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<u>RPTS HUMISTON</u>

<u>DCMN ROSEN</u>

21ST CENTURY TECHNOLOGY FOR 21ST CENTURY CURES

WEDNESDAY, JULY 17, 2014

House of Representatives,

Subcommittee on Communications and Technology,

Joint with

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

    The subcommittees met, pursuant to notice, at 9:32 a.m., in Room 2123, Rayburn House Office Building, Hon. Greg Walden [chairman of the Subcommittee of Communications and Technology] presiding.

    Present: Representatives Walden, Upton, Barton, Shimkus, Pitts, Terry, Burgess, Blackburn, Gingrey, Scalise, Latta, Lance, Cassidy, Guthrie, Gardner, Kinzinger, Griffith, Bilirakis, Long, Ellmers, Waxman, Pallone, Eshoo, Green, DeGette, Butterfield, Barrow,

Matsui, and Braley.

Staff Present: Clay Alspach, Counsel, Health; Gary Andres, Staff Director; Ray Baum, Senior Policy Advisor/Director of Coalitions; Sean Bonyun, Communications Director; Matt Bravo, Professional Staff Member; Leighton Brown, Press Assistant; Noelle Clemente, Press Secretary; Andy Duberstein, Deputy Press Secretary; Paul Edattel, Professional Staff Member, Health; Gene Fullano, Detailee, Telecom; Kelsey Guyselman, Counsel, Telecom; Sydne Harwick, Legislative Clerk; Robert Horne, Professional Staff Member, Health; Grace Koh, Counsel, Telecom; Carly McWilliams, Professional Staff Member, Health; David Redl, Counsel, Telecom; Charlotte Savercool, Executive Assistant, Legislative Clerk; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Health; Jean Woodrow, Director, Information Technology; Ziky Ababiya, Minority Staff Assistant; Eric Flamm, Minority FDA Detailee; Karen Lightfoot, Minority Communications Director and Senior Policy Advisor; Margaret McCarthy, Minority Professional Staff Member; Rachel Sher, Minority Senior Counsel; Matt Siegler, Minority Counsel; and Ryan Skukowski, Minority Policy Analyst.

Mr. <u>Walden.</u> Okay. We are going to call the hearing to order. Thank you all for being here this morning. Good morning and welcome. Today, the Subcommittee on Communications and Technology and Subcommittee on Health joint hearing on the 21st Century Technologies For 21st Century Cures. I would like to thank all of our witnesses for testifying today. Your testimony is extraordinary and most helpful in our endeavors.

When Chairman Upton and I announced that we would begin the process in updating the Communications Act, we knew it would be a difficult but much-needed process. So I am pleased today to be joining the Communications Act update with another important Energy and Commerce Committee initiative, 21st century cures, the communications and technology sectors that are an enormous boost to our Nation's struggling economy due in part to the high investment and in innovation in wireless technology and other devices.

As we craft the legislation to update our laws, it is essential to hear from a wide variety of people who are on the front lines of developing and using these types of technologies in all spaces. Their unique viewpoints and expertise will help inform our consideration as we move forward, as well as underscore exactly why we have undertaken these challenging efforts to revamp existing laws.

It makes sense to unite these two initiatives, as they are both critically important not only to industries that are crucial to the

economy, but also for every person here. This is an opportunity to recognize the benefits wireless smartphones and devices can provide to improve an individual's health and the healthcare community.

We have seen examples of this intersection already from wearable devices that track activity, to the use of mobile apps reminding users of their individual health needs, to a patient's ability to easily and remotely communicate with their doctor through a telehealth device. The growth in this area has been remarkable. There is a technological revolution happening in the healthcare space.

In the communications and technology world, there has been a good deal of focus on the so-called virtuous cycle of technology; that is, the investment in devices and networks creates opportunities for app developers to create new and innovative uses for these devices, driving demand for consumers, which then spurs further investment. The healthcare technology field the perfect setting for this engine of invention and development.

As healthcare technologies proliferate, patients, doctors and researchers will realize the potential for the technology, and as a result, demand will increase. Increased demand means even greater incentive for investors to place their bets on the technology, which, in turn, spurs the cycle even further.

In reading the testimony submitted by our witnesses in advance of today's hearing, I was impressed by what they can already do in the

healthcare field using technology that exists and what the potential is as we develop. In Mr. Misener's written testimony, he describes how leveraging cloud technology allowed scientists to conduct an experiment at a cost that was orders of magnitude less than it would have been using traditional data center and infrastructure. And I believe it was 39 years compressed into 9 hours. This is exactly what we are hoping to learn about today in more detail and how we can take advantage of these opportunities.

With that, again, thank you for being here.

And I now recognize Mr. Pallone for 3 minutes.

Mr. <u>Pallone.</u> Thank you. Thank you, Chairman Pitts and Chairman Walden.

We are here today to discuss the ways in which promising new technologies may be harnessed by the healthcare industry to provide better quality care, inform healthcare research, and empower Americans to better maintain their own health. The Subcommittee on Health has explored this issue in a number of different hearings this Congress, most recently in April, when we examined how 21st century technology can benefit patients. And what we have learned today and what I hope we will hear more about today is that these technologies may not just improve patient outcomes, but also have the potential to bring down the cost of care for everyday Americans and for the Nation.

Many health systems are responding to the Affordable Care Act's

call to reduce costs and improve quality by adopting the use of technologies like electronic health records, health analytics, telemedicine and mobile health applications. By monitoring patient progress in real time, providers will limit costly readmissions and prevent the onset of advanced stages of disease. In fact, declining readmission rates played a significant role in slowing the growth of our Nation's health spending in the years following passage of the ACA, and in the long-term budget outlook published Tuesday, the CBO found that the decline in our health spending will allow the Medicare trust fund to remain solvent for an additional 6 years.

And this testifies to how the law is pushing providers to improve the quality of care, but also to the potential of health technology like telemedicine and patient tracking systems to relieve the financial burden of preventable conditions on the entire healthcare system.

In keeping with the ACA's embrace of preventive care, many of these technologies will help -- will keep people healthy and enable patients with chronic disease to better manage their conditions on their own. The CDC estimates that 133 million Americans live with at least one chronic illness disease like diabetes, heart disease and cancer, and the treatment of chronic illness accounts for more than 75 percent of all health spending, so it should be clear that keeping Americans healthy must be a national priority. Additionally, with access to quality data, health researchers at the NIH and throughout

the country will be better able to study the range of conditions which afflict Americans, research that can be used to develop more effective treatments and inform the practice of evidence-based medicine.

Meanwhile, health analytics will allow insurers to design value-based benefit plans which will reimburse providers for the quality and not the quantity of care they render. And with this monetary incentive, providers will more often invest in an ounce of prevention than wait to deliver a pound of care.

Many of the technologies discussed today can improve Americans' health, yet we must remember that the adoption of technology for its own sake does little good and can contribute to the escalating cost of medicine. We have to work to ensure that advances in health technologies serve to improve all Americans' health, stopping the onset of preventable conditions while not exacerbating health disparities along socioeconomic lines. And further, we must make certain that the transfer of these data and doctor-patient communications complies with Federal regulations and that Federal law ensures the confidentiality of patient data.

Our witnesses today represent firms developing these technologies, and I thank them for their testimony as well as their efforts to improve Americans' health.

And Mr. Chairman, I am looking forward to hearing what is now in the field and how this further contributes to the past work of our

committee. Thank you.

Mr. <u>Walden.</u> Thank you, Mr. Pallone. Appreciate that.

Now we go to the chairman of the Health Subcommittee, Mr. Pitts, for an opening statement.

Mr. <u>Pitts.</u> Thank the chairman for this joint hearing of the Subcommittees on Communications and Technology and Health, and welcome all of our witnesses here this morning.

As part of our committee's 21st century cures initiative, we are examining the discovery, development and delivery process to speed new treatments and cures to patients. One of the most promising avenues to facilitate this goal is new technology, and we are witnessing the impact of that technological innovation that it has played in every aspect of our economy. Technology has the potential to transform health care as well, and in doing so, address many of the challenges that we currently face. The question before us is how do we ensure that our healthcare system can take advantage of the innovation going on in the tech world.

We now have mobile medical apps that can make health care more personalized, if we don't over regulate them. We have electronic health records that can be shared among various providers to help better coordinate the care we receive, if we can ensure they are interoperable. These and other technologies hold great potential for the future of health care and personalized medicine. In order to realize this

potential, however, we are going to have to address barriers that currently make full integration difficult.

Our witnesses are here today to help us think through these technologies and the role they can play in a 21st century healthcare system. So I thank all of the witnesses for being here today.

And as I yield back, I ask for unanimous consent to submit for the record a letter from the Telecommunications Industry Association.

Mr. Walden. Without objection, so ordered.

[The letter follows:]

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

Mr. <u>Walden.</u> We now turn to the gentlelady, my friend from California, Ms. Eshoo, for opening comments.

Ms. <u>Eshoo.</u> Thank you, Mr. Chairman. And welcome to the witnesses. And I want to thank the leaders of the two subcommittees for having this joint hearing. I think it is a terrific idea and an important one, to talk about the combination, the intersection of technology and medicine. And I think that in both areas, it represents American genius, and that is why I find it so exciting.

My Silicon Valley District is the home of modern day innovation. It really is the innovation capital of our country, of the world. It embodies an entrepreneurial spirit and it attracts those who identify challenges and turn them into opportunities. They drive new technologies, expand education and find creative ways to build a better world and to improve humankind.

The valley has a long history of pioneering technological advancements. After World War II, the development of the semiconductor industry, which is really the foundation of Silicon Valley, led the way to the desktop computer and then to the explosion of the Internet, which continues to flourish. And I could tick off a whole list of honor roll names of companies that are identified with the Valley.

What is equally important, in my view, in Silicon Valley, and it is not always widely recognized, are the parallel advancements in

health care. My district is the birthplace of biotechnology in our country, and we have more biotechnology companies there than any other place in the country and in the world. So it is an eloquent statement about the region and what takes place.

There are hundreds of young companies developing the latest therapeutics, medical devices, diagnostics, genomic tests and wireless healthcare technologies. And the ability for these two industries, high technology and health care, to mature side by side has really yielded, I think, unparalleled advancements for patients and dramatically improved healthcare outcomes. So that the whole issue of the power of broadband and wireless connectivity, it is the intersection of technology and health care, I think is more dynamic than ever.

In Mountain View in my district, iHealth's blood pressure monitor is empowering individuals to take charge of their health care by wirelessly connecting this data to a smart phone. That used to be for James Bond. Now it is for the average person.

Similarly, Proteus, a Redwood City-based company is improving patient health care through an ingestible sensor which wirelessly sends information using blue tooth technology. I mean, this -- it really is -- it is not only cutting-edge, it is exciting and it is important.

I am very proud to have Dr. Dan Riskin here today from my district testifying. Thank you for coming across the country to do so. He is

a serial entrepreneur. He is the founder of Health Fidelity and consulting faculty at Stanford University School of Medicine. So thank you, Dr. Riskin. And he serves on the eHealth Initiative Leadership Council and collaborated with the Bipartisan Policy Center on their oversight framework for assuring patient safety and health information technology. Jeez, I thought only in government did we have long titles like this, but I guess it is in academia as well.

So want to welcome all the distinguished witnesses here today. And, again, I thank the leadership of both of the subcommittees for putting this important hearing together.

Mr. Walden. Thank you.

Ms. Eshoo. And I yield back.

Mr. Walden. Thank the gentlelady.

We now turn to the chairman of the full committee, the gentleman from Michigan, Mr. Upton, for opening comments.

The Chairman. Well, thank you, Mr. Chairman.

With this hearing, we are going to continue our commitment to modernizing laws and regulations to keep pace with the breakneck speed of the innovation era. Two leading initiatives have been our Comm Act update, which seeks to update the 80-year-old laws governing the communications and technology sectors, and obviously 21st Century Cures, which aims to accelerate the pace of cures in treatments.

Today we have the unique opportunity to bring together two of our

subcommittees and look at the intersection of these efforts and the ways in which new technology is enabling remarkable advances in medical care and treatment and research.

Our witnesses include established tech companies that are hoping to bring their expertise to bear on the challenges of modern health care as well as startups that are focused solely on tech solutions for patients and clinicians, from electronic health records, to cloud storage of genome research and apps that identify preventative health strategies, we are looking at the future of medicine. Technology is supporting proactive solutions, collaborative research, and improved communications between patients and their physicians.

Our committee has gone great lengths to encourage investment in innovation in the U.S. tech sector, and there are few applications of that work more important than the health of all Americans. We have the opportunity to not only enable new cures, but accelerate the pace at which they are realized. By taking full advantage of available technology, the possibilities for the future of health care indeed gives us hope.

