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

In the Matter of the Accusation Against: **MEDISCA, INC.** **661 Route 3 Unit C** **Plattsburgh, NY 12901** **Out of State Distributor License No. OSD 3220** **and** **MEDISCA, INC.** **3955 W. Mesa Vista Ave. No. 10** **Las Vegas, NV 89118** **Out of State Distributor License No. OSD 5046** Respondent.	Case No. 4926 **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.

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2. On or about August 23, 1996, the Board of Pharmacy issued Out of State Distributor License Number OSD 3220 to Medisca, Inc. (Respondent), located at 661 Route 3 Unit C, Plattsburgh, NY 12901. The Out of State Distributor License was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2014, unless renewed.

3. On or about June 2, 2008, the Board of Pharmacy issued Out of State Distributor License Number OSD 5046 to Medisca, Inc. (Respondent), located at 3955 W. Mesa Vista Ave. No. 10, Las Vegas, NV 89118. The Out of State Distributor License was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2014, unless renewed.

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 4300 of the Code states, in pertinent part:

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

STATUTORY PROVISIONS

6. Section 651 states, in pertinent part:

"(a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to disseminate or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he or she is licensed. A "public communication" as used in this section includes, but is not limited to, communication by means of mail, television, radio, motion picture, newspaper, book, list or directory of healing arts practitioners, Internet, or other electronic communication.

"(b) A false, fraudulent, misleading, or deceptive statement, claim, or image includes a statement or claim that does any of the following:

"(1) Contains a misrepresentation of fact.

"(2) Is likely to mislead or deceive because of a failure to disclose material facts.

"(3)(A) Is intended or is likely to create false or unjustified expectations of favorable results, including the use of any photograph or other image that does not accurately depict the results of the procedure being advertised or that has been altered in any manner from the image of the actual subject depicted in the photograph or image.

"...

"(5) Contains other representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

"...

(g) Any violation of this section by a person so licensed shall constitute good cause for revocation or suspension of his or her license or other disciplinary action. . . ."

7. Section 652 of the Code states:

"Violation of this article [Article 6, commencing with Section 650 of the Code] in the case of a licensed person constitutes unprofessional conduct and grounds for suspension or revocation of his or her license by the board by whom he or she is licensed, or if a license has been issued in connection with a place of business, then for the suspension or revocation of the place of business in connection with which the violation occurs. The proceedings for suspension or revocation shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code [the Administrative Procedure Act], and each board shall have all the powers granted therein."

8. Section 4076 of the Code states, in pertinent part:

"(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled. . . ."

9. Section 4077 of the Code states, in pertinent part, that except as provided in subdivisions (b) and (c) of this section, no person shall dispense any dangerous drug upon prescription except in a container correctly labeled with the information required by Section 4076.

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10. Section 4300.1 of the Code 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."

11. 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:

". . .

"(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.

". . ..

"(*l*) 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.

". . .

"(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(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. . . ."

COST RECOVERY

12. 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.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Conviction of a Crime Substantially Related to Qualifications, Functions, and Duties of Licensee)

13. Respondent is subject to disciplinary action under section 4301(*l*) of the Code in that Respondent has been convicted of a crime that is substantially related to Respondent's qualifications, functions, and duties as an Out of State Distributor. The facts and circumstances of this conviction are as follows:

14. On or about March 14, 2012, in *United States of America v. Medisca, Inc.*, United States District Court, Northern District, Case No. DNYN811CR000476-001, Respondent pled guilty to misbranding drugs (a violation of Title 21 of the United States Code, sections 331(a) and 352(a)). The facts and circumstances of this conviction are as follows:

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a. On or about September 23, 2011, Respondent entered into a plea agreement under which Respondent admitted to introducing, or causing to be introduced, into interstate commerce a drug that was misbranded. Respondent further admitted that:

i. From approximately June 2004 through approximately February 2007, Respondent purchased and received a drug called "Somatropin" that was manufactured in China, and then distributed the Somatropin from Respondent's Plattsburgh, New York facility to numerous pharmacies located throughout the United States. The pharmacies, in turn, dispensed the Somatropin to patients for certain uses. Somatropin is a synthetic or naturally occurring growth hormone from the human pituitary gland, and is defined under the Federal Food, Drug, and Cosmetic Act, Title 21, United States Code, Sections 301-399 (the "FDCA") to mean "human growth hormone."

