EDMUND G. BROWN JR.
Attorney General of California
MARC D. GREENBAUM
Supervising Deputy Attorney General
NICHOLAS A. SANCHEZ
Deputy Attorney General
State Bar No. 207998
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 897-2542
Facsimile: (213) 897-2804

Attorneys for Complainant

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

In the Matter of the Accusation Against: **NM TH PHARMACEUTICALS INC., dba HOLT PHARMACY, GIANG L. HA, President and Pharmacist-in-Charge** **1101 E. Holt Ave., #F** **Pomona, CA 91767** **Original Pharmacy Permit No. PHY 49084** **and** **GIANG L. HA** **761 Guadalupe Dr.** **Upland, CA 91786** **Original Pharmacist License No. RPH 57897** Respondents.	Case No. 3593 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On or about August 4, 2008, the Board issued Original Pharmacy Permit No. PHY 49084 to NM TH Pharmaceuticals Inc. to do business as Holt Pharmacy, Giang L. Ha, President and Pharmacist-In-Charge (Respondent Pharmacy). The Original Pharmacy Permit was in full

force and effect at all times relevant to the charges brought herein and will expire on August 1, 2010, unless renewed.

Giang L. Ha is and has been the President and Pharmacist-In-Charge since August 4, 2008.

3. On or about November 23, 2005, the Board issued Original Pharmacist License No. RPH 57897 to Giang L. Ha (Respondent Ha). The Original Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2011, unless renewed.

JURISDICTION

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

5. Section 118, subdivision (b), of the Code provides that the suspension, expiration, surrender, or cancellation of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

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

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

8. Section 4402(a) of the Code provides that any license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall be canceled by operation of law at the end of the three-year period.

STATUTORY PROVISIONS

9. Section 4081 of the Code states, in pertinent part:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A

current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

"(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section."

. . .

10. Section 4105 of the Code provides, in pertinent part, that all records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form for a period of three years from the date of making.

11. Section 4113, subdivision (b) of the Code states:

"The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

12. Section 4126.5 of the Code provides, in pertinent part, that a pharmacy may furnish dangerous drugs only to: (1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired; (2) The pharmaceutical manufacturer from whom the dangerous drug was acquired; (3) A licensed wholesaler acting as a reverse distributor; (4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care; (5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law; (6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs; or (7) Another pharmacy under common control. "Common control" means the power to direct or cause the direction of the management and policies of another, by ownership, voting rights, contract, or other means.

///

13. 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:

. . .

"(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

"(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

"(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."

. . .

///

14. Section 4332 of the Code states:

"Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor."

REGULATORY PROVISIONS

15. California Code of Regulations, title 16, section 1717, states, in pertinent part:

"(a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.

"Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, store in a cool, dry place."

. . .

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

"'Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

"The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory."

17. California Code of Regulations, title 16, section 1761, states:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

///

"(b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose."

18. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

19. Title 21, Code of Federal Regulations, section 1307.11 (hereinafter "21 C.F.R. § 1307.11") provides in pertinent part that a practitioner who is registered to dispense a controlled substance may distribute (without being registered to distribute) a quantity of such substance to (1) another practitioner registered to dispense that substance for the purpose of general dispensing by the practitioner to patients, or to (2) a reverse distributor who is registered to receive such controlled substance(s).

20. Title 21, Code of Federal Regulations, section 1307.21 (hereinafter "21 C.F.R. § 1307.21") provides in pertinent part that any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the Special Agent in Charge of the Drug Enforcement Administration (DEA) in the area in which the person is located for authority and instructions to dispose of such substance. In the event of a properly-made request, the Special Agent in Charge shall authorize and instruct the applicant to dispose of the controlled substance by transfer to a person registered under the Drug Enforcement Act and authorized to possess the substance, by delivery to an agent of the DEA, by destruction in the present of an agent of the DEA or other authorized person, or by other appropriate means.

///

///

///

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

21. Section 4021 of the Code states:

"'Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

22. Section 4022 of the Code states, in pertinent part:

"'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self-use, except veterinary drugs that are labeled as such, 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."

23. Health and Safety Code section 11153 states, in pertinent part:

"(a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her 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. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use."

. . .

24. Phenergan with Codeine - a brand name formation of Promethazine with Codeine, is classified as a Schedule V controlled substance pursuant to Health and Safety Code section 11058, subdivision (c)(1), and is a dangerous drug within the meaning of Business and Professions Code section 4022.

25. Dilaudid - a trade name for the narcotic substance hydromorphone, is classified as a Schedule II controlled substance pursuant to Health and Safety Code section 11055, subdivision (b)(1)(k), and is a dangerous drug within the meaning of Business and Professions Code section 4022.

COST RECOVERY

26. Section 125.3 of the Code 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.

CHARGES AND ALLEGATIONS

27. On March 16, 2009, the Board received a call from the Bureau of Narcotic Enforcement (BNE) informing the Board that BNE had received a call from the Fort Worth Texas Police Department (FWPD). The FWPD stated they had found a shipment of 21 pints of Phenergan with Codeine, which was traced back to Respondent Pharmacy.

28. On or about October 28, 2009, a Board inspector conducted a routine inspection of Respondent Pharmacy and collected records. Respondent Ha was interviewed during the inspection and questioned where he stored the Phenergan with Codeine. Respondent Ha stated that he did not carry any Phenergan with Codeine and the Drug Enforcement Administration (DEA) accused him of some violations and he voluntarily surrendered his DEA registration and controlled substances on or about March 26, 2009.

