BEFORE THE

OREGON MEDICAL BOARD

STATE OF OREGON

In the Matter of	)	
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ELIZEBETH ROSE HARMON, MD	)	ORDER OF EMERGENCY
LICENSE NO. MD15582	)	SUSPENSION
	)	

1.

The Oregon Medical Board (Board) is the state agency responsible for licensing, regulating and disciplining certain health care providers, including physicians, in the State of Oregon. Elizebeth Rose Harmon, MD (Licensee) is a licensed physician in the State of Oregon.

2.

The acts and conduct that support this Order for Emergency Suspension follow:

2.1 Licensee entered into a Stipulated Order with the Board in July 2017, which imposed terms of discipline and conditions of probation. Licensee subsequently entered into an Interim Stipulated Order (ISO) with the Board in January 2018, providing that Licensee must not perform lipoplasty on any patient.

2.2 Licensee is board certified in obstetrics and gynecology (OBGYN) practicing in Salem, Oregon, where Licensee owns and operates the Bella Rose Medispa, which is co-located with the Salem Women's Clinic. Board investigators went to Licensee's clinic for a site visit in December 2017, where Licensee informed the investigators that she performed minor surgeries, to include lipoplasty, at her clinic. A review of patient medical charts provided by Licensee revealed that at least five patients underwent a lipoplasty procedure in which more than 500 cc of supernatant fat was removed. The Board's Division 017 regulations for Office Based Surgical Facilities require that lipoplasty involving the removal of more than 500 cc of supernatant fat must be performed as a Level II or III surgical procedure. Licensee's clinic was not accredited as a Level II or III office based surgical facility when the surgeries took place, which placed her

patients at serious risk of harm. Licensee's conduct displayed a disregard for board rules that are designed to protect patient safety, and violated ORS 677.190(17) and the Board's Division 017 administrative rules, Office-Based Surgery or Procedures.

2.3 During the site visit in December 2017, Licensee informed the Board investigators that she often performs procedures to insert BioTE testosterone[1] pellets into adult male and female patients to treat certain symptoms, such as "mind fog," fatigue, hot flashes and sexual dysfunction. The Board conducted a review of patient charts (Patients A – J), in which Licensee treated adult male and female patients with BioTe testosterone pellets,[2] and for some patients, treatment with estrogen pellets as well as oral thyroid medication. The Board's review revealed that Licensee is treating pre- and post-menopausal women with testosterone to address non-specific symptoms such as fatigue, "mind fog" and low libido. Licensee also inserts testosterone pellets into men whose testosterone levels tested within the normal range. Licensee's work-up of her patients for this treatment was consistently incomplete. Prior to initiating treatment in male patients, Licensee does not confirm a diagnosis of hypogonadism with lab studies reflecting a consistently low serum testosterone level or perform a prostate or testicular examination. Licensee also failed to consistently conduct follow-up examinations or studies after initiating treatment with high doses of testosterone to check for complications. In some cases, patients had pellets that extruded from the incision site, requiring removal.

2.4 The U. S. Food and Drug Administration (FDA) issued a caution on March 3, 2015, that prescription testosterone products are approved only for men who have low testosterone caused by certain medical conditions.[3] On May 22, 2017, the FDA issued a warning letter to the principal owner and chairman of BioTE Medical, LLC for making false and misleading claims about their products. The Endocrine Society's Clinical Practice Guideline

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[1] Testosterone is a Schedule III controlled substance.

[2] BioTE testosterone pellets are not FDA approved. The pellets are inserted using a small incision, typically in the upper buttocks/hip area under local anesthesia.

[3] The Clinical Practice Guideline published by the Endocrine Society in March 2018 addressing testosterone therapy in men with hypogonadism recommends "...making a diagnosis of hypogonadism only in men with symptoms and signs consistent with testosterone (T) deficiency and unequivocally and consistently low serum T concentrations."

(August 20, 2014) recommends against the general use of testosterone to treat women for infertility, sexual dysfunction (other than hypoactive sexual desire disorder) and other health conditions. Peer reviewed medical literature does not support Licensee's contention that bioidentical hormone therapies are efficacious and safe in the manner that Licensee is using them. In her informed consent form, Licensee lists some side effects associated with female testosterone and/or estradiol insertion, and claims many benefits, to include increased libido, energy and sense of well-being, decreased frequency and severity of migraine headaches, mood swings, anxiety, as well as decreased risk or severity of diabetes, risk of heart disease, and risk of Alzheimer's and dementia. These claims of benefits for a wide spectrum of patients are not supported by peer reviewed controlled studies or a consensus of the medical community. Licensee failed to inform her patients in her consent form of the FDA caution or that BioTE testosterone pellets have not been approved by the FDA. Licensee also failed to inform her patients of the possible increased risk of heart disease, stroke, thrombosis, weight gain; the possibility of long term unknown risks; or for her male patients—that testosterone replacement induces temporary or semi-permanent suppression of spermatogenesis.