In June we held a round table to explore the opportunities and obstacles surrounding digital health care, and I look forward to continuing that conversation. It is my hope that this hearing, like the round table, will help us identify ways in which this committee and the Congress can support the adoption of lifesaving technologies

in the healthcare sector. I thank you all for being here, and I yield back the balance of my time.

Mr. Walden. The gentleman yields back the balance of his time.

The chair now recognizes the distinguished gentleman and former chairman of the committee, Mr. Waxman, for 3 minutes.

Mr. Waxman. Thank you very much, Mr. Chairman.

This joint subcommittee hearing is a chance for members to learn more about the technological innovation taking place in our healthcare system. Technology can play an important role in expanding access to care, improving the quality of care, improving health outcomes, and reducing costs.

In recent years, we have witnessed incredible innovation in our healthcare system, venture capital funding for digital health companies is at a record level, new innovators are entering the industry every day. And it is not a coincidence that all of this innovation has occurred in the years since we passed the Affordable Care Act. As a managing director of a major startup incubator put it, "We are seeing a lot of tailwinds from the healthcare reform. It has put a lot of pressure on existing stakeholders to reduce costs."

It is also not a coincidence that this innovation is occurring following our unprecedented investment in expanding the use of health information technology through the Recovery Act. The number of doctors using these technologies has quadrupled in just 3 years. The

percentage of hospitals using them has grown from 16 percent to 94 percent.

It is not a coincidence that we have seen all of this innovation with FDA and the FCC offering important guidance and using their enforcement discretion wisely. And it is not a coincidence that we have seen this innovation at the same time that HHS has opened up vast amounts of data to the public while recognizing innovation with awards and grants to help startups shake up the health system.

I mention these important ways the Federal Government has helped foster a climate of innovation, because this hearing and the committee's 21st century cures initiative should focus on these successes.

I look forward to hearing from today's witnesses about what needs to be done to continue these trends that are improving our healthcare system every day. We should legislate only where appropriate and necessary, otherwise, we risk jeopardizing the integrity of a system that is already functioning quite well.

Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. Walden. Thank the gentleman for his opening comments. And now we go directly to the witnesses.

Thank you all again for submitting your testimony in advance. We appreciate that. And we will open up with Mr. Dave Vockell. Is that right? Did I say that correctly?

Mr. <u>Vockell.</u> Close enough.

Mr. <u>Walden.</u> And turn on that microphone.

Chief executive officer of Lyfechannel. We are delighted to have you here. Please proceed.

STATEMENT OF DAVE VOCKELL, CHIEF EXECUTIVE OFFICER, LYFECHANNEL; DAN RISKIN, FOUNDER, HEALTH FIDELITY; PAUL MISENER, VICE PRESIDENT, GLOBAL PUBLIC POLICY, AMAZON; ROBERT JARRIN, SENIOR DIRECTOR, GOVERNMENT AFFAIRS, QUALCOMM INCORPORATED; DR. JONATHAN NILOFF, CHIEF MEDICAL OFFICER AND VICE PRESIDENT, MCKESSON CONNECTED CARE AND ANALYTICS, MCKESSON CORPORATION

STATEMENT OF DAVE VOCKELL

Mr. <u>Vockell.</u> Good morning, Chairman Walden and Pitts. I am Dave Vockell, the CEO and founder of Lyfechannel, Inc. It is a great honor for me to be here today, and I want to thank you for the opportunity to testify on this very important topic of innovative technology and the current and potential impacts to population health.

I would like to briefly cover three topics today: first, a short overview of Lyfechannel to give you some context as to the role that startups can play in the rapidly evolving healthcare delivery landscape; second. I will cover three lessons learned and the "so what" that might inform how you evaluate health technology opportunities; and third, I am going to share a list of large insiders who I think are forward thinkers and innovators in working with new technology, and to try to discover what is next for healthcare delivery.

Lyfechannel, Inc., builds mobile patient programs that translate physician instruction into patient action, which help patients new to diabetes, pre-diabetes, COPD, heart health and smoking cessation begin to build basic good habits to support their chronic conditions. We also operate a preventive health program targeting the chief health officer of a household. We create programs that connect the patient and their personal support team and their care providers through integration across mobile experiences and the provider's electronic health record.

Over the past 3 years, we have worked closely with patients, pharma companies, government agencies, payers, EHR's, providers and other technology companies to translate changes in technology and consumer behavior into opportunities to impact long-term health. We have learned three important lessons relevant to consumer facing health. First, if you are not integrated into the existing patient flow, whether it would be the physician or the provider or payer, it is almost impossible to become part of a patient's health journey. Consumer health actions are not only the behaviors that new technology companies need to engage, but they are also hospital procedures, billing protocols, prescribing habits, hundreds of habits within the system that we need to be a part of.

Number two, technology doesn't change behavior, it just potentially creates a new access point to things that do change patient

behavior. A cool app on your phone doesn't make you take your meds by reminding you or making a game out of it. You don't skip your Lipitor because it wasn't fun or because you forgot; you skip it for the basic human behavior that you feel great and you are not connecting your current health behavior to long-term health. Technology experiences that reinforce the drivers of good health behavior create patient-led, not technology-led solutions.

And finally, there remains a strong economic incentive not to release the data that will drive patient insights and recommendations for the next 10 years. Many payers do not release claims data that could fuel incredible insights into pinpointing health intervention opportunities, because they have a large business selling that data to pharma companies. Electronic health record companies don't make it simple to exchange data with other EHR's, because it reduces switching costs of moving to a different HR for a hospital.

There are a handful of innovative large institutions that unleashed great innovative momentum through aggressive piloting and partnership with third parties, and the pattern of their innovation is similar. They make public a problem they are trying to solve, they make data available to support solving that problem, and then they find a pathway to engaging technology innovators to solve that problem.

Here are a couple examples of those leading innovators. The Office of Disease Prevention and Health Promotion, under the guidance

of Linda Harris, Ellen Langhans and Silje Lier of the ODPHP are pioneers in co-design of digital experiences incorporating health literacy principles. They not only engaged third-party technology companies against the goal of the ODPHP, but also systematically share their learnings with other government and public sector groups to advance best practices and patient literacy around preventive health. Their Myfamily mobile program has been a pilot for the past 10 months and is about to release version 2, which includes EHR integration and connectivity with the new Apple Healthkit platform.

Boehringer-Ingelheim, under the guidance of Jon Doniger in their new business model group, aggressively engages new technology companies to help his organization understand the role that pharma could play in healthcare delivery in 10 years.

The Allscripts EHR platform under the leadership of Tina Joros has also embraced third-party developers and platform openness to tap into the power of technology innovators.

Johnson & Johnson, Robert J. Wood Hospital System, Box and CMS have also been aggressive in identifying problems, making data available to entrepreneurs and helping them try to solve their hardest problems.

In summary, we believe that technology companies that partner with large insiders and lead with patient behavior versus cool technology have the greatest opportunity to impact health outcomes in

the next 10 years. There are some great innovators that should serve as a model, and no shortage of technology innovators with limitless energy and caffeine to try to impact population health.

Thank you again to the chairpersons and members of the subcommittee for your time today and the opportunity to participate in this hearing. I would love to answer any questions you have. Thank you.

Mr. Walden. Thank you very much, Mr. Vockell. We appreciate your testimony as well.

[The prepared statement of Mr. Vockell follows:]

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Mr. Walden. And now we are going to go to Mr. Riskin. We appreciate your being here. And founder of Health Fidelity. Thank you for being here, Dan. And turn that microphone on, pull it close. And we look forward to your comments.

STATEMENT OF DAN RISKIN

Dr. Riskin. Great. Good morning, Chairman Walden.

Mr. Walden. You have to push the little button on there.

Dr. Riskin. Ah. Good morning, Chairman Walden.

Mr. Walden. One more time. We are a technology subcommittee.

Dr. Riskin. All right. How are we doing.

Mr. Walden. There we go.

Dr. Riskin. Thank you.

Good morning, Chairman Walden, Chairman Pitts, Ranking Member Eshoo, Ranking Member Pallone and members of the subcommittees. It is an honor to testify.

I am a serial entrepreneur, founder of Health Fidelity, a leading big data analytics company, and consulting faculty at Stanford University School of Medicine. In addition, I am a practicing physician, board certified in surgery, critical care, palliative care, and clinical informatics. I serve on eHealth Initiative Leadership Council and collaborated with Bipartisan Policy Center on their efforts

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toward patient safety and healthcare IT.

I have been fortunate to succeed as an entrepreneur, educator and surgeon, and I am grateful to the Federal Government for contributing to my success. I have been awarded multiple grants from the NIH and National Science Foundation, each grant resulting in creation of multiple longstanding, long-term, high-paying skilled jobs. Every Federal dollar received has resulted in $15 of follow-on private sector investment. These efforts have led to companies and products used at Harvard, Stanford and other leading institutions to benefit patients and enhance medical knowledge. My background has afforded me unique insight into healthcare innovation and practice.

21st century technology in health care includes devices, data, information-enabled work flow. This newly emerging data-driven health care not only offers the right information at the right time for the right patient, but also provides a needed pathway for population health, analytics and patient engagement. The goal is a more efficient, effective and approachable healthcare system. Collaboration and innovation are required, and government has a critical role to play.

Today I will focus on three actionable recommendations to promote safe and meaningful innovation in health care. These include re-defining interoperability to share the information that is needed for clinical analytics and population health; revising our approach

to quality to better align with improved outcomes and reduced costs, and research to better understand safety and healthcare IT.

I recently cared for a very nice woman who was failed by our healthcare system. A heart murmur had been noted during physical exam years earlier. Unfortunately, on changing her insurance, the information was buried and lost in medical documentation. Her failing heart valve was only discovered years later when she presented to the emergency department unable to breathe. She required an emergency operation, leading to an extended ICU stay and millions of dollars at taxpayer expense. If her condition had been recognized early and treated electively, the likely costs would have been far lower, and she and her family would have been spared a month-long stay in the hospital. I will discuss recommendations in the context of her case.

The first actionable recommendation is a better definition of interoperability. Current efforts and proposed regulations focus on sharing patient's summaries only. Unfortunately, there is simply not enough information in these summaries for innovative analytics companies like mine to promote data-driven health care. In this clinical case, an exam finding was documented in the physician narrative, but did not show up on the problem list and would not be present in an interoperable summary. To support interoperability of summaries only, as is proposed in current regulation is to ignore critically important information such as home environment, medication

compliance, exam findings and hospital course. Innovation and care improvement will be hobbled for years to come by this arbitrary limitation.

Through the Meaningful Use program, our country has subsidized electronic capture of clinical data. Why wouldn't we require that all data we paid to capture be available for use by innovative companies and technologies to actually improve care.

The second actionable recommendation is an enhanced definition of quality. This patient's care met all process measures required, she had routine tests, documented counseling, weight documented, but did she receive great care? Quality measures and increasingly selected for feasibility, meaning we often select for what is easy to measure rather than what really influences outcomes. In this case, a relevant measure of quality would be whether the patient received appropriate follow-up for her heart murmur. If quality measures are our national target, this is the time to refine our approach and require accurate and meaningful quality measures in health care.

Finally, my patient's information was exposed to many healthcare software systems. Were these systems safe and effective? While the country defines a first-pass approach to healthcare IT safety, we must acknowledge these IT systems are new, innovative and rapidly evolving. To refine our regulatory approach over time, we will need information on how and when healthcare software is safe versus potentially

dangerous. Supportive academic and clinical research in healthcare IT benefits and risks would go a long way to help us refine regulation over time.

We are going in the right direction. Health systems, payers and vendors are collaborating through new financing models and newly available data with new enthusiasm, but there is a great deal of work left to do if we are to bridge the gap from electronic information to better and more efficient care.

I look forward to continuing to work with you to leverage our national HIT investment to create data-driven health care. The U.S. is well poised to revolutionize health care and to benefit our people and economy at home while showing global leadership in this critical industry.

Mr. Walden. Thank you very much, Mr. Riskin. We appreciate your testimony.

[The prepared statement of Dr. Riskin follows:]

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Mr. <u>Walden.</u> We will go now to Mr. Misener, vice president, Global Public Policy at Amazon. Paul, please go ahead. Thanks for being here.

STATEMENT OF PAUL MISENER

Mr. <u>Misener.</u> Thank you, Chairman. Good morning, Chairman Walden, Chairman Pitts and Ranking Members Eshoo and Pallone, subcommittees. My name is Paul Misener, and I am the vice-president of Global Public Policy at Amazon.com. On behalf of Amazon and our customers, thank you for inviting me to testify today on how 21st century technology enables 21st century cures.

