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THE DISRUPTER SERIES: HEALTH CARE APPS

HEARING

BEFORE THE

SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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THE DISRUPTER SERIES: HEALTH CARE APPS

WEDNESDAY, JULY 13, 2016

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:20 a.m., in room 2322, Rayburn House Office Building, Hon. Michael C. Burgess, M.D., (chairman of the subcommittee) presiding.

Present: Representatives Burgess, Lance, Blackburn, Harper, Olson, Kinzinger, Bilirakis, Brooks, Mullin, Schakowsky, Clarke, Kennedy, Butterfield, Welch, and Pallone (ex officio).

Staff Present: Rebecca Card, Assistant Press Secretary; James Decker, Policy Coordinator, Commerce, Manufacturing, and Trade; Graham Dufault, Counsel, Commerce, Manufacturing, and Trade; Melissa Froelich, Counsel, Commerce, Manufacturing, and Trade; Giulia Giannangeli, Legislative Clerk, Commerce, Manufacturing, and Trade, Environment and the Economy; Paul Nagle, Chief Counsel, Commerce, Manufacturing, and Trade; Tim Torres, Deputy IT Director; Olivia Trusty, Professional Staff, Commerce, Manufacturing, and Trade; Michelle Ash, Minority Chief Counsel, Commerce, Manufacturing, and Trade; Jeff Carroll, Minority Staff Director; Lisa Goldman, Minority Counsel, Commerce, Manufacturing and Trade; Caroline Paris-Behr, Minority Policy Analyst; Matt Schumacher, Minority Press Assistant; and Ryan Skukowski, Minority Policy Analyst.

Mr. BURGESS. The subcommittee on Commerce, Manufacturing, and Trade will come to order. The chair will recognize himself for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. Good morning. Thanks to everyone for being here. It is a hearing I have been looking forward to for some time. This is part of our Disrupter Series, and the Disrupter Series this morning is going to be examining mobile health apps.

With health care being 17 percent of the Nation's economy, it seems appropriate for the Disrupter Series to be in this space. I will also tell you I am a physician. I served the people of north Texas for over 25 years. And I am encouraged by this emerging technology within the healthcare system, and I look forward this morning to examining how it is transforming the way in which doc-

tors, patients and consumers approach and manage the delivery of care.

Health apps are powered by the deployment of advanced broadband Internet technology and the mere ubiquitous smartphone adoption. The draw of mobile healthcare tools and services and health apps particularly lies in their potential to radically improve health care. The potential comes in part from enabling both sides of the equation: doctors and patients. For healthcare providers, health apps enable constant, instant, and real-time access to patient data, helping to make streamlining of work flows and decisionmaking processes, so the data is both more complete and more accessible. Doctors are also able to remotely monitor patient healthcare conditions, collaborate, and implement care.

The emergence of mobile apps within the healthcare system is particularly exciting because of how they empower patients to gain access to and manage aspects of their health. Patients are using apps to track symptoms, send vital sign information to doctors, and set up medication adherence reminders. Patients are also using the technology to gain faster access to more routine healthcare services that are often inconvenient or time-consuming. Apps available on the market today create virtual waiting rooms where users can receive their prescriptions, engage in face-to-face video consultations with physicians, compare prices for health care, and make payments to a healthcare provider. The last is obviously, to me, very important. By enabling physicians to remotely monitor a patient's health condition or by empowering consumers with information to engage in healthier living, health apps are driving more robust healthcare management and oversight from both patients and doctors. This can help improve the continuum of care.

There are important issues that need to be addressed as more individuals turn to healthcare apps. Some of these issues include understanding how health apps are impacting the overall quality of care compared to in-person visits, whether the proper financial incentives are in place to increase the adoption of health apps, what additional infrastructure is needed to support the development and the use of health apps, some of the legal and policy barriers to health app adoption, and how to adequately educate patients and consumers about the capabilities and limitations of health apps, and finally, whether the regulatory framework governing our healthcare system today is, in fact, able to keep pace with lifesaving innovations made available through these apps.

So I look forward to examining each of these issues throughout our discussion today. In addition, as with all Internet-connected things, applications, and devices, adequately addressing the privacy and security implications associated with health apps will be essential to driving this market.

We have seen that healthcare data has a growing appeal among identity thieves and bad actors. We only need to look at the recent data breaches and the increase in ransomeware attacks on hospitals. It is critical that every actor in this space start by addressing privacy and security. If industry fails to do this, then Congress will be forced to do this. And, unfortunately, whatever Congress would like to do could very likely limit the potential of development

of this space and limit the ultimate success of the health apps market.

It is interesting this summer is the 20-year anniversary of the passage of the Kennedy-Kassebaum Act. Needless to say, I was not here when that bill passed. Since it contains HIPAA, there is a downside, but the plus side is the Kennedy-Kassebaum Act allowed for the first time a demonstration project where 750,000 medical savings accounts were permitted. I was one of the early adopters of the medical savings account. In fact, I was fearful after the bill was signed into law that I would not get there in time to be able to set up a medical savings account. It turns out I needn't have worried. The 750,000 subscriptions were not filled. But then that led in 2004 to the development of health savings accounts.

And here's the thing: The Commonwealth Foundation has published information on what they call the activated patient. Consumer-directed health care also helps to activate a patient. We want patients to be involved in their care. We think they make better decisions. I think that is the opportunity to hold down the cost in health care. So it is the marriage of the Health Savings Act, the consumer-directed health plan, and the activated patient all brought together by this technology that I think holds great promise for our system.

Throughout this Disrupter Series, we have explored how technology is changing business, creating jobs, and improving the quality of life for Americans everywhere. The breakthrough of mobile apps into the healthcare system opens a significant opportunity to improve patient care, reduce healthcare costs, and make health care more accessible.

I will thank the witnesses in advance for their testimony. I would now like to recognize the gentlelady from Illinois, Ms. Schakowsky, 5 minutes for an opening statement, please.

[The prepared statement of Mr. Burgess follows:]

PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Good morning and welcome to our Disrupters Series hearings on mobile health apps. As a doctor who has served the people of North Texas for over 25 years, I am particularly delighted to explore this emerging technology within the health care system and examine how it is transforming the way in which doctors, patients, and consumers approach and manage the delivery of care.

Health apps are powered by the deployment of advanced broadband internet technology and nearubiquitous smartphone adoption. The draw of mobile health care tools and services, and health apps in particular, lies in their potential to radically improve health care. The potential comes in part from enabling both sides of the equation, Doctors and patients.

For health care providers, health apps enable constant, instant and real-time access to patient data, helping to streamline workflows and decision-making processes. So the data is both more complete and more accessible. Doctors are also able to remotely monitor patient health care conditions, collaborate and implement care.

The emergence of mobile apps within the health care system is particularly exciting because of how they empower patients to gain access to care and manage their health. Patients are using apps to track their symptoms, send vital sign information to doctors, and set-up medication adherence reminders. Patients are also using the technology to gain faster access to more routine health care services that are often inconvenient and time-consuming. Apps available on the market today create virtual waiting rooms where users can:

- receive prescriptions;
- engage in secure face-to-face video consultations with physicians;
- compare prices for care;

• and make payments to a health care provider.

By enabling physicians to remotely monitor a patient's health condition or empowering consumers with information to engage in healthier living, health apps are driving more robust health care management and oversight from both patients and providers. This can help improve the quality and continuum of care.

There are important issues that need to be addressed as more individuals turn to health care apps.Some of these issues include:

• Understanding how health apps are impacting the overall quality of care compared to in-person visits;

• Whether the proper financial incentives are in place to increase the adoption of health apps;

• What additional infrastructure is needed to support the development and use of health apps;

• Legal and policy barriers to health app adoption at both the federal and state level;

• How to adequately educate patients and consumers about the capabilities and limitations of health apps;

• And whether the regulatory framework governing our health care system today is keeping pace with the life-saving innovations made available through these apps. I look forward to examining each of these issues throughout our discussion today.

In addition, as with all Internet-connected things, applications, and devices, adequately addressing the privacy and security implications associated with health apps will be essential to driving this market forward. We have seen that healthcare data has a growing appeal among identity thieves and other bad actors—just look at the recent data breaches and an increase in ransomware attacks. It is critical that every actor in this space start by addressing privacy and security. If industry fails to do this then Congress will be forced to address it. And unfortunately, whatever Congress would do would likely limit the potential in this space and limit the success of the health apps market.

Throughout the disrupter series we have explored how technology is changing business, creating jobs and improving the quality of life for Americans everywhere. The breakthrough of mobile apps into the health care system opens a significant opportunity to improve patient care, reduce health care costs, and make health care more accessible and affordable to all Americans.

I thank the witnesses for their testimonies and I look forward to a thoughtful discussion on this topic.

OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. So, today, we are continuing this Disrupter Series with healthcare apps. We talked about these apps a little during our recent hearing on wearables. Consumers use apps to track their calories, their exercise, and their sleep. The technology is advancing far beyond that. Health apps may help in the treatment of chronic medical conditions like diabetes.

From a consumer perspective, health apps seem to blur the line between your smartphone and a more traditional medical device. However, that distinction can have important ramifications for the protections that consumers have. The efficacy and privacy standards for apps depend on whether it is a medical device or it is associated with an entity covered by HIPAA.

Generally speaking, the Food and Drug Administration only regulates health apps when they are an accessory to a medical device or perform the function of a regulated medical device. Apps that dispense information or simply store data are usually not reviewed by the FDA.

Without FDA review, consumers face the threat of false claims, which can be very dangerous when a person's health is at issue. Last year, the Federal Trade Commission took action against two

apps that claimed to detect symptoms of melanoma using a smartphone camera. But the apps did not have a scientific basis for their claims to detect or diagnose melanoma in users.

This case is yet another example of the FTC's critical work to protect consumers from deceptive claims. Later today, we will be marking up a bill to undermine the FTC's authority by shortening consent decrees and bogging down the FTC by requiring unnecessary review and analysis when it takes action.

Innovation is good and should be encouraged, but industry self-regulation does not work. Bad actors will continue to make potentially life-threatening claims about what their products can do. We need a strong FTC to go to bat for consumers and stop bad actors from falsely claiming to diagnose skin cancer, for example. America's health is at stake.

Consumers want to be sure that health apps that they install don't give false information. They also want their personal information on those apps protected. If you download an app to track blood sugar, that download in and of itself tells the app that you probably might or do have diabetes. The app is able to and often does sell this information to advertisers.

A recent study in the Journal of the American Medical Association found that 80 percent of diabetes apps have no privacy policy in place and half of those that did have privacy policies that shared user data with third parties.

In many cases, apps are not connected with entities covered by HIPAA. Only apps tied to health plans and healthcare providers would have the responsibility to safeguard protected health information. If it is a random app you found in the app store, your information is probably not protected.

As with other technologies we have discussed in this Disrupter Series, we need to make sure that innovation and consumer protection go hand in hand as health apps continue to develop. These apps need to be designed with the well-being and the security of consumers in mind. So I look forward to hearing from our witnesses about the exciting new technologies coming to the market, and I hope to hear how we can ensure that consumers receive accurate information and that their sensitive health information is protected.

I yield back, unless anybody wants my remaining time.

Seeing none, I yield back.

Mr. BURGESS. The chair thanks the gentlelady. The gentlelady yields back.

The chair would like to recognize the vice chairman of the full committee, Mrs. Blackburn, 5 minutes for an opening statement please.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. I want to welcome all of our witnesses. We are appreciative that you are here.

And, Mr. Chairman, I thank you for the attention to the issue. And I want to just bring up the SOFTWARE Act, which Mr. Green and I have put a lot of effort into over the past several years. It

has been included in the Cures legislation. We look forward to the Senate finishing that and moving Cures to the President's desk. But the SOFTWARE Act really addresses much of what we are going to discuss today. And, as the chairman said, technological innovation around health informatics and health software and wireless platforms, such as smartphones and iPads, holds great promise for the healthcare system, both for patients and for providers. And we are excited about some of the innovation that can be there, whether it is Bluetoothing, pharmaceuticals, or home healthcare providers that are entering and transmitting and holding data on their patients.

There are concerns about the regulatory framework that exists around this, and I will say simply, as we have worked on this issue through the years, we have to go back and look historically at what we did with the FDA. Congress said, in the 1930s, this is what is a pharmaceutical. In the 1970s, we defined a medical device. And now it is time for us to create a classification for healthcare technology and put the FDA on the right track. Should there be some regulatory flexibility there, because technology changes faster than Congress is going to change a statute? Absolutely, there should be that flexibility. But there should also be the awareness that most of the healthcare informatics components, the smartphone apps, whether they are used for providers or by patients, should be able to go directly to the marketplace. They shouldn't be over to the FDA and shouldn't have to have this subjective approach of, if we think it is necessary, then we will on a case-by-case basis decide how we regulate technology. We think that that is inappropriate in and of itself. We want some clarity and some certainty for innovators. Therefore, we are encouraging the completion of the SOFTWARE Act through 21st Century Cures.

We know that it would be helpful to the delivery of health care, to the telemedicine concepts for meeting the healthcare needs of those in remote areas the more we utilize healthcare technology and informatics.

And, Mr. Chairman, I thank you for your attention to the matter. We thank you all for being here today for the discussion, look forward to the conversation. And I will yield my time back to you or to anyone who is in search of time.

[The prepared statement of Mrs. Blackburn follows:]

Mr. BURGESS. Very well. The gentlelady yields back. The chair thanks the gentlelady.

The chair recognizes the gentleman from New Jersey, Mr. Pallone, 5 minutes for an opening statement, please.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

Mobile devices have become an indispensable part of our daily lives, and apps are a major reason why. For millions of consumers, the smartphone has become more than just a means to call or text. It is now their personal scheduler, navigator, jukebox, television and much more, thanks to apps available for download online.

Health apps, which have risen in popularity in recent years, look to add physician, personal trainer, and dietician to that list as well. Many of these apps perform relatively simple tasks, such as helping users keep track of their calories or sending out a reminder to take a prescription. Other apps may actually analyze and diagnose a medical condition, effectively eliminating the need for a doctor's appointment altogether in some cases. And consumers and physicians alike are embracing health apps as a way to better manage and administer care. A growing health app marketplace mirrors a rising health consciousness amongst Americans, and we should support technology that yields positive outcomes for consumers.

Like many of the technologies this subcommittee has examined this Congress, however, we must also be aware of the potential risks to personal safety, privacy, and data security. The safety and effectiveness of these apps should be closely examined. An inaccurate calorie counting app may be an inconvenience, but an app that incorrectly diagnoses a cancerous skin condition could be fatal. It is, therefore, essential that consumers and physicians understand the limitations of each app and recognize when they cannot substitute for a doctor's visit.

Personal health information is a prime target for hackers, and breaches of this type of information in recent years have been devastating for consumers. In addition to these security gaps, I am also concerned with the lack of adequate privacy protections on a large percentage of these health apps. Healthcare data contains addresses, Social Security numbers, in addition to diagnosis and prescription history. The more apps that handle this information, the greater the risk of a privacy breach for consumers. And exacerbating the health privacy problems is consumer confusion and, frankly, confusion by many stakeholders. Most people believe health information to be especially personal, requiring a higher level of privacy and security, yet the law protecting a person's personal health records, the Health Insurance Portability and Accountability Act, HIPAA, applies only to health plans, healthcare clearinghouses, mosthealthcare providers, and their business associations. Many, if not most, health apps available right now in the app store are not covered entities under HIPAA. So, even if these apps collect the same information as a healthcare provider, the same protections may not apply.

So mobile health technology is where we are, where we are going. As the mobile app industry continues to grow, I believe that prioritizing privacy, security, and safety will benefit consumers and businesses alike. And so I look forward to learning more about the potential of health apps to improve health outcomes for consumers and the protections that these apps are putting in place.

Unless someone on my side wants the time, I yield back. Thank you, Mr. Chairman.

Mrs. BLACKBURN. If the gentleman would yield to me.

I am thrilled that Mr. Pallone is revealing his age by using the term "jukebox."

I yield back.

Mr. PALLONE. I'm sorry. I didn't say "icebox," at least. That is even worse. And I say that sometimes too.

I yield back.

Mr. BURGESS. The gentleman yields back.

We will await punching B17 on the jukebox.

That concludes member opening statements. The chair would like to remind members that, pursuant to committee rules, all members' opening statements will be made part of the record.

Again, we do want to thank all of our witnesses for being here this morning, taking time to testify before the subcommittee. Today's witnesses will have the opportunity to give opening statements, followed by a round of questions from members.

Our witness panel for today's hearing will include Dr. Matt Patterson, President at AirStrip; Dr. Bettina Experton, President and CEO of Humetrix; Dr. Laura Ferris, Assistant Professor, University of Pittsburgh, Department of Dermatology; Dr. Ray Dorsey, Professor of Neurology and Director of the Center for Human Experimental Therapeutics at the University of Rochester Medical Center; Ms. Diane Johnson, Senior Director, North America Regulatory Affairs Policy and Intelligence Medical Devices, at Johnson & Johnson; and Mr. Nicolas P. Terry, Professor of Law and Executive Director of the William S. and Christine S. Hall Center for Law and Health at Indiana University, Robert H. McKinney School of Law.

We appreciate each of you being here today. Ordinarily, we would begin the panel with Dr. Patterson, but are we still waiting for some technical assistance? Yes.

OK. I do this all the time. This is the premier predominant technological committee in the United States House of Representatives, the greatest deliberative body in the free world, and we frequently have trouble with our electronics here.

So, Dr. Experton, let us begin with you, and we will come back to Dr. Patterson at the end.

STATEMENTS OF BETTINA EXPERTON, M.D., M.P.H., PRESIDENT AND CEO, HUMETRIX; LAURA FERRIS, M.D., ASSISTANT PROFESSOR, UNIVERSITY OF PITTSBURGH, DEPARTMENT OF DERMATOLOGY; 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; DIANE JOHNSON, NORTH AMERICA REGULATORY AFFAIRS POLICY AND INTELLIGENCE MEDICAL DEVICES, JOHNSON & JOHNSON; 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; AND MATT PATTERSON, M.D., PRESIDENT, AIRSTRIP

STATEMENT OF BETTINA EXPERTON, M.D., M.P.H.

Dr. EXPERTON. Chairman Burgess, and distinguished subcommittee members, thank you for the opportunity to appear before you today to discuss the disruptive role of mobile health applications in transforming the U.S. healthcare system. My name is Dr. Bettina Experton, and I am the founder and CEO of Humetrix, a mobile health technology company based in Del Mar, California.

As a member of the Consumer Technology Association's, CTA, Health and Fitness Technology Board, Humetrix actively worked on the CT Guiding Principles on the Privacy and Security of Personal Wellness Data because it is important that consumers understand both the potential value of patient-facing technologies and the privacy options they have. We believe that this will help drive adoption of these important lifesaving apps. Humetrix's mobile health apps address critical health needs and can literally save lives.

One of our apps, SOS QR, recently won the prestigious FCC Chairman's Award and was designed to help anyone in an emergency situation. Through the app, anyone can call for help, send their GPS location, and even if the user is incapacitated, his or her critical health information can be made immediately accessible to emergency responders. And when you travel abroad, this information can be displayed in the language of that emergency responder automatically.

Another Humetrix app, TENSIO, can help more than 30 million Americans with uncontrolled high blood pressure, managing their hypertension in consultation with their physicians.

But, today, I would like to focus on our iBlueButton app, which won multiple industry innovation awards, which can greatly improve patient safety and reduce healthcare costs by addressing the issue of the lack of interoperability of disparate electronic health record systems.

The average Medicare beneficiary sees seven different doctors in a given year. Our veterans who access the VA healthcare system receive, in fact, more than 50 percent of their care outside the VA. Often they are transitioned from the DOD health system with complex medical needs. And the care transition is not optimum, as the exchange of VA and DOD records is complex to operate. In this environment, the potential of medical errors as a result of incomplete information is high.

However, there is a cure: patient-facing mobile apps that put patients' medical data in their own hands, securely and effectively.

Randy Watson is a disabled Army veteran who served in Korea and Vietnam and is an active user of the Humetrix iBlueButton mobile app to assemble and annotate his health records from the VA, Medicare, and his private providers directly and securely on his own smartphone. Randy manages various service-connected health problems, survived multiple heart attacks and had several surgeries, some of which were performed by non-VA surgeons. Because the closest VA Medical Center is more than an hour away, in emergency situations, he often finds himself in a non-VA hospital closer to his home. He reports that having his VA and Medicare records on his mobile device has resulted in doctors quickly getting the information they need and, in many cases, avoiding repeating costly tests like MRIs.

When Randy uses iBlueButton, the app will automatically get his Medicare claim data, translate billing codes and assemble these with his VA and private providers' EHR data, automatically creating a usable and actionable summary record with all of his medications in one place, providers' contact details, and the dates of his past tests and procedures on his mobile phone. This ensures that

his information is immediately accessible wherever he seeks care. And because all of his personal information resides on the device itself and all the computing is done in real time in the app, all personal data is safely and only stored on the user's mobile device, encrypted under the user's own control, rather than in the cloud or other servers, where it could be subject to hacking.

With iBlueButton, more than 55 million Americans covered by Medicare, 10 million in the TRICARE program, and 9 million veterans using the VA system can securely download, understand, annotate, and share their medical history with any doctor to help ensure their own safety and control costs. Today, with the same goals, the State of New York is planning to provide next year a version of iBlueButton to their millions of Medicaid beneficiaries, who will be empowered with their own health information on their own phones wherever they receive care.

In closing, I would like to thank you again for inviting me to testify today. At Humetrix, we believe that disruptive mobile technology, developed in the private sectors and placed in the consumer's hands, can be the needed disrupter to change the face of health care. I look forward to answering any questions. Thank you.

[The prepared statement of Dr. Experton follows:]

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Prepared Statement of Bettina Experton, M.D., M.P.H.
Humetrix President & CEO
before the
Subcommittee on Commerce, Manufacturing, and Trade
Energy and Commerce Committee
U.S. House of Representatives

Hearing on
Disrupter Series: Healthcare Apps
July 13, 2016

Chairman Burgess, and distinguished Subcommittee Members, thank you for the opportunity to appear before you today to discuss the disruptive role of health apps in transforming the U.S. health care system. My name is Dr. Bettina Experton, and I am the founder and CEO of Humetrix, a mobile health technology company, based in Del Mar, California. As a former practicing physician, data scientist and public health officer, I became a healthcare IT entrepreneur focusing on mobile technology because I believed that the best way to treat patients, improve health outcomes, and reduce waste is to put patients' critical health information into their own hands, so they can share that information with their physicians when needed.

With 68 percent of Americans using a smart phone daily[1], and new HIPAA rules giving each of us a legal right to electronically access our health records, consumer facing mobile health applications can be a cure to the *information blocking* which is still plaguing our health care system. After the disbursement of close to $35 billion in Electronic Health Record (EHR) incentive payments, only 18 percent of physicians regularly exchange patient records, despite the fact that 96 percent of hospitals are now using federally certified EHRs[2].

In a healthcare environment in which one-third of expenditures are wasted[3] on redundant care, and medical errors representing the third leading cause of death in the U.S. today[4], having immediate access to a patient's health history can literally save lives and also significantly reduce healthcare costs.

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[1] Pew Research Center, "Technology Device Ownership: 2015" http://www.pewinternet.org/2015/10/29/technology-device-ownership-2015/
[2] Joseph Conn, Hospitals achieve 96% EHR adoption rate; data exchange still needs work", Modern Healthcare, May 31, 2016
[3] Erin P. Balogh, Bryan T. Miller, and John R. Ball, Improving Diagnosis in Health Care, 2015; Committee on Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine; The National Academies of Sciences, Engineering, and Medicine
[4] Martin A. Makary, Michael Daniel BMJ 2016;353:i2139; Ariana Eunjung Cha, Researchers: Medical errors now third leading cause of death in United States," Washington Post, May 3, 2016

Leveraging Patient-Facing Mobile Apps to Cure Information Blocking

Unfortunately, business barriers, outdated technologies, and difficult patient consent procedures leave patients relying solely on their doctors to assemble their health history from multiple records. In contrast, just by opening Humetrix's iBlueButton mobile app, more than 50 million Americans covered by Medicare, 10 million active duty and retired military personnel and their families, and 9 million Veterans actively using VA healthcare services can securely download, understand, annotate and share their medical history whenever they need to from their smart phone.

The average Medicare beneficiary sees seven different doctors every year. And our Veterans receive more than 50 percent of their care outside of the VA health system. Often they are transitioned from the DoD health system with complex health needs and the coordination of their care is not optimum as the exchange of records between these two systems is complex and expensive to maintain.

