drug</b>             | <b>Package Units Ordered</b> |
| 7  | Aciphex                 | 18                           |
| 8  | Actonel 150 mg          | 6                            |
| 9  | Actonel 35 mg           | 24                           |
| 10 | Advair Diskus 100/50    | 5                            |
| 11 | Advair Diskus 250/50    | 18                           |
| 12 | Advair Diskus 500/50    | 1                            |
| 13 | Aggrenox 200/25 mg      | 18                           |
| 14 | Alphagan P Ophth. Susp. | 2                            |
| 15 | Atelvia 35 mg           | 20                           |
| 16 | Amitiza 24 mg           | 35                           |
| 17 | Aricept 23 mg           | 13                           |
| 18 | Atrovent HFA Inhaler    | 1                            |
| 19 | Avelox 400 mg           | 1                            |
| 20 | Avodart .5 mg           | 5                            |
| 21 | Azilect 1 mg            | 1                            |
| 22 | Benicar 20 mg           | 1                            |
| 23 | Benicar 40 mg           | 6                            |
| 24 | Benicar HCT 20/12.5     | 9                            |
| 25 | Benicar HCT 40.12.5     | 15                           |
| 26 | Benicar HCT 40/25       | 6                            |
| 27 | Bystolic 10 mg          | 8                            |
| 28 |                         |                              |

|    |                                 |     |
|----|---------------------------------|-----|
| 1  | Bystolic 5 mg                   | 17  |
| 2  | Calcium Acetate 667 mg          | 1   |
| 3  | Celebrex 100 mg                 | 1   |
| 4  | Celebrex 200 mg                 | 292 |
| 5  | Cialis 20 mg                    | 2   |
| 6  | Cialis 30 mg                    | 2   |
| 7  | Ciprodex Otic Suspension 7.5 ml | 5   |
| 8  | Colcrys .6 mg                   | 1   |
| 9  | Combivent 200 mg                | 4   |
| 10 | Combivent Respimat              | 5   |
| 11 | Coreg CR 20 mg                  | 11  |
| 12 | Creon 12000 units               | 4   |
| 13 | Creon 24000 units               | 60  |
| 14 | Creon 36000 units               | 2   |
| 15 | Crestor 5 mg                    | 8   |
| 16 | Crestor 10 mg                   | 35  |
| 17 | Crestor 20 mg                   | 22  |
| 18 | Crestor 40 mg                   | 2   |
| 19 | Cymbalta 30 mg                  | 2   |
| 20 | Cymbalta 60 mg                  | 32  |
| 21 | Daliresp                        | 3   |
| 22 | Detrol LA 4 mg                  | 2   |
| 23 | Dexliant 30 mg                  | 3   |
| 24 | Dexliant 60 mg                  | 17  |
| 25 | Diovan 160 mg                   | 3   |
| 26 | Dulera MDI 100                  | 1   |
| 27 | Dulera MDI 200                  | 2   |
| 28 |                                 |     |

|    |                             |     |
|----|-----------------------------|-----|
| 1  | Edarbi 80 mg                | 2   |
| 2  | Edarbichlor 40/25 mg        | 1   |
| 3  | Effient 10 mg               | 6   |
| 4  | Effient 5 mg                | 1   |
| 5  | Enablex 15 mg               | 1   |
| 6  | Enablex 7.5 mg              | 4   |
| 7  | Evista 60 mg                | 28  |
| 8  | Exelon patch 4.6 mg         | 30  |
| 9  | Exelon patch 9.5 mg         | 17  |
| 10 | Flector patch               | 18  |
| 11 | Janumet 50/1000 mg          | 19  |
| 12 | Janumet 50/500 mg           | 17  |
| 13 | Januvia 100                 | 40  |
| 14 | Januvia 50                  | 8   |
| 15 | Lidoderm 5% patch           | 877 |
| 16 | Linzess 145                 | 2   |
| 17 | Linzess 290                 | 2   |
| 18 | Lovaza                      | 80  |
| 19 | Lumigan Ophthalmic solution | 1   |
| 20 | Micardis 40 mg              | 1   |
| 21 | Micardis 80 mg              | 11  |
| 22 | Multaq 400 mg               | 2   |
| 23 | Myrbetriq 25 mg             | 5   |
| 24 | Namenda 10 mg               | 49  |
| 25 | Namenda 5 mg                | 12  |
| 26 | Namenda XR 28 mg            | 4   |
| 27 | Nasonex nasal spray         | 90  |
| 28 |                             |     |

