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

In the Matter of the Accusation and Petition to Revoke Probation Against: **MEDICAL DENTAL PHARMACY, INC.,** **dba MEDICAL DENTAL PHARMACY** **DIANA LYNN SMITH,** **aka DIANA SMITH** **aka DIANA MORTON,** **aka DIANA LYNN MORTON, CEO/PIC** **CAROLYN SMITH,** **aka CAROLYN ELIZABETH SMITH,** **TREAS/CFO** **689 E. Nees** **Fresno, CA 93720** **Pharmacy Permit No. PHY 44342,** **DIANA LYNN SMITH** **aka DIANA LYNN MORTON** **9798 N. Sunnyside Avenue** **Clovis, CA 93619** **Pharmacist License No. RPH 45423,** **and** **DAREK TERRELL JONES** **1218 E. Champlain Drive, #208** **Fresno, CA 93729** **Pharmacist License No. RPH 59702** **Respondents.**	Case No. 5547 **ACCUSATION AND PETITION TO REVOKE PROBATION** **(Petition as to Respondent Darek Terrell Jones only)**

Complainant alleges:

PARTIES

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

2. On or about August 13, 1999, the Board issued Pharmacy Permit Number PHY 44342 to Medical Dental Pharmacy, Inc. ("Respondent MDP"), doing business as Medical Dental Pharmacy, with Carolyn Smith, also known as Carolyn Elizabeth Smith, as chief financial officer and treasurer and Diana Lynn Smith, also known as (aka) Diana Lynn Morton, aka Diana Morton, aka Diana Smith ("Respondent Smith"), as secretary. On or about September 1, 2005, Respondent Smith became the pharmacist-in-charge. On or about January 25, 2010, Respondent Smith became the chief executive officer. The pharmacy permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2016, unless renewed.

3. On or about August 12, 1992, the Board issued Pharmacist License Number RPH 45423 to Respondent Smith. The pharmacist license was in full force and effect at all times relevant to the charges brought herein and will expire on May 31, 2016, unless renewed.

4. On or about July 3, 2007, the Board issued Pharmacist License Number RPH 59702 to Darek Terrell Jones ("Respondent Jones"). The pharmacist license was in effect at all times relevant to the charges brought herein and will expire on January 31, 2017, unless renewed.

5. In a disciplinary action entitled "In the Matter of the Accusation Against: Darek Terrell Jones," Case No. 3813, the Board issued a Decision and Order effective May 18, 2012, in which Respondent Jones' pharmacist license was revoked. However, the revocation was stayed and Respondent's pharmacist license was placed on probation for five (5) years with certain terms and conditions. Respondent was also suspended from the practice of pharmacy for ninety (90) days beginning on the effective date of the Decision.

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JURISDICTION AND STATUTORY PROVISIONS

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

7. Section 4300 states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

8. Section 4300.1 states:

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

9. Section 4301 states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
>
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency . . . .

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10. Section 4306.5 states in pertinent part:

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

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

(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.

(c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.

11. Section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

12. Section 4025 states:

> "Drug" means any of the following:
>
> (a) Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement of any of them.
>
> (b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.
>
> (c) Articles (other than food) intended to affect the structure or any function of the body of human beings or other animals.
>
> (d) Articles intended for use as a component of any article specified in subdivision (a), (b), or (c).

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

> The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and

Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

14. Health and Safety Code section 111335 provides that any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290.)

15. Health and Safety Code section 110290 states:

In determining whether the labeling or advertisement of a food, drug, device, or cosmetic is misleading, all representations made or suggested by statement, word, design, device, sound, or any combination of these, shall be taken into account. The extent that the labeling or advertising fails to reveal facts concerning the food, drug, device, or cosmetic or consequences of customary use of the food, drug, device, or cosmetic shall also be considered.

16. Health and Safety Code section 111330 states that [a]ny drug or device is misbranded if its labeling is false or misleading in any particular.

17. Health and Safety Code section 111400 provides that 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.

18. Health and Safety Code section 111440 provides that it is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

19. Health and Safety Code section 111450 provides that it is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

20. Health and Safety Code section 111550 provides, in pertinent part:

> No person shall sell, deliver, or give away any new drug or new device unless it satisfies either of the following:
>
> (a) It is one of the following:
>
> (1) A new drug, and a new drug application has been approved for it and that approval has not been withdrawn, terminated, or suspended under Section 505 of the federal act (21 U.S.C. Sec. 355).
>
> (b) The department has approved a new drug or device application for that new drug or new device and that approval has not been withdrawn, terminated, or suspended . . .

