U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

July 11, 2016

TO: Members, Subcommittee on Commerce, Manufacturing, and Trade

FROM: Committee Majority Staff

RE: Hearing entitled "The Disrupter Series: Health Care Apps"

I. INTRODUCTION

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 entitled "The Disrupter Series: Health Care Apps."

II. WITNESSES

- Diane Johnson, North America Regulatory Affairs Policy and Intelligence Medical Devices, Johnson & Johnson;
- Matt Patterson, M.D., President, AirStrip;
- 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, Humetrix;
- Laura Ferris, M.D., Assistant Professor, University of Pittsburgh, Department of Dermatology; and
- Nicolas P. Terry, Hall Render Professor of Law and Executive Director of the William S. and Christine S. Hall Center for Law and Health, Indiana University Robert H. McKinney School of Law.

III. BACKGROUND

A. Overview: Health Care Apps

Health care applications (apps) are part of a broader mobile health and telemedicine market that is transforming how health care is delivered and how individuals are engaging in the health care system.[1] Using a smartphone or tablet, users traditionally download a health care app from an app store, which enables the remote delivery of health care services or clinical information through the app's program and software design.[2]

[1] See http://www.wsj.com/articles/the-future-of-medicine-is-in-your-smartphone-1420828632
[2] See http://www.americantelemed.org/about-telemedicine/faqs#.V2Fhi7srLcs

There are approximately 165,000 health care apps on the market today.[3] These apps offer a wide range of health care services and clinical information to users, including chronic care management, remote patient monitoring, symptom tracking, face-to-face consultations, general health and fitness activity tracking, access to personal health records, medication adherence reminders, and clinical decision support.[4] In some instances, consumers may need a separate wearable or hardware device to support certain monitoring or tracking functions provided through the app, but that is not always necessary.[5]

Like other forms of health information technology, health care apps are creating opportunities to improve the efficiency, cost-effectiveness, quality, accessibility, and safety of medical care delivery within the U.S. health care system.[6] Health care apps in particular are enabling these opportunities by providing meaningful tools for physicians to diagnose, monitor, consult, and treat common diseases at their fingertips.[7] Apps offer physicians readily available access to information, quality resources, and other clinical support, such as alerts and reminders about a patient's medical history, clinical guidelines, and diagnostic tools.[8] This technology helps to streamline the decision-making process for health care providers and accelerate the delivery of care.[9]

Health care apps also create opportunities for increased patient engagement in the health care system, which can create additional cost savings and efficiencies.[10] Through apps, a health care provider's support and guidance can extend to a patient outside of the traditional office setting.[11] Apps also empower patients with more information and personal statistics about their health conditions in real-time.[12] Increased access to physician communication and support, along with personalized health information, can motivate healthier living and behavior among patients and encourage more proactive engagement in prescribed treatment plans.[13] This may ultimately drive improved patient outcomes and experiences, and reduce the need for future doctor visits, medication, and other health-related expenses.[14]

Over the past five years, the health care apps market has experienced significant growth. This growth has largely been attributed to increased smartphone adoption, including tablets and other mobile platforms, as well as advances in broadband internet technology.[15] Valued at $85

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[3] See http://research2guidance.com/2015/11/11/the-mhealth-app-market-will-grow-by-15-to-reach-31-billion-by-2020/
[4] See http://www.marketsandmarkets.com/PressReleases/mhealth-apps-and-solutions.asp;
[5] See http://www.wareable.com/apps/how-to-use-apple-health-iphone-fitness-app-960
[6] See http://www.ncbi.nlm.nih.gov/books/NBK37992/
[7] See https://www.infosys.com/industries/insurance/white-papers/Documents/health-challenges-benefits.pdf
[8] See https://www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds
[9] Id. (https://www.infosys.com/industries/insurance/white-papers/Documents/health-challenges-benefits.pdf)
[10] See http://www.himss.org/mhealth-app-essentials-patient-engagement-considerations-and-implementation
[11] See http://www.startribune.com/mobile-apps-changing-the-doctor-patient-relationship/328283411/
[12] See http://www.startribune.com/mobile-apps-changing-the-doctor-patient-relationship/328283411/
[13] See http://www.himss.org/mhealth-app-essentials-patient-engagement-considerations-and-implementation
[14] See http://www.himss.org/mhealth-app-essentials-patient-engagement-considerations-and-implementation
[15] See http://www.marketsandmarkets.com/PressReleases/mhealth-apps-and-solutions.asp

