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

In the Matter of the Accusation Against: **GURPARTAP S. BASRAI, doing business as MEDICAL PAVILION PHARMACY** **9460 No Name Uno, Ste. 100** **Gilroy, CA 95020** **Original Permit License No. PHY 47105,** **and** **DAVID DONG KIEU** **1476 Myrtle Ave.,** **San Jose, CA 95118** **Pharmacist License No. RPH 61202** Respondents.	Case No. 5738 **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, Department of Consumer Affairs.

2. On or about July 27, 2005, the Board of Pharmacy issued Original Permit License Number PHY 47105 to Gurpartap S. Basrai to do business as Medical Pavilion Pharmacy ("Pharmacy MP Pharmacy"). The Original Permit License was in full force and effect at all

times relevant to the charges brought in this Accusation and will expire on July 1, 2016, unless renewed.

3. On or about July 24, 2008, the Board of Pharmacy issued Pharmacist License Number RPH 61202 to David Dong Kieu ("Respondent Kieu"). The Pharmacist License was in full force and effect at all times relevant to the charges brought in this Accusation and will expire on August 31, 2017, unless renewed. Since June 1, 2010, Respondent Kieu served as Respondent MP Pharmacy's Pharmacist-in-Charge ("PIC").

JURISDICTION

4. 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.

5. Section 118, subdivision (b) states:

"(b) The suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground."

6. Section 4300 of states, in part:

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

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

"(1) Suspending judgment.

"(2) Placing him or her upon probation.

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

"(4) Revoking his or her license.

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

. . .

"(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure."

RELEVANT STATUTES AND REGULATIONS

7. Health and Safety Code section 111335 states:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

8. Health and Safety Code section 111375 states, in part:

"Any drug or device is misbranded unless its labeling bears all of the following information:

. . .

"(c) Adequate warning against unsafe dosage or methods or duration of administration or application.

"Warnings shall be in a manner and form as are necessary for the protection of users.

"If the department determines that any requirement of subdivision (a), as applied to any drug or device, is not necessary for the protection of the public health, the department may adopt regulations exempting the drug or device from these requirements.

Any drug or device exempted under Section 502(f) of the federal act (21 U.S.C. Sec. 352(f)) is exempt from the requirement of this section. The department, however, may adopt any regulation including a drug or device within, or excluding a drug or device from the requirements of this section, whether or not the inclusion or exclusion of the drug or device is in accord with the federal act."

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9. Health and Safety Code section 111400 states:

"Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling."

10. Section 4169 states, in part:

"(a) A person or entity shall not do any of the following:

. . .

"(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

. . . ."

11. Section 4301 states, in 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:

. . .

"(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.

. . . ."

12. Section 4306.5 states, in part:

"Unprofessional conduct for a pharmacist may include any of the following:

. . .

"(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.

. . . ."

COST RECOVERY

13. Section 125.3 provides, 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.

RELEVANT DRUG INFORMATION

14. "Domperidone," also known as Motilium, is an anti-dopaminergic drug which acts as an antiemetic and a prokinetic agent. It is used in many countries for the treatment of gastroparesis, a condition in which the stomach cannot empty itself of food in a normal fashion. Compounding with domperidone is not allowed in the United States with the exception of investigational new drug application filing. Only Dougherty's Pharmacy, located in Dallas, Texas, is approved to compound domperidone at this time. Distribution of any domperidone-containing products is illegal. The Federal Drug Administration ("FDA") has instructed its field personnel to detain shipments of domperidone and refuse its admission into the United States.

15. Domperidone is believed to promote lactation. But the drug is not approved in any country, including the United States, for promoting lactation. In fact, the FDA warns against using domperidone for promoting lactation. In particular, on June 7, 2004, the FDA published a talk paper titled "FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase Milk Production,"[1] in which it warns about the public risks associated with use of the drug:

> The [FDA] is concerned with the potential public health risks associated with domperidone. There have been several published reports and case studies of cardiac arrhythmias, cardiac arrest, and sudden death in patients receiving an intravenous form of domperidone . . . . In several countries where the oral form of domperidone continues to be marketed, labels for the product contain specific warnings against use of domperidone by breastfeeding women and note that the drug is excreted in breast milk that could expose a breastfeeding infant to unknown risks. Because of the possibility of serious adverse effects, FDA recommends that breastfeeding women not use domperidone to increase milk production.
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> . . .

[1] http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm173886.htm

> The letters issued by FDA today stated that all drug products containing domperidone (whether compounded or not) violate the Federal Food, Drug, and Cosmetic Act (the Act) because they are unapproved new drugs and misbranded. In addition, distribution within the U.S., or importation of domperidone-containing products, violates the law. FDA informed the warning letter recipients that further violations of the Act may result in enforcement actions including seizure and injunction.

