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

In the Matter of the Accusation Against: **HOAN T.L. NGUYEN dba** **ABORN PHARMACY** **2060 Aborn Road, Suite 150B** **San Jose, CA 95121** **Original Permit No. PHY 43166** **and** **HOAN T.L. NGUYEN** **2060 Aborn Road, Suite 150B** **San Jose, CA 95121** **Pharmacist License No. RPH 44283** Respondents.	Case No. 6300 **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 August 13, 1997, the Board issued Original Permit Number PHY 43166 to Hoan T.L. Nguyen dba Aborn Pharmacy, Hoan T.L. Nguyen, Owner (Respondent Pharmacy). The Original Permit was in full force and effect at all times relevant to the charges brought in this

Accusation and will expire on August 1, 2018, unless renewed.

3. On or about June 17, 1991, the Board issued Original Pharmacist License Number RPH 44283 to Hoan T.L. Nguyen (Respondent Nguyen). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on August 31, 2018, 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 (Code) unless otherwise indicated.

5. Section 4011 of the Code provides that the Board shall administer and enforce both the Pharmacy Law (Bus. & Prof. Code, § 4000 et seq.) and the Uniform Controlled Substances Act (Health & Safety Code, § 11000 et seq.).

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

7. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or suspension of a Board-issued license, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

STATUTORY PROVISIONS

8. Section 4301 of the Code provides, 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 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . .

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

. . .

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

9. Section 4058 of the Code states: "Every person holding a license issued under this chapter to operate a premises shall display the original license and current renewal license upon the licensed premises in a place where it may be clearly read by the public."

10. Section 4076 of the Code provides, in pertinent part:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

. . .

"(7) The strength of the drug or drugs dispensed."

11. Section 4104, subdivision (b) of the Code states: "Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy."

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

13. Section 4307 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, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied,

revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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

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

. . ."

14. Health and Safety Code section 11165, subdivision (d) provides, in pertinent part:

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

. . ."

15. Health and Safety Code section 111260 states: "Any drug or device is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess."

16. Health and Safety Code section 111295 states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated."

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REGULATORY PROVISIONS

17. California Code of Regulations, title 16, section 1707.5, subdivision (d) states:

"The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter."

18. California Code of Regulations, title 16, section 1707.6 provides, in pertinent part:

"(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

"(b) The notice shall contain the following text:

"NOTICE TO CONSUMERS

"California law requires a pharmacist to speak with you every time you get a new prescription.

"*You* have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

"*Interpreter* services are available to you upon request at no cost.

"*Before* taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

"*This* pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

"*You* may ask this pharmacy for information on drug pricing and of generic drugs.

"(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

"*Point* to your language. Interpreter services will be provided to you upon request at no cost.

. . ."

19. California Code of Regulations, title 16, section 1711 provides, in pertinent part:

"(a) Each pharmacy shall establish or participate in an established quality assurance 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.

. . .

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

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

20. California Code of Regulations, title 16, section 1714, subdivision (c) states: "The pharmacy and fixtures and equipment shall be maintained in a clean and orderly condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly lighted. The pharmacy shall be equipped with a sink with hot and cold running water for pharmaceutical purposes."

21. California Code of Regulations, title 16, section 1714.1, subdivision (f) states:

"The pharmacy shall have written policies and procedures regarding the operations of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods. The policies and procedures shall include the authorized duties of ancillary staff, the pharmacist's responsibilities for checking all work performed by ancillary staff and the pharmacist's responsibility for maintaining the security of the pharmacy. The policies and procedures shall be open to inspection by the board or its designee at all times during business hours."

22. California Code of Regulations, title 16, section 1715, subdivision (a) states: "The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education."

23. California Code of Regulations, title 16, section 1716 provides, in pertinent part: "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 with Section 4073 of the Business and Professions Code."

24. California Code of Regulations, title 16, section 1735.2 provides, in pertinent part:

"(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

"(1) Active ingredients to be used.

"(2) Equipment to be used.

"(3) Expiration dating requirements.

"(4) Inactive ingredients to be used.

"(5) Process and/or procedure used to prepare the drug.

"(6) Quality reviews required at each step in preparation of the drug.

"(7) Post-compounding process or procedures required, if any.

. . .

"(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.

. . .

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"(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is 'Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment' Form 17M-39 Rev. 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

25. California Code of Regulations, title 16, section 1735.3 provides, in pertinent part:

"(a) For each compounded drug product, the pharmacy records shall include:

"(1) The master formula record.

. . .

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

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

26. California Code of Regulations, title 16, section 1735.5, subdivision (a) states: "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."

27. California Code of Regulations, title 16, section 1735.7 provides, 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.

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"(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."

