MOBILE MEDICAL APP ENTREPRENEURS: CHANGING THE FACE OF HEALTH CARE

HEARING

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UNITED STATES
HOUSE OF REPRESENTATIVES

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MOBILE MEDICAL APP ENTREPRENEURS: CHANGING THE FACE OF HEALTH CARE

THURSDAY, JUNE 27, 2013

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
SUBCOMMITTEE ON HEALTH AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 10:00 a.m., in Room 2360, Rayburn House Office Building. Hon. Chris Collins [chairman of the subcommittee] presiding.

Present: Representatives Collins, Coffman, Luetkemeyer, and Hahn.

Chairman COLLINS. Good morning. I call the hearing to order.

I want to welcome all of our witnesses and thank you all for being here. I think this is going to be a fun hearing and showcase entrepreneurship at its best.

Today, we are meeting to learn more about how American small businesses and how they are changing health care through innovations in mobile medical applications, or "apps."

According to a Pew Center report, a majority of adults in the United States now own a smartphone. Our overall economy is still weak, but the apps economy seems to be thriving. Some studies have found that mobile devices and their apps are responsible for creating over 500,000 jobs, and global revenue for mobile apps exceeded $20 billion last year.

Apps that can help individuals monitor their health are becoming more prevalent and popular. Worldwide, an estimated 500 million smartphones will be using a medical app by 2015, and 78 percent of top app developers are small businesses.

In fact, entrepreneurs have pioneered apps for purposes as varied as tracking fitness routines to reading a patient's digital images. These are groundbreaking medical apps to help empower consumers to make better health care decisions; allow patients to access critical health data in real time; and guide physicians to diagnose or monitor patient conditions. Apps may also help reduce hospital readmissions and cut the cost of managing chronic diseases.

To help get these products to the public, small businesses have to navigate a complex web of challenges, product financing, marketing, taxes, and regulations. We are eager to learn more about these innovations as well as the challenges that all of you face each day in bringing your apps to market.

Today's hearing format is a little bit different. Each witness will be allocated the customary five minutes. But during that time, when they do testify, they are going to actually be demonstrating

their apps for us. As they explain this app, we have got the two screens on either side which will help visually. We appreciate the participation of all of our witnesses, and we do look forward to your testimony.

I now yield to Ranking Member Janice Hahn for her opening remarks.

Ms. HAHN. Thank you, Mr. Chairman.

You are right. Mobile medical apps are a real exciting area of innovation that has tremendous promise for American small businesses and health care providers and patients across the country. These applications on smartphones, tablets, web platforms stand to dramatically improve the practice of medicine in this country, reducing inefficiencies, confusion, and disorganization that costs money and lives.

For doctors, these applications can help put more patient data in their hands, so they can make more informed decisions more efficiently wherever they are. And for patients, these applications can cut through the fog of overlapping medical instructions and prescription medication schedules, providing reminders and helping people to stay on track.

This is not just a matter of convenience, and it is not just some cool-looking new toy. Medical errors kill as many as 98,000 people a year, including over 7,000 from medication errors. That is more than die every year in car accidents, breast cancer, or AIDS. Bringing all the patient's medical information together and putting it literally into the hands of that patient and their doctors could help avoid these deadly errors.

I am particularly excited about what these applications could do for disadvantaged and the elderly population, the most vulnerable with chronic conditions who have a hard time sorting through all their medications without help. If anyone has ever taken care of someone with a chronic disease, or even recovering from a serious illness, you know how confusing and difficult that can be and how handy and easy-to-use application that provides reminders and tracks treatment could be.

I want to be sure that these exciting advances in mobile medicine do not leave behind those people that may not be able to afford a smartphone. And on top of all those great benefits to these apps, delivering less costly, more efficient care that makes our nation healthier, this is a field where small business can really lead the way. I think that is a really exciting and really American prospect—U.S. small businesses remaking our world with their innovation and ingenuity.

It is estimated that mobile technology industry will grow to be valued at roughly $25 billion and account for an estimated 500,000 jobs. The development of mobile medical apps has steadily increased with roughly 27,000 unique apps currently on the market, and about 500 new ones being launched every month. So when you say "is there an app for that," there will be.

Small developers are critical to the success of the mobile medical industry. Last year, the mobile health care sector saw venture capital investments reach more than $900 million. And in 2013, it is expected to exceed $1 billion. However, small MMA developers' ability to continue receiving such investment is highly dependent

on the regulatory front. That is why it is important for us to understand how they bring their apps to the market and ensure that the process does not hinder their growth, which is why I am glad you are holding this hearing today and we want to be a part of the solution to this. Thank you, and I yield back.

Chairman COLLINS. If Subcommittee members have an opening statement prepared, I will ask that they submit those for the record.

And now I would like to take a moment and explain the timing lights to our witnesses. You each have five minutes to deliver your testimony. The light will start out as green. When you have one minute remaining, the light will turn yellow. And finally, it will turn red at the end of your five minutes. I would ask that you adhere to those time limits if at all possible.

Our first witness is Alan Portela. Mr. Portela is chief executive officer for AirStrip Technologies, which is based in San Antonio, Texas. He has more than 25 years of experience in bringing groundbreaking technology solutions to market. AirStrip's app allows physicians to securely access real-time clinical patient data at any time, anywhere, expediting decision-making. AirStrip was the first app approved by the FDA for the app store.

Welcome. You have five minutes to present your testimony. We look forward to your demonstration.

STATEMENTS OF ALAN PORTELA, CHIEF EXECUTIVE OFFICER, AIRSTRIP TECHNOLOGIES; KEITH BROPHY, CHIEF EXECUTIVE OFFICER, IDEOMED; CHRISTOPHER BURROW, EVP MEDICAL AFFAIRS, HUMETRIX, ON BEHALF OF THE APP DEVELOPERS ALLIANCE; SABRINA CASUCCI, PH.D. CANDIDATE, INDUSTRIAL AND SYSTEMS ENGINEERING, UNIVERSITY AT BUFFALO.

