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

12 In the Matter of the Accusation Against:

Case No. 5300

13 **TOWER PHARMACY, INC.,**  
14 **dba QUESENBERRY'S WATERFORD PHARMACY**

15 **DARIN L. NELLE,**  
16 **PRESIDENT/PHARMACIST-IN-CHARGE**  
17 **12641 Bentley Street**  
18 **Waterford, California 95386**

19 **Pharmacy Permit No. PHY 50624**

20 **and**

21 **DARIN L. NELLE**  
22 **1801 Colorado Avenue 100**  
23 **Turlock, California 95382**

24 **Pharmacist License No. RPH 44309**

25 Respondents.

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

26 Complainant alleges:

27 **PARTIES**

- 28
1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs.
  2. On or about October 28, 2011, the Board issued Pharmacy Permit Number PHY 50624 to Tower Pharmacy, Inc. ("Respondent Tower Pharmacy, Inc."), doing business as

1 Quesenberry's Waterford Pharmacy, with Darin L. Nelle ("Respondent Nelle") as president and  
2 pharmacist-in-charge. The pharmacy permit was in full force and effect at all times relevant to  
3 the charges brought herein and will expire on October 1, 2015, unless renewed.

4 3. On or about August 2, 1991, the Board issued Pharmacist License Number RPH  
5 44309 to Respondent Nelle. The pharmacist license was in full force and effect at all times  
6 relevant to the charges brought herein and will expire on December 31, 2016, unless renewed.

### 7 JURISDICTION

8 4. This Accusation is brought before the Board under the authority of the following  
9 laws. All section references are to the Business and Professions Code unless otherwise indicated.

### 10 STATUTORY AND REGULATORY PROVISIONS

11 5. Code section 4300 states, in pertinent part:

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

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

15 (1) Suspending judgment.

16 (2) Placing him or her upon probation.

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

19 (4) Revoking his or her license.

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

21 6. Code section 4300.1 states:

22 The expiration, cancellation, forfeiture, or suspension of a board-issued  
23 license by operation of law or by order or decision of the board or a court of law, the  
24 placement of a license on a retired status, or the voluntary surrender of a license by a  
25 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.

26 7. Code section 4301 states, in pertinent part:

27 The board shall take action against any holder of a license who is guilty  
28 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:

....

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

....

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or non-existence of a state of facts.

....

(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 . . . .

8. Code section 4307 (a) of the Code provides in pertinent part:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

....

9. Code section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

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

(d) 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

1 Regulations, the dispensing pharmacy, clinic, or other dispensers, shall report the following

2 information to the Department of Justice as soon as reasonably possible but not more  
3 than seven days after the date a controlled substance is dispensed, in a format  
4 specified by the Department of Justice:

4 (1) Full name, address, and, if available, telephone number of the ultimate user or  
5 research

5 subject, or contact information as determined by the Secretary of the United States  
6 Department of Health and Human Services, and the gender, and date of birth of the  
7 ultimate user.

8 (2) The prescribers category of licensure, license number, national provider identifier  
9 (NPI)

9 Number, if applicable, the federal controlled substance registration number, and the  
10 state medical

10 license number of any prescriber using the federal controlled substance registration  
11 number of a government-exempt facility.

12 (3) Pharmacy prescription number, license number,

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

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

16 (5) Quantity of the controlled substance dispensed.

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

18 (7) Number of refills ordered.

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

21 (9) Date of origin of the prescription.

22 (10) Date of dispensing of the prescription.

23 11. Code of Federal Regulations, title 21, section 1305.05 provides in pertinent part:

24 (a) A registrant may authorize one or more individuals, whether or not located at his  
25 or her registered location, to issue orders for Schedule I and II controlled substances  
26 on the registrant's behalf by executing a power of attorney for each such individual, if  
27 the power of attorney is retained in the files, with executed Forms 222 where  
28 applicable, for the same period as any order bearing the signature of the attorney. The  
power of attorney must be available for inspection together with other order records.

27 //

28 //

1 12. California Code of Regulations, title 16, section 1707.2 states, in pertinent part:

2 (a) A pharmacist shall provide oral consultation to his or her patient or the  
3 patient's agent in all care settings:

4 (1) upon request; or

5 (2) whenever the pharmacist deems it warranted in the exercise of his or  
her professional judgment.

