

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
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WASHINGTON, DC 20515-6115

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**MEMORANDUM**

**July 11, 2016**

**To: Subcommittee on Commerce, Manufacturing, and Trade Democratic Members and Staff**

**Fr: Committee on Energy and Commerce Democratic Staff**

**Re: Hearing on “Disrupter Series: Health Care Apps”**

On Wednesday, July 13, 2016, at 10:15 a.m. in 2322 Rayburn House Office Building, the Subcommittee on Commerce, Manufacturing, and Trade will hold a hearing titled “Disrupter Series: Health Care Apps.”

**I. BACKGROUND**

The growing use of smartphones among U.S. consumers in recent years has fueled a vast marketplace for mobile applications (“apps”).<sup>1</sup> Some of the most widely-adopted mobile apps allow users to efficiently consume news and media, personalize text messages, and increase their productivity.<sup>2</sup> A fast-growing segment of the mobile app marketplace is focused on health and wellness, offering consumers a variety of tools to count calories, track sleep, and manage

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<sup>1</sup> Tech Crunch, *Mobile App Usage Up 58 Percent in 2015, With Emoji Keyboards Leading the Pack* (Jan. 5, 2016) (online at [techcrunch.com/2016/01/05/mobile-app-usage-up-58-percent-in-2015-with-emoji-keyboards-leading-the-pack/](http://techcrunch.com/2016/01/05/mobile-app-usage-up-58-percent-in-2015-with-emoji-keyboards-leading-the-pack/)).

<sup>2</sup> *Id.*

exercise routines through their mobile device.<sup>3</sup> There are currently more than 165,000 health and wellness apps available for download through the major online app stores.<sup>4</sup>

Like the smartphone itself, mobile apps have become more sophisticated in recent years. Today, consumers have access to many health apps that perform basic functions such as counting steps or reminding a user to drink enough water.<sup>5</sup> But they also have access to apps that can effectively turn a smartphone into a medical device, such as an electrocardiogram with the ability to monitor heart rhythm data and share information with a doctor in real time.<sup>6</sup>

Mobile apps have the potential to decrease healthcare costs and improve patient outcomes, particularly for underserved populations.<sup>7</sup> At the same time, patient harm is also possible, and apps that make false claims or are used incorrectly could be fatal for consumers and expose healthcare providers to unnecessary risk.<sup>8</sup> While mobile apps that monitor health indicators or repackage publicly available information are generally considered to be of minimal risk to consumers, those that attempt to diagnose and treat a patient's condition may draw the attention of regulatory agencies.<sup>9</sup>

## **II. FEDERAL GOVERNMENT ROLE**

### **A. Food and Drug Administration**

The Food and Drug Administration (FDA) defines “mobile medical apps” as applications that meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetics Act.<sup>10</sup> FDA issued guidance in February 2015 to inform consumers and manufacturers of mobile medical apps regarding how the agency intends to apply its regulatory

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<sup>3</sup> CNET, *The Best Fitness Apps for Android and iPhone* (Jan. 30, 2016) (online at [www.cnet.com/news/the-best-fitness-apps-for-android-and-iphone/](http://www.cnet.com/news/the-best-fitness-apps-for-android-and-iphone/)).

<sup>4</sup> Los Angeles Times, *Health Apps: Unlimited Promise or ‘Like Having a Really Bad Doctor’* (Apr. 12, 2016) (online at [www.latimes.com/business/technology/la-me-mobile-health-safety-20160412-story.html](http://www.latimes.com/business/technology/la-me-mobile-health-safety-20160412-story.html)).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

<sup>7</sup> InputHealth, *Healthcare Apps Should Be Treated Like Over-The-Counter Meds* (May 16, 2016) (online at [inputhealth.com/2016/05/16/healthcare-apps-treated-like-counter-meds/](http://inputhealth.com/2016/05/16/healthcare-apps-treated-like-counter-meds/)).