STATEMENT OF ALAN PORTELA

Mr. PORTELA. Thank you, Mr. Chairman. It is an honor to be part of this Committee at such an exciting time in health care. This is probably the biggest transformation ever.

If you look at the model today, it is changing from hospital-centric to patient-centric. We are looking really at an approach on chronic disease management. Unfortunately, 160 million Americans suffer at least one chronic disease. And what we have to do is to be able to figure out a way to manage those patients with the challenges at hand.

The challenge today is that we have a shortage of caregivers, physicians, specialists, and we have the patient population that is increasing by the millions under the Affordable Care Act. So now physicians are becoming more and more mobile professionals. The data has to be delivered to them via mobile devices—data that is clinically relevant, so they can make informed decisions, rather than them going to desktop computers to be able to get that data. So definitely, the model is changing.

Now, we have to make sure that mobility becomes a key element to support the new model. AirStrip core products are a medical device in mobility solutions, and they are patent-protected, FDA cleared, and recently, we received the DoD DIACAP certification

for security. So these milestones were never viewed as barriers to entry for us; they are considered what make us unique. And also, it allows us to impact a number of lives. Today, one out of every five babies born in the U.S. are covered or are monitored by doctors that are looking at these babies before they are born using AirStrip solutions, and we have documented cases that moms that deliver from high-risk pregnancies that deliver babies, those babies would have not been alive today if it was not because of diagnostic-quality remote in monitoring.

We also caught a number of patients with heart disease, and I am going to use that for our demonstration as a use case. It takes about 90 minutes for a patient with a heart attack with a full blockage to go from the emergency department into the cath lab so they can clear that artery with the right procedure. The reason it takes 90 minutes is because usually a cardiologist, the specialists are on-call and they are not in the emergency department at all times. So they are the ones that need to make that diagnosis, to approve the procedure.

What we do with our product is that now physicians, the cardiologist, can actually access that data immediately when the patient is in the ambulance; not when they come to the emergency department. So now they can make a decision before the patient comes in, and they can have the care coordination team ready to take care of that patient. So we are actually reducing the time to intervention to more than half, to 30 minutes in some cases. There is actually a firefighter in New York that was able to go back to work after a full blockage after three weeks and he was on national TV.

So the reality is that we are producing better heart and muscle as a result of time to intervention, but also better quality of life.

Also, the physicians are able to monitor patients as they go home, also in the intensive care units. You can look at a patient and look at all their charted data, documented data by the nurses, the rates, the pressures, the respiration rates, laboratory results, medications administered, but also you can look at the alerts and you can also look at the live patient monitor and data. This is something that can be done remotely and it is actually diagnostic quality. We are actually taking this to home monitoring for cardiac monitoring for cardiac patients, patients in underserved communities, rural health care. Now you are going to be able to monitor that remotely. We are also taking this to chronic diseases such as diabetes, COPD, and others.

So today, we are not representing the large companies, but we are representing the hundreds of thousands of patients that are alive because of those doctors and nurses that were able to take care of those patients using our products.

The partnership with the Federal government for us really is what drove our innovation process and the FDA made us relevant. The DoD made our patient data secure. And together we improve the quality of care. What we really want to urge as part of this Committee is for the FDA to provide guidance on the regulation on diagnostic quality medical device mobility. So now also there is more security that is attached to this because lack of guidance is encouraging medical device manufacturers to offer inferior solutions and give those to the customers without the proper clearance,

which is hurting us as a small business, but it is also hurting you and I as patients. So the other consequence of being the first one and taking the lead in the industry is that we are part of the only companies that are paying the medical device tax that is introduced as part of the Affordable Care Act when those companies are not paying for that tax on the mobile device application.

So thank you for the opportunity.

Chairman COLLINS. Thank you. And I am sure we will have some questions at the end of this.

Our next witness is Keith Brophy, who is chief executive officer for Ideomed in Grand Rapids, Michigan. Mr. Brophy was Western Michigan's Entrepreneur of the Year in 2004, and received his bachelor's degree in computer science from the University of Michigan. Ideomed's app, Abriiz, is designed to improve health outcomes and lower costs by motivating patients with chronic conditions to adhere to medication schedules.

Welcome. You have five minutes to present your testimony and demonstrate your app.

STATEMENT OF KEITH BROPHY

Mr. BROPHY. Chairman Collins, Ranking Member Hahn, and members of the Subcommittee, I am Keith Brophy, CEO of Ideomed, and I appreciate the opportunity to address you today.

Ideomed is a Michigan-based company launched by Spectrum Health with a national focus on the staggering costs of chronic disease.

I am also here today as a member of Association for Competitive Technology (ACT), a trade association that assists mobile development companies in understanding and aligning with regulations to build effective solutions. Chronic conditions, such as asthma, heart failure, and diabetes are the untamed frontier of health care with over a trillion dollar a year impact to our U.S. economy. Much of this cost could be prevented if individuals effectively manage their health on a daily basis. This is where Abriiz and Ideomed step in. We engage patients in assisted self-management through mobile technology and human behavior science. We call our platform Abriiz because our goal is to make the managing of one's health a breeze. Abriiz represents a new breed of health application. It does not dispense medical advice; rather, it extends the reach of the clinician and inspires the patient to take control of their own health. This is a winning combination.

We sell this platform directly to insurers who bear the cost of chronic disease, such as managed Medicaid providers. They in turn deploy Abriiz to the subsets of their populations with the most severe chronic conditions.

As we will now demonstrate on the screen, Abriiz engages. On our mobile device you can see the version of Abriiz which Alex, a hypothetical patient with severe asthma would use. Abriiz is a friend on Alex's shoulder that provides medication reminders. An alert pops up at appropriate times and leads Alex to quickly record his dose. For example, here he records his dose of Advair. If he misses a dose, his mother and insurance case manager receive alerts. If he records it, they immediately see the results, whether they are across town or across the country.

Alex can also record symptoms and custom triggers that fit his life; for example, his neighbor's long-haired cat, Mr. McFluffy, which can induce asthma attacks. This personalized tracking allows Alex to see how asthma maps to his world. As Alex successfully completes each day's medication, he is awarded with digital creatures. These creatures, called Abriizlings, are badge-based incentives the child earns over time. Alex can also earn tailored family incentives, such as a visit to the park. These features are based on motivational psychology and gamification science. Their use deepens the positive engagement Alex has with his daily management.

