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

In the Matter of the Accusation Against**:** **TOWER PHARMACY** **DARIN NELLE, OWNER AND PHARMACIST-IN-CHARGE** **501 E. Olive Avenue** **Turlock, California 95382** **Pharmacy Permit Nos. PHY 47000 and PHY 54174** **and** **DARIN L. NELLE** **1801 Colorado Avenue 100** **Turlock, California 95382** **Pharmacist License No. RPH 44309** **Respondents**.	Case No. 5301 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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 December 30, 2004, the Board issued Pharmacy Permit Number PHY 47000 to Darin L. Nelle, owner and pharmacist-in-charge of Tower Pharmacy ("Respondent Tower"). On or about February 1, 2016, Pharmacy Permit No. PHY 54174 was issued to

Respondent Nelle as owner and pharmacist-in-charge of Tower Pharmacy due to a change in location. The pharmacy permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2017 unless renewed.

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

JURISDICTION

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

5. Section 4307 states:

> "(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, 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 follow:
>
> (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...."

STATUTORY AND REGULATORY PROVISIONS

(Statutory Provisions)

6. Section 4300 states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.

(2) Placing him or her upon probation.

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

(4) Revoking his or her license.

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

7. Section 4300.1 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.

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8. Section 4301 states, in pertinent part:

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

. . . .

(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 nonexistence 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.

. . . .

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board . . .

9. Section 4040.5 states:

""Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous drugs.

10. Section 4043 states:

"Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

11. Section 4081, subdivision (a), states, in pertinent part:

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

12. 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.

13. Section 4160, subdivision (a), states that "[a] person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board."

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14. Section 4342, subdivision (a), states:

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

15. Health and Safety Code section 110290 states:

In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement,

word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered.

16. Health and Safety Code section 111335 states that "[a]ny drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

17. Health and Safety Code section 111340 states, in pertinent part:

> Any drug or device is misbranded unless it bears a label containing all of the following information:
>
> . . . .
>
> (b) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count . . .

(Regulatory Provisions)

18. California Code of Regulations, title 16, section ("Regulation") 1735.2 states, in pertinent part:

> . . . .
>
> (g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
>
> (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
>
> (i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product . . .

19. Regulation 1735.3 states, in pertinent part:

> (a) For each compounded drug product, the pharmacy records shall include:
>
> (1) The master formula record.

(2) The date the drug product was compounded.

(3) The identity of the pharmacy personnel who compounded the drug product.

(4) The identity of the pharmacist reviewing the final drug product.

(5) The quantity of each component used in compounding the drug product.

(6) The manufacturer, expiration date and lot number of each component . If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted . . .

(7) A pharmacy assigned reference or lot number for the compounded drug product.

(8) The expiration date of the final compounded drug product.

(9) The quantity or amount of drug product compounded.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

20. Regulation 1735.5 states, in pertinent part:

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented . . .

21. Regulation 1735.6 states, in pertinent part:

. . . .

(b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.

(c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

22. Regulation 1735.7 states, in pertinent part:

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

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

23. Regulation 1735.8 states, in pertinent:

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

. . . .

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

COST RECOVERY

24. 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.

BOARD INSPECTIONS OF SEPTEMBER AND OCTOBER 2013

Inspection of September 26, 2013

25. On or about August 9, 2013, the Board received an anonymous complaint from a "concerned consumer", alleging that Tower Pharmacy was engaging in illegal business practices.

26. On or about September 26, 2013, an inspector of the Board went to Tower Pharmacy to conduct an inspection and was assisted by Respondent. Respondent had a separate compounding room and a small room designated for bubble packing in addition to the larger retail pharmacy area and drug inventory.

27. While the inspector was in the bubble packing room, she observed numerous open paper cups with unlabeled prescription drugs in them, some with a stock bottle placed inside the cup. There were also numerous empty bubble pack cards in the trash and unlabeled plastic bags containing drugs sitting on the shelf or rubber-banded to a stock bottle. The inspector opened various stock bottles and found that some were over-filled. The inspector also saw stacks of boxes containing full bubble pack cards that appeared to have been filled several months earlier.