For millions of patients – Veterans, TRICARE beneficiaries and older Americans – many with complex healthcare needs, safety and care coordination require access to an up-to-date picture of their medical history at every point of care. In today's environment, where hospital systems and doctors don't often share records, the potential for medical errors as a result of incomplete information is high. However, there is a cure: patient-facing mobile technology that puts each patient's medical data in their own hands, securely, and effectively.

The competitive business barriers that keep hospital systems from communicating with one another do not exist between a doctor and his or her patient. Humetrix has developed a suite of standards-based medical apps, which use the existing EHR infrastructure to help solve the interoperability challenge by having patients access and share their personal health information with their own mobile devices.

Humetrix's iBlueButton App: A Case Study for Safer Care of Veterans at VA and Non-VA Providers

Randy Watson, a disabled Army veteran who served in Korea and Vietnam, is an active user of Humetrix's iBlueButton mobile app to aggregate and annotate his health records from the VA, Medicare and his private providers directly and securely on his mobile phone. Watson manages various service-connected health problems, survived multiple heart attacks, and has had several surgeries, some of which were performed by specialists outside VA facilities. Because the closest VA Medical Center is more than an hour away, in emergency situations, he often finds himself in a non-VA hospital closer to his home. He reports that having his VA and Medicare records on his mobile device has resulted in doctors quickly getting his information, and in many cases, avoiding repeating costly tests like MRIs.

Randy, and millions of Veterans like him, can use iBlueButton to aggregate their VA, Medicare and other provider records, into a longitudinal health record that is easy to read and annotate. The app takes claim (Medicare, Medicaid) or EHR data (from VA, DoD or private providers) and decodes it, reformatting the information on the fly into a usable format, so that information about all medications, providers' contact details, and the dates of tests and procedures are easily accessible on the patient's mobile device. And because the information resides on the device itself, it is accessible even without an Internet connection, and is safely encrypted and saved under the user's own control, rather than in the cloud or on servers where it is vulnerable to hackers.

iBlueButton: A Readily Available Commercial Application

iBlueButton offers the VA, as well as other government agencies, the use of a widely available commercial mobile application on both iOS and Android devices that can help bridge this interoperability and data sharing gap that exists between the VA, DoD and private health providers. The VA even recognized iBlueButton as a finalist for the 2012 VA Innovation Initiative (VAi2) and elevated Humetrix to the level of a named Blue Button health partner. Our observation has been that in spite of this official recognition from the VA for our continued excellence in developing state of the art patient-centric mobile health record technologies, the VA is continuing to rely on an approach that models their EHR modernization effort when it comes to fielding mobile health applications. The VA awarded several mobile health apps Custom Development Software contracts in the past several years, some of which have come under question in a preliminary report by the VA Inspector General in terms the procurement process and the type of funds used[5]. The VA has had a very long and public history of trying to build custom developed applications, which have tended to run over budget and delivered less than state of the art solutions given the commercial products that exist on the market that can readily meet the VA requirements in many instances. Commercially available solutions should in most cases be the first source for trying to meet government IT solution needs, before moving out with expensive and lengthy custom development efforts that typically fall far short of capability and are in many cases fielded way behind schedule or not at all.

In its June 30, 2016 report[6], the Commission on Care appointed through VACCA (Veterans Access, Choice, and Accountability Act of 2014) recommends that IT procurement use "flexible contract structures to allow the onboarding of emerging technologies in a competitive fashion". Although GSA procurement rules under the FAR Part 12 – Acquisition of Commercial Items, allows for and specifies the requirements for the purchasing of computer software from commercial vendors, those acquisition rules still provide major obstacles for commercial firms such as Humetrix to do business with the VA. We have made numerous attempts to engage with the VA on how iBlueButton could best serve the needs of the VA patient

[5] https://www.meritalk.com/articles/exclusive-va-spending-on-mobile-apps-and-vista-enhancements-violated-appropriations-law/

[6] Final Report of the Commission on Care June 30, 2016; http://commissiononcare.sites.usa.gov/

population. Hopefully the Commission on Care June 30 Report will provide an impetus for the VA to take action to truly facilitate the on-boarding of emerging technologies such as iBlueButton, using more streamlined and less cumbersome contracting approaches that can field significant innovations to help Veterans better manage and take control of their health care.

Health Apps for Cost Control in Government Health Programs

Health apps like iBlueButton deliver on the promise of both the HITECH Act and President George W. Bush's 2004 health record initiative by putting their own personal longitudinal health record into the hands of every American. In addition to saving lives, the ability to share records at the point of care can make a huge difference in terms of cost containment for government health programs. The State of New York is planning to provide next year a State Medicaid version of iBlueButton to their millions of Medicaid beneficiaries. By giving Medicaid beneficiaries the ability to share their medical history at every point of care, iBlueButton will help to address both the critical patient safety needs and cost efficiency needs of State Medicaid programs serving a population of Americans who often lack care coordination in a very fragmented system.

Health Apps: EHR Standards-Based and Privacy Focused

Humetrix has been an active participant in efforts led by the Office of the National Coordinator for Health IT to devise standards now required of EHR systems to enable Americans to securely download their records into applications complying with these standards. Humetrix technology is built on the HL7 C-CDA content and "DIRECT" data transport standards and on the upcoming FHIR standard. In recognition of Humetrix's innovative applications of the standards, we have won three ONC/HHS Industry Innovation awards and have recently been named as a winner of the HHS sponsored "Medicare Blue Button on FHIR" code-a-thon. Humetrix has also led a group of technology companies and patient organizations to encourage the HHS Office of Civil Rights (OCR) to require that providers make use of their federally certified EHR systems to transmit machine readable records to patients' applications for them to share with other physicians (see January 30, 2015 Humetrix letter to the OCR[7]).

As a member of the Consumer Technology Association's (CTA) Health and Fitness Technology Board, Humetrix actively worked on the CTA Guiding Principles on the Privacy and Security of Personal Wellness Data[8] because it is important that consumers understand both the potential value of health technologies and the privacy options they have. We applaud CTA's efforts to drive these guiding principles across the industry, as we believe it will drive adoption and awareness of important medical apps that can literally save lives.

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[7] http://www.humetrix.com/letter_2015_01_30_ocr_direct.pdf
[8] https://www.cta.tech/News/Press-Releases/2015/October/Association-Unveils-First-of-Its-Kind,-Industry-Su.aspx

Humetrix Health Apps to Tackle Biggest Public Health Challenges in the US and Abroad

On November 5, 2015 before the French parliament in Paris, at the invitation of the French Secretary of Health, Humetrix highlighted iBlueButton as a model of how to provide French citizens mobile access to their personal health information. In the UK, Secretary of Health Jeremy Hunt recently announced that British citizens will have mobile access to their health records, citing the US Blue Button initiative and commercially available U.S mobile apps such as iBlueButton as models. In the UK, two other Humetrix mobile health technology platforms, SOS QR and TENSIO, have both been selected this year for deployment by the U.K.'s National Health Service (NHS) as part of the NHS England Innovation Test Beds program, which is focused on modernizing NHS services.

SOS QR: An Award-Winning Smartphone Application for Emergency Care

SOS QR was designed to keep individuals safe wherever they are. Available for iOS and Android devices and the Apple Watch, SOS QR lets anyone easily create an emergency record that includes medical conditions, medications, allergies and emergency contacts, and makes it available via a QR code on the lock screen of the user's device. The SOS QR code can also be printed on a wallet card or stickers.

Using any QR code scanner, emergency responders (EMTs, ED personnel, Good Samaritans) can scan the SOS QR code and quickly access pertinent medical history. In addition to providing critical information, when activated, the app automatically generates messages to the user's emergency contacts, including the GPS location where the incident took place.

SOS QR also features an SOS Button that allows users to notify their own emergency contacts of the need for help and their location with the touch of a button; and an OK button that can let contacts know when help has arrived or if they are safe in a disaster scenario. For Apple Watch users, the SOS and OK buttons can be accessed with a quick tap on the wrist, turning SOS QR into a personal alert system.

SOS QR also dynamically changes the language of the record retrieved by emergency responders as users travel to different regions of the world; automatically pulling the local versions of medications that correspond to the ones the patient takes at home. SOS QR is available in English, Spanish, French, Portuguese and Mandarin Chinese.

The app is designed for use by anyone – young, old, able or disabled – facing an emergency situation, or who might need to communicate his or her critical health and personal information. In June 2016, SOS QR was recognized as an important tool to help individuals with disabilities lead independent lives, receiving the prestigious FCC Chairman's Award for Advancements in Accessibility. As legislative milestones like

ADA, IDEA and ABLE continue to expand opportunities for people of all abilities, technologies like SOS QR support independence through the transformative power of mobile technology. By making it easy to call for help and share critical personal information in an emergency, SOS QR turns consumer devices into mobile personal alert systems, providing the security and accommodation that people of different abilities need to achieve greater independence. In France, SOS QR was also recently selected as a 2016 finalist of the prestigious international "Prix Galien" award for digital health.

Humetrix's SOS QR technology has also been recognized with an Industry Innovation Award given by the Office of the National Coordinator/Department of Health and Human Services in October 2013, and was one of three mobile apps showcased at the White House Innovation for Disaster Response and Recovery Demo Day in July 2014.

TENSIO Addresses the Needs of the 75 Million American Adults with Hypertension

TENSIO was especially designed to help the 50 percent of diagnosed hypertensive patients whose blood pressure (BP) cannot be controlled with the usual clinic-based care. TENSIO uses mobile technology to advance the recognized need for home blood pressure monitoring and includes a life style modification approach to hypertension treatment. By integrating data from self-monitoring devices (BP monitors, digital scales, and activity trackers) with the patient's own medical record data automatically imported from iBlueButton, and an onboard expert system for personal coaching, TENSIO provides alerts and notifications on the patient's smartphone or Apple Watch so they can better manage their prescribed medication, diet, and exercise regimen. Alerts and notifications are generated by the app itself and immediately appear on the user's device without requiring an Internet connection. This technology approach bypasses the need for any personal information storage in the cloud where it can be vulnerable to hackers. Armed with ongoing guided personal coaching, consumers can actively manage their health, and in communication with their doctors, achieve better treatment and blood pressure control.

Conclusion

In closing, I would like to thank you again for allowing me to testify today. At Humetrix, we believe that disruptive mobile technology, developed in the private sector, and placed in consumers' hands, can be the needed disrupter to change the face of health care. I look forward to answering your questions.

Humetrix Addendum

Policymaking should reflect that patients also share data
June 17, 2015, 12:30 pm
By Bettina Experton, MD, MPH

Patients are using their own health information. The husband who uses his smartphone to download his wife's health records after she's in a car accident. The veteran who saves his own life by noticing a critical medication error in his Blue Button record. The adult daughter who uses her cell phone to share her mother's updated Medicare health history with each of the different doctors her mother sees for her multiple chronic conditions.

These are just examples of situations across the country where patients and family caregivers are using mobile tools to help them manage their own health and health care, as well as that of their loved ones. According to a 2014 poll conducted by the Pew Research Institute, 64 percent of American adults now own a smartphone, and 62 percent of these adults have used their devices to look up information about a health condition in the past year.

Given the ubiquity of smartphones and their growing adoption among seniors, as well as their high rates of use among low-income populations, it is clear that these devices are transformational tools that can be used by Americans to manage their health and be engaged in their care whenever and wherever they may be. For at-risk populations, the ability to more actively engage with their own care can be truly revolutionary.

Empowered with their mobile devices, Americans have the power to completely by-pass the lack of information sharing between health systems. Despite a $30B investment by taxpayers, business barriers to data sharing - more so than a lack of system interoperability – continue to affect providers' ability to communicate with one another. With mobile devices, patients can now take control of the data-sharing process and "bring their own" to every care interaction.

Patients are also now able to track and share information about their lifestyle (such as nutrition, physical activity, etc.), their experience with prescribed treatment,

specific health condition monitoring (such as hypertension or diabetes), and in some instances, aggregate it with their health record data. Seeing the whole picture of a person's health through this type of data aggregation, under the direct control of the individual, can greatly improve outcomes by delivering the right care at the right time, avoiding medical errors and redundant care and realizing the promise of value-based care as we move away from fee-for-service payment.

Yet, despite the important role of consumer mobile tools in helping to transform health care, much of the public dialogue about health IT to date has centered on system-to-system health information exchange (HIE) and interoperability using 90s technology. This is an outdated worldview that ignores the unparalleled impact that an engaged and technology-empowered consumer can have in driving health care quality and reducing costs in the short-term.

In fact, many of the barriers experienced in system-to-system exchange (i.e., business barriers, privacy and security issues) are not present with "consumer-mediated" exchange. Patients have a legal right to access their own data so there is no need to worry about HIPAA privacy requirements when sending a patient his/her own record.

Mobile tools – like Humetrix's iBlueButton and several others – already exist to help patients access and share their records with their providers as they choose. These tools also help providers make better use of the costly taxpayer investment in certified EHRs by making it easy to transmit health records to their patients' mobile applications of choice. Meaningful use standards ensure that these transmissions can be made in a standardized and secure way so that records can be read and assembled by their patients' mobile applications for them to share with their next provider.

Patient-supported exchange through mobile applications is a near-term solution that is immediately available to facilitate greater health information exchange. Truly value-based care cannot be achieved without greater rates of patient engagement, and tools are available now to help patients access and share their health data. Policymakers and providers alike should leverage these tools to the greatest extent possible to both advance interoperability and ensure patient safety.

New technologies are making existing policies for both providers and patients easy to implement. This is not the time to relax these policies by only considering system-to-system means of health information exchange when the world has evolved to widely adopt user-friendly mobile technology. With their own mobile devices, patients are unlocking information throughout the healthcare system and using it to improve their health. Isn't that a win for everyone?

Experton is the CEO of Humetrix.
http://thehill.com/blogs/congress-blog/healthcare/245222-policymaking-should-reflect-that-patients-also-share-data

Consumer Technology Association

This App Is Helping Veterans Manage Their Health Records
May 26, 2016
By Bronwyn Flores

On Monday, people across the United States will observe Memorial Day by honoring the men and women who have served in the U.S. armed forces. For one California-based tech startup though, veterans and military personnel are top of mind every day of the year.

Humetrix, which stands for "human metrics," uses sensor technologies and personalized algorithms to allow patients to access health records via their mobile devices. More specifically, their iBlueButton software lets veterans safely aggregate and store records from the U.S. Department of Veterans Affairs, Department of Defense and private providers.

We spoke with Humetrix CEO Bettina Experton to learn more about what her company is doing in health tech space to support veterans.

You recently exhibited at CES on the Hill. Tell us a little about your experience.
CES on the Hill is a unique experience, offering an intimate venue for companies to interact with legislators and their staff. Because technology is so central to our lives today, it is important that they engage with tech leaders and experience firsthand the wide range of transformational technologies that affect their constituents.

Because healthcare issues are so important, we were excited about the opportunity to demo our mobile health technology for legislators and talk about how information technology is directly impacting the lives of all Americans.
Our participation has resulted in some follow-up meetings on Capitol Hill with legislators who are keenly interested in improving the safety and cost-effectiveness of our healthcare system by empowering patients.

How does Humetrix's iBlueButton help veterans?
While healthcare is obviously important for everyone, our veterans in particular should get the best treatment – and the best tools for managing their health. Some vets come home with severe injuries and conditions, many requiring lifelong care and management.

As a result, veterans are often at much higher risk of medical errors both because they often have multiple health issues and because they access health care services from multiple places – in both Veterans Affairs (VA) and military system facilities and civilian doctors and clinics. More than 50 percent of the care vets receive comes from outside of the VA.

iBlueButton is the only software available that lets any veteran get and store records from the VA and Department of Defense health systems, as well as private providers; aggregate all of the information in an actionable format; and store it securely on the user's mobile device so he or she can easily share it with doctors and other caregivers.

Armed with this data, they can much more effectively ensure that every doctor they see is armed with all relevant information about their medical history to prevent deadly medical errors.

What measures does your company take to protect veterans' medical records?
Your mobile device is actually one of the most secure places to store your data because you control it. That is why we have chosen to secure this very private information on the user's own device — and nowhere else.
Humetrix is unique in the fact that individual data is never seen or stored on our servers. Veterans' medical records are downloaded directly from the VA or military health systems or Medicare and securely encrypted on the veteran's own smartphone. It can't be hacked or stolen from "the cloud" because it isn't stored there.

Besides helping veterans streamline their medical records, what else is Humetrix working on?

We're going beyond just providing anytime access to medical information — which is critically important — to the next step, which is using analytics and medical intelligence to help individuals better use their own data to manage chronic care conditions. For example, our TENSIO app uses analytics, medical intelligence, sensor data and the user's own health record to coach patients on the best way to monitor hypertension – high blood pressure. We can tell them how different medications will affect their blood pressure, remind them to take medication, and make recommendations regarding diet and exercise to manage their blood pressure.
In the future, we'll be rolling out additional apps on this same platform that assemble biometric and medical data and use medical intelligence and smart analytics to help coach patients through managing a range of other chronic conditions.

https://www.cta.tech/News/Blog/Articles/2016/May/This-App-Is-Helping-Veterans-Manage-Their-Health-R.aspx

Humetrix Blog Post
From Fitness to Health – How the Next Generation of Software Powered Devices is Changing the Health Tech Industry
June 3, 2016
By Dr. Bettina Experton

When we talk about health tech for consumers – we are really looking at an industry that is rapidly evolving from fitness to health. What does that mean?

Fitness technology appeals to a very specific segment of the population. Users are overwhelmingly young and active and very focused on exercise and diet. But a much larger population of consumers are interested in improving and maintaining their health – beyond tracking steps, heart rate, or sleep. The consumer health tech industry is learning that growth means appealing to this broad universe of potential users.

Good examples of this move are mobile technologies for the management of chronic conditions, like Humetrix's own Tensio mobile patient coaching platform for managing hypertension. These new products use the consumer's own health information and apply data analytics and algorithms to coach and guide them toward making healthy lifestyle choices, and complying with their doctor's medication treatment and care plan.

These new approaches require a much more complex offering than simple fitness biometric products that count steps or measure heart rate. When managing a chronic condition, the value of the device itself can be greatly magnified if it is embedded with or connected to intelligent software that applies smart analytics and algorithms on a comprehensive set of personal health data.

Until now, connecting to the critical health information that will power these new coaching solutions has been a challenge – so progress has been stalled. Today, new HIPAA laws give consumers the right – and the means – to access electronic versions of their own health records and port it to the mobile applications that are powering these new health-coaching platforms.

This development, along with growth among devices that allow consumers to digitally monitor their own blood pressure, blood glucose, and other health parameters, has made it possible for intelligent software solutions to bring health applications and devices to the next level of personalized chronic care management.

There is a revolution taking place today – consumers are no longer passive patients, but rather, active participants in their own healthcare. They need more intelligent and smarter devices that help them take control of their own health. The tracking device on its own is not enough. It is the device connected software that guides and informs us and helps us make smart decisions that can improve health outcomes.

The health tech industry is on an interesting path toward putting medical intelligence and powerful computing technology in the hands of consumers so they can better manage their health in consultation with their physicians. We must also focus on educating everyone about their right to access and use their own health records – and clearly illustrate the benefits of doing so. With the right information at our fingertips everyone will now be able to use this next generation of tracking devices to take control of their health and make meaningful changes in how they take care of themselves.

http://www.humetrix.com/post-be-34.html

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Humetrix Blog Post
At HIMSS 2016, Let's Remember that Patient-Mediated Exchange Can Drive Interoperability
February 25, 2016
By Dr. Bettina Experton

As we approach HIMSS 2016, I feel compelled to remind the health IT community that when tackling interoperability, we must remember that patient-mediated health information exchange is an important means to not only engage patients in their care but also to help providers receive and use health information when and where it is needed. I hope to see discussions at HIMSS center on how we can capitalize on our existing EMR infrastructure and available patient facing tools to encourage not just provider-to-provider communication, but communication between providers and their patients.
Health information exchange between providers and patients was the main recommendation called for by EMR industry leaders and echoed by patient facing organizations and developers like Humetrix during the ONC "Interoperability Governance Roundtable" last March. Now is the time to refocus our attention as the HIT community reconvenes in Las Vegas next week.

DIRECT secure messaging is part of all certified EMRs and can be used in combination with individual PHR tools, including mobile PHRs like Humetrix's own iBlueButton, or other standard-based solutions developed by NATE members like

NoMoreClipBoard or GetRealHealth, to achieve broad interoperability and health information exchange, especially with and via patients. If we want to make meaningful progress in our quest to improve interoperability and data flow, it is critical that we make the existing standard-based technologies that are prevalent on the provider side put to use for data exchange with patients and for consumer-mediated health information exchange. By opening provider-to-patient data flow, we not only allow patients to exercise their new HIPAA rights to access their personal health records, give them tools to ensure their safety across our disjointed healthcare system, but also help data flow between providers via consumer-mediated exchange.

The recent Senate HELP Committee draft HIT bill has brought the critical role of the patient to the forefront. Among the important provisions in the bill is: Empowering Patients and Improving Patient Access to Their Electronic Health Information, which supports the certification and development of patient-centered health record technology. The goal is to ensure that patients can access their health information through secure and user-friendly software so that their up to date medical history can be communicated to their physicians wherever they receive care. Making health information available via mobile devices – which are far more portable and ubiquitous than a PC – should be a key component of the strategy for care coordination and interoperability. More than 100,000 providers who use SureScripts' HISP service with their Epic EMRs, and scores of hospitals using Cerner EMRs can use DIRECT today to securely transmit EMR data and transition of care summaries to their patients' mobile devices via iBlueButton.

It is time to stop allowing the challenge of interoperability to delay broad deployment of patient-centric solutions. Using DIRECT and iBlueButton, patients can assemble their own comprehensive, longitudinal healthcare record from disparate systems, and annotate, share and update it, right on their own mobile devices, that they always carry with them, at any point of care. Turning on DIRECT, which is embedded in any certified EMR system is easy to do. So why aren't more health care institutions doing this? And why aren't they being incentivized to do so? It's a simple fix that can make a huge difference in improving care for any patient whether they are being discharged after a procedure, continuing their care at another facility, or managing their own health at home.

We will only succeed in transforming healthcare to a value-based system when we achieve true patient empowerment, giving patients access and control over their health records. At HIMSS 2016, I look forward to hearing from my colleagues in the HIT community about their initiatives to drive the use of technology that puts the patient at the center of their care and HIT team.

http://www.humetrix.com/post-be-33.html

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Humetrix Blog Post
"iBlueButton Saved My Father's Life!"
March 7, 2013
By Dr. Bettina Experton

Healthcare Informatics journalist Gabe Perna reported in a March 6th blog post the true story of Pennsylvania resident Beth Schindele, who says she saved her father's life by using the medical information in iBlueButton on her smartphone.

According to the blog post, Schindele used iBlueButton during her father's recent hospitalization to prevent doctors from discharging him with a prescription for Coumadin, a medication which had been prescribed to his father in error and which had been discontinued for over two years. The drug is a blood thinner often prescribed for atrial fibrillation, a heart disorder closely associated with stroke, a condition which Schindele's father had suffered from two years prior this last hospitalization. Schindele who directs a Delaware program that helps physicians implement electronic health records, argued that the drug showing on her father's chart should not be prescribed again, as it was erroneously done during a prior hospitalization. Standing in her father's hospital room, she called up three years' worth of his Medicare health records using iBlueButton on her smartphone. The app helped reveal that her father had previously had an EKG with a normal diagnosis associated with the test and not that of Atrial Fibrillation, and that he had not been treated with Coumadin in the last two years.

Confronted with this information, her father's doctors reluctantly admitted their error and canceled the prescription. It's a good thing they did. Just five hours after being discharged from the hospital, Schindele's father fell while trying to maneuver his walker up the stairs at home, lacerating his head and wrist. Had he been taking Coumadin at the time, Schindele is convinced, he may have died from uncontrolled bleeding (a hazard associated with the drug).

"Because I had the data in my hands (with iBlueButton), I was... instrumental in saving his life," Schindele says. You can read Beth Schindele's full story here:
http://www.healthcare-informatics.com/blogs/gabriel-perna/when-blue-button-saved-life
http://www.humetrix.com/post-be-03.html

http://www.humetrix.com

http://www.ibluebutton.com

http://www.sos-qr.com

http://www.tensio.com

Mr. BURGESS. The chair thanks the gentlelady. The gentlelady yields back.

Dr. Ferris, you are recognized for 5 minutes for an opening statement, please.

STATEMENT OF LAURA FERRIS, M.D.

Dr. FERRIS. Thank you. I appreciate the opportunity to testify today. I was invited here based on work that I have done showing the potential harm of mobile health technology, which both of you actually mentioned in your opening statements. However, I also do want to discuss how technology may improve patient care and access, particularly in my field of dermatology.

