STATE OF VERMONT
SECRETARY OF STATE
OFFICE OF PROFESSIONAL REGULATION
NATUROPATHIC PHYSICIANS

In re: Emily C. Maiella **Docket no. 2017-789**
License no. 099.0000233

FINAL ORDER

Appearances:
Prosecuting Attorney: Jennifer B. Colin, Esq.
Respondent's Attorney: Daniel D. Crisp, IV, Esq.
Respondent: Dr. Emily C. Maiella

Administrative Law Officer:
Michael S. Kupersmith, Esq.

The parties appeared before Administrative Law Officer Michael S. Kupersmith at the Office of Professional Regulation on August 14, 2018. On July 18, 2018, the ALO issued a Decision which found that the Respondent had engaged in unprofessional conduct because she had violated 26 V.S.A. § 4122(b)(3): she had used for therapeutic purposes a medical device, the EXT120 Briefcase Ozone Generator System, regulated by the FDA which had not been approved by the FDA. A copy of the Decision is hereby incorporated into this final order and is appended hereto.

A hearing was scheduled for the ALO to consider the appropriate sanction to impose for Respondent's violation. At hearing, Ms. Colin recommended the sanction set forth below, which the Respondent did not oppose.

The Administrative Law Officer hereby ORDERS as follows:

1. The Respondent is *reprimanded* for unprofessional conduct.

2. The Respondent is directed to file with the Office of Professional Regulation within thirty (30) days of the date of entry of this final order a certification, affirmed under the pains and penalties of perjury, that she is not using and will not use the EXT120 Briefcase Ozone Generator System or any similar device in the course of her practice unless and until such device is approved by the FDA or such use is otherwise authorized by law.

Dated at Montpelier, Vt., August 15, 2018,

Michael S. Kupersmith
Administrative Law Officer

Date of Entry: 8-24-18

APPEAL RIGHTS

This is a final administrative determination by the Administrative Law Officer. A party aggrieved by a final decision may appeal the decision by filing a written Notice of Appeal with the Director of the Office of Professional Regulation, 89 Main St., 3rd floor, Montpelier, VT 05620-3402, within 30 days of the entry of this Order. If an appeal is filed, the Director of the Office of Professional Regulation shall assign the case to an Appellate Officer. The review shall be conducted on the basis of the record created before the Administrative Law Officer. In cases of alleged irregularities in procedure before the Administrative Law Officer, not shown in the record, proof on that issue may be taken by the Appellate Officer. 3 V.S.A. §§ 129(d) and 130a. A stay of this Order may be requested.

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DECISION

On or about December 19, 2017, the prosecuting attorney for the State of Vermont filed a Specification of Charges against Respondent Emily A. Maiella. The Specification alleged that the Respondent, a person licensed as a Naturopathic Physician, provides "major auto-hemotherapy" to treat certain diseases or ailments in patients. Major auto-hemotherapy involves withdrawing blood from a patient, infusing the blood with ozone generated by a machine, and infusing the ozone-treated blood back into the same patient. The prosecuting attorney charged that the Respondent engaged in unprofessional conduct in that she, "Use[d] for therapeutic purposes any device regulated by the United States Food and Drug Administration (FDA) that has not been approved by the FDA." On or about January 8, 2018, the Respondent filed an Answer to the Specification in which she denied engaging in unprofessional conduct as alleged and interposed a number of affirmative defenses.

On or about May 18, 2018, the attorneys for the parties requested, and were granted leave to submit the dispute to the undersigned Administrative Law Officer (ALO) on briefs in lieu of a final hearing. The attorneys agreed that the dispute could be settled by the resolution of two legal issues: (1) whether the ozone generator[1] used by the Respondent is a medical device regulated by the FDA that has not been approved by the FDA; and (2) if the ozone generator is a medical device, whether Respondent's use of the generator is exempt from FDA regulation under 21 C.F.R. § 807.65(d).[2]

On June 12, the parties filed an eleven-paragraph Stipulated Facts. Subsequently, each party filed a timey brief and on July 13, the State filed its reply brief. The ALO hereby adopts the Stipulated Facts (SF) and hereby incorporates the same into this Decision.

