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8
9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

11 In the Matter of the Accusation Against:

Case No. 4237

A C C U S A T I O N

12
13 **TRANG DOAN NGUYEN**
14 **aka TRACY NGUYEN aka**
DOANTRANG THI NGUYEN
15 **32 Gray Dove**
Irvine, CA 92618

16 **Designated Representative License No. EXC**
17 **17183**

18 Respondent.

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 September 9, 2003, the Board of Pharmacy issued Designated
25 Representative License Number EXC 17183 to Trang Doan Nguyen aka Tracy Nguyen aka
26 Doantrang Thi Nguyen (Respondent). The Designated Representative License was in full force
27 and effect at all times relevant to the charges brought herein and will expire on September 1,
28 2013, unless renewed.

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.

4. 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.

5. Section 4300, subdivision (a) of the Code states "Every license issued may be suspended or revoked."

STATUTORY PROVISIONS

6. Section 482 of the Code states:

Each board under the provisions of this code shall develop criteria to evaluate the rehabilitation of a person when:

(a) Considering the denial of a license by the board under Section 480; or

(b) Considering suspension or revocation of a license under Section 490.

Each board shall take into account all competent evidence of rehabilitation furnished by the applicant or licensee.

7. Section 490 of the Code provides, in pertinent part, that a board may suspend or revoke a license on the ground that the licensee has been convicted of a crime substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

8. Section 493 of the Code states:

Notwithstanding any other provision of law, in a proceeding conducted by a board within the department pursuant to law to deny an application for a license or to suspend or revoke a license or otherwise take disciplinary action against a person who holds a license, upon the ground that the applicant or the licensee has been convicted of a crime substantially related to the qualifications, functions, and duties of the licensee in question, the record of conviction of the crime shall be

1 conclusive evidence of the fact that the conviction occurred, but only of that fact,
2 and the board may inquire into the circumstances surrounding the commission of
3 the crime in order to fix the degree of discipline or to determine if the conviction is
4 substantially related to the qualifications, functions, and duties of the licensee in
5 question.

6 As used in this section, "license" includes "certificate," "permit,"
7 "authority," and "registration."

8 9. Section 4301 of the Code states:

9 The board shall take action against any holder of a license who is guilty
10 of unprofessional conduct or whose license has been procured by fraud or
11 misrepresentation or issued by mistake. Unprofessional conduct shall include, but is
12 not limited to, any of the following:

13 (a) Gross immorality.

14

15 (f) The commission of any act involving moral turpitude, dishonesty,
16 fraud, deceit, or corruption, whether the act is committed in the course of relations as
17 a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

18

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

21

22 (l) The conviction of a crime substantially related to the qualifications,
23 functions, and duties of a licensee under this chapter. The record of conviction of a
24 violation of Chapter 13 (commencing with Section 801) of Title 21 of the United
25 States Code regulating controlled substances or of a violation of the statutes of this
26 state regulating controlled substances or dangerous drugs shall be conclusive
27 evidence of unprofessional conduct. In all other cases, the record of conviction shall
28 be conclusive evidence only of the fact that the conviction occurred. The board may
inquire into the circumstances surrounding the commission of the crime, in order to
fix the degree of discipline or, in the case of a conviction not involving controlled
substances or dangerous drugs, to determine if the conviction is of an offense
substantially related to the qualifications, functions, and duties of a licensee under this
chapter. A plea or verdict of guilty or a conviction following a plea of nolo
contendere is deemed to be a conviction within the meaning of this provision. The
board may take action when the time for appeal has elapsed, or the judgment of
conviction has been affirmed on appeal or when an order granting probation is made
suspending the imposition of sentence, irrespective of a subsequent order under
Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of
guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or
dismissing the accusation, information, or indictment.

29

30 (o) Violating or attempting to violate, directly or indirectly, or assisting in

1 or abetting the violation of or conspiring to violate any provision or term of this
2 chapter or of the applicable federal and state laws and regulations governing
3 pharmacy, including regulations established by the board or by any other state or
4 federal regulatory agency.

5 (p) Actions or conduct that would have warranted denial of a license.

6 **REGULATIONS**

7 10. Title 16, California Code of Regulations, section 1769, states:

8

9 (b) When considering the suspension or revocation of a facility or a personal
10 license on the ground that the licensee or the registrant has been convicted of a crime,
11 the board, in evaluating the rehabilitation of such person and his present eligibility for
12 a license will consider the following criteria:

13 (1) Nature and severity of the act(s) or offense(s).

14 (2) Total criminal record.

15 (3) The time that has elapsed since commission of the act(s) or offense(s).

16 (4) Whether the licensee has complied with all terms of parole, probation,
17 restitution or any other sanctions lawfully imposed against the licensee.

18 (5) Evidence, if any, of rehabilitation submitted by the licensee.