28. California Code of Regulations, title 16, section 1761, subdivision (a) states: "No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription."

29. California Code of Regulations, title 16, section 1793.7 provides, in pertinent part:

"(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

"(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures."

30. Code of Federal Regulations, title 21, section 1304.11 provides, in pertinent part:

"(a) General requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. . . .

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

"(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial

inventory date."

31. Code of Federal Regulations, title 21, section 1305.13, subdivision (e) states: "The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser."

32. Code of Federal Regulations, title 21, section 1305.22, subdivision (g) states: "When a purchaser receives a shipment, the purchaser must create a record of the quantity of each item received and the date received. The record must be electronically linked to the original order and archived."

COSTS

33. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FACTUAL BACKGROUND

34. Respondent Nguyen has been the pharmacist-in-charge of Respondent Pharmacy from August 13, 1997, to the present.

35. On or about March 4, 2016, Respondent Pharmacy dispensed prescription #776264 to a patient for 60 thyroid/microcrystal capsules. The patient had been prescribed liothyronine/levothyroxine in 18.75mcg/100mcg capsules. The original prescription document did not indicate the strength of liothyronine/levothyroxine prescribed. Respondent Pharmacy compounded the thyroid/microcrystal capsules using liothyronine powder and levothyroxine powder. Respondent Pharmacy's staff compounded the liothyronine and levothyroxine using the wrong ratio, which resulted in an inaccurate dose that varied from the prescription. Also, the label on the prescription bottle did not show the medication strength of the capsules and stated that the product expired on March 4, 2017. Respondent Pharmacy's dispense history record

indicated that the product expired on October 25, 2017.

36. On or about October 25, 2016, three Board inspectors performed an inspection at Respondent Pharmacy. During the inspection, the inspectors observed a pharmacy technician who was not wearing a name tag. The inspectors also observed a pharmacy clerk sitting at a computer terminal eating bananas.

37. In Respondent Pharmacy's compounding room, the inspectors observed a counter that was cluttered with prescription documents and an open container of yogurt. The inspectors also noticed several bags of oranges stored below a rack filled with prepared prescriptions.

38. The inspectors looked through medication stock bottles used for compounding and found several expired medications. They also noticed that the sink in the compounding room was not equipped with hot water.

39. While at Respondent Pharmacy, the inspectors discovered the following expired medications:

a. A bottle of atenolol 2.5mg/ml solution dated January 9, 2015. Behind the label on the bottle was a handwritten label that read: "Atenolol 2.5mg/ml exp. 7/11/15."

b. A container of ascorbyl palmitate for compounding that had expired on December 12, 2015.

c. Two (2) boxes of Novolog insulin that had expired in August and September of 2016.

d. Several bottles of expired hydrocodone/acetaminophen products.

40. One of the inspectors reviewed recent electronic compounding logs and found that the logs were missing the identity of the pharmacy personnel who compounded the product and the identity of the pharmacist who verified the final compounded product. The logs were also missing the expiration date of several of the components used for compounding, as well as the expiration date of the final product.

41. One of the inspectors asked the pharmacy manager for a master formula for levothyroxine and liothyronine. Respondent Pharmacy did not have a master formula for those drugs. The inspector also asked to see the pharmacy's compounding self-assessment, compounding policies and procedures, and staff competency and training records. Pharmacy staff

was unable to provide those documents to the inspector.

42. The inspectors reviewed Respondent Pharmacy's pharmacy permit and noticed that it was not posted within public view. The inspectors also noticed that the pharmacy had an old version of the "Notice to Consumer" sign and no "Point to Your Language" sign posted at the pharmacy.

43. The inspectors requested Respondent Pharmacy's pharmacy policies and procedures regarding temporary absence of a pharmacist, quality assurance, theft by or impairment of staff, and language assistance, as well as a pharmacy technician job description and a copy of Respondent Pharmacy's most recent DEA biennial controlled substance inventory. Pharmacy staff was unable to provide any of this documentation to the inspectors. There were also no documented quality assurance reviews available for any medication errors.

44. One of the inspectors reviewed recent invoices for Schedule II controlled substances purchased by Respondent Pharmacy. The invoices were not signed and there were no DEA Form 222s attached to them containing the number of commercial or bulk containers received or the date those containers were received. Another inspector later reviewed several of Respondent Pharmacy's DEA Form 222s and noticed that they did not contain a signature or date received.

45. The inspectors further determined that Respondent Pharmacy had not submitted required prescription data to CURES when dispensing controlled substances.

FIRST CAUSE FOR DISCIPLINE

(Failure to Complete Self-Assessments)

46. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, sections 1715, subdivision (a) and 1735.2, subdivision (j), in that Respondent Nguyen failed to complete (1) a timely self-assessment of Respondent Pharmacy's compliance with federal and state pharmacy law; and (2) a timely self-assessment for compounding pharmacies developed by the Board. The circumstances of this conduct are set forth above in paragraph 41.