The three points I would like to make and focus on are that direct-to-consumer apps that function as medical devices making unsubstantiated claims and that are not data-driven can put patients at a higher degree of risk, and regulatory oversight should reflect this.

Telehealth applied to the field of dermatology does have the potential to improve patient access to high-quality care. And mobile health applications that aid in making a diagnosis really are most appropriately and safely used in the hands of physicians, and the regulatory path to developing such technologies should take into consideration the difference in risk posed by a medical device in the hands of a physician versus in the hands of a patient.

So, because of the visual nature of my field of dermatology, we were really among the first fields to experience the breadth of applications that can be used in delivering mobile health care to patients. So I am going to talk a little bit about the good and the bad.

So the first is my work as a researcher and clinician at the University of Pittsburgh. So I had many patients who came in and casually asked me about apps that they could download on their smartphone that allowed them to use their camera to take a picture of a mole and then the app would tell them "this looks good" or "this looks bad." And so my research team and I thought this would be something interesting to study, because there really wasn't data to back these up.

So we decided to look at three different apps that were available in the app store that were automated, inexpensive or free, and gave an immediate response as to if that lesion was likely to be skin cancer or not, and then a fourth app that sent the image to a board certified dermatologist who then gave feedback on it.

What we found is that these three automated apps missed a third to over 90 percent of the melanomas, which is our most deadly form of skin cancer, that we presented to them. The board certified dermatologist missed only one. Really, that was less than 2 percent of the melanomas in our study.

What does this mean? This means that if a patient had decided to save some time and money and used one of these apps, they could have been dissuaded at least a third of the time from seeking medical attention for something that is a curable disease when it is caught and treated early but fatal when it is caught late.

However, they wouldn't have been aware of this, because these apps didn't provide them with data, and they didn't provide an adequate warning of the risk of a missed melanoma. So mobile medical

apps that interact directly with the patient without physician input had the greatest potential for harm.

Our findings did also show, however, that store-and-forward teledermatology can be an effective way to diagnose skin cancer. However, this must be done safely. In the apps that we used, the physician was not providing an extension of an existing relationship, and they were not able to do things such as arrange followup care. And there are several similar apps in dermatology that are currently available online, and many of these actually don't even provide care from a physician who is licensed in the United States.

So it is important to realize that it is easier to ignore an app than it is to ignore a physician. It is also important to realize that a physician can provide care remotely as long as it is done safely.

Finally, it is important that we have access for our patients to dermatologic care. We do have an issue of limited availability, particularly of dermatologists, and we think that this is a way that we can provide access to patients who might not have it otherwise.

Finally, in addition, although I have already pointed out some of the pitfalls of using technology, in my own work, in collaboration with Carnegie Mellon University, we have developed a system that allows us to take an image taken with a tool attached to a smartphone called a dermatoscope that can allow us to upload an image of a skin lesion to a classifier, which can then analyze that and give an idea, give a score that helps to predict if that lesion is malignant or not. In our own study, we found that we could accurately identify 97 percent of melanomas with this tool.

Others have developed similar technologies. We have always seen this as a tool that would be helpful in the hands of another healthcare provider, such as a primary care provider who may be seeing a patient with a suspicious lesion. It would allow them to get a basic risk assessment and communicate back with us. We have not seen this as a tool that would be helpful directly placed in the hands of a patient.

So, in summary, I would just like to say that we think that the oversight of such tools should reflect the risk and that the risk in the hands of a physician is much lower than the risk directly in the hands of a patient. In addition, privacy concerns are allayed, because physicians in healthcare systems are covered entities under HIPAA. Thank you.

[The prepared statement of Dr. Ferris follows:]

Testimony to the Subcommittee on Commerce, Manufacturing, and Trade

July 13, 2016

Laura K. Ferris, MD, PhD

Associate Professor of Dermatology

University of Pittsburgh, School of Medicine

Summary:

Chairman Burgess and members of the subcommittee, thank you for the opportunity to share this testimony on mobile health applications. I will focus on their value and limitations, including possible risk to patients, as they relate to my specialty of dermatology. I support the use of technology to improve patient access to high-quality dermatologic care as well as to improve early detection and diagnosis of skin cancer. My own research has shown that with easy distribution of apps to consumers, several poor-quality apps that claimed to be able to diagnose skin cancer were sold or made available for free to consumers and I am glad that our work helped the Federal Trade Commission to take these out of the marketplace. However, technology, properly tested and placed in the hands of physicians rather than provided directly to the consumer in a way that bypasses the physician-patient relationship, has the potential to improve early detection of skin cancer. In addition, mobile technology helps to deliver health care to patients who do not have access to the care and expertise of a dermatologist and to allow the current work force of dermatologists to more efficiently deliver care and reduce patient wait times to see a dermatologist.

My testimony will focus on the following points:

1. Direct-to-consumer apps that function as medical devices, make unsubstantiated claims, are not data-driven put patients at a high degree of risk and regulatory oversight should reflect this risk.
2. Telehealth applied to the field of dermatology has the potential to improve patient access to high-quality dermatologic care.
3. Mobile health applications that provide computer assistance in making a diagnosis are most appropriately and safely used by physicians and not directly by patients and the regulatory path to developing such technologies should take into consideration the difference in risk posed by a medical device in the hands of physicians vs. patients.

Appropriate regulation can help to keep patients safe; over regulation and lack of clarity in a changing landscape will stifle innovation.

Statement:

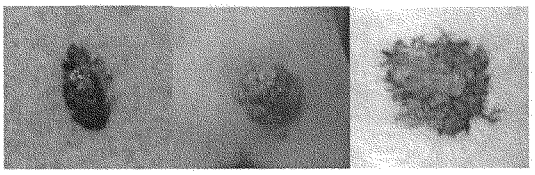
Because of the visual nature of the field of dermatology, we were among the first fields of medicine to experience the breadth of application of mobile health technology to patient care. I am here to share with you both the good and the bad that can result from this.

As a dermatologist at the University of Pittsburgh, a large part of my clinical practice and research is focused on the early detection of skin cancer. My interest in mobile health applications came from casual inquiries from my patients about apps available for their smartphones that claimed to be able to analyze a photograph that they had taken of a skin lesion and to give them information about if the lesions was benign, suggesting that they did not need to seek medical attention, or malignant, meaning they should see a doctor to determine if they had skin cancer and if a skin biopsy should be performed. My research team and I decided to test out some of these apps using photographs we had taken of skin lesions on our patients prior to biopsy and for which we thus knew the correct diagnosis. Three of these apps were inexpensive or free and gave an instantaneous answer, based on computer analysis,

Application No.	Evaluable Image, No. (%)	Sensitivity, % (95% CI)	Specificity, % (95% CI)
1	182 (96.8)	70.0 (56.6-80.8)	39.3 (30.7-48.6)
2	185 (98.4)	69.0 (55.3-80.1)	37.0 (28.7-46.1)
3	170 (90.4)	6.8 (2.2-17.3)	93.7 (87.0-97.2)
4	159 (84.6)	98.1 (88.8-99.9)	30.4 (22.1-40.3)

stating that the lesions was either at high or low risk of being skin cancer. None provided data about how they worked or if or how they had been validated. The fourth app sent the image to a board-certified dermatologist who then determined if that lesion was high or low risk but provided no care or guidance as to what to do from there. In our study, we found that the three automated apps missed 30-93% of the melanomas, the most deadly form of skin cancer, we presented to them. The board-certified dermatologist missed only one lesion (1.9%). Our results, are shown in this table (sensitivity is the proportion of melanomas that were correctly classified as melanoma; specificity is the percentage of benign lesions that were correctly classified as benign). [1]

Melanomas missed by automated apps:



This means that if a patient decided to save time and money by trusting their health to one of these apps that was easily available on their smartphone, at least a third of the time they would be dissuaded from seeking medical attention for a skin cancer that is generally curable when caught early and fatal when caught late. However, the user of one of these apps would not be aware of this because these apps did not provide data on their accuracy, nor did they adequately explain the consequence of a delay in the diagnosis of melanoma. These types of apps are no longer widely available to the public

due to actions by the Federal Trade Commission which charged app makers with making deceptive health claims. Mobile medical apps that interact with the patient directly, with no physician input, have the greatest potential to cause harm and thus require the greatest degree of oversight and should not be marketed with unsubstantiated claims directly to consumers.

Our findings also showed that store and forward telemedicine was actually quite accurate in detecting of melanomas, a finding repeated by other studies as well which show that show a high correlation between in-person and telemedicine evaluation in the evaluation of skin lesions .[2] However, unlike other telehealth applications that provide an extension of the existing patient-physician relationship, the app in our study provided a single assessment from a physician who has no relationship with the "patient" on the other end of the app. Currently, many similar such apps are still widely available. In such apps, often the physician's credentials are not available to the patient (and in some cases the doctor is not licensed in the US) and the physician does not have access to the patient's medical history and would not be able to perform the counseling or arrange in-person follow up that may be an essential part of patient care. A patient with one of the lesions pictured above does not just need someone to decide if a biopsy should be performed; that patient needs a physician who can explain the consequences of opting not to do have the lesion biopsied, who will follow up with a phone call if the patient initially declines a biopsy, and who will ultimately help guide them through their treatment when they are diagnosed for melanoma. An app that simply provides a reading of "high risk," even if it is correct, is easier to ignore than a physician who can explain the consequences of a delayed diagnosis of melanoma.

Teledermatology provided in the context of a legitimate physician-patient relationship can improve patient access to dermatologists, particularly in underserved populations.[3, 4] There are currently multiple platforms that allow for the delivery of teledermatology. Reimbursement for appropriate teledermatology services would expand access to this service, which has the potential to result in the

earlier diagnosis of skin cancer[5] in addition to improving access for patients with a variety of skin diseases. Reimbursement for high-quality teledermatology services, provided by a licensed physician and within a physician-patient relationship or as part of physician-to-physician consultation, will allow for the growth of these services. Such services should augment but not be intended to replace or be a requirement for ultimately obtaining face-to-face care from a dermatologist when either the patient or the physician feels this is the best option.

While my initial work highlighted some of the potential pitfalls of technology released directly to patients too quickly and without evidence or physician involvement, I see great promise in the use of technology to improve patient care, particularly in the field of the early diagnosis of skin cancer. I have been working with collaborators at Carnegie Mellon University to develop a system that applies computer vision to skin cancer diagnosis. We have developed a program that accurately identified 97% of melanomas using images taken with a small device called a dermatoscope that can be attached to a smartphone which can then send that image to a server where the image can be processed and a score can be given to help to determine how likely that lesion is to be malignant.[6] Others have developed similar technologies that use computer-assisted diagnosis to provide more information about skin lesion that can ultimately aid in making a diagnosis. [7] While we can make a claim of performance based upon published data, our vision for this technology has never been to put it directly in the hands of patients. We see this as a tool that gives a non-dermatologist medical professional, such as a primary care physician, additional information, to use along with their clinical judgement, to better triage which lesions need to be seen by a dermatologist immediately and which can be evaluated later- either through a teledermatology consult or in person. The important factor here is that this is a tool for physician-to-physician communication that will be used only when both the dermatologist and the primary care physician are comfortable that the evidence supports its use. As physicians, we use data to determine how we interpret test results and we are trained to understand the limitations of tests.

We are trained to think in terms of sensitivity, specificity, and positive and negative predictive value. We take these into consideration when we use tests and tools. One of the hurdles we face in advancing the development of our technology is the uncertain future landscape of telehealth and how the FDA will classify and oversee such tools as medical devices. If is important to distinguish such a tool and the potential risk it may pose, used in physician to physician communication and triage, which provides data but not a stand-alone diagnosis, from the apps that are directly marketed to patients that attempt to make a stand-alone diagnosis. This technology and many others like it are likely to be halted in development without clear guidance on their classification and path to regulatory approval. This path is best laid out in a collaborative relationship between the FDA, technology innovators, patients, and physicians.

In summary, while I was invited to testify based upon my work showing the potential harms of technology that is made available directly to patients, with claims not substantiated by research or data, and cutting the physician out of the relationship, I am also a strong believer in the value that technology can bring to health care. I encourage you to provide clear guidance that will allow us to move ahead with developing new technologies, making existing technologies more robust, and finding new, more efficient ways of delivering health care. Technology should enhance the physician-patient relationship and opens up new treatment options for patients and should first of all do no harm by promising more than can safely be delivered.

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Mr. BURGESS. The chair thanks the gentlelady.

Dr. Dorsey, you are recognized for 5 minutes for an opening statement, please.

STATEMENT OF E. RAY DORSEY, M.D., M.P.H.

Dr. DORSEY. Chairman Burgess, Ranking Member Schakowsky, members of the Commerce, Manufacturing, and Trade subcommittee, today we have the means to enable anyone anywhere to receive care, to participate in research, and to benefit from those advances. Unfortunately, policy barriers limit adoption of these new tools.

I am a neurologist at the University of Rochester Medical Center in Rochester, New York, and for the past decade, my colleagues and I have been applying technologies, including smartphones, wearable sensors, and video conferencing, to enhance research and improve care for individuals with Parkinson's disease and Huntington's disease. Currently, clinical trials are plagued by limited participation and insensitive outcome measures. For example, only 3 percent of individuals with cancer participate in clinical trials, and today, we assess whether a new drug works for Parkinson's disease with paper diaries and subjective assessments of finger tapping. We can progress faster with better tools, including smartphones.

In March 2015, Apple created ResearchKit, an open-source platform for creating smartphone research applications, and released applications for asthma, breast cancer, cardiovascular disease, diabetes and Parkinson's disease. Within a day, 2,000 individuals were participating in the Parkinson's disease study. In 7 months, over 70,000 individuals from every State in the union had enrolled in the study. In 1 year, nearly 10,000 Parkinson's disease study participants were sharing their data with researchers globally. Because of their potential, pharmaceutical companies are incorporating smartphones into clinical trials. Such use could help determine whether new therapies are efficacious in smaller, shorter, cheaper studies and accelerate our ability to find treatments for Parkinson's disease and other neurological disorders that will affect almost all of us.

In addition to smartphones, we use video conferencing to care for individuals with Parkinson's disease. Because of distance and disability, over 40 percent of Medicare beneficiaries with Parkinson's disease do not see a neurologist. Those that do not see one are more likely to fracture their hip, more likely to be placed in a skilled nursing facility, and more likely to die prematurely. Simple videoconferencing, like Skype, enables clinicians to reach patients in their homes. In a pilot study, these virtual house calls were feasible, provided comparable outcomes to in-person care, and saved patients and their caregivers 3 hours of time and 100 miles of travel. With 18 centers, including Baylor, Northwestern, University of Kansas, and the University of Florida, we are conducting the first national randomized controlled trial of virtual house calls for Parkinson's disease.

Demand for telehealth is high. Over 11,000 individuals from 80 countries and all 50 states visited the study's Web site, and nearly 1,000 individuals with Parkinson's disease wanted to participate in this 200-person study, which will complete this summer.

Despite the promise and potential of these new technologies, policy barriers, including State licensure laws and Medicare's narrow coverage, limit adoption. In 2015, Medicare spent less than one-hundredth of 1 percent of its budget on telehealth. Currently, Medicare pays neurologists $150 to see a patient with Parkinson's disease in a hospital-based clinic, $80 for a visit in a community-based clinic, and zero dollars to see a patient remotely in her home. In essence, Medicare subsidizes institution-based care and disincents patient-centered care.

Fortunately, policy solutions are available. The Tele-Med Act would enable any Medicare provider to care for me Medicare beneficiary. The act mirrors how physicians in the Veterans Administration can care for any veteran anywhere in the U.S., and last year, the VA provided over 2 million telehealth visits.

The Medicare Telehealth Parity Act would expand Medicare's coverage of telehealth, which today reaches veterans, military personnel, Medicaid beneficiaries, and prisoners, but largely excludes 50 million older Americans.

Fifty-one years ago, a Texan signed legislation that guaranteed all older Americans healthcare coverage. Two generations later, Medicare is showing its age. However, this committee, led by a Texan, can help ensure that this generation's tools fulfill Medicare's founding vision and extend care to every American senior everywhere.

Thank you very much for your time and service.

[The prepared statement of Dr. Dorsey follows:]

Testimony to the Subcommittee on Commerce, Manufacturing, and Trade

Wednesday, July 13, 2016

Ray Dorsey, MD
David M. Levy Professor in Neurology
University of Rochester Medical Center, Rochester, NY

Summary

Currently, we have tools and technologies that increasingly can enable anyone anywhere to receive care, participate in research, and benefit from its advances. However, policy barriers, especially antiquated state licensure laws and Medicare policies, limit their adoption and access to care. To enable these technologies, including use of smartphones and objective sensors to measure disease and video conferencing to connect patients to convenient care, the federal government could consider the following:

1. The U.S. Food and Drug Administration could provide affirmative guidance to the life sciences industry encouraging and supporting adoption and incorporation of mobile technologies into clinical trials and into the development and evaluation of novel therapeutics.
2. Congress could pass and the President could sign legislation like the Tele-MED Act, which will enable any Medicare beneficiary in the country to receive care from any Medicare provider in the country.
3. Congress could pass and the President could sign legislation like the Medicare Telehealth Parity Act to expand Medicare's coverage of telehealth. Importantly, coverage alone is not enough. Legislation must incent (through higher reimbursement rates) clinicians to adopt telehealth as a means to increase access to care for all Medicare beneficiaries (not just rural ones). Currently, Medicare provides higher reimbursement to care provided in hospital-based clinics. Rather than subsidizing high cost, institution-based care, Congress should incent potentially lower cost, patient-centered care delivered to where patients (not institutions) are.

Statement

Chairman Burgess, Congresswoman Schakowsky, members of the Commerce, Manufacturing and Trade Subcommittee, today we have the means to enable anyone anywhere to receive care, to participate in research, and to benefit from those advances. Unfortunately, policy barriers limit adoption of these new tools.

I am a neurologist at the University of Rochester Medical Center in Rochester, NY and for the past decade, my colleagues and I have been applying technologies, including smartphones, wearable sensors, and video conferencing , to enhance research and improve care for individuals with Huntington disease and Parkinson disease. Currently clinical trials are plagued by limited participation and insensitive outcome measures. For example, only 3% of individuals with cancer participate in clinical trials, and today we assess whether a new drug works for Parkinson disease with paper diaries and subjective assessments of finger tapping. We can progress faster with better tools, including smartphones.

In March 2015, Apple created ResearchKit, an open-source platform for creating smartphone research applications, and released applications for asthma, breast cancer, cardiovascular disease, diabetes, and Parkinson disease. Within a day, 2000 individuals were participating in the Parkinson disease study. In seven months, over 70,000 individuals from every state had enrolled in a study. In one year, nearly 10,000 Parkinson disease study participants were sharing their data with researchers globally.

Because of their potential, pharmaceutical companies are incorporating smartphones into clinical trials. Such use could help determine whether new therapies are efficacious in smaller, shorter, cheaper studies and accelerate our ability to find treatments for Parkinson disease and other neurological disorders that will affect almost all of us.

In addition to smartphones, we use video conferencing to care for individuals with Parkinson disease. Because of distance and disability, over 40% of Medicare beneficiaries with Parkinson disease do not see a neurologist. Those that do not are more likely to fracture their hip, to be placed in a skilled nursing facility, and to die prematurely. Simple video conferencing like Skype enables clinicians to reach patients in their homes. In a pilot study, these virtual house calls were feasible, provided comparable outcomes to traditional care, and saved patients and caregivers 100 miles of travel and three hours of time. With eighteen centers, including Baylor, Northwestern, University of Kansas, and University of Florida, we are conducting the first national randomized controlled trial of virtual house calls for Parkinson disease. Demand for telehealth is high. Over 11,000 individuals from 80 countries and all 50 states visited the study's website, and nearly 1000 individuals wanted to participate in this 200-person study, which will complete this summer.

Despite the promise and potential of these new technologies, policy barriers, including state licensure laws and Medicare's narrow coverage, limit adoption. In 2015, Medicare spent less than one hundredth of one percent of its budget on telehealth. Currently, Medicare pays neurologists ~$150 to see a patient with Parkinson disease in a hospital-based clinic, $80 for a visit in a community-based clinic, and $0 to see a patient remotely in her home. In essence, Medicare subsidizes institution-based care and disincents patient-centered care.

Fortunately, policy solutions are available. The Tele-Med Act (H.R. 3081) would enable any Medicare provider to care for any Medicare beneficiary. The Act mirrors how physicians in the Veterans' Administration can care for any veteran anywhere in the U.S., and last year the VA provided over two million telehealth visits. The Medicare Telehealth Parity Act (H.R. 2948) would expand Medicare's coverage of telehealth, which today reaches veterans, military personnel, Medicaid beneficiaries, and prisoners but largely excludes 50 million older Americans.

Fifty-one years ago, a Texan signed legislation that guaranteed all older Americans health care coverage. Two generations later, Medicare is showing its age. However, this Committee – led by a Texan – can help ensure that this generation's tools fulfill Medicare's founding vision and extend care to every American senior everywhere.

Thank you very much for your time and service.

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Disclosures

Equity interests

Dr. Dorsey is a member of the medical advisory board for and has stock options in Grand Rounds.

Consulting

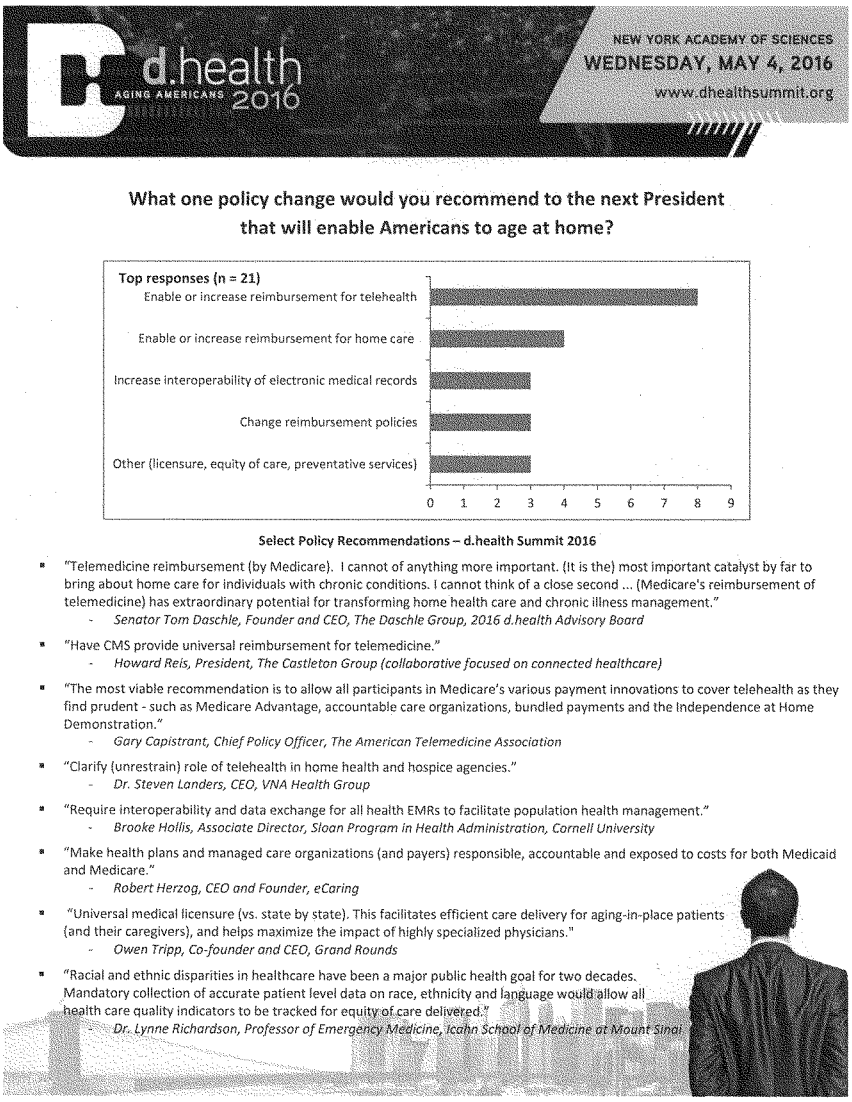
Dr. Dorsey has served as a consultant to the National Institute of Neurological Disorders and Stroke, Clintrex, GlaxoSmithKline, MC10, MedAvante, Shire, and UCB.

Grant funding

Dr. Dorsey has received research funding from AMC Health, Davis Phinney Foundation, Duke University, Greater Rochester Health Foundation, Great Lakes Neurotechnologies, Huntington Study Group, Michael J. Fox Foundation, National Institute of Neurological Disorders and Stroke, National Science Foundation, Patient-Centered Outcomes Research Institute, Prana Biotechnology, Raptor Pharmaceuticals, Roche, Safra Foundation, Sage Bionetworks, Teva Pharmaceuticals, and University of California Irvine.

