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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, D.C.

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.

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 doctors, 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 content -- 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. We think that is the -- 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:]

******** COMMITTEE INSERT ********

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.

[The prepared statement of Ms. Schakowsky follows:]

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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.

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.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

[The prepared statement of Mrs. Blackburn follows:]

******** COMMITTEE INSERT ********

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.

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, most healthcare 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.

[The prepared statement of Mr. Pallone follows:]

******** COMMITTEE INSERT ********

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," you know, 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.

Okay. 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.

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

[The prepared statement of Dr. Experton follows:]

******** INSERT 1-1 ********

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 things that I would like to -- 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 health care mobile-y 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 lesion -- 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, you know, 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:]

******** INSERT 1-2 ********

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:]

******** INSERT 1-3 ********

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, 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:]

******** INSERT 1-4 ********

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 approach 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:]

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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. Okay. 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:]

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

******** INSERT 1-6 ********

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, quote, "going online for health advice was more likely to result in getting no advice or incomplete advice than the right advice," unquote.

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?

RPTR ZAMORA

EDTR HOFSTAD

[11:18 a.m.]

Mr. Terry. Patient-facing.

Ms. Schakowsky. -- 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 okay, 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 know, 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 -- you know, 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 necessarily the physician -- 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 is sufficient -- 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. Okay.

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, you know, 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. Okay. 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 utilization 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, email, 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, you know, 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, you know, 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. Yeah.

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, you know, 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, you know, 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, you know, 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 data is now -- 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?

You know, 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 okay, 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 okay 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 provider 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, you know, 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 kind of recreational data versus, you know, professional-grade data. So, in my mind, we have to set a very clear bar on, you know, 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 a blood pressure that high before. But, you know, 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 emailed 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.

I mean, 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 registered medical devices -- 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. Yeah. 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, you know, 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, you know, I am thinking back to the flip phone that I had when I started in the Congress. Yeah, I could take a picture with it, and you could almost make out the images. I mean, 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.

I mean, 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 okay.

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," you know,

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 having the patient -- you know, 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 follows:]

******** INSERT 2-1 ********

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.]