6 (b)(1) In addition to the obligation to consult set forth in subsection (a), a  
7 pharmacist shall provide oral consultation to his or her patient or the patient's agent in  
any care setting in which the patient or agent is present:

8 (A) whenever the prescription drug has not previously been dispensed to  
9 a patient; or

10 (B) whenever a prescription drug not previously dispensed to a patient in  
the same dosage form, strength or with the same written directions, is dispensed by  
11 the pharmacy . . .

12 13. California Code of Regulations, title 16, section 1716 states, in pertinent part:

13 Pharmacists shall not deviate from the requirements of a prescription except upon the  
prior consent of the prescriber or to select the drug product in accordance  
14 with Section 4073 of the Business and Professions Code.

15 14. California Code of Regulations, title 16, section 1711 states:

16 (a) Each pharmacy shall establish or participate in an established quality assurance  
17 program which documents and assesses medication errors to determine cause and an  
appropriate response as part of a mission to improve the quality of pharmacy service  
and prevent errors.

18 (b) For purposes of this section, "medication error" means any variation from a  
19 prescription or drug order not authorized by the prescriber, as described in Section  
20 1716. Medication error, as defined in the section, does not include any variation that  
is corrected prior to furnishing the drug to the patient or patient's agent or any  
variation allowed by law.

21 (c)(1) Each quality assurance program shall be managed in accordance with written  
22 policies and procedures maintained in the pharmacy in an immediately retrievable  
form.

23 (2) When a pharmacist determines that a medication error has occurred, a pharmacist  
shall as soon as possible:

24 (A) Communicate to the patient or the patient's agent the fact that a medication error  
25 has occurred and the steps required to avoid injury or mitigate the error.

26 (B) Communicate to the prescriber the fact that a medication error has occurred.

27 (3) The communication requirement in paragraph (2) of this subdivision shall only  
28 apply to medication errors if the drug was administered to or by the patient, or if the  
medication error resulted in a clinically significant delay in therapy.

1 (4) If a pharmacist is notified of a prescription error by the patient, the patient's agent,  
2 or a prescriber, the pharmacist is not required to communicate with that individual as  
3 required in paragraph (2) of this subdivision.

4 (d) Each pharmacy shall use the findings of its quality assurance program to develop  
5 pharmacy systems and workflow processes designed to prevent medication errors. An  
6 investigation of each medication error shall commence as soon as is reasonably  
7 possible, but no later than 2 business days from the date the medication error is  
8 discovered. All medication errors discovered shall be subject to a quality assurance  
9 review.

10 (e) The primary purpose of the quality assurance review shall be to advance error  
11 prevention by analyzing, individually and collectively, investigative and other  
12 pertinent data collected in response to a medication error to assess the cause and any  
13 contributing factors such as system or process failures. A record of the quality  
14 assurance review shall be immediately retrievable in the pharmacy. The record shall  
15 contain at least the following:

- 16 1. the date, location, and participants in the quality assurance review;
- 17 2. the pertinent data and other information relating to the medication error(s)  
18 reviewed and documentation of any patient contact required by subdivision (c);
- 19 3. the findings and determinations generated by the quality assurance review; and,
- 20 4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

21 The pharmacy shall inform pharmacy personnel of changes to pharmacy policy,  
22 procedure, systems, or processes made as a result of recommendations generated in  
23 the quality assurance program.

24 (f) The record of the quality assurance review, as provided in subdivision (e) shall be  
25 immediately retrievable in the pharmacy for at least one year from the date the record  
26 was created.

#### 27 COST RECOVERY

28 15. Code section 125.3 provides, in pertinent part, that a 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.

#### CONTROLLED SUBSTANCE

16. "Marinol", a brand of dronabinol, is a Schedule III controlled substance as designated  
by Health and Safety Code section 11056, subdivision (h). Marinol is used as an appetite  
stimulant and to treat nausea.

1 17. "Lexapro", a brand of Escitalopram, is a dangerous drug as defined in Business and  
2 Professions Code section 4022. Lexapro is used as an anti-depressant.

3 18. "Vasotec", a brand of Enalapril, is a dangerous drug as defined in Business and  
4 Professions Code section 4022. Vasotec is used as a Blood Pressure medication.