I. The EXT120 Briefcase Ozone Generator System is a medical device regulated by the FDA which has not been approved by the FDA.

The Respondent has been charged with a violation of 26 V.S.A. § 4122(b)(3) which provides as follows:

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[1] The name of the ozone generator is the EXT120 Briefcase Ozone Generator System. See SF § 4. It will variously be referred to here as the System or the EXT120 System.

[2] The parties have phrased the issues in slightly different terms, but this paragraph captures the essence of the agreed issues of law.

(b) A person licensed under this chapter [which regulates Naturopathic Physicians] shall not perform any of the following acts:

> **(3)** Use for therapeutic purposes any device regulated by the United States Food and Drug Administration (FDA) that has not been approved by the FDA.

The parties agree that the EXT120 System has not been approved by the FDA. SF 8. The issue to be resolved, then, is whether the System is a medical device that is subject to FDA regulation.[3]

The definition of "device" is found at 21 U.S.C. § 321(h)

> **(h)** The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
>
> **(1)** recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> **(2)** intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> **(3)** intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 360j(o) of this title.

The parties appear to agree that whether or not the System is a "device" within the meaning of 21 U.S.C. § 321(h) depends on whether it meets the definition set forth in subsection (h)(2), i.e., whether the System is "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . .."

The Respondent contends that the only intent that the ALO can consider is the manufacturer's claims as to the product's use. *Brown & Williamson Tobacco Corp. v. Food & Drug Admin.* 153 F.3d 155, 163 (4th Cir. 1998) ("As noted by the district court, 'no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the [Act] absent manufacturer claims as to that product's use.'") (citation omitted).

In *Brown & Williamson* the issue was whether the FDA could regulate tobacco products

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[3] The burden of proof is on the State to show by a preponderance of the evidence that the Respondent has engaged in unprofessional conduct. In this case, the factual basis has been met by the Stipulated Facts. Whether the stipulated activity constitutes unprofessional conduct is strictly a question of law.

as a drug. 153 F.3d at 160. As the court noted, the FDA can only regulate products within the categories authorized by Congress. *Id.* The FDA had asserted jurisdiction over tobacco products under 21 U.S.C. § 321. *Id.* "According to the FDA, tobacco products fit within these definitions because they are 'intended to affect the structure or any function of the body.'" *Id.* The court concluded that the FDA would have jurisdiction if tobacco products met the definition of "drug or device," and that it could only do so of the products affected the structure or function of the body *and* that they were intended by the manufacturer to do so. 153 F.3d at 163. The plaintiffs never claimed that their products had any medical benefits whatsoever and there was no basis on which to infer such intent. It is in this context that the comment quoted by Respondent was made. The Fourth Circuit was loath to infer such intent absent objective evidence of the same.

The ALO is not persuaded that he must rely only on the manufacturer's express intent in applying section 321(h)(2). Logic and reason suggest that the ALO can consider all of the relevant facts and reasonable inferences drawn therefrom. See, e.g., *Brown & Williamson Tobacco Corp. v. Food & Drug Admin.* 153 F.3d at 177 (listing examples of how intent may be inferred) (Hall, J. dissenting). Indeed, 21 C.F.R. 801.4 states that the terms "intended uses or words of similar import" refer to the objective intent of the persons legally responsible for labeling devices and the intent may be inferred from virtually any source. Some of these are suggested in the regulation:

> It may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer.. . .

In support of her position, Respondent points to the manufacturer's disclaimer, set forth in paragraph 11 of the Stipulated Facts.

> Disclaimer: In order to abide by guidelines of the Competition Bureau of Canada and the Federal Trade Commission of the USA, Longevity Resources, Inc. clarifies that products displayed on this web site are not approved medical devices (unless otherwise stated). No approved medical ozone generators exist in North America due to the fact that governing health authorities do not support the use of ozone in medicine. Longevity Resources, Inc. makes no claims or suggestions regarding the use of ozone, oxygen, saunas or ozone related products for ozone therapy for cancer or any other diseases or health challenges. Please consult a qualified physician before using any products, drugs, or devices that may affect your health.