Attachments

My colleagues recently hosted a d.health Summit (www.dhealthsummit.org) on May 4, 2016 in 2016 to foster technology-enabled disruptive care models to enable Americans to age at home. The Summit assembled policy, technology, and health leaders and provided multiple recommendations (**Attachment A**) to enable aging at home, a stated goal of 88% of Americans.



What one policy change would you recommend to the next President that will enable Americans to age at home?

Select Policy Recommendations – d.health Summit 2016

- "Telemedicine reimbursement (by Medicare). I cannot of anything more important. (It is the) most important catalyst by far to bring about home care for individuals with chronic conditions. I cannot think of a close second ... (Medicare's reimbursement of telemedicine) has extraordinary potential for transforming home health care and chronic illness management."
  - *Senator Tom Daschle, Founder and CEO, The Daschle Group, 2016 d.health Advisory Board*
- "Have CMS provide universal reimbursement for telemedicine."
  - *Howard Reis, President, The Castleton Group (collaborative focused on connected healthcare)*
- "The most viable recommendation is to allow all participants in Medicare's various payment innovations to cover telehealth as they find prudent - such as Medicare Advantage, accountable care organizations, bundled payments and the Independence at Home Demonstration."
  - *Gary Capistrant, Chief Policy Officer, The American Telemedicine Association*
- "Clarify (unrestrain) role of telehealth in home health and hospice agencies."
  - *Dr. Steven Landers, CEO, VNA Health Group*
- "Require interoperability and data exchange for all health EMRs to facilitate population health management."
  - *Brooke Hollis, Associate Director, Sloan Program in Health Administration, Cornell University*
- "Make health plans and managed care organizations (and payers) responsible, accountable and exposed to costs for both Medicaid and Medicare."
  - *Robert Herzog, CEO and Founder, eCaring*
- "Universal medical licensure (vs. state by state). This facilitates efficient care delivery for aging-in-place patients (and their caregivers), and helps maximize the impact of highly specialized physicians."
  - *Owen Tripp, Co-founder and CEO, Grand Rounds*
- "Racial and ethnic disparities in healthcare have been a major public health goal for two decades. Mandatory collection of accurate patient level data on race, ethnicity and language would allow all health care quality indicators to be tracked for equity of care delivered."
  - *Dr. Lynne Richardson, Professor of Emergency Medicine, Icahn School of Medicine at Mount Sinai*

Mr. BURGESS. Thank you, Dr. Dorsey.

Ms. Johnson, you are recognized for 5 minutes for an opening statement, please.

STATEMENT OF DIANE JOHNSON

Ms. JOHNSON. Before I begin my testimony, I would first like to thank Chairman Burgess for his key leadership on this issue and others. He has been a longstanding advocate for patients, and we appreciate his tireless efforts.

Distinguished members of the subcommittee, thank you for the opportunity to come before you today and to detail critical applications within development at the Johnson & Johnson family of companies that will enhance physician and patient interaction while delivering additional patient tools in innovative ways. In addition, my testimony will focus on how Congress can help support these ongoing activities.

As part of the Johnson & Johnson credo, we believe our first responsibility is to the doctors, nurses and patients, mothers and fathers, and all others who use our products. The commitment to safety is part of our DNA, factoring into our decisions and development of our products and services.

With that credo in mind, J&J has developed a number of apps to help individuals monitor their health or health of their family and support the doctor-patient relationship. I will describe a few key points, but there are many more.

The goal of this suite of apps is to empower patients, reduce cost of care, and enhance patient outcomes.

OneTouch Reveal allows patients to check blood sugar results on a mobile phone or tablet. The app provides overviews and a 365-day logbook with colorful visuals and simple navigation. It provides the patient with the ability to share ongoing information with his or her physician, allowing for enhanced care management for people with diabetes.

Care4Today Mobile Health Manager is a mobile app and Web site designed to support and motivate people to stay on schedule with their medication and report adherence to their treatment plan as prescribed by their physician. The application helps ensure that the physician is aware of possible drug interactions or problems with medication adherence.

The PATIENT ATHLETE Program is designed to help patients preparing for surgery to take their experience beyond merely reducing the pain. The program encourages patients to emerge stronger, healthier, and ready for the next chapter of life. Key components include a self-guided video-based training program led by a performance coach who had a bilateral knee replacement and uses the same concepts to enhance his own experience. Eight core lessons, two per week, to complete over a 4-week period prior to surgery and 11 refresher lessons to complete post surgery.

The Johnson & Johnson 7 Minute Wellness for Expecting and New Moms App is a science-based wellness resource designed to help new moms manage and expand their energy during pregnancy and after giving birth.

The Digital Health Scorecard helps one determine one's health score and better understand the likelihood of developing common

chronic diseases such as diabetes, heart or respiratory disease, or cancer.

HEALTHYDAY gathers data from the same trusted sources that doctors and hospitals use and cross-references information with local crowd-sourced data to determine what illnesses are trending nearby. This help informs the user to determine whether what they are feeling may be a cold, the flu, or pesky allergies. Then when you are feeling great, it lets you see what is going on around local and sends real-time alerts to help you know what to watch out for.

With this demand for cutting-edge technologies and continuous innovation, we as manufacturers must remain diligent in ensuring that cyber security is an integral part of the process. We believe that patient safety, including security of their data, is the most important consideration. To that end, foundational to our approach to cyber security is the development of a formalized security framework for our products. From a policy perspective, we believe that, in order to ensure the continuous innovation, smart regulation is critical.

Currently, the FDA has shown great flexibility in establishing the types of apps for which the agency intends to exercise enforcement discretion; that is, the FDA will not enforce the requirements of the act. FDA released a guidance document that provides examples. This guidance document is extremely useful, and J&J is supportive of this approach, but having specific criteria that determines what is and is not regulated is key.

Johnson & Johnson worked extensively with the HELP committee and other stakeholders to craft the language of the SOFTWARE Act that would provide this clarity. While additional work may need to be done to reconcile the SOFTWARE Act with the MEDTECH Act, the goals are similar, and we would encourage Congress to complete the work and provide companies with the regulatory certainty that will foster innovation and encourage investment in this space.

We think the following considerations are critical, that the functionality is what is critical, what the app does—not the platform it runs on—and that the findings should be applied regardless of whether the app developer is or is not considered a medical device manufacturer.

The policy changes are similar to those raised in the wearable devices hearing, including device security, data ownership, and privacy laws.

We hope you can ascertain that Johnson & Johnson strongly encourages and supports these activities, which enhance the doctor-patient relationship and improve patient empowerment and access to medical products. We look forward to continue working with Congress. Again, thank you for the opportunity.

[The prepared statement of Ms. Johnson follows:]

STATEMENT OF DIANE JOHNSON
SENIOR DIRECTOR, NORTH AMERICAN REGULATORY AFFAIRS POLICY AND INTELLIGENCE
JOHNSON & JOHNSON

FOR PRESENTATION BEFORE THE
HOUSE ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE
HEARING TITLED "DISRUPTER SERIES: HEALTH CARE APPS"
JULY 13, 2016

Before I begin my testimony, I would first like to thank Chairman Burgess for his key leadership on this issue and others. He has been a longstanding advocate for patients, and we appreciate his tireless efforts.

Subcommittee Chairman Burgess, Ranking Member Schakowsky, and Distinguished Members of the House Energy and Commerce Committee Subcommittee on Commerce, Manufacturing, and Trade:

Thank you for the opportunity to come before you today to detail critical applications within development at the Johnson & Johnson Family of Companies that will enhance the physician and patient interaction while delivering additional patient tools in innovative ways. In addition, my testimony will focus on how Congress can help support those ongoing activities.

As part of the Johnson & Johnson credo, we believe our first responsibility is to the doctors, nurses and patients, mothers and fathers and all others who use our products. The commitment to safety is part of our DNA, factoring into our decisions and development of our products and services.

With that credo in mind, the Johnson & Johnson Family of Companies has developed a number of apps to help individuals monitor their health or the health of their family and support the doctor-patient relationship by extending clinical care outside of the in-person consultation. I will describe a few key apps created by the Johnson & Johnson operating companies as well as in cooperation with partnering organizations, but there are many more. The goal of this suite of apps is to empower patients, reduce costs of care, and enhance patient outcomes.

OneTouch Reveal ("diabetes") – One Touch Reveal Allows a patient to check blood sugar results on a mobile phone or tablet. This app provides a 14, 30, or 90 day overview and a 365 day logbook—with colorful visuals and simple navigation. In addition, it allows a patient to share results with his or her physician — as progress reports (PDF) or as data tables (CSV). It provides the patient with the ability to share ongoing information with his or her physician, allowing for enhanced care management for people with diabetes.

Care4Today™ Mobile Health Manager 2.0 (medication management) -- The Care4Today™ Mobile Health Manager 2.0 is a free mobile app and website with new features, including Care4Family™ and Care4Charity™, designed to support and motivate people to stay on schedule with their medications and report their adherence to a treatment plan as prescribed by their physician. By assisting with medication compliance issues, the application helps ensure that the physician is aware of possible drug interactions or problems with medication adherence.

The PATIENT ATHLETE™ Program (surgery patients) -- The PATIENT ATHLETE™ Program is designed to help patients preparing for surgery to take their experience beyond merely reducing the pain. The program encourages patients to align their personal purpose with their daily behaviors to emerge stronger, healthier and ready for the next chapter of life. Key components include:

- Self-guided, video-based training program led by a Performance Coach who had bilateral knee replacements and used these same concepts to enhance his own experience,
- Utilizes science-based tools and techniques from the Johnson & Johnson Human Performance Institute®,
- Eight core lessons (two per week) to complete over the four week period prior to surgery,
- Ideas for immediate application with simple action steps, and
- Eleven refresher lessons to complete post-surgery for sustained focus and encouragement.

Johnson & Johnson 7 Minute Wellness for Expecting and New Moms™ App (new mothers) -- The Johnson & Johnson 7 Minute Wellness for Expecting and New Moms™ App is a science-based wellness resource designed to help new moms manage and expand their energy during pregnancy and after giving birth.

Digital Health Scorecard (health management) -- The Digital Health Scorecard helps one determine one's personal "health score" and better understand the likelihood of developing common chronic diseases such as diabetes, heart or respiratory diseases or cancer.

HEALTHYDAY App (surveillance) -- HEALTHYDAY gathers data from the same trusted sources that doctors and hospitals use, cross-references information with local, crowd-sourced data to determine what illnesses are trending nearby. This helps inform a user to determine whether what they're feeling may be a cold, the flu, or pesky allergies. Then when you're feeling great, it lets you see what's going around locally and sends real-time alerts to help you know what to watch out for.

Given the wide variety of apps under development at the Johnson & Johnson Family of Companies, we see demographic and technology trends in healthcare shifting toward more consumer-driven decision making and self-care activities. With this demand for cutting-edge technologies and continuous innovation, we as manufacturers must remain diligent in ensuring that cybersecurity is an integral part of the process. We believe that patient safety (including the security of their data) is the most important consideration.

To that end, foundational in our approach to cybersecurity at Johnson & Johnson is the development of a formalized security framework for our products, which is based on both the National Institute of Standards and Technology (NIST) Cybersecurity Framework for Critical Infrastructure and the Food and Drug Administration (FDA) Guidance Documents. This framework enables us to more effectively drive integration of cybersecurity standards, guidelines and practices into all aspects of product innovation, including digital assets such as Mobile Medical Applications and Software as Medical Devices.

From a policy perspective we believe that in order to ensure the continuous innovation of these vitally important apps, smart regulation is critical. Currently, the FDA has shown great flexibility in establishing types of apps for which the Agency intends to exercise "enforcement discretion", that is FDA will not enforce the requirements of the Federal Food, Drug and Cosmetic Act, even if the app could be considered to fall within the definition of a medical "device". FDA released a guidance document that provides specific examples of apps for which FDA intends to exercise such enforcement discretion, while

also identifying the types of higher risk apps which it will continue to actively regulate. This guidance is extremely useful and J&J is supportive of their approach, but having the specific criteria that determines what is and is not regulated would provide more certainty, especially for small companies that may be less familiar with enforcement discretion. Both the SOFTWARE Act and the MEDTECH Act strive to achieve this goal, and we encourage Congress to finalize a flexible yet clear distinction between what should be regulated as a medical device, and what should not be regulated as such.

Johnson & Johnson worked extensively with the HELP committee and other stakeholders to craft the language in the SOFTWARE ACT that would provide this clarity. While additional work may be needed to reconcile the two bills the goal is similar and we would encourage Congress to complete this work and provide companies with the regulatory certainty that will foster innovation and encourage investment in this space. We would request that the following be considered during the deliberation: the medical device industry generally believes that the determination should be based on functionality (what the app does) not on the platform on which it runs (for example a smartphone, a computer, a server, or in the cloud) and that the determination should apply equally to all developers regardless of whether or not they are currently considered medical device manufacturers. These considerations are necessary in order to ensure that, at the end of the day, patient safety is the most important part of the decision making process.

With respect to the policy challenges, they are similar to those raised in the Wearable devices hearing that was held on March 3rd by this committee. Data security, data ownership, privacy law challenges – these all apply to mobile apps in much the same way as they do the wearables. The combination of wearable with apps could drive even more dramatic innovation. Johnson & Johnson believes that combined technologies such as electronic informed consent, remote patient monitoring through approved devices, tracking medication adherence, and wearables could revolutionize the way clinical trials are conducted by removing barriers associated with where a patient lives. This could help promote a key companion of patient empowerment, which is patient access.

As I hope you can ascertain from my comments, Johnson & Johnson strongly supports activities which help enhance the doctor-patient relationship, and improve patient empowerment and access to medical products. We look forward to continuing to work with our partners to develop additional interoperability while addressing any potential cybersecurity issues.

Given the myriad of activities which are underway, Congress has provided some incentives, especially in the area of cybersecurity. The current environment allows us to continue to innovate and drive key activities forward. Any additional legislation should support interoperability while understanding the resultant cybersecurity risks, maintain the level playing field for competition in the marketplace, support the continued dialogue and collaboration by not creating punitive barriers, and focus any additional restrictions in areas where there may be patient harm.

Again, thank you for the opportunity to discuss Johnson & Johnson's innovation in the medical apps space. I welcome your questions.

Mr. BURGESS. The chair thanks the gentlelady.

Mr. Terry, you are recognized for 5 minutes for an opening statement please.

STATEMENT OF NICOLAS P. TERRY

Mr. TERRY. Chairman Burgess, Vice Chairman Lance, Ranking Member Schakowsky, and members of the subcommittee, it is a privilege to share my thoughts and some of the legal and regulatory issues involving healthcare apps. I congratulate this committee on its Disrupter Series and its engagement on these forward-looking and exciting issues.

I live in a small village just north of Indianapolis, where I receive particularly superior representation. My day job is serving as a professor at Indiana University Robert H. McKinney School of Law. There I teach and write about health law and policy, with a particular interest in information technologies and healthcare data protection.

Some of my work is examining the question, why health information technology, such as electronic health records or clinical decision support systems, has failed to transform or disrupt health care. I concluded there were several overlapping explanations. These included typical healthcare market failure problems, overarching structural issues, the illiquidity of healthcare data, and underperforming technologies.

Not surprisingly, Federal and State policymakers have turned toward subsidy and command-control models in an attempt to promote HIT adoption. Mobile health and healthcare apps potentially avoid these problems. They posit inexpensive care pulled by patients only when needed and delivered away from inconvenient, centralized locations.

Obviously, many mobile health apps will be developed with regard to existing healthcare relationships, offering improved condition management, particularly for chronic diseases. Many of these apps will be subject to existing regulatory models.

However, the most disruptive health apps are those that are patient-facing. These create or may create a direct app-patient relationship that lacks professional intermediation and, as a result, traditional regulation of safety, quality, and confidentiality.

The regulatory framework for most of these apps is complicated and, in some cases, troubling. Here, the oversimplified binary of regulation versus innovation is a poor frame. Rather, we have a current technological space that is subject to both over-regulation and under-regulation. This is also a space I would suggest where overarching labels, such as health apps, mobile health, or digital health, are not always helpful. Different apps for different functions used in different contexts by different persons pose quite diverse policy questions.

For present purposes, I restrict my comments to three issues: safety, effectiveness, and data protection.

First, the Food and Drug Administration has used a subregulatory guidance to signal a light touch regarding most categories of apps. However, patient diagnosis and treatment-recommending apps, that arguably could be useful and stimulate innovation, remain subject to traditional device regulation. Arguably, this ap-

proach frightens off responsible innovators while the FDA lacks the bandwidth to deal with the many industry minnows selling apps on the app stores that seem to cross the regulatory line. Such a state suggests that additional regulatory clarity is required, together with some innovative regulatory models that is more attuned to the rapid iteration in the mobile industry.

Second, there is the question of app efficacy or effectiveness. Even if they are safe, many health apps are simply ineffective. The structure of the app market and the absence of effective infomediaries create immense problems for consumers looking for quality apps, creating doubts as to whether the market will function effectively. This is a classic consumer protection problem, and in my opinion, the Federal Trade Commission has taken the correct approach in demanding competent and reliable scientific evidence in app cases involving, for example, claims of melanoma detection and vision improvement. However, sufficient regulatory resources must be deployed in this endeavor lest innovative apps are drowned out by mobile health snake oil.

Third, data protection. This is an area of acute under-regulation. Most patient-facing apps existing exist in what I call a HIPAA-free zone, subject only to a small number of State laws or, in the most egregious cases, to the FTC's unfairness jurisdiction. Here, our flawed sectoral downstream approaches to data protection are on full display.

This country has enjoyed a deep-rooted cultural expectation of and professional commitment to health privacy, no doubt in part because healthcare data seems particularly susceptible to discriminatory and other harmful uses. Every day, doctors rightfully reassure their patients as to the legally enforced confidentiality of the information they share while their offices distribute mandated privacy notices. However, the same or similar data collected on mobile devices lack these protections. Most mobile health apps, particularly the more disruptive patient-facing ones, are not subject to HIPAA privacy and security rules, leaving patient wellness and health data woefully unprotected. In my opinion, Federal data protection law that obviates the gaps between our commercial sectors and protects health information wherever it happens to reside is overdue and is a necessary precondition for the full embrace of disruptive health apps by both medical professionals and consumers.

Again, I express my thanks to the committee.

[The prepared statement of Mr. Terry follows:]

Opening Remarks for House Energy and Commerce Subcommittee Hearing
on Health Care Apps

Nicolas P. Terry
Hall Render Professor of Law
& Executive Director, Hall Center for Law and Health
Indiana University Robert H. McKinney School of Law

July 13, 2016

Chairman Burgess, Vice Chairman Lance, Ranking Member Schakowsky and members of the Committee, it is a privilege to share my thoughts on some of the legal and regulatory issues involving health care apps. I congratulate the Committee on its "Disrupter Series" and its engagement on these forward-looking and exciting issues.

Some of my work has examined the question why health information technologies (HIT) have failed to transform or disrupt healthcare. I concluded that there were several overlapping explanations. These included typical healthcare market failure problems, overarching structural issues, the illiquidity of healthcare data, and underperforming technologies. As a result, federal and state policymakers have turned towards subsidy and command-control models in an attempt to promote HIT adoption.

Mobile health and health care apps potentially avoid these problems. They posit inexpensive care pulled by patients only when needed and delivered away from inconvenient, centralized locations. Obviously, many mobile health apps will be developed with regard to existing health care relationships, offering improved condition management particularly for chronic diseases. Many of those apps will be subject to existing regulatory models. However, the most disruptive mobile health apps are those that are patient-facing. Those create a direct app-patient "relationship" that lacks professional intermediation and, as a result, traditional regulation of safety, quality, and confidentiality.

The regulatory framework for most of these apps is complicated and in some cases troubling. Here, the oversimplified binary of regulation versus innovation is a poor frame. Rather, we have a current technological space that is subject to both over-regulation and under-regulation.

For present purposes I restrict my comments to three issues, safety, effectiveness, and data protection. First, the Food & Drug Administration has used a sub-regulatory guidance to signal a light touch regarding most categories of apps. However, patient diagnosis and treatment recommending apps that arguably could be useful and stimulate innovation typically remain subject to traditional device regulation. Arguably this approach frightens off responsible innovators while the FDA lacks the bandwidth to deal with the many industry minnows selling apps that cross the regulatory line. Such a state suggests that additional regulatory clarity is required together with some innovative regulatory model that is more attuned to the rapid iteration of the mobile industry.

Second, there is the question of app efficacy or effectiveness. Even if they are safe, many health apps are simply ineffective. The structure of the app market and the absence of effective infomediaries creates immense problems for consumers looking for quality apps, creating doubts as to whether the market will function effectively. This is a classic consumer protection problem and, in my opinion, the Federal Trade Commission has taken the correct approach in

demanding competent and reliable scientific evidence in app cases involving, for example, claims of melanoma detection and vision improvement. Sufficient regulatory resources must be deployed in this endeavor lest innovative apps are drowned out by mobile health "snake oil."

Third, data protection. This is an area of acute under-regulation. Most patient-facing apps exist in a "HIPAA-free" zone, subject to a small number of state laws and, in the most egregious cases, by the FTC's "unfairness" jurisdiction. Here, our flawed sectoral, downstream approaches to data protection are on full display.

This country has enjoyed a deep-rooted cultural expectation of and professional commitment to health privacy, no doubt in part because healthcare data seems particularly susceptible to discriminatory and other harmful uses. Every day doctors rightfully reassure their patients as to the legally-enforced confidentiality of the information they share while their offices distribute required privacy notices. However, the same or similar data collected on mobile devices lack these protections. Most mobile health apps (particularly the more disruptive, patient-facing examples) are not subject to the HIPAA privacy and security rules leaving patient wellness and health data woefully unprotected. In my opinion federal data protection law that obviates the gaps between our commercial sectors and protects health information wherever it happens to reside is overdue and a necessary precondition for the full embrace of disruptive health apps by both medical professionals and consumers.

Again, I express my thanks to the Committee for permitting me to raise these issues.

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Mr. BURGESS. The chair thanks the gentleman.

The gentleman yields back.

Dr. Patterson, we will come to you finally. Are we good?

Dr. PATTERSON. I hope so, sir.

Mr. BURGESS. I hope so too. Very well. You are recognized for 5 minutes. Regardless of whether the technology works, we are happy you are here and look forward to what you have to say.

STATEMENT OF MATT PATTERSON, M.D.

Dr. PATTERSON. Chairman Burgess, Ranking Member Schakowsky, and members of the subcommittee, thank you for the opportunity to be here with you.

I am excited to hopefully show a glimpse of the software that my firm, AirStrip, creates because I think that that is the best way to really demonstrate the opportunity for mobile health to improve healthcare outcomes as well as to set the platform to talk about some of the challenges.

So, as a United States Navy physician, I got my first taste of the value of mobile technology in remote care. I left clinical practice to devote my career toward the improvement of healthcare access, quality, and cost efficiency at scale in the United States. Before I joined AirStrip, I consulted with major U.S. health firms around the country as they transitioned from fee-for-service based reimbursement to value-based reimbursement. And I saw firsthand that, after waves of cost-cutting, they finally realized that the only way to really move the needle further and get further gains is to bring about broad transformation in healthcare delivery, and that is shifting high-quality care to lower cost settings, using all the resources. So now, as president of AirStrip, I feel very fortunate to be creating solutions to address that challenge.

I would like to show you what AirStrip created with the following scenario. So imagine I am a doctor, and I am in a value-based care program like the Medicare Shared Savings Program. I get a call from a patient from the call center on a patient, who was discharged 2 weeks ago with heart failure, now feeling short of breath at home and wondering what to do. The primary care doctor is a colleague, but let's say I don't know the patient very well. I get a name and phone number from the call service and that is it.

So when I was in this situation as a doctor, I would try desperately to create some kind of objective context before I made that phone call. But, since that was usually impossible, most of those phone calls ended with: You should go to the emergency department.

Today, we must do better. We must prevent avoidable escalations in care while improving outcomes, and we need the right tools to do that. So, hopefully, if all goes well, I can show you that.

The eagle has landed. OK. So I would, of course, have to authenticate and log in, either with biometrics or a password, but once I am in and I find my patient, I get, in near real time, a longitudinal view of this patient's data, multiple tiles populating on the fly from multiple disparate sources of information.

So, if this patient had home monitors, I would be able to pull up home monitoring data, see trended vital signs, like weight and blood pressure, since the patient was discharged. Since I don't

know the patient that well, I could then view documents that were logged by their primary care doctor. And since the patient was just recently discharged from the hospital, I could also take a look at a different electronic medical record note that came from the hospital setting.

So, right there, with 10 seconds and three clicks, I can do what was previously impossible for doctors. I mean, I can't explain the revelation that doctors have of being able to go to one place and not have to log in 20 different times in order to view this data.

