Before the Naturopathic Medicine Committee
Osteopathic Medical Board of California
Department of Consumer Affairs
State of California

In the Matter of the Accusation Against: Case No. 11-04091-NM

AMANDA MARIE WARD, N.D. ACCUSATION

806 Capri Road
Encinitas, California 92924

Naturopathic Doctors License No. ND-273

Respondent.

Complainant alleges:

PARTIES

1. Francine Davies (Complainant) brings this Accusation solely in her official capacity as the Interim Executive Officer of the Naturopathic Medicine Committee, within the Osteopathic Medical Board of California, Department of Consumer Affairs.

2. On or about November 6, 2007, the Naturopathic Medicine Committee of California issued Naturopathic Doctors License Number ND-273 to Amanda Marie Ward, N.D. (Respondent). The Naturopathic Doctors License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2013, unless renewed.

////////
JURISDICTION

3. This Accusation is brought before the Naturopathic Medicine Committee (Committee), within the Osteopathic Medical Board of California (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 3663 of the Code states the Committee shall have the responsibility for reviewing the quality of the practice of naturopathic medicine carried out by licensed naturopathic doctors, the Committee may discipline a naturopathic doctor for unprofessional conduct and the Committee may deny, suspend, revoke, or place on probation the license of, or reprimand, censure, or otherwise discipline a naturopathic doctor.

5. Section 3662 of the Code states “[i]t shall constitute unprofessional conduct for a naturopathic doctor to violate, attempt to violate, assist in the violation of, or conspire to violate, any provision or term of this chapter or any regulation adopted under it.”

6. California Code of Regulations, title 16, section 4260 states:

For the purpose of Sections 3662 and 3663 of the Code, unprofessional conduct includes:

“...

“(b) The aiding or abetting of any unlicensed person to practice naturopathic medicine.

“...

“(g) The violation of any of the provisions of the Act or the regulations contained in this division.

“...

“(l) The presence of unsanitary or unsafe office conditions, as determined by the customary practice and standards of the naturopathic medical profession.

“...

“(p) Any action or conduct which would have warranted the denial of the license.
7. Section 3640.2 of the Code states:

"Notwithstanding any other provision of law, a naturopathic assistant may do all of the following:

(a) Administer medication only by intradermal, subcutaneous, or intramuscular injections and perform skin tests and additional technical support services upon the specific authorization and supervision of a licensed naturopathic doctor. A naturopathic assistant may also perform all these tasks and services in a clinic licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code upon the specific authorization of a naturopathic doctor.

(b) Perform venipuncture or skin puncture for the purposes of withdrawing blood upon specific authorization and under the supervision of a licensed naturopathic doctor if prior thereto the naturopathic assistant has met the educational and training requirements for medical assistants as established in Section 2070. A copy of any related certificates shall be retained as a record by each employer of the assistant.

(c) Perform the following naturopathic technical support services:

(1) Administer medications orally, sublingually, topically, vaginally, or rectally, or by providing a single dose to a patient for immediate self-administration. Administer medication by inhalation if the medications are patient-specific and have been or will be repetitively administered to the patient. In every instance, prior to administration of medication by the naturopathic assistant, the naturopathic doctor shall verify the correct medication and dosage.

(2) Apply and remove bandages.

(3) Collect by noninvasive techniques and preserve specimens for testing, including urine, sputum, semen, and stool.

(4) Assist patients to and from a patient examination room or examination table."
“(5) As authorized by the naturopathic doctor, provide patient information and instructions.

“(6) Collect and record patient data, including height, weight, temperature, pulse, respiration rate, and blood pressure, and basic information about the presenting and previous conditions.

“(7) Perform simple laboratory and screening tests customarily performed in a medical office.

“(d) Perform additional naturopathic technical support services under the regulations and standards established by the committee. The committee shall, prior to the adoption of any regulations, request recommendations regarding these standards from appropriate public agencies, including, but not limited to, the Osteopathic Medical Board of California, the Medical Board of California, the Board of Registered Nursing, the Board of Vocational Nursing and Psychiatric Technicians of the State of California, the Laboratory Field Services division of the State Department of Public Health, and the Physical Therapy Examining Committee. The Naturopathic Medicine Committee shall also request recommendations regarding these standards from associations of medical assistants, physicians, and others, as appropriate, including, but not limited to, the Osteopathic Physicians and Surgeons of California, the California Medical Association, the California Society of Medical Assistants, and the California Medical Assistants’ Association. Nothing in this subdivision shall be construed to supersede or modify that portion of the Administrative Procedure Act that relates to the procedure for the adoption of regulations set forth in Article 5 (commencing with Section 11346) of Chapter 3.5 of Part 1 of Division 3 of Title 2 of the Government Code.