The disclaimer states that the manufacturer "makes no claims or suggestions" regarding the use of ozone "for ozone therapy for cancer or any other diseases or health challenges." It is possible to infer from this statement that the manufacturer does not intend its product to be used for treatment of disease, but the disclaimer does not make that representation; only that it makes no claims about such use. The more reasonable inference, and the ALO does so infer and conclude, is that the manufacturer has included the disclaimer precisely because it knows that end-purchasers will use the machine in the manner used by the Respondent, that is, for treatment of

"health challenges." One must ask, what is the purpose of the System other than the purpose for which it is being used by the Respondent? The Respondent does not imply or suggest that the System has any purpose or function other than the one she employs.

It is clear from the Respondent's Answer that *she* intends to use and does use the ozone generated by the System to treat her patients:

> Dr. Maiella infuses a patient's blood with an approximate 98% oxygen, 2% ozone combination produced from the EXT120 Briefcase Ozone Generator System.. . . As previously stated, Dr. Maiella only uses this system as part of a process of treating and/or mitigating certain medical conditions and/or diseases.

Answer, ¶ 7. See also, Stipulated Facts ¶ 6.

The Respondent argues, in circular fashion, that the System is not a medical device because the manufacturer has not registered the System with the FDA as a medical device. *Sub rosa*, Respondent suggests that if the System were a medical device, the FDA would take measures to secure compliance with registration laws. The ALO cannot account for FDA action or inaction. The ALO draws no inference from the manufacturer's failure to register the system other than it has not attempted to do so.

The ALO concludes that the EXT120 System is a medical devise subject to regulation by the FDA because it is intended, both by the manufacturer and the Respondent, "for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . .." 21 U.S.C. § 321(h)(2).

II. The Respondent's use of the EXT 120 System is not exempt from FDA regulation under 21 C.F.R. § 807.65(d).

21 C.F.R. § 807.65(d) provides:

> The following classes of persons are exempt from registration in accordance with § 807.20 under the provisions of section 510(g)(1), (g)(2), and (g)(3) of the act, or because the Commissioner of Food and Drugs has found, under section 510(g)(5) of the act, that such registration is not necessary for the protection of the public health. The exemptions in paragraphs (d), (e), (f), and (i) of this section are limited to those classes of persons located in any State as defined in section 201(a)(1) of the act.
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> * * *
>
> (d) Licensed practitioners, including physicians, dentists, and optometrists, who manufacture or otherwise alter devices solely for use in their practice.

21 C.F.R. § 807.65 exempts certain persons from "registration" in accordance with §807.20. Section 807.20 affects only

> (a) An owner or operator of an establishment . . . who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use . . ..

The Respondent is not a person who "is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing" of the EXT120 device. Respondent admits that she does not "manufacture the System." See Brief of Respondent, p. 7. See also, Stipulated Facts, ¶ 10. Rather, she claims that, "the attachment of a Leur-Lock to the System for the purpose of Major Auto-Hemotherapy procedure would constitute the alteration of the System solely for use in Dr. Maiella's practice." Brief of Respondent, p. 7.

There are a number of problems with Respondent's position: First and foremost, section 807.65(d) applies only to situations in which a licensed practitioner alters a *device* for use in his or her own practice. The section exempts certain persons from the application of section 807.20. Section 807.20 applies only to those who "engage[] in the manufacture, preparation, propagation, compounding, assembly, or processing of a device . . .." But the Respondent does not engage in any of these activities.

The term "device" is defined in 21 U.S.C. § 321(h). By reading together C.F.R sections 807.65(d) and 807.20, it is clear that they are intended to apply only when a licensed practitioner alters an approved device for his or her own use. The regulation is intended to negate a possible implication that a practitioner would be subject to section 807.20 by reason of altering a device. It would be anomalous, as well as contrary to the purpose of the Federal Food, Drug, and Cosmetic Act, to authorize the use of an unapproved machine simply because of practitioner made some minor adjustment to it.