28. The inspector asked pharmacy technician B. M. about the bubble pack cards. B. M. stated that some of the cards were returned for destruction by the assisted living facilities they serviced. The inspector left the area to retrieve her camera. Later, when the inspector returned to the bubble packing room, she noticed that all of the paper cups and drugs in the plastic bags were missing. The inspector looked in the trash cans and boxes under the counter and found empty and discarded bubble park cards with prescription labels still affixed to them. The inspector collected the cards, then continued looking through the trash. The inspector found the paper cups stacked together, with the drugs still inside them, below the layers of papers. The inspector asked B. M. why the paper cups were in the trash. B. M. stated that she "knew it would look bad", so she removed the cups from the drug shelves.

29. The inspector had B. M. and Respondent retrieve the prescription information for one of the empty bubble pack cards she removed from the trash. The computer record showed that the prescription had been filled and the claim had been transmitted to a third party; however, the patient never received the medication as evidenced by the empty bubble pack.

30. The inspector asked one of Respondent's other pharmacy technicians to explain the return to stock process for prescriptions that were not picked up by patients. The technician brought the inspector a binder and showed her a document titled "New Office Policy RTS Prescriptions". The policy stated that when returning prescriptions in the pharmacy system not picked up by customers, staff was not to reverse the claim to the insurance company.

31. The inspector selected random prescription numbers from the binder and asked Respondent to bring up the transaction information related to each in the computer. The transaction records indicated that all of the prescriptions were "RTS'd". Respondent told the

inspector that if a prescription was received by a patient, the Script Pickup Status report would indicate "picked up" along with the date. None of the Script Pickup reports had a pick-up date. The inspector found that none of the prescriptions had been reversed even though Respondent had received payment for the claims from the insurance companies. The inspector told Respondent to copy the entire contents of the binder, review all of the reports, and reverse the insurance billings for all prescriptions that were not received by the patients and were returned to stock.

32. The inspector showed Respondent the bubble pack cards she found in the current inventory. Respondent claimed that the cards were returned to stock because the prescriptions were canceled. The inspector requested and received from Respondent the prescription transaction reports and Script Pickup Status reports for each of the bubble pack cards she removed from the drug shelves. The inspector found that the billings were not reversed to the insurance companies and that the prescriptions had each been delivered or dispensed. The inspector determined based on the presence of the bubble packs in the pharmacy and the computer records that Respondent was reusing medications which had been returned for destruction by the assisted living facilities. The inspector warned Respondent that he was not authorized to accept returned medications from the facilities for destruction.

33. The inspector went to the compounding room with Respondent and observed numerous expired compounding ingredients and syringes filled with compounded products labeled with odd numbers and expiration dates (some syringes had no dates) in the compounding area. Respondent stated that he used the syringes to draw up compounded medications from the containers, reused the syringes after filling an order, and labeled each syringe once and did not update the label. The inspector asked Respondent to show her which patients received the product from a batch he compounded. Respondent claimed that he knew which patients were getting medications compounded, so he would make multiple orders to meet their needs.

34. The inspector asked Respondent for his compounding policies and procedures, training records, and quality assurance monitoring policy and procedures. Respondent was unable to provide the inspector with the documents. The inspector also asked Respondent for his compounding records, and he showed her a log book. The inspector found in reviewing the log

that there were no master formulas for the compounded products in the pharmacy. The inspector instructed Respondent to suspend all compounding activities until he removed all of the outdated products, discarded the used syringes he utilized for drawing up compounded products, removed the batch compounds that were not made pursuant to a patient specific order, and produced all policies and procedures for compounding, quality assurance, and training. The inspector also instructed Respondent to quarantine all expired inventory in his pharmacy, including the returned bubble pack cards and unlabeled cups and plastic bags containing drugs.

Re-inspection of October 4, 2013

35. On or about October 4, 2013, the inspector returned to the pharmacy for a re-inspection and found expired drug products in the current inventory, more loose pills and unlabeled drugs in small plastic bags in the bubble packing area, and large plastic bags (many unlabeled) with compounding bulk ingredients in the cabinets of the compounding area.

36. The inspector requested and obtained Respondent's compounding policies and procedures as well as his pharmacy and compounding self-assessments. The inspector told Respondent that his recordkeeping and compounding policies were not in compliance with the Board's regulations.

37. The inspector asked Respondent if he had reversed the billings for all of the prescriptions that had been returned to stock and had not been reversed as determined during the prior inspection. Respondent provided the inspector with various documents, including a report titled "3rd Party Recon Scripts List", showing all of the reversals Respondent had processed from the RTS binder. The inspector compared the prescription numbers on the Scripts List with the prescription numbers on the will call reports from the RTS binder, and found that Respondent had reversed approximately 146 prescriptions.