/////
8. Section 3674 of the Code states "[t]he name of a naturopathic corporation and any name or names under which it may render professional services, shall contain the words 'naturopathic' or 'naturopathic doctor' and, as appropriate, wording or abbreviations denoting its status as a corporation."

FIRST CAUSE FOR DISCIPLINE
(Unprofessional Conduct)

9. Respondent has subjected her Naturopathic Doctors License Number ND-273 to disciplinary action under sections 3663 and 3662, as defined by California Code of Regulations, Title 16, section 4260, subdivisions (b), (g), (I) and (p), in that she has engaged in unprofessional conduct, as more particularly alleged herein:

10. Respondent, a licensed Naturopathic Doctor, is the founder, owner and "Medical Director" of Bloom Natural Health located in Encinitas, California. Respondent advertises her professional services over different websites including, but not limited to "bloomnaturalhealth.com" and "skinnyshots.com.” According to these websites, respondent operates her business, Bloom Natural Health, as "a Natural Medicine Center" whose “mission is to serve as a space where people can begin their journeys into wellness and 'blossom' into their higher selves physically, emotionally, mentally and spiritually.” Among other things, Bloom Natural Health advertises “six important steps to health and fitness” which include the initial “discovery phase” to assess a patient’s health history and health future followed by other phases and/or services which include, but are not limited to, detoxification, replenishment, repatterning, nourishment and/or beautification. The websites identify various programs including, but not

---

1 "Naturopathic medicine is a distinct and comprehensive system of primary health care that uses natural methods and substances to support and stimulate the body’s self healing process.” (A Consumer’s Guide to Naturopathic Medicine published by the State of California’s Department of Consumer Affairs (September 2009).) Naturopathic doctors are trained in a wide variety of complimentary and alternative therapies including: herbal and homeopathic medicine, clinical nutrition and diet; vitamins, amino acids, minerals, enzymes and nutraceuticals; physical medicine such as massage, bodywork, exercise therapy and hydrotherapy; counseling and behavioral therapies; and health and lifestyle counseling. In addition, naturopathic doctors may prescribe hormones and may also order other prescription drugs in collaboration with a medical doctor. (Ibid.)
limited to, a “health plan” program, a “weight loss” program, a “healthy shots” program, a “Notox beauty” program, a “skinny shots” program, a “hormones” program, an “allergies” program and an “IV therapy” program. There are also various “events” advertised on the websites that the public and patients can participate in which include, but are not limited to, the “Skinny Shot Happy Hour,” the “Skinny Shot Party,” the “Healthy Hormones Happy Hour,” the “Healthy Shots Happy Hour,” the “Reconnection to Earth” event and/or the “Breast Health” event. Bloom Natural Health also offers “IV Therapy” which purportedly provides the following benefits: “[i]ncrease in energy,” “[d]etoxification,” “[r]educe/eliminate migraines,” “stress and anxiety relief,” and “[s]upport[ing] healthy immune function.” The websites also reference the “Bloom Blend Bar,” the “Bloom Replenish Lounge” and the “Notox Beauty Bar.”

11. In the course of offering her professional services as a Naturopathic Doctor, respondent purchased and used products in the care and treatment of her patients at Bloom Natural Health that had been recalled by the manufacturer and parent company that sold and distributed the products. These products included, but were not limited to, Guna injectables that were injected into Bloom Natural Health patients as part of the “Notox” and “Skinny Spot Shot” program.

2 The “healthy shots” program lists the various shots that are available including the “Skinny Shot,” the “Girl Power” shot, the “Super Charger” shot, the “Detox” shot, the “Skin Glow” shot, the “Tranquil Shot,” the “Super Skinny Shot,” the “Adrenal Recover Shot,” and the “Skinny Spot Shot.”

3 The “popular IV’s” in the “IV Therapy” program are listed as the “IV Nutritional Therapy,” the “Immune Boost IV,” the “Infection Fighter IV,” the “Blood Sugar IV,” the “Sports IV,” the “Tranquil IV,” the “Hormone Imbalance IV” and the “Detox IV.”

4 The Bloom Natural Health website states that the Notox treatment consists of “[n]on-toxic homeopathic injections from Milan, Italy” that are used “to stimulate and reveal your beautiful face.”

5 The Bloom Natural Health website describes “Skinny Spot Shots” as “a cutting edge injectable cocktail available exclusively at Bloom Natural Health.” The website further states that “This specialized shot consists of several homeopathic ingredients that are imported from Italy. These components work to keep lymphatic flow while also helping to stimulate local fat burning. This can be very beneficial for stubborn areas of excess body fat and cellulite. Our patients have had great success in describing fat bulges from their backs, buttocks, and thighs. Consider it a gentle and natural body sculpting booster.” The “Skinny Spot Shots” cost $30 for a single shot, $200 for a package of ten, or $370 for a “twenty-pack.” A reduced rate is offered at the “Skinny Shot Happy Hour” and “Skinny Shot gift cards” are also available.
treatments. The Guna products were manufactured by Jenahexal Pharm GmbH in Jenna, Germany, and sold and distributed by the Guna Corporation, a pharmaceutical company with offices in Italy and the United States. The Guna products that were purchased and used in the care and treatment of patients were imported from Bogota, Columbia.