|    |                               |     |
|----|-------------------------------|-----|
| 1  | Nevanac ophthalmic suspension | 5   |
| 2  | Nexium 40 mg                  | 310 |
| 3  | Onglyza 5 mg                  | 10  |
| 4  | Pataday ophthalmic solution   | 29  |
| 5  | Patanol ophthalmic solution   | 6   |
| 6  | Plavix 75 mg                  | 1   |
| 7  | Pradaxa 150 mg                | 7   |
| 8  | Pradaxa 75 mg                 | 2   |
| 9  | Premarin                      | 1   |
| 10 | Proair HFA inhaler            | 2   |
| 11 | Ranexa 1000 mg                | 7   |
| 12 | Ranexa 500 mg                 | 14  |
| 13 | Rapaflo 8 mg                  | 3   |
| 14 | Restasis .05% ophthalmic      | 55  |
| 15 | solution                      |     |
| 16 | Savella 25 mg                 | 1   |
| 17 | Singulair 10 mg               | 8   |
| 18 | Pririva 18 mcg inhalation     | 7   |
| 19 | capsules                      |     |
| 20 | Symbicort 80/4.5              | 1   |
| 21 | Symbicort 160/4.5             | 7   |
| 22 | Tekturna                      | 4   |
| 23 | Toviaz 4 mg                   | 3   |
| 24 | Tradjenta 5 mg                | 4   |
| 25 | Trilipix 135 mg               | 5   |
| 26 | Tudorza Pressair              | 4   |
| 27 | Uloric 40 mg                  | 16  |
| 28 |                               |     |

|    |                             |       |
|----|-----------------------------|-------|
| 1  | Uloric 80 mg                | 5     |
| 2  | Vesicare 10 mg              | 27    |
| 3  | Vesicare 5 mg               | 39    |
| 4  | Viagra 100 mg               | 5     |
| 5  | Vigamox ophthalmic solution | 4     |
| 6  | Vytorin 10/20               | 21    |
| 7  | Vytorin 10/40               | 12    |
| 8  | Welchol 625 mg              | 1     |
| 9  | Xarelto 15 mg               | 4     |
| 10 | Xarelto 20 mg               | 5     |
| 11 | Xopenex HFA inhaler         | 1     |
| 12 | Zenpep 200000               | 2     |
| 13 | Zatia 10 mg                 | 29    |
| 14 | Zovirax 5%                  | 5     |
| 15 | Total Units Ordered         | 2,752 |

16        **SUPPLEMENTAL QUESTIONNAIRE SENT TO RESPONDENT PHARMACY**

17        66.    The Board's Inspector sent the questionnaire to the Respondent Pharmacy on March  
18        30, 2016 and asked Respondent PIC to return the completed questionnaire to me by April 6, 2016.  
19        Respondents through their counsel were granted an extension of time to respond. On April 8,  
20        2016, The Board's Inspector received an email from Respondent PIC stating "I left C.T.  
21        Pharmacy since last December and I am not PIC at present."

22        67.    On May 5, 2016, The Board's Inspector received a voicemail from a person who  
23        identified herself as a representative of Respondent Shen and Respondent Pharmacy. The  
24        voicemail stated that Respondent Pharmacy discontinued business on May 4, 2016 and asked if  
25        they still needed to respond to the questionnaire. The Board's Inspector explained although  
26        Respondent Pharmacy was no longer operating, Respondent Shen and Respondent PIC were still  
27  
28

1 required to complete the questionnaire. Respondent Shen stated that Respondent PIC had already  
2 mailed the questionnaire to me and that the Board's Inspector would be receiving it shortly.