We can also accommodate FDA-regulated medical devices. In fact, we were pioneering the first medical software to be a Class II regulated medical device. So I can view at 12G ECG on this patient if they had a body sensor monitoring them at home, and I can view that side by side with an electrocardiogram that was done perhaps in the hospital. And the level of fidelity that I can pull up in real time using pinch and zoom and normal gestures that we all use on our smart devices, I can see very, very minute detail.

Let's say that I wanted to get a quick opinion from a cardiologist about this patient. I could send a HIPAA-compliant secure text to another doctor, and I could share in real time where I was in this exact link to this electrocardiogram. So text-based asynchronous work flows are the norm now in health care. It has totally replaced phone calls in many circumstances.

So, as a recipient cardiologist, when I get this, I can then explore other places in the work flow, to include looking at other monitors that may be hooked up to the patient—in this case a cardiac monitor—that I can search through, or I can even look as if I am standing at the bedside in near real time, wherever I am, wherever the patient is, across the continuum of care.

So, with a view like this, when I have all of the data in one place, it is much easier for me to come to a conclusion to tell this patient "you should come to my office, and I can see you immediately right now" or "come tomorrow morning," and I will feel a lot more confident about that if that is the right decision.

So if we are going to do anything when it comes to helping clinicians in a value-based reimbursement climate, we have to address work flow improvement. And by "work flow," I mean, the way that people interact with data on devices. It is the clicks they have. It is the swipes of the screen that they do. And I think that that is the thing that is making the biggest difference in mobile health technology on the provider side and the physician side, is making it easier for them to interact with that data.

I describe several challenges in my written testimony, but very, very briefly, I think mobile help applications require true interoperability with existing data sources. So, in technical terms, we need open, bidirectional, complete, and affordable outpatient programming interfaces. And the technology already exists to do that today. We don't need future standards.

Interoperability enforcement can be strengthened through seamless grant and incentive structures. On the regulatory front, there is an opportunity to improve and clarify mobile health technology classification by the FDA and to expedite real-time communication on submissions for innovative solutions that may not fit in previous categories.

Finally, updating telehealth definitions for HIPAA and other policies to reflect the current state of technology offerings would be very welcome.

Thank you again for the opportunity. I apologize for taking a little bit of extra time, but I appreciate the opportunity to show our software to you.

[The prepared statement of Dr. Patterson follows:]

Prepared statement of:

Matthew Patterson, MD

President, AirStrip

AirStrip as pioneer - the promise and challenge of mobile healthcare application innovation

Before the 114th Congress of the United States

House of Representatives

Energy and Commerce Committee

Subcommittee on Commerce, Manufacturing, and Trade

July 13, 2016

Summary

Chairman Burgess, Ranking Member Schakowsky, and members of the Subcommittee, thank you for the opportunity to share this testimony and appear before you to discuss the promise of mobile health application innovation and what challenges its realization. My goals today are threefold:

1. Share AirStrip's story as an illustration of how mobile health applications can disrupt and improve healthcare delivery,
2. Describe the trade, policy, and regulatory challenges faced by mobile health application developers, and
3. Suggest ways our government can foster an environment for mobile health application innovators to create solutions that will improve healthcare delivery and outcomes

The landscape for mobile health applications

The challenges we face to deliver high quality, affordable, and accessible healthcare are well documented so I will provide only brief context before sharing AirStrip's story. Health systems and physicians face complex reimbursement models and payments increasingly aligned to value as opposed to fee for service. After waves of traditional cost cutting to preserve financial margins, providers realize that remaining gains can only be achieved through care transformation – shifting quality care to lower cost settings using novel human and technological resources. Connected health technologies like AirStrip demonstrate that innovative solutions can reduce costs and improve care quality and engagement. Healthcare must and will look significantly different going forward.

AirStrip engages with stakeholders across medical and technology communities to improve healthcare. We participate in ACT | The App Association's Connected Health Initiative (CHI),[1] a key effort to collaborate with the connected health ecosystem to identify outdated health regulations, incentivize the use of advanced technological solutions, and ensure patients and consumers can see improvement in their health. Recently, the CHI provided comments to the Center for Medicare and Medicaid Services (CMS) to inform the implementation of the Medicare Access and CHIP Reauthorization Act of 2015 by establishing the Merit-based

[1] *See* http://connectedhi.com.

Incentive Payment System (MIPS) for MIPS-eligible clinicians or groups under the Physician Fee Schedule as well as incentives for participation in certain alternative payment models (APMs).[2]

As a physician serving in the U.S. Navy, I got my first taste of digital and mobile technology in healthcare. I served with the submarine community at Naval Submarine Base New London, the SEAL community at Naval Special Warfare Center, and the broader Navy community at Naval Medical Center San Diego. To provide consultation to remote settings we relied on digital technology ranging from simple email communication to the use of complex body sensors and scopes to transmit high-resolution diagnostic video images. We practiced what is commonly referred to as "telehealth" – a term that is often associated with real-time videoconferencing interaction between physicians and patients. In contrast, mobile health applications or "apps" are frequently discussed in the realm of mobile health or "mHealth." This term often evokes imagery of consumer oriented wearable devices or smart phone applications used to promote well-being independent of healthcare provider supervision.

For this testimony and discussion on mobile health applications, terms like "telehealth" or "mHealth" or "apps" reveal imperfections because innovation moves faster than classification can keep up. This is particularly relevant in the challenges that innovators face in the policy and regulatory landscape. The AirStrip story will illustrate this clearly, highlighting one of the most important things that mobile health applications can deliver: an optimal

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[2] *See* Comments of the Connected Health Initiative regarding CMS' Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (CMS-5517-P), filed June 27, 2016, available at https://www.regulations.gov/document?D=CMS-2016-0060-3058.

workflow for busy, information overloaded clinicians doing the best they can to care for others. Clinicians and consumers desire flexibility in how they interact with each other and with data. Sometimes it is best for real-time communication like traditional telehealth, but the preferred mode of communication is often "asynchronous" interactions through mobile applications, just like people prefer text messaging rather than phone calls in many cases.

Workflow optimization is the principal promise of mobile health applications, and it requires true interoperability and regulatory accommodation to succeed. What is workflow? It is easiest to describe as the "way" one interacts with information on a digital device to arrive at a conclusion, to make decisions, and to take action. It is the buttons pushed, the swipes of the screen, and the text entered. As consumers we take for granted the vast array of elegant, simple to use applications that allow us to shop, bank, and be entertained via intuitive workflows. In healthcare, workflows are rarely described in positive terms and are a frequent source of frustration for doctors, nurses, and patients.[3] Mobile health application innovation has the ability to address this and thereby improve healthcare delivery and outcomes, but only with improvements in the interoperability and regulatory landscape.

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[3] Recent research has explored why certain technologies or systems, such as electronic health record products and services, intended to make providing healthcare easier instead make patient encounters more cumbersome and inefficient. See, *e.g.*, Holman *et al*, *The myth of standardized workflow in primary care*, Journal of the American Medical Informatics Association, DOI: http://dx.doi.org/10.1093/jamia/ocv107 (published Sept 2, 2015).

The AirStrip story – disrupting and improving healthcare delivery

AirStrip, which started more than 10 years ago with a chance meeting between a software engineer and an obstetrician in a church parking lot in San Antonio, TX, is today a recognized leader in mobile healthcare innovation. AirStrip software is deployed at hundreds of U.S. hospitals and used by thousands of clinicians for millions of patient encounters annually. The company was the first to create mobile health application software cleared by the FDA as a Class II medical device. AirStrip also pioneered advanced security in mobile health such as multi-factor authentication, at one point even achieving Department of Defense Information Assurance Certification Accreditation Process (DIACAP) certification - the highest level of certification for mobile medical device solutions we could identify at the time.

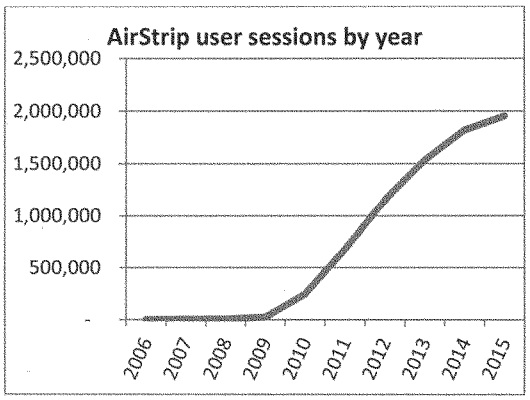

Figure 1 – AirStrip utilization

From the beginning, the core innovation and disruption that AirStrip brought to the market was to be agnostic when connecting to clinical data sources and when displaying information on disparate devices. In other words, AirStrip provided a way that a clinician could use any smart device they wanted to connect to any vendor system anytime, anywhere. While today the concepts of mobility and interoperability are touted by health IT solutions, this was highly disruptive at the time and essentially created mobile application care delivery models.

AirStrip began with solutions for obstetric care. Even before smartphones, AirStrip allowed doctors who were away from the hospital to view waveforms of fetal heart rate and maternal contractions on their portable devices. Prior to AirStrip, nurses had to describe over the phone highly visual and nuanced waveform data that evolved over long periods of time. With AirStrip, it was as if physicians and nurses were standing side by side at the bedside, no matter where the physician was. In Figure 2, you see an example of a mobile application providing both near real time as well as asynchronous capabilities that defies traditional classification of telehealth or remote monitoring. In a practical sense, it allowed physicians to expedite decisions and attend to life-threatening events during labor in ways that were previously impossible. It was recognized as clearly benefiting patient outcomes for mothers and newborns, safety, and clinician efficiency. This obvious use case of technology is essentially becoming the standard of care in obstetrics. AirStrip software is used on over 20% of annual births in the United States and has been used during over 4 million births to date.

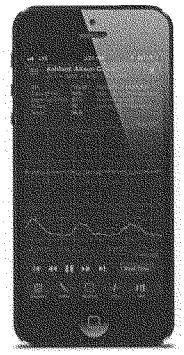

Figure 2 - Screenshot of AirStrip obstetrics functionality

Success in obstetrics led AirStrip to develop cardiovascular solutions to display static and dynamic electrocardiogram (EKG) and other monitoring waveforms. This allowed AirStrip to address prevalent and costly conditions such as myocardial infarction (heart attack), congestive heart failure (CHF), and dysrhythmias. For example, AirStrip pioneered the ability to send a digital EKG directly from an ambulance to a cardiologist's smart device before the patient even arrived to the hospital. This allowed for the activation of the cath lab and an expedited "door to balloon time" – the critical metric of how quickly hospitals get a heart attack patient from arrival to the deployment of an angioplasty balloon in their obstructed artery. Though national benchmarks of 90 minutes or less are standard of care, public accounts of the use of AirStrip reported times as low as 18 minutes. There is overwhelming evidence that shorter times lead to less cardiac damage, greater survival, and lower costs.

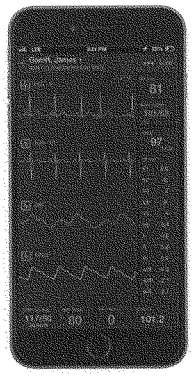

Figure 3 - Screenshot of AirStrip patient monitoring functionality

Given the success of waveform related solutions and feedback from clients, in 2014 AirStrip released AirStrip ONE. AirStrip ONE is a mobile interoperability software platform that enables care coordination and serves as a catalyst for health system innovation. Plainly, AirStrip ONE allows a clinician to log in to one application and view relevant information on their patient from essentially any clinical data source anytime, anywhere – no matter where they are and no matter where their patient is. Though seemingly an obvious solution for healthcare, it is difficult to explain the massive disruption this solution represented when introduced. Instead of creating a mobile app exclusively linked to a specific branded data source like a monitor or an electronic medical record, AirStrip ONE represented the first solution to focus exclusively on creating the optimal workflow for clinicians. No matter what systems were capturing data on patients (FDA regulated or not), and no matter what device a clinician wanted to use, we would bring everything to their fingertips in one place in near real time.

Figure 4 - Screenshot of AirStrip ONE

While the potential uses of AirStrip now span all clinical domains, what is most exciting is how our software can enable the necessary shift of healthcare delivery to lower acuity and increasingly out of hospital settings. Doctors are managing large populations of individuals with significant chronic disease burdens. They are being tasked with producing better outcomes at lower costs and this is only possible with the appropriate tools.

For example, consider a doctor called after hours about a Medicare patient who was recently discharged from a hospital after a CHF exacerbation, is feeling short of breath, and is wondering what to do. Whether in an accountable care organization (ACO) or another "at-risk" financial model or not, an avoidable readmission for this patient would be both medically and financially unacceptable in today's climate. If this doctor is being asked to do whatever they can

to prevent an avoidable readmission, then this doctor deserves to have any data point they need at their fingertips instantaneously. He or she should be able to see medical record data from disparate sources (e.g. different systems deployed for hospitals vs. office) or remote monitoring data from body sensors deployed in the patient's home – all displayed in a simple, intuitive workflow that would lead to the best decision possible. Not only does the doctor deserve this kind of access, but the patient, in other words all of us, expects his or her doctor to have immediate access to all of our relevant medical information to make the most informed decision possible. As obvious and necessary as a solution like this may sound given the economic realities of healthcare in the United States, this simply did not exist in the world we released AirStrip ONE to. The challenges we encountered revealed many of the reasons why.

Challenges to healthcare mobile application innovation and deployment

Though the previous section was focused specifically on AirStrip's story, the challenges presented here are intentionally not unique to AirStrip and resonate among fellow innovators in mobile health application development. While certainly not exhaustive, the focus here is on two themes highly relevant to this subcommittee. The first involves the intersection of health information technology (HIT) policy and trade practice realities. The second relates to the intersection of Food and Drug Administration (FDA) regulation and technology innovation.

Initially, I'd like to note that a consistently growing body of evidence demonstrates that the wide array of connected health technologies available today – whether called "telehealth,"

"mHealth," "store and forward," "remote patient monitoring," or other similar terms – improves patient care, reduces hospitalizations, helps avoid complications, and improves patient engagement, particularly for the chronically ill.[4] Importantly, a literature review from the Department of Health and Human Services' Agency for Health Research Quality recently validated this.[5] These tools, ranging from wireless health products, mobile medical device data systems, telehealth screening and preventive services, converged medical devices, and cloud-based patient portals (to name a few) are revolutionizing the medical care industry by allowing the incorporation of patient-generated health data (PGHD) into the continuum of care. To illustrate the effectiveness of these diverse solutions, we have appended to this comment a non-exclusive list of studies we strongly urge CMS to review.

Interoperability is frequently mentioned, poorly defined, poorly understood, and yet remains a principal obstacle to mobile health application development. What is needed most is an open landscape for systems to talk to each other in a manner that gives clinicians and consumers the information they need in near real time so they can make the right decisions. In technical terms, what are needed are open, bidirectional, complete, and affordable application programming interfaces (APIs). Though these solutions are available today and tremendous efforts have been taken to bring about adoption of standards that address the interoperability

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[4] See Hindricks, et al., The Lancet, Volume 384, Issue 9943, Pages 583 - 590, 16 August 2014 doi:10.1016/S0140-6736(14)61176-4. See also U.S. Agency for Healthcare Research and Quality (AHRQ) Service Delivery Innovation Profile, Care Coordinators Remotely Monitor Chronically Ill Veterans via Messaging Device, Leading to Lower Inpatient Utilization and Costs (last updated Feb. 6, 2013), available at http://www.innovations.ahrq.gov/content.aspx?id=3006.

[5] Agency for Healthcare Research and Quality, *Technical Brief Number 26, Telehealth: Mapping the Evidence for Patient Outcomes From Systematic Reviews*, AHRQ Publication No. 16-EHC034-EF (June 2016.

challenge, serious issues remain. The sad truth is that the technology already exists to address this challenge. Unfortunately, financial distortions were introduced by otherwise well-intentioned policies that created disincentives for HIT firms to allow for the free sharing of data.

The Health Information Technology for Economic and Clinical Health (HITECH) Act enacted in 2009 created significant incentives for the rapid deployment and "meaningful use" of electronic health record (EHR) solutions. The initial goals of meaningful use were well intentioned (Stage 1 – data aggregation & data access; Stage 2 – healthcare information exchange and care coordination; and Stage 3 – outcomes improvement). While Stage 3 introduced measures for incorporating patient-generated health data into the EHR system, the interoperability aspects of the first stage were not enforced as much as needed to achieve later outcomes improvement. Instead, the effort was directed to the implementation of EHRs for data entry, which created silos around few vendors who subsequently protected their market position. Then, the consolidation and collaboration of healthcare providers that resulted from the Affordable Care Act (ACA) exposed even further the necessity and lack of interoperability. Health systems were faced with government and commercial reimbursement models that demanded interoperability but had no choice to proceed down a roll out of data system silos and vendors reluctant to make data sharing easy.

Data blocking is real. It can take political, financial, and technical forms. Politically, it happens when large HIT firms put pressure on health system clients to shun innovative firms or else risk the deployment timeline of critical systems such as HITECH Act meaningful use

incentivized functionality. Financially it occurs when HIT firms demand exorbitant fees to allow data to be shared with third party workflow solutions. Technically it occurs when HIT firms deliberately turn off functionality that would allow bidirectional sharing of data because it threatens their underlying business model. I understand that this Committee has been looking into this issue, but I would re-iterate that time is of the essence. Enabling true interoperability represents the single most important thing that can be addressed to unleash the power of innovation for mobile health applications.

As we move from the "essential" to the merely urgent, we see physicians and hospital systems confronting uncertainty on other fronts as well. For example, the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules provide a set of minimum standards for protecting electronic protected health information that a covered entity and business associate create, receive, maintain, or transmit.[6] The concerns addressed by these laws are taken seriously by AirStrip, and we implemented processes and measures to ensure we meet the letter and spirit of the law through such means as strong encryption. However, some of the relevant HIPAA guidance applicable to mobile apps has not been updated since before the introduction of the iPhone. This persistent lack of clarity around HIPAA applicability in a mobile environment (for example, the use of texting or storing data in the cloud) prevents many patients from benefiting from these services. As a result, clear guidance does not exist to explain how physicians and patients can text or email each other appropriately. Similar to

[6] 45 CFR Part 160; 45 CFR Part 164 Subparts A and C.

interoperability, this is a problem more with policy than technology – if hospitals aren't sure what the rules are, they will not use technology no matter how well it works.

There is some hope on HIPAA: through efforts such as ACT | The App Association's Connected Health Initiative, we have worked with Congress to attain a direct public commitment from Department of Health and Human Services (HHS) Secretary Burwell to provide much-needed clarity.[7] But progress has been slow, and even positive efforts are stymied by an HHS website that is very difficult to navigate.

AirStrip has and always will be a strong proponent of thoughtful FDA regulation on mobile healthcare applications and appreciates ongoing dialogue on how best to evolve the regulatory landscape to support innovation. We maintain that all mobile software applications displaying near real time medical device and body sensor data and waveforms need careful oversight – even for software only solutions. Though our path to FDA clearance was long it resulted in a better and more differentiated solution for the market. In addition, any solution that aggregates data or analytics powered insights that directly guide a decision-making clinician such as a physician to come to a conclusion on what is best for a patient (i.e. clinical decision support) requires FDA oversight. The FDA's current risk-based framework, as outlined in the September 2013 guidance, appears to be a functionally sound approach, though there are continuing challenges with an FDA trying to modernize its approach.

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[7] Letter from ACT | The App Association, et al., to Reps. Tom Marino and Peter DeFazio, U.S. House of Representatives (September 15, 2014).

The challenges on the FDA regulatory front emerge from the predictable predicament of innovation outpacing regulation. Specifically, there is a risk that innovative solutions not fitting an existing FDA classification or not matching the functionality of the predicate device(s) that must be identified when submitting for clearance, get pushed by the FDA toward a pre-existing best-fit classification. This can result in the FDA indirectly determining a technology firm's development roadmap instead of what should be the opposite. For example, consider a situation where a firm develops the ability to detect important changes in a patient's condition being monitored at home through a body sensor. If the FDA can only best classify this as an alarm solution, it may apply requirements that are only relevant for hospital situations because that is the closest best-fit classification it has to consider the new solution. As a result, the firm applying for clearance may be faced with a hopeless path of engineering "hospital-like" features to its solution even though everything in the world of healthcare is pushing that firm to create something that can solve problems outside of the hospital.

Suggestions for fostering an environment for mobile health application innovation

Given the pervasive nature of mobile technology broadly, hopefully similar approaches will flourish in healthcare. I humbly offer suggestions to foster this path.

1. **Enforce interoperability** – HHS and more specifically the Office of the National Coordinator (ONC) for Health Information Technology have an opportunity to focus on

and enforce meaningful interoperability as opposed to pushing a future standards-based agenda that will not meet the needs of the market today. Specifically, there is messaging that the third stage of meaningful use (requiring portability of data to consumer facing applications) will address interoperability challenges but this is not completely thought through. Creating consumer-facing applications that allow patients to assimilate all of their healthcare data will not be enough to solve the workflow challenges of those who care for them. When a patient shows up to an emergency department as part of an ACO and all incentives are aligned on preventing an avoidable admission of that patient to the hospital, the emergency room doctor needs a solution that works for them. Consumer facing applications will absolutely fall flat in this setting. As a minimal initial step, HHS should promote true interoperability via open, affordable, complete, bidirectional application programming interfaces by withholding incentives and innovation grant funding for any applicants who are not using vendors that comply.

2. **Create a "hot-line" between innovators, health systems, and the FDA** – The greatest benefit of having a long history of clearance with the FDA when it comes to mobile health applications is the opportunity for dialogue. Innovation will always outpace classification and regulation. Therefore, real-time dialogue is essential to expedite classification and clearance. As stated previously, careful regulation is essential for mobile health applications that are in the realm of near real time monitoring and clinical decision support. That said, innovation by definition will blur all lines and therefore expanded resources are needed at the FDA for thoughtful dialogue, problem solving,

and co-navigation to clearance. The FDA should be viewed as an innovation and safety partner and not an obstacle.

3. **Help clarify the markets of "consumer driven" and "health system driven" mobile health applications** – There is great confusion about what mobile health means. To some, it involves consumer oriented body sensors and applications focused on fitness and wellness in the absence of clinician supervision. To others, it involves FDA regulated body sensors and applications involved in the remote delivery of healthcare. The former market is important and will be consumer directed and paid for. This forms the leaves of the health care delivery tree. The latter market is equally important and will be directed and paid for by providers, payers, and joint collaboration risk-bearing entities like ACOs. This is the trunk of the tree. Different policy and regulatory standards are likely appropriate and should be clarified broadly for those innovating in the marketplace. As a threshold issue for subsidized medicine, CMS cannot continue to rely on Medicare's over 15-year-old definitional restraints on "telehealth" in 42 CFR 410.78 to serve as a definition of telehealth. To shift to a value-driven approach, the Medicare system must leverage the wide array of advanced connected health technology solutions available today, as well as future innovations we cannot predict, by evolving its telehealth definition to one that takes a technologically-neutral approach to the use of connected health and provides the flexibility for eligible practitioners to appropriately utilize the range of these solutions, lowering costs to Medicare while vastly improving patient care.

4. **Incentivize and fund efforts to prove value** – The traditional method of randomized controlled clinical trials, or the FDA investigational device process, to prove efficacy are extremely difficult to apply to the fast paced world of mobile health application innovation. Innovators would benefit from dialogue with government and health system partners on how best to demonstrate value so that appropriate, fast paced initiatives can be funded and publicized for others to learn about clinical and operational benefits of mobile health application technology.

5. **Feed the pipeline of software developers** – Any efforts to promote the interest and education of future software developers in the realm of healthcare technology would be widely welcome.

In conclusion, mobile health technologies like those that Airstrip create incredible benefits to the American healthcare system, but their full potential can not be met without a careful and coordinated effort between Congress, federal agencies, and the industry as a whole. Without meaningful action to address important issues like interoperability, market clarity, agency efficiency, and the talent gap, we risk the quality of care physicians can provide patients. I thank you again for the opportunity to present testimony about Airstrip and our role in the mobile health ecosystem. I look forward to answering your questions, as well as continuing this important dialogue and offer my support to help advance measures that empower mobile health.

Mr. BURGESS. The chair thanks the gentleman.

So I want to thank all of our witnesses for their succinct presentations this morning.

Dr. Patterson, it was worth the wait to see your mobile device up on the big screen.

We are going to move to the question-and-answer portion of the hearing, and I would like to recognize the gentleman from New Jersey, Mr. Lance, to begin the questioning.

Five minutes, please.

Mr. LANCE. Thank you, Mr. Chairman.

And good morning to the panel.