to $100 million in 2010, the health care apps market is now projected to be worth $6 to 10 billion.[16] While research suggests that only a small percentage (16 percent) of health care professionals currently use mobile apps with their patients, 46 percent of professionals plan to do so within the next five years as physicians adopt more patient-centered care models and user demand increases.[17] These factors are expected to drive a 15 percent annual growth rate in the health care apps market over the next few years, reaching a value of $31 billion by 2020.[18]

B. Adoption Challenges

Health care apps offer many opportunities to improve the quality, accessibility, affordability, and efficiency of care. However, despite these benefits, there are obstacles impeding the widespread adoption of this technology. For example, many who are most likely to benefit from health care apps, such as older patients with chronic conditions, are least likely to possess smartphones and may not have the technical skills to operate the mobile device or app.[19] A lack of clinical evidence demonstrating the benefits, accuracy, and overall effectiveness of health care apps may also slow their adoption among health care professionals, caregivers, and consumers.[20] Additionally, the limitations of health care apps and their reliability have not yet been fully explored, raising concerns about liability among health care professionals, which may deter adoption as well.[21]

Interoperability is another issue that may delay the adoption of health care apps. When patients opt to share their health care app data with providers, many physicians may not have the appropriate systems or software in place to readily accept or view the information collected by the app.[22] The physician may have to go to a separate database and leave the patient's electronic health record to view the information, which creates a secondary workflow and diminishes the efficiency value of the technology.[23] Until health care apps can integrate data directly into a physician's electronic record, their utility in decision-making for health care professionals may remain limited.[24]

The U.S. health care system's fee-for-service reimbursement model presents another challenge to health care app adoption. The current fee-for-service reimbursement model "rewards reactive, sickness-based care," which is driven by the quantity of the services

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[16] See http://www.mhealthshare.com/mfactsheet.htm; See also http://mhealthintelligence.com/news/mhealth-app-market-sees-400-million-growth-in-five-years
[17] See http://www.modernhealthcare.com/article/20151128/MAGAZINE/311289981; See also http://mhealtheconomics.com/the-8-drivers-and-barriers-that-will-shape-the-mhealth-app-market-in-the-next-5-years/
[18] See http://mobihealthnews.com/48413/prediction-health-app-market-to-top-31b-by-2020-driven-by-hardware-sales
[19] See http://medicaleconomics.modernmedicine.com/medical-economics/news/prescribing-mobile-apps-what-consider?page=full
[20] Id.
[21] See http://www.modernhealthcare.com/article/20151128/MAGAZINE/311289981
[22] See (http://medicaleconomics.modernmedicine.com/medical-economics/news/prescribing-mobile-apps-what-consider?page=full)
[23] Id.
[24] Id.

performed.[25] Alternatively, a value-based reimbursement system that emphasizes "the quality of care delivered and the outcome of that care," creates greater incentives for providers to integrate this technology within their practices.[26] A continuation of the fee-for-service model offers limited financial incentives for health care professionals to adopt health care apps and other mobile technologies that may have the potential to improve the quality and efficiency of care.[27]

Physician state licensing laws also may impede the adoption of health care apps. Many states "require physicians to be licensed to practice in the originating site's state," and some states require health care providers using telehealth technology – including some health care apps- across state lines "to have a valid state license in the state where the patient is located."[28] This requirement may slow or prevent the adoption of health care apps that support consultations, medication prescription, or other electronic-enabled interactions between patients and physicians across state lines.[29]