19 11. Title 16, California Code of Regulations, section 1770, states:

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

27 **COST RECOVERY**

28 12. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
administrative law judge to direct a licensee 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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FACTS

13. On September 9, 2003, the Board issued Original Certificate Number EXC 17183 to Respondent. When Respondent submitted her license renewal, she admitted that she had been convicted of a misdemeanor in Alabama related to the pharmaceutical industry. In particular, she reported:

An unscrupulous Alabama pharmaceutical wholesaler sold me pharmaceuticals that were allegedly imported. I pleaded guilty to a misdemeanor of shipping misbranded drugs. No alcohol or DEA controlled substances were involved. I do not do business with this wholesaler anymore.

14. Although the renewal application and subsequent Board Correspondent asked for certified documents related to the arrest, such as police reports, arrest reports, booking reports, complaints, citations, or tickets, as well as certified court documents, such as notice of charges, complaint, or indictment, plea agreements, sentencing orders, probation orders, or judgment, dismissal, probation release, or court discharged, Respondent only included a copy of her sentencing order and probation order.

15. On December 12, 2008, in *USA vs. Trang Doan Nguyen and AQ Pharmaceuticals, Inc.*, Western District Court for Western District of Missouri, Case No. 05-00315-15-CR-W-ODS, Respondent individually and on behalf of her company pled guilty to one count of a violation of 21 U.S.C. 331(a) and 333(a)(1) (introduction into interstate commerce of a misbranded drug), a misdemeanor.

16. The documents that the Board asked for on the reapplication, and which Respondent did not turn over to the Board, reflect the serious and ongoing nature of the conduct that Respondent and her company engaged in that led to the conviction.

17. The Second Superseding Indictment dated January 3, 2007, reflects the role that Respondent, and several co-defendants, served in the fraudulent wholesale of misbranded drugs in the United States. Although some of the conspiracy charges continued as to the other co-defendants, the charges against Respondent were modified by a Superseding Information.

18. The Superseding Information filed on December 11, 2008, by the United States Attorney's Office provided that:

Between on or about March 28, 2002, and on or about April 30, 2003, in Kansas City, Jackson County, within the Western District of Missouri and elsewhere, the defendants, Trang Doan Nguyen, a/k/a Tracy Nguyen, and AQ Pharmaceuticals, Inc., introduced, delivered for introduction, and caused the introduction and delivery for introduction, into interstate commerce of a misbranded drug, as the term drug is defined in 21 U.S.C. § 321(g)(1), to wit: after receiving from [GS] and [JF] quantities of Lipitor® and Celebrex® that were not intended or approved for sale in the United States, along with quantities of counterfeit Lipitor® (collectively referred to as "drugs" or "the drugs"), said defendants repackaged the drugs in a manner that caused them to be misbranded pursuant to 21 U.S.C. § 352(a), in that the labeling the defendants affixed on the repackaged drugs was false and misleading because it did not disclose that the drugs were counterfeit or not approved for sale in the United States, and said defendants thereafter sold said drugs and shipped them across state lines from the State of California to locations in other states, including a location in Kansas City, Missouri. All in violation of 21 U.S.C. §§ 331(a) and 333(a)(1) and 18 U.S.C. § 2.

19. In the Plea Agreement, the parties admitted the facts and allegations as set forth in the Superseding Information were true and accurate.

20. On December 17, 2008, Respondent was sentenced to 5 years probation with certain terms and conditions as well as a \$50,000 fine.

21. On March 2, 2009, Respondent was ordered to pay restitution in the amount of \$597,420 to Pfizer, Inc. In the Restitution Order, the Court described the scope of the conduct:

Based on the evidence introduced at the hearing, the Court finds Defendants diverted 1,631,400 tablets of Lipitor and 300,000 tablets of Celebrex from Brazil into the United States.

22. On July 22, 2010, in *Doantrang Thi Nguyen aka Trang Doan Nguyen aka Tracy Nguyen and AQ Pharmaceuticals, Inc. Petitioner, v. The Inspector General*, Department of Health and Human Services Appeals Board Case No. CR2191 (OI File 7-07-40391-9), the Inspector General (IG) of the Department of Health and Human Services excluded Respondent and her company from participating in the Medicare, Medicaid, and all federal health care programs for 13 years. This action was taken pursuant to section 1128(b)(1) of the Social Security Act because Respondent and her company had been convicted of misdemeanor offenses relating to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct in connection with the delivery of a health care item or service. In particular, upon review of the plea agreement and other court documents, the Inspector General upheld the

1 exclusion and found no mitigating factors to justify decreasing the period of exclusion, in
2 particular, the IG noted:

3 Labeling and selling drugs with "false and misleading" labels is fraud.
4 Drugs are health care items. Petitioners are therefore subject to exclusion under
section 1128(b)(1).

5 Petitioners were guilty of repackaging and selling counterfeit drugs as
6 well as drugs not approved for sale in the United States. . . .mislabeling drugs under
the FDCA is fraudulent.

7 Petitioner refused to comply with reasonable requests for information;
8 Petitioner Nguyen was reluctant to accept responsibility for her complicity in the
crime; and she 'steadfastly refused to cooperative and instead has tried to suggest that
9 she has been victimized by many others, including law enforcement.'