FIRST CAUSE FOR DISCIPLINE

(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

38. Respondent's pharmacy permit and pharmacist license are subject to disciplinary action pursuant to section 4301, subdivisions (f) and (g), for unprofessional conduct, in that

Respondent committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption, as follows:

a. Respondent failed to reverse the claims/billings on the prescriptions identified below, as determined during the Board inspection of September 26, 2013, even though Respondent had not dispensed the medications to the patients and had received payment for the drugs from the patients' insurance companies; or had previously dispensed the medications to the patients, had received the drugs back from the patients' assisted living facilities for destruction, and had reused and/or attempted to reuse the drugs. Further, the Board's inspector identified over 140 additional prescriptions requiring reversal as determined during the re-inspection of October 4, 2013.

Rx No.	Rx. Fill Date	Patient Name	Transmission Status & Rx Pick up Status
180940	07/24/2013	Marisa G.	Transmitted "t"; no pick up date
179961	07/10/2013	Carol M.	Transmitted "t"; no pick up date
180406	07/16/2013	Eunice J.	Transmitted "n"; no pick up date
180215	07/13/2013	Francisco S.	Transmitted "n"; no pick up date
183854	08/30/2013	Virginia A.	Transmitted "t"; no pick up date
178062	08/24/2013	Louise H.	Transmitted "t"; no pick up date
175713	08/26/2013	Greg A.	Transmitted "t"; no pick up date
134124	12/19/2011	Chris L.	Transmitted "t"; no pick up date
182662	08/14/2013	Jacqueline M.	Transmitted "n"; no pick up date
177854	06/12/2013	Sophia S.	Transmitted "n"; no pick up date
177339	06/05/2013	Greg P.	Transmitted "t"; no pick up date
177417	06/06/2013	Jerrie T.	Transmitted "t"; no pick up date
181385	07/30/2013	Brandon S.	Transmitted "t"; pick up date 07/30/2013; delivery log confirmed delivery to patient
185660	09/19/2013	Aaron J.	Transmitted "t"; pick up date 09/20/2013; delivery log confirmed delivery to patient on 09/20/2013
C175622	05/21/2013	Joyce W.	Transmitted "t"; pick up date 05/22/2013; delivery log confirmed delivery to patient
178297	07/15/2013	Uriel C.	Transmitted "n"; pick up date 07/16/2013; delivery log confirmed drug delivered on 07/16/2013
180014	07/11/2013	Cornel J.	Transmitted "t"; pick up date 07/11/2013; delivery log was for the wrong date
C178416	06/27/2013	Evelyn V.	Transmitted "n"; pick up date 06/28/2013; signature log showed pick up on 06/28/2013
162349	02/18/2013	Guy P.	Transmitted "t"; pick up date 02/25/2013; delivery log confirmed delivery to patient on 02/22/2013
184370	09/05/2013	Charlie F.	Transmitted "n"; pick up date 09/16/2013; delivery log confirmed delivery to patient on 09/05/2013
168875	07/26/2013	Alexis W.	Transmitted "t"; pick up date 07/31/2013; delivery log confirmed delivery to patient on 07/26/2013
178049	06/14/2013	Joseph S.	Transmitted "n"; pick up date 06/14/2013
169353	07/31/2013	Trung L.	Transmitted "t"; pick up shows no date
169353	04/22/2013	Trung L.	Transmitted "t"; pick up date 04/24/2013

179926	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
179927	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
179928	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
179930	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
179931	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
179932	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
175725	05/13/2013	Robert C.	Transmitted "t"; pick up date 05/15/2013
179429	07/03/2013	Robert C.	Transmitted "t"; no pick up date

b. On or before September 26, 2013, Respondent reused and/or attempted to reuse bubble pack cards containing prescription medications that had previously been dispensed to patients and had been returned to Tower Pharmacy by the patients' assisted living facilities for destruction, in order to re-dispense the drugs to different patients.