12. On or about February 6, 2012, Bloom Natural Health was inspected by the State of California, Division of Occupational Safety and Health (OSHA). During the course of this inspection, OSHA found numerous health and safety violations at Bloom Natural Health.

13. On or about July 23, 2012, OSHA provided respondent with a Notice of Proposed Penalties and a Citation and Notice of Penalty for each of the violations observed during the inspection of Bloom Natural Health on February 6, 2012. The Notice of Proposed Penalties set forth total proposed penalties in the amount of $13,415.00 with an abatement date of August 23, 2012, for each of the violations. These health and safety violations included, but were not limited to, the following:

(a) Citation 1, Item 1 (General Violation): “At the time of the inspection the employer had not established and implemented a written Injury and Illness Preventions Program” with all required elements. This general violation was based on a violation of California Code of Regulations, tit. 8, section 3203, subdivisions (a)(4) and (a)(7).

/ / / / /

6 On or about October 19, 2011, the U.S. Food and Drug Administration issued a warning letter to Jenahexal Pharm GmbH, the pharmaceutical manufacturing facility for the Guna products, advising it of the Current Good Manufacturing Practice (CGMP) violations that were discovered when the facility was inspected by the FDA on October 25-29, 2010. These violations included, but were not limited to, (1) failing to establish “appropriate written testing procedures designed to assure the sterility of drug products purporting to be sterile [21 C.F.R. §211.167(a)];” (2) the quality control unit’s failure to establish and document “the analytical methods used within your laboratory are adequate for their intended use [21 C.F.R. §211.165(e)]; (3) not establishing “a written assessment of stability of homeopathic drug products based at least on testing or examination of the drug product for compatibility of the ingredients and marketing experience with the drug product to indicate that there is no degradation of the product for the normal or expected period of use [21 C.F.R. §211.166(c)(1)]; and (4) failing to test each component [of the manufactured product] with all appropriate specifications for purity, strength, and quality [21 C.F.R. §211.84(d)(2)]. In addition to the CGMP violations, the FDA set forth several unapproved new drug violations. According to FDA documents, the Guna product recall began on November 15, 2010.
(b) Citation 1, Item 2 (General Violation): “At the time of the inspection the employer had not established and implemented a written Exposure Control Plan” containing all the required elements. This general violation was based on a violation of California Code of Regulations, tit. 8, section 5193, subdivision (c)(1)(B).

(c) Citation 1, Item 3 (General Violation): “At the time of the inspection, the employer’s Sharps Injury Log did not include all the required elements [and] [t]he descriptions of each exposure incident were not complete.” This general violation was based on a violation of California Code of Regulations, tit. 8, section 5193, subdivision (c)(2).

(d) Citation 1, Item 4 (General Violation): “At the time of the inspection employees perform[ed] injections, IV placements, cleaning, and sharps disposal which expose[d] them to the hazard of contact with blood, contaminated sharps and the employer did not ensure the worksite [was] maintained in a sanitary condition. The employer did not determine appropriate written methods and schedules for cleaning as required [by the regulation] such as sanitizing with Environmental Protection registered product against HIV and HBV.” This general violation was based on a violation of California Code of Regulations, tit. 8, section 5193, subdivision (d)(3)(H).

(e) Citation 1, Item 5 (General Violation): “At the time of inspection, employees performing injections and IV placements, had not received the Hepatitis B vaccination from the employer, or had not signed the declination statement in Appendix B.” This general violation was based on a violation of California Code of Regulations, tit. 8, section 5193, subdivision (f)(2)(A).

(f) Citation 1, Item 6 (General Violation): “At the time of inspection, employees perform[ed] injections, IV placements, cleaning, and sharps disposal which expose[d] them to the hazard of contact with blood and contaminated sharps and the employees had not been provided with training and all information as required by [the California Code of Regulations].” This general violation was based
on a violation of California Code of Regulations, tit. 8, section 5193, subdivision (g)(2)(G).

(g) Citation 1, Item 7 (General Violation): “At the time of inspection the employer had not developed and implemented a written Hazard Communication Program which [met] all the requirements of [the California Code of Regulations]. Employees [were] exposed to hazardous substances in the workplace such as but not limited to chemicals what are flammable [and] skin/eye irritants [that are] used on a regular basis for cleaning and sanitizing.” This general violation was based on a violation of California Code of Regulations, tit. 8, section 5194, subdivisions (e)(1)(A) and (e)(1)(B).

