

**Statement of Chairwoman Ramirez, Commissioner Brill, and Commissioner McSweeney
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 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

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).

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).

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 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.

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.