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

In the Matter of the Accusation Against:

LAURA MICHELLE DAWLEY, Pharmacist License No. RPH 55947 Case No. 5694

OAH No. 2017051408

Respondent.

DECISION AND ORDER

The attached Proposed Decision of the Administrative Law Judge is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter

This Decision shall become effective at 5:00 p.m. on March 28, 2018.

It is so ORDERED on February 26, 2018.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

Ву

Amy Gutierrez, Pharm.D. Board President

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

In the Matter of the Accusation Against:

LAURA MICHELLE DAWLY, Pharmacist License No. RPH 55947,

Respondent.

Case No. 5694

OAH No. 2017051408

PROPOSED DECISION

Howard W. Cohen, Administrative Law Judge (ALJ), Office of Administrative Hearings, State of California, heard this matter on November 20, 2017, in Los Angeles.

Sheronda L. Edwards, Deputy Attorney General, represented complainant Virginia K. Herold, Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

Herbert L. Weinberg, Fenton Law Group, LLP, represented respondent Laura Michelle Dawly, who was present.

The parties agreed to redact all documents offered in evidence to protect the privacy rights of third parties in lieu of requesting a protective sealing order. The ALJ ordered the court reporter to replace any reference to a patient's name in the transcript with the patient's initials.

Oral and documentary evidence was received. The record was held open to allow the parties to submit simultaneous closing briefs by December 13, 2017, and to allow complainant to file a reply closing brief by December 20, 2017. Complainant and respondent timely filed closing briefs, which were marked for identification as exhibits 46 and E, respectively. Complainant filed no reply closing brief.

The record was closed and the matter was submitted on December 20, 2017.

SUMMARY

Complainant seeks to revoke or suspend respondent's pharmacist license for errors in prescription practices, alleging she incorrectly processed and verified prescriptions, dispensed a dangerous drug in an incorrectly labeled container, failed to complete quality assurance reports for all medication errors, dispensed a post-dated prescription, and incorrectly dispensed methylphenidate tablets that had been returned to the pharmacy by a patient. Respondent admitted the errors and offered evidence of mitigation and rehabilitation. As discussed below, there is cause to revoke respondent's license, suspend the revocation, and place respondent's license on probation for three years on certain terms and conditions.

FACTUAL FINDINGS

Jurisdiction and Parties

- 1. Complainant filed the Accusation in her official capacity. Respondent timely filed a notice of defense.
- 2. The Board issued Pharmacist License number RPH 55947 to respondent on August 5, 2004. The license is scheduled to expire on December 31, 2019.
- 3. From March 8, 2011 to January 14, 2015, and from May 21, 2015, to the present, respondent has been the pharmacist-in-charge (PIC) of Rite Aid Pharmacy #6514 in Victorville. She was PIC at that pharmacy at all times relevant to the charging allegations.

Board Investigation

- 4. On May 12, 2014, the Board received a complaint from Marisa Rodriguez, a pharmacy technician employed by Rite Aid #6514, claiming that she observed respondent fail to report medication errors, reuse returned medications, and fill postdated prescriptions. Rodriguez testified at hearing to substantiate her observations and reaffirm her complaint. She admitted that, though she was aware of the mistakes when they were made, she did not call the mistakes to respondent's attention, or to anyone else's attention. She testified that she was willing to allow incorrectly filled prescriptions to be distributed to patients even though she knew they were filled in error, because she was not the pharmacist and it was not her responsibility to take any corrective action. Rodriguez's admission that she chose to engage in what appears to be unethical behavior potentially harmful to patients lends support to respondent's claim of Rodriguez's animus toward her; it does not, however, call into question the basis for the substantive charges against respondent in light of other evidence on the record.
- 5. On January 6, 2015, Board Inspector Anna Yamada, accompanied by another inspector, inspected Rite Aid Pharmacy #6514. Yamada discovered evidence of multiple violations, including variations from prescriptions; dispensing a prescription with incorrect dosage instructions; failing to complete quality assurance reports for multiple medication errors;

filling and dispensing postdated prescriptions for morphine; and dispensing adulterated methylphenidate.

6. Yamada interviewed Rodriguez and Samy Farag, a licensed pharmacist who works for Rite Aid, filling in at different pharmacies as a "floater." She inspected the pharmacy and obtained witness statements.

Deviations from Prescriptions

- 7. At hearing, respondent admitted that, on January 30, 2014, she incorrectly processed and verified a prescription as methylphenidate 5mg Rx #320772 to patient MD, instead of the prescribed methylphenidate ER 54mg, without the prior consent of the prescribing physician.¹
- a. On February 5, 2014, the patient appeared at the pharmacy to complain about the incorrect prescription. Farag, who was filling in for respondent, corrected the error and dispensed methylphenidate ER 54mg Rx #323796 to patient MD. He wrote "patient return" on the label of the returned medication and placed the bottle in the designated area for expired or damaged items in a cabinet containing controlled substances. He also telephoned respondent and notified her of the error.
- b. Respondent subsequently admitted to Yamada that she filled the methylphenidate prescription in error. She said she did not recall speaking with Farag on February 5, 2014, while she was out of the state, or the details of the medication error. Respondent was distraught because she received an emergency call from her sister in Arkansas on January 30, 2014, before filling the prescription, stating her mother had a heart attack and was scheduled to have quadruple bypass heart surgery. Respondent planned immediately to fly to Arkansas, and informed Rite Aid management so another pharmacist could take her place.
- 8. On February 17, 2014, respondent incorrectly dispensed a prescription for erythromycin 250mg Rx #326326 for patient TF instead of the prescribed patient, her son EF, without the prior consent of the prescribing physician.
- a. The following day, on February 18, 2014, another pharmacist at the pharmacy corrected the error and dispensed erythromycin 250mg Rx #326641 for patient EF.
- b. Rodriguez had prepared the incorrect label for the bottle but had not called the error to respondent's attention. Respondent told Yamada that she did not recall the prescription error, but remembered staff informing her that a customer was upset about her son's medication being incorrectly dispensed.

The prescription was for the extended release version of the medication, at a higher dose than that actually dispensed to the patient.

Labeling Errors

9. Respondent admitted to Yamada and at hearing that, on April 5, 2013, when respondent dispensed triamterene/HCTZ 37.5/25 as Rx #262434 to patient RB, she incorrectly labeled the bottle with directions to "take one capsule by mouth once daily one capsule by mouth twice daily," instead of the prescribing doctor's directions to "take one capsule daily." On April 19, 2013, three weeks later, respondent corrected the error and processed and verified patient RB's prescription, with the correct labeling, under a new prescription number, Rx #270129.

Quality Assurance Program Errors

- 10. During her January 6, 2015, inspection, Yamada found that the pharmacy did not complete quality assurance reports for all reported medication errors.
- a. On March 8 and April 5, 2013, patient RB's triamterene/HCTZ 37.5/25 Rx #262434 was dispensed with the incorrect directions. On April 19, 2013, the error was corrected, but there was no quality assurance report of this medication error available when requested on January 6, 2015.
- b. On January 30, 2014, patient MD's methylphenidate ER 54mg prescription was incorrectly dispensed as methylphenidate 5mg Rx #320772. On February 5, 2014, the error was corrected, but there was no quality assurance report of this medication error available when requested by the Board on January 6, 2015.
- c. On February 17, 2014, patient EF's erythromycin 250mg was incorrectly dispensed to TF as erythromycin 250mg Rx #326326. On February 18, 2014, the error was corrected, but there was no quality assurance report of this medication error available when requested by the Board on January 6, 2015.
- 11. When Farag corrected the methylphenidate error on February 5, 2014, he was not aware that he was required to prepare a quality assurance report. He testified, and told Yamada during her inspection, that he did not learn of this requirement until the date of the inspection. Farag telephoned respondent on February 5 to inform her about the medication error; he testified she told him she would report the error upon her return. Respondent does not recall the conversation, and disputes that she would have made such a statement, as it is Rite Aid policy that the pharmacist on duty must complete a quality assurance review within two days of discovering an error, and the policy is posted throughout the pharmacy. Rite Aid had not trained

² The monthly prescription had previously been mislabeled when dispensed to the patient a month earlier, on March 8, 2018; at that time, respondent had by hand corrected the label instructions before the medication was provided to the patient. The timing of the April refill suggests that the patient took the correct dose.

Farag to understand he was required to prepare a quality assurance report in respondent's absence.

