

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

FEDERAL TRADE COMMISSION,

FINDINGS

1. This Court has jurisdiction over this matter.
2. The Complaint charges that Defendants participated in deceptive acts or practices in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52, in the advertising and sale of Mole Detective, Mole Detective 2, Mole Detect, and Mole Detect Pro (the “Mole Detective apps”). In particular, the Complaint charges that Defendants misrepresented that the Mole Detective apps accurately analyze moles for the ABCDE symptoms of melanoma and increase consumers’ chances of detecting skin cancer in early stages.
3. The Complaint states a claim upon which relief may be granted under Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, and the Commission has the authority to seek the relief it has requested.
4. On April 21, 2015, the Court entered a default against Defendant L Health Ltd. because it failed to answer or otherwise defend against the Complaint. (Dkt. 18.)
5. Defendant L Health Ltd. has violated Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, as alleged in Count I of the Complaint.
6. A reasonable approximation of consumer injury resulting from Defendant L Health Ltd.’s violations of the FTC Act is \$58,623.42.
7. Entry of this Order is in the public interest. It is also appropriate, in light of Defendant L Health Ltd.’s violations of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

DEFINITIONS

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

1. “Defendant” means Defendant L Health Ltd.
2. “Defendants” means all of the Defendants named in the caption of this Order,

detecting melanoma or risk of melanoma, including, but not limited to, Mole Detective, Mole Detective 2, Mole Detect, and Mole Detect Pro.

7. “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.

8. The term “including” in this Order means “including without limitation.”

9. 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.

ORDER

I.

PROHIBITED DECEPTIVE CLAIMS, INCLUDING FALSE AND/OR UNSUBSTANTIATED CLAIMS, REGARDING MELANOMA DETECTION

IT IS ORDERED that Defendant, its 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, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Device, are hereby permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a Device name, endorsement, depiction, or illustration, any representation 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, they possess and rely upon competent and reliable scientific evidence to substantiate that the representation is true. For purposes of this Section, 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, include a representative range of skin lesions, and 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 relevant field as relevant to an assessment of such testing as set forth in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission.

II.

OTHER PROHIBITED DECEPTIVE HEALTH-RELATED EFFICACY CLAIMS, INCLUDING FALSE AND/OR UNSUBSTANTIATED CLAIMS

IT IS FURTHER ORDERED that Defendant, its 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, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product or service, are permanently restrained and enjoined from making, or assisting others in

III.

MONETARY JUDGMENT

IT IS FURTHER ORDERED that:

A. Judgment in the amount of Fifty-Eight Thousand, Six Hundred Twenty-Three Dollars and Forty-Two Cents (\$58,623.42) is entered in favor of the Commission against Defendant as equitable monetary relief.

B. Defendant is ordered to pay to the Commission Fifty-Eight Thousand, Six Hundred Twenty-Three Dollars and Forty-Two Cents (\$58,623.42). Such payment must be made within 7 days of entry of this Order by electronic fund transfer in accordance with instructions provided by a representative of the Commission.

C. If payment is not timely made, interest at the statutory rate will be computed and charged from the date of entry of this Order.

D. All funds 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, with the Court's prior approval, the Commission may apply any remaining money for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Defendant's practices alleged in the Complaint, or deposit funds not used for such equitable relief to the U.S. Treasury as disgorgement. Defendant has no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

IV.

FDA APPROVED CLAIMS

IT IS FURTHER ORDERED that nothing in this Order shall prohibit Defendant from:

- A. Making any representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and
- B. Making any representation for any product that is specifically permitted in

C. Failing to destroy such customer information in all forms in Defendant's possession, custody, or control within 30 days after entry of this Order.

Provided, however, that customer information need not be disposed of, and may be disclosed, to the extent requested by a government agency or required by law, regulation, or court order.

VI.

**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

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 any Defendant, or by any person or entity affiliated with or acting on behalf of any Defendant, including officers, agents, representatives, and employees, or by any other person or entity in active concert or participation with any Defendant ("Defendant's affiliates"), or (2) by the supplier or manufacturer of the product at issue, or (3) by a supplier to any Defendant, to Defendant's affiliates, or to the product's manufacturer of any ingredient or component contained in such product.

For any test conducted, controlled, or sponsored, in whole or in part, by Defendant or any business that it, individually or collectively with any other Defendants, is a majority owner or controls directly or indirectly, Defendant 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 their size and complexity, the nature and scope of their activities, and the sensitivity of the personal information collected from or about the participants.

representatives of the Commission may use to communicate with Defendant; (b) identify all of 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 products and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant; (d) describe in detail whether and how 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.

B. For 10 years following entry of this Order, Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following: (a) any designated point of contact; or (b) the structure of 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: the 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.

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

compliance with this Order:

A. Within 14 days of receipt of a written request from a representative of the Commission, 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 also is 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 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 Defendant or any individual or entity affiliated with any Defendant, 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 shall retain jurisdiction of this matter for

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

SO ORDERED this 29th day of May, 2015:


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