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FEDERAL TRADE COMMISSION

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

Case No.: 4:22-cv-7307-HSG

FEDERAL TRADE COMMISSION,
Plaintiff,

v.

STIPULATE

THEREFORE, IT IS ORDERED as follows:

FINDINGS

1. This Court has jurisdiction over this matter.

2. The Complaint charges that Defendants participated in deceptive acts or practices in violation of Section 5 of the FTC Act, 15 U.S.C. § 45, and the COVID-19 Act in connection with the labeling, advertising, marketing, distribution, and sale of products they claim to treat, prevent, or mitigate COVID-19.

3. Defendants neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Order. Only for purposes of this action, Defendants admit the facts necessary to establish jurisdiction.

4. Defendants waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agree to bear their own costs and attorney fees.

5. Defendants and the Commission waive all rights to appeal or otherwise challenge or contest the validity of this Order.

DEFINITIONS

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

A. "Covered Product" means any Drug, Food, or Dietary Supplement including the products Defendants have marketed as COVID Resist and VIRUS Resist. Covered Product does not include Devices.

B. "Defendants" means the Individual Defendant and Corporate Defendant, individually, collectively, or in any combination.

1. "Corporate Defendant" means Precision Patient Outcomes, Inc. its successors and assigns.

2. "Individual Defendant" means Margrett Priest Lewis.

C. "Device" 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 humans or other animals; or (3) intended to affect the structure or any function of the body of humans or other animals; and which does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

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 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. "Drug" means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals; (3) articles (other than Food) intended to affect the structure or any function of the body of humans or other animals; and (4) articles intended for use as a component of any article specified in (1), (2), or (3); but does not include Devices or their components, parts, or accessories.

F. "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 in the field indicates that the amount and combination of additional ingredients are unlikely to impede or inhibit in the effectiveness of the ingredients in the Essentially Equivalent Product.

G. "FDA" means the United States Food and Drug Administration.

H. "Food" means (1) any article used for food or drink for human or other animals; (2) chewing gum; and (3) any article used for components of any such article.

ORDER

I. BAN AGAINST COVID-19 PREVENTION AND TREATMENT CLAIMS

IT IS ORDERED WKDW 'HIHQGDQWV 'HIHQGDQWV¶ RIILFHUV DJHQWV UHSUHVHQWDWLYHV DQG DWWRUQH\V DQG DOO RWKHU SHUVRQV LQ DFWLYH FRQFHUW RU SDUWLFLSDWLRQ ZLWK DQ\ RI WKHP ZKR UHFHLYH DFWXDO QRWLFH RI WKLV 2UGHU ZKHWKHU DFWLQJ GLUHFWO\ RU LQGLUHFWO\ LQ FRQQHFWLRQ ZLWK WKH PDQXIDFWXULQJ ODEHOLQJ DGYHUWLVLQJ SURPRWLRQ RIIHULQJ IRU VDOH VDOH RU GLVWULEXWLRQ RI DQ\ SURGXFW DUH SHUPDQHQWO\ UHVWUDLQHG DQG HQMRLQHG IURP PDNLQJ DQ\ UHSUHVHQWDWLRQ WKDW VXFK SURGXFW SUHYHQWV RU UHGXFHV WKH OLNHOLKRRG RI LQIHFWLRQ ZLWK RU FRPPXQLW\ WUDQVPLVVLRQ RI WKH 6$56-&R9-2 YLUXV UHGXFHV WKH VHYHULW\ RU GXUDWLRQ RI &29,'-19 RU RWKHUZLVH FXUHV PLWLJDWHV RU WUHDWV &29,'-19 XQOHVV WKH)'$ KDV VSHFLILFDOO\ DSSURYHG WKH UHSUHVHQWDWLRQ