Alex is not alone on this journey. On the Abriiz website, his care team can monitor Alex's daily interactions, as well as establish medication schedules, set incentives, and view trends. From Alex's perspective, Abriiz provides control and confidence regarding his asthma. To his care team, it provides conducted peace of mind.

Early on in the development of the platform that you have just seen there were skeptics who questioned the potential of mobile engagement. We heard misgivings about the ability to engage children on a sustained basis, and that the need for wireless connectivity would be too restricting. We have now carried out many successful deployments that suggest those concerns were unfounded.

Here you can see that in each of these small population trials, emergency room visits noticeably declined. We have also expanded our aim. Abriiz Heart has been in use by congestive heart failure patients, average age 77, for over six months with a sustained daily engagement rate of over 80 percent. Engagement rates across our Medicaid asthma initiatives have similar affirming numbers.

We continue to expand our portfolio to other conditions, including diabetes, cancer journeys, and more. We started just three years ago with a visionary seed funder and spectrum health and a determination to make a difference. We have blossomed from start-up with a couple team members and no office to a booming business with 32 expert team members with diverse skill sets and a national product line. Our original product was a sleeve device that slid onto an asthma inhaler to provide medication reminders.

It became clear that the mobile technology landscape was rapidly offering alternative approaches. We found the cost to achieve FDA device approval and bring the sleeve to market would be prohibitive, so we shifted strategy, leveraged the insights we had gained, and mobile-based Abriiz was born.

We are vigilant about building solutions that are of the highest caliber for our users and that safeguard their data. Our success has been shaped by our ability to turn assumptions upside down and ultimately to empower individuals to steward their health with a connectedness of a broader team.

We look to a future of touching lives and peer ahead to anticipate the still emerging FDA mobile health guidelines. Ideomed encourages and welcomes clear, timely, and right-sized governance. These are historic times of change in American health care. We are proud to be an engine of responsible transformation to a new era of mobile patient engagement. Thank you.

Chairman COLLINS. Thank you, Mr. Brophy.

At this time I would like to yield to Ranking Member Hahn for her introduction of our next witness.

Ms. HAHN. Thank you, Mr. Chairman.

It is my pleasure to introduce Dr. Chris Burrow. Dr. Burrow is executive vice president for Medical Affairs at Humetrix. Is that right? Did I pronounce that right? Humetrix, a small, woman-owned business in Delmar, California. Before joining Humetrix, Dr. Burrow was an executive and founder of two California start-up biotechnological companies. He is here today on behalf of the App Developers Alliance, an industry association dedicated to meeting the needs of developers as creators, innovators, and entrepreneurs.

Welcome, Dr. Burrow.

STATEMENT OF CHRISTOPHER BURROW

Mr. BURROW. Thank you, Chairman Collins, Ranking Member Hahn, and distinguished Subcommittee members. Thank you for the opportunity to appear before you today. It is an honor and a pleasure. I appreciate it.

My name is Chris Burrow, as you have just heard, and I am EVP Medical Affairs at Humetrix. And as you also heard, a small, woman-owned business in Delmar, California. We are a member of the App Developers Alliance, and we appear today on their behalf.

Humetrix was founded in 1998. It has been a pioneer in the development of mobile technology. Over the last 15 years we developed numerous mobile applications that enable consumers to engage the world around them in new and innovative ways. Despite significant progress in electronic health record adoption in the last few years, essential health information is still not readily accessible by patients in today's provider-centric health care system. By enabling patients to access their own health information at the point of care with an easy-to-use mobile application, Humetrix's IBlueButton Solution, our app, is free of many of the challenges encountered by the current system-to-system health information exchange initiatives in the nation. Our technology, IBlueButton, is based on the federal Blue Button initiative. I have the icon right here on my lapel, Blue Button. The idea is very simple. Give patients access to their own health information using an easy-to-identify symbol that could be adopted and used by any organization holding valuable patient data, a Blue Button.

Humetrix recognized the transformative potential of Blue Button data early on and built on these federal efforts by creating the IBlueButton app, both for IOS devices and Android devices, to provide patients and care givers with easy, reliable, and secure access to their health record as maintained by both public and private payers.

For Medicare, our application transforms the beneficiary level claims data currently produced by the CMS blue button record into a user-friendly, longitudinal health record that can be accessed on a mobile device and exchanged by patients and providers at the point of care. This comprehensive health record can be viewed directly on a smartphone or tablet and contains a patient's key health information, such as problems, medication list, as well as a detailed history of all the patient's health care encounters, includ-

ing inpatient admissions, outpatient visits, imaging services, labs and procedures.

I will now briefly demo our technology. So on the screen is my iPad, and here I am playing the role of a patient first. So I am going to launch the blue button app. And the first thing I have to do is I have to put in my password because this is a password protected app so that no one else—if I lose my phone, no one else can get into this. And the data is held at high-level encryption on the device. In order to download a Medicare record, the only thing a Medicare patient has to do is go to Mymedicare.gov and fill out a brief questionnaire designed by Medicare to get a user name and password. Once they have acquired that user name and password, they simply enter the user name and password here into the app. They save it, and now they are ready to download their record.

All they have to do to download their record is hit that download button and here is the record. The record is laid out beautifully. We have diagnoses showing all the conditions that the patient has. For any one of those, the patient can do a quick lookup of what that partly Latin term may mean. It is not so easy, and if you are not completely conversant in English, it is even harder.

You can also see all of your medications, not just the medication from the doctor you saw today, but all the medications that have been paid for under Part D. So that is quite, we think, transformative.