After briefly describing cloud computing technology, my testimony will illustrate how innovative healthcare organizations, both large and small, established and startup, public and private already use cloud computing to foster the innovation cycle of discovery, development and delivery of new biomedical treatments and cures. I will conclude by suggesting three ways that Congress could help accelerate this cycle by adopting policies to facilitate use of cloud computing for health care.

With cloud computing, information technology users, including healthcare enterprises now can acquire technology resources such as compute power and storage on an as-needed basis instead of buying,

owning and maintaining their own data centers and servers.

In 2006, Amazon's cloud computing business, Amazon Web Services, or AWS, began offering developer customers access to in-the-cloud infrastructure services. AWS now has hundreds of thousands of customers, including over 3,000 academic institutions and 800 government agencies.

In the healthcare sector, enterprises of all sizes and types are beginning to use cloud computing technology for the discovery of new biomedical treatment and cures. As the chairman mentioned earlier, in 2013, Novartis scientists discovered a large molecule involved in the disease mechanism for a particular type of cancer. The scientists wanted to virtually screen 10 million compounds against the large molecule. Such a large number of screenings is extremely computationally intensive. Novartis did not have the capacity in their existing data center to do this type of test, and building new infrastructure would have cost an estimated $40 million. Instead, using AWS, they built a virtual high performance computing center in the cloud and were able to perform the equivalent of 39 years of science in less than half a day and for under $5,000.

Enterprises are also beginning to use cloud computing for the development of new biomedical treatments and cures. For example, in the summer of 2012, Merck was noticing higher than usual discard rates for certain vaccines. The high discard rates could result from many

factors. Evaluating these factors for every vaccine produced was extremely challenging using a traditional spreadsheet approach, so instead, Merck worked with a partner to implement a cloud-based solution using AWS, and over a 3-month period, they were able to combine all of their data sources and perform over 15 billion calculations and more than 5.5 million vaccine batch-to-batch comparisons, and thus they were able to precisely identify how characteristics of fermentation had direct impact on vaccine discard rates.

Lastly, enterprises are beginning to use cloud computing for the delivery of new biomedical treatments and cures. For example, the USFDA, which receives 900,000 handwritten reports of adverse drug effects each year, needed a way to make the data entry process more efficient and reduce costs. Using AWS cloud computing, the FDA and Captricity quickly turned manual reports into machine readable information, reducing costs from $29 per page to $0.25 per page.

Chairman Walden and Chairman Pitts, please allow me to suggest three ways that Congress could help accelerate the innovation cycle of discovery, development and delivery of new biomedical treatments and cures by facilitating the use of cloud computing for health care. First, to help accelerate the discovery of new biomedical treatments and cures, Congress could work with NIH to establish and operate cloud-based data management platforms to which federally funded researchers could upload their research data along with any relevant

software resources required to reproduce their analysis of the data. Other researchers in the field could then access the data in software in order to reproduce the results, re-analyze previously collected data in novel ways, or even automate the analysis of new data using the same approach as the original experiment.

Second, to accelerate the discovery and development of new biomedical treatments and cures, Congress could enact both H.R. 967 and H.R. 1232. These are bills that would assess and facilitate the use of cloud computing by Federal science agencies.

And third, to help accelerate the delivery of new biomedical treatments and cures, Congress could work with HHS to modernize implementation of HIPAA so that healthcare providers could readily employ the benefits of cloud computing. By narrowing the application of HIPAA to situations where cloud services providers have access to and knowledge of health information, time and money won't be wasted on contracts that are mostly inapplicable, and cloud services providers can more reasonably comply with HIPAA by focusing on areas where they actually have access and knowledge of health information.

Chairman Walden and Chairman Pitts, thank you again for holding today's hearing and for inviting me to testify. I look forward to your questions.

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 Mr. Misener follows:]

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Mr. Walden. Those are wonderful recommendations. Thanks for your testimony. It is always impressive to see what is happening out there.

For the members' benefit, we have -- we are about 10 minutes to go in the first vote, but we always know that takes a little longer, so we will try and get through the witnesses if we can.

We will go now to Mr. Robert Jarrin, Senior Director, Government Affairs, Qualcomm Incorporated. Thank you for being here. We look forward to your testimony.

STATEMENT OF ROBERT JARRIN

Mr. Jarrin. Thank you, Chairman. Good morning, Chairman Walden and Chairman Pitts, Ranking Members Eshoo and Pallone, and members of the subcommittees. On behalf of Qualcomm, an American company and the world's largest wireless chipset supplier and largest licensor of mobile technology, it is an honor to be here again. Thank you for inviting me.

Mobile technology, Qualcomm's specialty, has become the largest communications platform in the history of the world, and it continues to grow. Currently, there are 355 million connections in the U.S. and over 7 billion globally.

We forget how quickly mobile technology has proliferated. The

Android OS and Apple's iPhone were launched in 2007, the iPad in 2010. You wouldn't know it, the way consumers rely upon these services and devices. Qualcomm can't make this happen by itself, which is why we work with many partners. I am pleased to be here today with one of them, Amazon.com. Their leading-edge Kindle Fire HDX tablet, Fire smartphone and Fire TV media player all incorporate Qualcomm's innovative Snapdragon chipsets.

Qualcomm's technologies are found in products that touch every aspect of society, including health care, which is why in 2011, we launched Qualcomm Life, a wholly-owned subsidiary focused on medical device connectivity and management of health data. At Qualcomm, we understand that nothing can transform a sector like mobile 3G and 4G technologies. Health care is a good example, one in which I have personal experience.

On August 16th, 2006, my mother was diagnosed with Stage III-C late term ovarian cancer. She was 65, a widow, with limited English proficiency. From the start of her odyssey, I discovered that doctors, clinics and hospitals were not sharing her healthcare information. I was struck by the lack of continuity of care. When she left the care provider or facility, there was no mechanism to remotely monitor her basic physiological status. This seemed dangerous in light of countless doses of chemotherapy, protein inhibitors, and toxic serums she endured, which caused horrible side-effects, including extreme

high blood pressure and edema.

In the years since my mom's initial diagnosis, mobile computing devices have helped personalize health care. Remote patient monitoring is now helping drive systemic changes in healthcare networks. Platforms, such as Qualcomm Life's HealthyCircles, facilitate the management and sharing of medical information between stakeholders across the patient's healthcare community.

Qualcomm Life and its partners produce novel commercially available 21st century mobile medical solutions, such as mobile ECG recorders, wireless telemetry sensors, mobile glucose monitors, software systems that deliver live patient data to a doctor's smartphone, smart inhalers, and radiological imaging viewers for mobile devices, and implantable pulmonary sensors that communicate wirelessly with bedside monitors.

The future is even more exciting. The X PRIZE Foundation and Qualcomm developed a $10 million competition, the Qualcomm Tricorder X PRIZE, to produce a device that diagnose 15 distinct diseases in a group of 15 to 30 people within 3 days by a consumer, independently of a healthcare worker or facility.

If investments are any sign of the future, the first half of this year shows 143 companies having raised $2.3 billion year to date, thus eclipsing the 2013 total of $2 billion. Those investments include some by the Qualcomm Life Fund, which was formed in 2011 and is now considered

one of the most prolific investors in wireless health.

However, challenges do persist. Lack of reimbursement is a major barrier to telehealth and remote patient monitoring technologies. Medicare telehealth provisions in the Social Security Act are overly restrictive and exclude the majority of these technological innovations, and that needs to be changed. Another is the Center for Medicare and Medicaid Services EHR incentive payment program, popularly referred to Meaningful Use rules, which do not include the ability to upload patient-generated health data into certified EHRs. Future stages of the program should specify the incorporation of patient-generated health data from home use medical devices into EHRs.

Another important issue is spectrum, the lifeblood of our wireless networks. Qualcomm commends this committee and Congress for all the work it is doing to make additional mobile broadband spectrum available. This work is critically important.

In closing, the speed of innovation should never come at the expense of patient safety. Health IT software and mobile medical apps developers should support data collection and quality mechanisms to foster patient safety and create a learning environment.

Nearly 8 years after my mom's diagnosis, I am thankful to her healthcare team that she is continuing to live an enjoyable life. I am also grateful for the advancements in 21st century medical technologies are helping society as a whole. Qualcomm has played a

significant role in mobilizing health care, to improve lives and

advance digital medicine, and it will continue to do so.

Thank you. I look forward to your questions.

[The prepared statement of Mr. Jarrin follows:]

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

Mr. <u>Walden.</u> Mr. Jarrin, thank you. And that is good news on your mother. Having lost a mother to ovarian cancer, I know how awful that --

Mr. <u>Jarrin.</u> I am sorry to hear that.

Mr. <u>Walden.</u> -- diagnosis is and the treatments can be. So I am glad to hear your mother is doing well.

We will now go to Dr. Jonathan Niloff, Chief Medical Officer and vice president, McKesson Connected Care & Analytics, McKesson Corporation.

And for our members, the Whip's office will keep the vote open until we get there, so we can conclude with our final witness this morning.

So Mr. Niloff, thank you.

STATEMENT OF JONATHAN NILOFF

Dr. <u>Niloff.</u> Thank you. Good morning, Chairman Walden and Pitts, Ranking Members Pallone and Eshoo, and distinguished members of the subcommittees. I appreciate the opportunity to appear before you today.

Throughout my career as a gynecologic oncologist in Boston, faculty member at Harvard Medical School, and founder of a small health IT company, I have seen firsthand the power of IT to improve outcomes,

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reduce costs, and accelerate the pace of change in our healthcare system.

As the largest health IT company in the world, McKesson is focused on the transformation of health care from a system burdened by paper to one empowered by interoperable electronic solutions.

There is a significant opportunity to improve our healthcare system, but to do so, we must fundamentally transform how care is delivered. We need to move from a fragmented model of care, where each patient visit is disconnected, to a model where care is coordinated across the entire continuum. Interoperable health IT is foundational to this transformation.

I would like to share today two recommendations which will advance health care in the 21st century. First, we must align payment and coordinated care models in order to create an environment that fosters interoperability; and second, we need a new risk-based regulatory framework that is specific to health IT.

We don't today have an easy, uniform way to move patient data between care settings. The interoperability we need requires collaboration among all stakeholders to develop uniform standards, coordinated policies, and the necessary infrastructure to promote interoperability and assure coordination of care.

ONC has provided an important role in providing common guardrails for the exchange of health information. It is important that we

maintain flexibility within those guardrails to allow for industry innovation. One example of innovation and interoperability is the CommonWell Health Alliance. CommonWell was founded by McKesson in partnership with our competitors to develop a software solution that will share patients' data, with their consent, across multiple settings of care. We have made significant progress in endeavor over the last 18 months. It is essential that we are able to share the right patient data in the right place and the right time. This solution is imperative to creating a new model of coordinating care.

Fostering innovation in the private sector is critical, but there is also a role for Congress to play. Policy changes are needed to reflect current advances in technology and promote ongoing innovation. A 21st century health system demands 21st century policies. We support a new regulatory framework that would establish three categories of health IT. Oversight of each category would vary according to potential risk to patients and the role of the clinician.

The FDA should continue its important role in regulating software with the highest potential risk; however, we believe Congress should amend the Food, Drug and Cosmetic Act to define each of these categories of health IT and provide clarity that clinical and administrative software should not be regulated as medical devices.

To realize a true 21st century healthcare system, we need fundamental change in our healthcare delivery model. We need to

replace our fragmented system with patient-centric coordinated care.

This transformation has begun, but we need to accelerate the pace of

change, and to do this, we must harness the power of technology.

Specifically, we must align reimbursement and payment models to promote

the adoption and also the interoperability of health IT, and Congress

must update the law to codify how health IT is regulated in a way that,

while assuring patient safety, is predictable and fosters innovation.

The result will be better outcomes, better access, better cost

efficiency, and better experiences for patients and their families.

Thank you for the opportunity to testify today.

[The prepared statement of Dr. Niloff follows:]

******** INSERT 1-5 ********

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.

Mr. <u>Walden.</u> Dr. Niloff, thank you for your testimony. Thanks to all our witnesses.

We will go vote and then members will come back and ask questions. We are probably going to be gone at least a half an hour, I would assume, so if you need to take a break, it is a good time. We will reconvene immediately after votes. Thank you very much.

We stand in recess.

[Recess.]

RPTS BAKER

DCMN HUMKE

[10:56 a.m.]