To Ms. Johnson from J&J, the FDA issued mobile medical app guidance in 2015 to help stakeholders understand how the FDA plans to oversee healthcare apps that include medical device functionalities. In your judgment, is there a need for more regulatory clarity and certainty, particularly regarding the FDA's enforcement discretion for healthcare apps that do not operate as medical devices?

Ms. JOHNSON. Yes. We do support that legislative clarity is needed in this area.

Mr. LANCE. Is regulatory uncertainty affecting investment and innovation in the healthcare apps market, not only regarding J&J but based upon your experience across the entire field?

Ms. JOHNSON. At Johnson & Johnson, we are a very large company. We have very sophisticated regulatory departments and extensive law departments. And I think for us it is somewhat easier to navigate. Where we see the real struggle is with the smaller innovative app developers, the one-, two-, three-people companies that don't have access to the level of expertise. Their level of comfort with enforcement discretion and the investor's level of comfort with enforcement discretion is certainly, from my experience, quite a bit lower than it is with J&J. So I believe it is really impacting the small companies.

Mr. LANCE. Are there other distinguished members of the panel who would like to comment on that? What would you propose is the right level of FDA and FTC oversight over apps that don't meet the definition of a mobile medical app under the FDA's guidance but may have health- and medical-related components, Ms. Johnson?

Ms. JOHNSON. Well, the decision should be risk-based, as long as they don't—they are not performing functions that meet the definition. The current regulatory environment is positive, but we do believe that the patient privacy aspects need to be better addressed and a patient's ownership of the data and the ability of people to sell patient's data should be more transparent.

Mr. LANCE. And I think we are all of that view, that patients' privacy should be foremost, and certainly that is something on which we should be working here in Washington. And I started with you because J&J is a great New Jersey company, and much of J&J is in the district I have the honor of serving.

Dr. Patterson, from your perspective, what are the biggest legal and policy barriers preventing or obstructing the adoption of healthcare apps and other digital healthcare technologies for patients and for providers?

Dr. PATTERSON. I think some of the greatest challenges right now that we face on the policy and regulatory front have to do with both interoperability enforcement as well as to clarity from the FDA on classification of more innovative solutions.

So, briefly, on the second point—and it feeds on what you were just talking about—I think that we have to consider situations where a platform can accommodate both data that is in the sophisticated medical device, medical grade world of sensors as well as be able to accommodate consumer-based data in one place, because the combination of those two data elements can lead to some very, very insightful analytics and predictive insights about patient behavior and outcomes.

And so the concept that I would introduce is one of provenance, and provenance refers to knowing where a piece of data comes from. So getting clarity on data provenance and what the burden is of provenance, that when a consumer device or a medical device shares its data with something else, you know where that data element came from and what grade of data element that was.

Mr. LANCE. And is provenance an area where, working together, we have to do a better job?

Dr. PATTERSON. I would agree so, yes.

Mr. LANCE. Thank you.

I yield back 35 seconds, Mr. Chairman.

Mr. BURGESS. The admonition to do a better job is so noted and will be taken under advisement by the chair.

The chair recognizes the gentlelady from Illinois, Ms. Schakowsky, 5 minutes for questions, please.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

Thank you, panel.

There was an article this week in the New York Times that prescribed caution for consumers seeking medical advice from Web sites and apps instead of going directly to a doctor.

The study, conducted by doctors at the Mayo Clinic, tested the quality of medical advice provided by health Web sites, and the doctors found that, "going online for health advice was more likely to result in getting no advice or incomplete advice than the right advice."

Now, Dr. Ferris, you conducted a similar study of apps meant to detect skin cancer. As you said in your testimony, you had similar results to the Mayo Clinic study. It seems that false negatives are a particular concern with these apps. What happens if an app falsely tells a person that a mole is benign?

Dr. FERRIS. If an app falsely tells a person that their melanoma is benign and reassures them that they can save their time and money and not go see a physician, the consequence will be that that melanoma is going to progress. It is going to be deeper. And it goes from being what is, diagnosed early, a fairly surgically curable disease with a simple inexpensive procedure to a fatal cancer.

Ms. SCHAKOWSKY. And were the apps that you tested intended to be used with physicians, or were they meant for consumer use? I guess you called that, Mr. Terry, consumer-facing, is that what you said?

Mr. TERRY. Patient-facing.

Ms. SCHAKOWSKY [continuing]. Patient-facing apps and using that app instead of going to a doctor?

Dr. FERRIS. In our study, we tested four apps. And the first three that were automated were intended to be patient-facing, and they were not used in conjunction with a physician. So it was to give the patient an assessment of the risk of their lesion being skin cancer, and it would say, looks OK, green light, things like that, or it would say, red light, caution, get this looked out.

They all contain some sort of small disclaimer but really not significant or sufficient information about the risk of misdiagnosis. None of them had data saying how likely they were to be wrong or the risk of a false positive versus a false negative.

Ms. SCHAKOWSKY. And none of them made a suggestion that they go see a physician if they have further questions?

Dr. FERRIS. They generally somewhere in their warnings would say things like, you should see a physician if you have concerns. The problem is that that wasn't highlighted in the output that they gave, and they still gave medical advice, they still gave an assessment of that lesion.

Ms. SCHAKOWSKY. I am just wondering from the panel, should we be considering this in two different categories, those that deal with professional health providers and those that are just alone, patient-facing? Is there anyone who disagrees with that?

Dr. FERRIS. So that is, I think, a very important distinction.

So part of the reason—I have been interested in this idea of using technology to diagnosis skin cancer, and I think that there is potential that it can be helpful and safe.

As I mentioned, sort of, at the end of my statement, I am working on a technology with computer scientists at Carnegie Mellon in Pittsburgh where, you know, we are doing validation studies. We are trying to understand how we can use technology to better understand melanoma.

We have very promising early results. However, I would never put that out and make it available to my patients, because I feel that this is technology better used in the hands of a physician. We all know, all of us who are physicians up here know that sometimes your clinical judgment overrules what the tests that you ordered showed.

And so, really, I am a proponent of having really a little more flexibility and regulations that respect the decreased risk when there is additional information provided to a physician and it is really physician-to-physician communication that is being impacted or data being provided to a physician who ultimately communicates that back to the patient and helps to make a decision about the course of the treatment of that patient.

Ms. SCHAKOWSKY. Dr. Patterson, in the display that you had, the doctor that is looking at all the data is not the physician that the patient normally goes to. Is that true?

Dr. PATTERSON. It can be a situation where it is a primary physician, or it could be a colleague or another member of the care team.

Ms. SCHAKOWSKY. But on that care team.

Dr. PATTERSON. Correct.

Ms. SCHAKOWSKY. I see.

Again, is there anyone here who thinks that there ought not to be a distinction between those that are physician-driven, that are healthcare-provider-driven, and just the app?

Did you want to answer that?

Ms. JOHNSON. I think when we were working on the language around the SOFTWARE Act, we tried very hard to embody the concept that there is a big difference and that, if it is the patient trying to make a decision, that is a lot different than the physician. And the physician who is getting the information needs to understand the context around the information that they are receiving. And we do believe it makes a critical difference.

Ms. SCHAKOWSKY. OK.

Can Dr. Dorsey reply?

Dr. DORSEY. The FDA guidance is around regulating apps that are used to diagnosis or treat a condition, and I think that is great guidance. Apps that empower consumers to give them more information on how they are sleeping, how they are eating, how they are exercising, potential medication interactions, those are all very valuable.

I think the concern comes around when you are giving a diagnosis or a treatment recommendation. I think that would be the distinction that I would highlight.

Ms. SCHAKOWSKY. Right.

And that is your expertise, too, Mr. Terry. What did——

Mr. TERRY. I think, yes, the patient-facing-against-professional-facing differentiation is important. But, equally, I think, as this moves forward with the pace that it is showing, we may end up with additional categories, including some sort of hybrid categories.

I think it is also quite possible that we would want to get more granular and distinguish between some patient-facing apps and others. So, for example, the risk of a melanoma negative, a false negative, is such that we maybe wouldn't want that. But, on the other hand, personally, I would find it quite useful if my watch would tell me when I am about to have a myocardial infarction and tell my car to pull over and also phone my spouse and tell her I am going to be late for dinner.

Ms. SCHAKOWSKY. Thank you.

Dr. EXPERTON. If I may add a point on this, Mr. Chairman, yes, those patient-facing mobile apps can also be extremely important in the physician-patient communication.

We discussed, you know, how we want to avoid medical harm. Today, in America, the third-leading cause of deaths are medical errors. About one-fourth of them are caused by the fact that, at any given point in time, a physician doesn't have the full picture of the history of that patient.

So when a patient comes with a medical app which provides the key information that a physician needs to properly diagnosis and treat, we can address a dramatic public health issue. And so, with those apps, we are talking about enhancing the physician-patient communication, and then the patient provides that information the physician is seeking, which often lacks when that Medicare beneficiary comes alone or with a family caregiver and comes a critical question from that physician: What medication do you take?

And oftentimes it can be half a dozen of those. And at one point that patient may say, "I take a pink pill, but I don't remember the name of it." Then comes the additional prescription which can interfere with that list of multiple medications that Medicare beneficiary is taking.

So those are the situations of life-and-death scenario, where more harm is being done with a lack of information. And arming the patient with tool to enhance their memory, to provide their physician with a list of medication which the physician can see, provided from that Medicare source it can trust, is lifesaving. So I would put that category of applications, of patient-facing applications, a hybrid indeed application, they are of critical use for the physician.

I am a former adjunct professor of medicine at University of California, San Diego. I am a former public health officer; I am a data scientist. And, at one point, it came to me that a commonsense approach to the lack of information we have is to outfit patients with the critical information they need to present to their physician. Because we are still in a very fragmented healthcare system. We spend $35 million in the HITECH Act. The patient has to be part of that story to communicate information that their physician needs.

Ms. SCHAKOWSKY. Thank you for your indulgence, Mr. Chairman.

And thank you, panelists.

Mr. BURGESS. Absolutely. You will pay for it later.

The chair would like to recognize the gentleman from Mississippi, Mr. Harper, 5 minutes for questions, please.

Mr. HARPER. Thank you, Mr. Chairman.

And thanks to each of you for being here. This is such an important topic for our future and for today.

Ms. Johnson, the Center for Telehealth at the University of Mississippi Medical Center in Jackson, Mississippi, is a leader in providing health care using telemedicine, especially to underserved populations.

How do telemedicine and other mobile health technologies, including healthcare apps, affect patient engagement in the healthcare system? And what does this mean for the accessibility, affordability, and delivery of care?

Ms. JOHNSON. Well, certainly, as the healthcare system as a whole becomes more interoperable and data-sharing is possible across the entire healthcare system and patients have access to all of their information, the patients will become more engaged. As the patients become more engaged, we believe this will help reduce healthcare costs, help them make more cost-conscious decisions.

So, really, as the whole ecosystem grows to be as one and the patients have access to their data, we do think it will change the way the healthcare system operates.

Mr. HARPER. Thank you.

Dr. Dorsey, in your testimony, you talk about Medicare's limited coverage of telehealth. How is Medicare's current reimbursement scheme impacting clinicians' adoption of telehealth and other mobile health technologies? Tell us your opinion on how that is working.

Dr. DORSEY. Congressman Harper, thank you very much for the question. Thank you very much for your advocacy for telehealth.

It really impacts patients. So, as I mentioned, 40 percent of Medicare beneficiaries with Parkinson's disease don't see a neurologist. And that happens in Mississippi, that happens in Texas, that happens in Nevada, and it even happens in New York City. And the reason they can't access it is because they are either an outsider—all of us in this room are healthcare insiders and we can readily access care, but many people can't because of distance or disability. And, increasingly, we ask people who are disabled, have limited mobility and impaired driving ability, to drive to urban centers to receive care. We have it backwards. We should be providing care to individuals on their terms, in their environments, and not in institutions.

And Medicare, which increasingly stands alone in its limited coverage of telehealth, is limiting access to care for Medicare beneficiaries, including 2 million homebound Medicare beneficiaries who can't access care increasingly, except by either physicians and clinicians visiting them or through telehealth.

Mr. HARPER. OK. So is there a role from Congress in addressing this issue?

Dr. DORSEY. Absolutely. The VA covers telehealth, and 2 million telehealth visits were conducted last year. Increasing reimbursement for telehealth would be an outstanding start, including coverage of telehealth provided into the home, where it is most beneficial, most convenient, and most centered on the needs of patients.

Medicare could stop incenting institution-based care by providing higher incentives to institutions for the same visits that could be conducted remotely that are centered on the needs of patients.

Mr. HARPER. Thank you, Dr. Dorsey.

Ms. Johnson, do you have specific examples of how your mobile healthcare technologies or these technologies generally have shown demonstrable changes in patients' health status or in improved patient health outcomes?

Ms. JOHNSON. Well, I can't say that there is published statistically significant data available, but, certainly, with the diabetes care solutions, in particular, we do see, generally speaking, the appearance of less excursions of blood sugar, you know, being too high and too low.

There is certainly literature to support that sort of improved control leads to a reduction in complications from the diabetes. But there is no published data to support that. But, certainly, with the diabetes, we see better control.

Mr. HARPER. Thank you very much.

And, Dr. Dorsey, the Congressional Budget Office, CBO, has raised concerns that expanding telehealth and remote patient monitoring, or RPM, services within Medicare will be costly to implement and sustain. The CBO scoring does not look at longer-term cost savings that could result from a healthier Medicare patient population.

Could you share any insight on those cost savings that telehealth and RPM services have provided in other settings and how that might impact Medicare in the future?

Dr. DORSEY. There is tremendous empirical evidence to get around this concern that increased reimbursement will lead to higher cost. Increased reimbursement will lead to increased utiliza-

tion of services, but in the grand scheme of things, physician visits at $70 a visit are much less expensive than $1,000 emergency room visits and $17,000 hip replacements.

The VA uses telehealth. They are under a fixed budget, and they view it as a cost-effective solution for providing patient-centered care to military veterans.

Kaiser Permanente this year will have more virtual visits, in the form of phone, e-mail, video, than in-person visits. They are under a capitated environment, and they obviously view this as a means for enhancing care at lower cost.

Bills like the Medicare Telehealth Parity Act are a step in that direction, and we are just scratching the surface of what is possible. Our chief areas right now are Medicare's limited reimbursement and our arcane licensure laws.

Mr. HARPER. Thank you, Dr. Dorsey.

And thanks to each witness for being here and sharing your testimonies with us.

And I yield back.

Mr. BURGESS. The gentleman yields back. The chair thanks the gentleman.

The chair recognizes the gentlelady from New York, Ms. Clarke, 5 minutes for questions, please.

Ms. CLARKE. I thank you, Mr. Chairman and our ranking member.

I thank our experts for your testimony here today. It has been extremely edifying and certainly has raised a number of issues that I think we are all going to have to grapple with. It is something that I believe will advance us if done correctly. And I thank you once again for your testimony here today.

Professor Terry, in your testimony, you mention that many apps are operating in a HIPAA-free zone. It is my understanding that, when HIPAA does not apply, the apps may be subject to FTC oversight. Is that correct?

Mr. TERRY. That is correct. The FTC has some general oversight with regard to unfairness that could apply and has been applied outside of the app space to security violations, for example, by businesses. However, the FTC's jurisdiction is very broad and therefore tends not to provide a lot of guidance for industry as a result, or certainty. And, of course, you have a major resource problem with regard to enforcement from that angle.

Ms. CLARKE. And I was going to go directly to that. The FTC is an enforcement-only regime when it comes to privacy. So is it the case that the FTC's privacy-related enforcement actions mostly have focused on companies' failure to comply with their own privacy policies?

Mr. TERRY. That is correct. And, as you point out, Congresswoman, it is an ex post facto regulation.

Ms. CLARKE. Right.

Mr. TERRY. The FTC has stated in a recent case that its jurisdiction does extend into the healthcare space as it tries to sort of break down one of the gaps between our privacy sectors. But there is a lot more that could be done, I think, in that way.

Ms. CLARKE. Absolutely.

Professor Terry, if a health app that is not covered by HIPAA does not have a privacy policy at all or if the privacy policy permits the app to share or sell information, is there anything that prevents that company from selling or sharing personal information it collects?

Mr. TERRY. It is very difficult to find any clear answer "yes" to that. Generally speaking, those apps are just going to be unregulated.

Now, obviously, some jurisdictions, some states, like California, have state laws that require a privacy policy. If you are using the care framework or the health framework or the health kit framework from Apple, then the Apple store requires you to have a privacy policy.

But the people that would comply with that are not our problem. It is the ones that don't comply with that that are the——

Ms. CLARKE. And, certainly, when we all are talking about portability in health care as well, if you are in California, great, but if you move someplace else, quality control becomes an issue, right?

How have the app developers, as relative newcomers to the technology space, affected data security practices in the industry?

Mr. TERRY. Well, again, I think you have to recognize, particularly my copanelists, when we are looking at extremely responsible companies with lots of lawyers and lots of risk managers who are doing fine things. But our main concern is going to be the apps that are out there that simply have inadequate security. And there have been studies showing that that is the case.

There have been studies shown, for example, in Canada that most wearable devices give off persistent tracking signals, creating privacy and security issues. And an English study showed that there were major security flaws even with apps that have been approved by the National Health Service for use there.

Ms. CLARKE. So how can we ensure that new companies are up to speed and know what they are doing with respect to data security before their products reach consumers?

Mr. TERRY. Well, I think I could have given my same presentation to any of the disrupter topics that you chose, and the reason for that is because we have this sectoral approach to privacy. And so my optimistic suggestion is that we move away from that and we have an overarching, comprehensive privacy law, data protection law, that would stop these gaps between these different industries or between the industries that are conventional and the disrupters, to stop those developing.

In the absence of that, in a shorter term, I think the existing agencies probably need to maybe be given some additional powers. If I may give you one example, we know, for example, that the ONC, with its meaningful-use program, now has APIs, application programming interfaces, in order to improve the interoperability of data and share it with patients. And we all believe that that is a good thing. Yet the moment that data leaves the hospital or physician her, it merges into unprotected space.

Ms. CLARKE. Yes.

Mr. TERRY. So I think maybe we need sort of a version of the Pottery Barn rule, right? So if we give an agency the power to push

the data out, we should also give that agency the power to protect it as it emerges from that sort of protective cocoon.

Ms. CLARKE. Dr. Experton, did you want to——

Dr. EXPERTON. Yes. Thank you for giving me the microphone. I think there is a very positive element in what technology can bring to that security question.

We have all learned that phones can be highly secure, they cannot be broken down, with the FBI having to reach out to try to get information in an older iPhone series 5. The phone can be highly secure, and it is a personal device. So your phone can indeed store securely when the data is encrypted, which is the case for multiple applications—iBlueButton or Tensio for hypertension measurement.

It is in your hands. It is under your control. You cannot break in. If hackers want to get to your data, they will have then to hack millions of phones instead of one server in a cloud. So I think technology has made incredible steps to give individual citizens control over their most personal and critical information, which is their health information.

And I mentioned the iBlueButton app. At no point does Humetrix store or share that data. The data comes directly from the source, whether it is Medicare or TRICARE, VA or privatized care providers, directly to the user's phone, where it is securely encrypted.

So modern technology and mobile technology answer critical healthcare needs. It is immediate access to information me, the patient, or my doctor needs. It is in my hands, under my own control. And we oftentimes forget that, indeed, technology has evolved to solve the very problems we have.

Ms. CLARKE. Thank you, Mr. Chairman. There is still an issue of quality control that we will all have to manage though. And I yield back, sir.

Mr. BURGESS. The chair thanks the gentlelady. The gentlelady yields back.

The chair recognizes the gentlelady from Indiana, Mrs. Brooks, 5 minutes for questions, please.

Mrs. BROOKS. Thank you, Mr. Chairman.

And thank you to our panel. This has been fascinating, and really appreciate your expertise.

We know that in the next year, I have been told, 500 million smartphone users worldwide will have a health app. So the apps are growing. We have to wrap our arms around what is the right way forward with respect to how we use these.

And, in Indiana, Eskenazi Health in Indianapolis recently hosted what was called "Connectathon," and it brought together software developers and innovators from across the state. And it was a competition, and the winning team built a medication adherence app that sends texts or mobile reminders to patients' smartphones to take or refill their prescription medications—obviously something critically important in patient care.

And so I am encouraged with all that is happening out there. And we need these creative app developers like the teams in Indianapolis and around the country, but we also need to protect health data.

And I must say, Professor Terry, welcome to Washington, D.C. You weren't a professor when I was at the law school in which you teach, and I wish to thank you for your leadership at the Hall Law and Health Center. And I think we all would really enjoy your classes, but I am happy I am not in law school any longer.

Mr. TERRY. You are always welcome.

Mrs. BROOKS. But had you been there, I would have certainly looked forward to taking your class.

But I want to talk to you a little bit about the issues of context and functionality of the apps in defining and properly classifying it for proper regulatory and policy purposes. And that is something you have studied actually far more than I have studied and maybe more than most of the panel has really given a lot of thought to. And I think that is very important.

Can you talk to us a bit more about—you talked about whether it is patient-facing versus physician- or provider-facing. As we are crafting this important area of law that is growing and that is needed, what are, kind of, the classification tools and categories we should be looking at? Or should we not be looking at classification categories?

It would be great also if you just gave us the proper privacy policy legislation that we could debate and discuss; we would welcome that. But what about with respect to the classifications in this space?

Mr. TERRY. Well, I think with respect to the classifications, Congressman Lance, you referred to the 2015 subregulatory guidance. That is, in fact, a republication of one that was in 2012. And the way that this stuff is developing so fast, maybe that is worth a reexamination to see if we have more categories or categories that we can better define.

I think that we probably know enough about this space now that there are some categories that have been proven to be risk-free, and we no longer need regulatory discretion; we just need to jettison now into the consumer electronic space and let them thrive as they can.

So then the question is, can we actually be slightly cleverer with regard to how we categorize some of these products? Should we start maybe saying the condition-diagnosis type of app is a little bit different from the treatment type of app, so that we can get some space in there?

And then I think the other thing that is a continual problem that high-tech disruptive industries face is that the timeframe for regulation is out of sync with the rapid iteration of these types of technologies. And I think it is going to take smarter people than myself to figure that piece out. But those will be the kind of pushes that I would throw out to the regulatory agencies to see if they could come up with something like that.

Mrs. BROOKS. And thank you. We look forward to your help and your continued suggestions in this space.

Dr. Experton, quick question with respect to the iBlueButton. Because I am on a Medicaid Task Force contemplating reforms to our Medicaid program, and I understand the iBlueButton is being contemplated for the millions of Medicaid beneficiaries as well.

And yet, can you please talk to us a little bit about what that app looks like, how it could help with cost containment, and, very briefly, how you have overcome with your products the HIPAA issues that Professor Terry brought up?

And sorry, that is a lot. Mr. Chairman, if I might indulge. Thank you.

Dr. EXPERTON. Thank you, Congresswoman, for this question.

Yes, the iBlueButton app I mentioned is also available for State Medicaid programs. And the State of New York took a leadership role in choosing that application, to have patients participate in solving the critical safety but also cost-control issue any State Medicaid program has.

So, with the iBlueButton app, we take the Medicaid claims the way we take the Medicare claims and, on the fly, on the app, decode financial information into clinical information in English for that Medicaid beneficiary to understand, review, annotate, research, and to share with their physician wherever they receive care.

Medicaid beneficiaries are, more than anyone, subject to a problem of access and coordination of care. And, at most instances, any given patient doesn't have the full history of their medical care. So they come with that information coming from their claims, turn into a longitudinal health record right there on their phone, securely encrypted, which they can present, whether it is in the emergency room, whether it is some specialist to the next.

So that is the use of iBlueButton. So we white-label and customize our iBlueButton app for a State Medicaid program, which is going to query directly from the app in the user's control that Medicaid database of claims and, in real-time, turn that claim data into a longitudinal record so that patient can say, "Here, Doctor, the medication that has been prescribed to me and the one I continue to take or do not take because of this side effect I discovered through the app. Here is a test I got. You don't need to repeat."

Medicaid program represents about one-third of the State budgets. There is an issue of cost control, but there is also an issue of safety with the lack of coordination of care in those States. So this patient visit type of technology is critical on both fronts.

Mrs. BROOKS. Thank you very much.

And thank you, Mr. Chairman, for the extra time. I yield back.

Mr. BURGESS. The chair thanks the gentlelady.

The chair recognizes the gentleman from North Carolina, Mr. Butterfield, 5 minutes for questions, please.

Mr. BUTTERFIELD. Thank you, Mr. Chairman.

And good morning, one and all. Thank you to all of the witnesses for coming today. I have been watching some of your testimony on television, and at other times I have been moving around the Capitol, as most of the members have today, trying to complete our work before the August recess. And so thank you for your testimony.