And here they all are. For any medicine you can do an easy lookup of drug information. That will give you basic information that comes from the National Library of Medicine telling you how you should take that drug, what you should watch out for. If you have any side effects, you may not know what they might be and here you can check them. If you see one you can enter yes. And so basically, now you have got your whole medical record under your fingertips wherever you want it. When you see your physician, I do not have time to show everything, but we have a companion app. You can push the record over to the physician's device. We generate a novel, optical QR code, and the physician can now scan your smartphone, which is displaying a QR code, and the record is now shown on the physician's device. All the physician needs is an iPad and our technology from either the Play Store or iTunes. And these alerts that the patient has entered will now be shown as little exclamation points saying whether the patient is or is not taking that medication and whether they do or do not have that condition.

Well, my time is up. I have gone pretty fast. I am delighted again to have been here and I want to thank everyone for that. Our one ask is we are trying to get the word out. Patient education is key. Provider education is key. We are working with private and public stakeholders to do just that. Thank you very much.

Chairman COLLINS. Thank you, Dr. Burrow.

Our next witness is Sabrina Casucci. Ms. Casucci is a doctoral candidate in Industrial and Systems Engineering at the University at Buffalo in Buffalo, New York. She holds a bachelor's degree in material science and engineering from Purdue, and a master's degree in business administration from the University at Buffalo. Ms. Casucci and her colleagues, who we are happy to say are joining

her today—welcome—received second prize in General Electric's Hospital Question Competition for their app, which introduces patient and caregiver choice into the discharge process and supports timely communication between the hospital and community care teams. Hospital readmissions are reduced, saving money.

Welcome. You have five minutes to present your testimony and demonstrate your app.

STATEMENT OF SABRINA CASUCCI

Ms. CASUCCI. Great. Chairman Collins and distinguished members of the Subcommittee, thank you again for the invitation to participate in today's hearing. I am honored to represent a talented team of fellow graduate students from the University at Buffalo Department of Industrial and Systems Engineering.

I want to briefly discuss how our group of young entrepreneurs are translating our individual health care and technology-related research into a mobile solution that will make hospital discharge planning a more effective and efficient process.

Discharge planning is a critical step in acute patient care. Yet, the inherent complexities of existing processes often result in undesirable outcomes for both the patient and the health care system. Annually, nearly one in five Medicare patients is readmitted to a hospital within 30 days of their initial discharge, with a cost of more than $17 billion. But despite recent efforts to make improvements in these areas, readmission rates have remained relatively constant. The recent GE Health Quest competition provided the catalyst for our group to develop a better solution for discharge planning, and we believe Discharge Roadmap will fundamentally redefine the process. Solutions like ours can fundamentally have a significant impact on health care in the U.S. Mobile solutions can connect fragmented care processes and improve continuity of care, both contributors to improved patient outcomes and reduced costs of care.

However, as a startup group in the early stages of development, there is a long and difficult road ahead. In addition to difficulties in obtaining funding and support for our product, we must confront complex technical issues such as interoperability. Improving interoperability standards will ensure that health care providers can choose a solution that best fits the needs of their patients and not just the needs of their existing health information technology systems. Through our app, we seek to make a meaningful contribution to reducing readmission rates by facilitating communication among patients, their families or informal caregivers, and hospital-based clinicians, and by improving continuity of care with community-based care providers.

I am going to take the next few minutes to give a brief overview of our app and a few of the unique features that it provides.

This is best demonstrated with an example of John, an 80-year-old patient hospitalized for congestive heart failure. And despite her busy schedule, John's daughter, Jane, is the only informal care giver available to help John in his recovery. Discharge Roadmap is designed to facilitate the discharge planning process, allowing it to begin much earlier in John's hospital stay. Using our app, John,

Jane, and John's doctors can be assured that all care needs and constraints are adequately considered in the process.

Today, bringing together these stakeholders to develop a discharge plan is a difficult undertaking. Using a systematic approach, we can connect this team and using the tools provided by Discharge Roadmap, improve their communication and coordination.

These customized tools can be categorized into three main functionalities—education, assessments, and referrals. John would first experience the educational component of our app, and in this section he can review several short modules explaining his diagnosis and care management, the same material that is available to Jane so that she can also learn the best ways to assist her father in improving his care. As John completes progress through this area, the results of his short teach-back quizzes are provided to both him and his doctor. After learning about his diagnosis and how to manage his care, John and Jane can both independently assess what his abilities are to manage his care post-hospitalization, as well as their abilities to meet those needs.

John's doctor will also complete their own assignments, and then is presented a prioritized summary of the results of all three of these assessments, allowing her to focus discharge planning discussions on areas where there is some discrepancy or inconsistency in answers. Once John's doctor then determines his post-discharge care needs, such as home care, John can learn about these services. In addition, he is provided an evidence-based prediction of what his outcomes would be if he were to follow through with those recommendations. The key piece then after that is figuring out who is going to provide this service. John and Jane can also review the local service providers and indicate their preferences for who they would prefer the referrals to go. And then, as Jane certainly is the one who will be taking her father to these appointments, it is important to know what her schedule and constraints are so she can also then communicate her availability through our app to the appointment schedulers.

And finally, our referral features provides continuity of care with community-based care providers by allowing John's doctor to quickly assemble and transmit detailed referrals to those community-based care providers.

So combined, we believe our education assessment and referral components are really redesigning the discharge planning process and we are honored to have shared them with you today. Thank you.

Chairman COLLINS. Thank you one and all. I think as we move forward with technology, I think we are going to be relying more and more on entrepreneurs to come up with solutions for a variety of reasons. In some cases it is to make money; in other cases it is to pursue your continued education. But in each of your cases, what you have given us is a great look at the marriage of entrepreneurs and technology and where we might go. And I would say really where we are going. All of us know health care costs are a number one concern. They are a number one concern to individuals—can they afford it—whether it is the cost of their drugs or insurance. For corporations, they are facing those issues now as we

move forward into a new world. And anything we can do to reduce the overall cost. And I think the solution is patients starting to take control of their own lives. In the past, the old model was you had insurance, you went to the doctor, you did not know exactly what it cost because someone else paid it, and you went home. Well, today, it is a very different model, and I think what you are showing is the next stage of patients taking control. But as we have got an aging population, certainly, the baby boomers, of which I am one, retiring 10,000 of us a day, and the story you are sharing of an 80-year-old man with his daughter helping out—Ms. Hahn wanted to know where the son was.