21. Section 201, subdivision (p), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 321, subdivision (p)), states, in pertinent part:

> The term "new drug" means--
>
> (1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the condition prescribed, recommended, or suggested in the labeling thereof . . .
>
> (2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

22. Title 21 United States Code section 352 states in pertinent part:

A Drug or device shall be deemed to be misbranded—

(f) Directions for use and warnings on label

> Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement. Required labeling for prescription devices intended for use in health care facilities or by a health care professional and required labeling for in vitro diagnostic devices intended solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

23. Section 505, subdivision (a), of the Act (21 U.S.C. section 355, subdivision (a)), states, in pertinent part, that ". . . [n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."

COST RECOVERY

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

DRUG

25. "Domperidone" is an anti-dopaminergic drug that acts as an antiemetic and a prokinetic agent. It is used relieve nausea and vomiting, and to increase lactation. It is a dangerous drug under Business and Professions Code section 4022. Domperidone is not currently a legally marketed human drug and is not approved for sale in the United States. The FDA has determined that any products containing domperidone are unapproved new drugs and misbranded. Consequently, any product containing domperidone violates the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.).

FACTUAL ALLEGATIONS

26. On or about June 7, 2004, the U.S. Food and Drug Administration ("FDA") issued a Talk Paper titled, "FDA Warns Against Women Using Unapproved Drug, Domperidone, to Increase Milk Production", warning breastfeeding women not to use the product because of safety concerns. The FDA stated that although domperidone was approved in several countries outside the U.S. to treat certain gastric disorders, it is not approved in any country, including the U.S., for enhancing breast milk production in lactating women and is also not approved in the U.S. for any indication.[1] The Talk Paper indicated that the FDA had issued six letters to pharmacies that compound products containing domperidone and firms that supply domperidone for use in compounding, stating that all drug products containing domperidone (whether compounded or not) violated the Federal Food, Drug and Cosmetic Act ("the Act") because they are unapproved new drugs and misbranded.

27. On or about June 7, 2004, the FDA issued a warning letter to Spectrum Chemicals & Laboratory Products. The FDA stated that their inspection of the firm revealed they were repacking and distributing bulk API (active pharmaceutical ingredient) domperidone for use in pharmacy compounding in violation of the Act. The FDA also stated that the drug's labeling did

[1] The FDA stated that there had been several published reports and case studies of cardiac arrhythmias, cardiac arrest, and sudden death in patients receiving an IV form of domperidone that had been withdrawn from marketing in a number of countries. Further, in several countries where the oral form of domperidone continued to be marketed, labels for the product contained specific warnings against use of domperidone by breastfeeding women.

not contain adequate directions for use and that domperidone was not an active ingredient contained in any FDA-approved drug product.

28. On or about April 9, 2010, the FDA issued a warning letter to Alexandria Medical Arts Pharmacy & Compounding Laboratory. The FDA found during their inspection of the firm that they had compounded domperidone products for human patients on numerous occasions. The FDA stated that the domperidone products compounded by the firm were new drugs as defined by section 201(p) [21 U.S.C. section 321(p)] of the Act and may not be introduced or delivered into interstate commerce under section 505(a) of the Act [21 U.S.C. section 355(a)] because no approval of an application filed pursuant to section 505 of the Act [21 U.S.C. section 335] is in effect for the products.

29. On or about March 12, 2012, the FDA issued Import Alert 61-07, stating that domperidone was being imported as a bulk API for pharmacy compounding and that importation of the drug presented a public health risk and violated the Act.

30. On or about March 20, 2015, the Board received a complaint, alleging that Respondent MDP was compounding domperidone.

31. On or about April 21, 2015, Board Inspectors conducted a routine inspection and complaint investigation of Respondent MDP's pharmacy and were assisted by Respondent Smith. The inspectors requested and obtained the pharmacy's compounding record for the past year and found that domperidone was being compounded for different strengths. One of the inspectors also located a 500 gram bulk container of domperidone powder inside the expired medication bin. The inspectors requested and obtained the pharmacy's domperidone dispensing record, compounding logs, and domperidone prescriptions filled within the last year. The inspectors asked Respondent Smith about the extent of domperidone compounding by the pharmacy. Respondent Smith stated that she stopped all domperidone compounding and dispensing activities upon receiving the domperidone alert from the Board, and placed the remaining bulk powder in the expired medication bin.

32. On or about May 27, 2015, Respondent Smith provided additional records to the Board.

33. Domperidone may be able to be compounded and dispensed if an Investigational New Drug (IND)Application is filed with the Federal Drug Administration (FDA) and approved. Respondents did not file an IND Application in order to compound or dispense domperidone.

