

FTC Cries Foul On Breathometer Accuracy Claims

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The FTC recently announced a settlement with [Breathometer, Inc.](#), a company that marketed a smartphone accessory that it claimed could detect blood alcohol levels. Users could simply plug the accessory into the headphone jack, open the Breathometer app, blow, and receive a reading of their blood alcohol content within five seconds. Breathometer marketed the products as “FDA registered devices,” featuring “law enforcement”-grade technology, to help you “make informed, dependable decisions” about whether to drive after drinking.

The FTC alleged that Breathometer did not have adequate substantiation for its performance claims. Specifically, the products were tested to determine accuracy at .02% blood alcohol content, not .08%, which is the legal limit under state laws. In addition, testing revealed that the accuracy of the Breeze version of the product degraded over time and the company did not have a means of recalibrating it remotely. Breathometer stopped selling the Breeze product but allegedly did not adequately inform consumers of the issue.

This case is yet another illustration of the FTC taking the lead on mobile health products that are or could potentially be regulated by the FDA. As readers of our [Food and Drug Law Access](#) blog may know, FDA has taken a risk-based approach to regulation of such products and, with the exception of products that could cause patient harm or death upon malfunction, is exercising regulatory discretion. Yet, many companies, particularly those who are new to the health market, presume that FDA is the primary, if not the only, regulator likely to have an interest in their product and claims.

Not so. The FTC has repeatedly voiced concerns about the proliferation of mobile health apps and whether claims were being properly substantiated, particularly where disease diagnosis, treatment, or mitigation claims are featured. Along with the Breathometer matter, the [Lumosity](#), [Melanoma Detective](#) and [Aura Labs](#) cases collectively demonstrate that when it comes to many consumer-directed mobile health products, the regulator most likely to take interest is the FTC.