- 12. Respondent wrote, in a statement provided to Yamada, that she was not aware there was a problem with the erythromycin prescription. "If I was made aware of a medication error; I would have immediately reported it as per Rite Aid policy." (Ex. 38.) At the hearing, however, respondent admitted to having some knowledge of the erythromycin error because she either heard of the aftermath of the customer's complaint or she personally resolved the matter with the customer. Respondent did not prepare or cause to be prepared a quality assurance report.
- 13. Pharmacies must retain quality assurance reports for at least one year from the date of correction. There is insufficient evidence on the record to demonstrate that reports of the March 8, 2013 and April 5, 2013 errors were not prepared. Yamada's inspection took place more than a year after the alleged incidents occurred, and complainant offered no evidence as to how long quality assurance reports were kept in Rite Aid's files. There is, however, sufficient evidence to demonstrate that the reports for January 30 and February 17, 2014, were not prepared.

Postdating Prescription

- 14. On September 26, 2013, the pharmacy received a postdated prescription, dated September 29, 2013, for morphine sulfate ER 60mg and morphine sulfate IR 30mg for patient WK. As she admitted at hearing, on September 26, 2013, respondent dispensed both morphine sulfate ER 60mg Rx #298354 and morphine sulfate IR 30mg Rx #298355 to patient WK.
- 15. At the hearing, respondent did not deny she filled and dispensed the morphine prescriptions early, but claimed she had committed an inadvertent oversight. Though morphine is a highly regulated Schedule II controlled substance, and pharmacists are trained to look very closely at the dates of prescriptions for Schedule II controlled substances and the doctor's signature, on the whole the evidence does not establish that the mistake was other than inadvertent.

Dispensing Adulterated Medication

- 16. On January 30, 2014, patient MD's methylphenidate 5mg Rx #320772 was incorrectly dispensed, and the patient returned the bottle, now containing 84 of the 90 dispensed tablets, to the pharmacy on February 5, 2014. (See Factual Finding 7a.) The methylphenidate bottle was commingled with the pharmacy's active drug stock and the contents of the returned medication bottle of methylphenidate 5mg were dispensed to another patient. On May 12, 2014, 60 of patient MD's returned methylphenidate 5mg tablets were used to dispense a prescription for methylphenidate 5mg Rx #344319 to patient MH.
- 17. Respondent testified that when the incorrectly dispensed methylphenidate prescription container was returned to the pharmacy, she placed it on the bottom shelf of the locked Schedule II controlled substance cabinet, in a red basket clearly marked for destruction.

Her testimony was corroborated by that of Farag. Respondent speculated to Yamada that somewhere along the line the methylphenidate prescription bottle must have been removed from the red return basket designated for receiving returned medications and placed into the regular drug stock, stating it may have occurred during the monthly drug inventories. Respondent was responsible for counting the adulterated drug to list in the pharmacy's "perpetual active inventory" and for conducting a monthly inventory and, as PIC, respondent was responsible for the staff pharmacist's re-dispensing of the adulterated methylphenidate.

Mitigation and Rehabilitation

- 18. Respondent admitted her mistakes. Some she attributed to the stress attending her mother's heart condition; with respect to others, respondent offered no excuse. Her license has never before been disciplined. When she received the Accusation in this matter, she was distraught, never having been in trouble before. She began taking continuing education courses related to the disciplinary charges brought against her, to improve her practical skills.
- 19. Respondent is respected by her professional peers and by patients using her pharmacy, as reflected in several character reference letters she submitted. William Zen, Pharm.D., wrote of her "sterling reputation," organization, commitment to excellence in treating customers and employees, her high ethical standards. (Ex. C.) Jill Sczech, M.S., Pharm.D., a Rite Aid floater, wrote that respondent's store "is one of the most organized and detail oriented stores that I have worked at." (*Id.*) She wrote of respondent's leadership skills, care for her patients, pharmaceutical knowledge, and integrity. Kathryn Chelekis Brown, R.Ph., a relief pharmacist at Rite Aid, wrote of respondent's attention to detail, organization, and professional skills. All were aware of the Accusation. Two patients wrote gratefully of respondent's attentiveness and care to them and their families.

Cost of Enforcement

20. The Board incurred investigative costs for inspectors and a supervising inspector in the amount of \$6,578.75, and enforcement costs, in the form of Attorney General fees and costs, in the amount of \$11,777.50, for a total of \$18,356.25. Those costs are reasonable. Complainant anticipated that the Board would incur approximately \$1,020 in additional attorney's fees from November 17, 2017, to the commencement of hearing. (Ex. 46.) A good faith estimate of costs may be used "where actual costs are unavailable." (Bus. & Prof. Code, 125.3.) Complainant did not establish why she could not submit evidence of actual additional enforcement costs at hearing. Without such evidence, an award of anticipated costs must be, and is, disallowed.

³ All further statutory references are to the Business and Professions Code, unless otherwise stated.

LEGAL CONCLUSIONS

Applicable Authority

- 1. The Board may suspend or revoke a license for unprofessional conduct. (§§ 4300, 4301.) Unprofessional conduct includes violating any laws regulating controlled substances and dangerous drugs (§ 4301, subd. (j)), and violating any laws governing pharmacy (§ 4301, subd. (o)). The Board retains jurisdiction to discipline an expired license. (§§ 118, subd. (b), 4300.1.)
- 2. "Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions." (§ 4001.1.)
- 3. "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." (§ 4113, subd. (c).) "Pharmacist-in-charge' means a pharmacist proposed by a pharmacy and approved by the Board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy." (§ 4036.5.)
- 4. "No person shall antedate or postdate a prescription." (Health and Saf. Code, § 11172.)
- 5. A person shall not sell dangerous drugs that the person knew or reasonably should have known were adulterated. (§ 4169, subd. (a)(2).) "Dangerous drugs" are those that may not be lawfully dispensed without prescription furnished under section 4006. (§ 4022.) The Board may adopt regulations restricting the sale of dangerous drugs. (§ 4006.) The Board may discipline a license "to prevent the sale of pharmaceutical preparations and drugs that do not conform to the [applicable] standard and tests as to quality and strength...." (§ 4342, subd. (a).) The Board may punish any knowing or willful violation of any regulation adopted under section 4006 by fine or imprisonment. (§ 4342, subd. (b).)
- 6. "A pharmacist shall not dispense any prescription except in a container... correctly labeled with...[t]he directions for the use of the drug." (§ 4076, subd. (a)(2).)
- 7. Every pharmacy must establish a quality assurance program that documents and assesses medication errors. (Cal. Code Regs. (CCR), tit. 16, § 1711, subd. (a)). "Medication errors" are variations from a prescription or drug order not authorized by the prescriber. (CCR, § 1711, subd. (b).) Each pharmacy must use its quality assurance program findings to develop systems and 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

⁴ All further references to the CCR are to title 16.

days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review." (CCR, § 1711, subd. (d).) Every quality assurance review record "shall be immediately retrievable in the pharmacy for at least one year from the date the record was created." (CCR, § 1711, subd. (f).)

- 8. "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." (CCR, § 1716.)
- 9. The Board bears the burden of proof by clear and convincing evidence, because pharmacists hold a professional license. (See *Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853.) Clear and convincing evidence requires proof that is so clear as to leave no substantial doubt and that is sufficiently strong to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478, 487.)

Cause for Discipline

- 10. Cause exists to discipline respondent's pharmacist license for unprofessional conduct under Business and Professions Code section 4301, subdivision (o), in that she deviated from the requirements of a prescription without the prior consent of the prescriber in violation of CCR section 1716, as set forth in Factual Findings 7 and 8.
- 11. Cause exists to discipline respondent's pharmacist license for unprofessional conduct under Business and Professions Code section 4301, subdivision (*o*), in that she dispensed a dangerous drug in an incorrectly labeled container in violation of CCR section 1716, as set forth in Factual Findings 9.
- 12. Cause exists to discipline respondent's pharmacist license for unprofessional conduct under Business and Professions Code section 4301, subdivision (o), in that she failed to complete quality assurance reports for all reported medication errors in violation of CCR section 1711, subdivisions (d) and (f), as set forth in Factual Findings 10 through 13.
- 13. Cause exists to discipline respondent's pharmacist license for unprofessional conduct under Business and Professions Code section 4301, subdivision (j), in that she dispensed a post-dated prescription in violation of Health and Safety Code section 11172, as set forth in Factual Findings 14 and 15.
- 14. Cause exists to discipline respondent's pharmacist license for unprofessional conduct under Business and Professions Code section 4301, subdivision (o), in that she dispensed dangerous drugs she knew or reasonably should have known were adulterated in that they had been returned by a patient and could not be shown to satisfy statutory requirements for quality and strength, in violation of Business and Professions Code sections 4342 and 4169, subdivision (a)(2), as set forth in Factual Findings 16 and 17 and Legal Conclusion 5.

