Keep Calm and Go Online: Regulatory Considerations Around the Spike in Demand for Mental Health Apps

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A recent Marketplace Tech podcast episode on the spike in demand for mental health apps caught our attention. As shocking headlines and stay-at-home orders rolled across the country, demand for mental health apps increased almost 30% since the pandemic began, according to CNBC. And there is a wide variety of options to choose from, with roughly 20,000 mental health apps available across app stores. This got the editors of Marketplace Tech asking two questions: Do mental health apps work? And what are the regulatory and privacy implications? It's worth a listen when you have time and we figured that we could weigh in as well.

Do they work?

One psychiatrist interviewed for the Marketplace Tech story questioned whether the apps should be required to demonstrate effectiveness to the FDA prior to being marketed. In fact, some of them are, but many are not.

The starting point for this analysis is whether the app or the software is regulated as a medical device. The Food Drug and Cosmetic Act defines a device as "…an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory", that is "… intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man …" or "… intended to affect the structure or any function of the body of man or other animals…" Apps that meet this definition are regulated as medical devices and are subject to FDA's pre-market review requirements, unless they are low risk and subject to FDA's enforcement discretion policy.

Given the need for patients and consumers to access mental health therapy remotely and in increased numbers over recent weeks, FDA relaxed its requirements for apps intended to help treat depression, anxiety, obsessive compulsive disorder and insomnia. FDA's Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency suspends the 510(k) premarket notifications, corrections and removal notifications, registration and listing requirements, and unique device identification (UDI) requirements for computerized behavioral health devices and other digital health therapeutic devices for psychiatric disorders where those devices do not create an undue risk during the COVID-19 emergency.

There are thousands of apps that relate to mental health and overall wellbeing in some way, however, many of which are not within the definition of "medical device" and do not require

premarket review. FDA's General Wellness: Policy for Low Risk Devices explains the agency's enforcement discretion approach more generally.

In addition, thinking about the "do they work" question, companies marketing these products should also be mindful of the FTC's claim substantiation requirements. Health claims are subject to a particularly high bar for claim substantiation – competent and reliable scientific evidence. In simple terms, this means evidence that is sufficient in quantity and quality such that experts in the field would agree that it supports the claim. The FTC has pursued app developers (see here and here) whose claims exceeded their substantiation and has issued dozens of warning letters to marketers making aggressive claims that their products can prevent or treat COVID-19. Companies marketing apps that claim to help address mental and physical health conditions should be mindful of the substantiation requirements and of closely tailoring their claims to their evidence.

What about privacy?

Many apps used by physicians are subject to HIPAA, but the vast majority of health-related apps are not covered by HIPAA. As health-related apps have proliferated, companies are collecting and storing massive amounts of consumer data. Many apps do not feature a clear explanation about privacy practices and how data is being stored or used. As we've chronicled here, non-HIPAA health privacy and the need for developers to be transparent with consumers about their privacy practices has been an FTC concern for several years. Our Advertising and Privacy Law Resource Center provides a wealth of free content to help app developers understand the applicable legal framework.

More specifically related to privacy and data tracking in the era of COVID-19, our "Data Privacy Considerations for Coronavirus Data Tools" provides key considerations for companies seeking to build contact tracing and related health apps. These include issues such as the following: whether personal information is involved, what level(s) of transparency are appropriate relative to data practices, how to address government requests for information, and considerations related to licensing COVID-19-related personal information.

What's the takeaway?

As daily life has increasingly shifted online, it's more important than ever for app developers to understand how their products are regulated and to build those features in to the product and how it is marketed. In addition, FDA's temporary relaxation of pre-marketing review standards for certain mental health apps does not mean that the FTC's claim substantiation and privacy compliance requirements are relaxed for health-related apps more generally. If anything, we should anticipate an increased regulatory focus on these issues.

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The latest episode of the Ad Law Access Podcast discusses three keys to making compliant health claims: determining the product regulatory classification, claim substantiation standards, and the importance of context. This episode is a prequel to her earlier Health Claims in the Context of COVID-

19 episode which focused on recent FTC and FDA enforcement relating to false COVID-19 health claims and the importance of considering the current pandemic context in health-related marketing.

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