SECOND CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and State Laws and Regulations Governing Pharmacy)

39. Respondent's pharmacy permit and pharmacist license are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondent violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.) and state laws and regulations governing pharmacy, as follows:

a. On or about September 26, 2013, Respondent had in his current inventory numerous expired compounding ingredients, numerous containers (paper cups and plastic bags) filled with medications without a label affixed to the container or any drug information, including lot number and/or expiration date, and overfilled stock bottles of drugs, in violation of section 4342. Consequently, the drugs were misbranded.

b. On or about September 26, 2013, Respondent failed to maintain or have available for inspection records of acquisition or disposition for the bubble pack cards he acquired from various assisted living facilities for destruction, in violation of section 4081, subdivision (a).

c. On or about September 26, 2013, Respondent acted as a reverse distributor by accepting or acquiring numerous bubble pack cards containing prescription medications from

various assisted living facilities for destruction when, in fact, he did not have a wholesaler's license issued by the Board, in violation of section 4160, subdivision (a).

d. On or about September 26, 2013, Respondent failed to prepare and/or maintain written policies and procedures reflecting the compounding activities of the pharmacy, including procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and/or other standard operating procedures related to compounding, in violation of Regulation 1735.5, subdivision (a).

e. On or about September 26, 2013, Respondent failed to prepare and/or maintain training records, written policies and procedures, or competency evaluations for pharmacy personnel involved in compounding, in violation of Regulation 1735.7, subdivisions (a) and (b).

f. On or about September 26, 2013, Respondent failed to maintain the master formula records for each compounded drug product in the pharmacy, certificates of analysis for bulk ingredients used in compounding, and records pertaining to the acquisition and disposition of chemicals, bulk drug substances, drug products, and/or components used in compounding, in violation of Regulation 1735.3.

g. On or about September 26, 2013, Respondent failed to prepare and/or maintain any written quality assurance plans for compounded prescriptions, in violation of Regulation 1735.8, subdivision (a).

FOLLOW-UP INSPECTIONS OF JULY AND AUGUST 2014

Inspection of July 31, 2014

40. On or about July 31, 2014, Board Inspector S. conducted a follow-up inspection at the pharmacy and was assisted by Respondent. The inspector checked the pharmacy bathroom and located seven boxes containing various expired drugs and bubble pack cards.

41. The inspector asked Respondent if the pharmacy was still taking back drugs and bubble packs from assisted living facilities. Respondent claimed they informed the facilities that they were no longer taking back medications, but then admitted that they had recently started

taking back drugs from one facility, Excell Center, for destruction. Respondent also claimed that they were storing the drugs in the bathroom quarantined for destruction. The inspector asked Respondent if he had obtained records of acquisition or disposition for the returned drugs. Respondent stated that he did not have the records, but could get them later (Respondent obtained the disposition records from Excell Center and produced them at the end of the inspection). The inspector asked Respondent when he started taking back drugs. Respondent called pharmacy clerk K. F. over to the inspector. K. F. told the inspector that she received five sealed boxes from Excell Center about one week ago and that each of the boxes was labeled with the facility's name. The inspector noticed that only one of the boxes was labeled Excell Center.

42. Later, the inspector looked through the compounding area of the pharmacy and found several expired compounds along with compounded drugs with beyond use dates in excess of 180 days. The inspector saw a master formula compounding record with a lot number of 0415201403. The record indicated that the final compounded drug had been sent for end-product testing on July 10, 2014. The inspector asked Respondent to show her the test results. While looking the information up on the Dynalab website, the inspector saw several test results for the pharmacy that were outside of the acceptable range. The inspector asked Respondent if he executed his recall procedure for the compounded drugs. Respondent told the inspector that K. C., the pharmacy technician for the compounding area, had reviewed the results. The inspector asked K. C. if they had taken any recall steps or any action to determine the cause of the out-of-range results. K .C. indicated that she had not executed a recall for the drugs or made any specific changes to the pharmacy's compounding process to improve the results. The inspector showed Respondent and K. C. the pharmacy's policy for recalls[1], and neither of them could

[1] Respondent's recall policy, "Plan for Recalled Products and Chemicals Used in Lab", dated October 2, 2013, states that "[w]hen any chemical or product used in dispensed prescriptions is recalled the pharmacist-in-charge shall remove the recalled item(s) from the lab and place in bathroom storage area,, box and dispose or return as required. The customer shall be contacted and informed of the recall after the pharmacist-in-charge consults with the customer's physician or prescriber and determines the course of action dictated by the customer's physician. In all cases the customer will be informed within the same business day of recalled products."

explain why they failed to follow their own procedures. The inspector told Respondent she would be returning the following day to complete the inspection since the pharmacy was closing.