- 15. The Board shall consider its Disciplinary Guidelines (rev. 10/2007) (Guidelines) when determining whether and how to discipline a license. (CCR, § 1774.) The Disciplinary Guidelines establish four categories for evaluating violations and determining discipline.
- 16. Category I violations are "potentially harmful" but "relatively minor" violations and repeated violations of a "relatively minor nature." (Guidelines at p. 6.) Category II violations are those that (1) exhibit a "serious potential for harm," (2) show "greater disregard" for public safety or Pharmacy Law, (3) reflect adversely on the licensee's ethics, care, or competence, or (4) result in a criminal conviction not involving controlled substances, their use, or their possession." (Id.) Category III violations include (1) drug related criminal convictions, (2) knowing or willful violations of the Pharmacy Law or the Uniform Controlled Substances Act, and (3) license-related acts of fraud. (Id. at p. 15.) Category IV violations are the most severe; they are not relevant here, and include such violations as possession and transportation of a controlled substance for sale.
- 17. For Category I violations, the Guidelines recommend revocation or stayed revocation with one year of probation. For Category II offenses, the Guidelines recommend revocation or stayed revocation with three years' minimum probation. For Category III violations, the Guidelines prescribe revocation or stayed revocation with 90 days' actual suspension and three to five years of probation. For multiple category violations, the Guidelines recommend imposing penalties for the highest category in which the licensee's conduct falls.
- 18. The following factors are also relevant when determining what discipline to impose on a license: actual or potential harm to the public, actual or potential harm to any consumer, prior disciplinary record, number and variety of current violations, nature and severity of the crimes under consideration, aggravating evidence, mitigating evidence, rehabilitation evidence, compliance with terms of any criminal sentence or probation, overall criminal record, evidence of expungement under Penal Code section 1203.4, time passed since the acts or offenses, whether the conduct was intentional or negligent or demonstrated incompetence, and financial benefit to the respondent from the misconduct. (Guidelines (p. 3); Code, § 4300.)
- 19. All of respondent's violations are Category I or II violations, except the violation of section 4169, subdivision (a)(2) (selling dangerous drugs that the person knew or reasonably should have known were adulterated). Respondent committed multiple violations, some entailing potential harm to patients. Applying all the relevant factors, however, and considering that respondent was not shown to act out of any improper motive, has never before been disciplined, and has taken steps to educate herself to prevent any further violations, the record in this case supports the conclusion that revocation stayed, with three years' probation on appropriate terms and conditions, should suffice to protect the public. The statutes relating to the licensing of professions generally are not designed to punish, but to protect the public from dishonest, untruthful, and disreputable licensees. (Arneson v. Fox (1980) 28 Cal.3d 440, 451.)

Cost Recovery

20. Complainant is entitled to the recover reasonable costs of investigation and prosecution of this matter in the amount of \$18,356.25, under Code section 125.3, as set forth in Factual Finding 20.

ORDER

Pharmacist license number RPH 55947, issued to respondent Laura Michelle Dawly, is revoked. The revocation is stayed, however, and respondent's license is placed on probation for three years on the following terms and conditions:

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- a. an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- b. a plea of guilty or nolo contendere in any state or federal criminal proceeding to any criminal complaint, information or indictment
 - c. a conviction of any crime
- d. discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall

be automatically extended until such time as the final report is made and accepted by the Board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of respondent's compliance with the terms and conditions of her probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board or its designee.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 5694 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause her direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the Board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5694 and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify her direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the Board of the terms and conditions of the decision in case number 5694 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy

employment service, respondent shall cause her direct supervisor with the pharmacy employment service to report to the Board in writing acknowledging that he or she has read the decision in case number 5694 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the Board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the Board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, parttime, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the Board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the Board its costs of investigation and prosecution in the amount of \$18,356.25. Respondent shall make said payments on a schedule to be determined by the Board.

There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

9. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

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10. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the Board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender her license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the Board.

Upon acceptance of the surrender, respondent shall relinquish her pocket and wall license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the Board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the Board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the Board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 30 hours per calendar month.

Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 30 hours per calendar month in California, respondent must notify the Board in writing within ten (10) days of the cessation of practice, and must further notify the Board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 30 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 30 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

14. Violation of Probation

If respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the Board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

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15. Completion of Probation

Upon written notice by the Board or its designee indicating successful completion of probation, respondent's license will be fully restored.

DATED: January 19, 2018

—Docusigned by: Howard W. Cohen

HOWARD W. COHEN
Administrative Law Judge
Office of Administrative Hearings

1 2 3 4 5	KAMALA D. HARRIS Attorney General of California ARMANDO ZAMBRANO Supervising Deputy Attorney General NANCY A. KAISER Deputy Attorney General State Bar No. 192083 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 897-5794 Facsimile: (213) 897-2804 Attorneys for Complainant				
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7 8					
9	BEFORE THE				
10	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS				
11	STATE OF CALIFORNIA				
12	In the Matter of the Accusation Against:	Case No. 5694			
13	I.ATPA MICHELLE DAWLY	·			
14	Century Plant Rd. Apple Valley, CA 92307	ACCUSATION			
15	Pharmacist License No. RPH 55947				
16	Respondent.				
17					
18	Complainant alleges:				
19	PARTIES				
20	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity				
21	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.				
22	2. On or about August 5, 2004, the Board of Pharmacy issued Pharmacist License				
23	Number RPH 55947 to Laura Michelle Dawly (Respondent). From on or about March 8, 2011 to				
24	on or about January 14, 2015, and from on or about May 21, 2015, to the present, Respondent has				
25	been the pharmacist-in-charge of Rite Aid Pharmacy #6514, located at 16120 Bear Valley Road,				
26	Victorville, CA 92395 ("Rite Aid Pharmacy"). The Pharmacist License was in full force and				
27	effect at all times relevant to the charges brought herein and will expire on December 31, 2017,				
28	unless renewed.				
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(LAURA MICHELLE DAWLY) ACCUSATION

JURISDICTION

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

STATUTORY PROVISIONS

- 4. Section 4300 states, in part, that "[e]very license issued may be suspended or revoked."
 - 5. Section 4300.1 of the Code states:

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

6. Section 4301 of the Code states, in part, that:

"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:

- "(j) The violation of any of the statutes of this state, or 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 [the Pharmacy Law, Bus. & Prof. Code, § 4000, et seq.) 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."

7. Section 4022 of the Code states, in part, that:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

- "(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
- "(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."
 - 8. Section 4076 of the Code states, in part, that:
- "(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:
 - (2) The directions for the use of the drug."
 - 9. Section 4169 of the Code states, in part, that:
 - "(a) A person or entity shall not do any of the following:
- (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code."
 - 10. Section 4342 of the Code states:
- "(a) 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).
- (b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4321 and 4336."

11. Health and Safety Code 11172 states: "No person shall antedate or postdate a prescription."

REGULATORY PROVISIONS

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12. California Code of Regulations, title 16, section 1711, states, in part, that:"(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.

"(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 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.

(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.

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

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

"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."

COST RECOVERY

14. Section 125.3 of the Code states, in 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.

15. DRUG CLASSIFICATIONS

Brand Name	Generic Name	Dangerous Drugs Per Bus. & Prof. Code, § 4022	Controlled Substance Per Health & Safety	Indications For Use
			Code (HSC)	
Ritalin	Methylphenidate	Yes	Yes HSC § 11055(d)(6)	ADHD
Concerta	Methylphenidate ER	Yes .	Yes HSC § 11055(d)(6)	ADHD
Erythrocin	Erythromycin	Yes	No	Antibiotic
Dyazide	Triamterene/HCTZ	Yes	No	Hypertension

FIRST CAUSE FOR DISCIPLINE

(Variation from Prescription)

- 16. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating California Code of Regulations, title 16, section 1716, in that Respondent deviated from the requirements of a prescription without the prior consent of the prescriber. The circumstances are as follows:
- 17. On or about January 30, 2014, while working at Rite Aid Pharmacy, Respondent incorrectly processed and verified a prescription as methylphenidate 5mg Rx #320772 to patient MD, instead of the prescribed methylphenidate ER 54mg. On or about February 5, 2014, another pharmacist at Rite Aid Pharmacy corrected the error and dispensed methylphenidate ER 54mg Rx #323796 to patient MD.

18. On or about February 17, 2014, while working at Rite Aid Pharmacy, Respondent incorrectly dispensed a prescription for erythromycin 250mg Rx #326326 for patient TF instead of the prescribed patient EF. On or about February 18, 2014, another pharmacist at Rite Aid Pharmacy corrected the error and dispensed erythromycin 250mg Rx #326641 for patient EF.

SECOND CAUSE FOR DISCIPLINE

(Dispensing Dangerous Drug in Incorrectly Labeled Container)

- 19. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating section 4076, subdivision (a)(2) of the Code, and California Code of Regulations, title 16, section 1716, for dispensing a dangerous drug in an incorrectly labeled container. The circumstances are as follows:
- 20. On or about April 5, 2013, while working at Rite Aid Pharmacy, Respondent dispensed triamterene/HCTZ 37.5/25 as Rx #262434 to patient RB, which was incorrectly labeled with directions to "take one capsule by mouth once daily one capsule by mouth twice daily," instead of the prescribed directions to "take one capsule daily." On or about April 19, 2013, Respondent corrected the error and processed and verified patient RB's prescription under a new prescription number of Rx #270129.