C. Food and Drug Administration

Under the Federal Food Drug and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is authorized to regulate medical devices.[30] Medical devices consist of instruments or machines used to diagnose, analyze, treat, or prevent disease.[31] They also are subject to certain premarketing and postmarketing regulatory controls – enforced by the FDA – to ensure the safety and effectiveness of the device.[32]

To address the development of health care apps that may meet the definition of a medical device under the FD&C Act, the FDA issued guidance on mobile medical apps in February 2015.[33] In the guidance, the FDA established that its oversight applies to mobile apps performing medical device functions – referred to as mobile medical apps.[34] It defined mobile medical apps as apps that are intended to be used either as "an accessory to a regulated medical device," or to "transform a mobile platform into a regulated medical device by using attachments, display screens, sensors, or other such methods."[35] The FDA also clarified in the guidance that it only intends to apply its oversight authority to those medical apps whose "functionality could pose a risk to a patient's safety if the mobile app were to not function as intended."[36] The FDA acknowledged that there are some apps that meet the definition of a medical device, however,

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[25] See http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4748838/
[26] See https://www.aapa.org/WorkArea/DownloadAsset.aspx?id=2147485051
[27] See http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4748838/
[28] See https://www.healthit.gov/providers-professionals/faqs/are-there-state-licensing-issues-related-telehealth
[29] Id.
[30] See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm
[31] Id.
[32] Id.
[33] See http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf
[34] Id.
[35] Id.
[36] Id.

because they pose a lower risk to the public, it only intends to exercise "enforcement discretion" over those apps, and does not intend to enforce requirements under the FD&C Act.[37]

D. Federal Trade Commission Activity

The Federal Trade Commission (FTC) has issued a handful of complaints against health care app developers and marketers over the last few years, primarily regarding misleading, deceptive, or unsubstantiated claims about the performance and health benefits of an app.[38] In 2011, for example, the FTC issued a complaint against the marketers of two acne apps that claimed to provide an effective acne treatment through blue and red light therapy, allegedly proven in a study published by the British Journal of Medicine.[39] The FTC charged that those claims were false and unsubstantiated.[40] The marketers of the acne apps agreed to a settlement with the agency that barred them from making acne treatment claims about the apps without competent and reliable scientific research.[41]

The FTC also issued a complaint against a health care app developer in 2015 who claimed that the app could help diagnose or assess consumers' melanoma risk.[42] The app directed users to take a photograph of a mole with a smartphone, and input other information.[43] The app would then "supposedly calculate the mole's melanoma risk as low, medium, or high."[44]The FTC charged the app developer for deceptively claiming that the app could accurately analyze melanoma risk without scientific backing.[45] The FTC settled with the developer barring the company from making further claims about melanoma risks without competent and reliable scientific evidence.[46]

In addition to these actions, the FTC released guidance in April to inform health care app developers about what federal laws and regulations may apply to their apps.[47]The interactive, web-based guidance tool takes developers through a series of questions about their app, including what type of data the app collects and its intended uses.[48] Based on the developers' answers, the guidance directs the developer to one or more of the following federal laws that

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[37] Id.
[38] See https://www.ftc.gov/news-events/press-releases/2015/09/ftc-charges-marketers-vision-improvement-app-deceptive-claims; See also https://www.ftc.gov/news-events/press-releases/2015/08/melanoma-detection-app-sellers-barred-making-deceptive-health; See also https://www.ftc.gov/news-events/press-releases/2011/09/acne-cure-mobile-app-marketers-will-drop-baseless-claims-under
[39] See https://www.ftc.gov/news-events/press-releases/2011/09/acne-cure-mobile-app-marketers-will-drop-baseless-claims-under
[40] Id.
[41] Id.
[42] See https://www.ftc.gov/news-events/press-releases/2015/02/ftc-cracks-down-marketers-melanoma-detection-apps
[43] Id.
[44] Id.
[45] Id.
[46] Id.
[47] See https://www.ftc.gov/news-events/press-releases/2016/04/ftc-releases-new-guidance-developers-mobile-health-apps
[48] See https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool