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SECOND CAUSE FOR DISCIPLINE

(Failure to Post Required Notices)

47. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, in that (1) Respondents posted a notice to consumer sign that did not contain the language required by California Code of Regulations, title 16, section 1707.6, subdivisions (a) and (b); and (2) Respondents failed to post the sign required by California Code of Regulations, title 16, section 1707.6, subdivision (c). The circumstances of this conduct are set forth above in paragraph 42.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Policies and Procedures Regarding Language Assistance)

48. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1707.5, subdivision (d), in that Respondents did not have policies and procedures in place to help patients with limited or no English proficiency understand the information on prescription labels in the patients' language(s). The circumstances of this conduct are set forth above in paragraph 43.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Display License)

49. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o), 4113, subdivision (c), and 4058 of the Code, in that Respondents failed to display Respondent Pharmacy's original license and current renewal license upon the licensed premises in a place where they were able to be clearly read by the public. The circumstances of this conduct are set forth above in paragraph 42.

FIFTH CAUSE FOR DISCIPLINE

(Holding and/or Offering for Sale Adulterated Drugs)

50. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and Health and Safety Code sections 111260 and 111295, in that Respondents held and/or offered for sale adulterated drugs. The

circumstances of this conduct are set forth above in paragraphs 38 and 39.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Inventory of Controlled Substances)

51. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and Code of Federal Regulations, title 21, section 1304.11, subdivisions (a), (b), and/or (c), in that Respondents failed to maintain an inventory containing a complete and accurate record of all controlled substances on hand at Respondent Pharmacy. The circumstances of this conduct are set forth above in paragraph 43.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Pharmacy in Clean Condition)

52. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1714, subdivision (c), in that Respondents failed to maintain the pharmacy in a clean and orderly condition, and they failed to equip the pharmacy with a sink with hot running water for pharmaceutical purposes. The circumstances of this conduct are set forth above in paragraphs 36, 37, and 38.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Maintain Written Policies Regarding Theft and Impairment)

53. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o), 4113, subdivision (c), and 4104, subdivision (b) of the Code, in that Respondents failed to maintain written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by Respondent Pharmacy. The circumstances of this conduct are set forth above in paragraph 43.

NINTH CAUSE FOR DISCIPLINE

(Failure to Maintain Policies Regarding Temporary Absence of Pharmacist)

54. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title

16, section 1714.1, subdivision (f), in that Respondents failed to maintain written policies and procedures regarding the operations of Respondent Pharmacy during the temporary absence of a pharmacist for breaks and meal periods. The circumstances of this conduct are set forth above in paragraph 43.

TENTH CAUSE FOR DISCIPLINE

(Failure to Wear Required Identification)

55. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1793.7, subdivision (c), in that a pharmacy technician employed by Respondent Pharmacy did not wear identification clearly identifying him or her as a pharmacy technician. The circumstances of this conduct are set forth above in paragraph 36.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Develop Job Description for Pharmacy Technicians)

56. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1793.7, subdivision (d), in that Respondents failed to develop a job description for the pharmacy technicians employed at Respondent Pharmacy. The circumstances of this conduct are set forth above in paragraph 43.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate Records of Controlled Substances Purchased)

57. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and Code of Federal Regulations, title 21, sections 1305.13, subdivision (e) and 1305.22, subdivision (g), in that the DEA Form 222s Respondents maintained for controlled substances purchased by Respondent Pharmacy did not contain the number of commercial or bulk containers received or the date those containers were received. Nor did Respondents create a record of the quantity of each controlled substance received or the date received. The circumstances of this conduct are set forth above in paragraph 44.

THIRTEENTH CAUSE FOR DISCIPLINE

(Failure to Report Controlled Substance Information)

58. Respondents' licenses are subject to disciplinary action under sections 4301, subdivisions (j) and/or (o), and 4113, subdivision (c) of the Code, in that Respondents failed to report to CURES the controlled substance dispensing information required by Health and Safety Code section 11165, subdivision (d). The circumstances of this conduct are set forth above in paragraph 45.

FOURTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Information for Compounded Drug Products)

59. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1735.3, subdivisions (a)(1), (a)(3), and (a)(4), in that the records Respondent Pharmacy maintained for compounded drug products did not contain the master formula information, the identity of pharmacy personnel engaged in compounding, or the identity of the pharmacist reviewing the final drug product. The circumstances of this conduct are set forth above in paragraphs 40 and 41.

FIFTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain a Compounding Manual)

60. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1735.5, subdivision (a), in that Respondents failed to maintain a written policy and procedure manual for compounding. The circumstances of this conduct are set forth above in paragraph 41.

SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Training Documentation)

61. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1735.7, subdivisions (a) and (b), in that Respondents failed to maintain written

documentation regarding the training of pharmacy staff engaged in compounding. The circumstances of this conduct are set forth above in paragraph 41.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Dispensing a Prescription Containing Incomplete Label)

62. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o), 4113, subdivision (c), and 4076, subdivision (a)(7) of the Code, in that a pharmacist employed by Respondent Pharmacy dispensed a prescription with a label that did not contain the strength of the drug dispensed. The circumstances of this conduct are set forth above in paragraph 35.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Dispensing a Prescription Containing a Significant Error or Omission)

63. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1761, subdivision (a), in that Respondents dispensed a prescription that contained a significant error, omission, irregularity, uncertainty, ambiguity, and/or alteration. The circumstances of this conduct are set forth above in paragraph 35.

NINETEENTH CAUSE FOR DISCIPLINE

(Deviating from Prescription Requirements)

64. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1716, in that Respondents deviated from the requirements of a prescription without the prior consent of the prescriber. The circumstances of this conduct are set forth above in paragraph 35.

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Quality Assurance Reviews)

65. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1711, subdivisions (a), (d), and/or (e), in that Respondents failed to maintain records

of quality assurance reviews for medication errors committed at Respondent Pharmacy, including the medication error pertaining to prescription #776264. The circumstances of this conduct are set forth above in paragraph 43.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Prepare Master Formula for Compounding)

66. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, in that Respondents compounded a drug product without first preparing a written master formula record containing the elements set forth in California Code of Regulations, title 16, section 1735.2, subdivisions (d)(1)-(d)(7). The circumstances of this conduct are set forth above in paragraphs 35 and 41.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Improper Expiration Date on Drug Product)

67. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1735.2, subdivision (h), in that the expiration date, or "beyond use date," for one of Respondent Pharmacy's compounded drug products exceeded 180 days from the date of preparation. The circumstances of this conduct are set forth above in paragraph 35.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Failure to Properly Perform and/or Supervise Compounding)

68. Respondents' licenses are subject to disciplinary action under sections 4301, subdivision (o) and 4113, subdivision (c) of the Code, and California Code of Regulations, title 16, section 1735.2, subdivision (i), in that Respondent Pharmacy failed to properly perform and/or supervise the compounding of a drug product. The circumstances of this conduct are set forth above in paragraph 35.

DISCIPLINE CONSIDERATIONS

69. To determine the degree of discipline, if any, to be imposed on Respondent Pharmacy, Complainant alleges that on or about September 4, 2015, in Case No. CI 2013 59107, the Board issued a citation to Respondent Pharmacy for violating California Code of Regulations, title 16,

section 1707.3 (failure to review a patient's drug therapy). That citation is now final and is incorporated by reference as if fully set forth in this Accusation.

70. To determine the degree of discipline, if any, to be imposed on Respondent Nguyen, Complainant alleges that on or about September 4, 2015, in Case No. CI 2015 66867, the Board issued a citation and fine to Respondent Nguyen for violating California Code of Regulations, title 16, section 1707.3 (failure to review a patient's drug therapy). That citation and fine is now final and is incorporated by reference as if fully set forth in this Accusation.

OTHER MATTERS

71. Pursuant to section 4307 of the Code, if discipline is imposed on Original Permit Number PHY 43166 issued to Hoan T.L. Nguyen dba Aborn Pharmacy, Hoan T.L. Nguyen, Owner, while Respondent Nguyen was a partner of Aborn Pharmacy and had knowledge of or knowingly participated in any conduct for which Original Permit Number PHY 43166 was disciplined, Respondent Nguyen shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Permit Number PHY 43166 is placed on probation or until Original Permit Number PHY 43166 is reinstated if it is revoked.

PRAYER

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

1. Revoking or suspending Original Permit Number PHY 43166 issued to Hoan T.L. Nguyen dba Aborn Pharmacy, Hoan T.L. Nguyen, Owner;

2. Revoking or suspending Original Pharmacist License Number RPH 44283 issued to Hoan T.L. Nguyen;

3. Prohibiting Hoan T.L. Nguyen from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 43166 is placed on probation or until Pharmacy Permit Number PHY 43166 is reinstated if Pharmacy Permit Number 43166 issued to Hoan T.L. Nguyen dba Aborn Pharmacy, Hoan T.L. Nguyen, Owner, is revoked;

4. Ordering Hoan T.L. Nguyen dba Aborn Pharmacy, Hoan T.L. Nguyen, Owner, and Hoan T.L. Nguyen 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,

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

DATED: 3/9/18

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

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