2.5 By extolling the benefits of and proceeding with testosterone, estradiol and thyroid treatment without clinical justification, Licensee exposed her patients to the risk of harm without clinical justification, and failed to conform her practice to the fundamental medical principle "to first, do no harm." Licensee's conduct, as revealed in paragraphs 2.3 and 2.4, and in the more detailed descriptions that follow, subjected Patients A – J to the risk of serious harm, and constituted unprofessional or dishonorable conduct, in violation of ORS 677.190(1)(a), as defined by ORS 677.188(4)(a), (b), and (c); violated ORS 677.190(9) making statements that Licensee knew, or with the exercise of reasonable care should know, are false and misleading, regarding skill or efficacy or value of the medicine, treatment or remedy prescribed or administered by Licensee; constituted gross or repeated acts of negligence, in violation of ORS 677.190(13); and also violated ORS 677.190(24) prescribing controlled substances without a legitimate medical purpose or prescribing without following accepted procedures for

examination of patients or procedures for record keeping. Specific concerns regarding Licensee's treatment of patients with BioTE testosterone pellets as well as estradiol and thyroid oral medications are set forth below:

a. Patient A, a 34-year-old female, who had a history of a post bilateral tubal ligation, presented to Licensee in March of 2017 with complaints of fatigue, menorrhagia, weight gain and diminished libido. On March 21, 2017, Patient A's thyroid functions were normal; her testosterone level was 17ng/dl and estradiol[4] level 83 pg/ml (within the normal range). On April 10, 2017, Licensee noted no contraindications for testosterone, and Licensee treated Patient A with thyroid, 1 gram per day and testosterone, 175 mg, in 2 pellets. On June 30, 2017, Licensee noted Patient A's estradiol level to be 92.33, her testosterone level 276.4, her FSH[5] to be 1.96 and TSH[6] of 1.76. Licensee increased the thyroid medication from 1 gram to 1.5 grams. Patient A underwent an evaluation for a hysterectomy for continued menorrhagia in January 2018 and received an additional 175 mg of testosterone in 2 pellets. Treatment of this patient with testosterone and thyroid was not medically indicated and exposed Patient A to the risk of harm.

b. Patient D is a 79-year-old female with a history of hypertension, stroke with a retinal artery occlusion, and two stents for coronary atherosclerotic heart disease (CASHD). The patient was taken off estrogen because of her CASHD. She complained of fatigue and hot flashes. Licensee noted fatigue and severe menopause symptoms. Lab studies revealed a normal thyroid function and estrogen levels in the normal range. Nevertheless, on May 25, 2017, Licensee treated Patient D with pellets containing 87.5 mg of testosterone and 10 mg of estrogen. Patient D's estradiol level rose from about 25 to 46 and her testosterone level was 146. Without further lab studies, Licensee gave Patient D a booster dose of 37.5 mg of testosterone and 10 mg of estrogen on July 27, 2017, and an additional dose of 137.5 mg of testosterone and 18.5 mg of estradiol on October 3, 2017. Licensee treated Patient D with another 137.5 mg of testosterone and 10 mg of estradiol on January 2, 2018. Licensee's treatment was not medically indicated

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[4] A form of estrogen.
[5] Follicle-stimulating hormone.
[6] Thyroid stimulating hormone.

and exposed Patient D to the risk of harm, to include the possible increased risk of heart disease, stroke and thrombosis, particularly in view of her advanced age and health history.

c. Patient F, a 40-year-old male with a history of ADHD, Bipolar Disorder, and morbid obesity (BMI 44), presented to Licensee on May 19, 2017, with complaints of fatigue and low libido. Patient F was taking Adderall (Schedule II, amphetamine/dexamphetamine) 80 mg, Latuda (Lurasidone) 120 mg, Lamictal (Lamotrigine) 200 mg, and Propecia (Finasteride) 1 mg. Laboratory studies obtained in January 2017 revealed a normal thyroid function, estradiol 56, a testosterone level of 300 (within normal range), and Prostate Specific Antigen (PSA) 0.19. Licensee did not conduct a genital or prostate examination or order a repeat testosterone test. His blood pressure was 158/98. Licensee treated Patient F with 2400 mg of testosterone in twelve 200 mg BioTE pellets. In August 2017, Patient F's testosterone level was 1080 and estradiol 114. Licensee prescribed an oral BioTE DIM (diindolylmethane) supplement that was said to improve estrogen metabolism. In November 2017, Patient F received a second treatment with 2400 mg of testosterone pellets, with no physical examination or repeat PSA check. Patient F's blood pressure was 140/76 and a BMI of 45.2. Licensee's treatment was not medically indicated and exposed Patient F to the risk of harm.

d. Patient H, a 43-year-old male with a history of sleep apnea, was seen by Licensee on February 13, 2017, complaining of fatigue, mental fog and decreased libido. His testosterone level was tested once, revealing a subnormal level of 144, with a normal PSA level of 1.08 and normal thyroid level. Patient H's hematocrit[7] and pituitary function were not checked. Without ordering a second test, Licensee treated Patient H with 2,000 mg of testosterone in ten pellets. On May 30, 2017, Patient H's testosterone level was 943 with an estradiol level of 46. He received another 2,000 mg of testosterone in pellets. On September 19, 2017, it was necessary to remove an extruding pellet and Patient H's testosterone level was noted to be 594. He was treated with 2,400 mg of testosterone pellets. On December 17, 2017, Patient H received a 600