34. The inspectors determined, based on the documents provided by Respondent Smith, that on and between April 21, 2014 and April 21, 2015, the pharmacy had compounded 32 batches and 3,400 capsules of various strengths of domperidone. 30 batches and 3,200 capsules had been compounded by Respondent Smith; 2 batches and 200 capsules had been compounded by Respondent Jones. The pharmacy had also dispensed approximately 47 prescriptions and 3,552 capsules to patients which were compounded from domperidone. Respondent Smith had dispensed approximately 43 of the prescriptions and approximately 3,288 of the capsules; Respondent Jones had dispensed approximately 4 of the prescriptions and approximately 264 of the capsules.

FIRST CAUSE FOR DISCIPLINE

(Failure to Exercise or Implement Best Professional Judgment or Corresponding Responsibility)

35. Respondents Smith and Jones are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5 subdivision (b), for failing to exercise or implement their best professional judgment or corresponding responsibility, by compounding and dispensing domperidone even though there was no IND Application approved by the FDA, as set forth in paragraphs 31-34, above.

SECOND CAUSE FOR DISCIPLINE

(Failing to Consult Appropriate Records)

36. Respondents Smith and Jones are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, as defined by Code section 4306.5 subdivision (c), for failing to consult appropriate records pertaining to compounding and dispensing domperidone even though there was no IND Application approved by the FDA, as set forth in paragraphs 31-34, above.

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THIRD CAUSE FOR DISCIPLINE

(Sold Misbranded Drugs)

37. Respondents MDP, Smith, and Jones are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301 subdivision (j), for violating statutes regulating controlled substances and dangerous drugs, in that Respondents sold misbranded drugs, as defined by Health & Safety Code sections 110290, 111330, and United States Code, title 21, section 352(f), in violation of Health and Safety Code section 111440, as set forth in paragraphs 31 through 34, above.

FOURTH CAUSE FOR DISCIPLINE

(Delivered or Proffered for Delivery Misbranded Drugs)

38. Respondents MDP, Smith, and Jones are subject to disciplinary action for unprofessional conduct pursuant to Code section 4301 subdivision (j), for violating statutes regulating controlled substances and dangerous drugs, in that Respondents delivered or proffered for delivery misbranded drugs, as defined by Health & Safety Code sections 110290, 111330, and 111400, in violation of Health and Safety Code section 111450, as set forth in paragraphs 31 through 34, above.

FIFTH CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and

Federal and State Laws Governing Pharmacy)

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

a. On and between April 21, 2014 and April 21, 2015, Respondents introduced or delivered for introduction into interstate commerce the drug, domperidone, by compounding and dispensing the drug to patients, as set forth in paragraph 34 above, when, in fact, there was no

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investigational new drug application ("IND") for domperidone approved by the FDA, in violation of 21 U.S.C. section 355, subdivision (a).

b. On and between April 21, 2014, and April 21, 2015, Respondents sold, delivered, or gave away the drug dromperidone by dispensing the drug to patients, as set forth in paragraph 34 above, when, in fact, there was no IND for domperidone approved by the FDA, in violation of Health and Safety Code section 111550.

PETITION TO REVOKE PROBATION

40. This Petition to Revoke Probation is brought before the Board under Probation Term and Condition Number 3 of the Decision and Order in the disciplinary action entitled, "In the Matter of the Accusation Against: Darek Terrell Jones", Case No. 3813. That term and condition states, in pertinent part, that Respondent shall obey all state and federal laws and regulations.

41. Respondent's probation is subject to revocation in that Respondent failed to obey all state and federal laws, as set forth in paragraph 26 above.

PRAYER

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

1. Revoking or suspending Pharmacy Permit No. PHY 44342, issued to Medical Dental Pharmacy, Inc., doing business as Medical Dental Pharmacy;

2. Revoking or suspending Pharmacist License No. RPH 45423 , issued to Diana Lynn Smith, aka Diana Lynn Morton, aka Diana Morton and aka Diana Smith;

3. Revoking the probation that was granted by the Board of Pharmacy in Case No. 3813 and imposing the disciplinary order that was stayed, thereby revoking Pharmacist License No. RPH 59702 issued to Darek Terrell Jones;

4. Revoking or suspending Pharmacist License No. RPH 59702, issued to Darek Terrell Jones;

5. Ordering Medical Dental Pharmacy, Inc., doing business as Medical Dental Pharmacy, Diana Lynn Smith, aka Diana Lynn Morton, aka Diana Morton, and Diana Smith, and

Darek Terrell Jones 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: 3/18/16

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

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