

Complaint

IN THE MATTER OF

HEALTH DISCOVERY CORPORATIONCONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECS. 5(A) AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4516; File No. 132 3211
Complaint, March 30, 2015 – Decision, March 30, 2015

This consent order addresses allegations that respondents Health Discovery Corporation, along with Kristi Kimball and her company, New Consumer Solutions LLC (collectively “Respondents”), deceived consumers concerning its mobile device software application. The complaint alleges that Respondents violated Sections 5(a) and 12 of the Federal Trade Commission Act by representing that its MelApp mobile device application accurately analyses moles and other skin lesions for melanoma and increases consumers’ chances of detecting melanoma in early stages. According to the complaint, the MelApp application instructed users to photograph a mole with a smartphone camera and input other information. The application would then supposedly calculate the mole’s melanoma risk as low, medium, or high. However, the Respondents lacked substantiation for these representations. The order bars the Respondents from making false representations regarding its products without scientific testing and substantiation. The order further requires the company to follow appropriate recordkeeping and compliance reporting requirements, as well as to preserve documents for human clinical studies that it conducts or sponsors.

Participants

For the *Commission*: *Mary Johnson and Karen Mandel.*

For the *Respondent*: *Timothy J. Fitzgibbon, Nelson Mullins Riley & Scarborough, LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Health Discovery Corporation, a corporation, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

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.

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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 acts and practices of Respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

4. MelApp is a "device" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

5. First sold in 2011, MelApp is available for purchase and download over the Internet through the Apple App Store and the Google Play Store. The retail cost of MelApp is \$1.99. U.S. sales of MelApp from January 2011 through July 2013 totaled more than \$17,000.

6. Respondent has disseminated or has caused to be disseminated advertisements and promotional materials for MelApp, including but not necessarily limited to the attached Exhibits A through C. These materials contain the following statements and depictions, among others:

- a. Screen excerpts from Apple App Store (Nov. 26, 2012)

(Exhibit A, pp. 1-2)

Whether sunning on the beach, cheering at the kids' outdoor sporting events or hitting the slopes, chances are you're being affected by damaging UV rays. MelApp for iPhone is an image-based risk assessment mobile app that assists in the early detection of melanoma. Melanoma is the fastest growing cancer worldwide, and the most deadly of all skin cancers, if not caught early.

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However, melanoma can be successfully removed and monitored by regular skin screenings in its early stages. The disease is deadly in its most advanced stages as few treatment options exist. The median lifespan for patients with advanced melanoma is less than one year. Performing regular self-exams could save your life or that of a loved one.

Checking a mole or freckle is quick and easy:

(1) Use MelApp to take a picture of the skin lesions of concern with an iPhone's camera, enlarging it with the zoom feature to fit into the green box, then

(2) Pin point the mole size and its evolution by sliding the corresponding indicator bar and tap on "Check Risk." Within seconds MelApp will provide a risk analysis of the uploaded picture being a melanoma.

MelApp uses highly sophisticated patent protected state-of-the-art mathematical algorithms and image-based pattern recognition technology to analyze the uploaded image. The app was validated using an image database licensed from Johns Hopkins University Medical Center.

- b. Screen excerpts from the Google Play Store (Jan. 31, 2014)

(Exhibit B, p. 1, bracketed punctuation supplied)

Whether sunning on the beach, cheering at the kids' outdoor sporting events or hitting the slopes, chances are you're being affected by damaging UV rays. MelApp for the Droid is an image-based risk assessment mobile app that assists in the early detection of melanoma.

Melanoma is the fastest growing cancer worldwide, and the most deadly of all skin cancers, if not caught early. However, melanoma can be successfully removed and monitored by regular skin screenings in its early stages. The disease is deadly in its most

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advanced stages as few treatment options exist. The median lifespan for patients with advanced melanoma is less than one year. Performing regular self-exams could save your life or that of a loved one.

Checking a mole or freckle is quick and easy:

(1) Use MelApp to take a picture of the skin lesions of concern with the phone's camera, fit the mole in the green circle and square by enlarging it with the zoom feature and/or resizing the green circle[;]

(2) Pin point the mole size and its evolution by sliding the corresponding indicator bar and tap on "Check Risk." Within seconds MelApp will provide a risk analysis of the uploaded picture being a melanoma.