Mr. Walden. I will call the subcommittee back to order and appreciate again the testimony of our extraordinarily distinguished panel of witnesses. Thank you very much.

And don't think you are off the hook because I think what you have given us here is very important, and we will be following up, I am sure, over the months and years ahead to dive deeper with you on how we can all get this right.

I am going to start off with questions, and the first one goes to Mr. Misener. Are there any laws or regulations that have impacted the development of the cloud that we should take a look at deeply, change that hinder what we are trying to accomplish here, what you are trying to accomplish here?

And I am not talking obviously we have got to protect data and privacy and security and all that, but are there other things we should be aware of that would facilitate advancements in the sectors we are talking about today?

Mr. Misener. Yes Mr. Chairman, thank you for the question. I think Government can serve as --

Mr. Walden. I'm not sure your mike is on, it may just need to

be closer.

Mr. <u>Misener.</u> I think it is. It is on.

Mr. <u>Walden.</u> Yeah, just closer that is all.

Mr. <u>Misener.</u> Okay here.

First of all, thank you for the question, Mr. Chairman. There are areas in which Government could lead, provide an example to private industry, and one particular roadblock we have run up against over the years trying to serve Government institutions including the U.S. Federal Government and its agencies, is that there is oftentimes money set aside for agencies to buy computers, to buy software, to invest capital essentially which is highly inefficient when instead money could be allocated for purchasing service, making it an operational cost rather than a capital investment.

And the Government could not only be able to be much more flexible that way, in other words, only purchase what is needed and then discard it if it is not needed, but also it allows Government to scale up and scale down as necessary. But we have also often run into problems where agencies are only given authority to buy specific things like hardware or software when actually they should be able to have the freedom to obtain services instead.

Mr. <u>Walden.</u> Got it. So on another issue, and back to you, Mr. Misener, and if others want to weigh in on these subjects, please feel free to do so. But, how can we modernize HIPAA to ensure that patient

information is protected but that we can still utilize data? There are other countries that have laws that protect patients but also facilitate data sharing and leveraging the research being done.

I know in our round table that Chairman Upton convened recently, Dr. Brian Druker who heads the Knight Cancer Research Center in Oregon, talked about I think it is 65 petabytes, did I say that right? Of data, just involving cancer patients that could be harnessed to do an analytic work and all and research. Are there some issues with HIPAA; are there things we should be looking at in that respect?

Mr. Misener. There are, Mr. Chairman. It is not a huge barrier at this point, but what we would like to be able do is recognize that there are sometimes when information is stored in the cloud where it is known to be health information and it is accessible to the cloud service provider. But most of the time that is not the case. We don't know what information is stored there, and it is also encrypted, so we can't get at it; and yet we still have to go through HIPAA hoops as if we had access to the information.

Mr. Walden. So what would that mean in real laymen's terms?

Mr. Misener. It means the health care enterprise that is storing data on our servers, has HIPAA requirements placed upon it, but those requirements are also placed on a cloud services provider, even though it is entirely unnecessary. We can't see that data, and usually we don't even know it is there.

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Mr. <u>Walden.</u> But from a practical standpoint, what does that mean in your company, you have to do?

Mr. <u>Misener.</u> I think it means asking NIH not to interpret the rules so broadly as to require a cloud services provider to comply with HIPAA where it is not necessary. But of course we do comply with HIPAA, Amazon Web Services does, when it is necessary.

Mr. <u>Walden.</u> Okay.

Dr. Niloff, what are the technical challenges your company is facing as you work to innovate in health care that we might need to take a look at, besides what you outlined in your testimony?

Dr. <u>Niloff.</u> Sure. So, I think the major technical challenges involve interoperability, and the typical environment in the health care system is very heterogeneous with multiple different EMRs and multiple different other systems that we need to connect to. And --

Mr. <u>Walden.</u> EMRs being electronic medical records?

Dr. <u>Niloff.</u> That is correct, sir. And solving that challenge, the technical challenge of connecting such heterogeneous environments, is a big barrier today.

Mr. <u>Walden.</u> All right, anybody else want to weigh in on these topics.

Mr. <u>Vockell.</u> I would say the HIPAA question initially, the inability of patients to give up their right to privacy, like the HIPAA requirements are kind of universal whether it is I have a cold or whether

I have HIV.   And there are some conditions where let's say I had celiac disease, I would love to tell everyone on earth that I have it because most likely that is how I am going to find out better ways to take care of myself.   But because of HIPAA, I can't even email my doctor.

And so I think if there were additional opportunities, let's make it super simple.   I want to email my doctor; he wants to email me back, but we don't because it is against HIPAA for him to send me health information, but both of us would agree that it is okay for me to talk about my kid's fever through email.   So I think what that kind of example we have around regulation is that when the FDA kind of took their very vague some mobile stuff might be good, some mobile stuff might not be good and made it we are all hanging around.

And they said, all right, you guys can leave the room; you guys come in, we want to talk some more, and you guys stay close, that changing very gray to more black and white allowed a lot of people to innovate and build something and do stuff.

Mr. Walden.   Yeah.   We did an oversight hearing on that very issue about a year ago because nobody was getting clarity whether your iPad was a medical device or not, and we got them to admit some of those things.

Mr. Vockell.   I would have stood up and applauded.   But I think similarly with HIPAA, if there could be another layer of, this is what is covered, and this is what isn't; it is okay to email your doctor

about your kid's flu, that would do a lot to create innovation points for better care.

Mr. <u>Walden.</u> All right. Thank you.

I have overextended my time. I will now turn to the gentleman from New Jersey, the ranking member on the Health Subcommittee, Mr. Pallone, for five minutes.

Mr. <u>Pallone.</u> Thank you.

Reading the testimony today, I was impressed by how much progress we are making towards a more technologically advanced health care system, and one important step the Federal Government is taking to encourage this innovation is to open up much of the data it collects to the public. That allows developers, programmers, and academics to dig into this data and develop new tools to help improve our system.

I wanted to ask Mr. Vockell, can you talk more about how you have put this open data to use and the potential benefits of this increased transparency over the long-term?

Mr. <u>Vockell.</u> Yeah, thank you very much. Life channel about six months ago, CMS released the big data set around exactly what every provider for Medicare charges for every protocol. And a couple weeks ago at the Health Data Paloosa, which is a lovely name that I think Tod Park came up with, that Government and public agencies come together to talk about the incredibly exciting topic of health data. They had a competition to say for this big data set, who can make it into

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something super interesting.

And LyfeChannel 1, largely based on some research that we did at the International House of Pancakes, the good example that CMS sets is they release data before it is totally perfect. The CMS data was 50 percent actionable. But we said early and they give entrepreneurs or any great data analytics house a chance to churn through it and pull out what they can and then make recommendations on what the next version of the data should look like.

I think the more that holders of that health data are encouraged to kind of release it when it is excellent, not when it is perfect, will allow entrepreneurs to get up on it like a shark and reveal if there is something inside or help identify what the next round of it should look like.

Mr. <u>Pallone.</u> Thank you. I think the steps that CMS and the other Federal agencies have taken in this area are really important. I wanted to ask Dr. Riskin, in your testimony you state that health quality measures are often selected because they are easy to track. Could you elaborate on your recommendation that we need more accurate and meaningful quality measures in health care?

Dr. <u>Riskin.</u> Yes. Thank you for your question, Mr. Pallone.

The challenge is whether we try to develop measures for what is easy to do today or whether we create a target for what we need to do to improve health care. If we create a target for what we need to do

to improve health care, we won't be able to hit it today. The technology doesn't exist. If we don't, if we pick what is easy, then we won't actually meaningfully reduce costs in health care in a short term.

So to give an example, an easy quality measure would be, are you counseling people for smoking cessation, and a hospital might meet that measure by on every discharge summary writing, you should not smoke. That doesn't do a lot of good if it is buried five pages down and mostly put in for non-smokers anyway.

On the other hand if the measure is, do you smoke and that ties to an outcome like reduced costs and improved quality of care, that is the kind of measure that is meaningful. We don't do a lot of that because it is so hard for an her to measure, but over time the really robust analytics companies will figure out a way to hit that target if the Government makes that known that that is the target to hit.

Mr. Pallone. Thanks. And, Mr. Jarrin, in September last year, FDA issued a final guidance on mobile medical applications. It provides a long list of applications that FDA does not intend to regulate at all. Basically I just wanted to get your views on this guidance. I mean, do you think that the FDA struck a proper balance between protecting patients safety on the one hand and allowing innovation to flourish on the other? And do you see any risks in trying to legislate in this area?

Mr. Jarrin. I think FDA did a good job by issuing the final guidance on mobile medical applications. It was definitely very different from the original draft. The original draft basically just restated the law without any clarity and without any vivid example.

In the final draft guidance, they provided numerous examples of what they were putting under enforcement discretion, enforcement discretion being the ability for the agency to state publicly we are not going to obligate regulatory requirements on certain medical devices. Even though by definition they are medical devices, we are not going to require regulatory obligations. So I think that was very helpful to the industry.

Mr. Pallone. What about the risk though in trying to legislate in this area?

Mr. Jarrin. I am not sure I would say that there is a risk in legislating the area. I think that that was the next evolution to what Congress had originally intended through FDAISA. Through FDAISA they had asked for a risk-based regulatory framework. The agencies then came out with that through the FDAISA draft report that they are contemplating currently. I think it is now the next step for Congress to decide whether it would like to go in and make those recommendations, you know, codify them. That is a higher pay grade than me.

Mr. Pallone. Thank you.

Thank you, Mr. Chairman.

Mr. Pitts. [Presiding.] The chair thanks the gentleman.

I will recognize myself five minutes for questions.

Mr. Misener, in your testimony you suggest that Congress work with NIH to establish and support the cloud-based management platforms. Can you expound a little bit more on why you think this is so important? What are some of the benefits, cloud based platforms might lend to 21st century cures?

Mr. Misener. Thank you, Chairman Pitts.

Modern biomedical research is a highly collaborative process. All scientific research these days is collaborative. The days of a major breakthrough coming from a sole, an individual working with a you know, a Bunsen burner and a test tube, it is over. You only need to look at some of the scientific journals and see the lists of authors. It is no longer unusual to see hundreds of authors listed in a major scientific paper, even over a thousand.

And so that kind of co-research requires collaboration. And if the Federal Government can establish a way for federally funded researchers to share their information, even outside their normal channels of collaboration, it will become far more efficient and more productive.

Mr. Pitts. And you mentioned one other concrete step that you recommended as we decide, if we decide to support this endeavor. List some other concrete steps that Congress can take. One was clarifying

HIPAA. What are others?

Mr. <u>Misener.</u> Well, there are two bills that the House has already address and hopefully they will be addressed in the Senate well, that actually would assess the Government's provision or accommodation of cloud computing for scientific agencies, and another would clarify Government agency's ability to obtain cloud services in lieu of hardware and software. Both of those are important pieces of legislation, not only on their own merits or on their own rights of what is going on within the U.S. Federal Government, but as setting an example to State and local governments, to private industry, to governments in other countries, that there is a great deal of efficiency that can be gleaned from the cloud in dealing with collaboration that I mentioned and also just the massive amounts of data that now go into any form of scientific research, including biomedical research.

So Government setting an example, I think is something that Congress can be part of right now.

Mr. <u>Pitts.</u> You mentioned Amazon worked with FDA to turn 900,000 handwritten reports of adverse drug effects each year into machine-readable information with 99.7 percent accuracy, reducing the cost from $29 per page to 25 cents per page. This cures initiative, is in part focused on using technology to relieve administrative burdens for agencies such as FDA, so they can use the resources to invest in more researchers and new development methods such as biomarkers.

Do you have other suggestions for other ways we can increase efficiency at FDA or other agencies?

Mr. Misener. Yes, Mr. Chairman. There is a model of scientists doing things that they don't need to be doing.

One would be for example, I don't know, producing their own electricity for their laboratories. You don't want them out in the back of the laboratory working on a diesel generator just so their labs have lights. Likewise, you don't want them to have to be tinkering with computing equipment, either for storage or for computation, in a way that that could easily be provided like a utility, like electricity. So let's figure out ways to allow our scientists to be scientists, our doctors to be doctors, and not have to have them be information technologists at the same time, even though as part of the collaboration and the data-intensive work that they are doing, computation is absolutely necessary. It is just that they don't need to be the ones doing it.

Mr. Pitts. Now, we talked a little bit about HIPAA. Are there other countries that have laws that protect patients but also facilitate data sharing, leveraging the research being done? Any of you who would like to --

Mr. Vockell. Yeah, I am not familiar with other countries' details.

Mr. Pitts. Anyone familiar with other models?

