

IN THE CIRCUIT COURT FOR DAVIDSON COUNTY, TENNESSEE
TWENTIETH JUDICIAL DISTRICT AT NASHVILLE

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SHARON R. HOCKER, CLERK
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STATE OF TENNESSEE,
ex rel. ROBERT E. COOPER, JR.,
ATTORNEY GENERAL and REPORTER,

Plaintiff,

v.

HRC MEDICAL CENTERS, INC., a domestic
corporation, *formerly known as* HAIR
RESTORATION CENTERS OF TENNESSEE,
INC., HRC MANAGEMENT MIDWEST, LLC,
a foreign limited liability company,
DAN E. HALE, D.O., *individually and as an*
officer, and DON HALE, *individually and as an*
officer,

Defendants.

JURY DEMAND

Case No. 12C4047

9.17.11 **PROPOSED EX PARTE STATUTORY TEMPORARY RESTRAINING ORDER**

Before the Court is the State's *Ex Parte* Motion for a Statutory Temporary Restraining Order. The State asserts that the Motion should be heard without notice to the Defendants to prevent additional consumers from being exposed to serious health risks and side effects and unsubstantiated efficacy, benefit, and safety claims about "bio-identical" hormone replacement therapy – without the consumers' knowledge.

In support of the State's Motion, the State has submitted 52 supporting exhibits, including Exhibit 1, a version of the Complaint that provides footnotes to the record for facts alleged in the Complaint, sworn testimonies from four former employees, twenty-two consumer affidavits, the affidavit of Ted Louis Anderson, M.D., PhD, Director of the

Department of Gynecology at Vanderbilt University Medical Center, the affidavit of Laurie Tompkins, an Advanced Practice Registered Nurse at Vanderbilt Women's Center and an Associate Professor at the Vanderbilt University Medical School, and the Defendants' "bio-identical" hormone replacement therapy ("BHRT") advertisements.

Based on a review of the record, the State's Motion is GRANTED as set forth below.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. This Court has jurisdiction over the subject matter of this case, and there is good cause to believe the Court will have jurisdiction over all parties hereto and that venue in this court is proper.

2. There is good cause to believe that Defendants HRC Medical Centers, Inc. ("HRC Medical"), Defendant HRC Management Midwest, LLC, Dan E. Hale, and Don Hale have engaged in, currently engage in, and are likely to engage in commercial acts or practices that violate the Tennessee Consumer Protection Act of 1977, Tenn. Code Ann. §§ 47-18-101, *et seq.*, ("TCPA") that the State is likely to succeed on the merits of this action, that this action is in the public interest, and that this order is within the authority granted to this Court under Tenn. Code Ann. § 47-18-108(a)(1).

3. Pursuant to Tenn. Code Ann. § 47-18-103(19), Defendants have engaged in "trade" and "commerce" by advertising and offering "bio-identical" hormone replacement therapy ("BHRT") for sale in Tennessee. Further, the Defendants have engaged in numerous transactions for BHRT in Tennessee, have sold the BHRT for monetary gain, and have advertised BHRT in Tennessee.

4. Pursuant to Tenn. Code Ann. § 47-18-115, the TCPA “shall be interpreted and construed consistently with the interpretations given by the federal trade commission and the federal courts pursuant to § 5(A)(1) of the Federal Trade Commission Act (15 U.S.C. §45(a)(1)),” which generally prohibits unfair and/or deceptive commercial acts or practices.

5. Under the TCPA, a deceptive act or practice is one that “causes or tends to cause a consumer to believe what is false, or that misleads or tends to mislead a consumer as to a matter of fact.” *Morrison v. Allen*, 338 S.W.3d 417, 439 (Tenn. 2011).

6. There is good cause to believe that the State will likely succeed in showing that the Defendants have misled or tended to mislead consumers that Defendant HRC Medical’s BHRT restores a user’s hormone levels to the levels that he or she had in his or her twenties or thirties or his or her prime when it does not, that specific medical studies contain quoted language when they do not, that Defendant HRC Medical’s BHRT is supported by more studies than it actually is, that the compounding pharmacy that is used for Defendant HRC Medical’s BHRT has been FDA-approved or adheres to high quality control measures when it has not and does not, that Dr. Dan Hale or other HRC Medical staff has more experience with respect to hormones than he or they actually have, and that the Defendants have more satisfied BHRT consumers than they actually have.