3 68. On May 9, 2016, the Board's Inspector received Respondent PIC's responses as  
4 follows:

5 (a) Is your computer software the primary source of record keeping and maintenance  
6 in this pharmacy? If not, what is? Answer: Yes.

7 (b) Is the following statement true or false: The electronic computer record of  
8 dispensed prescriptions stored in the pharmacy software system is a true and accurate  
9 representation of the hard copy (paper) prescription record? Answer: True.

10 (c) From October 1, 2013 to October 15, 2015, do you have any records of  
11 dispositions other than dispensing for the following medications? Answer: (1)  
12 Promethazine/codeine syrup; (2) Symbicort 160/4.5 mg inhaler; (3) Invokana 100 mg; (4)  
13 Spiriva Handihaler; (5) Ranexa 500 mg; (6) Creon 24000 units; (7) Crestor 10 mg; and (8)  
14 Voltaren gel. Additional records of disposition could include invoices of transfer to a reverse  
15 distributor, losses reported on DEA Forms 106, or sales to prescriber or other pharmacies on  
16 invoices. If so, please provide these records. Answer: For item a., the answer is 'No'; For item b.  
17 to h., the answer is 'No' except for drugs disposed through reverse distributor.

18 (d) From October 1, 2013 to October 15, /2015, did you acquire any of the drugs  
19 above from sources other than the wholesalers listed below? If so, please provide those records  
20 of acquisition. Answer: (a) Cardinal Health; (b) Anda; (c) Smart Source; (d) Colossal Health; (e)  
21 CTMP, Inc.; (f) E S P Medical, Inc.; (g) Drogueria de la Villa; (h) Associated Pharmacies Inc.; (i)  
22 Valley Wholesale Drug Co.; (j) TopRx; and (k) LLC Wholesale Supply. No, other than samples  
23 sent by physicians for disposal.

24 (e) Does CT Pharmacy have any records of acquisition for the sample medications  
25 identified in the pharmacy on 09/25/2015? If CT Pharmacy has any invoices or other records of  
26 receiving these sample medications, please provide those records. Answer: No.

27 (f) After the inspection, you provided a statement from Dr. H.C.W., he indicated  
28 Respondent Pharmacy ordered prescription pads and Dr. H.C.W. paid Respondent for the pads.

1 Do you have any records of receiving payment from Dr. H.C.W. for the prescription pads? If so,  
2 please provide those records. Answer: "I was told by Mr. Robert Shen (owner) that Dr. H.C.W.  
3 paid for the prescription pads. I have no access to those records since I am no longer working at  
4 the Respondent Pharmacy anymore."

5 (g) During the inspection on September 25, 2015, the Board's Inspector collected  
6 pads of blank prescription documents for Dr. H.C.W. Those pads had varying numbers of  
7 prescription documents remaining. For example, one of the pads had 21 prescription forms  
8 remaining; one pad had 75 prescription documents remaining, etc. Do you know why this was the  
9 case? Answer: Sometimes when we received orders to refill prescriptions for patients of Dr.  
10 H.C.W., he wanted us to write them as new prescriptions and dispensed medications to patients.  
11 Then Dr. H.C.W. will collect, sign the prescriptions, update patients' records in his office and  
12 returned the signed prescriptions back to pharmacy for filing.

13 (h) Have you ever received a pedigree or DSCSA Transaction History from Colossal  
14 Health? If so, please provide the pedigree or pedigrees. Answer: No.

15 (i) Do you know of any other pharmacies that order medications from Colossal  
16 Health? Answer: No.

