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WILLIAM BLUMENTHAL General Counsel

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CLERK US. TETHOCT COURT HIDDLE DISTRICT OF FLORIDA FT. MYERS, FLORIDA

SHIRA D. MODELL
Federal Trade Commission
600 Pennsylvania Ave., N.W., Room NJ-3212
Washington, D.C. 20580
Tel: (202) 326-2174, -3116

Attorneys for Plaintiff
FEDERAL TRADE COMMISSION

UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA

FEDERAL TRADE COMMISSION.

Plaintiff,

EMERSON DIRECT, INC. d/b/a COUNCIL ON NATURAL HEALTH, MICHAEL J. CONNORS, THOMAS DE BLASIO, M.D., and SHERRY BRESNAHAN, D.C., Hon.

Civil Action No. 2105-(V-377-AM-33

STIPULATED FINAL ORDER FOR PERMANENT INJUNCTION AS TO DEFENDANT SHERRY BRESNAHAN, D.C.

Defendant.

Plaintiff, the Federal Trade Commission ("FTC" or "Commission") filed a Complaint for permanent injunction and other relief against Sherry Bresnahan, D.C. ("Defendant"), pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Defendant denies the allegations in the Complaint, except jurisdictional facts, but is willing to agree to the entry of the following Stipulated Final Order for Permanent Injunction ("Order").

The Commission and the Defendant have stipulated to the entry of the following Order in settlement of the Commission's Complaint against the Defendant. The Court, being advised in the premises, finds:

FINDINGS

1. This Court has jurisdiction over the subject matter of this case and jurisdiction over all parties. Venue in the Middle District of Florida is proper.

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- The Complaint states a claim upon which relief can be granted, and the 2. Commission has the authority to seek the relief it has requested.
- The activities of the Defendant are in or affecting commerce, as defined in 15 3. U.S.C. § 44.
- The Defendant waives all rights to seek judicial review or otherwise challenge 4. or contest the validity of this Order. The Defendant also waive any claims that she may have held under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action to the date of this Order.
- Each party shall bear its own costs and attorneys' fees. 5.
- 6. Entry of this Order is in the public interest.
- 7. Pursuant to Federal Rule of Civil Procedure 65(d), the provisions of this Order are binding upon the Defendant, and her officers, agents, servants, employees and all other persons or entities in active concern or participation with them, who receive actual notice of this Order by personal service or otherwise.
- 8. This Order resolves only claims against the named Defendant and does not preclude the United States or the Commission from initiating further action or seeking any remedy against any other persons or entities, including without limitation, persons or entities who may be subject to portions of this Order by virtue of actions taken in concert or participation with the Defendant, and persons or entities in any type of indemnification or contractual relationship with the Defendant.
- 9. The Commission and the Defendant stipulate and agree to this Final Order, without trial or final adjudication of any issue or law or fact, to settle and resolve all matters in dispute with the Defendant arising from the Complaint to the date of entry of this Final Order. By stipulating to this Final Order, the Defendant does not admit any of the allegations set forth in the Complaint, other than jurisdictional facts.

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- This Order does not constitute, and shall not be interpreted to constitute, an 10. admission by the Defendant or a finding by the Court that the Defendant has engaged in any violations of law.
- The paragraphs of this Order shall be read as the necessary requirements for 11. compliance, and not as alternatives for compliance, and no paragraph serves to modify another paragraph unless expressly so stated.

DEFINITIONS

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

- Unless otherwise specified, "Defendant" shall mean Sherry Bresnahan, D.C. 1.
- "Smoke Away" shall mean the "Smoke Away System" and any other smoking 2. cessation product or program.
- "Competent and reliable scientific evidence" shall mean tests, analyses, 3. research, studies, or other evidence based on 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.
- "Food" and "drug" shall mean as defined in Section 15 of the FTC Act, 15 4. U.S.C. § 55.
- "Covered product" shall mean Smoke Away or any food, drug or dietary 5. supplement.
- "Commerce" shall mean as defined in Section 4 of the FTC Act, 15 U.S.C. § 6. 44.
- The term "including" in this Order shall mean "without limitation." 7.
- The terms "and" and "or" in this Order shall be construed conjunctively or 8. disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.
- "Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b). 9.

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CONDUCT PROHIBITIONS REPRESENTATIONS AND ENDORSEMENTS

T.

