FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

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.

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]

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 *P* , 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:

''[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 away the implied claim that using these apps would increase their chances of detecting skin cancer in the early stages

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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.

[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 ://
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[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. 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).

[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.

[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