It is clear that for most Americans health information is so very personal, requiring a high degree of privacy and data security. But as Mr. Pallone said in his opening statement, I think there is some confusion for the average consumer when it comes to the privacy of their health information.

And so, Professor Terry, it is my understanding that, despite the fact that that is not true, most people assume that health information is generally protected by HIPAA. Do you have any of those same concerns?

Mr. TERRY. I definitely do. Let me illustrate it by the simplest-of-all type of exchange that could involve a smartphone app, which is that I use an app to access my electronic health record. We want that kind of sharing, right?

Well, the moment that that data leaves the electronic health record of the provider and enters the smartphone app, there is considerable confusion as to the legal state of it. Now, if that app was provided by the hospital or the provider or a business associate, then the HIPAA shield would be all over it. If it was not, if it was an app that the patient just purchased from an app store, then it is highly likely HIPAA would not apply.

Now you have two sets of data, identical data, one on the her, one on the phone, identical data. One bundle is subject to the most stringent privacy protection we have in this country; the other is basically unregulated.

The patient then, for example, could add some wellness information from a Fitbit app or something to that electronic health record. Now the data is different. The patient could then send that back to the doctor, back across the threshold. Now you have two more sets of data, but, again, completely different protective systems applying to them.

I considered that certainly beyond my ability to explain to any patient.

Mr. BUTTERFIELD. I think I read in the material that there are 160,000 apps that are out there.

Mr. TERRY. I think that is about right, yes, and growing.

Mr. BUTTERFIELD. And growing.

Does HIPAA protect all health-related information?

Mr. TERRY. No, it does not. So, for example, there is tons of data, probably more health-related data is being generated outside of the traditional healthcare environment than is being generated within it. So every time you use a supermarket loyalty card and you pick up, I don't know, a diabetes testing kit or an over-the-counter pregnancy testing kit, that little piece of data goes up into the data broker cloud.

You are all familiar with the Target story of early diagnosis of pregnancy by the use of preferences with regard to hand lotion; exhaust data that comes off online sites that sell products, online resellers. Social media sites and, more and more frequently, mobile devices are all building this sort of surrogate version of your health life completely outside of the regulation of HIPAA. And it is being sold back to insurers and employers as body scores or health scores, which are potentially extremely discriminatory.

Mr. BUTTERFIELD. All right.

I have 45 seconds remaining. Let me do this very quickly. Let's say that an app that monitors blood pressure is offered by the patient's primary care physician, who would be a HIPAA entity. Does HIPAA cover the information that is collected and stored by the physician?

Mr. TERRY. If that app was developed by the physician or the hospital or a business associate, then it is highly likely that it would be covered.

Mr. BUTTERFIELD. Would be covered. Yes.

Again, let's say that a doctor recommends that a patient use a blood pressure monitoring app, but the doctor does not offer the app. If the patient shares the information collected with his or her doctor, is information held by the doctor covered by HIPAA?

Mr. TERRY. That would be covered by HIPAA. Of course, there is the overarching question as to whether any sane physician would recommend an app without knowing it inside-out because of the liability issues that could well occur there.

Mr. BUTTERFIELD. Thank you. You have been very kind.

Thank you. I yield back.

Mr. BURGESS. The chair thanks the gentleman.

The chair would note to the members of the subcommittee that the chair has deferred his questions till the end. I did that on purpose so that I could accumulate all of the time that each of you went over, and I have now aggregated that, and I yield myself the next hour and a half.

No, I do want to thank all of you for being here this morning. It has been terribly illuminating and illustrative. I have made a number of notes here. And I do, of course, as always, will have opportunities for questions for the record if time does not permit all the questions to be asked.

But, Dr. Patterson, let me just ask you—you know, you gave such a wonderful demonstration. It really was worth the wait. I mean, I cannot tell you the times—look, we just had a big series on opiates within the full committee and Subcommittee on Health.

And I will tell you, as a practicing physician, I think you just hated to realize that maybe you got scammed on that prescription. So, in order to avoid that, even though it was 3 o'clock in the morning, I would go back up to my office that was physically adjacent to the hospital. A patient would call in and say, look, your partner prescribed whatever because I had surgery, and the dog ate my homework, and could you just get me enough to get me through my 3-week vacation that is coming up in just a few hours here?

I would fall for it once, but next time—"Well, meet me at the emergency room. I just want to check and make sure everything is OK, and I will be happy to write you a prescription." I would go to my office and pull the record. The patient almost invariably did not show up in the emergency room.

But, boy, how powerful to have what you demonstrated to us, where you could basically access that information at home. So, like, in a five- or six-physician practice, all of those records would be available to the physician on call for the practice. Is that correct?

Dr. PATTERSON. That is correct, yes.

Mr. BURGESS. Now, Mr. Terry pointed out that, once that data leaves the confines of the medical records department at the clinic or the hospital, now it is in a different world. But that is OK on your device? There is a proper protection on that device?

Dr. PATTERSON. Yes. So everything that we provide in our platform is done under a business associate agreement with the pro-

vider side, so either the health system clients or the physician groups where our software is deployed.

I think that the challenge that comes with a platform like ours is that we are positioned to incorporate device data from anywhere, so we are agnostic to the source. And so there is a host of consumer-facing applications and sensors out there where that data could be very useful for the broader context of caring for a patient.

So, as a doctor, I don't mean to be crass, but I really don't care how many steps you take, and I don't really care how many calories you have eaten on a day-to-day basis. That is not what I am going to be spending my time on and probably shouldn't be, for that level of decisionmaker. But if I can see data that links how many steps somebody takes to their onset of depression because they are no longer taking their dog for a walk, and then that is linked to their medication noncompliance, and then that is linked to a rehospitalization, suddenly I might be very, very interested in having that being pulled together through machine learning or algorithms.

And so we have to find a way to accommodate various disparate sources of data. So I liken it to recreational data versus professional-grade data. So in my mind, we have to set a very clear bar on what is recreational and what is professional-level. And I don't necessarily think it is who is using it, but I do think it is more related to the level of risk and the safety involved. And that should be the primary criterion, is what is safe, what is not safe.

And then, subsequent to that, there needs to be a crosswalk capability that allows recreational data to be drafted to the big leagues, so to speak, down the line. So there has to be some way that we can bridge the gap between these two and do that safely.

And I feel that provenance is one of the most important things. You always have to be able to tell where a data element originated from. If that is lost in the little pieces of metadata that surround that data element—for example, if I have a glucose reading, I want to know where did that glucose reading come from on that diabetic, what type of device, how is that regulated, how much can I trust that.

I think if we solve for some of those issues, we can probably clarify a lot of the classification issues that are coming up where we don't have to have 20 different classifications. And the legislation would never be able to keep up with the innovation.

Mr. BURGESS. One of the things that got me interested in this several years ago, I was able to download an app onto my phone that used the flash attachment to measure heart rate, so that was kind of neat.

And then at a prayer breakfast, Dr. Collins, the head of the NIH, was seated next to me, and his iPhone had an EKG on it. Well, wait a minute, Dr. Collins, I want an EKG on my iPhone. So I figured out how to get it. It actually is an FDA-approved device. You do have to have a physician's license in order to have that; you can't just download that for regular consumer use. But now I have two ways to measure heart rate on my iPhone, one with the light sensor and one with the EKG app.

But, Mr. Terry, your last comments about the blood pressure cuff—the other thing that made me interested in this, I used to

practice OB/GYN. Yes, it has been a few years since I have done so. But, invariably, the last patient at 4:45 on a Friday afternoon comes in for a routine prenatal check up at 36 or 37 weeks pregnancy, about a month away from delivery, and her diastolic blood pressure is 90 millimeters of mercury. Yikes. She has never had blood pressure that high before. But, is this the harbinger of something very bad that is about to happen, or is this a one-off because I didn't provide adequate parking out in front of my office and she got mad at her husband because he had to drive around to drop her off? You don't know that at 4:45 on a Friday afternoon. Sure, recheck the blood pressure, perhaps wait 15 minutes.

But how empowering—you make one decision and say, "I am sorry. You have never had blood pressure this high before. Although you have no other symptoms and no other criteria, I am going to have to ask you to come into the hospital for observation." Three days later, with no elevated blood pressure, rather sheepishly you are discharging that patient. She is angry because of having to arrange daycare for her other kids. Or, 3 o'clock on Sunday morning, that patient is back in the emergency room either having had an eclamptic seizure or a platelet count of 2,000 or something very bad has happened.

So how great to be able to use that blood pressure now that is available in the home. I mean, you don't even have to tell someone to go down to Walgreens and sit in the chair. A $40 peripheral and you can measure that blood pressure at home and have perhaps several blood pressures a day e-mailed to the doctor on call for that weekend. What is wrong with that? That seems like it is a way to extend the ability to give good care and make good decisions.

Mr. TERRY. I completely agree. And, in fact, I would go further than Dr. Patterson, because I don't think we are talking about just wellness or fitness data that could be valuably incorporated into this very professional environment that you are talking about. But, as we know from the Institute of Medicine and work that is being done elsewhere at HHS, we are really trying very hard to incorporate a lot more health-determinant information data into our records to push that environmental piece back into it.

So not only would you be able to look at the blood pressure of that patient, but you would get a sense of the different environments that maybe have pushed or lowered that blood pressure, which would, again, I think, give you even more data.

The problem is that, after a while, you wonder whether this really can stay on that encrypted device for that level of processing and whether, in fact, our desire for sharing and additional processing will in the end force this up into the cloud and, therefore, raise so many of the privacy and security risks that we have discussed.

Mr. BURGESS. Very well.

Let me ask you this, because you brought up the question of industry minnows. And although we don't deal with endangered species on this committee, I couldn't help but wonder about the delta smelt and if that was one of those industry minnows. But, seriously, that is—and Ms. Johnson referenced some of the difficulties that the FDA has.

That potentially is an enormous task on the regulatory side. Industry minnows are turning out health apps. The regulatory body

that, oh, by the way, in addition to the 180,000 health apps that they are trying to regulate, they have also got 11,000 laboratory-developed tests that they now say they are going to regulate as medical devices—I mean, suddenly just the workflow through the agency becomes problematic.

What do you foresee in that situation?

Mr. TERRY. Well, I think unless there is tight regulation and enforcement, I think the minnows are going to get worse. You only have to do a brief search through app stores these days amongst health-related apps to find all sorts of apps that look like they are doing device-like things but are not approved medical devices.

And, frequently, you will see when you click on the "more" button on that app site, it will proudly tell you that this is for informational or educational or game enjoyment only and should not be used for diagnosis. Yet, at the same time, they are selling these things for what looks like diagnosis.

Unless that gets tightened up, I worry that the good companies will find themselves just sort of overwhelmed by the bad. Generally speaking, it is my belief, at least, that our finest corporations actually will embrace regulation because it brings certainty. And good enforcement might help that.

Mr. BURGESS. Yes. This is the disrupter series, however, and I think the admonition to pay attention to the provenance of the data is—I mean, I think that is valid and I think that is wise.

Dr. Ferris, let me just ask you, because not this subcommittee but another subcommittee of the Energy and Commerce Committee, in 2012, did a number of hearings leading up to the FDA user-fee agreement reauthorization, the FDA Safety and Improvement Act. And as part of those hearings leading up to that, we had a member who is no longer here in Congress but was very concerned. His daughter had a melanoma. He was interested in—it wasn't a consumer app. It was something called the MelaFind camera.

MelaFind had difficulty getting approval and then did. And then I don't know what the difficulties were after the fact, but I think, if I understand correctly, it is back on. So it sort of speaks to some of the difficulty that you raised.

And yet, at the same time, I am thinking back to the flip phone that I had when I started in the Congress. Yes, I could take a picture with it, and you could almost make out the images. The technology is getting a lot better literally every year. I rather expect, when we have the user-fee agreement reauthorizations, we are likely to have other devices that are talked about at that time because of the advance of the technology.

So do you have a sense how the improvements in technology, how that may impact the ability to provide this type of information? And I am not even thinking so much at the consumer-level. I am thinking at the level of a primary care doctor, like I was.

Basically, it is a binary choice for me. If a patient shows me a mole and asks me if she needs to be worried about it, I say, "You need to go to the dermatologist to get it biopsied." Because if she's worried about, I am worried about it, and we are all going to worry about it until you tell us it is OK.

Yes, if there were an intermediate step that dealt with a transmission of data on a—whether it was a consumer-driven app or an FDA-approved app, that just seems to me that that would increase utilization of trying to diagnose those lesions.

Dr. FERRIS. Yes. Thank you.

So I am familiar with MelaFind device and actually participated in the pivotal trials that resulted in, ultimately, FDA approval after a very long process of that.

So there is a difference between a device like MelaFind—because it is truly on optical device. It is doing image capture. It is doing analysis within the app and giving a score. And part of the reason it needed approval was that it actually did initially give a binary output, a biopsy recommended or no biopsy recommended. So that is purely a recommendation.

In the scenario that you are talking about, where you have a patient who has a mole and you just say, "Go see dermatology," if you were doing that in western Pennsylvania, where I practice, if you were not within the city of Pittsburgh and didn't have my cell phone number, you would potentially be telling that patient to either drive at least an hour to see a dermatologist or to call our office, where they would be told that our next available appointment may be up to 4 to 6 months later because of the access-to-care issues.

So now we have better ways to do that. So one is you can take a photo, and, through a HIPAA-secure system, you can send that to a dermatologist, because we can very quickly triage. So, one, that should be more widely available. That is not a direct-to-consumer. That is physician-to-physician communication.

Two, the technology that we are trying to work on is that we could outfit your office with an attachment to your iPhone that is maybe a couple hundred dollars that would give us an even more clear and analyzable image of that lesion, that you could either, one, get an even better opinion from us quickly through telemedicine, or, two, that we, by having a tool that can analyze that image, we could actually give you a score of risk.

We are not giving that to the patient; we are giving that to you as a physician. We know how to set the bar. I can talk to you about sensitivity and specificity or positive and negative predictive value in a way that I can't talk to a patient about it. We can set the bar such that, if it comes back high-risk, you don't have to go through having your office call my office. We have a way to immediately get that patient triaged. And then if it comes back as very low-risk, that can go into perhaps a more cumbersome process of maybe having that image reviewed by a dermatologist. But this can really speed up the process.

Again, I think that the bar for safety is lower when it is physician-to-physician or when it is data being provided to a physician. I can in real-time improve that app as I get more images. If I have to go through full-bore FDA approval every single time we tweak an algorithm to make it better, we are not going to make products better; we are going to come up with what we think we can get approved and not continue to develop and use technology to make health care better.

Mr. BURGESS. Correct. That is the regulatory risk.

Dr. Patterson—but, really, just for the panel in general—I don't think we can discount how the young physician—medical students, residents—are going to change how this is all viewed. I went and talked to either one of my medical schools or residency programs down in Fort Worth a couple of years ago. And the residency director opined—I guess they had a system like yours that they did defensively because it was impossible to keep the residents from taking a picture of something in the emergency room, sending it to their attending and saying, what do you think, can I close this here or does it have to go to the OR, that kind of question, which were the same questions that I asked as a resident to my faculty, but there we had a rotary dial phone, and now, of course, they have these very, very fancy smartphones with quite accurate cameras.

So that hospital actually had to develop something like your system that was a secure system where, in a HIPAA-compliant way, data could be transferred. And the only reason I bring that up is the young physicians coming up are either going to demand or they are just going to drive in a direction that they want to go, whether or not we thought it was a great idea or not in a congressional hearing.

This has been a very fascinating hearing. I have a number of questions for folks in writing, but I am way over time, and it always makes Ms. Schakowsky nervous when I do that. So, in deference to her—oh, well, I would yield to the gentlelady if she had a followup question she wanted to ask.

Ms. SCHAKOWSKY. No, I don't. Thank you.

Mr. BURGESS. So, seeing that there are no further members wishing to ask questions for this panel, I will thank all of our witnesses for being here.

Before we conclude, I need to submit the following documents for the record by unanimous consent: a letter from Fitbit that tells me to get busy—I am way behind; a letter from the Competitive Carriers Association; a letter from the Consumer Technology Association; a letter from the American Medical Association; a letter from Opternative, Incorporated.

[The information appears at the conclusion of the hearing.]

Mr. BURGESS. Pursuant to committee rules, I remind members they have 10 business days to submit additional questions for the record. I ask the witnesses to submit their responses witness 10 business days upon the receipt of those questions.

Without objection, the subcommittee is adjourned.

[Whereupon, at 12:13 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Today we continue our Disrupter Series as we examine health care apps that are truly revolutionizing how folks in Michigan and across the country are managing their health.

As the sponsor of the 21st Century Cures Act, with my good friend and colleague, Congresswoman Diana DeGette, it's no secret that we have been fighting to modernize and personalize our health care system to find faster cures and better treatments for all Americans.

And we face some of the same concerns with health apps in terms of ensuring that government is encouraging rather than hindering the development of new life saving technologies. Today, we will examine what it means for patients as mobile

apps have the potential to modernize, personalize, and improve the overall delivery of care.

The development and proliferation of health apps is an essential part of our effort to cultivate a healthier population and save more lives. Because of remarkable advancements in technology, doctors and patients both receive information that is more accurate and timely, which accelerates better diagnoses and preventative treatment plans. This technology's ability to seamlessly connect doctors and patients together through a smartphone or connected device opens the door to a wide range of medical discoveries, possibilities, and insights, not to mention the potential to prevent medical problems before they occur.

An additional benefit of mobile health apps is that they help to drastically reduce skyrocketing health care costs. By integrating the Internet into practically everything we own, we have generated productivity and efficiency gains, and cost savings across multiple economic sectors. The health care sector is no different—if anything, there is no sector in greater need of this modernizing. Better care achieved more efficiently can lead to reduced doctor visits, decreased complications and risks, lower hospital readmissions, and much more.

The potential stemming from this technology is undeniable and exciting. To ensure that these life-saving tools are accessible to folks in Michigan and every corner of the country, we need the right regulatory framework in place. A framework that encourages innovation, removes barriers to investment, and advances new opportunities for patients and providers to engage in the health care system. At the same time privacy and security are absolute musts. This is one of the most important policies that industry must show leadership on.

As the world's leader in medical innovation, the time to make these promising health care advances available to American families is now.

Statement of Woody Scal
Chief Business Officer
Fitbit, Inc.

Disrupter Series: Health Care Apps
Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
U.S. House of Representatives
July 13, 2016

Mr. Chairman, Ranking Member Schakowsky, members of the Subcommittee, thank you for the opportunity to share some important information regarding how Fitbit and the broader wearables industry are empowering people around the world to better manage their overall health and wellness. As Fitbit Inc.'s 11th employee and Chief Business Officer, I'm thrilled to have the opportunity to share with you some of the important work we are doing, and the critical role that data security and privacy play in what we do both at a company and industry level.

Fitbit's mission is to empower people to lead healthier, more active lives by providing them with data, inspiration and guidance to reach their goals. Around the world, individuals and businesses are looking for solutions to improve overall health and wellness. At the same time, high rates of chronic conditions such as obesity, diabetes and hypertension are driving individuals and healthcare providers to look for innovative ways to reinforce healthier habits. Fitbit believes a healthier, more active lifestyle is within everyone's reach.

When someone starts their journey with us, they're not just getting a fitness tracker. They are getting a solution that helps them manage their overall health and wellness, which includes connected health and fitness devices, the app experience, and personalized content and insights – all aimed at helping them reach their health and fitness goals. All of this combines to help people be more active, get more exercise, eat smarter, sleep better, and manage their weight – key components in living a healthier life. Just as important, these are the very lifestyle changes that many chronic disease management programs are trying to encourage people to sustain. And our wide variety of products and tools aim to serve people across the health and fitness spectrum, from people just getting started all the way through performance athletes.

After nearly a decade of building and leading this emerging industry, we have a deep understanding of what consumers want in a health and fitness device and we've maintained a strict focus on that segment. During that time, we've sold more than 43 million devices, and in the process established a brand that is both loved and trusted by millions of users around the world, becoming the brand of choice for consumers seeking a fitness-focused wearable device.

Digital Health

Fitbit's success as a consumer brand is helping to drive our longer-term vision and evolution into a leading Digital Health platform that helps people live healthier lives, with the goal of integrating more deeply into the healthcare ecosystem to improve healthcare research, outcomes, costs and reach. With a well-recognized and trusted global brand that is strongly associated with health and fitness, we believe that a focus on a healthy lifestyle – including daily activity, a healthy diet and plenty of sleep – is critical to promote individual and population-based health, and may even prevent the onset or advancement of chronic disease.

There's no simple answer for how to solve the growing problem of chronic diseases like obesity, diabetes and cardiovascular disease. While there are many initiatives to manage these diseases, there is not enough effort being placed on prevention today. What we do know, is that the majority of the healthcare costs today are being driven by poor lifestyle choices. According to the Chief Medical Officer for the Wellness Institute at the Cleveland Clinic, 87 percent of the total health care expenditure is for the management of chronic disease[1]. Chronic diseases also account for almost 90 percent of all hospital admissions, and over 90 percent of prescription costs are for the treatment of chronic disease. An astonishing 76 percent of all visits to a physician involve the treatment of chronic illness. Fortunately, almost 75 percent of chronic illnesses can be improved or cured by changing these major lifestyle choices and this is where we see an enormous opportunity to help engage the healthcare system. At Fitbit, we believe we can do more to help consumers take a more proactive role when it comes to their health and wellness. By providing them with more data and information about their history and behaviors, we have more opportunities to find and develop a personalized approach to health and wellness. Access to this type of data can empower consumers to take a more proactive role in their health, monitor and track their health metrics, motivate themselves to be healthier and more active, and take appropriate preventive measures that can help prevent the onslaught of chronic diseases.

Everything begins with the data. Data not only provides key insights into an individual's health and helps drive behavior changes that lead to better health outcomes, but, at a macro level, it can also provide much larger insights about population health.

The advent of wearable devices has revolutionized our ability to collect and monitor health data on a much larger scale. What could once only be collected in the lab can now be tracked 24/7, which is both powerful and motivating, and has longer term potential around medical screening and diagnostic capabilities. Before wearables, to obtain data on your sleep, you would have had to go to a sleep lab or wear a specialized device. Now, you can get it from an everyday wearable device. To know your heart rate, you would have had to wear an uncomfortable chest strap or go to the doctor. Today you can track trends on your wrist in real-time. We have reached a point where advanced technology and biometrics provide us with the opportunity to track critical health information in new and more accessible ways, and what we're seeing today is just the beginning of what's possible. Connected device platforms like ours can serve as a means for better patient engagement and deeper clinical collaboration, and hopefully lead to better health outcomes, fewer hospital visits, and reduced healthcare costs.

Fitbit has been used in over 100 research studies to date with academic and clinical research institutions, such as the Mayo Clinic and Johns Hopkins Medicine. Most recently, the company announced a partnership with the Dana-Farber Cancer Institute to support a study that looks at the impact of physical activity and weight loss on breast cancer recurrence by having study participants track their activity and weight loss to share with health coaches using Fitbit Charge HR activity trackers, Aria Wi-Fi Smart Scale, and a subscription to FitStar by Fitbit.

Hopefully this helps you better understand the power of what we are doing and the critical role our technology and those like it can play in helping to improve the health and wellness of those around the world.

Data Protection and Privacy

As I described above, our brand is loved and trusted by millions of people around the world and this is no accident. The trust of our users is paramount, and this is reflected by the robust privacy and security measures we have in place.

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[1] Dr. Roizen is the chief medical officer for the Wellness Institute at the Cleveland clinic: http://www.dailyherald.com/article/20131216/entlife/712129592/

As the leader in the connected health and fitness category, Fitbit has always been committed to protecting consumer privacy and keeping data safe. Fitbit users are in full control of when or if they share their data with other parties and whether they choose to export it. Furthermore, it has always been our policy not to sell personal user data; we have never sold it and do not share it unless a user specifically directs us to do so, or under the limited exceptions described in our privacy policy (http://www.fitbit.com/privacy).

We have used privacy by design principles to make sure transparency, consumer choice, and security are prioritized in the design of all Fitbit products and services. Fitbit is investing heavily in security measures to protect consumer privacy and keep data safe:

- We have assembled an experienced information security team and continue to educate our engineers about product security.
- We carefully design security measures for our new products and systems, continuously assess our existing products and systems for their resilience against new threats, and rapidly respond to any identified issues, making improvements where needed.
- We also welcome feedback from the community, and encourage individuals to report any security concerns with Fitbit products or online services to security@fitbit.com.

In addition to our company-specific policies, as the leader in the category, we actively work with the wearables industry to help keep this important topic at the forefront of industry and stakeholder discussions, and provide guidelines and best practices where appropriate, serving as an example to other companies in the space.