THIRD CAUSE FOR DISCIPLINE

(Quality Assurance Program)

- 21. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating California Code of Regulations, title 16, 1711, subdivisions (d) and (f), for failure to complete quality assurance reports for all reported medication errors. The circumstances are as follows:
- 22. On or about January 6, 2015, a Board inspection of Rite Aid Pharmacy revealed that, while Respondent was the pharmacist-in-charge, Rite Aid Pharmacy did not complete quality assurance reports for all reported medication errors, as follows:
- a. On or about March 8, 2013, and on or about April 5, 2013, patient RB's triamterene/ HCTZ 37.5/25 Rx #262434 was dispensed with the incorrect directions. On or about April 19,

2013, the error was corrected, but there was no quality assurance report of this medication error available when requested on January 6, 2015.

- b. On or about January 30, 2014, patient MD's methylphenidate ER 54mg prescription was incorrectly dispensed as methylphenidate 5mg Rx #320772. On or about February 5, 2014, the error was corrected, but there was no quality assurance report of this medication error available when requested by the Board on January 6, 2015.
- c. On or about February 17, 2014, patient EF's erythromycin 250mg was incorrectly dispensed to TF as erythromycin 250mg Rx #326326. On or about February 18, 2014, the error was corrected, but there was no quality assurance report of this medication error available when requested by the Board on January 6, 2015.

Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 16 through 20 above, as though set forth in full herein.

FOURTH CAUSE FOR DISCIPLINE

(Pestdating Prescription Prohibited)

- 23. Respondent is subject to disciplinary action under section 4301, subdivisions (j) and (o), of the Code, for violating Health and Safety Code 11172, in that on or about September 26, 2013, Respondent dispensed a post-dated prescription. The circumstances are as follows:
- 24. On September 26, 2013, Rite Aid Pharmacy received a postdated prescription, dated September 29, 2013, for morphine sulfate ER 60mg and morphine sulfate IR 30mg for patient WK. On September 26, 2013, while working at Rite Aid Pharmacy, Respondent dispensed both morphine sulfate ER 60mg Rx #298354 and morphine sulfate IR 30mg Rx #298355 to patient WK.

FIFTH CAUSE FOR DISCIPLINE

(Sales of Preparations or Drugs Lacking Quality or Strength)

25. Respondent is subject to disciplinary action under section 4301, subdivision (o), of the Code, for violating sections 4342 and 4169, subdivision (a)(2), of the Code, for dispensing dangerous drugs that she knew or reasonably should have known were adulterated. The circumstances are as follows:

(LAURA MICHELLE DAWLY) ACCUSATION

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......DO NOT FOLD OR STAPLE ABOVE THIS LINE.....

Nevada State Board of Pharmacy - Renewal Application - PHARMACIST

431 W Plumb Lane • Reno, NV 89509 • nvbop.com

For the period of November 1, 2017 to October 31, 2019 (NO BUSINESS or PERSONAL CHECKS, NO CASH)

Money Order ONLY \$180.00 (postmarked on or before 10/31/2017) OR \$320.00 (postmarked after 10/31/2017)

LICENSE: 11563 Steven Arthur Levin ALGUNAS RD, Woodland Hills, CA 91364 Please make any changes to name or address next to the old information

RENEW BY MAIL

- 1. Complete ALL sections on this form
- 2. Sign and date this form
- 3. Send MO with this form (do NOT staple)
- 4. Mail original form/payment to address above
- 5. NO COPIES

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RENEW ONLINE

- 1. Go to nvbop.com
- 2. FOLLOW the instructions on the page
- 3. Once you've successfully completed your license renewal, you will receive an email with a link to your certificate. We no longer mail certificates so please do not discard this link.

6. NO SIGNA	ATURE STAMPS A	CCEPTED				
Section 1: Since your last renewal or recent licensure have you: (Please fill in completely) Yes No						
Section 1:					103 110	
Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?						
Board Admir	nistrative Action:	State	Date:		Case #:	
Sec	Attache	}	/ /			
Criminal	State	Date:	Case #:	County	Court	
Action:		1				
Section 2: Are you the subject of a court order for the support of a child?						
Section 3: (Fees apply to either status) (see colored insert for details)						
By signing below, you certify that you have completed ALL required CE Hours due for the 17/19 Renewal period. (Dated from Nov. 1, 15 – Oct. 31, 17; 1.25hrs per mo.). The exemption period is 2yrs after graduation only. OR you may check the box for Inactive if you did NOT complete CE Inactive - By checking this box you certify that you are NOT practicing in NV and do not wish to comply with the CE requirements of NV and would like your license changed to inactive status. Before re-activating your license it will be necessary to submit an application and to become compliant with current CE requirements (NAC 639.219). See reverse of insert for more information.						
Section 4: NON-DISCIPLINARY STATE-MANDATED QUESTIONS 1. Though it is NOT required to have, SB21 requires the Board to ask if you have a Nevada State Business license and if you do, please provide the #:						
Military Occup	Military Occupation/Specialty: Dates of Service:					
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			and and will be imposed for micro	presentation I hereby certify that I h	ave read this application. I certify that all	

Section 5: It is a violation of Nevada law of alkity this application and sanctions will be imposed for misrepresentation. I hereby certify that I have read this application. I certainly statements made are true and correct. I attest to know hedge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. I understand that Nevada law requires a licensed pharmacist who, in their professional or occupational capacities comes to know or has reasonable cause to believe, a child has been abused neglected, to report the abused open control to a local law enforcement agency. Date: Original Signature:

Supplement to Question 1 Numbers 2 & 3 on Nevada Renewal Application

Section 1: Since your last renewal or recent licensure have you:

- 2. Been the subject of a board citation or an administrative action whether completed or pending in any state?
- 3. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?

Response / Explanation:

Since the last renewal the following has occurred regarding the license of Steven A. Levin RPh:

- The Louisiana Board of Pharmacy under Case No. 2016-115 issued a Letter of Reprimand on May 4, 2016 to PIC Steven Levin for failure to disclose prior discipline in Oregon. A copy of the final consent order is attached.
- 2. The Texas Board of Pharmacy issued a Preliminary Notice to Woodland Hills Pharmacy on December 2, 2016 alleging failure to disclosure a) the denial on January 27, 2015 by the Alabama Board of Pharmacy of the RPIC Steven A. Levin for pharmacist licensure in Alabama. b) the consent order issued on April 28, 2015 by the Oregon Board of Pharmacy for failure to disclosure a 1983 conviction and c) the denial on September 3, 2015 by the South Carolina Board of Pharmacy of the application for licensure by Woodland Hills Pharmacy for failure to meet the initial requirements of a licensee in South Carolina. A copy of the Texas Preliminary Notice is attached. No further information has been received and the matter is pending.
- 3. The Nebraska Board of Pharmacy under Case No 170216 RP issued an Order on February 7, 2017 adopting the Agreed Settlement regarding PIC Steven A. Levin for failure to disclosure his1983 conviction and the 2012 California Board of Pharmacy administrative action. A copy of the order of agreed settlement is attached.
- 4. The California Board of Pharmacy under Cased No 5704 instituted an accusation on February 13, 2017 against Woodland Hills Pharmacy and its RPIC Steven A. Levin for the sale of adulterated drugs and for failure to properly store and deliver compounded medication. A copy of the accusation is attached. The matter is currently pending.

1 2 3 4 5 6 7 8	XAVIER BECERRA Attorney General of California MARC D. GREENBAUM Supervising Deputy Attorney General ZACHARY T. FANSELOW Deputy Attorney General State Bar No. 274129 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 897-2562 Facsimile: (213) 897-2804 Attorneys for Complainant BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA				
10	In the Matter of the Accusation Against: Case No. 5704				
11 12	ALGUNAS INC. DBA WOODLAND HILLS PHARMACY, STEVEN A. LEVIN PRESIDENT 20631 Ventura Blvd., Ste. 305				
13	Woodland Hills, CA 91364 STEVEN A. LEVIN, Pharmacist-in-Charge				
14	Original Permit No. PHY 50815				
15 16	STEVEN A. LEVIN Algunas Road Woodland Hills, CA 91364				
17	Original Pharmacist License No. RPH 46443				
18	Respondents.				
19 20	Complainant alleges:				
21	PARTIES				
22	1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity				
23	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.				
24	2. On or about February 1, 2012, the Board of Pharmacy issued Original Permit Number				
25	PHY 50815 to Algunas Inc., doing business as Woodland Hills Pharmacy, with Steven A. Levin				
26					
27					
28	will expire on February 1, 2018, unless renewed.				
	(ALGUNAS INC. DBA WOODLAND HILLS PHARMACY; STEVEN A. LEVIN) ACCUSATION				

pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

- 9. Section 4169 states, in pertinent part:
- "(a) A person or entity shall not do any of the following:

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250)

of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code."