17 (j) After the inspection, you provided a Job Sheet from RxReverse. The Job Sheet  
18 noted you requested a destruction letter for the sample medications collected by RxReverse. Did  
19 RxReverse send an additional letter? If so, please provide the letter. Answer: I am not sure since  
20 I do not have access to the pharmacy after November 14, 2015.

21 69. Respondent PIC notified the Board's Inspector that he notified the Board that his  
22 position as PIC had been terminated by the Respondent Shen, president of Respondent Pharmacy  
23 since November 14, 2015. The Board Inspector attempted to reach the owner of Respondent  
24 Pharmacy, Respondent Shen, to ask if Respondent PIC's date of termination was correct to  
25 Respondent Shen's knowledge. However, Respondent Pharmacy was no longer operating and the  
26 Board Inspector was told that Respondent Shen was out of the country.

27 ///

28 ///

### DR. H.C.W.'S PRESCRIPTION PADS AT CT PHARMACY

70. The Board Inspector found several "pads" of blank prescription documents with Dr. W.'s information preprinted inside Respondent Pharmacy. There were 10 pads of prescription documents in various locations in the pharmacy, including next to the computer used for processing prescriptions. Five of the pads contained California security prescription documents. These prescription documents met the requirements of Health and Safety Code Section 11162.1 which specifies the requirements for forms used to prescribe controlled substances in California. The pads had various numbers of prescription documents remaining. For example, one of the pads had 21 prescription forms remaining; one pad had 75 prescription documents remaining, etc. This suggested the pads were in various stages of use.

71. During the investigation, Respondent PIC made inconsistent statements regarding the prescription pads.

- During the inspection, Respondent PIC stated the prescription forms were purchased by CT Pharmacy from Hildebrand Printing and provided to Respondent PIC, free of charge, as a professional courtesy. However, subsequently, he provided a statement from Dr. H.C.W. indicating Dr. H.C.W. paid Respondent Pharmacy in full for the prescription forms. Dr. H.C.W.'s statement did confirm Respondent Pharmacy purchased prescription documents from Hildebrand Printing on his behalf.

- Respondent PIC also initially stated the blank prescription forms were retained in the pharmacy as samples to show Dr. H.C.W. in the event he wished to ask CT Pharmacy to purchase more pads. However, subsequently, he stated sometimes pharmacy staff wrote prescriptions on the blank documents and gave them to Dr. H.C.W. to sign. Later on, in the supplemental questionnaire, Respondent PIC stated Respondent Pharmacy staff would write prescriptions on these prescription forms, dispense the prescriptions to patients, and later have Dr. H.C.W. sign the prescription documents.

72. It is not typical for a pharmacy to have a prescriber's prescription pads in the pharmacy. When a prescriber provides a prescription directly to a pharmacy, the prescriber typically provides the prescription electronically, via fax, or over the phone to the pharmacist.

1 When the pharmacist transcribes a verbal prescription, the pharmacist writes the prescription on a  
2 form used by the pharmacy, not a form provided by the prescriber. Additionally, the Code of  
3 Federal Regulations Section 1306.03 regarding controlled substances allows only a prescriber or  
4 his or her agent to issue a prescription. There is no provision to allow pharmacists to fill out  
5 prescription documents on behalf of prescribers. There is no reason consistent with typical  
6 pharmacy practice for Dr. H.C.W.'s blank prescription documents to be inside the Respondent  
7 Pharmacy. Further, this situation presented a serious risk for drug diversion. A person in  
8 possession of blank California security prescription documents could use those documents to  
9 attempt to obtain any controlled substance from any pharmacy. Because of this risk of diversion,  
10 California Security Printers are required to develop procedures to ensure California security  
11 prescription documents are only delivered to the prescriber for whom they are issued. Health and  
12 Safety Code Section 11161.5 states in part (h) Controlled substance prescription forms shall be  
13 provided directly to the prescriber either in person, by certified mail, or by a means that requires a  
14 signature signifying receipt of the package and provision of that signature to the security printer.  
15 Controlled substance prescription forms provided in person shall be restricted to established  
16 customers. Security printers shall obtain a photo identification from the customer and maintain a  
17 log of this information. Controlled substance prescription forms shall be shipped only to the  
18 prescriber's address on file and verified with the federal Drug Enforcement Administration or the  
19 Medical Board of California. Dr. H.C.W.'s statements and Respondent PIC's statements  
20 indicated Hildebrand printing failed to comply with this regulation when it sold prescription  
21 documents to CT Pharmacy.