Inspection of August 1, 2014

43. On or about August 1, 2014, Inspector S. returned to the pharmacy accompanied by Board Inspector I. Respondent assisted them with the inspection. Inspector S. began checking the boxes of returned drugs that were allegedly awaiting destruction. Inspector S. noticed that there were four more boxes labeled "Excell Center" and asked Respondent about the additional boxes. Respondent claimed that they found the boxes in the trunk of their delivery driver's car. Inspector S. noticed that only one of the four boxes was sealed. Inspector S. inventoried the contents of the five boxes labeled Excell Center as well as the other six boxes of returned drugs, and found numerous bubble pack cards for various patients from several different assisted living facilities, including Excell Center. Inspector S. also found numerous prescription vials from other pharmacies.

44. The inspectors went to the compounding area. Inspector I. found that Respondent's calibration records for the weight scale were not in compliance with state regulations, that there were numerous wetting agents and ingredients stored in unlabeled containers covered with cardboard around and inside the powder safe hood, and that the TopiClick delivery system was being used improperly. The inspectors reviewed some of Respondent's master formula records and noticed that PCCA was the source of his formulas. Some of the formulas lacked information regarding the storage requirements of the compounded drugs, the capsule size of the drug, lot number, expiration date, etc. The inspectors asked Respondent for the source data or original master formulas from PCCA. Respondent admitted that he did not have the records available.

45. K. C. showed Inspector S. the Dynalab result for the compounded drug sample identified during the inspection of July 31, 2014. When reviewing the records with K. C., Inspector S. noticed that some of the Dynalab results were outside of the acceptable range. Inspector I. reviewed the results for potency testing for the compounded drugs indicated. Four of the 18 samples provided by the pharmacy in 2013 and 2014 had results outside of the acceptable potency range. The inspectors asked Respondent for the compounding master formula records

pertaining to the four failed results. Respondent was able to locate only two of the records and provided them to the inspectors.

46. The inspectors reviewed the records and identified several prescriptions that had been dispensed using the two compounded drugs. Inspector I. asked Respondent whether he took any action regarding the out-of-range results for the drugs that had been dispensed to the patients. Respondent admitted that he took no action and had failed to execute his policies and procedures for compounding recalls. At the conclusion of the inspection, Inspector S. asked Respondent to provide her with various documents within 14 days, including the compounding records and dispensed prescriptions relating to the two failed results he was unable to provide. About two weeks later, Inspector S. received the compounding records for the two failed results from Respondent's legal representative; however, the dispensing records were provided for only one of them.

THIRD CAUSE FOR DISCIPLINE

(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

47. Respondent's pharmacy permit and pharmacist license are subject to disciplinary action pursuant to section 4301, subdivision (f), for unprofessional conduct, in that Respondent committed an act involving moral turpitude, dishonesty, fraud, deceit, or corruption, as follows: On or about July 31, 2014, Respondent falsely represented to Board Inspector S. that the pharmacy was taking back drugs for destruction from only one assisted living facility (Excell Center). In fact, Respondent had accepted or acquired numerous prescription medications from several different facilities, including Excell Center.

FOURTH CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and State Laws and Regulations Governing Pharmacy)

48. Respondent's pharmacy permit and pharmacist license are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondent violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or

conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.) and state laws and regulations governing pharmacy, as follows:

a. On or about July 31, 2014 and August 1, 2014, Respondent acted as a reverse distributor by accepting or acquiring bubble pack cards containing prescription medications from various assisted living facilities for destruction and prescription drugs from other pharmacies when, in fact, he did not have a wholesaler's license issued by the Board, in violation of section 4160, subdivision (a). Further, Respondent continued taking back drugs for destruction even though he had been warned during the inspection of September 26, 2013, that he was not authorized to accept returned medications from the facilities for destruction.

b. On or about July 31, 2014 and August 1, 2014, Respondent failed to maintain or have available for inspection records of acquisition or disposition for the bubble pack cards he acquired from the assisted living facilities for destruction and the prescription drugs he received from other pharmacies, in violation of section 4081, subdivision (a).

c. On or about July 31, 2014 and August 1, 2014, Respondent had in his current inventory numerous batch compounded drug products that were expired, in violation of section 4342.

d. In and between October 2013 and June 2014, Respondent failed to follow the pharmacy's written policies and procedures for recalling compounded drugs which were below the minimum standards for integrity, potency, quality or labeled strength, in violation of Regulation 1735.8, as follows: Respondent failed to recall 4 compounded drugs which were below the minimum standards for potency, including the 3 drugs identified below, even though he knew, or should have known, that the drugs were dispensed to at least 16 patients.