10. 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 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, or 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."
 - 11. Section 4307 states, 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."
- "(a) 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).
- "(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006 shall be subject to punishment in the same manner as is provided in Sections 4321 and 4336."
- 13. Health and Safety Code section 111285 states: "Any drug or device is adulterated if its strength differs from, or its purity or quality is below, that which it is represented to possess."

REGULATORY PROVISIONS

14. California Code of Regulations, title 16, section 1735.2, subdivision (j), states: "The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation."

COST RECOVERY

15. Section 125.3 states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

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DANGEROUS DRUGS

16. Amphotericin, brand names AmBisome, Fungizone, and Amphocin, is a dangerous drug pursuant to Business and Professions Code section 4022.

FACTUAL BACKGROUND

- 17. On or about November 28, 2014, the Board received a complaint from S.C. regarding her prescription for amphotericin filled at Respondent Pharmacy. In her complaint, S.C. alleged that after she moved to Hawaii, it took five days for her amphotericin prescription to arrive from Respondent Pharmacy and the amphotericin was shipped without ice. Within three days of taking the amphotericin, S.C. alleged that she had trouble breathing. S.C. notified Respondent Levin but continued to have problems properly receiving the medication. S.C. alleged that a shipment of amphotericin she received in June was again shipped without ice and did not work, and another shipment of amphotericin she received in November was shipped with no ice and did not work, causing her to have difficulty breathing. S.C. then submitted her complaint to the Board.
- 18. On or about May 11, 2015, a Board inspector performed a complaint investigation at Respondent Pharmacy. Respondent Levin was present during the investigation and told the Board inspector the amphotericin solution was compounded at the pharmacy, that it was not shipped with ice, but included instructions to be refrigerated upon arrival.
- 19. During the investigation at Respondent Pharmacy, the Board inspector inspected the pharmacy's refrigerator and found a compounded preparation of amphotericin that was packaged in a plastic opaque bottle and not protected from light. The master formula for amphotericin requires that the compounded medication be refrigerated and protected from light. At the conclusion of the investigation, the board inspector requested that Respondent Levin provide a copy of laboratory testing results for the compounded amphotericin within fourteen days.
- 20. On or about May 18, 2015, the Board inspector spoke with Respondent Levin who stated that he received laboratory test results for the compounded amphotericin, but that the compounded amphotericin had only a sixty (60) percent potency. Potency range must be within plus or minus ten (10) percent of the expected potency to be acceptable. Respondent Levin stated

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that he would revise his policies and procedures for preparing amphotericin and obtain additional laboratory results.

21. On or about May 28, 2015, Respondent Levin faxed the Board inspector a written statement, wherein Respondent Levin admitted that after reviewing the master formula, he realized he made an error in obtaining solubility by heating the amphotericin solution instead of using a cold preparation process. Over the next month, Respondent Levin compounded additional amphotericin, with solution potency ranging from 83.3% to 125%. Respondent Levin was instructed to continue testing his samples to assure his master formula was reliable and to determine appropriate beyond use dating prior to dispensing the compound.

FIRST CAUSE FOR DISCIPLINE

(Sale of Adulterated Dangerous Drugs)

- 22. Respondent Pharmacy and Respondent Levin (collectively, Respondents") are subject to disciplinary action under section 4301, subdivisions (j), and (o), in conjunction with section 4169, subdivision (a)(2), and Health and Safety Code section 111285 in that Respondents sold adulterated dangerous drugs that did not conform to standards and tests as to quality and strength. The potency of the dangerous drugs sold by Respondents also deviated well outside of the acceptable range for the medication.
- 23. The circumstances of the violation include that between January 15, 2014, and May 8, 2015, Respondents dispensed at least 249 prescriptions of amphotericin that were found to be adulterated and lacking in potency. During the Board's inspection of Respondent Pharmacy on May 11, 2015, it was revealed that Respondents compounded amphotericin using incorrect procedures, including using a hot plate instead of a cold plate and that the final amphotericin preparation was packaged in a plastic polypropylene container which resulted in polymer degradation and caused the amphotericin to fail to meet its stated quality and strength. Complainant refers to, and by this reference incorporates, the allegations contained in paragraphs 17 through 21, as though set forth fully.

SECOND CAUSE FOR DISCIPLINE

(Failure to Properly Store and Deliver Compounded Medication)

- 24. Respondents are subject to disciplinary action under section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.2, subdivision (j), in that Respondents failed to properly store and deliver compounded amphotericin.
- 25. The circumstances of the violation include that between January 15, 2014, and May 8, 2015, Respondents dispensed at least 249 prescriptions of amphotericin that had not been properly stored and delivered. Respondent Pharmacy's master formula for the amphotericin solution required that the compounded medication be refrigerated and protected from light. However, the compounded medication was not packaged in a light sensitive container and was shipped without proper refrigeration. Complainant refers to, and by this reference incorporates, the allegations contained in paragraphs 17 through 21, as though set forth fully.

DISCIPLINARY CONSIDERATIONS

- 26. To determine the degree of discipline, if any, to be imposed on Respondent Levin, Complainant alleges the following:
- a. On or about January 4, 2012, the Board of Pharmacy issued Respondent Levin Citation Number CI 2011 50850, with a \$4,000.00 fine. Respondent Levin complied with the citation and it is final. The citation alleged the following violations:
- b. Respondent Levin, during a pharmacy Board inspection, failed to provide a written copy of the pharmacy's pharmacy technician job description and policies and procedures in violation of California Code of Regulations, title 16, section 1793.7, subdivision (d).
- c. Respondent Levin, during a pharmacy Board inspection, failed to provide a written copy of the pharmacy's theft and impairment policies and procedures in violation of section 4104, subdivisions (a) and (b).
- d. Respondent Levin allowed a clerk to transcribe new telephone prescriptions in violation of California Code of Regulations, title 16, section 1793.1, subdivision (a).

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- e. Respondent Levin failed to complete a compounding self assessment prior to allowing any drug product to be compounded in violation of California Code of Regulations, title 16, section 1735.2, subdivision (j).
- f. Respondent Levin failed to keep records of compounded drug products in violation of California Code of Regulations, title 16, section 1735.3, subdivision (a).
- g. Respondent Levin, during a pharmacy Board inspection, was found to have assigned an expiration date to a final compounded product that was beyond the expiration date of ingredients used to compound the product in violation of California Code of Regulations, title 16, section 1735.2, subdivision (h).

OTHER MATTERS

- 27. Pursuant to section 4307, if discipline is imposed on Original Permit Number PHY 50815 issued to Algunas Inc., doing business as Woodland Hills Pharmacy, then Algunas Inc., doing business as Woodland Hills Pharmacy, 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 50815 is placed on probation or until Original Permit Number PHY 50815 is reinstated if the license is revoked.
- 28. Pursuant to section 4307, if discipline is imposed on Original Permit Number PHY 50815 issued to Algunas Inc., doing business as Woodland Hills Pharmacy, while Steven A. Levin has been an officer and owner and had knowledge of, or knowingly participated in, any conduct for which Algunas Inc., doing business as Woodland Hills Pharmacy, was disciplined, Steven A. Levin 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 50815 is placed on probation or until Original Permit Number PHY 50815 is reinstated if the license 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:

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- 1. Revoking or suspending Original Permit Number PHY 50815, issued to Algunas Inc., doing business as Woodland Hills Pharmacy, with Steven A. Levin as the President, Pharmacist-in-Charge, and 100% shareholder;
- 2. Prohibiting Algunas Inc., doing business as Woodland Hills Pharmacy, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Permit Number PHY 50815 is placed on probation or until Original Permit Number PHY 50815 is reinstated if Original Permit Number PHY 50815 issued to Algunas Inc., doing business as Woodland Hills Pharmacy, is revoked;
- 3. Prohibiting Steven A. Levin from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Original Permit Number PHY 50815 is placed on probation or until Original Permit Number PHY 50815 is reinstated if Original Permit Number PHY 50815 issued to Algunas Inc., doing business as Woodland Hills Pharmacy, is revoked;
- Revoking or suspending Original Pharmacist License Number RPH 46443 to Steven
 A. Levin;
- 5. Ordering Algunas Inc., doing business as Woodland Hills Pharmacy, and Steven A. Levin 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: 2/13/17