## **FIRST CAUSE FOR DISCIPLINE**

### **(Self Assessment)**

24 73. Respondent Pharmacy and Respondent PIC (collectively as Respondents) are subject  
25 to disciplinary action under California Code of Regulation, Title 16, section 1715, subdivisions  
26 (a) and (d) in that on or about September 25, 2015, during an inspection at the Respondent  
27 Pharmacy, Respondents were unable to locate a self-assessment completed prior to July 1, 2015  
28 or July 1, 2013.

1 **SECOND CAUSE FOR DISCIPLINE**

2 **(Inventory Requirements for Controlled Substances)**

3 74. Respondents are subject to disciplinary action under Title 21 Code of Federal  
4 Regulations Section 1304.11, subdivision (b) and (c) as related to California Code of Regulations  
5 Section 1718, in that on or about September 25, 2015, during an inspection at the Respondent  
6 Pharmacy, Respondents were unable to locate any inventories of controlled substances.

7 **THIRD CAUSE FOR DISCIPLINE**

8 **(Prohibited Acts- Purchasing Dangerous Drug at Wholesale from and Unlicensed Entity)**

9 75. Respondents are subject to disciplinary action under Business and Professions Code  
10 Section 4169, subdivision (a), in that between September 21, 2012 and April 7, 2014, Respondent  
11 Pharmacy purchased 2,752 units (meaning bottles, tubes, inhalers etc.), on 71 invoices for a total  
12 purchase price of \$711,402.68 from ESP Medical Inc., located at 8513 W. Washington Blvd.,  
13 Culver City, CA 90232, when ESP Medical Inc. was not licensed as a wholesaler with the Board.

14 **FOURTH CAUSE FOR DISCIPLINE**

15 **(Prescription Drugs Not Bearing a Manufacturer's Expiration Date)**

16 76. Respondents are subject to disciplinary action under California Code of Regulations  
17 Section 1718.1, in that on or about September 25, 2015, during an inspection at the Respondent  
18 Pharmacy, Respondent Pharmacy had medications in inventory stored in unlabeled bottles. As  
19 these bottles did not bear a manufacturer's expiration date, they were deemed to have expired and  
20 should not have been held for sale.

21 **FIFTH CAUSE FOR DISCIPLINE**

22 **(Unprofessional Conduct: Assisting in or Abetting the Violation of Pharmacy Regulations)**

23 77. Respondents are subject to disciplinary action under Business and Professions Code  
24 Section 4301, subdivision (o), in that Respondent Pharmacy purchased and received California  
25 security prescription forms for Dr. H.C.W., MD from Hildebrand Printing (SP 176) and stored the  
26 blank forms inside Respondent Pharmacy. Hildebrand Printing made these sales in violation of  
27 California Health and Safety Code Section 11161.5, subdivision (h) and Respondent Pharmacy  
28 assisted in or abetted this violation by making the purchases.

1 **SIXTH CAUSE FOR DISCIPLINE**

2 **(Acting as a Reverse Distributor Without Obtaining a License From the Board)**

3 78. Respondents are subject to disciplinary action under Business and Professions Code  
4 Section 4160 subdivision (a) as related to Business and Professions Code Section 4040.5 and  
5 Business and Professions Code Section 4043, in that Respondent Pharmacy received and stored  
6 drug samples from physicians for the purpose of disposal of the samples. In managing the  
7 disposal of these samples, Respondent Pharmacy acted as a reverse distributor and therefore as a  
8 wholesaler without being licensed to do so.