There are other problems with Respondent's argument. In her brief, Respondent claims that she attaches "a Leur-Lock to the System for the purpose of Major Auto-Hemotherapy." Brief at p. 7. The claim is not part of the Stipulated Facts; therefore there is no evidence to support her claim. There is no evidence of what a Leur-Lock is. There is no evidence of what Respondent must do to attach a Leur-Lock to the System. There is no evidence to support Respondent's contention that the attachment of a Leur-Lock constitutes an alteration of the System.

The ALO concludes that the Respondent's use of the EXT 120 System is not exempt from FDA regulation under 21 C.F.R. § 807.65(d).

III. Miscellaneous Issues.

In her Brief, Respondent raises legal issues that were beyond the understanding of the attorneys when they agreed to submit the dispute on legal briefs. See, Motion for Permission to File Brief in lieu of Final Hearing, p. 2. Nevertheless, the ALO will address the issues raised.

A. Denial of Due Process.

Respondent claims that, "any action taken against Dr. Maiella's license on the basis of 26 V.S.A. § 4122(b)(3) would violate Dr. Maiella's right to due process." Brief of Respondent, p. 10. She explains that, section 4122(b)(3), referenced as a basis for discipline, does not, as applied to this case, "'convey[] a definitive warning as to proscribed conduct when measured by

common understanding and practices.'" (quoting *Brody v. Barasch*, 155 Vt. 103, 111 (1990)).

26 V.S.A. §4122 provides as follows:

(b) A person licensed under this chapter shall not perform any of the following acts:

(3) Use for therapeutic purposes any device regulated by the United States Food and Drug Administration (FDA) that has not been approved by the FDA.

In *Brody v. Barasch*, the issue raised by the appellant was that the statute under which he had been subjected to disciplinary action was void for vagueness. 155 Vt. at 110. The appellant, a psychologist, argued that the statutory prohibition against "moral unfitness to practice psychology" was unconstitutionally vague. *Id.* The Supreme opined that,

> Although the term "moral unfitness" is undefined, this does not necessarily render it unconstitutionally vague. To make a statute sufficiently certain to comply with constitutional requirements, it is not necessary that it detail each and every act or conduct that is prohibited.. . . Statutory language that conveys a definite warning as to proscribed conduct when measured by common understanding and practices will satisfy due process.

155 Vt. at 111. (citations omitted).

Brody is inapposite. The language in 26 V.S.A. 4122(b)(3) is specific and clear. The Respondent is complaining that she did not understand that she was not permitted to use the EXT120 System because she did not understand that it was a device regulated by the FDA and she was not exempted from application of the statute. The fact that she did not understand that use of the EXT120 System was prohibited by the statute does not render the statute void for vagueness.

B. Section 4122(b)(3) does not unreasonably discriminate against Naturopathic Physicians.

Respondent claims that the statute unreasonably discriminates against Naturopathic Physicians because a medical doctor would not be prohibited from offering major auto-hemotherapy to his or her patients. In support of her position, Respondent cites Title 26, chapter 23, without further explanation or definition. (The ALO has not searched chapter 23 in its entirety, but assumes that the chapter does not contain a provision similar to section 4122(b)(3).)

The Respondent cites no legal authority in support of her contention. As such, it need not be considered by the ALO. See, *KPC Corp. v Book Press, Inc.* 161 Vt. 145, ___ (1993) (assertion in brief not accompanied by facts, law or reasoning need not be considered). The ALO notes in passing that each profession has its own rules of practice, including perhaps, which practices are permitted and which are prohibited. Even if medical doctors are permitted to utilize major auto-hemotherapy—the absence of a statute in chapter 23 similar to 4122(b)(3) is not determinative of the issue—that does not mean that section 4122(b)(3) *unreasonably* discriminates against Naturopathic Physicians. The ALO suspects, for example, that Naturopathic Physicians cannot perform brain surgery either.

CONCUSION

The Administrative Law Officer concludes that the Respondent has engaged in unprofessional conduct in violation of 26 V.S.A. §4122(b)(3) in that she used for therapeutic purposes a medical device, the EXT120 Briefcase Ozone Generator System, regulated by the FDA which has not been approved by the FDA. The Respondent's use of the EXT120 System is not exempt from FDA regulation under 21 C.F.R. § 807.65(d).