7. Applying the general definition of deception, the FTC has stated that a representation may be misleading if the advertiser lacks adequate support for a given claim. *Advertising Substantiation Policy Statement*. Appended to: *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff’d* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

8. Further, express or implied claims that communicate that the advertiser has more support than the advertiser actually has are deceptive. *Id.* The FTC has held that when the Defendants represent that scientific proof exists when it does not, the substantiation has to consist of the precise type and amount of proof that would satisfy the relevant scientific community. *In the Matter of Removatron Int'l Corp.*, 111 F.T.C. 206 (1988) (citing *Thompson Medical Co.*, 104 F.T.C. 648, (1984), *aff'd* 791 F.2d 189 (D.C. Cir. 1986); *Bristol-Meyers*, 102 F.T.C.21 (1983), *aff'd* 738 F.2d 554 (2d Cir. 1984)).

9. If no amount of substantiation is communicated, the FTC has stated that advertisers must have a reasonable basis for making objective claims before the claims are disseminated. *Advertising Substantiation Policy Statement*. Appended to: *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), *aff'd* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987). Further, under FTC case law, health and safety claims, such as those presented in the State's Complaint are subject to a higher level of substantiation based on "competent and reliable scientific evidence." See, e.g. *Brake Guard Products, Inc.*, 125 F.T.C. 138 (1998), *ABS Tech Sciences, Inc.*, 126 F.T.C. 229 (1998); *In the Matter of Removatron Int'l Corp.*, 111 F.T.C. 206 (1988).

10. Here, there is good cause, based on the affidavits of Jim Vaughn, Suzanne Linden, Ted Louis Anderson, M.D., PhD, Laurie Tompkins, a board-certified advanced practice registered nurse, and statements from the United States Food and Drug Administration, the American Medical Association, the Endocrine Society, the American Congress of Obstetricians and Gynecologists, the North American Menopause Society, the American Association of Clinical Endocrinologists, and the American Cancer Society, that the State will likely be successful in showing that the Defendants made the claims at issue in

the Complaint and that the Defendants do not have the represented levels of substantiation, adequate substantiation generally, or competent and reliable scientific evidence to support claims that Defendant HRC Medical's BHRT:

is safe, is absolutely safe, has no or minimal side effects, has no cancer risk, protects against cancer, increases one's lifespan, acts as a general anti-aging therapy, provides cardiovascular benefits, prevents, treats, or cures heart disease, reduces cholesterol, prevents, treats, or cures high cholesterol levels, prevents, treats, or cures Alzheimer's Disease, prevents, treats, or cures memory loss generally, prevents, treats, or cures diabetes, prevents, treats, or cures Attention Deficit Hyperactivity Disorder, prevents, treats, or cures depression, increases head hair growth, increases head hair thickness, prevents, treats, or cures fibromyalgia, prevents, treats, or cures arthritis, prevents, treats, or cures restless leg syndrome, causes weight loss or helps one maintain weight, is safer, more effective, and less risky than traditional hormone replacement therapy regimens, and that BHRT restores a users hormone levels to the levels that they had in their twenties and thirties or their prime.

11. Under the TCPA, deceptive conduct can also be based on a party's omission or silence. *Tucker v. Sierra Builders*, 180 S.W.3d 109, 116 (Tenn. Ct. App. 2005). An advertisement may be false by either misstating a fact or failing to disclose a material fact. *FTC v. Simeon Management Corp.*, 532 F.2d 708, 714 (9th Cir. 1976). An advertisement is also false if it fails to disclose sufficient facts to counter any false assumptions created by the advertisement, *id.* at 716, including omissions of any negative material facts. *J.B. Williams Co. v. FTC*, 381 F.2d 884, 890 (6th Cir. 1967). Three types of claims are presumed to be material: (1) express claims, (2) implied claims where there is evidence that the seller intended to make the claim; and (3) claims that significantly involve health, safety, or other issues that would concern reasonable consumers. *FTC Deception Policy Statement*. Appended to: *Cliffdale Assocs.*, 103 F.T.C., 110 at 175, 182 (1984); *Kraft, Inc. v. FTC*, 970 F.2d 311, 322 (7th Cir. 1992).