IT IS HEREBY ORDERED that the Defendant, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and her officers, agents, representatives, employees, attorneys, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Smoke Away, are hereby permanently restrained and enjoined from representing that she is an expert in nicotine addiction or smoking cessation unless, at the time the representation is made, the Defendant possesses the level of education, training, or experience that experts in those fields generally recognize as sufficient to qualify her as an expert in nicotine addition or smoking cessation.

П.

IT IS FURTHER ORDERED that the Defendant, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and her officers, agents, servants, employees and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, are hereby permanently restrained and enjoined from misrepresenting, in any manner, expressly or by implication, her profession, expertise, training, education, experience, or qualifications.

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IT IS FURTHER ORDERED that the Defendant, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and her officers, agents, servants, employees and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with

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25 27 the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, are hereby permanently restrained and enjoined from making any representation, in any manner, expressly or by implication, about the absolute or comparative benefits, performance, or efficacy, of such covered product unless, at the time it is made, the Defendant possesses and relies upon competent and reliable scientific evidence that substantiates the representation, including any such representation made through the use of endorsements or trade names. Provided, however, that for any representation made as an expert endorser, the Defendant must possess and rely upon competent and reliable scientific evidence, and an actual exercise of her represented expertise, in the form of an examination or testing of the product or program.

FDA APPROVED CLAIMS

IV.

IT IS FURTHER ORDERED that:

- A. Nothing in this Order shall prohibit the Defendant from making any representation for any drug that is permitted in labeling for such drug underany tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and
- Nothing in this Order shall prohibit the Defendant from making any В. representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

COMMISSION'S AUTHORITY TO MONITOR COMPLIANCE

V.

IT IS FURTHER ORDERED that, for the purpose of monitoring and investigating compliance with any provision of this Order:

Within ten (10) days of receipt of written notice from a representative of the

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Commission, the Defendant shall submit additional written reports, sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and/or provide entry during normal business hours to any business location in the Defendant's possession or direct or indirect control which engages in the manufacturing, labeling, advertising, promotion, offering for sale, sale or distribution of any covered product, to inspect the business operation;

- В. In addition, the Commission is authorized to monitor compliance with this Order by all other lawful means, including but not limited to the following:
 - 1. obtaining discovery from any person, without further leave of court, using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36, and 45;
 - 2. posing as consumers or suppliers to the Defendant, the Defendant's employees, or any other entity managed or controlled in whole or in part by the Defendant which engages in the manufacturing, labeling, advertising, promotion, offering for sale, sale or distribution of any covered product, without the necessity of identification or prior notice; and
- C. The Defendant shall permit representatives of the Commission to interview any employer, consultant, independent contractor, representative, agent, or employee who has agreed to such an interview, relating in any way to any conduct subject to this Order.

Provided that nothing in this Order shall limit the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).

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COMPLIANCE REPORTING BY THE DEFENDANT

VI.

IT IS FURTHER ORDERED that, in order that compliance with the provisions of this Order may be monitored:

- A. For a period of three (3) years from the date of entry of this Order,
 - 1. The Defendant shall notify the Commission of the following:
 - a. Any changes in the Defendant's residence, mailing addresses, and telephone numbers, within ten (10) days of the date of such change;
 - b. Any changes in the Defendant's employment status (including self-employment), and any change in the Defendant's ownership in any business entity, within ten (10) days of the date of such change. Such notice shall include the name and address of each business that the Defendant is affiliated with, employed by, creates or forms, or performs services for; a statement of the nature of the business; and a statement of the Defendant's duties and responsibilities in connection with the business or employment;
 - c. Any changes in the Defendant's name or use of any aliases or fictitious names; and
- B. One hundred eighty (180) days after the date of entry of this Order, the Defendant shall provide a written report to the FTC, sworn to under penalty of perjury, setting forth in detail the manner and form in which she has complied and is complying with this Order. This report shall include, but not be limited to:
 - The Defendant's then-current residence address, mailing addresses, and telephone numbers;

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- 2. The Defendant's then-current employment and business addresses and telephone numbers, a description of the business activities of each such employer or business, and the Defendant's title and responsibilities for each such employer or business;
- 3. A copy of each acknowledgment of receipt of this Order obtained by that Defendant pursuant to Paragraph VII; and
- 4. Any other changes required to be reported pursuant to Subparagraph A of this Section.
- C. For purposes of this Order, the Defendant shall, unless otherwise directed by the Commission's authorized representatives, mail all written notifications to the Commission to:

Associate Director for Advertising Practices
Federal Trade Commission,
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580.
Re: FTC v. Emerson Direct, Inc. et al., Civil Action No.