5 **BOARD INSPECTION OF SEPTEMBER 25, 2013**

6 19. On or about July 22, 2013, the Board received a complaint from a former employee  
7 of Quesenberry's Waterford Pharmacy ("Quesenberry's), alleging, among other things, that the  
8 pharmacy was engaging in fraudulent billing practices.

9 20. On or about September 25, 2013, an inspector of the Board went to Quesenberry's to  
10 conduct an inspection and was assisted by pharmacist R. J. and pharmacy technician J. S. The  
11 inspector began reviewing the pharmacy's drug inventory, and noticed numerous prescription  
12 vials marked "RTS" (return to stock) on the drug shelves. The inspector selected two bottles with  
13 the same prescription number from the shelf marked "RTS; one bottle had a fill date of July 27,  
14 2013, and the other had a fill date of September 3, 2013. The inspector asked J. S. to retrieve the  
15 prescription information in the computer for the two bottles. When J. S. pulled up the transaction  
16 information, the record for the July 27, 2013 fill date showed that it was processed, but not  
17 reversed.

18 21. The inspector continued looking through the drug inventory and found additional  
19 prescription vials with "RTS" written on the labels. The inspector asked J. S. to retrieve screen  
20 prints for each vial pulled by the inspector. While J. S. was printing the transaction information,  
21 the inspector observed pharmacy clerk B. A. selling prescriptions to several patients without  
22 offering consultation by a pharmacist (the inspector did not hear the clerk call the pharmacist for  
23 consultation). The inspector asked B. A. for the prescription information for one of the customers  
24 she had sold a prescription to as observed by the inspector. B. A. gave the inspector the  
25 prescription record, patient profile, and pick-up record for patient S. J. The records showed that  
26 the prescription was for a new strength of Marinol and that there was a change in the directions  
27 from the original prescription dispensed to the patient on October 10, 2012.

28







1221400	07/02/2013	Oxybutynin 5 mg
1189908	07/17/2012	Tribenzor 40-10-25 mg
1222059	07/08/2013	Trazodone 50 mg
1215049	06/03/2013	Montelukast 4 mg chewable tablets
1205960	01/18/2013	Cyclobenzaprine 10 mg

**SECOND CAUSE FOR DISCIPLINE**

**(knowingly making or signing a certificate or document with false information)**

32. Respondent Quesenberry Waterford Pharmacy's pharmacy permit and Respondent Nelle's pharmacist license are subject to disciplinary action pursuant to Code section 4301, subdivision (g), for unprofessional conduct, in that Respondents in that they billed insurance companies for prescriptions which were returned to stock as more specifically set forth above in paragraph 30.

**THIRD CAUSE FOR DISCIPLINE**

**(Violations of State Regulations Governing Pharmacy)**

33. Respondent Tower Pharmacy's permit and Respondent Nelle's pharmacist license are subject to disciplinary action pursuant to Code section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate state regulations governing pharmacy, as follows: On or about September 25, 2013, Respondents' pharmacy clerk, B. A., sold a prescription for patient S. J. without offering consultation by a pharmacist even though there had been a change in the dosing and directions of the prescription, in violation of Regulation 1707.2, subdivisions (b)(1)(B). Further, the Board Inspector did not observe or hear the clerk call the pharmacist to request a consultation at any time during the inspection.

**FOURTH CAUSE FOR DISCIPLINE**

**(Failure to Comply with CURES Reporting)**

34. Respondent Tower Pharmacy's permit and Respondent Nelle's pharmacist license are subject to disciplinary action pursuant to Code section 4301, subdivision (o), in conjunction with Health and Safety Code section 11165 subdivision (d) and California Federal Regulations, Title 25 section 1305.05 for unprofessional conduct, in that Respondents violated or attempted to

1 violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate state  
2 regulations governing pharmacy, as follows: For the period from February 15, 2015 to February  
3 20, 2015, respondent's failed to comply with the reporting requirements for CURES.

4 **FIFTH CAUSE FOR DISCIPLINE**

5 **(Failure to Maintain a Power of Attorney)**

6 35. Respondent Tower Pharmacy's permit, and Respondent Nelle's pharmacist license  
7 are subject to disciplinary action pursuant to Code section 4301 (o) in conjunction with Code of  
8 Federal Regulation, Title 21, section 1305.05 in that during the inspection on June 3, 2015, it was  
9 discovered that Respondents did not maintain a power of attorney permitting pharmacists to order  
10 schedule prescriptions.