12. There is good cause to believe that the State is likely to succeed in showing that all of the Defendants have omitted material facts in advertisements and other promotional materials relating to the safety, risks, and side effects of Defendant HRC Medical's BHRT. Further, there is good cause to believe that the State is likely to succeed in showing that Defendants HRC Medical, Don Hale, and Dan Hale omitted material facts in advertisements concerning whether the consumer had a material connection to HRC Medical, had a material connection to a principal at HRC Medical, received a benefit for giving the testimonial, or experienced side effects that were not disclosed.

13. Under the TCPA, an unfair act or practice is one where "the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." *Morrison v. Allen*, 338 S.W.3d 417, 439 (Tenn. 2011). Consumer injury will be deemed substantial "if a relatively small harm is inflicted on a large number of consumers or if a greater harm is inflicted on a relatively small number of consumers." *Tucker*, 180 S.W.3d at 117 (internal citations omitted). Substantial injury "must be more than trivial or speculative." *Tucker*, 180 S.W.3d at 117 (internal citations omitted). "Consumers cannot reasonably avoid injury when a merchant's sales practices unreasonably create or take advantage of an obstacle to the free exercise of consumer decision-making." *Tucker*, 180 S.W.3d at 117 (internal citations omitted). "Practices that unreasonably interfere with consumer decision-making include (1) withholding important information from consumers, (2) overt coercion, or (3) exercising undue influence over a highly susceptible class of consumers." *Tucker*, 180 S.W.3d at 117 (internal citations omitted).

14. There is good cause to believe that the State will be able to show that the use of a contract containing a "no-refund" or "store credit" term for a contract involving the provision of future medical services without knowing whether the BHRT will be appropriate at that time given, before blood levels are drawn, or how the consumer will respond to the therapy even initially is unfair.

15. Further, the State has met its burden under Tenn. R. Civ. P. 65.03 by showing that immediate and irreparable injury, loss or damage will result to the State, the commercial marketplace, and to the consumers it is statutorily mandated to protect before the adverse party can be heard in opposition.

16. There is good cause to believe that immediate and irreparable harm to the health and safety of Tennessee consumers will result from Defendants' ongoing violations of the TCPA unless Defendants are restrained by order of this Court. Based on the record, there is a strong likelihood that consumers will be exposed to serious health risks and side effects and unsubstantiated efficacy, benefit, and safety claims – without the consumers' knowledge – if this restraining order is not entered.

17. Weighing the equities and considering the State's likelihood of ultimate success, a Temporary Restraining Order ("Order") is in the public interest. There is good cause to believe that the Defendants possess no right to lawfully make the representations or engage in the commercial activities prohibited below.

18. Under Tenn. Code Ann. § 47-18-108(a)(4), courts are authorized to issue orders and injunctions to restrain and prevent violations of this part, and such orders and injunctions shall be issued without bond.

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

1. "Bio-Identical Hormone Replacement Therapy" or "BHRT" means the hormone replacement therapy offered through subcutaneous pellet insertion by Defendant HRC Medical and Defendant HRC Management Midwest in Tennessee under the name "bio-identical," "bio-natural," "bio-equivalent," "bio-available," "Amor Vie," or any other name. For women, "BHRT" is defined to include estrogen in pellet form, testosterone in pellet form, and/or micronized progesterone delivered through oral tablet. For men, "BHRT" is defined to include testosterone.
2. "Competent and reliable scientific evidence" is defined as tests, analyses, research, studies, or other evidence based upon the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
3. "Material Connection" shall mean a familial relationship by blood, law, or marriage, or by business relationship, employment relationship, ownership interest, or other monetary interest.

