

FTC Settles with Health App Marketers for Unsubstantiated Melanoma Detection Claims

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February 25, 2015

The Federal Trade Commission announced this week that it has reached settlements with two marketers for “deceptively claiming their mobile apps could detect melanoma, even in its early stages.” MelApp and Mole Detective claim to have the ability to accurately screen for a mole’s analyzed melanoma risk despite the absence of clinical testing. The FTC alleged this was a deceptive tactic as the marketers lacked sufficient evidence to prove these claims.

The settlements prohibit each company “from claiming that a device, such as an app, can detect or diagnose melanoma, unless the representation is truthful, not misleading, and supported by competent and reliable scientific evidence in the form of human clinical testing of the device.” The agency will pursue litigation against two additional marketers who did not agree to settle.

These settlements are noteworthy because they signal that the FTC’s interest in health benefit claims is not limited to consumable products such as foods, which may be news to newcomers in the health technology area. It is also a departure from the Food and Drug Administration’s enforcement discretion position relative to low-risk health apps geared toward consumers. The lesson for industry is that even if FDA does not require a pre-market clearance showing of safety and efficacy in order to market apps such as these, the FTC still holds marketers to the “competent and reliable scientific evidence” claim substantiation standard.