may apply to the app: the FTC Act, the FTC's Health Breach Notification Rule, the Health Insurance Portability and Accountability Act, and the FD&C Act. The FTC released this guidance tool in conjunction with the Department of Health and Human Services' Office of National Coordinator for Health Information Technology, Office for Civil Rights, and the FDA.[49] The FTC also released additional guidance regarding data privacy and security best practices to help app developers comply with the FTC Act.[50]

E. Protecting Personal Information

The data generated from health care apps has the potential to positively alter patient behaviors and yield life-saving insights to providers that could radically transform the health care system we understand and experience today.[51] Despite this potential, the sensitive and personalized nature of patient and consumer information collected and shared through health care apps gives rise to certain data privacy and security concerns. Research also suggests that health data has become a growing target for identity thieves and other bad actors given the permanence of medical and prescription records, and the comprehensive nature of health data.[52] With the health care apps market still in its formative stages, the challenge will be to establish a market that promotes continued development and innovation, while providing appropriate data security and privacy protections for patients and consumers both inside and outside the traditional medical office setting.

The Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act (HIPAA) was enacted by Congress in 1996 to protect the privacy and security of protected health information maintained in electronic, paper, or oral form.[53] Protected health information includes data related to an individual's physical or mental health condition, the provision or payment of health care to an individual, and any other information that may reasonably be used to identify an individual.[54] Under HIPAA, the U.S. Department of Health and Human Services established the Privacy Rule and the Security Rule, through which it established national standards for the use, disclosure, and transmission of individuals' health information.[55]

HIPAA rules apply to individuals, organizations, and agencies that meet the definition of a covered entity or business associate under the law.[56] Covered entities include health care

[49] See https://www.ftc.gov/news-events/press-releases/2016/04/ftc-releases-new-guidance-developers-mobile-health-apps
[50] See https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-app-developers-ftc-best-practices
[51] See http://www.wsj.com/articles/the-future-of-medicine-is-in-your-smartphone-1420828632
[52] See http://www.infoworld.com/article/2983634/security/why-hackers-want-your-health-care-data-breaches-most-of-all.html
[53] See http://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/;
See also http://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf
[54] Id.
[55] Id. See also http://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/
[56] See http://www.hhs.gov/hipaa/for-professionals/covered-entities/

providers, health plans, insurance companies, and health care clearinghouses.[57] A business associate refers to an individual or organization that a covered entity has engaged, and has entered into a written business associate contract or other arrangement, to help it carry out its health care activities and functions.[58] Not all health care apps are covered under HIPAA rules, however, those that collect, store, or share protected health information with covered entities or business associates must be HIPAA-compliant.[59] Health care apps that are not covered under HIPAA rules are subject to the FTC's data privacy and security requirements under the FTC's Health Breach Notification Rule or the FTC Act.[60]

IV. ISSUES

The following issues will be examined at the hearing:

- How to define and classify health care apps.
- How health care apps are disrupting the way health care professionals, caregivers, patients, and consumers are engaging in the health care system.
- How health care apps impact patient engagement and the quality, accessibility, affordability, and efficiency of care.
- The legal and regulatory hurdles affecting the development and adoption of health care apps.
- The safety and effectiveness of health care apps, and how to educate consumers about the use of this emerging technology.
- How to address data privacy and security concerns in the health care apps market.

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Paul Nagle or Olivia Trusty of the Committee Staff at (202) 225-2927.

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[57] Id.
[58] Id.
[59] See http://www.informationweek.com/healthcare/security-and-privacy/hipaa-compliance-what-every-developer-should-know/a/d-id/1297180
[60] See https://www.ftc.gov/tips-advice/business-center/guidance/complying-ftcs-health-breach-notification-rule