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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
San Francisco Division

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

WELLNESS SUPPORT NETWORK, INC., a corporation,

ROBERT HELD, individually and as an officer of Wellness Support Network, Inc., and

ROBYN HELD, individually and as an officer of Wellness Support Network, Inc.,

Defendants.

Case No. 3:10-cv-4879 JCS

~~[Proposed]~~ FINAL JUDGMENT AND ORDER FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

THIS MATTER comes before the Court on the Motion for Summary Judgment filed by Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), which motion was GRANTED on February 19, 2014. The Court incorporates the findings and conclusions from that Order.

THEREFORE, it is hereby ORDERED, ADJUDGED, and DECREED as follows:

DEFINITIONS

For the purpose of this Order, the following definitions apply:

A. **"Defendants**" means all of the Individual Defendants and the Corporate Defendant, individually, collectively, or in any combination.

1. **"Corporate Defendant"** means Wellness Support Network, Inc., and its successors and assigns.
2. "**Individual Defendants"** means Robert Held and Robyn Held.

B. **"Commerce"** means as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

C. **"Covered Product"** means Diabetic Pack, Insulin Resistance Pack, WSN Glucose Support Formula, or any other drug, food, or dietary supplement.

D. **"Dietary supplement"** means:

1. any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or
2. any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that are a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.

E. **"Disease"** means impairment of an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g. hypertension); including (a) the characteristic signs or symptoms of a specific disease or class of diseases; and (b) abnormal conditions associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm.

F. **"Endorsement"** means as defined in 16 C.F.R. § 255.0(b).

G. **"Essentially Equivalent Product"** means a product that contains the identical ingredients, except for inactive ingredients (e.g., inactive binders, colors, fillers, excipients), in the same form and dosage, and with the same route of administration (e.g., orally, sublingually), as the Covered Product; provided that the Covered Product may contain additional ingredients if reliable scientific evidence generally accepted by experts demonstrates that the amount and combination of additional ingredients are unlikely to impede or inhibit the effectiveness of the ingredients in the Essentially Equivalent Product.

H. **"Food"** and **"drug"** mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

ORDER

I. PROHIBITED REPRESENTATIONS: DISEASE CLAIMS

IT IS ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, are hereby permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product:

A. is an effective treatment for diabetes;

B. reduces or eliminates the need for insulin and other diabetes medications;

C. lowers blood glucose levels in persons with diabetes;

D. maintains blood glucose levels in persons with diabetes;

E. prevents or reduces the risk of diabetes;

F. reverses insulin resistance;

G. manages insulin resistance;

H. prevents or reduces the risk of insulin resistance;

I. reverses metabolic syndrome;

J. manages metabolic syndrome; or

K. prevents or reduces the risk of metabolic syndrome,

unless the representation is non-misleading and, at the time it is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Part, "competent and reliable scientific evidence" shall consist of at least two adequate and well-controlled human clinical trials of the Covered Product, or of an Essentially Equivalent Product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true. Such studies shall be randomized, double-blind, and placebo-controlled; utilize, if applicable, valid surrogate endpoints generally recognized by experts in the relevant disease field; yield statistically significant between-group results; and be conducted by researchers, qualified by training and experience to conduct such studies and who are experts who have specialized in the specific disease at issue. Defendants shall have the burden of proving that a product satisfies the definition of an Essentially Equivalent Product.

II. PROHIBITED REPRESENTATIONS: OTHER HEALTH CLAIMS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, are hereby permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation, other than representations covered under Section I of this Order, about the health benefits, performance, or efficacy of such product,

unless the representation is non-misleading, and, at the time of making such representation, Defendants possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Section, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

III. PROHIBITED REPRESENTATIONS REGARDING TESTS OR STUDIES

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, in or affecting commerce, are hereby permanently restrained and enjoined from misrepresenting, or assisting others in misrepresenting, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration:

A. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or research; or

B. That the benefits of such product are scientifically proven.

IV. FDA APPROVED CLAIMS

IT IS FURTHER ORDERED that:

A. Nothing in this Order shall prohibit Defendants from making any 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 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997; and

B. Nothing in this Order shall prohibit Defendants from making any representation for any drug that is permitted in the labeling for such drug under any 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.

V. MONETARY JUDGMENT

IT IS FURTHER ORDERED that:

A. Judgment in the amount of Two Million, One Hundred and Ninety Eight Thousand, Six Hundred and Twelve Dollars and Twelve Cents ($2,198,612.12) is entered in favor of the Commission against Individual Defendants and Corporate Defendant, jointly and severally, as equitable monetary relief.