Ms. HAHN. Always the daughter.

Chairman COLLINS. Always the daughter.

That is the world we live in. Our parents are living longer because of advances, but in many cases they are on some kind of chronic medication and/or we are always worried about admissions to hospitals. So you have made great strides.

So my first question, really, because we do not have all the regulations out and I know with IBlueButton what you have done will maybe—in fact, why do we not start with Dr. Burrow on the HIPAA issue, the privacy issue? You mentioned if you lose your cell phone someone is not going to be able to get in and get that information. And I know we are all concerned about privacy and who has access to our medical information. So maybe you could explain what you are doing. And then I am curious to hear whether that is an issue for the other three witnesses.

Mr. BURROW. Thank you, Chairman Collins, for that question. It is a very important question.

Our view, and the way we have designed these apps, is that you, the patient, should be able to access your own records. You acquire the credentials to do so from the data holder. The example I gave is Medicare. So you go to the Medicare website and you comply with the requirements of that data holder. So once you have done that, as we frequently see in banking and other aspects of our lives, you acquire a user name and password. That is securely scored in the IBlueButton app. It is encrypted and the download takes place in a secure fashion. And the record, once on your phone, is, in fact, encrypted and stored there so that if you lose your phone, the only data that could be acquired maliciously would be a file of encrypted ones and zeros, which would be—I hesitate to say impossible, but virtually impossible to break. So your data is secure, and losing a phone would not be a problem. No one would have the password to get into your app and no one would be able to see your data.

Chairman COLLINS. Thank you.

Mr. Portela.

Mr. PORTELA. Well, as I mentioned before, we just received a certification for DoD and it is called DIACAP certification for security. It is our position as we are going through that process with the Department of Defense we clearly recognize the risks for cyber attacks out there that are way beyond what the private citizen will see. Basically, the way the DoD handles the security through the DIACAP certification is that they have a number of engineers that are looking for hackers on a regular basis, and every time they find

hackers trying to break in, they are automatically publishing those vulnerabilities to all the vendors that are DIACAP certified.

So what we need to do as vendors is immediately identify how we are going to mitigate those vulnerabilities, and in some cases they are category ones, which they consider these are very risky, but every month they are identifying new vulnerabilities that could break the patient data. So what happens is that if at some point we start getting closer and closer to the medical devices and eventually managing those devices remotely, if we are vulnerable to hackers we are going to have a lot of problems. HIPAA, today, and the FCC with the open SSL standard, they primarily direct the security to the application level but they do not do that on the operating system level so much. The DoD requirement, it keeps audit trails on everything that happens also in the operating system, preventing hackers from coming in. So what I recommend is that we take a look at what the DoD is doing and bring in some of that certification process into the private sector.

Chairman COLLINS. Thank you.

Now, Mr. Brophy, your example was a young man whose family is watching him. I am assuming, too, that would apply not just to kids, if I am correct, but also, again, how does your app manage HIPPA and privacy and is that a worry for you?

Mr. BROPHY. The privacy and protection of data is something we take very seriously in designing the app. And we have an approach that is similar to those shared with encryption at the technology level. And also, above and beyond that, the people process that is built into the application is an important element. For example, our data is self-reported data reported by the patient, but the model supports the care team that can remotely monitor their data. That access is not provided unless the patient or their guardian specifically consents to sharing their data in that fashion. So we build the people approval and the technology protection in two layers.

Chairman COLLINS. Thank you. Ms. Casucci, how does your app handle the privacy issues?

Ms. CASUCCI. Sure.

Well, we are still in the development process of our app, so we have no official solution to that yet, but that is certainly one of the concerns from that startup perspective. So we know that there are various standards that we do need to adhere to. And figuring out how to navigate that standard system and trying to determine the proper solution for our app is that first big hurdle. So it is certainly one of those barriers that we need to overcome and understand better.

Chairman COLLINS. We will come back for some other questions, but at this point I will yield to Ranking Member Hahn for her questions.

Ms. HAHN. Thank you, Mr. Chairman.

Ms. Casucci, you touched on interoperability. And when I am listening to everybody's presentation, which were all extremely interesting and really very exciting and certainly where we need to be in terms of quality health care, obviously, you know, the doctor who would be treating the patient for a kidney problem would have to be able to talk to the cardiologist who is treating the heart prob-

lem. I would ask that to all the witnesses, is this a problem, interoperability, and what do we need to do in Congress to encourage the interoperability of these applications and health care data systems overall?

Ms. CASUCCI. So really what we view on this is that integration of our system is really key. So we as a third-party vendor need to talk with everybody. There really are several different types of standards that people are discussing currently but no unified or agreed upon standard as to how these different technologies can communicate with each other. But we do not see data as that competitive advantage; we see the communication piece at enabling that. So if we can do that, then we can eliminate all these needs for redundant testing and really reduce the cost of care by enabling test results from one facility or one system to be communicated across to another.

So really, what we are looking for is just some guidance as to what is the best approach to do all this. Do we need to create customized solutions for each different software vendor that is out there? Or can there be more of a unified agreement that we can all work towards and then communicate via that?

Ms. HAHN. Thank you.

Mr. Portela.

Mr. PORTELA. Thank you. And I do have about 20 years experience in this area. Yes, interoperability is a huge problem.

What happens is we are not lacking the standards; the standards need to be enforced. And what happens also then there is a tendency to protect the data to preserve some of the advantages that they have. And I am talking primarily about the large vendors. So you have to look at front-end integration and backend integration. The front-end is more around the episode of care, and the backend is really maintaining a longitudinal record. The backend is going to take 10 years until really the vendors start supporting the standards that the government has to enforce that are not enforced today. But at least what we are trying to do on the mobile side with mobile technology is dealing with the episode of care. All of us really trying to capture the data from all these systems to be able to display that episode of care. So physicians can look at electronic medical record data, medical device data, images, videoconferencing for telehealth, and others.