MelApp uses highly sophisticated patent protected state-of-the-art mathematical algorithms and image-based pattern recognition technology to analyze the uploaded image. The app was validated using DermAtlas, an open access, physician-edited database of over 10,000 high quality histological and clinical images of skin conditions.

- c. Screen excerpts from Respondent's website, www.melapp.net

(Aug. 5, 2013) (Exhibit C, pp. 1-2)

Whether sunning on the beach, cheering at the kids' outdoor sporting events or hitting the slopes, chances are you're being affected by damaging UV rays. MelApp is an image-based risk assessment mobile app that assists in the early detection of melanoma.

Melanoma is the fastest growing cancer worldwide, and the most deadly of all skin cancers, if not caught early. Performing regular self-exams could save your life or that of a loved one.

Checking a mole or freckle is quick and easy:

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1. Use MelApp to take a picture of the skin lesions of concern with a smartphone's camera, enlarging it with the zoom feature to fit into the green box, then
2. Pin point the mole size and its evolution by sliding the corresponding indicator bar and tap on "Check Risk." Within seconds MelApp will provide a risk analysis of the uploaded picture being a melanoma.

MelApp uses highly sophisticated patent protected state-of-the-art mathematical algorithms and image-based pattern recognition technology to analyze the uploaded image. The app was validated using DermAtlas, an open access, physician-edited database of over 10,000 high quality histological and clinical images of skin conditions.

COUNT I
FALSE OR UNSUBSTANTIATED MELANOMA DETECTION
CLAIM

7. In connection with the advertising, promotion, offering for sale, or sale of MelApp, Respondent has represented, directly or indirectly, expressly or by implication, that:

- a. MelApp accurately analyzes moles and other skin lesions for melanoma or risk of melanoma; and
- b. MelApp increases consumers' chances of detecting melanoma in early stages.

8. The representations set forth in Paragraph 7 are false or misleading, or were not substantiated at the time the representations were made.

COUNT II
FALSE ESTABLISHMENT CLAIM

9. In connection with the advertising, promotion, offering for sale, or sale of MelApp, Respondent has represented, directly or indirectly, expressly or by implication, that scientific testing proves that MelApp accurately detects melanoma or risk of melanoma.

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10. In fact, scientific testing does not prove that MelApp accurately detects melanoma or risk of melanoma. Therefore, the representation set forth in Paragraph 9 is false or misleading.

VIOLATIONS OF SECTIONS 5 AND 12

11. The acts and practices of Respondent as alleged in this complaint constitute deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this thirtieth day of March, 2015, has issued this Complaint against Respondent.

By the Commission, Commissioner Ohlhausen dissenting.

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

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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:

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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.

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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.

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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

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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

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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

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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:

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- 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,*

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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;

Analysis to Aid Public Comment

- 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.

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order as to Health Discovery Corporation (hereafter "the company").

The proposed consent order ("proposed order") has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed order and the comments received, and will decide whether it should withdraw or make final the agreement's proposed order.

Analysis to Aid Public Comment

This matter involves the company's advertising for the MelApp mobile device software application. The Commission's complaint alleges that the company violated Sections 5(a) and 12 of the Federal Trade Commission Act by representing that MelApp accurately analyses moles and other skin lesions for melanoma and increases consumers' chances of detecting melanoma in early stages, because such claims were false or misleading, or were not substantiated at the time the representations were made. The complaint also alleges that the company violated Sections 5(a) and 12 by making the false or misleading representation that scientific testing proves that MelApp accurately detects melanoma.

The proposed order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. The proposed order covers any Device, as the term is used within the meaning of Sections 12 and 15 of the FTC Act, 15 U.S.C. §§ 52, 55. As additional fencing-in relief, the proposed order requires the company to follow appropriate recordkeeping and compliance reporting requirements, as well as document preservation requirements for human clinical studies that it conducts or sponsors on the Device.

Part I prohibits any representation that a Device detects or diagnoses melanoma or risk factors of melanoma, or increases users' chances of detecting melanoma in early stages, unless it is non-misleading and supported by competent and reliable scientific evidence. Such evidence must consist of human clinical testing of the Device that is sufficient in quality and quantity, based on standards generally accepted by experts in the field, is blinded, conforms to actual use conditions, includes a representative range of skin lesions, and is conducted by researchers qualified by training and experience to conduct such testing. In addition, the company must maintain all underlying or supporting data that experts in the relevant field generally would accept as relevant to an assessment of such testing.