In 2015, as chair of the Consumer Electronics Association's (now Consumer Technology Association's) Health and Fitness Technology Board, I was heavily involved in developing CTA's "The Guiding Principles on Privacy," which provides recommendations for voluntary best practices that mitigate risks that consumers may perceive with respect to personal wellness data.

The Principles are baseline, voluntary guidelines for companies that handle personal wellness data. They're a response to consumers' desire for more privacy. They demonstrate consensus among CTA's members that there are key steps companies should take to address tangible privacy risks and consumer preferences.

These Principles are the first of their kind with respect to personal wellness data. They demonstrate consensus among health and fitness technology companies that there are certain privacy risks that arise when personal wellness data is collected, used, or transferred from consumers to companies and between companies. Consensus helps companies respond more effectively to consumer preferences and regulators. Additionally, these Principles can help companies foster consumer trust in health and fitness devices.

More recently, we worked with the Center for Democracy & Technology (CDT), a leading advocacy group dedicated to protecting global online civil liberties, inviting the CDT into our research labs to explore how privacy and ethics come into play in the research and development (R&D) process. The result of this collaboration was a report that offers guidance on privacy-protective and ethical internal research procedures for wearable technology companies.

The report recommends that wearable companies invest in employees with privacy and ethics backgrounds, empower researchers with embedded tools for data stewardship, set clear security protocols for use of user data, and establish formal accountability measures.

Fitbit has also announced compliant capabilities under the Health Insurance Portability and Accountability Act (HIPAA), which will enable Fitbit Group Health to serve a broader market and, in certain cases, integrate more effectively with HIPAA-covered entities, including health plans and self-insured employers. With this initiative, Fitbit will be able to meet the applicable requirements of the security and privacy regulations under HIPAA.

Thank you for inviting me to share with the Subcommittee the important work we are doing at Fitbit and the critical role that data protection and privacy play in that journey. We greatly appreciate the opportunity to submit this testimony and look forward to working with members of the Subcommittee to provide more clarity on anything referenced above.

Competitive Carriers Association
Rural • Regional • Nationwide®

July 13, 2016

The Honorable Michael Burgess
Chairman
Subcommittee on Commerce, Manufacturing, and Technology
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC, 20515

The Honorable Janice Schakowsky
Ranking Member
Subcommittee on Commerce, Manufacturing, and Technology
House Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC, 20515

Dear Chairman Burgess and Ranking Member Schakowsky:

Competitive Carriers Association ("CCA") respectfully submits this letter for the record regarding today's hearing on "Disrupter Series: Health Care Apps." CCA is the nation's leading association for competitive wireless providers and stakeholders across the United States. CCA's membership includes nearly 100 competitive wireless providers ranging from small, rural carriers serving fewer than 5,000 customers to regional and national providers serving millions of customers. CCA also represents close to 200 associate members including vendors and suppliers that provide products and services throughout the mobile communications supply chain. From our members' experience with constructing networks and providing wireless connections that facilitate continued innovation and growth in consumer use of mobile applications, we have seen firsthand how new technology supports advances in healthcare. These developments are changing the lives of consumers in densely-populated urban areas, and in rural America in particular, where patients may need to travel much greater distances to receive monitoring and care. CCA commends the Subcommittee for its continued focus on these issues, and for considering ways to expand innovation and meet future demand for mobile services moving forward.

As industry moves toward 5G, the development of the Internet of Things and next generation technology will help to power certain critical life operations such as precision agriculture, limitless education and employment prospects, public safety services, and telehealth opportunities. Specifically, the Agency for Healthcare Research and Quality at the U.S. Department of Health and Human Services recently found that telehealth can positively impact outcomes relating to mortality, quality of life, and hospital admissions when used to monitor chronic conditions, particularly cardiovascular and respiratory disease. Industry also has noted that remote health applications are one of the main benefits that 5G could be capable of delivering. As the Subcommittee appropriately recognizes today, such apps are one part of a larger transformation in delivering care.

CCA members provide innovative services and will continue to innovate towards new services and technologies. For example, Ericsson recently launched an initiative to prove that 5G will have the capability to replace a surgeon's hand. At its demonstration, Ericsson revealed a robotic "finger" that provides a sense of touch to surgeons for remote, minimally invasive surgery. Similarly, in the rural Mississippi Delta, the University of Mississippi Medical Center, GE Care Innovation, and C Spire collaborated to deploy wireless glucometers, sphygmomanometers (blood pressure cuffs), scales, and tablets that transmit vital health data and video conference to and from healthcare providers, which is helping to control diabetes and reduce patient visits to the hospital. Each of

these innovations will be furthered by 5G technology, which will advance the mobile data connections needed to facilitate remote healthcare.

Despite this progress, there is still work to be done. Many competitive carriers serve the most rural areas of the United States and often face challenges obtaining the costly infrastructure necessary to provide services, or face uncertainty and barriers to deploy new facilities. Importantly, 5G densification will require increased access to backhaul services.

None of these new technologies will be realized until comparable mobile broadband services are available throughout rural and remote areas. Ongoing Universal Service Fund ("USF") reform therefore must provide a mechanism to enable broadband access in urban and rural areas, while expanding networks to address important economic, health care, and public safety goals. Specifically, continued innovation can be spurred by Mobility Fund Phase II reform. As many as 1 in 5 households are now mobile-only, a number that has doubled since 2013. Any reform, especially to the Mobility Fund, must take these marketplace realities, and the overwhelming consumer preference for mobile applications, into account. Carriers need certainty regarding USF support to continue to invest to meet growing demands. Funding should be made available to meet the laudable goal of expanding mobile broadband networks to portions of the country that are currently unserved, while preserving existing networks in rural areas to ensure these services are preserved and expanded.

CCA commends the Subcommittee for its continued focus on fostering economic and technological advancements that only mobile broadband can produce. Ensuring the capabilities of future networks will help to meet the needs of urban and rural consumers alike and spur development of 5G services, including health care applications. CCA appreciates the opportunity to contribute to the record for today's hearing, and looks forward to continued work with the Subcommittee, its Members, and Congress on these important issues to advance mobile broadband services and support innovation throughout the industry.

Please do not hesitate to contact me with any questions.

Sincerely,

Steven K. Berry
President & CEO

CTA Member Company Humetrix Testifies Before House Energy and Commerce Committee

Today, the Consumer Technology Association (CTA)™ announced member company Humetrix will testify on the impact of mobile phone health applications on the medical ecosystem at the House Energy and Commerce Subcommittee on Commerce, Manufacturing, and Trade hearing, *Disrupter Series: Health Care Apps*. Humetrix is a mobile health company that offers applications including iBlueButton, which lets patients automatically and securely access their individual online healthcare records using a smartphone or tablet.

"We're glad the committee recognizes the improvements that companies such as Humetrix are making to the American healthcare system and our individual health," said Gary Shapiro, president and CEO, CTA. "Technology can ensure that Americans have access to the information they need to make the best possible decisions about their health. Innovation in healthcare is truly allowing our nation to develop patient-centered care, where mobile apps or trackers can help monitor and share patients' data real-time to providers."

Through its mobile application iBlueButton, Humetrix enables military veterans to aggregate their health records – from both VA hospitals and private providers – securely on their mobile phones for easy access. Allowing patients to share their healthcare records with providers, even in the case of an emergency, provides a more personalized, and often effective, treatment plan for patients.

"In a healthcare environment in which one-third of expenditures are wasted on redundant care and medical errors represent the third-leading cause of death in the U.S. today, having immediate access to a patient's health history can save lives and also significantly reduce healthcare costs," said Dr. Bettina Experton, CEO, Humetrix. "Thanks to the continued growth of technology, our healthcare system is undergoing a transformation, and we look forward to continuing our efforts to support innovations that are making a difference and improving the standard of care for all."

STATEMENT

of the

American Medical Association

for the Record

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade

Re: The Disrupter Series: Health Care Apps

July 13, 2016

Division of Legislative Counsel
(202) 789-7426

STATEMENT

of the

American Medical Association

for the Record

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade

The Disrupter Series: Health Care Apps

July 13, 2016

The American Medical Association (AMA) appreciates the opportunity to submit this statement for the record as part of the U.S. House of Representatives, Committee on Energy and Commerce Subcommittee on Commerce, Manufacturing, and Trade hearing, *The Disrupter Series: Health Care Apps*. The broad array of digital medicine tools and services has begun a fundamental transformation of health care delivery. The AMA is strongly committed to accelerating the adoption and integration of digital medicine services and tools into everyday practice that promote improved patient health outcomes, support care coordination, and improve communication. Our efforts to achieve these goals include modernization of AMA policy, focused federal and state advocacy efforts to streamline and update regulatory oversight and expand private and public payer coverage, enhanced medical education, key collaborations with innovators, and tools to assist physicians utilize these new technologies.

As we move forward there are many opportunities and challenges that will require focused efforts by policymakers and health care stakeholders. Below we highlight a number of initiatives where the AMA has gained significant experience in the area of digital medicine and outline thereafter important policy priorities that the Subcommittee should advance in this area. Namely, innovations in the digital medicine arena must be validated, evidence-based, actionable, and connected while preserving important patient protections that are time-tested and relevant today. For new technologies to reach their potential, they must exhibit these primary features in order to bring patients and physicians closer together for the common purpose of improving health outcomes.

AMA's focus on innovation and digital medicine

Early innovators have been prodigious and creative, but too frequently have not accounted for system-wide and patient point of care considerations that ensure security, accountability, accessibility, usability, and interoperability. In addition, the clinical evidence base for many of these innovations, though not all, remains a work in progress. Within this context, for the past several years the AMA has strategically and rapidly expanded the foot print of practicing physicians into the digital medicine ecosystem to champion digital health solutions that achieve the stated promise of saving overall health costs, expanding patient access, and improving clinical care and outcomes.

The AMA's range of telemedicine and mobile app related initiatives and efforts have covered the breadth of AMA focus areas and components. For example, the AMA has leveraged its role as a convener and hosted regular meetings with the national medical specialty societies to encourage the development of objectives and initiatives to support digital medicine adoption, including the use of telemedicine and

mobile health apps. In addition, the AMA's focus on Accelerating Change in Medical Education initiative and grant funding includes participating medical schools promoting e-learning and innovations that encourage increased literacy and fluency in the digital medicine space. In another key focus area, the AMA offers an online tool kit, STEPS*forward*, which is a medical practice transformation series comprised of a collection of interactive, educational modules developed by the AMA to help physicians address common practice challenges, including a module on *Adopting Telemedicine in Practice.* Each module addresses a specific challenge by offering real-world solutions, steps to implementation, practical examples, case studies, and downloadable tools and resources. Physicians and their practice staff can use these modules to help improve practice efficiency and ultimately enhance patient care, physician satisfaction, and practice sustainability. The telemedicine STEPS*forward* module highlights important considerations for physicians including applicable federal and state laws.

In addition to the above areas of focus, the AMA has partnered with leaders across health care that are keenly focused on technologies that work better for our patients and physicians and seeking ways to bring the physician voice into the innovation space. The AMA is building bridges to technology innovators and entrepreneurs so that physicians have a seat at the table as new products and services are being developed. New digital tools that support medical practice must address real-world challenges for physicians. The AMA is a founding partner of Health2047, an integrated health care innovation company along with leading institutions to make widely available system-level solutions that enhance care delivery and practice of medicine. Health2047 is designed to catalyze collaboration across a network of partners including technology firms, product companies, physicians and payers to drive rapid and responsive change that makes new solutions possible. Health2047 incorporates physician perspective to inform every step—from the design process, to testing prototypes, early access to solutions, and the ability to submit ideas of their own—so that health technology solutions work well in the practice setting and benefit physicians and patients.

Another partnership includes the AMA at MATTER, an effort to support ideation and collaboration with hundreds of entrepreneurs to ensure the physician perspective is included in the development of new tools and innovative solutions from the outset, and includes an interaction studio so entrepreneurs are able to test their solutions in a simulated clinical and non-clinical environment and collaborate with physicians virtually. Since the partnership was established in 2015, hundreds of physicians have visited MATTER or offered insight and feedback to entrepreneurs working on early stage technologies and solutions. Additionally, the AMA at MATTER partnership has brought physicians and entrepreneurs together for a variety of educational workshops, interactive simulations, and collaboration events focused on optimizing health care.

Beyond Health2047 and AMA at MATTER, the AMA continues to develop partnerships and collaborations that support the AMA's strategic focus area activities with outside innovators including:

- Ongoing monitoring and interaction with digital health companies connected to our focus areas.
- Collaboration established with a leading digital diabetes prevention company to scale physician referral into these programs.
- Efforts to build and disseminate principles and guidelines for digital health tools and applications.

Furthermore, since 2014 the AMA is an active participant and board member of the Substitutable Medical Applications & Reusable Technology (SMART) Platforms project. This initiative with Boston Children's Hospital and Harvard University's Medical School is working to use a mobile app infrastructure to improve existing electronic health record (EHR) technology and enhance interoperability. The project also promotes the development and use of mobile healthcare apps with the goal of making such applications widely available to practicing physicians and patients.

Key subcommittee considerations

While encouraging and supporting innovation, the AMA is equally committed to ensuring digital medicine is implemented in a manner that protects patient safety and promotes improved patient health outcomes. The diversity of telecommunication technologies, clinical practice settings, and medical specialties, along with the rapid rate of innovation, are factors that should be carefully weighed by policy-makers.

Mobile Apps and Electronic Health Records

AMA advocacy related to EHRs has also long promoted the use of mobile apps and other technology to improve upon existing health IT barriers. In particular, we have welcomed efforts to allow patients to use application-program interfaces (APIs) rather than solely patient portals to supports data access and exchange, as this new technology may provide more usable and accessible tools. Furthermore, the lower costs of apps and APIs may improve care access and prevent resources from being diverted away from patient care.

Patient safety (state licensure and consumer protection)

The nationwide standard in the United States continues to recognize that the practice of medicine occurs where the patient is located, rather than where the provider is located. This is a patient-centered, time-tested, and practice-proven precedent. Each state establishes its own licensing and medical practice standards, regulations, and laws that meet the needs of the individuals receiving care within the state's borders. State-based regulation of the practice of medicine ensures that state medical boards have the legal capacity and practical capability to regulate physicians treating patients within the borders of their state, and to attest that those physicians meet the qualifications necessary to safely practice medicine. Changing the site of practice to where the physician is located would be highly disruptive and complex, and would be antithetical to the principles of Federalism upon which our current system of regulating physicians and protecting patients rests.

The AMA opposes federal legislation that would change the site of practice from the state where the *patient* is located to the state where the *physician* is located for purposes of licensure, disciplinary actions, or the applicability of state medical practice laws. States use licensure authority to protect patients located in their state and hold health care providers accountable to their practice, patient safety, and liability laws. Changing the site of practice would undermine a state's ability to enforce its laws on public health issues including:

- Medical marijuana
- Assisted suicide
- Parental consent and minors
- Abortion
- Controlled substances
- Prescribing
- End of life
- State based disciplinary authority

Rather than reduce barriers to adoption of telemedicine and mobile apps, the AMA believes such an approach would compromise patient safety by making it exceedingly difficult and potentially impossible

for patients and state medical boards where the care is rendered to address improper and unprofessional care.

At the same time, the AMA recognizes the need to modernize and stream-line the state licensure process, particularly for those physicians who wish to obtain licenses to practice medicine in multiple states, whether that practice be via telemedicine or in person. For this reason, the AMA strongly supports the Interstate Medical Licensure Compact, a newly proposed licensing option under which qualified physicians seeking to practice in multiple states would be eligible for expedited licensure in all Compact member states. In addition to easing the burden of obtaining and maintaining licensure in multiple states, the Compact will strengthen public protection by facilitating state medical board sharing of investigative and disciplinary information that they cannot share now. Since 2015, seventeen states have joined the Compact including, Alabama, Arizona, Colorado, Idaho, Illinois, Iowa, Kansas, Minnesota, Mississippi, Montana, Nevada, New Hampshire, South Dakota, Utah, West Virginia, Wisconsin, and Wyoming. The Compact continues to gain financial support as well; in June 2016, the Health Resources and Services Agency (HRSA) Licensure Portability Grant Program announced a $250,000 annual three-year grant to support implementation of Compact activities. The AMA is encouraged by the Compact's promise to modernize, simplify and streamline the state licensure process while maintaining the state's authority over the practice of medicine, and as such, continues to encourage stakeholders to support the Compact and other mechanisms through which to support physicians who wish to practice medicine in multiple states.

Promoting patient centered care and care coordination

The AMA urges policymakers to promote telemedicine and mobile apps that will support care delivery that is patient centered, promotes care coordination, and facilitates team-based communication. We urge policymakers to support telemedicine and mobile apps that promote interoperability of systems, products, and platforms—or minimally portability of data. Digital medicine tools should be consistent with and serve as infrastructure for new value-based accountable care delivery models, and without data portability, new telemedicine models—particularly outpatient care—may further fragment care and create additional silos instead of building medical neighborhoods of collaboration. Promoting patient care coordination through medical home and accountable care models will become achievable where data portability and interoperability are promoted in the context of telemedicine and mobile apps. The foregoing is more likely where telemedicine and mobile app technologies are used to extend the capacity and reach of physicians and health care practices and systems in the community where a patient resides. Alternatively, such care coordination and new delivery models will become more difficult to implement if new telemedicine platforms and options create barriers to engagement with a patient's treating physicians, medical home team, and neighborhood.

As part of the AMA's research and analysis of telemedicine, mobile app, and remote patient monitoring technologies, we have had the opportunity to consider a number of innovative platforms—this review remains ongoing. The companies offering telemedicine and remote patient monitoring platforms and technologies have approached the need for care coordination with the medical home and the medical team, and the need to construct technologies and policies that support patient centered care between traditional and new locations of care and members of the patient's medical team with differing levels of importance. Currently, some new telecommunication vendors that use free-standing platforms to triage urgent care, for example, have relatively weak methods to support care coordination with a patient's medical home where an established physician-patient relationship exists outside of the telemedicine platform offered. On the other hand, some vendors have developed models that emphasize partnerships with existing community providers to scale or extend the patient's medical home's reach utilizing telemedicine models. One vendor, for example, offers a variety of data sharing interfaces via the Health Insurance Portability and Accountability Act-compliant standards to allow the vendor to support information sharing with the patient's medical home. Again, the AMA urges policymakers to promote

telemedicine and mobile apps that will support care delivery that is patient centered, promotes care coordination, and facilitates team-based communication.

Evidence base and clinical standards of care

Policymakers should also increase support for further development of research and evidence regarding the impact telemedicine and mobile apps have on quality and costs. There is a developing body of research on an array of telemedicine and mobile app technologies and services, but the evidence base in some areas does not exist or is limited. As the technologies proliferate and the medical services that are covered expand, there will be increasing pressure to ensure that there is a clinical evidence base to support new applications, and that uses are safe and efficacious. Research has moved from demonstrating the technology works and is functional to evaluating the comparative effectiveness of services offered through telecommunication modalities as compared to in-person services.

Telemedicine and remote patient monitoring are not part of a separate medical specialty. Standards of care for telemedicine services and remote patient monitoring in some areas are well-established, but in many other areas remains a work in progress where a number of pace setting specialties have been very involved in developing relevant clinical practice guidelines. National medical specialty societies continue to develop clinical guidelines or position statements relating to telemedicine and remote patient monitoring—these include the American College of Radiology, American Academy of Dermatology, American Psychiatric Association, and Society of American Gastrointestinal and Endoscopic Surgeons, for example. The AMA is engaging both national specialty and state medical societies concerning practice guidelines as well as policies broadly governing telemedicine and expects more activity in this area.

While there is growing evidence that certain uses of telemedicine and mobile apps can improve care coordination and adherence, there is equally concerning indications that certain telemedicine and mobile app prescribing practices in urgent care settings and where care is not coordinated with a medical home or compliant with practice guidelines may lead to public health threats. Specifically, the prescribing of antibiotics without appropriate diagnostic testing may further exacerbate the serious and growing problem of antibiotic resistance—a persistent and deepening public health threat.

AMA policy and reports

Over the past several years, the AMA's House of Delegates comprised of physician leaders from every major national medical specialty society and state medical association, has adopted a growing number of reports and policies supporting appropriate uses and adoption of telemedicine and mobile apps.[1] In June 2014, the AMA's House of Delegates adopted the Council on Science and Public Health's Report 5: Guidelines for Mobile Medical Applications and Devices (attached) (Report). The Report covers many of the topics identified by the subcommittee and includes a number of recommendations that the AMA has moved forward to implement through ongoing and developing collaborations with stakeholders in the digital medicine space.

[1] The reports include: Council on Medical Education Report: Telemedicine and Medical Licensure (Annual Meeting 2010); Board of Trustees Report: Professionalism in Telemedicine & Telehealth (Annual Meeting 2013); Council on Medical Service Report: Coverage and Payment for Telemedicine (Annual Meeting 2014); Board of Trustees Report: Facilitating State Licensure for Telemedicine Services (Interim Meeting 2014); Council on Ethical and Judicial Affairs Report: Ethical Practice in Telemedicine (Annual Meeting 2016); Council on Medical Service Report: Virtual Supervision of "Incident to" Services (Annual Meeting 2016); and Council on Medical Education Report: Telemedicine in Medical Education (Annual Meeting 2016).

We appreciate the opportunity to comment and look forward to working with the subcommittee and Congress.

OPTERNATIVE

Opternative, INC
175 N. Ada St. #200, Chicago, IL 60607

Written Testimony of **Opternative, INC**
IN SUPPORT OF Mobile Health Applications and their Affordability, Accessibility & Delivery of Care,
Before the House Subcommittee on Commerce, Manufacturing and Trade

July 13, 2016

Chairman Burgess and members of the committee,

Thank you for taking time to read the written testimony I am submitting on behalf of Opternative in support of Mobile Health Applications.

Our company, Opternative, was founded with a sincere belief that glasses and contact lens prescriptions should be accessible and affordable to everyone.

Anyone who wears glasses or contacts knows the frustration and inconvenience of getting a new prescription and purchasing vision correction. Appointments, time off work, waiting rooms, and hidden fees, this process and equipment has seen little innovation in the past 75 years. We knew there had to be a better way, so we created Opternative.

The Opternative online eye exam is the most convenient way to get a prescription for contacts and glasses. With just a computer and smartphone, you can take your exam anywhere, anytime, and your doctor issued prescription can be used to shop everywhere.

Whether you have good insurance, bad insurance, or no insurance at all, Opternative can save you time and money on your next eye exam and prescription. Almost half of our patients are covered by vision insurance and still choose to use Opternative because of the additional cost saving over a traditional eye exam. Based on a recent third party survey of 600 Opternative patients, 88% reported saving money and 96% reported saving over an hour from the traditional eye exam process.*

Many consumers across the United States do not have an optometrist within reasonable travel distance. Access is further restricted because basic vision care is not part of normal health insurance and is not mandated for adults (19 or older) by the ACA. The needs are staggering: according to the Vision Council's VisionWatch study, 67 million American adults have not had an eye exam in the last two years due to convenience and cost issues, and millions of Americans have never had an eye exam. Meanwhile, an estimated three-quarters of the US population needs some form of corrective vision care.

OPTERNATIVE

At Opternative, we believe in a transparent exam process and flat pricing to educate and empower our patients. At just $40 for a prescription for glasses or contacts and $60 for both, we provide a medical necessity without the costly bills that often follow a visit to an optometrist. Getting a prescription for glasses or contacts through Opternative saves a patient on average 68.5% on a typical optometrist visit for an eye exam which cost $127 on average, based on a study by the Management & Business Academy.**

Our mission is to help the world see and feel better. Eye exams for glasses and contact prescriptions are just the beginning. The potential for Opternative is much bigger than simply saving our patients time and money. We envision a world where technology enables patients and doctors to connect to make all aspects of vision care more convenient and accessible.

Optometrists are trying to ban ophthalmologists from issuing prescriptions for glasses and contact lenses via telemedicine tools. New clinically proven technologies like Opternative would be blocked from providing patients access to safe, convenient, and low cost prescriptions for glasses and contacts.

We believe that legislation should enhance, not diminish, consumers' access to telehealth by: maximizing the types of technology that can be used; empowering providers to use the technology of their choice with patients; requiring secure use of information technology; eliminating barriers such as requiring prior in-person visits; and recognizing that telehealth is a tool, not a separate practice of medicine. Our 99.6% satisfaction rating is a testament to how much our patients love the Opternative experience. Patients come first, it is that simple.

I urge the committee to support the healthcare advances within mobile application technologies.

Sincerely,

Aaron Dallek
CEO & Co-Founder

*Preliminary results from July survey of 600 Opternative patients. Survey managed by First Insights.
** MBA for Eyecare Professionals http://ecpu.com/media/wysiwyg/docs/paa_keymetrics_0415.pdf