Unfortunately, the only standard that exists that most of the vendors support is something that is called a continuity of care document (CCD) that is a very small subset of the data that you can get from a patient visit. The real data, you have to get it from interfacing to each of those vendors, and there are different ways of doing that. But definitely there is one standard that is called HL7 standard that at least all of us are trying to comply with that and it gives you the ability to take data, receive the data, but right back into those systems. But vendors need to be forced to collaborate. We are in a new world.

Ms. HAHN. Any other witnesses?

Mr. BROPHY. I would agree with Mr. Portela. The standards, such as HL7, are out there, and the mobile application vendors build solutions that often can be integrated if the other side of the equation has the bridges for that integration.

In the case of Ideomed with Abriiz, we build it to be what I would describe as a flexible building block. It can plug into other systems, and it can plug into various scenarios. As we look at the healthcare landscape in the case, for example, of a congestive heart failure patient, when they are discharged from the hospital their care team could be a varied cast of characters from an insurance company case manager, to a cardiologist, to a heart education nurse, to a visiting home health nurse, to family members. So there are not only multiple players but multiple data systems that could potentially share the data. Companies, such as Ideomed, build flexible pieces. Then it is a matter of finding out where in the ecosystem they can integrate.

Mr. BURROW. Thank you for that question. So our national strategy is built on three different approaches. One, system-to-system exchange between doctors or EMR systems. And you have heard a little bit about that so I will not comment. The patient-consumer mediated exchange model that we embody is this other idea, the new idea that if everyone has access to a summary medical record that they can carry, if you will, on their mobile device, that will help solve the interoperability problem out there. Humetrix has been part of the Blue Button initiative. We have come together both on the private and government side to define new Blue Button plus standards, which we believe will be important going forward to mediate this patient model where you have on your phone your record. After all, for your financial information you have an ATM card and you get your data easily. So our vision is that every citizen should have the ability to get their data and have it with them.

Ms. HAHN. Thank you. Again, I just think that is something we ought to look at as we move forward. The technology exists, but interoperability is so key. I look at that in so many areas. Even law enforcement still is struggling with interoperability in the event of a major disaster. We still have a lot of different agencies out there that cannot talk to each other. So I think it is something we need to look at.

I have got more but I will save them for the next round.

Chairman COLLINS. Very good.

Thank you. At this point in time we would like to recognize the gentleman from Missouri, Mr. Luetkemeyer, for five minutes.

Mr. LUETKEMEYER. Thank you, Mr. Chairman. I guess this means I have got to put my rotary phone away.

Thank all of you for being here today. I know last week I was very disappointed and actually was very frustrated by the lack of information in the testimony of the witnesses. Today, it is very encouraging to see witnesses that are absolutely on the cutting edge and have the answers. And I admire what you are doing and I quite frankly hope you keep it up because obviously it is going to make this a better world for all of us what you are doing. So thank you.

Very quickly, what regulations are in place that you have to deal with every day with regards to the barriers that are put in front of you that you have to overcome that we could have an impact on to help make your job of developing these things easier or running your businesses better? What do you see as some problems?

Just go down the line. Mr. Portela.

Mr. PORTELA. So I can start. And again, I think I am just one of those rare vendors that are really here to propose regulation. And when it comes to diagnostic quality, when it comes to saving lives, when it comes to moving into a model outside of the four walls of the hospital, we want more regulation from the FDA on diagnostic quality and security. So the reality is that we deal on a day-to-day basis with the FDA as we submit new products and enhancements to the existing products, but we feel that that process is improving significantly. What we want to make sure is that right now we are proactively complying with requirements that are not out there yet. We would like the FDA to really recognize what we are trying to do as a leader in the industry and the impact that we are bringing to patient safety and to be able to go across the board and really make the regulations so everybody has to comply with the same regulation.

Mr. LUETKEMEYER. Very good. You guys are on the cutting edge here, so a lot of times the rules are not there to be able to reign in or to allow what you are doing to be done in a most effective and cost-efficient way.

Mr. Brophy.

Mr. BROPHY. We understand and align with regulations such as HIPAA and protection of privacy. Our key regulation that will impact us is the FDA mobile health guidelines. And we look forward to those governances and the clarity that it will provide. The last couple of years as we have designed the system, we have anticipated and speculated what the eventual mobile health guidelines may be, so we have tried to be proactive and build a solution that will align well with the FDA guidelines. But that is with anticipation and expectation of what they might be. So we welcome those guidelines when they roll out.

Mr. LUETKEMEYER. Dr. Burrow, your group?

Mr. BURROW. Right. So I think the regulations that might affect us the most are HIPAA, and we have designed our solution to be fully compliant, both with encryption on the device and in the technology I did not get to show, the encryption with a one-time key when you push the record to your doctor. Since Humetrix does not store any data—in fact, Humetrix has no way of touching your data. You have your phone, you download your data, you own the data. Humetrix is not a part of that. We do not store your data.

So that is the one that we are thinking most about. As a member of the App Developers Alliance, of course, we support the approach that will be flexible and will ensure patient safety, and I echo some of the comments of my colleagues here. For us, right now, I am not a regulatory expert but I do not have anything additional to add to my colleagues on those other subjects.

Mr. LUETKEMEYER. Ms. Casucci.

Ms. CASUCCI. I will just agree, certainly, and support everything that has been said so far. From the very early stages of this I will say certainly you are navigating that regulatory system and understanding really what your options are and how you need to comply with some of those. So that is really the point that we are at at this point, is how to best implement the right levels of security to comply with those regulations.

Mr. LUETKEMEYER. Very good.

I have just got 30 seconds left here, so quickly, I think measuring the success of what you do is going to be very important. The difference you are making in the lives of the people. Is there a measurement that you have been able to establish so far, a way that you tried to measure this both in success of saving lives or better lives lived or the cost that you have been able to save, monies with what you are doing, Mr. Portela?

Mr. PORTELA. Yes. So definitely in today's economy, no vendor can actually bring their systems to the market without a clear ally—organizational, clinical, and financial. So everything that we do we look at the value. We do assess models so we have to demonstrate the value at every step of the way, otherwise, the customers will go away.