Part II prohibits any representation about the health benefits or health efficacy of a Device, unless it is non-misleading and supported by 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

Analysis to Aid Public Comment

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 that have been conducted by a qualified person in an objective manner and are generally accepted in the profession to yield accurate and reliable results. When that evidence consists of a human clinical trial, the company must maintain all underlying or supporting data and documents that experts in the relevant field generally would accept as relevant to an assessment of such testing.

Part III, triggered when the human clinical testing requirement in Parts I or II applies, requires the company to secure and preserve all underlying or supporting data and documents generally accepted by experts in the relevant field as relevant to an assessment of the test, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test's researchers. There is an exception for a "Reliably Reported" test, defined as a test that is published in a peer-reviewed journal and that was not conducted, controlled, or sponsored by any proposed respondent or supplier. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Part IV prohibits the company from misrepresenting, including through the use of a product or service name, endorsement, depiction, or illustration, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research, or 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.

Part V provides the company will pay an equitable monetary payment of Seventeen Thousand Six Hundred Ninety-three Dollars (\$17,693).

Statement of the Commission

Part VI contains recordkeeping requirements for advertisements and substantiation relevant to representations covered by Parts I through III, as well as order receipts covered by Part VII.

Parts VII through IX require the company to deliver a copy of the order to officers, employees, and representatives having managerial responsibilities with respect to the order's subject matter, notify the Commission of changes in corporate structure that might affect compliance obligations, and file compliance reports with the Commission.

Part X provides that, with exceptions, the order will terminate in twenty years.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint or proposed order, or to modify the proposed order's terms in any way.

STATEMENT OF THE COMMISSION

Today the Commission is announcing actions in two matters challenging the advertising for the mobile apps MelApp and Mole Detective.¹ Both of these apps claimed to provide an automated analysis of moles and skin lesions for symptoms of melanoma and increase consumers' chances of detecting melanoma in its early stages.

¹ The Commission has voted to accept for public comment a consent agreement with the sole respondent in *In the Matter of Health Discovery Corporation* (addressing the MelApp mobile app). In *FTC v. Avrom Boris Lasarow, et al.* (addressing the Mole Detective mobile app), the Commission has authorized the filing of a federal court complaint against four defendants and approved a proposed settlement with two of those defendants, Kristi Zuhlke Kimball and New Consumer Solutions LLC.

Statement of the Commission

Advertising for MelApp stated that it used “patent protected state-of-the-art mathematical algorithms and image-based pattern recognition technology to analyze the uploaded image [of a skin lesion],” to “provide a risk analysis of the uploaded picture being a melanoma” and “assist[] in the early detection of melanoma.”² Advertising for Mole Detective stated that it “is the first and only app to calculate symptoms of melanoma right on the phone,” and that it could “analyze[] your mole using the dermatologist ABCDE method and give[] you a risk factor based on the symptoms your mole may or may not be showing,” “increase the chance of detecting skin cancer in early stages,” and “save[] lives through the early detection of potentially fatal melanoma,” using “shape recognition software.”³

The claims that these apps would provide an accurate, automated analysis of skin lesions were the central selling points for both MelApp and Mole Detective, and these claims needed to be substantiated.⁴ Although Commissioner Ohlhausen does not appear to disagree with this assessment, she believes the Commission’s complaint needs to articulate a comparative reference point for any “accuracy” claim to set an appropriate level of substantiation in the accompanying orders. Absent extrinsic evidence, she believes it is reasonable to read the ads as claiming that the automated assessment is more accurate than unaided self-assessment, and that it is not reasonable to read the ads as claiming that the automated assessment is as accurate as a dermatologist.

We disagree. We think the powerful language of the advertising, such as that quoted above, is clear on its face, so no extrinsic evidence of consumer interpretation is needed to support the challenged representations that the apps accurately analyze

² See MelApp Complaint ¶ 6(A).

³ See Mole Detective Complaint ¶¶ 18(A)-(B), 18(D); Ex. A-2.

⁴ *FTC Policy Statement Regarding Advertising Substantiation*, 104 F.T.C. 839 (1984) (appended to *Thompson Med. Co.*, 104 F.T.C. 648 (1984)) (“[W]e reaffirm our commitment to the underlying legal requirement of advertising substantiation – that advertisers and ad agencies have a reasonable basis for advertising claims before they are disseminated.”), *aff’d*, 791 F.2d 189, 193 & 196 (D.C. Cir. 1986), *cert. denied*, 479 U.S. 1086 (1987).