9 **SEVENTH CAUSE FOR DISCIPLINE**

10 **(Failure to Maintain Current Inventory)**

11 79. Respondents are subject to disciplinary action under Business and Professions Code  
12 Section 4081, subdivision (a) as related to California Code of Regulations Section 1718, in that  
13 Respondent Pharmacy received drug samples from physicians without receiving and retaining  
14 acquisition records. As such, Respondent Pharmacy did not maintain a current inventory of the  
15 dangerous drugs acquired as samples.

16  
17 **EIGHTH CAUSE FOR DISCIPLINE**

18 **(Operational Standards and Security)**

19 80. Respondents are subject to disciplinary action under California Code of Regulations  
20 Section 1714, subdivision (b), in that an audit of promethazine/codeine syrup at Respondent  
21 Pharmacy determined that Respondent Pharmacy could not account for inventory shortages of  
22 155,706 mL of promethazine/codeine syrup from January 2, 2014 to September 25, 2015.

23 **NINTH CAUSE FOR DISCIPLINE**

24 **(Failure to Maintain a Current Inventory)**

25 81. Respondents are subject to disciplinary action under Business and Professions Code  
26 Section 4081, subdivision (a) as related to California Code of Regulations Section 1718, in that an  
27 audit of promethazine/codeine syrup at the Respondent Pharmacy determined that Respondent  
28

1 Pharmacy could not account for inventory shortages of 155,706 mL of promethazine/codeine  
2 syrup from January 2, 2014 to September 25, 2015.

3 **OWNERSHIP PROHIBITION**

4 82. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number  
5 PHY 46522 to Grabo United Inc. dba CT Pharmacy (Respondent Pharmacy) and Pharmacist  
6 License Number RPH 46920 to Yung Po Wong (Respondent PIC) while acting as the manager,  
7 administrator, owner, member, officer, director, associate, or partner of Respondent Pharmacy,  
8 had knowledge of or knowingly participated in any conduct for which Pharmacy Permit Number  
9 PHY 46522 to Grabo United Inc. dba CT Pharmacy was revoked, suspended or placed on  
10 probation, Respondent PIC (Yung Po Wong) and Respondent Robert Shen (Respondent Shen)  
11 shall be prohibited from serving as a manager, administrator, owner, member, officer, director,  
12 associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 46522 issued  
13 to Respondent Pharmacy is placed on probation or until Pharmacy Permit Number PHY 46522,  
14 issued to Respondent Pharmacy is reinstated if it is revoked.

15 **PRAYER**

16 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,  
17 and that following the hearing, the Board of Pharmacy issue a decision:

18 1. Revoking or suspending Pharmacy Permit Number PHY 46522, issued to Grabo  
19 United Inc. dba CT Pharmacy, Yung Po Wong, Robert Yu-Ming Shen

20 2. Ordering Yung Po Wong, Robert Shen and Grabo United Inc. dba CT Pharmacy,  
21 jointly and severally, to pay the Board of Pharmacy the reasonable costs of the investigation and  
22 enforcement of this case, pursuant to Business and Professions Code section 125.3;

23 3. Prohibiting Yung Po Wong from serving as a manager, administrator, owner,  
24 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit  
25 Number PHY 46522 issued to Respondent Pharmacy is placed on probation or until Pharmacy  
26 Permit Number PHY 46522, issued to Respondent Pharmacy is reinstated if it is revoked;

27 4. Prohibiting Robert Yu-Ming Shen from serving as a manager, administrator,  
28 owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy

1 Permit Number PHY 46522 issued to Respondent Pharmacy is placed on probation or until  
2 Pharmacy Permit Number PHY 46522, issued to Respondent Pharmacy is reinstated if it is  
3 revoked; and

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

5  
6 DATED:

7/10/18



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

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