And what we are doing, if we just take that cardiac patient that I was explaining before, you reduce the time to intervention, better quality of life. You reduce false activation of cath labs when patients are coming in and they activate the cath lab that they do not need to $7,500. That is what you save every time that you activate the cath lab and it is not necessary. Then we reduce the length of stay in the ICU because better quality of your heart muscle, less time in the ICU. And then also—that is about 0.85 days length of stay reduction. And then also, when looking at the readmission, the reduction of readmission for cardiac patients that are under the Affordable Care Act, two out of the three conditions that are going to be penalized for 30-day readmission are cardiac conditions. And we are also seeing a decrease of 25 percent on readmissions, which is a significant problem in the U.S. And you can continue in each of the service lines and see we have for each service line on obstetrics, patient monitoring. What is the benefit that we bring to the table?

Mr. LUETKEMEYER. My time is up. I have to ask for the indulgence of the chair if we want to continue with this.

Chairman COLLINS. No problem. We would like to hear the rest of the witnesses.

Mr. LUETKEMEYER. Okay. Thank you.

Mr. Brophy, it is interesting to hear that you have to have a cost-benefit analysis of each one of these apps brought to the table in order to be able to fully develop it. Is that what you have experienced as well, Mr. Brophy?

Mr. BROPHY. We have experienced that. And as I shared in the testimony, we faced initially skepticism about the power of mobile health apps to engage. So we have laid out a very careful stepping stone journey to progressively build proof points, and more and more proof points. We have started with health outcome measures, and one of the most significant, you saw the chart of the reduction in ER visits. But other health outcome measures as well. All outcomes have been affirming and positive. As the next step, we are collecting cost data, working with multiple insurance companies so we can have the hard cost data that maps to the health outcomes. And we likewise continue to scale up in the scope and size of our clinical trials so they will have more and more relevance. So we look at a combination of improved health and improved cost backed by black and white data.

Mr. LUETKEMEYER. Okay. I would like to stop right there. Can you give me, for instance, on one of your apps, did you have some data that showed how many lives it would save? Or the amount of money saved by lessening the amount of time in the hospital or in recuperative care?

Mr. BROPHY. Right. We have hard data on areas like the reduction in ER visits for select measured populations.

Mr. LUETKEMEYER. Can you give me one?

Mr. BROPHY. Yes. We had a study of Medicaid asthma patients, 26 individuals. They had 12 collective ER visits prior to the six months of a study, and during the six months of our study that was reduced to zero ER visits.

Mr. LUETKEMEYER. Really?

Mr. BROPHY. So we can project that to other staggering cost savings. In the world of clinicians and insurers, there is a high bar of diligence for proving out just such claims, but the early health outcomes would suggest that the cost savings will be very significant.

Mr. LUETKEMEYER. Mr. Burrow.

Mr. BURROW. We are early on and have not collected data that would directly answer your question; however, I would say that many studies have shown that having a complete comprehensive list of medications that have been prescribed to the patient when they present at the point of care is crucial in preventing the adverse drug reactions that were cited by Ranking Member Hahn; namely that as many as 7,000 of the 98,000 preventable deaths per year are from adverse drug reactions. So we are intrigued by going beyond that obvious point to collect data but have not yet done so.

Mr. LUETKEMEYER. I appreciate your testimony. And Ms. Casucci, I guess you guys are still in the development stage; right?

Ms. CASUCCI. We are.

Mr. LUETKEMEYER. Have you got some data that shows what you can anticipate saving?

Ms. CASUCCI. More anecdotal evidence at this point.

Mr. LUETKEMEYER. Okay.

Ms. CASUCCI. So there certainly will be, we anticipate, a reduction in readmission rates, so there is going to be some cost savings from that, but we have been looking at more the intangible costs at this point. So the benefit to having that better understanding of the care process on both the patient's behalf and their caregiver. So having this more complete understanding and comprehension of what those care needs are is certainly going to have a lot of intangible cost to the health care system and a more longer term perspective.

Mr. LUETKEMEYER. Very good. I appreciate the chair's indulgence. It was very informative. Thank you.

Chairman COLLINS. Thank you.

I have just got kind of a general question as we are going through this, and that is your financial model. Three out of the four of you are in business. We talk about return on investment, and I think it is just always intriguing as entrepreneurs come forward ultimately to say how do you make money on what it is you are doing? I thought it was an interesting comment Mr. Portela made that as he is developing his app he is already subject to the

medical device tax of Obamacare because it is not based on profits; it is based on revenue. But that is a slightly different topic.

I am just curious, because I am already hearing one of you is focused on selling to an insurance company; some of you may be focused on selling to consumers; there may be different ways to get to market, and part of an entrepreneur's job is after you have invented this great app, how do you get it out there? How do you get customers? And so just real briefly, I would be curious to hear the different financial models to the extent you would like to share that.

Mr. PORTELA. Yes, of course.

Firstly, I want to mention if we look at what happened over the last few years at AirStrip, we had significant growth in the last three years but definitely we are starting to see a significant impact from the beginning of the Affordable Care Act because definitely I think the model eventually could work because you are reducing the reimbursement and putting more money on uninsured patients that eventually will come back into the system and increase admissions to the system. But I think that starting in April, sequestration created a huge, huge problem. If you just look at in New York, North Shore Medical Center, from 20,000 patients, cancer patients, they are rejecting 16,000 of those patients because they cannot afford to keep those patients on the system. So we are starting to see throughout all health care organizations the fact that they are starting to look at their operating expenses. They were looking more at how to manage the Affordable Care Act as it came in but nobody was ready for sequestration.

So what happens is we are partners to those health care organizations. We are here because we have the passion to make an impact to the quality of care. We started with models, always a success model, subscription as a service, partnering with them and going at risk. So what we are doing right now is evaluating our prices and make sure that we clearly measure the benefit that we bring to them so at no point they are losing any money. So that is our approach.

Chairman COLLINS. Thank you.

Mr. Brophy.

Mr. BROPHY. We do sell to insurance companies and specifically, we sell population licenses. So we provide licenses that cover a broad swath of an insurer's population. They focus Abriiz on the subset that has the most severe conditions. We work together to roll it out to those populations. And the savings that the insurer realizes as the ER visits are reduced go directly to the insurance company's bottom-line. So we are a return on investment sale proposition for the insurers by purchasing the licenses for their population and employing it they reduce costs significantly.