All right let me just go finally, one common recommendation was for fully harnessing the potential of interoperable technology. Are we talking about just electronic health records, or do you think that medical devices, other health care sources of data should be interoperable, if you will elaborate on that any of you?

Dr. Niloff?

Dr. Niloff. Yes. Thank you. I think that the interoperability has to extend beyond just electronic health records. There are multiple sources of both clinical and non-clinical data that are important to aggregate together with the clinical data in electronic health records, and that interoperability should exist.

There are also a variety of an analytic solutions which are important to improving population health. So solutions that identify patients that are likely to be hospitalized, patients who have progressing illnesses, and the ability to link clinicals and claims data with those type of systems to allow the early proactive intervention in the care of those patients, is a very valuable intervention to driving improved health, decreasing hospitalizations, and decreasing emergency room visits.

Mr. Pitts. Chair thanks the gentleman.

Now recognize the gentlelady from California, Ms. Eshoo, five minutes for questions.

Ms. Eshoo. Thank you, Mr. Chairman.

I want to say to each of you bravo. I think you have -- every single one of you have been terrific witnesses and you have given us, which is so important in a hearing, instead of starting with Adam and Eve, you have gone right into the meat of the subject matter to make recommendations for us and that really is so helpful. So thank you to you.

On this issue of interoperability, obviously there is more than one part of it, and what I wanted to ask you, Dr. Niloff is, is there anything that the Government is doing today that stands in the way of interoperability, as you just described it; i.e., in patient's record, is a physician prohibited from putting in the last line these are the most important things to track with this patient? I am not a doctor, so I am probably not stating it, you know, as beautifully as I should.

But I am trying to figure out where we have regulations that need to be written, where we have regulations that don't make any sense anymore, or what we need to write and put on the books, and all of these areas are really important. So can you answer my question?

Dr. Niloff. Sure. Thank you. So, electronic medical records typically have a lot of flexibility but we are --

Ms. Eshoo. Thank you. I helped write the legislation on it, so it is nice to hear.

Dr. Niloff. But, you know, I think that with electronic health records and the rest of healthcare technology, we are at the beginning

of a journey, and it is a journey that is going to take us many years to get to both to the level of sophistication in the solutions and in the level --

Ms. Eshoo. But specifically though, when it comes to interoperability and electronic health records, are there regulations that you think don't make sense, or are you calling for something that will help advance interoperability? We deal with interoperability all the time at communications and technology relative to the telecommunications industry. This is a different deal. That is why I am probing here.

Dr. Niloff. Sure. I think that the thing that will drive interoperability the most and where the Government can have the greatest influence, is in making the business case for interoperability for those who are going to pay for it and what that means is that we need to align the payment models --

Ms. Eshoo. I think that for the most part now is private sector though, because there were initial grants or whatever to get the electronic records going. I think that money has been spent. So I don't think we are players in it.

Dr. Niloff. If I may, I am not talking about direct incentives. What I am referring to is that --

Ms. Eshoo. We need to speed it up. I have 1 minute and 20 seconds left. You have had 4 of my minutes almost.

Dr. Niloff. Okay. I apologize.

Ms. Eshoo. That is all right. Go ahead.

Dr. Niloff. How we pay for medicine and what I mean by that is if we are doing global payments, if we incent the delivery model to do a coordinated care model and the payment is aligned with the delivery model --

Ms. Eshoo. I understand that part of it.

Dr. Niloff. We will drive the adoption of this type of technology.

Ms. Eshoo. Well, thank you very much.

To Dr. Riskin, I see you nodding, and I think you want to say something.

Dr. Riskin. So to the same question, there are choices that are being made right now that could be better. So the choice for interoperability right now is we only share information out of the electronic health record that is perfectly structured, meaning only information --

Ms. Eshoo. So how do we make this more robust and meaningful so that the right information is extracted because that feeds through the whole system?

Dr. Riskin. Sure. So if a doctor wrote right now what is really important here is these three things, that would be ignored and never shared. What is needed is --

Ms. <u>Eshoo.</u>   But the Federal Government shouldn't be instructing doctors how to write something.

Dr. <u>Riskin.</u>   It doesn't matter how -- the doctors will write what they write, but the Federal government is instructing what needs to be shared in interoperability format.

Ms. <u>Eshoo.</u>   So share is the operative word?

Dr. <u>Riskin.</u>   That is right.   And if we share all of the information, then the analytics companies can pick up the useful information.

Ms. <u>Eshoo.</u>   I just have so many questions, but my time has run out.   I think what I will do is to submit questions to you both about the cloud, software, hardware; that is another whole thing.   I am so thrilled that your mother, that you told a beautiful story, and it means a lot I think to all of us.   Certainly to you.

Thank you, Mr. Chairman.

[The information follows:]

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

Mr. <u>Pitts.</u> The chair thanks the gentlelady.

Now recognize the gentleman from Illinois, Mr. Shimkus, for five minutes of questions.

Mr. <u>Shimkus.</u> Thank you, Mr. Chairman. It is great to have you all here, and I am going to try to be quick, too.

But I am going to just segue right after my colleague, Congresswoman Eshoo's question, is getting out of order the way I wanted to go.

But, Mr. Riskin, this data information is really the crux, and so I am concerned that, or the question is, if you are going into the genomics debate and personalized medicine, the data, are we in the way because of HIPAA or some other rules and regs that we are afraid to put the data available to a larger field because of the rules and regs we have in place?

Dr. <u>Riskin.</u> Yes. Thank you for the question. Yes, certainly the privacy and security policies make it tougher to share data. With that said, I am one of the biggest proponents of keeping data safe. We are asked as a big data company to use genomic data and combine that with phenotypic data, the clinical information, and figure out what it means. Keeping it safe is critically important. That doesn't mean that you shouldn't share it safely. So if the private sector can keep it safe and follow regulations to do that but there is also a requirement that the information come out in certain formats so it can actually

be used, that is a very powerful setup, so all of the data we have paid to collect can be used to do meaningful things.

Mr. Shimkus. So let me move to Mr. Misener on kind of the same talk. A lot of folks are afraid to go into this field because they have done a business analysis. They don't know if there is a return on investment. You guys have decided to try and move in this, and so data storage and computation is the area that you think obviously can get you a business model plus improve.

You know, I am a market capitalist, so we don't get these investments unless there is a return on investment. We don't get that unless there is improved health access and the like. So is that the model, the business model that you think that you all can do is this big data storage and computation while keeping that data safe and secure.

Mr. Misener. Yes, Mr. Shimkus. We very much believe in this business. We are very passionate about it as well. We kind of backed into it as a retail company online. We figured out at one point that, gee, we have a business in keeping data safe and organizing it and storing it and being very efficient about it. So we started making it just kind of a service available to developer customers. We think in the medical field, the medical sector, there are many opportunities for the storage and sharing of data in a way that is highly secure.

We not only believe that security is incredibly important to our

business, but it is actually much easier to do at scale. We have the ability to provide security measures in the cloud that just aren't available for local storage of information and so we are passionate about it, and I think we are an enabler of the genius that you see at the table here.

Mr. Shimkus. Just because I want to get the last two in. In the mid 1970's, Congress defined medical devices, which I think for the most part people thought at that time was good and helpful. The question is, is it time for us to look at codifying terminologies to help us through these processes? I mean a lot of us talk about FDA and how do we expedite, but don't you think it might be time to look at some new words and definitions and define them in the law so that we can get some application speedily and I just kind of throw that up as a comment. Anyone want to jump in real quick? I got one more question so if you can be brief.

Dr. Niloff?

Dr. Niloff. Yes, so I believe that, that is very important. You know, when I went to medical school, we didn't have computers. This is all new stuff, and that is the era the law was developed, and I think that we need sort of new law that conforms with the state of the world as it exists today. I think that is really essential to driving investment and --

Mr. Shimkus. Let me follow-up because your testimony, you really

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talk about developing a new risk-based regulatory framework that is specific to health information technology. With my remaining time do you want to talk about that a little bit?

Dr. Niloff. Sure. So you know, I think it is essential. I go back to you know, when I started my company. I raised four rounds of venture capital, and the process was very similar every time. Once you figured out the business model with the investors, they wanted to know two things. What's the IP issues or the patent problems, and what is the regulatory environment and how is that going to affect their investment and the risk of their investment, and it happened every time.

And also predictability, a stable environment where everything is codified and predictable is critical, and it has to be over the long-term. I thought one round was going to do it, and I was all set, but we ended up with four rounds. And it is a long process, you need a stable environment for it to drive technology and innovation.

Mr. Shimkus. Thank you.

Mr. Pitts. The chair thanks the gentleman.

Now recognize the gentleman from Texas, Mr. Green. Five minutes for questions.

Mr. Green. Thank you, Mr. Chairman. Again, thank you for calling the hearing on joint telecomm and health care.

In a July 4th article in Forbes the co-founders of Google were asked if they would imagine Google becoming a health company. Their

response was no. To quote Mr. Page, "generally health is so heavily regulated, it is a painful business to be in. Even though we do have some health projects, we will be doing that in a certain extent, but I think the regulatory burden of the U.S. is so high I think it would dissuade a lot of entrepreneurs. In my experience this is not an isolated sentiment from the tech community."

Doctor, now in your experience, is Google's view of innovation in the health care sector a common one?

Dr. <u>Niloff.</u> Yes, sir. You know, I think as I have had you know, sort of lots of opportunities over the years when I was running my company to meet with other entrepreneurs and largely through forums through our investors, and this was a common topic of discussion. You know, overregulation is an inhibition to investment and an inhibition to innovation.

So having, as I just stated, a stable environment that is predictable and where we are not prohibiting investment and therefore innovation is important and I believe widespread.

Mr. <u>Green.</u> Well, just from what some of us know, and this is such a good coordination of these two subcommittees because of what we can do with the combination of the high tech and the health care, it literally could open up so many avenues for folks. I know there are some supporters of the current regulatory approach of health care that suggest that the regulatory uncertainty under the FDA is a proper

approach, which I don't obviously agree with that.

However, my constituents are concerned when leaders in the tech space like Google suggest health sector is an unwelcome place for innovators. Frankly if that is true, millions of patients will be harmed, and this is a huge problem.

Dr. Niloff, what can we do to attract more tech innovators into the health care space, and can Congress play a role in helping to create more certainty for innovators in the health care space?

Dr. Niloff. Yes, thank you. So, I think that there are two things. I think that the first thing reflects on my previous comment, is we need an environment that from a regulatory point of view that drives investment, and that is all around certainty about the future so that that doesn't become a barrier, we don't have, if you will, a risk premium on investments related to health IT.

I think the second area is certainty or greater certainty about what the environment is going to be, the delivery environment is going to be, and how we are going to pay for health care in that environment, so that there is greater certainty around what the market is going to be for these innovations.

And specifically I am referring to, from a congressional perspective, is that CMS with respect to the various programs that it promulgates defines the payment model, and the private sector commonly follows what is promulgated by CMS. Providers are challenged when they

have to work in part fee for service world and part accountable care world, and you need to reach a tipping point where enough of your business is in the accountable care world, and I called it the coordinated care world, so it is worth making the investments in the technology to support that care model.

To the extent that collaboratively between the private sector and the public sector we can drive past a tipping point, where investments in technology make sense and are economically sound, we will both help our healthcare delivery systems be more viable and successful while at the same time driving better access, better quality, better patient safety, and more cost effective care.

Mr. Green. Thank you.

My colleagues, we have legislation called the Software Act to establish a commonsense approach to regulating mobile apps and other health information technologies under the FDA and our work is a work in progress, and our office has worked with Ms. Blackburn, Mr. Butterfield, Chairman Walden and others that takes into account the feedback we have received from various stakeholders over the last few months.

And I would commend my colleagues on their leadership but also the important issue we could urge the chairman to address this in the 21st Century Cures and that is what you just said is something I keep hearing. We need to have a payment system that reflects, are we going

to go to the outcomes-based, or are we just going to continuing with the same pay for procedure, and maybe we need to provide leadership from that.

Mr. Chairman, thank you for having this hearing.

Mr. Pitts. The chair thanks the gentleman.

Now recognizes the gentleman from Georgia, Dr. Gingrey, five minutes for questions.

Dr. Gingrey. Mr. Chairman, thank you, Chairmen Walden and Pitts, and thank you for holding today's joint hearing on an important nexus within the jurisdiction of the full committee.

I would like to focus my line of questioning on a topic that has been the focus of the committee for a long time. Ms. Eshoo was getting to that point as well. Innovation and health information technology, HIT,. Dr. Niloff, you state in your testimony, and I quote, interoperable health IT is foundational to health care transformation. We cannot change the health care delivery model without it. Do you believe that we are on path to interoperability, or are there changes to the law that we should consider as part of the 21st Century Cures Initiative?