II. PROHIBITED REPRESENTATIONS: REGARDING HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

IT IS FURTHER 25'(5('WKDW 'HIHQGDQWV DQG 'HIHQGDQWV¶ RIILFHUV DJHQWV UHSUHVHQWDWLYHV DQG DWWRUQH\V DQG DOO RWKHU SHUVRQV LQ DFWLYH FRQFHUW RU SDUWLFLSDWLRQ ZLWK DQ\ RI WKHP ZKR UHFHLYH DFWXDO QRWLFH RI WKLV 2UGHU ZKHWKHU DFWLQJ GLUHFWO\ RU LQGLUHFWO\ LQ FRQQHFWLRQ ZLWK WKH PDQXIDFWXULQJ ODEHOLQJ DGYHUWLVLQJ PDUNHWLQJ SURPRWLRQ RIIHULQJ IRU VDOH RU VDOH RI DQ\ &RYHUHG 3URGXFW DUH SHUPDQHQWO\ UHVWUDLQHG DQG HQMRLQHG IURP PDNLQJ RU DVVLVWLQJ RWKHUV LQ PDNLQJ DQ\ UHSUHVHQWDWLRQ H[SUHVVO\ RU E\ LPSOLFDWLRQ LQFOXGLQJ WKURXJK WKH XVH RI D SURGXFW QDPH HQGRUVHPHQW GHSLFWLRQ RU LOOXVWUDWLRQ RWKHU WKDQ UHSUHVHQWDWLRQV FRYHUHG XQGHU WKH 6HFWLRQ RI WKLV 2UGHU HQWLWOHG %DQ $JDLQVW &29,'-19 3UHYHQWLRQ RU 7UHDWPHQW &ODLPV WKDW VXFK SURGXFW FXUHV PLWLJDWHV RU WUHDWV DQ\ GLVHDVH XQOHVV WKH UHSUHVHQWDWLRQ LV QRW PLVOHDGLQJ DQG DW WKH WLPH RI PDNLQJ VXFK UHSUHVHQWDWLRQ WKH\ SRVVHVV DQG UHO\ XSRQ FRPSHWHQW DQG UHOLDEOH VFLHQWLILF HYLGHQFH VXEVWDQWLDWLQJ WKDW WKH UHSUHVHQWDWLRQ LV WUXH)RU SXUSRVHV RI WKLV 6HFWLRQ [3] FRPSHWHQW DQG UHOLDEOH VFLHQWLILF HYLGHQFH PHDQV WHVWV DQDO\VHV UHVHDUFK VWXGLHV RU RWKHU VWXGLHV FRQGXFWHG E\ SHUVRQV TXDOLILHG E\ H[SHUWLVH WUDLQLQJ RU H[SHULHQFH DQG SURFHGXUHV RI VXIILFLHQW TXDOLW\ DQG TXDQWLW\ EDVHG

on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be (1) randomized, double-blind, and placebo-controlled; and (2) be conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an DVVHVVPHQW RI VXFK WHVWLQJ DV GHVFULEHG LQ WKH 6HFWLRQ &RPSHWHQW DQG 5HOLDEOH +XPDQ &OLQLFDO 7HVWLQJ for Substantiation and RU production to the Commission. Persons covered by this Section have the burden of proving that a product satisfies the definition of Essentially Equivalent Product.

III. PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER 25'(5('WKDW 'HIHQGDQWV DQG 'HIHQGDQWV¶ attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, or sale of any Covered Product, are permanently restrained and enjoined from making, or assisting others in making, any representation, expressly or by implication, other than representations covered under the Sections of this Order entitled Ban Against COVID-19 Prevention or Treatment Claims and Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing for Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the Covered Product, or of an Essentially Equivalent Product, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as GHVFULEHG LQ WKH 6HFWLRQ RI WKLV 2UGHU HQWLWOHG ³3 and Reliable Human Clinical Tests or Studies´ PXVW EH DYDLODEOH IRU LQVS to the Commission or Plaintiff. Defendants will have the burden of proving that a product satisfies the definition of an Essentially Equivalent Product.

IV. PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ³7HVW´ XSRQ ZKLFK HVWDQG DQ\ PH relied to substantiate any claim covered by this Order, Defendants must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the Test, including:

A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the Test, and drafts of such documents reviewed by the Test sponsor or any other person not employed by the research entity;

B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. Documents sufficient to identify all Test participants, including any participants who did not complete the Test, and all communications with any participants relating to the Test; all raw data collected from participants enrolled in the Test, including any participants who did not complete the Test; source documents for such data; any data dictionaries; and any case report forms;

