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MIDDLE DISTRICT OF FLORIDA
FT. MYERS, FLORIDA

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10 UNITED STATES DISTRICT COURT
11 MIDDLE DISTRICT OF FLORIDA

12 FEDERAL TRADE COMMISSION,
13 Plaintiff,
14 v.
15 EMERSON DIRECT, INC. d/b/a COUNCIL
16 ON NATURAL HEALTH, MICHAEL J.
CONNORS, THOMAS DE BLASIO, M.D.,
and SHERRY BRESNAHAN, D.C.,
17 Defendant.

Hon.
Civil Action No. 2:05-cv-377-FTM-33

STIPULATED FINAL ORDER
FOR PERMANENT INJUNCTION
AS TO DEFENDANT THOMAS
DE BLASIO, M.D.

18 Plaintiff, the Federal Trade Commission ("FTC" or "Commission") filed a Complaint
19 for permanent injunction and other relief against Thomas De Blasio, M.D. ("Defendant"),
20 pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §
21 53(b). The Defendant denies the allegations in the Complaint, except jurisdictional facts, but
22 is willing to agree to the entry of the following Stipulated Final Order for Permanent
23 Injunction..

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

FINDINGS

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

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2. The Complaint states a claim upon which relief can be granted, and the Commission has the authority to seek the relief it has requested.
3. The activities of the Defendant are in or affecting commerce, as defined in 15 U.S.C. § 44.
4. The Defendant waives all rights to seek judicial review or otherwise challenge or contest the validity of this Order. The Defendant also waive any claims that he 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.
5. Each party shall bear its own costs and attorneys' fees.
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 his 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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CONDUCT PROHIBITIONS
REPRESENTATIONS AND ENDORSEMENTS

I.

IT IS HEREBY ORDERED that the Defendant, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and his 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 making any representation, in any manner, expressly or by implication, about the absolute or comparative benefits, performance, efficacy, safety, or side effects of such program or product, including but not limited to any representation that:

A. Such program or product:

1. Enables smokers to quit smoking in 7 days or less;
2. Enables smokers to quit smoking quickly, effortlessly, and permanently;
3. Eliminates nicotine cravings; or
4. Is more effective than nicotine patches, nicotine gum and prescription medications for smoking cessation; or

B. Smokers who use such program or product have no withdrawal symptoms and no side effects, such as weight gain, insomnia or tension;

unless the representation, including any such representation made through the use of endorsements or trade names, is true, non-misleading, and, at the time it is made, the Defendant possesses and relies upon competent and reliable scientific evidence that substantiates the representation. *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 his represented expertise, in the form of an examination or

1 testing of the product or program.

2 **II.**

3 **IT IS FURTHER ORDERED** that the Defendant, directly or through any corporation,
4 partnership, subsidiary, division, trade name, or other device, and his officers, agents,
5 servants, employees and all persons or entities in active concert or participation with them
6 who receive actual notice of this Order, by personal service or otherwise, in connection with
7 the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of
8 any covered product, are hereby permanently restrained and enjoined from making any
9 representation, in any manner, expressly or by implication, about the absolute or comparative
10 benefits, performance, or efficacy, of such covered product unless, at the time it is made, the
11 Defendant possesses and relies upon competent and reliable scientific evidence that
12 substantiates the representation, including any such representation made through the use of
13 endorsements or trade names. *Provided, however,* that for any representation made as an
14 expert endorser, the Defendant must possess and rely upon competent and reliable scientific
15 evidence, and an actual exercise of his represented expertise, in the form of an examination or
16 testing of the product or program.

17 **FDA APPROVED CLAIMS**

18 **III.**

19 **IT IS FURTHER ORDERED** that:

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

1 process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1, to obtain any
2 documentary material, tangible things, testimony, or information relevant to unfair or
3 deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. §
4 45(a)(1)).

5 **COMPLIANCE REPORTING BY THE DEFENDANT**

6 **V.**

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

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

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to:

1. The Defendant's then-current residence address, mailing addresses, and telephone numbers;
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

VI.

IT IS FURTHER ORDERED that, for a period of six (6) years from the date of entry of this Order, the Defendant and his 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,

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royalty, expense reimbursement, options, loans, stock dividends, gifts, or other transfer arrangement made to the Defendant by any person or 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;

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

1 pursuant to this Order.

2 **DISTRIBUTION OF ORDER**

3 **VII.**

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

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

24 **ACKNOWLEDGMENT OF RECEIPT OF ORDER**

25 **VIII.**

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

RETENTION OF JURISDICTION

IX.

IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

SO STIPULATED:

Rosemary Rosso
ROSEMARY ROSSO
SHIRA D. MODELL

Thomas De Blasio
THOMAS DE BLASIO, M.D.

Federal Trade Commission
601 Pennsylvania Avenue, N.W.,
Rm. NJ-3212
Washington, D.C. 20580
(202) 326-3259 (facsimile)
Attorneys for Plaintiff

FEDERAL TRADE COMMISSION

SO ORDERED

DATED: August 11, 2005

Richard M. Hendry
UNITED STATES DISTRICT JUDGE