16. On April 14, 2015, the Board issued a "subscriber alert" stating: "Domperidone is **not** FDA-approved for any use in humans in the United States. Drug products compounded using domperidone are subject to the approval requirements of the Federal Food, Drug, and Cosmetic Act."

17. The FDA currently permits patients of 12 years of age and older with various gastrointestinal conditions that are refractory to standard therapy to be treated with Domperidone through an Expanded Access Program. Physicians interested in obtaining expanded access to Domperidone must submit an investigational new drug application to the FDA. Currently, no pharmacies are authorized to compound Domperidone under the FDA's Expanded Access Program.

FACTUAL BACKGROUND

18. In August 2015, in response to an inquiry from a Board investigator, Respondent MP Pharmacy provided records showing that it had dispensed Domperidone as follows:

a. 3,000 capsules of Domperidone 10 mg, between April 23, 2015 and August 11, 2015;

b. 240 capsules of Domperidone 20 mg, between May 7, 2015 and 16, 2015;

c. 90 capsules of Domperidone 8 mg on June 12, 2015; and

d. 300 capsules of Domperidone 5 mg on May 29, 2015.

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19. In response to the same Board inquiry, in August 2015, Respondent Kieu, on behalf of Respondent MP Pharmacy, provided the following statement:

"A. Domperidone is not an FDA approved drug.

. . .

"E. From 4/15/15 to 8/25/15, 3630 capsules and 37.02 grams of domperidone were compounded and 3150 capsule (sic) and 32.52 grams of domperidone were dispensed [by Respondent MP Pharmacy]. None of the prescriptions were dispensed to breastfeeding mothers to increase lactation. They were all used for GI motility disorders.

. . . ."

FIRST CAUSE FOR DISCIPLINE
(Sale of Misbranded Drug)
(Bus. & Prof. Code § 4169, subd. (a)(3); and Health and Safety Code §§ 111335; 111375, subd. (c); and 111400)

20. Respondent MP Pharmacy and Respondent Kieu have subjected their Original Permit and Pharmacist Licenses, respectively, to disciplinary action for their trade, sale, or transfer of a dangerous drug that they knew or reasonably should have known was misbranded, as defined in Health and Safety Code section 111335. (Bus. & Prof. Code § 4169, subd. (a)(3); and Health and Safety Code §§ 111335; 111375, subd. (c); and 111400). The circumstances are set forth in paragraphs 14 through 19, above.

SECOND CAUSE FOR DISCIPLINE
(Failure to Exercise Professional Judgment)
(Bus. & Prof. Code § 4306.5, subd. (b))

21. Respondent MP Pharmacy and Respondent Kieu have subjected their Original Permit and Pharmacist Licenses, respectively, to disciplinary action for failing to exercise or implement their best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services. (Bus. & Prof. Code § 4306.5, subd. (b)). The circumstances are set forth in paragraphs 14 through 19, above.

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THIRD CAUSE FOR DISCIPLINE
(Unprofessional Conduct – Violation of the Law Governing Pharmacy)
(Bus. & Prof. Code § 4301, subd. (o); and Health and Safety Code §§ 111375, sub. (c), and 111400)

22. Respondent MP Pharmacy and Respondent Kieu have subjected their Original Permit and Pharmacist Licenses, respectively, to disciplinary action for unprofessional conduct by violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate applicable federal and state laws and regulations governing pharmacy. ((Bus. & Prof. Code § 4301, subd. (o); and Health and Safety Code § 111375, sub. (c), and 111400)). The circumstances are set forth in paragraphs 14 through 21, above.

DISCIPLINARY CONSIDERATIONS

23. To determine the degree of discipline, if any, to be imposed on Respondent MP Pharmacy, Complainant alleges that on or about October 5, 2011, in a prior action, the Board issued Citation Number CI 2009 42612 against Respondent MP Pharmacy for Dispensing Dangerous Drug in Incorrectly Labeled Container/Prescription Container – Requirements for Labeling/Protocol; Expiration Date; Physical Description (Bus. & Prof. Code § 4077, subd. (a) and 4076, subds. (a)(1), (a)(9), and (a)(11)(A)). The Citation is now final and incorporated by reference as if fully set forth.

PRAYER

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

1. Revoking or suspending Original Permit License Number PHY 47105, issued to Respondent MP Pharmacy;

2. Revoking or suspending Pharmacist License Number RPH 61202, issued to Respondent Kieu;

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3. Ordering Respondent MP Pharmacy and Respondent Kieu 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

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

DATED: 7/11/16

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

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