Dr. Niloff. Thank you, sir. I believe that we are on the path. I think it is a challenging and long journey. I think we can help accelerate that path with some of the suggestions I made in the response to my last question.

I think a good example of that is the work that we have accomplished with the Commonwealth Alliance where we have brought together essentially competitors to collaborate and work together to be able to move patients' health information with their consent around a health care system. We have pilots in place today. It is working. We have tremendously positive feedback from both patients and providers, so I think, sir, that we are, indeed, on the path.

Dr. Gingrey. Well, I agree with what you said, and I hope we are, but I am very concerned, the Rand Corporation report that was published last month found that the main her electronic health record vendor, with over half of the stimulus dollars paid out to medical providers going to their customers, was operating a closed platform which in essence means that they cannot be interoperable.

And Congress has spent, as we all know, something like $24 billion over the past six years buying products to facilitate interoperability only to have the main vendor under the program, Epic, sell closed platforms. Do you believe that the Federal Government and the taxpayers are getting their money's worth subsidizing products that are supposed to be interoperable but they are not? And I will ask any of the panel if they want to weigh in on that. Yes, Mr. Jarrin.

Mr. Jarrin. If I may Congressman, thank you.

One of the assets that we have been pushing for when we discuss interoperability is medical device interoperability, and I mean very

specifically home use medical devices because interoperability can be many things. Health information data exchange between electronic health records, that is one aspect, systems-wide within a hospital, and that would include high acute medical devices. That is another kind of interoperability.

But when you leave a care facility, the electric health records incentive payment program right now that is run by CMS and the ONC which you have quoted, the $24 billion, I believe it goes all the way up to $27 billion, not really much of that really engages patients and families in their care.

As part of the meaningful use stages, stage one, stage two, and stage three, in stage one they described that they were looking at potentially including uploading patient-generated health data into the electronic health record. That would be a way of interoperability. That happens right now because there are many companies that are actually doing that and allowing medical device that is are used at home, like wireless glucometers for example, wireless sensors on inhalers, et cetera. That information can go straight into a portal. It can easily go into an electronic health record, but that is not something that is happening at all and part of that is because the meaningful use stages have not actually stated that very directly. They should.

Dr. Gingrey. Well Mr. Chairman, this committee has primary

jurisdiction over the Office of the National Coordinator, ONC, and the High Tech Act that is responsible for the tens of billions of dollars being spent on non-interoperable products, if the June 2014 Rand report is true, we have been subsidizing systems that block information instead of allowing for information transfers, which was never the intent of the statute. It may be time that this committee take a closer look at the practices of vendor companies in this space giving the possibility that fraud may be perpetrated on the American taxpayer.

Furthermore, Mr. Chairman, as I see my time is elapsed, I would like to ask unanimous consent to include in the record an article from June 17, 2014, from iHealthBeat entitled, Coalition Calls For Action Against EHRs That Block Interoperability. That gets, I think, Mr. Chairman, to the very point I am talking about. With that I yield back, Mr. Chairman.

Mr. <u>Pitts.</u> Without objection, so ordered.

[The information follows:]

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Dr. Gingrey. And with that I yield back Mr. Chairman thank you.

Mr. Pitts. The chair thanks the gentleman.

I now recognize the gentlelady from California, Mrs. Matsui, for five minutes for questions.

Ms. Matsui. Thank you, Mr. Chairman. Thank you for holding today's hearing. It is been very, very interesting listening to all of you.

American innovation is transforming health care, integrating science, medicine and technology, to provide individuals with realtime access to vital health information, much of which was previously unavailable outside of a hospital or a doctor's office. Smart phones are really creating pathways for virtual interactions between doctors and patients. Texting between doctors and patients is becoming more common.

Now, telehealth is really at a critical juncture and increasingly becoming an integral component of the country's healthcare system. But one of the challenges of implementing telehealth is that there is no consistent standard. What we have is an inconsistent and often dated patchwork of state laws. States are currently considering passing legislation addressing telehealth policies which means there is a wide variation in how telehealth is defined and this inconsistency hinders the national deployment of telehealth, hurting those who need care the most.

And that is why I along with my colleague here on the committee, Representative Bill Johnson, introduced the Telehealth Modernization Act to create a workable definition for telehealth services. It provides a strong incentive for states to adopt consistent standards to remove the regulatory barriers to telehealth.

Now, you know, we move forward with all this, too, I am listening to all of this, and I want to ask the question here of Mr. Misener. You talked about some of the ways that cloud computing is enabling medical research, and I think that cloud technologies are useful to foster innovation and research.

And if we think really broadly, and I think about Amazon and all the data you have and all the information that you have and what you are doing now in the cloud, how can big data impact the healthcare sector and be expansive? And I would like to hear comments from the others, too.

Mr. <u>Misener.</u> Thank you, Ms. Matsui. I think there are a dozen or so examples that I offered in my written testimony, but generally I think you are right on point that cloud services are an enabler of the biomedical field both in discovery and development but also in delivery, so I have tried to give you examples in each. But one way to think about this is a researcher today is typically constrained to thinking about questions that he or she may address only with the computing power that they have available in their laboratory, and so

they can't think about big questions because they don't have much computing capacity.

But, if all of a sudden available to them on a temporary basis, however much or little they need, is computing power, they now can think about questions that are far beyond what their laboratory constraints impose upon them today. And so it really is an enabler of that discovery side of things, and it does again enable researchers, scientists, doctors, to focus on what they are best at and not have to worry about the technology that enables them.

Ms. Matsui. Okay.

And Dr. Riskin, I would like your comments, too.

Dr. Riskin. Sure. We are a big data company, so we see a lot of data.

Ms. Matsui. Right.

Dr. Riskin. One of our partners, a large health system sent us a million longitudinal records at one point recently and said we want to understand the association of concepts.

If you have a disease, diabetes, and you take a drug, is there any correlation with the an adverse event there. We didn't have the processing power locally certainly to do that kind of effort. Fortunately we do work with Amazon and we have a good relationship with them, and we asked them can you spin up 100 servers and 20 threads per server, and can we have massive processing power, and we crunched away

at the numbers for a day.

Ms. Matsui. For a day.

Dr. Riskin. Cross referencing every concept with every other concept. There is a challenge here, it is powerful. You get information that you may not want to have, and we work closely with the large academic centers to understand what information is useful and what information is not and put useful information out into the community. But there is a great responsibility behind that kind of work.

Ms. Matsui. Absolutely. And would you be analyzing a lot of this data yourself, or are you going to, as you contract out with the other institutions, have them take that responsibility?

Dr. Riskin. In terms of what gets published, we think it is best for the health systems, the large academic centers, to create protocols and publish, so we can crunch numbers and support them in their protocol. In terms of internal development, we certainly use information to develop the next products to influence patient care.

Ms. Matsui. Do you see big data assisting in as far as the implementation as you get into the healthcare practices themselves down to the very ground level?

Dr. Riskin. I hope so. I don't see that happening in the short term, a year or two, but I sure hope that happens in the long-term. It is one of the best approaches to reduce costs and improve outcomes

in health care.

Ms. <u>Matsui.</u> Okay. I thank you, and I went over my time.

Thank you. I yield back.

Mr. <u>Pitts.</u> The chair thanks the gentlelady.

Now recognize the gentleman from Ohio, Mr. Latta, five minutes for questions.

Mr. <u>Latta.</u> Well thank you, Mr. Chairman, and thanks so much to the panel for being here. It is been a very enlightening discussion that you have all given us today.

And if I could start with Mr. Jarrin, in your written testimony, you stated that another important component of any 21st century technology for 21st century cures is spectrum, which is the lifeblood of our wireless networks. Mobile health solutions are part and parcel of an enormous surge in wireless data usage which is causing the spectrum crunch we are all now facing.

Now in this committee we have had many hearings, we have heard about on the spectrum side and what is happening out there. One was that worldwide by 2017 there would be 1.4 mobile devices per person across the globe. Well, that is not really going to happen because we know that in some areas of the globe of the technological challenges.

But I was also in another meeting the other day that they thought by 2017 in the United States alone there would be seven per person. So when you look at the numbers that are happening out there and also

what you want to be doing with this whole technology, what can Congress be doing to help on this whole spectrum crunch to make sure that the technologies can advance in the future on your end?

Mr. Jarrin. Thank you. More spectrum is the lifeblood -- spectrum is the lifeblood of mobile technologies and modern communications, modern wireless communications, and this committee and Congress in particular have actually shown a lot of leadership in trying to make more spectrum available. And when I mean spectrum, I mean licensed spectrum, shared spectrum, and unlicensed spectrum.

I believe recently there was a bill introduced to help make more sense of the five gigahertz spectrum. We welcome that. M health is not unique to any particular band of spectrum. It is just going to add to the spectrum crunch. There was a task force that was put together by the former chairman of the FCC a few years ago which I helped be a part of, and one of the findings of the task force was that through radiological imaging and videoconferencing, spectrum is going to be really even taxed more within the next couple of years because this is what is expected out of some of the systems and some of the services that we are discussing.

So the more that we have available spectrum, the better it is for the user because we are face a spectrum crunch. The FCC has been very honest about that. So it is something that we at Qualcomm take very

seriously. We actually have an internal challenge where we are trying

to maximize the use of spectrum 1,000-fold what we can today. Called

the 1,000 X challenge, so I believe that Congress is really taking steps

to do that, and thank you.

Mr. Latta. Thank you.

Dr. Niloff, in the 21st Century Cures Initiative, the clinical

trials process is one of the main focuses for the area and in my home

State of Ohio I have toured many of the premier research institutions

across the state, and I have seen firsthand the important work that

these individuals are doing to find cures for many different

life-threatening diseases. Can you give us some examples of how these

new technologies will assist with the clinical trial process and make

it more effective and efficient?

Dr. Niloff. Sure. So I think that the first thing that is sort

of the lifeblood of any trial is the identification of appropriate

patients who would meet the criteria, specifically have the disease

that is to be studied, and by having patient registries, having

patients' diseases codified as structured data in these electronic

systems allows for the easy or more facile and rapid identification

of the large populations of patients that you need as candidates for

these trials. So I think having that data available will expedite and

increase the number of patients available for clinical trials.

The second part in clinical trials, is the ability to follow

patients longitudinally and have good reliable structured data about the course of their disease and the different parameters of their disease to understand if the treatment under study is effective or not effective and by having an electronic source of that data that captures the patients clinical status and the response to the treatment under study in a repeatable, standard way, is very helpful in assessing the outcomes of the study and the conduct of the trials.

Mr. Latta. Well thank you very much.

And, Mr. Chairman, I see my time is about to expire, and I yield back.

Mr. Pitts. The chair thanks the gentleman.

I now recognize the gentlelady from California, Ms. DeGette, five minutes for questions.

Ms. DeGette. Thank you very much, Mr. Chairman.

I really want to thank the panel for this excellent presentation this morning.

You might know that I am co-chairing this initiative with Chairman Upton, and oftentimes we have people come in and sort of talk vaguely about how great it would be to have a revision of the system, but you really came in with some specific suggestions, and we appreciate that as we look later this fall towards actually drafting legislation.

I just want to follow-up with whoever wants to answer this on some discussion we have been having about interoperability. Everybody

agrees interoperability is important, and we are striving for that even now under the system that we have. We are making some progress, but I frequently meet with smaller companies as well as individual physicians who are talking about electronic medical records, and the concern that smaller companies have is that they really don't have the resources to work with patient data and to get that interoperability.

And I am wondering, Dr. Niloff, Dr. Riskin, and also Mr. Vockell, if you can sort of address what we can do to incentivize this kind of interoperability throughout the system, not just with the larger players who can afford to do it?

Dr. Niloff. So I think that the solution to that is through collaboration, and it is not necessary for each individual company to reinvent the wheel multiple times, but through for instance the Commonwealth Collaboration that I referred to earlier is a mechanism where companies who might otherwise compete, be they large or small, can collaborate together and pool resources to develop technologies for interoperability that can then be broadly adopted.

Ms. DeGette. Do you think there is any governmental role in making those things happen, Doctor?

Dr. Niloff. I think the Government role, again, at the end these solutions need to be paid for, and it all harkens back, if you will, to creating the economic environment and payment environment where the ultimate purchasers of the technology and the interoperability have

a business case for purchasing it, which means aligning around a payment model, where having that technology makes the providers successful in the payment model or care delivery model that they are operating under.

Ms. DeGette. Dr. Riskin, do you have a perspective on this?