ii. Respondent received the Chinese Somatropin in glass vials. Each vial bore a label that was affixed by the Chinese manufacturer. The label included information such as the name of the product, "Somatropin," the quantity of Somatropin in each vial, as well as the product's expiration date and lot number. In addition, the label contained the manufacturer's National Drug Code number (NDC #). After receiving the vials, Respondent removed the manufacturer's label and replaced it with its own label that contained, among other information, Respondent's NDC # for the Somatropin product.

iii. The NDC is a numbering system the United States Food and Drug Administration (FDA) utilizes to assign a drug listing number to each drug or class of drugs a manufacturer lists and submits to FDA on a form when it registers with FDA.

iv. Unless otherwise exempt, owners and operators of all drug establishments that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs are required to register with the FDA and submit a list of every drug in commercial distribution.

v. Under the FDCA, the term "manufacture, preparation, propagation, compounding, or processing" includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original

place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

vi. Using the NDC numbering system, the FDA will assign a drug listing number to each drug or class of drugs the manufacturer lists on its application.

vii. FDA's assignment of an NDC number to a drug or class of drugs does not mean FDA has approved the drug for commercial distribution. Indeed, FDA's regulations explicitly state that "assignment of a NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of registration or possession of registration number or NDC number is misleading and constitutes misbranding."

viii. From in or about July 2004 through in or about February 2007, Respondent distributed over 1,737 grams of Somatropin to pharmacies throughout the United States. Beginning as early as March 4, 2005, Respondent used promotional literature to facilitate the sale of its Somatropin product which represented to the pharmacies that Respondent's Somatropin product was either "FDA approved" and/or from "an FDA approved facility" by virtue of the fact that the Chinese manufacturers had obtained an NDC number for the product.

ix. In other literature sent to pharmacies, Respondent stated, "Medisca Group of Companies ensures that the underlying chemical is from an FDA approved facility. . . ."

x. This promotional literature was signed by Respondent's officers and either provided to Respondent's sales representatives to distribute to the pharmacies, or sent directly to the pharmacies by Respondent's officers. The promotional literature was used by Respondent to convince the pharmacies to purchase Respondent's Somatropin product rather than Respondent's competitors' Somatropin products.

xi. From on or about March 4, 2005, through in or about February 2007, Respondent introduced and caused the introduction into interstate commerce of a misbranded drug, Somatropin, such drug being misbranded in that its labeling was, under 21 U.S.C. § 352(a) and 21 C.F.R. § 207.39, false or misleading.

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SECOND CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

15. Respondent is subject to disciplinary action under section 4301(f) of the Code in that Respondent committed acts involving moral turpitude, dishonesty, fraud, deceit, and corruption as more fully set forth in paragraph 14 and all of its subparts.

THIRD CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Violation of Provisions of Business and Professions Code, and Applicable Federal and State Laws and Regulations Governing Pharmacy)

16. Respondent is subject to disciplinary action under sections 652 and 4301(o) of the Code in that Respondent violated provisions of the Business and Professions Code (including Sections 651(a) and (g), and 4076-4077), and applicable federal and state laws and regulations governing pharmacy as more fully set forth in paragraph 14 and all of its subparts.

FOURTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct—Discipline by Another State)

17. Respondent is subject to disciplinary action under section 4301(n) of the Code in that Respondent's Out-of-State Wholesaler licenses in Colorado, Kansas, Rhode Island, Illinois, Iowa, South Carolina, Tennessee, Louisiana, and Oregon have been disciplined by the pharmacy boards in these states based upon Respondent's criminal conviction as more fully set forth in paragraph 14 and all of its subparts. The circumstances of the out-of-state discipline are as follows:

18. On or about March 27, 2012, in case no. 2012-002037, the Colorado Board of Pharmacy placed the Colorado Out-of-State Wholesaler license for Respondent's Plattsburgh, NY location on probation for three years. Respondent agreed not to distribute human growth hormone of any kind or any drug containing human growth hormone into Colorado during the probationary period.