10 **FIRST CAUSE FOR DISCIPLINE**

11 **(December 12, 2008 Criminal Conviction for Introducing Misbranded Drugs Into**
12 **Interstate Commerce Between 2002 and 2003)**

13 17. Respondent is subject to disciplinary action under sections 490 and 4301, subdivision
14 (l) of the Code in that Respondent was convicted of a crime substantially related to the
15 qualifications, functions and duties of a Designated Representative¹ as outlined in paragraphs 12
16 to 22, above, which are incorporated by reference herein.

18 **SECOND CAUSE FOR DISCIPLINE**

19 **(Unprofessional Conduct – Gross Immorality)**

20 23. Respondent is subject to disciplinary action under section 4301, subdivision (a), of
21 the Code in that Respondent engaged in conduct that was grossly immoral as outlined in
22 paragraphs 12 to 22, above, which are incorporated by reference herein. In particular,
23 Respondent diverted 1,631,400 tablets of Lipitor and 300,000 tablets of Celebrex from Brazil into
24 the United States, potentially affecting hundreds of thousands of patients who need these
25 medications. Counterfeit drugs may be contaminated, or contain the wrong active ingredient, or
26 the wrong amounts of an active ingredient. They may contain no active ingredients at all. The

27 ¹ A Designated Representative is an individual who performs clerical, inventory control,
28 housekeeping, delivery, maintenance, or similar functions related to the distribution or dispensing
of dangerous drugs or dangerous devices.

1 drugs may cause unforeseen allergic reactions. Placing such medication into the stream of
2 commerce, potentially harming hundreds of thousands of sick consumers is grossly immoral.

3 **THIRD CAUSE FOR DISCIPLINE**
4 **(Unprofessional Conduct – Act Involving Moral Turpitude,**
5 **Dishonesty, Fraud, Deceit, or Corruption)**

6 24. Respondent is subject to disciplinary action under section 4301, subdivision (f), of the
7 Code in that Respondent engaged in conduct that involved moral turpitude, dishonesty, fraud,
8 deceit, or corruption as outlined in paragraphs 12 to 22, above, which are incorporated by
9 reference herein. Specifically, labeling and selling drugs with “false and misleading” labels is
10 fraudulent, dishonest, and corrupt.

11 **FOURTH CAUSE FOR DISCIPLINE**
12 **(Unprofessional Conduct – Violation of United States Drug Laws)**

13 25. Respondent is subject to disciplinary action under section 4301, subdivision (j), of the
14 Code in that Respondent engaged in conduct that violated United States drug laws as outlined in
15 paragraphs 12 to 22, above, which are incorporated by reference herein.

16 **FIFTH CAUSE FOR DISCIPLINE**
17 **(Unprofessional Conduct – Violation of United States Pharmacy Laws)**

18 26. Respondent is subject to disciplinary action under section 4301, subdivision (o), of
19 the Code in that Respondent engaged in conduct that violated federal laws governing pharmacy as
20 outlined in paragraphs 12 to 22, above, which are incorporated by reference herein.

21 **SIXTH CAUSE FOR DISCIPLINE**
22 **(Unprofessional Conduct – Actions That Would Warrant Denial of a License)**

23 27. Respondent is subject to disciplinary action under section 4301, subdivision (p), of
24 the Code in that Respondent engaged in actions that would warrant denial of a license as outlined
25 in paragraphs 12 to 22, above, which are incorporated by reference herein. Specifically,
26 Respondent engaged in this conduct in 2002 and 2003, before she was licensed by the Board.
27 Had the Board been aware that she was engaging in the practice of labeling and selling
28 mislabeled drugs, she would have been denied a license. Respondent and her company were

1 convicted of misdemeanor offences relating to fraud in connection with the delivery of a health
2 care item or service and she has been excluded from participating in the Medicare, Medicaid, and
3 all federal health care programs for 13 years.

4 **PRAYER**

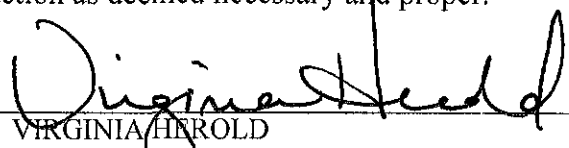
5 WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
6 and that following the hearing, the Board of Pharmacy issue a decision:

7 1. Revoking or suspending Designated Representative License Number EXC 17183,
8 issued to Trang Doan Nguyen;

9 2. Ordering Trang Doan Nguyen to pay the Board of Pharmacy the reasonable costs of
10 the investigation and enforcement of this case, pursuant to Business and Professions Code section
11 125.3;

12 3. Taking such other and further action as deemed necessary and proper.

13 DATED: 10/10/12


14 VIRGINIA HEROLD
15 Executive Officer
16 Board of Pharmacy
17 Department of Consumer Affairs
18 State of California
19 Complainant

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