VIRGINIA HEROLD

Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California
Complainant

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XAVIER BECERRA Attorney General of California 2 MARC D. GREENBAUM Supervising Deputy Attorney General GILLIAN E, FRIEDMAN 3 Deputy Attorney General 4 State Bar No. 169207 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 269-6294 Facsimile: (213) 897-2804 6 E-mail: Gillian.Friedman@doj.ca.gov 7 Attorneys for Complainant 8 BEFORE THE BOARD OF PHARMACY 9 DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA 10 11 In the Matter of the Accusation Against: Case No. 5704 12 ALGUNAS INC. DBA WOODLAND OAH No. 2017050144 HILLS PHARMACY, STEVEN A. LEVIN 13 PRESIDENT STIPULATED SETTLEMENT AND 20631 Ventura Blvd., Ste. 305 DISCIPLINARY ORDER 14 Woodland Hills, CA 91364 STEVEN A. LEVIN, Pharmacist-in-Charge 15 Original Permit No. PHY 50815 16 STEVEN A, LEVIN 17 Algunas Road Woodland Hills, CA 91364 18 Original Pharmacist License No. RPH 46443 19 Respondents. 20 21 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-22 23 entitled proceedings that the following matters are true: 24 **PARTIES** Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy 25 (Board). She brought this action solely in her official capacity and is represented in this matter by 26 Xavier Becerra, Attorney General of the State of California, by Gillian E. Friedman, Deputy 27 28 Attorney General. STIPULATED SETTLEMENT (5704)

2. Respondent Algunas Inc dba Woodland Hills Pharmacy with Steven A. Levin as President and Respondent Steven A. Levin Pharmacist in Charge (Respondents) are represented in this proceeding by attorney Noah Jussim, whose address is: Hinshaw & Culbertson LLP, 633 West 5th Street, 47th Floor, Los Angeles, California, 90071, Tel: 213-614-7326.

- 3. On or about February 1, 2012, the Board of Pharmacy issued Original Permit Number PHY 50815 to Algunas Inc., doing business as Woodland Hills Pharmacy, with Steven A. Levin as the President, Pharmacist-in-Charge, and 100% shareholder (Respondent Pharmacy). The Original Permit was in full force and effect at all times relevant to the charges brought herein and will expire on February 1, 2018, unless renewed.
- 4. On or about August 13, 1993, the Board of Pharmacy issued Original Pharmacist License Number RPH 46443 to Steven A. Levin (Respondent Levin). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on December 31, 2018, unless renewed.

JURISDICTION

5. Accusation No. 5704 was filed before the Board, and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on February 23, 2017. Respondents timely filed their Notice of Defense contesting the Accusation. A copy of Accusation No. 5704 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 6. Respondents have carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 5704. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.
- 7. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of

documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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

CULPABILITY

- 9. Respondents admit the truth of each and every charge and allegation in Accusation No. 5704.
- 10. Respondents agree that Original Permit Number PHY 50815 and Original Pharmacist License Number RPH 46443 are subject to discipline and they agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.
- pursuant to Business and Professions Code section 4301 subdivision (n) due to out of state discipline. The circumstances are that on May 2, 2017, Respondents entered into an Agreed Board Order #F-16-036 with the Texas State Board of Pharmacy whereby Respondents were required to pay an administrative penalty in the sum of \$1,000 for failing to disclose in their renewal of pharmacy license application the following: (a) the denial of Respondent Levin's reciprocity application for licensure as a pharmacist by the Alabama State Board of Pharmacy on January 25, 2015 based upon discipline by the California Board and a 1983 conviction for transportation/ sale of marijuana in Long Beach, California; (b) a Consent Order with the Oregon State Board of Pharmacy on April 28, 2015 following Respondent Levin's application for licensure as a Pharmacist. The Consent Order required Respondent Levin to pay a fine and complete three hours of continuing education due to his arrest for the transport/sale of marijuana; and (c) the denial of Respondent Pharmacy's nonresident pharmacy permit on September 3, 2015 with the South Carolina State Board of Pharmacy due to testimony received by that board from Respondent Levin relating to the compounding of pain medications.
- 12. Respondents admit the truth of each and every charge and allegation set forth in paragraph 11 above.

understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

- 14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.
- 15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER AGAINST ALGUNAS INC DBA WOODLAND HILLS PHARMACY

IT IS HEREBY ORDERED that Original Permit Number PHY 50815 issued to Algunas Inc., doing business as Woodland Hills Pharmacy with Steven A. Levin as the President, Pharmacist-in-Charge, and 100% shareholder (Respondent Pharmacy) is revoked. However, the revocation is stayed and Respondent Pharmacy is placed on probation for four (4) years on the

following terms and conditions.

1. Obey All Laws

Respondent owner shall obey all state and federal laws and regulations.

Respondent owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the

 Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Pharmacy Permit or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the

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board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent owner shall jointly and severally with Respondent Levin be responsible to pay to the Board its costs of investigation and prosecution in the amount of \$7870.50. Costs may be paid on a payment plan approved in writing by the board. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent owner shall not relieve respondent of his responsibility to reimburse the board its costs of investigation and prosecution.

6. Probation Monitoring Costs

Respondent owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. Status of License

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent owner's license expires or is cancelled by operation of law or otherwise at any

time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondent owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondent owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondent owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

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9. Notice to Employees

Respondent owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondent owner shall submit written notification to the board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondent or respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. Posted Notice of Probation

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

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12. Violation of Probation

 If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent owner violates probation in any respect, the board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

13. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent license will be fully restored.

14. Consultant for Owner or Pharmacist-In-Charge

If during the period of probation Respondent Levin serves as a pharmacist-in-charge, Respondent Pharmacy shall retain an independent consultant at its own expense who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by respondent with the obligations of a pharmacist-in-charge. The consultant shall be a pharmacist licensed by and not on probation with the board and whose name shall be submitted to the board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. The Consultant must have compounding experience. Respondent shall not be a pharmacist-in-charge at more than one pharmacy. Failure to timely retain, seek approval of, or

ensure timely reporting by the consultant shall be considered a violation of probation.

During the period of probation, the board or its designee retains the discretion to reduce the frequency of the pharmacist consultant's review of Respondent Pharmacy's operations.

15. Remedial Education

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to compounding for all pharmacy staff involved in compounding. The program of remedial education shall consist of at least six (6) hours and shall be completed within six months of probation at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require pharmacy staff of the respondent, at respondent pharmacy's expense to take an approved examination to test the respondent's knowledge of the course. If the pharmacy staff does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

DISCIPLINARY ORDER AGAINST PHARMACIST STEVEN A. LEVIN

IT IS HEREBY ORDERED that Original Pharmacist License Number RPH 46443 to Steven A. Levin (Respondent Levin) is revoked. However, the revocation is stayed and Respondent Levin is placed on probation for four (4) years on the following terms and conditions.

16. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

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- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's Pharmacy license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

17. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

18. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

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Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

Continuing Education 20.

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

21. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 5704 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause their direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5704, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify their direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 5704 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause their direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that they has read the decision in case number 5704

and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

22. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board other than Algunas Inc., doing business as Woodland Hills Pharmacy nor serve as a consultant, unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

23. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent Levin shall pay to the board its costs of investigation and prosecution in the amount of \$7,870.50.

Respondent Levin shall be jointly and severally responsible for payment of costs with Respondent Pharmacy. Costs may be paid on a payment plan approved in writing by the board.

Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to reimburse the board its costs of investigation and prosecution.

24. Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as

directed by the board or its designee, Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

25. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

26. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender their license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish their pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

27. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new

~ / employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(cs), or phone number(s) shall be considered a violation of probation.

28. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

29. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until

all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

30. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

31. Restricted Practice

Respondent shall be restricted from the practice of pharmacy compounding until he has satisfactorily completed a Board approved remedial compounding course (Live attendance required course) and must do so within one year of the effective date. Respondent must complete at least six (6) hours of compounding related courses prior to resuming compounding activities. Respondent shall submit proof satisfactory to the board of compliance with this term of probation.

32. Community Services Program

Within sixty (60) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, a community service program in which respondent shall provide free health-care related services on a regular basis to a community or charitable facility or agency for at least thirty-two (32) hours per year within one year of the effective date. Within thirty (30) days of board approval thereof, respondent shall submit documentation to the board demonstrating commencement of the community service program. A record of this notification must be provided to the board upon request. Respondent shall report on progress with the community service program in the quarterly reports. Failure to timely submit, commence, or

comply with the program shall be considered a violation of probation.

33. Remedial Education

Within sixty (60), days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to compounding. The program of remedial education shall consist of at least six (6) hours, which shall be completed yearly at respondent's own expense. At least 50% of the training must be in person training. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at their own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

Respondent shall be restricted from the practice of compounding until the initial six (6) hours of remedial education program has been successfully completed.