Compounded Drug/Lot No.	**Dynalabs Results**	**Rx Number**	**Date Dispensed**
Testosterone 50 mg/gm gel; Lot #10172013-8	124.43% (acceptable range: 90-110%); results signed by Dynalabs on 11/08/2013	188008	10/17/2013
		187881	10/16/2013
		181294	10/16/2013
		162826	10/16/2013

		183232	10/18/2013
		181576	10/18/2013
		189070	10/31/2013
Naltrexone 4.5 mg capsules Lot #01272014-02	69.3% (acceptable range: 90-110%); results signed by Dynalabs on 03/02/2014	196459	01/23/2014
		190874	02/10/2014
Naltrexone 4.5 mg capsules Lot #01272014-02	69.3% (acceptable range: 90-110%); results signed by Dynalabs on 03/02/2014	195722	02/14/2014
		198850	02/20/2014
Naltrexone 4.5 mg capsules Lot #02282014-04	67.96% (acceptable range: 90-110%); results signed by Dynalabs on 05/01/2014	199356	02/26/2014
		202032	03/28/2014
		199356	04/23/2014
		205015	04/30/2014
		207927	06/03/2014

e. On or about July 31, 2014 and August 1, 2014, Respondent failed to document in the calibration records for the compounding (weight) scale the calibration readings of the scale or the method used to calibrate the equipment, in violation of Regulation 1735.6, subdivisions (b) and (c).

f. On or about July 31, 2014 and August 1, 2014, Respondent stored the bulk compounding ingredients around and inside the powder safe hood in glass containers without lot numbers or expiration dates, and failed to store the ingredients in the manufacturers' original containers, in violation of Regulation 1735.2, subdivision (g). Further, Respondent covered the glass containers with cardboard, increasing the risk of contamination of the ingredients.

g. On or about July 31, 2014 and August 1, 2014, Respondent failed to use the Topi-Click delivery system properly in preparing compounded drugs, in violation of Regulation 1735.2, subdivision (i), in that Respondent measured the compound ingredients using weight measurement when, in fact, the device is only approved for volume measurement.

h. On or about July 31, 2014 and August 1, 2014, Respondent failed to maintain and/or have available for inspection the source data for the master formulas from PCCA, and failed to ensure that the master formulas had all of the required information, including the storage requirements of the compounded drugs, the capsule size, lot number, and expiration date, in violation of Regulation 1735.3, subdivisions (a)(1), (b), and (c).

i. On or about July 31, 2014 and August 1, 2014, Respondent had in his current inventory compounded drugs with beyond use dates exceeding 180 days, in violation of Regulation 1735.2, subdivision (h).

FIFTH CAUSE FOR DISCIPLINE

(Subverting or Attempting to Subvert an Investigation of the Board)

49. Respondent's pharmacy permit and pharmacist license are subject to disciplinary action pursuant to section 4301, subdivision (q), for unprofessional conduct, in that on or about September 26, 2013 and July 31, 2014, Respondent subverted or attempted to subvert an investigation of the Board, as set forth respectively in paragraphs 28 and 46 above.

OTHER MATTERS

50. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 54174, issued to Tower Pharmacy, Tower Pharmacy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 54174 is placed on probation or until Pharmacy Permit Number PHY 54174 is reinstated if it is revoked.

51. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 54174, issued to Tower Pharmacy while Darin L. Nelle has been an officer and owner and had knowledge of or knowingly participated, in any conduct for which the licensee was disciplined, Darin L. Nelle shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 54174 is placed on probation or until Pharmacy Permit Number PHY 54174 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Pharmacy Permit Number PHY 54174, issued to Darin Nelle, owner of Tower Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 44309, issued to Darin L. Nelle;

3. Prohibiting Tower Pharmacy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 54174 is placed on probation or until Pharmacy Permit Number PHY 54174 is reinstated if it is revoked;

4. Prohibiting Darin L. Nelle, Pharmacist License Number RPH 44309, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of or partner of a licensee for five years if Pharmacy Permit Number PHY 54174 is placed on probation or until Pharmacy Permit Number PHY 54174 is reinstated if it is revoked;

5. Ordering Darin L. Nelle, individually, and as owner of Tower Pharmacy, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: 11/3/16

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

SA2014117777