11 **SIXTH CAUSE FOR DISCIPLINE**

12 **(Deviation from Prescribed Medication)**

13 36. Respondent Tower Pharmacy's permit is subject to disciplinary action pursuant to  
14 Code section 4301 (o) in conjunction with California Code of Regulation, Title 16 , section 1716,  
15 for deviation from a prescription in that a prescription for Lexapro was filled with Vasotec as set  
16 forth above in paragraphs 25 and 26.

17 **SEVENTH CAUSE FOR DISCIPLINE**

18 **(Failed to Investigate Medication Errors)**

19 37. Respondent Tower Pharmacy's permit and Respondent Nelle's pharmacist license are  
20 subject to disciplinary action pursuant to Code section 4301 (o) in conjunction with California  
21 Code of Regulation, Title 16 , section 1711, subdivision (d) (e), in that Respondents did not  
22 investigate medication errors through a pharmacy quality assurance program as set forth above in  
23 paragraphs 25 and 26.

24 **EIGHTH CAUSE FOR DISCIPLINE**

25 **(Failed to Keep Record Quality Assurance Review)**

26 38. Respondent Tower Pharmacy's permit and Respondent Nelle's pharmacist license are  
27 subject to disciplinary action pursuant to Code section 4301 (o) in conjunction with California  
28

1 Code of Regulation, Title 16 , section 1711, subdivision (e), in that Respondents did not keep a  
2 record of the quality assurance review related to the medication errors as described above in  
3 paragraphs 25 and 26.

4 **OTHER MATTERS**

5 39. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number  
6 PHY 50624 issued to Tower Pharmacy, Inc., doing business as Quesenberry's Waterford  
7 Pharmacy, Tower Pharmacy, Inc. shall be prohibited from serving as a manager, administrator,  
8 owner, member, officer, director, associate or partner of a licensee for five years if Pharmacy  
9 Permit Number PHY 50624 is placed on probation, or until Pharmacy Permit Number PHY  
10 50624 is reinstated if it is revoked.

11 40. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number  
12 PHY 50624 issued to Tower Pharmacy, Inc., doing business as Quesenberry's Waterford  
13 Pharmacy, while Darin L. Nelle has been an officer and owner and had knowledge of or  
14 knowingly participated in any conduct for which the licensee was disciplined, Darin L. Nelle  
15 shall be prohibited from serving as a manager, administrator, owner, member, officer, director,  
16 associate or partner of a licensee for five years if Pharmacy Permit Number PHY 50624 is placed  
17 on probation, or until Pharmacy Permit Number PHY 50624 is reinstated if it is revoked.

18 **PRAYER**

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

- 21 1. Revoking or suspending Pharmacy Permit Number PHY 50624, issued to Tower  
22 Pharmacy, Inc., doing business as Quesenberry's Waterford Pharmacy;
- 23 2. Revoking or suspending Pharmacist License Number RPH 44309, issued to Darin L.  
24 Nelle;
- 25 3. Prohibiting Tower Pharmacy, Inc., from serving as a manager, administrator, owner,  
26 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit  
27 Number PHY 50624 is placed on probation or until Pharmacy Permit Number PHY 50624 is  
28

1 reinstated if Pharmacy Permit Number PHY 50624 issued to Quesenberry's Waterford Pharmacy  
2 is revoked.

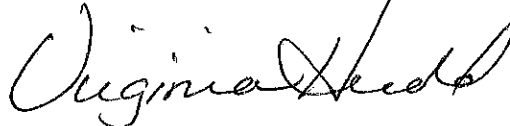
3 4. Prohibiting Darin L. Nelle from serving as a manager, administrator, owner, member,  
4 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number  
5 PHY 50624 is placed on probation or until Pharmacy Permit Number PHY 50624 is reinstated if  
6 Pharmacy Permit Number PHY 50624 issued to Quesenberry's Waterford Pharmacy is revoked.

7 5. Ordering Tower Pharmacy, Inc., doing business as Quesenberry's Waterford  
8 Pharmacy, Darin L. Nelle to pay the Board of Pharmacy the reasonable costs of the investigation  
9 and enforcement of this case, pursuant to Business and Professions Code section 125.3;

10 6. Taking such other and further action as deemed necessary and proper.

11  
12 DATED: \_\_\_\_\_

8/15/16



VIRGINIA HEROLD

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

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