This Decision is not a final order. The docket clerk will set this matter for further hearing pursuant to 3 V.S.A. § 129a(d) to determine the appropriate disciplinary action to be imposed. A final order will be issued at that time.

Dated at Montpelier, Vt., July 18, 2018

Michael S. Kupersmith
Administrative Law Officer

Date entered: 7-25-18

STATE OF VERMONT
SECRETARY OF STATE
OFFICE OF PROFESSIONAL REGULATION
NATUROPATHIC PHYSICIANS

IN RE:
Emily C. Maiella
License No. 099.0000233

Docket No. 2017-789

STIPULATED FACTS

NOW COME the State of Vermont, by and through Prosecuting Attorney Jennifer B. Colin, and Respondent Emily C. Maiella, by and through her counsel, Daniel T. Crisp, IV, Esq., and hereby Stipulate and Agree to the following facts:

1. Emily C. Maiella ("Respondent") of Brattleboro, Vermont is licensed by the State of Vermont as a naturopathic physician under license number 099.0000233. This license was originally issued on November 19, 2007 and expires on September 30, 2018.

2. Respondent owns and works as a Naturopathic Physician at Windhorse Naturopathic Clinic in Brattleboro, Vermont.

3. In her practice, Respondent employs an oxidative therapy called "Ozone Therapy" or "Major Auto-Hemotherapy" to help patients with rheumatoid diseases, arterial and circulatory disorders, osteoporosis and osteoarthritis pain, viral and bacterial diseases, and immune deficiencies caused by Lyme Disease and other medical conditions.

4. To provide Ozone Therapy or Major Auto-Hemotherapy, Respondent draws blood from the patient, infuses the blood with a combination of oxygen and ozone produced from the EXT120 Briefcase Ozone Generator System (an ozone generator machine), which packages the oxygen and ozone combination into a syringe. Respondent then mixes the oxygen/ozone combination with the patient's blood in an intravenous ("IV") bag. Thereafter, Respondent intravenously infuses the oxygenated/ozonated blood back into the patient.

5. The EXT120 Briefcase Ozone Generator System is not connected to the patient during the process, nor is ozone directly infused from the machine into the patient, by blood or inhalation, at any time.

6. Respondent uses the EXT120 Briefcase Ozone Generator System for medical and health-related purposes, by providing Ozone Therapy or Major Auto-Hemotherapy to treat and/or mitigate certain medical conditions and/or diseases.

7. To the best of the parties' knowledge, Dr. Maiella is the only Naturopathic Physician in Vermont who offers Ozone Therapy.

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Prosecuting Attorney
Office of
Professional Regulation
89 Main Street
3rd Floor
Montpelier, VT
05620-3402

8. The U.S. Food and Drug Administration ("FDA") regulates devices that generate ozone by design or as a byproduct. *See generally* 21 C.F.R. §801.415.

9. The EXT 120 Ozone Generator System used by Respondent has not been approved by the FDA as a medical device.

10. Longevity Resources Inc. is the manufacturer of the EXT 120 Ozone Generator System.

11. In its online advertisement for the sale of the EXT 120 Ozone Generator System, Longevity Resources Inc. provides the following disclaimer:

Disclaimer: In order to abide by guidelines of the Competition Bureau of Canada and the Federal Trade Commission of the USA, Longevity Resources, Inc. clarifies that products displayed on this web site are not approved medical devices (unless otherwise stated). No approved medical ozone generators exist in North America due to the fact that governing health authorities do not support the use of ozone in medicine. Longevity Resources, Inc. makes no claims or suggestions regarding the use of ozone, oxygen, saunas, or ozone related products for ozone therapy for cancer or any other diseases or health challenges. Please consult a qualified physician before using any products, drugs, or devices that may affect your health.

STATE OF VERMONT
SECRETARY OF STATE

By: _____ 6/11/18
Jennifer B. Colin date
Prosecuting Attorney
(802)828-1219
Jennifer.Colin@sec.state.vt.us

COUNSEL FOR RESPONDENT

By: _____ 6/11/18
Daniel T. Crisp, IV, Esq. date
Downs Rachlin Martin, PLLC

STATE OF VERMONT
Prosecuting Attorney
Office of
Professional Regulation
89 Main Street