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

In the Matter of the Accusation Against:

Case No. 4237

TRANG DOAN NGUYEN aka TRACY NGUYEN aka DOANTRANG THI NGUYEN 32 Gray Dove Irvine, CA 92618

Designated Representative License No. EXC 17183

Respondent.

DECISION AND ORDER

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on August 21, 2013.

It is so ORDERED on July 22, 2013.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

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By

STANLEY C. WEISSER Board President

1	KAMALA D. HARRIS		
2	Attorney General of California JAMES M. LEDAKIS		
3	Supervising Deputy Attorney General DIANE DE KERVOR		
4	Deputy Attorney General State Bar No. 174721		
5	110 West "A" Street, Suite 1100 San Diego, CA 92101		
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7	Facsimile: (619) 645-2061 Attorneys for Complainant		
8		RE THE	
9		PHARMACY CONSUMER AFFAIRS	
10		CALIFORNIA	
11	In the Matter of the Accusation Against:	Case No. 4237	
12	TRANG DOAN NGUYEN aka	STIPULATED SURRENDER OF	
13	TRACY NGUYEN aka	LICENSE AND ORDER	
14	DOANTRANG THI NGUYEN 32 Gray Dove	. ,	
15	Irvine, CA 92618	N	
16	Designated Representative License No. EXC 17183		
17	Respondent.		
18		<u>.</u>	
19	IT IS HEREBY STIPULATED AND AGI	REED by and between the parties in this	
20	proceeding that the following matters are true:	y and obtained the parties in this	
21		<u>CTIES</u>	
22			
23	1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.		
	She brought this action solely in her official capacity and is represented in this matter by Kamala		
24	D. Harris, Attorney General of the State of California, by Diane de Kervor, Deputy Attorney		
25	General.		
26	2. Trang Doan Nguyen aka Tracy Nguyen aka Doantrang Thi Nguyen (Respondent) is		
27	represented in this proceeding by Michael J. Sundstedt, Esq., whose address is 2100 Main Street,		
28	Suite 200, Huntington Beach, CA 92648.		
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3. On or about September 9, 2003, the Board of Pharmacy issued Designated Representative License No. EXC 17183 to Trang Doan Nguyen (Respondent). The Designated Representative License was in full force and effect at all times relevant to the charges brought in Accusation No. 4237 and will expire on September 1, 2013 unless renewed.

JURISDICTION

4. Accusation No. 4237 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on October 10, 2012.

Respondent timely filed her Notice of Defense contesting the Accusation. A copy of Accusation No. 4237 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

- 5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 4237. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.
- 6. Respondent is fully aware of her 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 her; the right to present evidence and to testify on her 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.
- 7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent understands that the charges and allegations in Accusation No. 4237, if proven at a hearing, constitute cause for imposing discipline upon her Designated Representative License.

- 9. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation and that those charges constitute cause for discipline. Without admitting to any of the charges in Accusation No. 4237 pertaining to fraud, or intentional wrongdoing, Respondent hereby gives up her right to contest that cause for discipline exists based on these charges.
- 10. Respondent understands that by signing this stipulation she enables the Board to issue an order accepting the surrender of her Designated Representative License without further process.

RESERVATION

11. The waiver of rights by Respondent herein is only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

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 surrender, without notice to or participation by Respondent or her counsel. By signing the stipulation, Respondent understands and agrees that she may not withdraw her 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 Surrender 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 facsimile copies of this Stipulated Surrender of License and Order, including facsimile signatures thereto, shall have the same force and effect as the originals.
- 14. This Stipulated Surrender of License and 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 Surrender of License and 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 Order:

<u>ORDER</u>

IT IS HEREBY ORDERED that Designated Representative License No. EXC 17183, issued to Respondent, is surrendered and accepted by the Board of Pharmacy.

- 1. The surrender of Respondent's Designated Representative License and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board of Pharmacy.
- 2. Respondent shall lose all rights and privileges as a Designated Representative in California as of the effective date of the Board's Decision and Order.
- 3. Respondent shall cause to be delivered to the Board her pocket license and, if one was issued, her wall certificate on or before the effective date of the Decision and Order.
- 4. If she ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 4237 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.
- 5. Respondent shall pay the agency its costs of investigation and enforcement in the amount of \$4,862.50 prior to issuance of a new or reinstated license.
- 6. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation, No. 4237 shall be deemed

ENDORSEMENT The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs. Dated: Respectfully submitted, Kamala D. Harris Attorney General of California James M. Ledakis Supervising Deputy Attorney General Deputy Attorney General Attorneys for Complainant SD2012702953 70680734.doc

Exhibit A

Accusation No. 4237

1 2 3 4 5 6 7 8	KAMALA D. HARRIS Attorney General of California JAMES M. LEDAKIS Supervising Deputy Attorney General DIANE DE KERVOR Deputy Attorney General State Bar No. 174721 110 West "A" Street, Suite 1100 San Diego, CA 92101 P.O. Box 85266 San Diego, CA 92186-5266 Telephone: (619) 645-2611 Facsimile: (619) 645-2061 Attorneys for Complainant		
9	BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
11 12 13 14 15 16 17	In the Matter of the Accusation Against: TRANG DOAN NGUYEN aka TRACY NGUYEN aka DOANTRANG THI NGUYEN 32 Gray Dove Irvine, CA 92618 Designated Representative License No. EXC 17183 Respondent.	Case No. 4237 ACCUSATION	
19 20 21 22 23 24 25 26 27 28	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 September 9, 2003, the Board of Pharmacy issued Designated Representative License Number EXC 17183 to Trang Doan Nguyen aka Tracy Nguyen aka Doantrang Thi Nguyen (Respondent). The Designated Representative License was in full force and effect at all times relevant to the charges brought herein and will expire on September 1, 2013, unless renewed.		

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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

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

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

9. Section 4301 of the Code states:

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:

(a) Gross immorality.

(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.

(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.

(1) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall 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.

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

Accusation

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:

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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

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

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

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

Petitioner refused to comply with reasonable requests for information; 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 she has been victimized by many others, including law enforcement.'

FIRST CAUSE FOR DISCIPLINE

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

17. Respondent is subject to disciplinary action under sections 490 and 4301, subdivision (1) of the Code in that Respondent was convicted of a crime substantially related to the qualifications, functions and duties of a Designated Representative¹ as outlined in paragraphs 12 to 22, above, which are incorporated by reference herein.

SECOND CAUSE FOR DISCIPLINE (Unprofessional Conduct – Gross Immorality)

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

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

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

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Act Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

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

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Violation of United States Drug Laws)

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

FIFTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Violation of United States Pharmacy Laws)

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

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Actions That Would Warrant Denial of a License)

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

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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) ingin and end		
14	VHRGINIA/HAROLD		
15	Executive Offider Board of Pharmacy		
16	Department of Consumer Affairs State of California		
17	Complainant		
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