D. For purposes of the compliance reporting and monitoring required by this
 Order, the Commission is authorized to communicate directly with the
 Defendant.

RECORD KEEPING PROVISIONS

VII.

IT IS FURTHER ORDERED that, for a period of six (6) years from the date of entry of this Order, the Defendant and her agents, employees, officers, corporations, successors, and assigns, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, is hereby restrained and enjoined from failing to continue to create and retain the following records:

A. All payments, whether by salary, consulting fees, retainer, percentage of sales, royalty, expense reimbursement, options, loans, stock dividends, gifts, or other transfer arrangement made to the Defendant by any person or entity engaged

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- in the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of a covered product, in connection with the Defendant's endorsement of that product;
- B. Copies of all draft and/or final versions of all endorsements, articles, advertisements, promotional materials, or other marketing materials provided to the Defendant by any person or business entity engaged in the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of a covered product in connection with the Defendant's endorsement of that product;
- C. Copies of all documents provided to the Defendant by any person or business entity in connection with each endorsement subject to Subparagraph B, above;
- D. All materials that were relied upon in making any representations subject to Subparagraph B above, including all documents evidencing or referring to the accuracy of any claim therein or to the efficacy of any covered product, including, but not limited to, all tests, reports, studies, demonstrations, and other evidence in the Defendant's possession that confirms, contradicts, qualifies, or calls into question the accuracy of such claims regarding the efficacy of such covered product;
- E. All examinations, tests, research, or other evaluations conducted by the
 Defendant in connection with each endorsement subject to Subparagraph B,
 above;
- F. All materials provided by the Defendant to any person or business entity in connection with each endorsement subject to Subparagraph B, above; and
- G. All records and documents necessary to demonstrate full compliance with each provision of this Order, including but not limited to, copies of acknowledgments of receipt of this Order and all reports submitted to the FTC pursuant to this Order.

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DISTRIBUTION OF ORDER

VIII.

IT IS FURTHER ORDERED that, for a period of three (3) years from the date of entry of this Order, the Defendant shall deliver copies of the Order as directed below:

- A. For any business that the Defendant controls, directly or indirectly, or in which the Defendant has a majority ownership interest, and that business engages, or assists others engaged in, the advertising, marketing, promotion, offering for sale, distribution or sale of any covered product, the Defendant must deliver a copy of this Order to all principals, officers, directors, and managers of that business. The Defendant must also deliver copies of this Order to all employees, agents, and representatives of that business who engage in conduct related to the subject matter of the Order. For current personnel, delivery shall be within five (5) days of service of this Order upon the Defendant. For new personnel, delivery shall occur prior to them assuming their responsibilities.
- B. For any business where the Defendant is not a controlling person but she engages in, or assists others engaged in, the advertising, marketing, promotion, offering for sale, distribution or sale of any covered product, the Defendant must deliver a copy of this Order to all principals and managers of such business before engaging in such conduct.
- D. The Defendant must secure a signed and dated statement acknowledging receipt of the Order, within thirty (30) days of delivery, from all persons receiving a copy of the Order pursuant to this Part.

ACKNOWLEDGMENT OF RECEIPT OF ORDER

IX.

IT IS FURTHER ORDERED that the Defendant, within five (5) business days of receipt of this Order as entered by the Court, must submit to the Commission a truthful sworn statement, in the form of Attachment A to this Order, acknowledging receipt of this Order.

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RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for

Kelly & Karras, Ltd.

Attorney for Defendant

purposes of construction, modification, and enforcement of this Order.

SO STIPULATED:

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6 SHIRA D. MODELL

8 Federal Trade Commission 601 Pennsylvania Avenue, N.W., 9 Rm. NJ-3212 Washington, D.C. 20580 (202) 326-3259 (facsimile) 10 11

Attorneys for Plaintiff

FEDERAL TRADE COMMISSION

SO ORDERED

UNITED STATES

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