34. No Ownership of Licensed Premises

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

35. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Noah Jussim, Esq., Hinshaw & Culbertson LLP. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 1/3/17

STEVEN A. LEVIN,

President & Pharmacist in Charge

ALGUNAS INC DBA WOODLAND HILLS

PHARMACY, Respondent

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Noah Jussim, Esq., Hinshaw & Culbertson LLP. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 11/3/17

STEVEN A. LEVIN Respondent

Į	I have read and fully discussed with Respondents Algunas Inc dba Woodland Hills
2	Pharmacy with Steven A. Levin as President, Pharmacist in Charge and Steven A. Levin,
3	Pharmacist the terms and conditions and other matters contained in the above Stipulated
4	Settlement and Disciplinary Order. I approve its form and content.
5	DATED: 11/3/17 Va
6	NoalyJussim, Esq. Hinshaw & Culbertson LLP
7	Attorneys for Respondent
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9	<u>ENDORSEMENT</u>
10	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully
11	submitted for consideration by the Board of Pharmacy. Dated: 1 2 Respectfully submitted.
1	11 3 1 7
12	XAVIER BECERRA Attorney General of California
13	MARC D. GREENBAUM Supervising Deputy Attorney General
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15	GHIAN E FRANKA
16	GILLIAN E. FRIEDMAN Deputy Attorney General
17	Attorneys for Complainant
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20	LA2016500082 12868526.doc
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Renewal Application

Section 1:

Since your last renewal or recent licensure have you: (Please fill in completely)

Been diagnosed or treated for any mental illness, including alcohol or substance abuse, or Physical condition that would impair your ability to perform the essential functions of your license?

- Yes

 No
- Been charged, arrested or convicted of a felony or misdemeanor in any state?

○ Yes **②** No

Upload Supporting Doc.

2. Been the subject of a board citation or an administrative action whether completed or pending in any state?

On or about April 8, 2016, the California State Board of Pharmacy initiated disciplinary proceedings against me and my former employer, Institutional



Upload Supporting Doc.

(Includes/Uploads/)

3. Had your license subjected to any discipline for violation of pharmacy or drug laws in any state?

O Yes • No	Upload Supporting Doc.
	he numbered questions (1-3) above, include the following e of an answer please type unknown.Please be as complete as
Board Administrative Action State:	:
CA	
Date:	
04/08/2016	
Case#:	
5240	
Criminal Action: State:	
Date:	
Case#:	
County:	
Court:	
Section 2:	urt order for the support of a child?
2. IF you marked YES to the qu ○ Yes ○ No	uestion above, are you in compliance with the court order?

Section 3:

Continuing	Education	Certification:
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Calculation=1.25 hours per month

Date Range= 11/01/2015 - 10/31/2017

- 1. Pharmacists are exempt from completing CE for the first 2 years after graduation. Did you graduate within the last 2 years?
 - Yes

 No
- 2. If you answered No to CE question 1 above, have you completed all YOUR required number of Continuing Education hours, including 1 hour in an approved NV law program if living or practicing in Nevada? (If you are a pharmacist practicing out-of-state and are currently in compliance with that state's continuing education requirements please select Yes.)
- Yes No

Section 4:

Though it is NOT required to have, SB21 required the Board to ask if you have a Nevada State Business license and if you do, please provide the number

NON-DISCIPLINARY STATE-MANDATED QUESTIONS:

1. Though it is **NOT** required to have, SB21 requires the Board to ask if you have a Nevada State Business license and if you do, please provide the

CA

Leave blank if non-applicable.

- 2. Have you ever served in the military, either active, reserve or retired?
 - Yes

 No

State:

From Date	
To Date	
· · · · ·	•
Section 5:	
misrepresentation. I hereby contact the statements made are true and guidelines of the Centers for Exansmission of infectious age understand that Nevada law resecupational capacity, comestand that paccupational capacity comes are true and capacity capacity.	to falsify this application and sanctions will be imposed for ertify that I have read this application. I certify that all correct. I attest to knowledge of and compliance with the disease Control and Prevention concerning the prevention of ints through safe and appropriate injection practices. I equires a licensed pharmacist who, in their professional or to know or has reasonable cause to believe, a child has been the abuse/neglect to an agency which provides child welfare rement agency.
☑ Yes, I Agree	
✓ Yes, I Agree	
Yes, I Agree Type your First Name and Last	Name to Agree
1	Name to Agree

1 2 3 4 5 6 7	XAVIER BECERRA Attorney General of California SHAWN P. COOK Supervising Deputy Attorney General ALVARO MEJIA Deputy Attorney General State Bar No. 216956 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 269-6284 Facsimile: (213) 897-2804 Attorneys for Complainant	THE		
8	BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA			
10	In the Matter of the Accusation Against:	Case No. 5240		
11	MINH TRI VAN NGUYEN Halsey Ave.	OAH No. 2017090875		
13	New Orleans, LA 70114	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER		
14	Pharmacist License No. RPH 61858 Respondent.			
15	respondent.			
16 17	IT IS HEREBY STIPULATED AND AGRI	EED by and between the partie	es to the above-	
18	entitled proceedings that the following matters are			
19	PART	TIES		
20	Virginia Herold (Complainant) is the land.	Executive Officer of the Board	l of Pharmacy	
21	(Board). She brought this action solely in her offi	cial capacity and is represente	d in this matter by	
22	Xavier Becerra, Attorney General of the State of C	California, by Alvaro Mejia, D	eputy Attorney	
23	General.			
24	2. Minh Tri Van Nguyen (Respondent) i	s represented in this proceeding	g by attorney	
25	Ivan Petrzelka, whose address is: California Phar	macy Lawyers, 49 Discovery,	Suite 240, Irvine,	
26	CA 92618-6713.			
27	3. On or about October 23, 2008, the Bo	ard issued Pharmacist License	No. RPH 61858	
28	to Respondent Minh Tri Van Nguyen. The Pharm	acist License was in full force	and effect at all	

28 | /

basis for the charges in the Accusation, and that Respondent hereby gives up his right to contest those charges.

11. Respondent agrees that his Pharmacist License is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

- 12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.
- 14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 61858 issued to Respondent Minh Tri Van Nguyen is revoked. However, the revocation is stayed and Respondent is placed on probation for three (3) years on the following terms and conditions.

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any
 criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency
 which involves respondent's pharmacist license or which is related to the practice of
 pharmacy or the manufacturing. obtaining, handling, distributing, billing, or charging
 for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in Accusation Case Number 5240 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in Accusation Case Number 5240, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in Accusation Case Number

5240 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he has read the decision in Accusation Case Number 5240 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of \$5,000.00. Respondent shall make said payments as follows: Installments of no less than \$166.66 per month beginning in the month following the effective date of this decision and continuing until paid in full.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to reimburse the board its costs of investigation and prosecution.

9. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted.

Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

12. Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s). name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of forty (40) hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of forty (40) hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least forty (40) hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least forty (40) hours as a pharmacist as defined by Business and Professions Code section 4000 et seq.

14. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

16. Remedial Education

Within ninety (90) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to pharmacy law, sterile compounding, and the role of a pharmacist-in-charge. The program of remedial education shall consist of at least 6 hours per year (50% must be in-person training), which shall be completed annually (total of 18 hours), at respondent's own expense. All remedial

education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for license renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof. in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at his own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

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1	ACCEPTANCE				
2	I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully				
3	discussed it with my attorney, Ivan Petrzelka. I understand the stipulation and the effect it will				
4	have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order				
5	voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the				
6	Board of Pharmacy.				
7 8	DATED: 18/2018 14. D				
9	MINH TRI VAN NGUYEN Respondent				
10	I have read and fully discussed with Respondent Minh Tri Van Nguyen the terms and				
11	conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.				
12	I approve its form and content.				
13	DATED: January 19, 2018				
14	DATED: January 19, 2018				
15	IVAN PETRZELAK Attorney for Respondent				
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STIPULATED SETTLEMENT (Case No. 5240)

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated:

1/24/2018

Respectfully submitted.