Statement of the Commission

moles for symptoms of melanoma and increase the chance of detecting skin cancer in its early stages. Because the defendants and the respondent lacked substantiation for those claims, we have reason to believe they violated Section 5. Thus, it is not necessary to hypothesize about what implied claims, such as the accuracy relative to different types of assessments, consumers may have read into the advertising.

Commissioner Ohlhausen also suggests that the orders would, *de facto*, require any future app the advertisers market to be as accurate as a dermatologist or biopsy. Again, we respectfully disagree. The orders do not prescribe a particular level of accuracy the apps must achieve prior to being marketed; rather, they require scientific testing demonstrating accuracy at a level appropriate to the claims being made.⁵ Thus, if scientific testing demonstrates that the app is accurate 60% of the time, the advertisers would be able to make a 60% accuracy claim. It would be incumbent upon these marketers to make sure that their advertising conveyed that level of accuracy and did not suggest a stronger level of science to reasonable consumers.

Technologies such as health-related mobile apps have the potential to provide tremendous conveniences and benefits to consumers. However, the same rules of the road apply to all media and technologies – advertisers must have substantiation to back up their claims. The Commission will continue to hold

⁵ Based on our application of the factors set out in *Pfizer*, 81 F.T.C. 23, 64 (1970), if these advertisers make future claims that any device detects or diagnoses melanoma, or increases a user's chances of detecting melanoma in its early stages, the orders would require that such claims be substantiated by human clinical testing. The orders specify that such testing must 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. These conditions are designed to ensure the accuracy and reliability of testing used to support a narrow and clearly defined set of claims relating specifically to the detection and diagnosis of melanoma, a serious and progressively deadly disease.

If these advertisers make other claims about the health benefits or efficacy of any product or service, the orders require such claims to be non-misleading and supported by competent and reliable scientific evidence. The orders further describe what constitutes competent and reliable scientific evidence and make it quite clear that the evidence required is directly tied to the claim made, expressly or implicitly, by the advertiser.

Dissenting Statement

advertisers accountable for the promises they make to consumers, especially when they pertain to diseases and other serious health conditions.

For the foregoing reasons, we have reason to believe that the complaint allegations and proposed relief reached by consent of the settling parties are appropriate.

**STATEMENT OF COMMISSIONER MAUREEN K.
OHLHAUSEN**

These matters are another example of the Commission using an unduly expansive interpretation of advertising claims to justify imposing an inappropriately high substantiation requirement on a relatively safe product.¹ As I have previously stated, “We must keep in mind. . . that if we are too quick to find stronger claims than the ones reasonable consumers actually perceive, then we will inadvertently, but categorically, require an undue level of substantiation for those claims.”² Because I fear this course of action will inhibit the development of beneficial products and chill the dissemination of useful health information to consumers, I dissent.

I do not dispute that companies must have adequate substantiation to support the claims that they make, and I thus would have supported complaints and substantiation requirements based on the app developers’ claims that their apps automatically

¹ See Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part In the Matter of GeneLink, Inc. and foru International Corp., (Jan. 7, 2014); Concurring Statement of Commissioner Maureen K. Ohlhausen, POM Wonderful, Docket No. 9344, at 3 (Jan. 10, 2013). These statements are available at <http://www.ftc.gov/about-ftc/biographies/maureen-k-ohlhausen#speeches>.

² Concurring Statement of Commissioner Maureen K. Ohlhausen, POM Wonderful, at 3.

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assessed cancer risk more accurately than a consumer's unaided self-assessment using the ABCDE factors.³

However, the complaints and orders in these cases go further, demanding a high level of substantiation for a wide range of potential advertising claims. Specifically, the orders require rigorous, well-accepted, blinded, human clinical tests to substantiate any claim that the app increases consumers' chances of detecting skin cancer in the early stages.⁴ Both orders also impose the same high substantiation standard on any claim that an app "detects or diagnoses melanoma or risk factors of melanoma."⁵ The orders could thus be read to require the app developers to demonstrate that their apps assess cancer risk as well as dermatologists, even if their ads make much more limited claims.