<sup>8</sup> *Id.*

<sup>9</sup> Modern Healthcare, *Easy on Those Apps: Mobile Medical Apps Gain Support, But Many Lack Clinical Evidence* (Nov. 28, 2015) (online at [www.modernhealthcare.com/article/20151128/MAGAZINE/311289981](http://www.modernhealthcare.com/article/20151128/MAGAZINE/311289981)).

<sup>10</sup> Food and Drug Administration, *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff* (Feb. 9, 2015) (online at [www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf](http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf)).

authority in this area.<sup>11</sup> The guidance explains how FDA intends to focus its oversight on mobile apps that either are used as an accessory to a regulated medical device or transform a mobile platform into a regulated medical device.<sup>12</sup> For example, apps that control the delivery of insulin on an insulin pump by transmitting control signals, or apps that use patient-specific parameters to calculate dosage for radiation therapy would be subject to FDA regulation.<sup>13</sup> On the other hand, informational apps that provide CPR tutorials, compare costs of drugs, and provide users with online portals to their healthcare provider would not be subject to FDA regulation so long as those apps comply with the Health Insurance Portability and Accountability Act (HIPAA).<sup>14</sup> In cases where a mobile app may meet the definition of a medical device but poses a lower risk to the public, FDA intends to exercise enforcement discretion.<sup>15</sup>

## **B. Federal Trade Commission**

The Federal Trade Commission (FTC) regulates mobile apps available to consumers pursuant to the FTC Act and brings enforcement action against violators of the Act. FTC released a web-based tool in April 2016 to help developers of health-related mobile apps understand what federal regulations may apply to their apps.<sup>16</sup> The tool was developed in coordination with the Department of Health and Human Services Office of Civil Rights, Office of National Coordinator for Health IT, and FDA.<sup>17</sup>

In recent years, FTC has also brought suit against developers of mobile health apps that made fraudulent claims about their products. Developers of a consumer-marketed mobile app agreed to pay \$150,000 in September 2015 to settle an enforcement action by FTC based on the app's claim that it was "scientifically shown to improve vision."<sup>18</sup> FTC determined that the promoters of the app did not have scientific evidence to support their claims.<sup>19</sup> Enforcement action has also been taken by FTC in the cases of two melanoma detection apps and an acne

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<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> Federal Trade Commission, *FTC Releases New Guidance for Developers of Mobile Health Apps* (Apr. 5, 2016) (online at [ftc.gov/news-events/press-releases/2016/04/ftc-releases-new-guidance-developers-mobile-health-apps](http://ftc.gov/news-events/press-releases/2016/04/ftc-releases-new-guidance-developers-mobile-health-apps)).

<sup>17</sup> *Id.*

<sup>18</sup> Federal Trade Commission, *FTC Charges Marketers of 'Vision Improvement' App with Deceptive Claims* (Sept. 17, 2015) (online at [ftc.gov/news-events/press-releases/2015/09/ftc-charges-marketers-vision-improvement-app-deceptive-claims](http://ftc.gov/news-events/press-releases/2015/09/ftc-charges-marketers-vision-improvement-app-deceptive-claims)).

<sup>19</sup> *Id.*

treatment app that made false claims about the effectiveness of their product, the latter of which was downloaded by almost 12,000 people before being taken off the market.<sup>20</sup>

### III. PRIVACY AND DATA SECURITY

Health apps may collect, store, and transmit a wealth of consumers' personal information, including sensitive medical data such as diagnosis of a disease and compliance with daily medication.<sup>21</sup> A recent study found that many of these apps share this information with third parties, including advertisers.<sup>22</sup> The same study also found that 80 percent of over 200 randomly selected diabetes apps had no privacy policies in place.<sup>23</sup> Of the 41 apps studied that did have privacy policies, more than 80 percent collected user data and almost 50 percent shared data.<sup>24</sup>

