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9
10 **BEFORE THE**
NATUROPATHIC MEDICINE COMMITTEE
OSTEOPATHIC MEDICAL BOARD OF CALIFORNIA
11 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA
12

13 In the Matter of the Accusation Against:

Case No. 11-04091-NM

14 **AMANDA MARIE WARD, N.D.**
15 **806 Capri Road**
Encinitas, California 92924

A C C U S A T I O N

16 **Naturopathic Doctors License No. ND-273**

17 Respondent.

18
19 Complainant alleges:

20 **PARTIES**

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

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

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1 JURISDICTION

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

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

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

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

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

16 “...
17

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

20 “...
21

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

24 “...
25

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

“...
29

“(p) Any action or conduct which would have warranted the denial of the
license.

1 " "

2 7. Section 3640.2 of the Code states:

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

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

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

17 "(c) Perform the following naturopathic technical support services:

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

24 "(2) Apply and remove bandages.

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

27 "(4) Assist patients to and from a patient examination room or
28 examination table.

1 “(5) As authorized by the naturopathic doctor, provide patient
2 information and instructions.

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

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

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

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1 limited to, a "health plan" program, a "weight loss" program, a "healthy shots" program,² a
2 "Notox beauty" program, a "skinny shots" program, a "hormones" program, an "allergies"
3 program and an "IV therapy" program.³ There are also various "events" advertised on the
4 websites that the public and patients can participate in which include, but are not limited to, the
5 "Skinny Shot Happy Hour," the "Skinny Shot Party," the "Healthy Hormones Happy Hour," the
6 "Healthy Shots Happy Hour," the "Reconnection to Earth" event and/or the "Breast Health"
7 event. Bloom Natural Health also offers "IV Therapy" which purportedly provides the following
8 benefits: "[i]ncrease in energy," "[d]etoxification," "[r]educe/eliminate migraines," "stress and
9 anxiety relief," and "[s]upport[ing] healthy immune function." The websites also reference the
10 "Bloom Blend Bar," the "Bloom Replenish Lounge" and the "Notox Beauty Bar."

11 11. In the course of offering her professional services as a Naturopathic Doctor,
12 respondent purchased and used products in the care and treatment of her patients at Bloom
13 Natural Health that had been recalled by the manufacturer and parent company that sold and
14 distributed the products. These products included, but were not limited to, Guna injectables that
15 were injected into Bloom Natural Health patients as part of the "Notox"⁴ and "Skinny Spot Shot"⁵

16
17 ² The "healthy shots" program lists the various shots that are available including the
18 "Skinny Shot," the "Girl Power" shot, the "Super Charger" shot, the "Detox" shot, the "Skin
19 Glow" shot, the "Tranquil Shot," the "Super Skinny Shot," the "Adrenal Recover Shot," and the
20 "Skinny Spot Shot."

21 ³ The "popular IV's" in the "IV Therapy" program are listed as the "IV Nutritional
22 Therapy," the "Immune Boost IV," the "Infection Fighter IV," the "Blood Sugar IV," the "Sports
23 IV," the "Tranquil IV," the "Hormone Imbalance IV" and the "Detox IV."

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

27 ⁵ The Bloom Natural Health website describes "Skinny Spot Shots" as "a cutting edge
28 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.

1 treatments. The Guna products were manufactured by Jenahexal Pharm GmbH in Jenna,
2 Germany, and sold and distributed by the Guna Corporation, a pharmaceutical company with
3 offices in Italy and the United States.⁶ The Guna products that were purchased and used in the
4 care and treatment of patients were imported from Bogota, Columbia.

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

8 13. On or about July 23, 2012, OSHA provided respondent with a Notice of Proposed
9 Penalties and a Citation and Notice of Penalty for each of the violations observed during the
10 inspection of Bloom Natural Health on February 6, 2012. The Notice of Proposed Penalties set
11 forth total proposed penalties in the amount of \$13,415.00 with an abatement date of August 23,
12 2012, for each of the violations. These health and safety violations included, but were not limited
13 to, the following:

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

19 /:/:/

20 ⁶ On or about October 19, 2011, the U.S. Food and Drug Administration issued a warning
21 letter to Jenahexal Pharm GmbH, the pharmaceutical manufacturing facility for the Guna
22 products, advising it of the Current Good Manufacturing Practice (CGMP) violations that were
23 discovered when the facility was inspected by the FDA on October 25-29, 2010. These violations
24 included, but were not limited to, (1) failing to establish "appropriate written testing procedures
25 designed to assure the sterility of drug products purporting to be sterile [21 C.F.R. §211.167(a)];"
26 (2) the quality control unit's failure to establish and document "the analytical methods used
27 within your laboratory are adequate for their intended use [21 C.F.R. §211.165(e)]; (3) not
28 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.

1 (b) Citation 1, Item 2 (General Violation): "At the time of the inspection
2 the employer had not established and implemented a written Exposure Control Plan"
3 containing all the required elements. This general violation was based on a violation
4 of California Code of Regulations, tit. 8, section 5193, subdivision (c)(1)(B).

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

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

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

24 (f) Citation 1, Item 6 (General Violation): "At the time of inspection,
25 employees perform[ed] injections, IV placements, cleaning, and sharps disposal
26 which expose[d] them to the hazard of contact with blood and contaminated sharps
27 and the employees had not been provided with training and all information as
28 required by [the California Code of Regulations]." This general violation was based

1 on a violation of California Code of Regulations, tit. 8, section 5193, subdivision
2 (g)(2)(G).

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

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

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

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

27 (k) Citation 1, Item 11 (General Violation): "At the time of inspection
28 portable fire extinguishers located in the Natural Bloom Health Center (sic) had not

1 been visually inspected monthly.” This general violation was based on a violation of
2 California Code of Regulations, tit. 8, section 6151, subdivision (e)(2).

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

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

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

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

23 16. Respondent, as the owner, operator and “Medical Director” of Bloom Natural Health,
24 has failed to use the required words and/or designations in offering and/or advertising her
25 professional services as part of “Bloom Natural Health” and/or “Bloom” in conformance with
26 Business and Professions Code section 3674.

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1 PRAYER

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

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

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

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

11
12 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

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