Substantiation requirements must flow from the claims made by the advertiser. Under *Pfizer*, the Commission should require a high level of substantiation if the advertiser expressly claimed or implied that the apps provide dermatologist-level accuracy and efficacy, and a lower level of substantiation if the advertiser claims a lower level of capability.⁶ The majority's statement appears to agree with that approach:

³ I agree with the majority that the companies claimed, without substantiation, that the apps' automated risk assessments were more accurate than a user's unaided self-assessment using the ABCDE factors, and I therefore would support complaints narrowly challenging this claim. Further, I would support orders prohibiting claims that an app "detects melanoma or risk factors of melanoma, thereby increasing, as compared to unaided self-assessment, users' chances of detecting melanoma in early stages," unless substantiated by competent and reliable scientific evidence.

⁴ Mole Detective Order at 5. The MelApp Order includes a similar prohibition. See MelApp Order at 3.

⁵ Mole Detective Order at 5; MelApp Order at 3.

⁶ Under *Pfizer*, the Commission determines the level of evidence an advertiser must have to substantiate its product efficacy claims by examining six factors: (1) the type of product advertised; (2) the type of claim; (3) the benefits of a truthful claim; (4) the cost of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation that experts in the field would require. *Pfizer, Inc.*, 81 F.T.C. 23, 64 (1970).

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“[I]f scientific testing demonstrates that the app is accurate 60% of the time, the advertisers would be able to make a 60% accuracy claim. It would be incumbent upon these marketers to make sure that their advertising conveyed that level of accuracy and did not suggest a stronger level of science to reasonable consumers.”⁷

Yet, having acknowledged that the app developers need only ensure that their advertising conveys the appropriate level of accuracy, the majority still supports complaints that do not specify what claimed level of accuracy their advertisements conveyed to consumers. Instead, the complaints describe the allegedly unlawful advertising claims amorphously. The Mole Detective complaint, for example, characterizes the defendants’ ads as claiming that the app “accurately analyzes moles for the ABCDE symptoms of melanoma; and/or increases consumers’ chances of detecting skin cancer in early stages.”⁸

This amorphous claim construction leaves two unresolved questions: “Accurate compared to what?” and “Increases chances compared to what?” We must know how reasonable consumers answered those questions – and thus establish what claims consumers likely took from the ads – before we can determine whether defendants provided the appropriate level of substantiation for those claims.⁹

There is little reason to think that consumers interpreted the ads to promise early detection as accurate and efficacious as a dermatologist. The ads never claim that the apps substitute for a dermatologist exam. In fact, the ads describe the apps as tools to enhance self-assessment in conjunction with visits to dermatologists, and both apps emphasize the importance of regular dermatologist visits. Without extrinsic evidence, I do not have reason to believe that a reasonable consumer would take

⁷ Statement of Chairwoman Ramirez, Commissioner Brill, and Commissioner McSweeney at 2.

⁸ Mole Detective Complaint ¶ 23. The MelApp complaint contains similar language. See MelApp Complaint at 4.

⁹ Because the ads do not expressly quantify (in absolute terms or by comparison) the accuracy or efficacy of the apps, any purported claims by the ads about accuracy or efficacy must be implied, not express.

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away the implied claim that using these apps would increase their chances of detecting skin cancer in the early stages as compared to an examination by a dermatologist.¹⁰

Thus, the orders impose a high level of substantiation despite lacking evidence that the marketing claims require such substantiation, and the complaints' vague claim construction obscures this flawed approach.¹¹ Despite the assurances in the majority's statement as to what the orders require, the complaints imply – and the majority appears to agree¹² – that reasonable consumers expected the apps to substitute for professional medical care. This disconnect raises the possibility that the Commission may use vague complaints to impose very high substantiation standards on health-related apps even if the advertising claims for those apps are more modest.

This approach concerns me. Health-related apps have enormous potential to improve access to health information for underserved populations and to enable individuals to monitor more effectively their own well-being, thereby improving health outcomes. Health-related apps need not be as accurate as professional care to provide significant value for many consumers. The Commission should not subject such apps to

¹⁰ When the FTC cannot “conclude with confidence” that a specific implied claim is being made – for example, if the ad contains “conflicting messages” – the FTC “will not find the ad to make the implied claim unless extrinsic evidence allows us to conclude that such a reading of the ad is reasonable.” *In re Thompson Med. Co.*, 104 F.T.C. 648, 788-89 (1984).