Health information has become a prime target for hackers in recent years given the high price such information commands on the black market.<sup>25</sup> Electronic health records, for example, may contain an individual's social security number, addresses, and employment history in addition to medical history, information that remains valuable for the entirety of a person's life.<sup>26</sup> The push toward more integrated healthcare has also increased the number of entities that may share in a person's medical data, therefore increasing the potential for breaches.<sup>27</sup>

Depending on the nature of the service provided by a health app to a consumer, it may be subject to HIPAA, which requires the protection and confidential handling of protected health

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<sup>20</sup> Federal Trade Commission, *FTC Cracks Down on Marketers of "Melanoma Detection" Apps* (Feb. 23, 2015) (online at [ftc.gov/news-events/press-releases/2015/02/ftc-cracks-down-marketers-melanoma-detection-apps](http://ftc.gov/news-events/press-releases/2015/02/ftc-cracks-down-marketers-melanoma-detection-apps)); Federal Trade Commission, *"Acne Cure" Mobile App Marketers Will Drop Baseless Claims Under FTC Settlements* (Sept. 8, 2011) (online at [ftc.gov/news-events/press-releases/2011/09/acne-cure-mobile-app-marketers-will-drop-baseless-claims-under](http://ftc.gov/news-events/press-releases/2011/09/acne-cure-mobile-app-marketers-will-drop-baseless-claims-under)).

<sup>21</sup> CBS News, *Health Apps May Pose Major Privacy Concerns* (Mar. 8, 2016) (online at [www.cbsnews.com/news/health-apps-may-pose-major-privacy-concerns/](http://www.cbsnews.com/news/health-apps-may-pose-major-privacy-concerns/)).

<sup>22</sup> Sarah R. Blenner, JD, MPH, et al., *Privacy Policies of Android Diabetes Apps and Sharing of Health Information*, *Journal of the American Medical Association* (Mar. 8, 2016).

<sup>23</sup> See note 20.

<sup>24</sup> *Id.*

<sup>25</sup> PBS NewsHour, *Has Health Care Hacking Become an Epidemic?* (Mar. 23, 2016) (online at [www.pbs.org/newshour/updates/has-health-care-hacking-become-an-epidemic/](http://www.pbs.org/newshour/updates/has-health-care-hacking-become-an-epidemic/)).

<sup>26</sup> *Id.*

<sup>27</sup> Brookings Institute, *Hackers, Phishers, and Disappearing Thumb Drives: Lessons Learned from Major Health Care Data Breaches* (May 2016) (online at [www.brookings.edu/~media/research/files/papers/2016/04/28-patient-privacy-yaraghi/patient-privacy504v3.pdf](http://www.brookings.edu/~media/research/files/papers/2016/04/28-patient-privacy-yaraghi/patient-privacy504v3.pdf)).

information (PHI) by covered entities.<sup>28</sup> Health plans, healthcare clearinghouses, and most healthcare providers are covered entities under HIPAA. Apps that create, receive, maintain, or transmit PHI on behalf of a covered entity must protect that information in compliance with HIPAA rules.<sup>29</sup> Apps that offer services directly to the consumer and do not collect PHI on behalf of a covered entity are not likely to be subject to HIPAA.<sup>30</sup>

#### IV. WITNESSES

**E. Ray Dorsey, M.D., M.B.A.**

Professor of Neurology and Director of the Center for Human Experimental Therapeutics  
University of Rochester Medical Center

**Bettina Experton, M.D., M.P.H.**

President and CEO  
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**Laura Ferris, M.D.**

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**Nicolas P. Terry**

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Executive Director of the William S. and Christine S. Hall Center for Law and Health  
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<sup>28</sup> Department of Health and Human Services, *Health App Use Scenarios & HIPAA* (Feb. 2016) (online at [hipaaqportal.hhs.gov/community-library/accounts/92/925889/OCR-health-app-developer-scenarios-2-2016.pdf](http://hipaaqportal.hhs.gov/community-library/accounts/92/925889/OCR-health-app-developer-scenarios-2-2016.pdf)).

<sup>29</sup> *Id.*

<sup>30</sup> *Id.*