**U.S. HOUSE OF REPRESENTATIVES**
**COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY**
**SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY**

# HEARING CHARTER

## *Smart Health: Empowering the Future of Mobile Apps*

Wednesday, March 2, 2016
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

## Purpose

On Wednesday, March 2, 2016, the Research & Technology Subcommittee will hold a hearing titled *Smart Health: Empowering the Future of Mobile Apps*. The purpose of the hearing is to examine the development of mobile applications (apps) and wearable technologies for monitoring, diagnosing, and tracking disease and medical conditions. The witnesses will provide an overview of various apps designed to help individuals with specific health concerns, such as various types of cancer, diabetes, and epilepsy, as well as an app to identify lower-cost healthcare options based on the patient's health insurer.

## Witness List

- **Mr. Morgan Reed**, Executive Director, The App Association
- **Dr. Bryan F. Shaw**, Assistant Professor, Department of Chemistry and Biochemistry, Baylor University
- **Mr. Howard Look**, President, CEO and Founder, Tidepool
- **Dr. Gregory Krauss**, Professor of Neurology, The Johns Hopkins Hospital
- **Mr. Jordan Epstein**, CEO & Founder, Stroll Health

## Background

In less than a decade, apps have become ubiquitous, since the introduction of Apple's iPhone in 2007. Apps have sparked a revolutionary change in how Americans work, live, and shop. Today, consumers spend more time on mobile apps than browsing the internet or watching traditional television. During the past Thanksgiving holiday weekend, shoppers purchased over $2.29 billion worth of products using mobile devices.[1]

The wearable and healthcare app market continues to grow rapidly. Healthcare apps have the potential to revolutionize medicine and help empower users to be active participants in managing their health as well as bring down costs.

However, a number of barriers are hindering some apps from being used more broadly and systematically by healthcare providers, patients and caregivers. The barriers include a complicated

[1] *State of the App Economy*, (4th Edition), The App Association, available at: http://actonline.org/wp-content/uploads/2016_State_of_App_Economy.pdf.

regulatory system, data security and privacy, and reimbursement issues. Consequently, healthcare apps have yet to be incorporated into the mainstream of the medical industry and are still considered a novelty.[2]

Despite these barriers, many healthcare providers, app developers, and consumers alike believe the benefits of these apps are worth the accompanying risks and regulatory hurdles. By 2017, 50 percent of smartphone users are expected to have downloaded mobile health apps and the total mobile health market revenue is expected to reach $26 billion.[3] A 2013 IMS Health report identifies four steps critical to the process of further integrating healthcare apps into the industry:

- Recognition by payers and providers of the role that apps can play in healthcare;
- Security and privacy guidelines and assurances being put in place between providers, patients and app developers;
- Systematic curation and evaluation of apps that can provide both physicians and patients with useful summarized content about apps that can aid decision-making regarding their appropriate use; and
- Integration of apps with other aspects of patient care.[4]

## Hurdles and Concerns

*Regulatory Agencies*

Three agencies currently share regulatory responsibility over mobile health apps: the US Food and Drug Administration (FDA), which applies regulatory oversight to medical apps, the Federal Trade Commission, which protects consumers from unfair or deceptive acts or practices, and the Federal Communications Commission, whose interest in such devices is based on its use as a communications device as opposed to a medical device. Dr. Gregory Krauss, one of the hearing witnesses, will describe modifications made to the EpiWatch to avoid it being classified as a medical device and thus further FDA review.

*Reimbursement*

Although almost 50 percent of healthcare apps are free, the other half can range in price from $1 to $100. Consequently, reimbursement issues range from trying to identify how a patient will pay for an app recommended by a physician to reimbursing physicians "to review remotely generated data via apps."[5]

Further, while physicians may understand and appreciate the value of healthcare apps, they are wary of formally endorsing or prescribing an app "without evidence of their benefit, clear professional guidelines regarding their use in practice, and confidence in the security of personal

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[2] *Patient Apps for Improved Healthcare – from Novelty to Mainstream*, October 2013, IMS Institute for Healthcare Informatics, available at: http://obroncology.com/imshealth/content/IIHI%20Apps%20report%20231013F_interactive.pdf; (hereinafter IMS Institute Report.)

[3] *Is Mobile Healthcare the Future?* (Infographic), Greatcall.com, available at: http://www.greatcall.com/greatcall/lp/is-mobile-healthcare-the-future-infographic.aspx.

[4] IMS Institute Report, *supra*, note 2.

[5] Ibid.

health information that may be generated or transmitted by the app."[6] Despite the FDA's approval of approximately 100 medical apps, the health industry is not yet at a point where physicians can easily make formal recommendations or write prescriptions for health apps because of legal, regulatory, and liability concerns.[7]

*Security Concerns*

A 2015 study found that some clinically accredited apps "may not have been complying with principles of data protection…[as] in some instances health apps were found to be sending unencrypted personal and health information."[8] This puts individuals' privacy and personal data at risk, which is a serious concern given that cybercriminals frequently target healthcare organizations because patient data, such as a complete medical record, can be worth around $500 in the underground market.[9]

*Funding*

Identifying funding sources to develop or disseminate healthcare apps and technology has also been identified as a hurdle. One of the hearing witnesses, Dr. Bryan Shaw, will describe his difficulties in securing grants from the National Institutes of Health to fund his efforts to clinically validate his app. Another witness, Mr. Howard Look, explained in an interview that, "Fundraising as a non-profit is much more challenging than I anticipated, and very different than my prior experience doing startup fundraising through the usual Silicon Valley, for-profit, venture capital channels."[10]

**Additional Reading**

For more information about the apps profiled by the witnesses at the hearing, please visit the following websites:

- Eye Cancer (*Dr. Shaw*): http://www.people.com/article/dad-creates-app-detects-eye-cancer-children
- Type 1 Diabetes (*Mr. Look*): http://tidepool.org/
- Epilepsy (*Dr. Krauss*): http://www.hopkinsmedicine.org/epiwatch#.VszbVeYYHzg
- Value-based healthcare decision-making (*Mr. Epstein*): http://strollhealth.com/

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[6] Ibid.
[7] Ibid.
[8] *Information Handling by Some Health Apps Not as Secure as it Should Be*, BioMed Central Press Release, available at: http://www.biomedcentral.com/about/press-centre/science-press-releases/25-09-2015.
[9] Patrick Kehoe, "2016 State of Application Security: Top Health Care Apps in Critical Condition," January 12, 2016, Security Intelligence, available at: https://securityintelligence.com/2016-state-of-application-security-top-health-care-apps-in-critical-condition.
[10] Adam Brown and Alex Wolf, "How the Tidepool Data Integration Platform Can Ease Diabetes Management: Our Interview With Tidepool CEO Howard Look," September 12, 2014, diaTribe Foundation, available at: http://diatribe.org/issues/69/diatribe-dialogue.