¹¹ These onerous substantiation requirements cannot be defended as “fencing-in.” The FTC does not traditionally fence in companies by requiring a heightened level of substantiation. Instead, past FTC decisions fence in companies by extending the scope of a substantiation requirement beyond the specific product, parties, or type of conduct involved in the actual violation. See *Federal Trade Commission v. Springtech 77376, LLC, et al.* (“*Cedarcide Industries*”), Matter No. X120042, Dissenting Statement of Commissioner Maureen K. Ohlhausen at 3 (July 16, 2013). Requiring past violators to meet a higher burden of substantiation would not fence them in – it would only make it more difficult for them to make truthful claims that could be useful to consumers. *Id.*

¹² “Commissioner Ohlhausen... believes...that it is not reasonable to read the ads as claiming that the automated assessment is as accurate as a dermatologist. We disagree.” Statement of Chairwoman Ramirez, Commissioner Brill, and Commissioner McSweeney at 1.

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overly stringent substantiation requirements, so long as developers adequately convey the limitations of their products. In particular, the Commission should be very wary of concluding that consumers interpret marketing for health-related apps as claiming that those apps substitute for professional medical care, unless we can point to express claims, clearly implied claims, or extrinsic evidence. If the Commission continues to adopt such conclusions without any evidence of consumers' actual interpretations, and thus requires a very high level of substantiation for health-related apps, we are likely to chill innovation in such apps, limit the potential benefits of this innovation, and ultimately make consumers worse off.¹³

I therefore respectfully dissent.

¹³ See, e.g., Scott Gottlieb and Coleen Klasmeier, "Why Your Phone Isn't as Smart as It Could Be," *Wall Street Journal* (Aug. 7, 2014) (blaming heavy regulation of consumer-directed health apps and devices for smartphones that are "purposely dumbed down" and "products that are never created because mobile-tech entrepreneurs choose to direct their talents elsewhere"), available at <http://online.wsj.com/articles/scott-gottlieb-and-coleen-klasmeier-why-your-phone-isnt-as-smart-as-it-could-be-1407369163>.

Complaint

IN THE MATTER OF

**PHOEBE PUTNEY HEALTH SYSTEM, INC.,
PHOEBE PUTNEY MEMORIAL HOSPITAL,
INC., PHOEBE NORTH, INC., HCA INC.,
PALMYRA PARK HOSPITAL, INC., AND
HOSPITAL AUTHORITY OF ALBANY-
DOUGHERTY COUNTY**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL TRADE
COMMISSION ACT

*Docket No. 9348; File No. 111 0067
Complaint, April 19, 2011 – Decision, March 31, 2015*

In April 2011, the Commission issued an administrative complaint challenging Phoebe Putney Health System, Inc.’s (“Phoebe Putney”) proposed acquisition of Palmyra Park Hospital, Inc. (“Palmyra”) from Hospital Corporation of America in Albany, Georgia. The complaint alleged the acquisition would harm patients, employers, and employees in Albany, Georgia by allowing Phoebe/Palmyra to raise prices for general acute-care hospital services charged to commercial health plans. The complaint further alleged that Phoebe attempted to use the Hospital Authority of Albany-Dougherty County (the “Authority”) to shield the acquisition from federal antitrust scrutiny under the “state action” doctrine. The administrative proceeding was then stayed pending the outcome of a parallel federal action challenging the transaction. After the Commission was successful on appeal in the federal action, the Commission lifted the stay on the administrative proceeding. Following discovery, the parties entered a settlement. Under the terms of the consent order, Phoebe and the Authority must notify the Commission in advance of acquiring any part of a hospital or a controlling interest in other healthcare providers in the Albany, Georgia area for the next decade. The order further bars the respondents from objecting to any certificate of need applications made by potential new hospital providers for the next five years.

Participants

For the *Commission*: Thomas H. Brock, Peter C. Herrick, Janet J. Kim, Sara Razi, Matthew Reilly, Scott Reiter, Mark Seidman, Joshua Smith, W. Stephen Sockwell, Matthew Tabas, Priya Viswanath, and Goldie V. Walker.

For the *Respondents*: Brian Burke, John Fedele, and Jennifer Semko, Baker & McKenzie LLP; Robert Baudino, Baudino Law