[7] Testosterone can increase the red cell count. A patient with a co-morbidity such as lung disease could have an adverse reaction if the hematocrit level rises too high.

mg boost of testosterone pellets to replace three pellets which had previously been extruded. On January 15, 2018, Patient H's estradiol level was 45, and his testosterone level was 623. Patient H received another 1,200 mg of testosterone. During the course of treatment, Licensee did not test Patient H's PSA level or conduct testicular or prostate examinations. Licensee's treatment for Patient H was not medically indicated and exposed him to the risk of harm.

e. Patient I, a 74-year-old male, had a family history of prostate cancer and a personal history of hypertension, lung cancer, stroke, and atrial fibrillation, and was maintained on a course of warfarin (Coumadin). Despite this health history, Patient I underwent a lipoplasty procedure in December 2013, in which Licensee removed 2,200 cc of fat. On April 9, 2017, Patient I presented to Licensee with complaints of diminished libido and low energy. Patient I's testosterone level was 282, PSA 2.28 and normal thyroid functions. Licensee did not perform a genital or prostate examination, and treated Patient I with testosterone pellets, 1,500 mg. On June 30, 2017, Patient I's estradiol level was 48 and testosterone level 1447. On August 2, 2017 and December 12, 2017, Licensee treated Patient I with testosterone 1,500 mg with no follow-up PSA or hematocrit tests. Licensee also prescribed a supplement (ADK-10) containing vitamin K, which could reverse Patient I's anticoagulant medication, warfarin. Licensee's treatment for Patient I was not medically indicated and exposed Patient I to the risk of harm, particularly the possible increased risk of heart disease, stroke and prostate cancer.

f. Patient J, a 75-year-old male, with a history of a mildly enlarged prostate and hyperlipidemia, presented to Licensee on August 23, 2017, with complaints of diminished energy. A lab study revealed a testosterone level of 688, PSA of 2.2 and a normal thyroid function. Despite these results that were in the normal range, Licensee treated Patient J with a dose of 1,200 mg of testosterone and thyroid (1 gram daily). Licensee did not conduct a genital or prostrate examination. On September 21, 2017, Patient J's testosterone level rose to 2,468 and an estradiol level of 55. On January 23, 2018, Patient J's testosterone level was 810 and a PSA level was 3.67. On February 14, 2018, Patient J's PSA level was 3.74 and he was referred to an urologist. Licensee's treatment for Patient E was not medically indicated and exposed him

to the risk of harm, including the possible increased risk of heart disease, stroke and prostate cancer.

3.

The Board has determined from the evidence available at this time that Licensee's continued practice of medicine would pose an immediate danger to the public and to her patients. Licensee was offered the opportunity to enter in an Interim Stipulated Order with the Board to voluntarily agree that she would not treat any premenopausal women with testosterone; follow Endocrine Society Clinical Guidelines for treating postmenopausal women; comply with the Endocrine Society Clinical Practice Guidelines for treatment with estrogen, testosterone, or thyroid hormones; refrain from treating male patients with testosterone whose testosterone levels test within the normal range; and refrain from treating patients whose thyroid-stimulating hormone level is within the normal range as recognized by the Endocrine Society. Licensee declined to do so. Therefore, it is necessary to immediately suspend her license to practice medicine. To do otherwise would subject Licensee's patients to the risk of harm while this case remains under investigation.

4.

Licensee is entitled to a hearing as provided by the Administrative Procedures Act (chapter 183), Oregon Revised Statutes. Licensee may be represented by legal counsel at a hearing. If Licensee desires a hearing, the Board must receive Licensee's written request for hearing within ninety (90) days from the date the mailing of this Notice to Licensee, pursuant to ORS 183.430(2). Upon receipt of a request for a hearing, the Board will notify Licensee of the time and place of the hearing and will hold a hearing as soon as practical.

5.

Pursuant to ORS 677.205(3) and by a majority vote of the Board on June 7, 2018, the Board suspends the license Elizabeth Rose Harmon, MD, on an emergency basis, effective June 13, 2018, at 5:00 p.m. Pacific Time, at which time Licensee must cease the practice of medicine until otherwise ordered by the Board.

6.

NOTICE TO ACTIVE DUTY SERVICEMEMBERS: Active duty servicemembers have a right to stay these proceedings under the federal Servicemembers Civil Relief Act. For more information contact the Oregon State Bar at 800-452-8260, the Oregon Military Department at 800-452-7500 or the nearest United States Armed Forces Legal Assistance Office through http://legalassistance.law.af.mil.

IT IS SO ORDERED THIS 12th day of June, 2018.

OREGON MEDICAL BOARD
State of Oregon

[redacted]

K. DEAN GUBLER, DO
BOARD CHAIR