Dr. Riskin. Yes. Thank you. The question is a great one. There is a boundary between the electronic health record and the analytics system.

Ms. DeGette. Right.

Dr. Riskin. When I work in the venture community in Silicon Valley, we look at opportunities, and there is very little coming through of new electronic health records. It is not where the new value is. The new value is in analytics and population health and patient engagement and we say for those companies to be successful, they need the data, so we will see company after company come in and say we are just going to have the data, and here is what we are going to do and we say that is not fundable because you can't get the data. It is too expensive.

So today, very expensive to get the data out. People are building custom interfaces into these electronic health records that is stifling innovation. There is a Government role here to say we paid for the data in the electronic health record, and here is the information we want out. Today's approaches have very limited information for analytics and population health, ignoring the compliance issues and

social issues and other things, so actually requiring broad data to be brought out would be powerful to promoting innovation.

Ms. DeGette. Thank you. And Mr. Vockell, what about you? Do you have a view on this?

Mr. Vockell. Yes. Earlier Mr. Gingrey talked about Epic and their slow path to making their information available and at the other end of the spectrum is Allscripts which has made a lot of their data available to third-party developers and the challenge has been that I believe Allscripts and some of the other providers have been told here is the format and the type of data you need to make available.

And they look at their own system and they built it in an era that didn't anticipate making that data available and so it is hard work for them to build to this outside set standard, and it makes them not include stuff that Dr. Riskin would find very valuable.

A different approach could be you have to make your data in whatever format you currently have it available, and if you do, entrepreneurs will be all over building Rosetta Stones to translate it between the services. But since you are telling the slowest moving, ingrained, less hungry technology group to build to something, it is slow, and you know, Epic started a year and a half ago to build a public API, and it is barely out the door.

Ms. DeGette. Thank you.

Thank you, Mr. Chairman.

Mr. <u>Pitts.</u> The chair thanks the gentlelady.

And I now recognize the vice chair of the full committee, Ms. Blackburn, five minutes for questions.

Mrs. <u>Blackburn.</u> Thank you, Mr. Chairman.

And thank you all for being here. We do appreciate the panel.

The 21st Century Cures Initiative, the impact of technology in that is something that is incredibly important to our committee and as you have seen from the questioning, we are working in a bipartisan way to address the needs that you all have, that patients have, and that the industry also needs.

And being from Tennessee, we have appreciated the convergence and the impact of technology on health care delivery and do feel like that some of the answers for not only health care delivery, but patient quality of life, are going to be achieved through these devices. And I know Mr. Green mentioned to you all the software act that he and I are working on. Ms. DeGette has joined us in this effort, and we feel is part of the backbone and that is necessary.

We are short on time. Votes are going to come up soon, so Dr. Niloff, I want to come to you and just have a couple of questions for you. The April 2014 FDAISA health IT report, are you familiar with that?

Dr. <u>Niloff.</u> Yes, I am.

Mrs. <u>Blackburn.</u> Okay. They have a framework that the ONC would

among other things create a health IT safety working center. Are you familiar with that plan for regulating some forms of software and health IT?

Dr. Niloff. Yes, I am.

Mrs. Blackburn. Okay. All right, recently Chairman Upton and a couple of our colleagues and I wrote over to ONC to see where they think they are going to get this authority. And, have you seen that letter? Are you familiar with that?

Dr. Niloff. I am familiar with it --

Mrs. Blackburn. We got a response recently, and we felt like that they really don't know where they have that authority, and like so many times agencies get into mission creep, and it concerns us.

We feel like the FDA wants to regulate our medical app products as medical devices, and they are not. And Congress in its infinite wisdom decided in 1996 to update the FDA statute by creating the definition of a medical device in order to differentiate it from drugs. Before that time there was no statutory difference between the two. So just like drugs, software is not a medical device. Medical devices are not drugs, and we think it is necessary to put some clarity in this structure.

So do you believe that Congress needs to get involved in the fix? Should we leave it to the FDA?   Should we leave it to the ONC?   Because it is beginning to us to look like a misguided system of regulation,

and we don't want this to run off the rails. So I would like to know

what your guidance and your thoughts would be on this?

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[11:55 a.m.]

Dr. Niloff. So, you know, when the Act was last updated, if you will, you know, technology as we know it today did not exist, and I think could not even have been contemplated, so we live in a completely different technology environment today than when that Act was written. And I believe that the Act should be updated with the framework as described, a risk-based framework, so that we have clarity for the community, both today and clarity for the development community and the investment community going forward so we are in a stable environment that will allow for innovation and us to make good progress.

Ms. Blackburn. I thank you for that.

Mr. Chairman, I think it is just vitally important that the FDA and the ONC work with Congressman Green and I as we work with the committee to come up with what a structure is going to be so that all of our low and moderate risk items can proceed to the marketplace, and things that are invasive and high risk have the oversight of the FDA, and that clarity is provided for this Nation's innovators.

With that, I yield back my time.

Mr. Pitts. The chair thanks the gentlelady. Now recognizes the gentleman from Louisiana, Dr. Cassidy, 5 minutes for questions.

Dr. Cassidy. Dr. Riskin, I have got some weird experiences here, man. I go to a banker's office or a lawyer's office, and they have fewer clerical workers because of computers. I go to a physician's office, and they are hiring a data enterer and someone to train the data enterer because of computers. Clearly this is socking productivity.

Now, both of you, Mr. Vockell and Dr. Riskin, suggested that there is minimal investment and little incentive on the interface side of it, whereas there is a heck of a lot on the back side. That is wrong.

Now, when I speak to people, they wonder if the High Tech Act is not the problem; that by defining standards, we have stuck in amber certain systems, but as a doc, and I speak to docs whose productivity is down 25 percent, some of whom are taking the penalty. They are tired of looking at a computer screen instead of looking in a patient's eyes.

Do you agree with that assessment, that how the High Tech Act has been implemented is the -- so to speak, we have met the enemy, it is us?

Dr. Riskin. Thank you, Dr. Cassidy. I appreciate the question. Mixed agreement, in that the --

Dr. Cassidy. Speak quickly, please, because I have only got 3 minutes now.

Dr. Riskin. The High Tech Act was powerful in terms of getting initial information in electronically, that is definitely needed, but

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the current processes of requiring information in certain ways has been excruciating for doctors.

Dr. <u>Cassidy.</u> So how do we unravel that?

Dr. <u>Riskin.</u> Probably the way to unravel is through usability.

Dr. <u>Cassidy.</u> Now, that is a little bit code for me.

Dr. <u>Riskin.</u> Yeah.

Dr. <u>Cassidy.</u> When you say "usability," what do you mean?

Dr. <u>Riskin.</u> The challenges, the doctor who is entering data right now or their proxy finds it -- finds they are putting in information that isn't that useful or they are being forced to put in information around billing that isn't clinically relevant. More of a focus on how can the systems be useable and how can we get the information --

Dr. <u>Cassidy.</u> I get that. So there is an incentive apparently right now, I spoke of I am told it is stuck in amber. Entrepreneurs don't have any incentive to go in this space. Mr. Vockell just kind of suggested that. So what I am really asking is how do we once more incentivize these entrepreneurs to begin to do this as oppose -- you know, get rid of the amber, so to speak.

Dr. <u>Riskin.</u> So to solve the data usability problem, the data entry problem, the incentive would require that EHR's be usable and the EHR's would then need to work with companies to create usability. Right now there is --

Dr. Cassidy. I accept that, but you can't just mandate from on high, Washington likes to think it can do so, make it useable. There has to be some penalty not doing so and there has to be some reward for doing so, not upon the doc, because the doc's already being penalized.

Dr. Riskin. Agreed. And the physician community is less and less capable to push for useable systems.

Dr. Cassidy. So, Mr. Vockell, what would you say to that, because you are nodding your head you are in agreement, but I am not sure I have understood yet how we get back to the entrepreneur in caring about this area.

Mr. Vockell. I think you have hit on what is the economic incentive. And right now there is no way for a doctor to translate, I could free up 25 percent of my time and see more patients or deliver a higher quality of care. And so if the payments that the physician were able to receive or the way that they were compensated was linked to the quality outcomes like --

Dr. Cassidy. No. But, see, I am not making my point. The doc is willing to do this. The doc has taken the 25 percent hit. The doc is hiring the scribe at $12 an hour plus benefits. So I actually don't think it is the doc's problem; I think it is the vendor, if you will, who is not creating the interface, because they are either not required to or there is no reward. Why not just foist it off upon the doc as

opposed to us taking the lumps. I mean, do you see my point?

Mr. Vockell. Yep. And I think they don't have the incentive, because there is such high switching costs to go from one system to another that --

Dr. Cassidy. So how do we create that incentive?

Mr. Vockell. I think it is -- I don't know how you will get an her to require to make their data interoperable, because that is the barrier to switching.

Dr. Cassidy. Do you agree with the critic that says the way that ONR has instituted this program does stick in amber so that the companies like Epic can get high market share, but they have little incentive in order to create that better user interface?

Mr. Vockell. Yeah. It makes them work towards the data center, yeah.

Dr. Cassidy. You agree with that?

Mr. Vockell. Yeah.

Dr. Cassidy. I have one more -- let me ask one more thing. You sat and read your testimony, didn't quite gather. To said there is strong economic disincentives for people to share data, but I didn't see you amplify that. What are those economic disincentives?

Mr. Vockell. So if you ask Humana to give you a data set around linked co-morbidities or protocols, it will cost you $500,000, because that is what they charged Pfizer for it. And so if you are a startup,

or even a data analytics company who is trying to add a relevant data set that only payers have, you can only do it if you have got a half a million bucks.

Dr. Cassidy. Gotcha. Thank you. I am out of time. I appreciate it.

Mr. Pitts. The chair thanks the gentleman. Now recognizes the gentlelady from North Carolina, Mrs. Ellmers, 5 minutes for questions.

Mrs. Ellmers. Thank you, Mr. Chairman. And thank you to our panel.

Dr. Niloff, I am going to direct my question to you in the interest of time. We were just discussing -- you know, kind of following up on some of the discussion, we were talking -- I certainly see all the benefits to patients on health IT. You know, this really is an area that -- of obviously much needed into the future, but there again, keeping in mind that we know that there are all the positives, what are the barriers? And I think we were just talking about some cost issues here for integrating the systems. Do you see this as an issue too, and are there other barriers that we need to be aware of?

Dr. Niloff. Sure. So I think that the main barrier and the main challenge today as we have discussed is interoperability and continued innovation. And I think that we need to have the right payment model in place to drive the purchase of these systems. We need our delivery systems to have sufficient alignment of their different contracts that

they are operating under so they are doing population health, coordinating care on a significant portion of their population, that they can make the investment both programmatically and technologically in these type of things, because that will drive innovation as the market grows.

Mrs. Ellmers. And when you say "they," are you talking about the physician themselves or are you talking about --

Dr. Niloff. I am really talking about at the health system level.

Mrs. Ellmers. Okay.

Dr. Niloff. I think much of this technology, because physicians are now working in organized systems of care where they are part of an integrated network, and we are really driving to coordinate care from the in-patient arena to the outpatient arena, to long-term care, that really what we are talking about is health systems making purchases of technology, and not just electronic medical record technology, but enterprise registries to drive preventive care and manage patients with chronic illnesses, care management systems, where they use technology to identify high-risk patients and then have skilled nurses manage those patients, that those are the types of technologies and related programs that are ultimately really going to drive us to a delivery system which is going to drive real improvements in health.

Mrs. Ellmers. So that would be, too -- you know, just actually playing into another question, so I am just assuming that that is kind

of the path that you see us taking as we are looking for the 21st century cures, and how we as legislators and here how we in Congress can help that effort, obviously you see that as an effort, too, when we are moving towards advancements in medical technology and curing disease and moving forward that way? Is that --

Dr. Niloff. Yes. You know, I think that it would be helpful if, as Congress considers sort of health care for the 21st century, that they think about health care in the context of not how we are delivering care today, but in a framework that thinks about the context of how we are going to deliver care in the future in a more optimal model; think about how we are going to have systems of care where everybody talks to each other, where when a patient moves from the hospital to a skilled nursing facility, their record moves with them, and it is not, you know -- it is not -- I am thinking about a family instance, but where, you know, an 80-some-year-old mother ends up having to be the major coordinator of care for her 93-year-old husband, because it is not happening electronically and the health system can't management.

And I think that is really the -- what we have to think to is what sort of care model system of care that we are going to move to that makes it not just better care, but better experience for patients and families, and how we are going to -- how Congress can modify the law to drive that type of system of care, which will benefit all Americans.

