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 *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

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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. 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.

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 as compared to an examination by a dermatologist.[10]

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[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).

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.

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.

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[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.

[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.