19. On or about June 25, 2012, in case no. 12-84, the Kansas Board of Pharmacy placed the Kansas Distributor licenses for Respondent's Plattsburgh, NY; Las Vegas, NV; and Irving, TX locations on probation for three years. The probation is subject to the terms and conditions of

the action taken by the Colorado Board of Pharmacy, to run concurrently with the order of the Colorado Board of Pharmacy.

20. On or about October 18, 2012, in a consent order, the Rhode Island Board of Pharmacy placed the Rhode Island Out-of-State Drug Manufacturer licenses for Respondent's Plattsburgh, NY; Las Vegas, NV; and Irving, TX locations on probation for six months.

21. On or about November 26, 2012, in case no. 2011-10584, the Illinois Division of Professional Regulation placed the Illinois Drug Distributor licenses for Respondent's Plattsburgh, NY; Las Vegas, NV; and Irving, TX locations on probation indefinitely. Respondent cannot petition to restore its Drug Distributor licenses for at least three years from the date of probation. Respondent shall not distribute Somatropin into Illinois. Respondent shall comply with all terms of discipline taken by the Colorado and Kansas Boards of Pharmacy. On successful termination of the probation orders in Colorado and Kansas, and after the minimum three years has passed, Respondent's licenses shall be removed from probation status.

22. On or about January 16, 2013, in case no. 2012-86, the Iowa Board of Pharmacy placed the Iowa Wholesale Drug licenses for Respondent's Plattsburgh, NY; Las Vegas, NV; and Irving, TX locations on probation for three years. Under the probationary terms, Respondent shall not distribute Somatropin of any kind or any drug containing Somatropin in Iowa during the period of probation, and will submit quarterly reports attesting to the fact that it did not distribute Somatropin in Iowa.

23. On or about January 10, 2012, the South Carolina Board of Pharmacy issued an order placing the South Carolina Non-Resident Wholesaler/Distributor/Manufacturer license for Respondent's Plattsburgh, NY location on probation for three years.

24. On or about May 15, 2013, in case nos. L13-PHR-RBS-2013000861 and L13-PHR-RBS-2013000871, the Tennessee Board of Pharmacy placed the Tennessee Manufacturer/Wholesaler/Distributor licenses for Respondent's Plattsburgh, NY; Las Vegas, NV; and Irving, TX locations on indefinite probation. Respondent will comply with all terms and conditions of consent orders ratified by other state boards of pharmacy. Respondent shall

immediately cease distributing Somatropin in Tennessee. After three years, Respondent may petition to lift the restrictions of the Tennessee Board of Pharmacy consent order.

25. On or about March 29, 2013, in case no. 13-0055, the Louisiana Board of Pharmacy suspended the Louisiana Controlled Dangerous Substance license for Respondent's Plattsburgh, NY location for three years, ending on January 10, 2016. The period of suspension was suspended and Respondent's license was placed on probation for the remainder of the suspension period. Respondent shall not violate or be found guilty of violating any local, state, or federal laws regarding controlled dangerous substances and shall pay the Louisiana Board of Pharmacy $250 as reimbursement for administrative costs.

26. On or about August 30, 2013, in case no. 2013-0262, the Oregon Board of Pharmacy placed the Drug Outlet Registrations for Respondent on probation for three years, ending on August 30, 2016. Under the terms of probation, Respondent must comply with all laws and rules, comply with all terms and conditions of the other state Board's discipline and Orders and notify the Board within fifteen calendar days of any modifications or changes in terms or conditions in the Orders, and notify the Board within fifteen calendar days of any action proposed or taken against it.

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 Out of State Distributor License Number OSD 3220, issued to Medisca, Inc., located at 661 Route 3 Unit C, Plattsburgh, NY 12901;

2. Revoking or suspending Out of State Distributor License Number OSD 5046, issued to Medisca, Inc., located at 3955 W. Mesa Vista Ave. No. 10, Las Vegas, NV 89118;

3. Ordering Medisca, Inc. 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

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

DATED: 12/2/13

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

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