Mrs. Ellmers. Thank you, Dr. Niloff.

And thank you, Mr. Chairman. I yield back the remainder of my time.

Mr. <u>Pitts.</u> The chair thanks the gentlelady. And now recognizes Mr. Butterfield, 5 minutes for questions.

Mr. <u>Butterfield.</u> Thank you very much, Mr. Chairman. And thank all of the witnesses for their testimony today. I want to commend you, Mr. Chairman, for the subject for the hearing today, 21st century technology for 21st century cures. I like that, and I hope that as the session that moves along this year, we can continue to develop some ideas.

To all of the witnesses, and I can't call on each one of you, but whoever feels the most comfortable, I would ask that you respond. We know that certain population segments, including seniors and Americans with disabilities, are less likely, less likely to adopt broadband at home. Do the broadband enabled innovations that we have discussed today help these Americans get online and receive all the benefits of the applications we are discussing today?

That is not fair to you. I guess I should have called on one or two, but let's do it this way, and then I will call on someone next.

Mr. <u>Jarrin.</u> Sure. So in the answer to broadband, the answer to big data, you know, when we are talking about big data, and I hear the theme coming up quite a bit today, part of that is connectivity. Without connectivity, there is no real big data, whether it is wired,

wireless or mobile. Increasingly, it is becoming mobile, and that is obviously represented in the figures I gave at the beginning, 355 million users in the U.S., 7 billion in the world.

So I believe that through, you know, products like those of Amazon, products like the chipsets that Qualcomm produces and go into those products, those consumer facing devices, et cetera, they are getting out there. I believe the FCC quoted that over 95 percent of the country is now covered by at least one mobile broadband provider. More needs to be done, both on spectrum. Also I know that the FCC is working hard towards reaching disparate populations through their rollup broadband program, but I believe that we are getting there. We are getting there.

Mr. <u>Butterfield.</u> All right. We have a buzzer to go to the floor, so I will just ask one more, Mr. Chairman.

Telehealth programs are critical to communities in rural areas like my district in eastern North Carolina. East Carolina University, for example, has set up a telehealth opportunity at clinics throughout many rural communities that enable constituents to receive specialized medical care without traveling long distances. And I know all of you are familiar with this and you are looking forward to the next generation of technology.

What are the major challenges, such as broadband access, that rural communities face in fully utilizing telehealth opportunities?

If each one of you could just do a couple of sentences, starting with Mr. Vockell.

Mr. <u>Vockell.</u> Well, I think probably they are more qualified down there, but I think it is the -- the device -- mobile devices are beginning to take over what that capacity is. It is less, you know, cables into the home and it is what used to be wired is now wireless. So as the Qualcomm guys continue to do their good work and 1000X the bandwidth.

Mr. <u>Misener.</u> If you wanted me to answer, Mr. Butterfield.

Mr. <u>Butterfield.</u> Sure.

Mr. <u>Misener.</u> Mr. Jarrin is exactly right. Connectivity is the key. And we have always heard, at least for the past two decades, that telehealth was going to be a major driver of the need for connectivity in rural areas, and now it is here. So I think the concept of ensuring broadband deployment nationwide, including in rural areas is extremely important, not just for telehealth, but especially for it.

Dr. <u>Riskin.</u> The answer, from my perspective, I actually have an appointment in a safety net hospital. I am very familiar with the access issues that occur. And I would say connectivity is critical, but patient engagement is just as difficult. Whatever modality you are using to reach your provider, if the patient isn't engaged in their care, and typically rural or safety net communities are more difficult to engage, they won't be able to work with that modality.

Mr. Jarrin. And I know that we are almost out of time, but one thing that I would like to mention: So Qualcomm sponsors many things. We have a program called Wireless Reach. One of our recent projects was delivering care in a Native American area near Flagstaff, Arizona. And there were issues with being able to get mobile broadband in those areas. There was no connectivity whatsoever, but there were -- there was one operator in particular that actually was able to reach this population. And what we did was we provided telephones, mobile, smart phones that connected with home use medical devices such as medical grade weight scales and blood pressure cuff monitors. And what happened was that a person with congestive heart failure would use these devices, it would connect with the smartphone, go into the hospital, and then a series of nurses and other care providers would actually develop a work flow and be able to inform the patient of when things were going badly. We were able to reduce hospital readmissions through that very well.

Mr. Butterfield. The chairman is tapping on his microphone. That is our --

Mr. Jarrin. Unlimited broadband is a very important thing for --

Mr. Butterfield. I get it. Thank you.

Mr. Pitts. The gentleman has time expired. We are in the middle of a vote. We have got 10 minutes left. We are going to try to finish here. Mr. Griffith, you are recognized 5 minutes for questions.

Mr. <u>Griffith.</u> Thank you very much, Mr. Chairman.

Thank you all. This have been a very educational hearing. As you can hear, there is bipartisan support for trying to figure out how we go forward. I have heard all kinds of things. You know, figuring out the payment model when we are using new devices that you may not even have to go in to see the doctor on and electronic health records.

My concerns parallel those of Ms. Blackburn when she talked about devices. It was sometime a year, a little over a year ago, we had an FDA representative in here, and I asked them about this $8 hack that had been used in Africa to send photographs to a hospital in the United States. You had a team of Canadian and I think Swiss doctors working on it, and they were able to identify a parasites out of the stool of children and get a -- and get a diagnostic fix figuring out which parasite it was and do the treatment the next day. I said, would this be a medical device? And the answer was, yeah. If it is diagnostic, it is a medical device, even though all they were doing was taking a picture on a smartphone with an $8 hack. Because it was being used diagnostically, the FDA thinks it is a medical device.

So I think it is very important that we pass language that we can approve in a bipartisan way that clears that up so that, as she said in her statement earlier today, if it is a truly -- you know, something that is invasive, we want FDA making sure it is safe, if it is just diagnostic, we want to make sure that we get it to the market.

And, Mr. Jarrin, I noticed, and it is in your written testimony and in your oral testimony, you mentioned like 15 devices that you could use that would give you some diagnostic capabilities without the healthcare provider being present. Are you all finding that that is an -- that FDA's worried about that or spending a lot of time on that?

Mr. Jarrin. Well, actually the X PRIZE included the FDA originally, so that way we wouldn't land into those issues and lack that clarity, because that was definitely an issue that we were considering, whether or not this would be obviously a medical device. So the FDA joined the project early on. I believe that Dr. Shuran, who may have been the person that you were referring to, actually even put a video on the FDA Web site about their involvement with the X PRIZE. So I am hoping that when everything is said and done, you know, we will all be on the same page.

One thing that I would mention, you have an excellent example of the kind of clarity that was needed and still needs -- we always -- there is never not enough, right?

Mr. Griffith. Right.

Mr. Jarrin. Because that exact example is something that they actually ended up putting into the draft -- the final guidance by saying that those mobile apps that can be used to visually augment, you know, whatever a provider is dealing with in a diagnosis would not be regulated under their enforcement discretion. So we -- you know, it

was very helpful. Again, Congress was very helpful, because when you ask those questions, I believe the agencies really do pay attention and listen, and the FDA in that very specific instance did exactly that. You know, they did release the mobile medical apps guidance document. I believe that FDASIA tries to deregulate 95 percent of what they -- what they say very specifically, most CDS products and mobile medical apps and health IT software, but now it needs to be codified.

Mr. Griffith. I might need to cut you short, because I have got to leave a little bit of time for Mr. Bilirakis to get a question or two in.

I would say that not only is that important, I am glad that they were listening, but the telemedicine is going to be very important. I represent a rural district, and it is going to be extremely important in the rural parts of this country.

Thank you so much. With that, Mr. Chairman, I yield back.

Mr. Pitts. The chair thanks the gentleman. Now recognize Mr. Bilirakis. 5 minutes for questions.

Mr. Bilirakis. Thank you. I appreciate it, Mr. Chairman. And thank you, Mr. Griffith, for keeping it short. I really appreciate it. I want to go quickly, too.

With regard to the cloud, unfortunately 10 percent of the agencies who adopt the cloud in the Federal Government, so it hasn't really been a success on the Federal level, unfortunately, but in the

private sector, the private sector has rapidly adopted cloud-based solutions. And I know Representative Matsui actually touched upon this, but I have a couple questions.

What are some of the barriers to the adoption and expanded use of cloud-based computing and cloud-based storage in the medical space, and how can we facilitate the expanded use of cloud? What are some of the laws that need to be examined, because of the way they interact with the clouding -- with the cloud computing?

And anyone on the panel can respond. Doctor?

Mr. <u>Vockell.</u> The cloud expert to start, probably.

Mr. <u>Misener.</u> Well, thank you, Mr. Bilirakis. I appreciate that. In our experience with Amazon Web Services, the take rate isn't as great as we would like it to be with government agencies, but it is changing, and as I mentioned in my testimony, we already serve many around the world, but in the Federal Government, there are areas where Congress could lead by example, either through legislation or working in their oversight roll over agencies to ensure that agencies do use cloud when it makes sense to.

Right now, sometimes agencies feel constrained to buy only traditional hardware and software and pay their own in-house people to run it, and that turns out to be highly inefficient, and so hopefully Congress, through the two acts that I mentioned in my testimony could -- including FITARA, could encourage the government use of cloud,

to the benefit of our taxpayers, of course. Thank you.

Mr. Bilirakis. Anyone else on the panel? Okay. I will get on to the next question.

With regard to the medical devices in the dialysis world, they have remained largely unchanged, you will agree with that. If you were to need kidney dialysis, you would basically be using the same devices your parents were using. There has not been any large innovations in that space. However, in the world of consumer electronics, there have been continued innovative -- innovations in this space. Television today, televisions are radically different from televisions in the 1990s, cell phones today are different than they were, the ones in the 1990s, tablet PC's are different than the laptops and notebooks from the past decade.

So my question is, how is it that we can have rapidly -- rapid innovation in consumer electronics with lower costs for consumers, but slower innovation with higher costs in the medical space? Is it the cost of the excessive regulation? Is it the higher barrier to entry? How do we encourage shaking up the status quo?

And whoever would like to begin, please.

Mr. Jarrin. I actually will take it only because I am aware of a pilot project that is actually part of the Center for Medicare and Medicaid innovation challenge grants which is being conducted at the George Washington University Hospital in consult with a company named

DeLier and a company named Baxter and a number of other partners, and it deals with kidney dialysis in one way or another. So I believe that that community is definitely listening. They are really looking into things like remote patient monitoring, et cetera.

But if I step back for a moment, I think one of the largest barriers to adoption for this entire field are the outdated rules that we have governing reimbursement for services, particularly when it is -- when we talk about remote patient monitoring, it automatically gets lumped into something called telehealth reimbursement, and it is not necessarily the same thing. Under the telehealth rules, you have to start off from an originating set of care that CMS stipulates; it has to be a specific disease condition, there is only about 20 or 25 of them; and it can't happen in a metropolitan statistical area, it has to happen in a health shortage area; it has to be live voice and video, which removes automatically all the stuff that we are working on. It is incredibly restrictive.

So according to the American Telemedicine Association, doctors are only able to access between 5 and $8 million, with an M, worth of reimbursements for telehealth consults. You know, the CMS budget is near $800 billion, so I would pause to think that some of that could by targeted towards incentivizing the uses of these types of equipment and services, because the issue is this: If I am a hospital or I am a health plan, if I am not being reimbursed by my largest population,

which happens to be Medicare, I am not going to be incentivized to adopt those technologies that I am not being paid to use, or to provide services that I am not going to be paid to provide.

So I think that is a real huge barrier to adoption. And then that folds into, of course, the incentive payment program, which has done a good job of incentivizing the use of electronic health records, but there is no aspect that actually allows for patient-generated health data to go into that electronic health record, so the patient is really literally cut out, except when he walks into the facility, and then you have got the situation that your colleague was mentioning where we have the scribe, you know, typing stuff in while the doctor and the patient discuss their care. So it is a real complex issue, but I think that I those are barriers to adoption.

Mr. <u>Bilirakis.</u> Thank you very much. Thank you, gentlemen, for your testimony.

I yield back, Mr. Chairman.

Mr. <u>Pitts.</u> Thank you.

Thank you again to the witnesses for sharing your expertise. This has been a very informative hearing. I am sure members will have a lot of follow-up questions. We will submit those to you in writing. We ask that you please respond promptly.

I remind members that they have 10 business days to submit questions for the record. Members should submit their questions by

the close of business on Thursday, July 31st.

Another very important, informative hearing. Thank you very much. Without objection, this subcommittee is adjourned.

[Whereupon, at 12:22 p.m., the subcommittee was adjourned.]