D. All documents referring or relating to any statistical analysis of any Test data,

including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any Test data; and

E. All documents referring or relating to the sponsorship of the Test, including all F R P P X Q L F D W L R Q V D Q G F R Q W U D F W V E H W Z H H Q D Q \ V S R Q V R U

Provided, however, the preceding preservation requirements do not apply to a Reliably Reported Test, unless the Test was conducted, controlled, or sponsored, in whole or in part by (1) ' H I H Q G D Q W V ' H I H Q G D Q W V ¶ R I I L F H H V V (2) any Qther person or entity in active concert or participation with Defendants; (4) any person or entity affiliated with or acting on behalf of Defendants; (5) any supplier of any ingredient contained in the product at issue to any of the foregoin R U W R W K H S U R G X F W ¶ V P D Q X I D F W X U H manufacturer of such product.

manner, expressly or by implication, including through the use of any product name, endorsement, depiction, or illustration:

A. That any Covered Product is scientifically or clinically proven to treat, prevent, mitigate, or cure COVID-19 or any disease or condition;

B. That the individual ingredients of any Covered Product are scientifically or clinically proven to treat, prevent, mitigate, or cure COVID-19 or any disease or condition;

C. That the performance or benefits of any Covered Product are scientifically or clinically proven or otherwise established; or

D. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

VI. NOTICE TO CUSTOMERS

IT IS FURTHER ORDERED that Defendants, within 45 days after the entry of this Order, must notify all customers, if any, who purchased COVID Resist or VIRUS Resist on or after May 1, 2021, through the entry of this Order, by

A. [illegible] active social media pages, for all such websites and social media pages that are being used or have been used to market COVID Resist, VIRUS Resist, or other Covered Products, as shown in Attachment A. The notices must remain published for 180 days. For the purposes of this Section, Defendants' websites and social media pages are considered active at any point during the 180 days that the notice must be published; and

B. To the extent that Defendants have in their possession, custody, or control the customers' Email Addresses, sending and/or emailing each customer a notice as shown in Attachment A:

1. The heading of the notice and the subject line for any email must read "[illegible] Notice from FTC & California Attorney General." The notice must be sent to each recipient individually from an address with the ppolab.com domain.

2. The Precision Patient Outcomes name and return address, for any mailing, must appear on the front of the envelope. The customer's name and

printed on the front of the envelope or be visible through a window in the envelope, and

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in easily noticed text near the E X V W R P H U ¶ V Q D P H D Q G D G G U H V V

3. The notice must not include any other materials, attachments, or messages

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VII. NOTICE TO RESELLERS

IT IS FURTHER ORDERED that within 30 days of the entry of this Order, Defendants must notify all retailers or resellers by sending each by first class mail, postage paid and return receipt requested, or by courier service with signature proof of delivery, the notification letter attached as Attachment B. Defendants must include a copy of this Order, but no other document or enclosure.

VIII. 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 each Corporate Defendant must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order and all 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.

IX. COMPLIANCE REPORTING

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

A. One year 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 the 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 5 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 any 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 names, 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 F R Q F O X G L Q J X Q G H U S H Q D O W \ R I S H U M X U \ V W D W H P H Q W V H W I R U W K D W W K H I R D Q G R F R U U H F W X H F X W H G R Q B B B B ´ D Q G V X S full name, title (if applicable), and signature.

E. Report and certify under penalty of perjury on the notification program required under the Section R I W K L V 2 U G H U H Q W L W O H G ³ 1 R W L F H W R & X V W R P H as follows:

1. Defendants must submit a report within 90 days after the entry of this 2 U G H U V X P P D U L] L Q J ' H I H Q G D Q W V ¶ F R P S O L D Q F H W R G D V eligible customers identified and notified.

2. If a representative of the Commission requests any information regarding the program, including any of the underlying customer data, Defendants must submit it within 10 days of the request.

3. Failure to provide required notices or any requested information will be treated as a continuing failure to obey this Order.

F. 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. Precision Patient Outcomes, Inc., et al.

X. RECORDKEEPING

IT IS FURTHER ORDERED that Defendants must create certain records for 5 years after entry of the Order, and retain each such record for 5 years. Specifically, Corporate Defendant and 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 number, job title or position, dates of service; and (if applicable) the reason for termination;

C. records of all consumer complaints concerning the subject matter of the Order 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; and

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

XI. 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