XAVIER BECERRA Attorney General of California

SHAWN P. COOK

Supervising Deputy Attorney General

ALVARO METIA

Deputy Attorney General Attorneys for Complainant

DOJ Matter ID: LA2014512809 52759178.docx

- 11					
1	KAMALA D. HARRIS Attorney General of California				
2	Armando Zambrano Supervising Deputy Attorney General				
3	ALVARO MEJIA				
4	Deputy Attorney General State Bar No. 216956				
5	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013				
6	Telephone: (213) 897-0083 Facsimile: (213) 897-2804				
7	Attorneys for Complainant	אונצותי הופ			
8	BEFORE THE BOARD OF PHARMACY				
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA				
10		Crar No. 5240			
11	In the Matter of the Accusation Against:	Case No. 5240			
12	INSTITUTIONAL PHARMACY SOLUTIONS	ACCUSATION			
13	6520 N. Irwindale Ave., Ste 228 Irwindale, CA 91702	ACCUSATION			
14	Pharmacy Permit No. PHY 50371,	·			
15	and				
16	MINH TRI VAN NGUYEN Halsey Ave.				
17	New Orleans, LA 70114				
18	Pharmacist License No. RPH 61858				
19	Respondent.	j			
20					
21	Complainant alleges:	, .,			
22		RTIES			
23	1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity				
24	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.				
25	2. On or about October 7, 2010, the Board of Pharmacy issued Pharmacy Permit				
26	Number PHY 50371 to Institutional Pharmacy Solutions ("Respondent Institutional Pharmacy").				
27	The Pharmacy Permit was in full force and effect at all times relevant to the charges brought				
28	herein and will expire on October 1, 2016, unles	ss renewed.			
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1				
	In the Matter of the Accusation Against: Institutional Pharmacy Solutions and Minh Tri Van Nguyen (Case No 5240)				

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STATUTES AND REGULATIONS

7. Section 4301 of the Code states, in pertinent part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

- "(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.
- "(j) The violation of any of the statutes of this state, or 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."
 - 8. Section 4076 of the Code states, 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."
 - 9. California Code of Regulations, title 16, section 1717.3 states:
- "(a) No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank.

"(b) A person may dispense a dangerous drug, that is not a controlled substance, pursuant to a preprinted multiple checkoff prescription blank and may dispense more than one dangerous drug, that is not a controlled substance, pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs he or she has prescribed.

"(c) "Preprinted multiple checkoff prescription blank," as used in this section means any form listing more than one dangerous drug where the intent is that a mark next to the name of a drug i.e., a "checkoff," indicates a prescription order for that drug."

- 10. California Code of Regulations, title 16, section 1735.2, subdivision (h) states:
- "(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."
 - 11. California Code of Regulations, title 16, section 1735.3, subdivision (a) states:
 - "(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. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia--National

Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

- "(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.
- 12. California Code of Regulations, title 16, section 1735.6 states:
- "(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products.

 Where applicable, this shall include records of certification(s) of facilities or equipment.
- "(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."
 - 13. United States Code, title 21, section 353 states, in pertinent part:
 - "(c) Sales restrictions.
- "(1) No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. For purposes of this paragraph and subsection (d), the term "drug sample" means a unit of a drug, subject to subsection (b), which is not intended to be sold and is intended to promote the sale of the drug. Nothing in this paragraph shall subject an officer or executive of a drug manufacturer or distributor to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade in violation of this paragraph by other employees of the manufacturer or distributor.
 - "(d) Distribution of drug samples.

///

- "(1) Except as provided in paragraphs (2) and (3), no person may distribute any drug sample. For purposes of this subsection, the term "distribute" does not include the providing of a drug sample to a patient by a--
 - "(A) practitioner licensed to prescribe such drug,
- "(B) health care professional acting at the direction and under the supervision of such a practitioner, or
- "(C) pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner and that received such sample pursuant to paragraph (2) or (3).
- "(2) (A) The manufacturer or authorized distributor of record of a drug subject to subsection (b) may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or other health care entities. . . ."
 - 14. Code of Federal Regulations, title 21, section 1306.04 states:
- "(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
- "(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.
- "(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the

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Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter."

COST RECOVERY

15. 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.

CONTROLLED SUBSTANCE

16. Ketamine is a Schedule III controlled substance pursuant to Health and Safety Code section 11056, subdivision (g) and is a dangerous drug pursuant to Business and Professions Code section 4022.

FIRST CAUSE FOR DISCIPLINE

(Unlawful Use of Pre-Printed, Multi-Check Off Prescription Blanks for Controlled Substances)

Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1717.3, on the grounds of unprofessional conduct in that during routine Board inspections of Respondent Institutional Pharmacy on November 15, 2012 and January 9, 2013, a Board Inspector discovered that Respondent Institutional Pharmacy accepted prescription orders for compounded drugs containing Ketamine, a Schedule III controlled substance, on pre-printed, multiple check-off prescription blanks. Multiple dangerous drugs were dispensed by the Respondents pursuant to the prescription blanks, but the prescriber did not indicate on the prescription blanks the number of dangerous drug that he or she had prescribed. 1// 111

SECOND CAUSE FOR DISCIPLINE

(Fraud or Deceit)

18. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivisions (f) and (g) on the grounds of unprofessional conduct in that during a routine Board inspection of Respondent Institutional Pharmacy on November 15, 2012, a Board Inspector discovered that Respondent Institutional Pharmacy had pre-printed order forms listing compounded formulations giving indications (i.e., uses of the compounded drug product) not approved by the Federal Drug Administration.

THIRD CAUSE FOR DISCIPLINE

(Improper Distribution of Drug Samples)

19. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (j), in conjunction with United States Code, title 21, section 353, subdivisions (c) and (d), on the grounds of unprofessional conduct in that Respondent Institutional Pharmacy distributed samples of drugs to prescribers at no charge. Applicable rules and regulations prohibit the distribution of drug samples by anyone other than: (1) practitioners licensed to prescribe such drugs; (2) health care professionals acting at the direction and under the supervision of such a practitioner; (3) a pharmacy of a hospital or of another health care entity that is acting at the direction of such a practitioner; or (4) the manufacturer or authorized distributor of record of the drug. Respondent Pharmacy does not fall into any of these categories. Nevertheless, as a result of a routine Board inspection of Respondent Institutional Pharmacy on November 15, 2012 and subsequent investigation, a Board Inspector discovered that Respondent Institutional Pharmacy distributed unauthorized samples of multiple compounded drugs. Furthermore, during 2012, Respondent Institutional Pharmacy sent sales representatives to make presentations about Respondent Institutional Pharmacy's products, specifically cancer chemotherapy drugs, and subsequently distributed by mail, samples of the products to attendees of the presentations.

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FOURTH CAUSE FOR DISCIPLINE

(Dispensing Controlled Substances Without a Prescription)

20. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (j), in conjunction with Code of Federal Regulations, title 21, section 1306.04, on the on the grounds of unprofessional conduct in that on or about November 15, 2012, a routine Board inspection of Respondent Institutional Pharmacy revealed that the pharmacy dispensed a compounded drug product, to wit, Rx# 102530, containing Ketamine, a Schedule III controlled substance, for the purpose of supplying an individual practitioner a prescription to be generally dispensed to patients.

FIFTH CAUSE FOR DISCIPLINE

(Compounding Facilities and Equipment)

21. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.6, in that on or about November 15, 2012, a routine Board inspection of Respondent Institutional Pharmacy revealed that the equipment in Respondent Institutional Pharmacy was not maintained according to manufacturer's specifications.

Respondent Institutional Pharmacy was using alcohol to clean the powder hood and scale when the manufacturer's manual stated, "10% bleach/water or acrylic cleaner. No solvents of any kind." The routine inspection also revealed that the calibration and cleaning of equipment was not documented and that the weighing scale and powder hood showed powder residue under the scale platform and the side walls of the hood.

SIXTH CAUSE FOR DISCIPLINE

(Prescription Container Not Meeting Labeling Requirements)

22. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with Code section 4076, subdivision (a)(7), on the grounds of unprofessional conduct in that on or about January 9, 2013, a routine Board inspection of Respondent Institutional Pharmacy revealed that the prescription containers labels failed to indicate the strength of the drugs dispensed.

SEVENTH CAUSE FOR DISCIPLINE

(No Expiration Date for Compounded Drugs)

23. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.2, subdivision (h), on the grounds of unprofessional conduct in that on or about January 9, 2013, a routine Board inspection of Respondent Institutional Pharmacy revealed that the compounding worksheet for Lot #551 for peripheral neuropathy cream, dispensed as RX #103382, did not have an expiration date.

EIGHTH CAUSE FOR DISCIPLINE

(Improper Record Keeping of Compounded Drugs)

24. Respondent Institutional Pharmacy and Respondent Nguyen are subject to disciplinary action under Code section 4301, subdivision (o), in conjunction with California Code of Regulations, title 16, section 1735.3, subdivision (a)(1), on the grounds of unprofessional conduct in that on or about January 9, 2013, a routine Board inspection of Respondent Institutional Pharmacy revealed that the master formula record for Lot #1331 was not available.

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 50371, issued to Institutional Pharmacy Solutions;
- 2. Revoking or suspending Pharmacist License Number RPH 61858, issued to Minh Tri Van Nguyen;
- 3. Ordering Respondent Institutional Pharmacy Solutions 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;
- 4. Ordering Respondent Minh Tri Van 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;

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