ORDER

I. PROHIBITED BUSINESS ACTIVITIES

IT IS THEREFORE ORDERED that Defendant HRC Medical Centers, Inc., Defendant HRC Management Midwest, LLC, their officers, agents, attorneys, Defendant Dan Hale, Defendant Don Hale, and any other person in active concert or participation with these entities and individuals who receives actual notice of this Temporary Restraining Order by personal service or otherwise are hereby restrained from engaging in the following commercial

acts or practices:

A. Representing any product, service, good, or other offering in a manner that misleads or has a tendency to mislead a consumer as to a matter of fact;

B. Representing any product, service, good, or other offering without having a reasonable basis for a given advertising claim before the advertisement containing the claim is disseminated unless a more specific standard identified below applies for the given claim;

C. Representing any product, service, good, or other offering as having a certain type or level of support without possessing the amount and type of substantiation the advertisement actually communicates to consumers;

D. Representing that not replacing one's hormones is unsafe or using words or phrases of similar import;

E. Representing that BHRT is safe, completely safe, absolutely safe, or using words or phrases of similar import;

F. Representing that BHRT involves no cancer risk or using words or phrases of similar import;

G. Representing that BHRT has no or minimal side effects or using words or phrases of similar import;

H. Representing that BHRT protects against cancer or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

I. Representing that BHRT has fewer side effects or risks than traditional hormone replacement therapy regimens or using words or phrases of similar import unless the

representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made. For purposes of (I), "traditional hormone replacement therapy regimens" shall mean conjugated equine estrogens and/or progestins or other forms of estrogen and/or progesterone;

J. Representing that BHRT can be used to increase one's lifespan, or to prevent, treat, or cure diseases or conditions associated with aging or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

K. Representing, without qualification, that BHRT protects against cardiovascular problems or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

L. Representing that BHRT reduces cholesterol or that BHRT can be used to prevent, treat, or cure high cholesterol or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

M. Representing that BHRT can prevent, treat, or cure Alzheimer's Disease or memory loss generally or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

N. Representing that BHRT can prevent, treat, or cure diabetes or using words or phrases of similar import unless the representation is not misleading, and, at the time of making

such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

O. Representing that BHRT can prevent, treat, or cure depression or operates as a safer alternative to FDA-approved anti-depressants with the efficacy or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

P. Representing that BHRT can prevent, treat, or cure Attention Deficit Hyperactivity Disorder (ADHD) or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

Q. Representing that BHRT can prevent, treat, or cure fibromyalgia or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

R. Representing that BHRT can prevent, treat, or cure arthritis or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

S. Representing that BHRT can prevent, treat, or cure Restless Leg Syndrome or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

T. Representing that BHRT can promote head hair growth, increase head hair thickness, or prevent, treat, or cure baldness or thinning hair or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

U. Representing that BHRT can cause weight loss or using words or phrases of similar import unless the representation is not misleading, and, at the time of making such representation, Defendants rely upon Competent and Reliable Scientific Evidence at the time the claim is made;

V. Representing that BHRT restores a consumer's hormone levels to the levels that he or she had in his or her prime or in his or her twenties and thirties, or using words or phrases of similar import, unless the BHRT actually restores a consumer's hormone levels to that level;

W. Representing that a study, trial, or journal article includes a quote or reaches a conclusion that it does not;

X. Representing that BHRT is supported by more substantiation through studies, trials, or otherwise than it actually is;

Y. Representing that a compounding pharmacy has been FDA-approved unless the compounding pharmacy has actually been approved as such by the United States Food and Drug Administration;

Z. Representing that a compounding pharmacy adheres to high quality control standards when this is not the case;

AA. Representing that Dr. Dan Hale or other staff has more hormone therapy expertise than he or they actually do;

BB. Representing that there are more satisfied BHRT consumers than there actually are;

CC. Advertising or otherwise promoting BHRT to women without clearly and conspicuously disclosing the following words below or other words of similar import, that BHRT increases a consumer's risk or possible risk of:

- (1) Developing endometrial cancer,
- (2) Developing breast cancer,
- (3) Developing blood clots, strokes, heart attacks, high blood pressure, or other cardiovascular problems,
- (4) Causing tissue edema,
- (5) Causing changes in lipids,
- (6) Causing a permanent or long-term enlargement of the clitoris,
- (7) Causing head hair loss,
- (8) Causing permanent hair growth on one's face, chest, buttocks, or other areas of the body,
- (9) Causing severe acne,
- (10) Causing a woman's voice to permanently deepen or deepen for an extended period of time,
- (11) Causing menstrual or menstrual-like bleeding in a menopausal woman, and
- (12) Developing psychological changes such as increased anger or aggressive behavior.

