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Increased FTC Enforcement as FDA Deregulates Low-Rish Health IT Devices

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The FTC steps up enforcement of misleading software and mobile app promotional claims as FDA deregulates low-risk health IT devices.

In recent weeks, the Federal Trade Commission (FTC) has taken several enforcement actions against companies that make misleading promotional claims for their software and mobile medical applications. Interestingly, this increased FTC enforcement activity has taken place concurrent with the Food and Drug Administration's (FDA's) deregulation of low-risk health IT devices. Although the FDA retains jurisdiction over the labeling and promotion of standalone software and mobile applications that make disease- or medical-related claims, these recent activities suggest that the FDA may be deferring to the FTC's overlapping authority over the advertising and promotion of such products.

FTC ENFORCEMENT ACTIONS

In January 2015, the FTC filed a complaint and proposed consent order against Focus Education, LLC, charging that the company and its officers violated the Federal Trade Commission Act (FTC Act) by making false or unsubstantiated claims that the ifocus system permanently improves children's focus, memory, attention, behavior, and/or school performance, including in children with attention deficit hyperactivity disorder (ADHD). The proposed order prohibits the company and its principals from making unsubstantiated claims about the benefits, performance, or efficacy of products or services that supposedly alter the brain's structure or function; improve cognitive abilities, behavior, or academic performance; or treat or reduce the symptoms of cognitive disorders, including ADHD.[1]

In February 2015, the FTC announced enforcement actions against two melanoma-detection applications or "apps": MelApp and Mole Detective. The two apps claim to increase consumers' chances of detecting melanoma by analyzing pictures of moles and skin lesions taken with smartphones. The FTC's complaint against MelApp states that the company made advertising claims that the product 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 by helping you check and track your moles."[3]

Marketers for both apps have agreed to settlements with the FTC that prohibit them from making any claims that the apps can accurately detect or diagnose symptoms of melanoma. MelApp's marketer, Health Discovery Corp., consented to a $17,063 fine as part of its settlement. Mole Detective's developer and original marketer, New Consumer Solutions, consented to a $3,930 fine. The FTC is pursuing a judgment against a separate British marketing firm, which has not elected to settle with the FTC.

FDA DEREGULATION OF LOW-RISK HEALTH IT DEVICES

The FTC's recent enforcement actions against health IT marketers have taken place at the same time that the FDA has been evaluating its role in regulating low-risk software and mobile medical apps. The FDA has faced increased pressure from industry, consumers, and Congress to deregulate health-related apps. For example, several bills have been introduced over the last two years that seek to exempt certain software from FDA regulation.[4] In response, the FDA has taken several actions to deregulate certain low-risk health IT devices, including the following:

- Announced its intent to exercise enforcement discretion for certain mobile apps that may meet the definition of a "device" under the Federal Food, Drug, and Cosmetic Act but that present low risk to patients' safety if the apps fail to function as intended.[5] This would include, for example, apps that provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment and apps that provide patients with simple tools to organize and track their health information.

- Finalized a guidance document that states FDA's intent to exercise enforcement discretion for Class I MDDS devices subject to 21 C.F.R. § 880.6310, as well as for Class I medical image storage devices subject to 21 C.F.R. § 892.2010 and Class I medical image communications devices subject to 21 C.F.R. § 892.2020.[6]

- Issued draft guidance on "general wellness" devices in which FDA proposes to exercise enforcement discretion for products intended for general wellness only (i.e., products designed to maintain or encourage a general state of health or a healthy activity or that may associate a healthy lifestyle with reducing the risk or effect of certain chronic diseases or conditions).

- Issued, together with the Office of the National Coordinator for Health Information Technology and the Federal Communications Commission, a joint report on proposed strategies and recommendations for the regulation of health IT.[7] This report, known as the FDASIA Health IT Report, recommended that software that performs health-management functions, including electronic access to clinical results, medication management, and "most clinical decision support technologies," not be subject to FDA oversight.

Through deregulation, the FDA has responded to industry's desire to increase the availability of mobile and other technologies that will enable consumers to better manage their health and communicate with healthcare providers. Although the FDA has emphasized that it intends to continue to regulate higher risk mobile apps that meet the definition of "device," it appears to have deferred to the FTC in the recent cases discussed above.

To date, the FTC's new pattern of enforcement appears to be consistent with FDA's policies concerning the types of mobile medical apps subject to regulation. For example, FDA stated in its Mobile Medical Application guidance document that apps that "analyze an image of a skin lesion using mathematical algorithms, such as fractal analysis, and provide the user with an assessment of the risk of the lesion" would be subject to FDA regulation.[8]

We will continue to monitor events in this area to assess whether this represents a trend or is unique to these few cases.

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[1]. 80 Fed. Reg. 4575 (Jan. 28, 2015) (Focus Education, LLC, Analysis of Proposed Consent Agreement to Aid Public Comment).

[2]. 80 Fed. Reg. 11437 (Mar. 3, 2015) (Health Discovery Corporation, Analysis of Proposed Consent Agreement to Aid Public Comment).

[3]. 80 Fed. Reg. 11437 (Mar. 3, 2015) (In the matter of FTC v. Lazerow et al., File # 132-3210).

[4]. See, e.g., SOFTWARE Act, H.R. 3303, 113th Cong. (2013).

[5]. See FDA, Guidance, "Mobile Medical Applications" (Sept. 25, 2013, updated Feb. 9, 2015), available here.

[6]. FDA, Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices (Feb. 9, 2015).

[7]. FDASIA Health IT – Proposed Strategy and Recommendations for a Risk-Based Framework (Apr. 2014), available here.

[8]. FDA, Guidance, "Mobile Medical Applications," at 28 (Sept. 25, 2013, updated Feb. 9, 2015).

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