132-3211

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeny

In the Matter of **HEALTH DISCOVERY CORPORATION, a corporation.**	**DOCKET NO. C-4516**

DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act, 15 U.S.C. § 45 *et seq.*; and

The respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order ("consent agreement") that includes: a statement that the agreement is for settlement purposes only and does not constitute an admission that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true; and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Health Discovery Corporation ("Respondent") is a Georgia corporation with its principal office or place of business at 4243 Dunwoody Club Drive, Atlanta, Georgia 30350.

2. Respondent has advertised, labeled, offered for sale, sold, and distributed products to consumers, including MelApp. MelApp is a consumer-directed software application that can be installed on mobile devices using the iOS or Android operating systems. MelApp purportedly can assess melanoma risk early by using mathematical algorithms and image-based pattern recognition technology to analyze specific characteristics (asymmetry, border, color, diameter, and evolution) of digital images of skin lesions captured by the device's camera.

3. The Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

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

1. Unless otherwise specified, "Respondent" shall mean Health Discovery Corporation, a corporation, its successors and assigns and its officers, agents, representatives, and employees.

2. "Advertising" and "promotion" shall mean any written or verbal statement, illustration, or depiction designed to effect a sale or create interest in the purchasing of products or services, regardless of the medium.

3. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

4. "Device" shall be construed as a "device" within the meaning of Sections 12 and 15 of the FTC Act, 15 U.S.C. §§ 52, 55 and shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is–

A. Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

B. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

C. Intended to affect the structure or any function of the body of man or other animals, and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

5. "Reliably Reported," for a human clinical test or study ("test"), means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

6. The term "including" in this order means "including without limitation."

7. The terms "and" and "or" in this order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that Respondent, directly or through any corporation, subsidiary, division, or other means, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Device including, but not limited to, MelApp, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a Device name, endorsement, depiction, or illustration, that the Device:

A. Detects or diagnoses melanoma or risk factors of melanoma, or

B. Increases users' chances of detecting melanoma in early stages,

unless the representation is non-misleading and, at the time of making such representation, Respondent possesses and relies upon competent and reliable scientific evidence to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence shall consist of human clinical testing of the Device that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant field, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing shall be blinded, conform to actual use conditions, and include a representative range of skin lesions; be conducted by researchers qualified by training and experience to conduct such testing; and all underlying or supporting data and documents generally accepted by experts in the relevant field as relevant to an assessment of such testing as set forth in Part III must be available for inspection and production to the Commission.

II.

IT IS FURTHER ORDERED that Respondent, directly or through any corporation, subsidiary, division, or other means, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Device in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a Device name, endorsement, depiction, or illustration, any representation, other than representations covered under Part I of this order, about the health benefits or health efficacy of such Device, unless the representation is non-misleading, and, at the time of making such representation, Respondent possesses and relies 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 Part, competent and reliable scientific evidence means tests, analyses, research, or studies (A) that have been conducted and evaluated in an objective manner by qualified persons; (B) that are generally accepted in the profession to yield accurate and reliable results; and (C) when they 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 set forth in Part III are available for inspection and production to the Commission.

III.

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Respondent relies to substantiate any claim covered by Parts I or II of this order, Respondent shall 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, but not necessarily limited to:

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, but not limited to, 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 contracts and communications between any sponsor and the test's researchers.

Provided, *however*, the preceding preservation requirement shall not apply to a Reliably Reported test, unless the test was conducted, controlled, or sponsored, in whole or in part (1) by Respondent, or by any person or entity affiliated with or acting on behalf of Respondent, including officers, agents, representatives, and employees, or by any other person or entity in active concert or participation with Respondent, or (2) by Respondent's programmers, manufacturers, or suppliers of any component of the Device.

For any test conducted, controlled, or sponsored, in whole or in part, by Respondent, Respondent must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures shall be documented in writing and shall contain administrative, technical, and physical safeguards appropriate to Respondent's size and complexity, the nature and scope of Respondent's activities, and the sensitivity of the personal information collected from or about the participants.

IV.

IT IS FURTHER ORDERED that Respondent, directly or through any corporation, subsidiary, division, or other means, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product or service in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product or service name, endorsement, depiction, or illustration:

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

B. That any benefits of such product or service are scientifically proven, including, but not limited to, that studies, research, testing, or trials prove that a product or service detects or diagnoses a disease or the risks of a disease,

unless the representation is true and non-misleading.

V.

IT IS FURTHER ORDERED that Respondent shall pay to the Federal Trade Commission the sum of Seventeen Thousand Six Hundred Ninety-three Dollars ($17,693.00). This payment shall be made in the following manner:

A. The payment shall be made by wire transfer made payable to the Federal Trade Commission, the payment to be made no later than fifteen (15) days after the date that this order becomes final.

B. In the event of any default in payment, which default continues for ten (10) days beyond the due date of payment, the amount due, together with interest, as computed pursuant to 28 U.S.C. § 1961(a), from the date of default to the date of payment, shall immediately become due and payable to the Commission. Respondent agrees that, in such event, the facts as alleged in the complaint shall be taken as true in any subsequent litigation filed by the Commission to enforce its rights pursuant to this order, including, but not limited to, a nondischargeability complaint in any subsequent bankruptcy proceeding.

C. All funds paid pursuant to this Part, together with any accrued interest, shall be used by the Commission in its sole discretion to provide such relief as it determines to be reasonably related to Respondent's practices alleged in the complaint, and to pay any attendant costs of administration. Such relief may include, but shall not be limited to, the rescission of contracts, payment of damages, and/or public notification respecting such unfair or deceptive acts or practices as alleged in the complaint. If the Commission determines, in its sole discretion, that such relief is wholly or partially impracticable, any funds not so used shall be paid to the United States Treasury. Respondent shall have no right to contest the manner of distribution chosen by the Commission. No portion of the payment as herein provided shall be deemed a payment of any fine, penalty, or punitive assessment.

D. Respondent shall make no claim to or demand for the return of the funds, directly or indirectly, through counsel or otherwise; and in the event of bankruptcy, Respondent acknowledges that the funds are not part of the debtor's estate, nor does the estate have any claim or interest therein.

VI.

IT IS FURTHER ORDERED that Respondent Health Discovery Corporation and its successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation;

C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and

D. All acknowledgements of receipt of this order obtained pursuant to Part VII.

VII.

IT IS FURTHER ORDERED that Respondent Health Discovery Corporation and its successors and assigns shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VIII.

IT IS FURTHER ORDERED that Respondent Health Discovery Corporation and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about which Respondent learns less than thirty (30) days prior to the date such action is to take place, Respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall 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: *In re Health Discovery Corporation*.

IX.

IT IS FURTHER ORDERED that Respondent Health Discovery Corporation and its successors and assigns shall, within sixty (60) days after the date of service of this order, file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports. Unless otherwise directed by a representative of the Commission in writing, these reports shall 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: *In re Health Discovery Corporation*.

X.

This order will terminate on March 30, 2035, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any Part in this order that terminates in less than twenty (20) years;

B. This order's application to any Respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, *further*, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Ohlhausen dissenting.

Donald S. Clark
Secretary

SEAL:
ISSUED: March 30, 2015