DD. Advertising or otherwise promoting BHRT to men without clearly and conspicuously disclosing the following through the words below or other words of similar import, that BHRT increases a consumer's risk or possible risk of:

- (1) Developing prostate cancer,
- (2) Developing blood clots, strokes, heart attacks, high blood pressure, or other cardiovascular problems,
- (3) Causing tissue edema,
- (4) Causing changes in lipids,
- (5) Causing testicular atrophy,
- (6) Causing infertility,
- (7) Developing breast tissue similar in appearance to that found in a woman,
- (8) Causing head hair loss,
- (9) Causing permanent hair growth on one's face, chest, buttocks, or other areas on the body, and

(10) Developing psychological changes such as increased anger or aggressive behavior;

EE. Using a consumer testimonial in an advertisement or other promotion involving a consumer with a Material Connection to HRC Medical Centers, Inc., HRC Management Midwest, LLC, Don Hale, or Dan Hale, without clearly and conspicuously disclosing the Material Connection;

FF. Using a consumer testimonial in an advertisement or other promotion involving a consumer who was compensated in any manner for their testimonial, including but not limited to payments, gifts, discounts off future or other offerings, or other material incentives without clearly and conspicuously disclosing the compensation given to the consumer;

GG. Using or continuing to use a consumer testimonial in an advertisement or other promotion featuring a consumer who experienced a side effect or adverse reaction to the product, service, or therapy being offered without clearly and conspicuously disclosing the side effect or adverse reaction to the product; and

HH. Using or enforcing a "no refund or store credit" contractual provision in a contract for a future medical product, service, or therapy without meeting with a medical professional first, without knowing whether the medical product, service, or therapy will be appropriate, and without knowing how the consumer will respond to the medical product, service, or therapy.

II. NO BOND REQUIRED

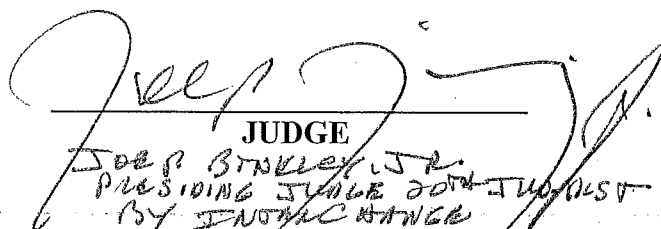
Pursuant to Tenn. Code Ann. § 47-18-108(a)(4) and Tenn. Code Ann. § 47-18-116, no bond shall be required of the State of Tennessee for the issuance of this temporary restraining order.

III. BINDING EFFECT AND DURATION OF ORDER

This restraining order becomes effective and binding on a Defendant at the time of service or when a Defendant is informed of this Order, whichever is earlier. This Order shall expire in 15 days, unless it is extended by this Court for up to an additional 15 days for good cause shown, or unless it is extended for a longer period with consent. The reasons for any extensions shall be entered in the record.

IT IS SO ORDERED, ADJUDGED, AND DECREED.

This the 10th day of October 2012, at 9:06 A. m.


JUDGE
JOSEPH BINKLEY, JR.
PRESIDING JUDGE 20th JUDICIAL
BY JUDICIAL OFFICE

A TEMPORARY INJUNCTION HEARING SHALL OCCUR WITHIN 15 DAYS OF ENTRY OF THIS ORDER ON ^{Friday -} October 19, 2012 at 1:00 p.m. THE HEARING SHALL TAKE PLACE AT 1 PUBLIC SQUARE, NASHVILLE, TN 37201 IN THE COURTROOM FOR THE 2nd CIRCUIT COURT. JUDGE AMANDA McCLendon

PRESIDING. 5th FLOOR DAVIDSON COUNTY HISTORIC COURT HOUSE