29. The Board inspector requested Respondent Ha provide him with a controlled substance report from July 1, 2008, to present. Respondent Ha provided the Board inspector a controlled substance report that did not list any disposition of Phenergan with Codeine at Respondent Pharmacy, which Respondent Ha said was a mistake. Respondent Ha admitted that he deleted the Phenergan with Codeine prescriptions on Respondent Pharmacy's computer and he lost the prescriptions for Phenergan with Codeine. Respondent Ha admitted to the Board inspector he shredded the prescription documents.

///

30. The Board inspector requested Respondent Ha provide him copies of Respondent Pharmacy's opening controlled substances inventory and the DEA receipt for the controlled substances he surrendered. The Board inspector also requested all Respondent Pharmacy's invoices from all wholesalers for purchases of Phenergan with Codeine, brand and generic, from October 1, 2008 to March 26, 2009 and the opening controlled substance inventory. The Board inspector also conducted a drug audit of Respondent Pharmacy's acquisition and disposition of tablets of Dilaudid 4mg. The audit result indicated 643 pints of Phenergan with Codeine and 2,750 tablets of Dilaudid 4mg were unaccounted for.

FIRST CAUSE FOR DISCIPLINE

As to Respondents Ha and Pharmacy

(Failure to Meet Requirements for Maintaining an Accurate Inventory)

31. Respondents are subject to disciplinary action pursuant to Code sections 4301(j) and/or 4301(o) for violating Code section 4081(a) in conjunction with California Code of Regulations, title 16, section 1718, for failing to meet requirements for maintaining an accurate inventory. The circumstances are as follows:

a. Between June 14, 2008 to March 26, 2009, Respondents destroyed prescription documents and deleted computer records for Phenergan with Codeine and Dilaudid 4mg. The Board inspector's audit of Respondent Pharmacy indicated 643 pints of Phenergan with Codeine and 2,750 tablets of Dilaudid 4mg were unaccounted for.

SECOND CAUSE FOR DISCIPLINE

As to Respondents Ha and Pharmacy

(Obliteration of Computer Records and Production of False Records)

32. Respondents are subject to disciplinary action pursuant to Code sections 4301(j) and/or 4301(o) and/or 4332 for violating Code section 4070(c) in conjunction with California Code of Regulations, title 16, section 1718, for changing, obliterating, destroying, or disposing of, dangerous drug dispensing information. The circumstances are as follows:

a. Between June 14, 2008 to March 26, 2009, Respondents destroyed prescription documents, deleted computer records for Dilaudid 4mg and produced false records of the Daily

Log of Combined Scripts and drug utilization report (DUR). The Board inspector's audit of Respondent Pharmacy's computer records showed discrepancies for the following prescription numbers and dates:

1. Rx 640096, dated September 16, 2008, patient C.E.[1], was not on the DUR or log.
2. Rx 640097, dated September 17, 2008, patient R.S., was not on the DUR or log.
3. Rx 642949, dated October 20, 2008, patient C.E., was not on the DUR or log.
4. Rx 642954, dated October 20, 2008, patient A.N., was not on the DUR or log.
5. Rx 642955, dated October 20, 2008, patient S.B., was not on the DUR or log.
6. Rx 642955, dated October 20, 2008, patient J.S., was not on the DUR or log.
7. Rx 642962, dated October 20, 2008, patient R.S., was not on the DUR or log.

THIRD CAUSE FOR DISCIPLINE

As to Respondents Ha and Pharmacy

(Filling of Erroneous or Uncertain Prescriptions and

Failure to Assume Co Responsibility in Legitimacy of a Prescription)

33. Respondents Ha and Pharmacy are subject to discipline under Code sections 4301(j) and/or 4301(o) in conjunction with Health and Safety Code section 11153 and California Code of Regulations, title 16, section 1761, in that from June 14, 2008 to March 26, 2009, Respondent Ha continuously and excessively filled and dispensed Dilaudid 4mg prescriptions without a legitimate medical purpose, clearly falling below the standard of care of a reasonable prudent pharmacist. The circumstances are as follows:

a. On October 3, 2008, Respondents filled a prescription for Dilaudid 4mg from Doctor Nazar Al-Bussam (Dr. Al-Bussam) for patient L.D. Review of the patient and physician addresses revealed none of the patients or physicians either lived or practiced in the Pomona area.

b. On October 3, 2008, Respondents filled a prescription for Dilaudid 4mg from Dr. Al-Bussam for patient B.A. Review of the patient and physician addresses revealed none of the patients or physicians either lived or practiced in the Pomona area.

[1] Initials are used to protect the privacy of the patients. Full names will be provided following a request for discovery.

c. On October 3, 2008, Respondents filled a prescription for Dilaudid 4mg from Dr. Al-Bussam for patient J.J. Review of the patient and physician addresses revealed none of the patients or physicians either lived or practiced in the Pomona area.

d. On October 3, 2008, Respondents filled a prescription for Dilaudid 4mg from Dr. Al-Bussam for patient R.D. Review of the patient and physician addresses revealed none of the patients or physicians either lived or practiced in the Pomona area.

e. On October 3, 2008, Respondents filled a prescription for Dilaudid 4mg from Dr. Al-Bussam for patient S.J. Review of the patient and physician addresses revealed none of the patients or physicians either lived or practiced in the Pomona area.

f. On October 3, 2008, Respondents filled a prescription for Dilaudid 4mg from Dr. Al-Bussam for patient J.F. Review of the patient and physician addresses revealed none of the patients or physicians either lived or practiced in the Pomona area.

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 Original Pharmacy Permit No. PHY 49084, issued to NM TH Pharmaceuticals Inc. to do business as Holt Pharmacy, Giang L. Ha, President and Pharmacist-In-Charge.

2. Revoking or suspending Original Pharmacist License No. RPH 57897, issued to Giang L. Ha.

3. Ordering Holt Pharmacy and Giang L. Ha 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. Taking such other and further action as deemed necessary and proper.

DATED: 4/14/10

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