B. Defendants relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

C. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for equitable relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is wholly or partially impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Defendants' practices alleged in the Complaint. Any money not used for such equitable relief is to be deposited to the U.S. Treasury as disgorgement. Defendants have no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

VI. CUSTOMER INFORMATION

IT IS FURTHER ORDERED that Defendants, their officers, agents, servants, employees, and attorneys, and all other persons in active concert or participation with any of them, who

receive actual notice of this Order, are permanently restrained and enjoined from directly or indirectly failing to provide sufficient customer information to enable the Commission to efficiently administer consumer redress. If a representative of the Commission requests in writing any information related to redress, Defendants must provide it, in the form prescribed by the Commission, within 14 days.

VII. ORDER ACKNOWLEDGMENTS

IT IS FURTHER ORDERED that Defendants obtain acknowledgments of receipt of this Order:

A. Each Defendant, within 7 days of entry of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 5 years after entry of this Order, each Individual Defendant for any business that such Defendant, individually or collectively with any other Defendants, is the majority owner or controls directly or indirectly, and the Corporate Defendant, must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees, agents, and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Section titled Compliance Reporting. Delivery must occur within 7 days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

VIII. COMPLIANCE REPORTING

IT IS FURTHER ORDERED that Defendants make timely submissions to the Commission:

A. Sixty days after entry of this Order, each Defendant must submit a compliance report, sworn under penalty of perjury:

1. Each Defendant must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Defendant; (b) identify all of that Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant (which Individual Defendants must describe if they know or should know due to their own involvement); (d) describe in detail whether and how that Defendant is in compliance with each Section of this Order; and (e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, each Individual Defendant must: (a) identify all telephone numbers and all physical, postal, email and Internet addresses, including all residences; (b) identify all business activities, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest; and (c) describe in detail such Defendant's involvement in each such business, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For 20 years after entry of this Order, each Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Defendant must report any change in: (a) any designated point of contact; or (b) the structure of the Corporate Defendant or any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, each Individual Defendant must report any change in: (a) name, including aliases or fictitious name, or residence address; or (b) title or role in

any business activity, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest, and identify the name, physical address, and any Internet address of the business or entity.

C. Each Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Defendant within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: FTC v. Wellness Support Network (FTC File No. (X110009).

IX. RECORDKEEPING

IT IS FURTHER ORDERED that Defendants must create certain records for 20 years after entry of the Order, and retain each such record for 5 years. Specifically, Corporate Defendant, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, and each Individual Defendant for any business that such Defendant, individually or collectively with any other Defendants, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. accounting records showing the revenues from all goods or services sold;

B. personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. all records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission;

E. a copy of each unique advertisement or other marketing material;

F. all materials that were relied upon in making any representations contained in the materials identified in Subparagraph E above, including all documents evidencing or referring to the accuracy of any claim therein or to the benefits, performance, or efficacy of any good or service, including, but not limited to, all tests, reports, studies, demonstrations, or other evidence that confirms, contradicts, qualifies, or calls into question the accuracy of any claim regarding the benefits, performance, or efficacy of each such good or service, including complaints from and other communications with consumers or governmental or consumer protection agencies;

G. records accurately reflecting the name, address, and telephone number of each manufacturer or laboratory engaged in the development or creation of any testing obtained for the purpose of manufacturing, labeling, advertising, marketing, promoting, offering for sale, selling, or distributing any Covered Product; and

H. copies of all contracts concerning the manufacturing, labeling, advertising, marketing, promotion, offering for sale, sale, or distribution of any Covered Product.

X. COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendants' compliance with this Order:

A. Within 14 days of receipt of a written request from a representative of the Commission, each Defendant must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission is also authorized to obtain discovery,

without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.

B. For matters concerning this Order, the Commission is authorized to communicate directly with each Defendant. Defendant must permit representatives of the Commission to interview any employee or other person affiliated with any Defendant who has agreed to such an interview. The person interviewed may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Defendants or any individual or entity affiliated with Defendants, without the necessity of identification or prior notice. Nothing in this Order limits 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.

XI. RETENTION OF JURISDICTION

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

IT IS SO ORDERED, this 19th day of February, 2014.

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA
Judge Joseph C. Spero

JOSEPH C.
UNITED STATES MAGISTRATE JUDGE