(h) Citation 1, Item 8 (General Violation): “At the time of inspection, the employer did not maintain copies of all the required material safety data sheets for each hazardous substance in the workplace. Employees did not have all MSDS’s readily accessible in the work area” as required by [the California Code of Regulations].” This general violation was based on a violation of California Code of Regulations, tit. 8, section 5194, subdivision (g)(8).

(i) Citation 1, Item 9 (General Violation): “At the time of inspection, employees [were] exposed to hazardous substances in the workplace such as but not limited to substances which [were] flammable, skin/eye irritants and the employees had not been provided with training and information.” This general violation was based on a violation of California Code of Regulations, tit. 8, section 5194, subdivision (h)(2).

(j) Citation 1, Item 10 (General Violation): “At the time of inspection, portable fire extinguishers were not readily accessible, located and identified.” This general violation was based on a violation of California Code of Regulations, tit. 8, section 6151, subdivision (c)(1).

(k) Citation 1, Item 11 (General Violation): “At the time of inspection portable fire extinguishers located in the Natural Bloom Health Center (sic) had not
been visually inspected monthly.” This general violation was based on a violation of California Code of Regulations, tit. 8, section 6151, subdivision (e)(2).

(I) Citation 2, Item 1 (Serious Violation): “At the time of inspection the employees were found to be recapping contaminated sharps and removing needles from devices after performing injections.” This serious violation was based on a violation of California Code of Regulations, tit. 8, section 5193, subdivision (d)(3)(B)(2).

(m) Citation 3, Item 1 (Serious Violation): “At the time of inspection, the employer was found to be using needle systems that did not have engineered sharps injury protection for injections and IV’s [and] the employer had not documented why engineering controls were not being used pursuant to any authorized exceptions.” This serious violation was based on a violation of California Code of Regulations, tit. 8, section 5193, subdivision (d)(3)(A).

14. On or about August 8, 2012, OSHA issued amended citations, which reduced the amount of the originally proposed fines, based on abatement of the aforementioned health and safety violations. The proposed total penalties were reduced from $13,415.00 to $5,405.00.

15. Respondent, as the owner, operator and “Medical Director” of Bloom Natural Health, failed to establish appropriate precautions, protocols and/or procedures for the storage, disposal and/or risk of exposure to biohazards and biohazardous waste which included, but was not limited to, the potential harm associated with “needle sticks” from contaminated injectables and her failure to properly dispose of biohazardous waste associated with, but not limited to, the injections and IV therapy administered at Bloom Natural Health.

16. Respondent, as the owner, operator and “Medical Director” of Bloom Natural Health, has failed to use the required words and/or designations in offering and/or advertising her professional services as part of “Bloom Natural Health” and/or “Bloom” in conformance with Business and Professions Code section 3674.
17. Respondent, as the owner, operator and “Medical Director” of Bloom Natural Health, has permitted other employees, who are not Naturopathic Doctors, to administer IV’s in whole or part during the course of providing IV therapy.

18. Respondent, as the owner, operator and “Medical Director” of Bloom Natural Health, has diagnosed, treated and/or provided supplies for dogs at Bloom Natural Health, in disregard of the potential health and safety risks to patients, and even though she has no formal training or education in veterinary medicine and is not a licensed veterinarian. Among other things, respondent has treated dogs with human-grade supplements and injectables, has provided treatment plans for dogs and has shipped products to be used in the treatment of dogs.

SECOND CAUSE FOR DISCIPLINE
(Unauthorized Use of Naturopathic Assistants)

19. Respondent has further subjected her Naturopathic Doctors License Number ND-273 to disciplinary action under sections 3663 and 3662, as defined by section 3640.2, of the Code, in that she has used Naturopathic Assistants for unauthorized activities, as more particularly alleged in paragraph 17, above, which is incorporated herein by reference and realleged as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE
(Failure to Properly Identify Naturopathic Corporation)

20. Respondent has further subjected her Naturopathic Doctors License Number ND-273 to disciplinary action under sections 3663 and 3662, as defined by section 3674, of the Code, in that she has failed to use the required words and/or names when referencing the name(s) of the businesses and/or entities under which she offers professional services, as more particularly alleged in paragraph 16, above, which is incorporated herein by reference and realleged as if fully set forth herein.
PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Naturopathic Medicine Committee, as a part of the Osteopathic Medical Board of California, Department of Consumer Affairs, issue a decision:

1. Revoking or suspending Naturopathic Doctors License Number ND-273, issued to respondent Amanda Marie Ward, N.D.

2. Ordering respondent Amanda Marie Ward to pay the Naturopathic Medicine Committee of California the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and

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

DATED: June 6, 2013

FRANCINE DAVIES
Interim Executive Officer
Naturopathic Medicine Committee
Osteopathic Medical Board of California
Department of Consumer Affairs
State of California
Complainant

SD2013805152
80761539.doc