[BILLING CODE: 6750-01S]

FEDERAL TRADE COMMISSION

[File No. 132 3211]

Health Discovery Corporation; Analysis of Proposed Consent Order to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order -- embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before March 25, 2015.

ADDRESSES: Interested parties may file a comment at https://ftcpublic.commentworks.com/ftc/melappsconsent/ online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Health Discovery Corporation - Consent Agreement; File No. 1323211" on your comment and file your comment online at https://ftcpublic.commentworks.com/ftc/melappsconsent/ by following the instructions on the web-based form. If you prefer to file your comment on paper, write "Health Discovery Corporation - Consent Agreement; File No. 1323211" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580,

or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Karen Mandel, Bureau of Consumer Protection, (202) 326-2491, 600 Pennsylvania Avenue, NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR § 2.34, notice is hereby given that the above-captioned consent agreement containing consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for February 23, 2015), on the World Wide Web, at http://www.ftc.gov/os/actions.shtm.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before March 25, 2015. Write "Health Discovery Corporation - Consent Agreement; File No. 1323211" on your comment. Your comment - including your name and your state - will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at http://www.ftc.gov/os/publiccomments.shtm. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which . . . is privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 CFR § 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR § 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at https://ftcpublic.commentworks.com/ftc/melappsconsent/ by following the instructions on the

[1] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR § 4.9(c).

web-based form. If this Notice appears at http://www.regulations.gov/#!home, you also may file a comment through that website.

If you file your comment on paper, write "Health Discovery Corporation - Consent Agreement; File No. 1323211" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at http://www.ftc.gov to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before March 25, 2015. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see http://www.ftc.gov/ftc/privacy.htm.

Analysis of Proposed 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.

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 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).

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.

By direction of the Commission, Commissioner Ohlhausen dissenting.

Donald S. Clark,
Secretary.

Statement of Chairwoman Ramirez, Commissioner Brill, and Commissioner McSweeny

In the Matter of Health Discovery Corporation, File No. 132 3211,

and FTC v. Avrom Boris Lasarow, et al., File No. 132 3210

February 23, 2015

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.

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

[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.

[2] See MelApp Complaint ¶ 6(A).

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 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.

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[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).

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 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.

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[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 of Commissioner Maureen K. Ohlhausen

In the Matter of Health Discovery Corporation, File No. 132-3211

and FTC v. Avrom Boris Lasarow, et al., File No. 132-3210

February 23, 2015

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

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[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.

[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.

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:

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).

"[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-

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[7] Statement of Chairwoman Ramirez, Commissioner Brill, and Commissioner McSweeny 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.

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 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 agree[12] – 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.

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[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 McSweeny at 1.

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 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.

[FR Doc. 2015-04348 Filed 03/02/2015 at 8:45 am; Publication Date: 03/03/2015]

[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.