We do sell as well to health systems, accountable care organizations, also to hospital systems that may be focusing on reducing Medicare readmissions or aligning with meaningful use guidelines. So we have a number of potential sales candidates within the health ecosystem but insurance companies, particularly the managed Medicaid insurers, realize the most direct cost benefit from the purchase.

Chairman COLLINS. Thank you.

Dr. Burrow.

Mr. BURROW. Right. So our apps are currently available on the iTunes store and the Play Store. And individuals can use our apps. Thirty-seven million Medicare patients can go acquire these apps. The app is free to download. We have a nominal charge for when they use the app to download and process the Medicare record, which is a few dollars for five records or a few dollars more for 25 records. We give a credit—every time a patient pushes that record to a doctor and shares that record with their doctor they get credited back. So if they download the app and use it frequently to share, the cost is really nominal.

We believe that Medicare CMS should consider policies that allow reimbursement for this type of technology, and we would, of course, be happy to discuss that with CMS. We think that having every Medicare beneficiary have access to their medication list, their problem list, their past procedures and all their doctors is a self-evident good. So we would be happy to discuss that with CMS further.

Chairman COLLINS. Now, if someone was going to download your app, what is it called?

Mr. BURROW. IBlueButton. Thank you for asking. Thank you for asking. Getting the word out is important.

Chairman COLLINS. That is the business side of me. Glad to do that.

Mr. BURROW. Thank you.

Chairman COLLINS. Ms. Casucci. I know, you are still in the development and we chatted earlier. Have you thought of the financial piece yet?

Ms. CASUCCI. We are. That is one of the big questions that we are tackling at the moment. So our goal certainly is to have the most people being able to use our app to obviously get the most benefit from it. So there are several options about how to best position our product to be able to do that, so I thank the panel here for giving us some interesting insight into how their models are and how they are working.

Chairman COLLINS. Thank you.

I see we are joined by Mr. Coffman from Colorado. We would certainly welcome any questions you may have for this very dynamic and appropriate panel in this technological age.

Mr. COFFMAN. Well, thank you all for testifying before Congress today. I have a Veterans Committee hearing scheduled at the very same time, so I left that early to come over here in interest for what you are doing.

I wonder if you could just, all of you, say what is the end state in terms of—and I think in terms of the questions that we all have surrounding health care quality, access, and cost, and how what you do influences those three critical areas that are so important to the American people?

Mr. Portela.

Mr. PORTELA. Okay. So, of course, you are mentioning quality, access, and cost. I think in our testimony we are addressing those three areas. Just so you know, we are a big proponent of, as I mentioned before, of the FDA regulating medical device mobility because as we are moving, as I said before, into a patient-centric

model outside of the four walls of the hospital, as we have fewer physicians taking care of more patients today, it is very important that the data that they get is really diagnostic quality and that they get that on a real-time basis. And the real-time basis is also very important. So that is as it relates to quality.

I think the area of cost also it is very important. I was mentioning before that we are partnering with a number of health care organizations like Dignity Health Care, Ardent Health Care, HCA, that are helping us to really figure out what is the right model moving forward. With all the different hits they are getting, we were talking about sequestration and the impact that brings into many of these health care organizations. So as far as cost, we are putting the models in place with them, and in some cases we are going on a risk-sharing basis to be able to work with them.

As far as access, what we talked about is the challenge of interoperability. The fact that there are a number of standards for health care information exchange but standards that are not enforced by the government and the vendors are not complying with, even though there are standards as we mentioned before, like HL7, there are certain areas of HL7 where the vendors get flexibility to put proprietary formats in that language. And for some reason, all the vendors decided to put 99 percent of their data there and 1 percent following the standard. So the Federal government really needs to take a very hard look into this and force all of us to collaborate. We are not realizing that as we move into an outcome-based reimbursement model, no longer fee for service, and as we are having the issue with shortage of caregivers and patients increasing, we are not going to be able to sustain this model without innovation and without vendors collaborating. We are all going to be responsible for this system to collapse if we do not open up.

Mr. COFFMAN. Okay. Mr. Brophy.

Mr. BROPHY. Yes. Our model is built with a desire to make a difference in the areas of quality access and cost, so I appreciate the question.

The insurance company of today, the managed Medicaid, the fixed price provider, essentially, manages the population, including those with severe chronic conditions, and often does that through case mangers. The case managers often reach out occasionally through telephone calls to try to connect with those patients, and we work directly with those case managers across the nation. And they are incredible individuals. They care. They are expert, and they can make a difference if they can just connect with, for example, the severe asthmatic. We, through our mobile application, give that case manager the opportunity to be present in a sense every day of that child's life with severe asthma, a connected way that is right there in the child's life that rolls back to the case manager website. They can provide incentives and motivations and insight. So we increase the scale and the reach of the case manager. In turn, that provides access. The solution has been deployed from urban Detroit to rural Kentucky for populations that otherwise would not have access to a daily stewardship of their condition. And in terms of the cost equation, we have targeted insurance companies because our belief is that as we lower the costs for insurers

that plays a significant role in lowering the cost of our nation's health care and lowering the costs of everybody's access.

Mr. COFFMAN. Mr. Chairman, can I have a unanimous consent to have one more minute?

Chairman COLLINS. Absolutely. This is very interesting.

Mr. BURROW. Thank you for the question, Congressman Coffman.

Given that you were just at the VA Committee, I should mention that our app also gives every veteran the ability to download their Blue Button record from the My Healthy Vet website.

What use case are we trying to solve? How are we trying to help? The veteran often gets care both at the VA and outside in the private community. By giving the veteran the ability to download their record from My Healthy Vet, which is output from Vista, when they see a physician out in the community, that physician now can see the record that our app is delivering, either on the patient's own smartphone or our smartphone allows the patient to transfer that record with an optical code to the physician's iPad. So this is a key problem for the VA that currently fax is often the mode of communication. So we believe by offering this, this is an important way we can affect quality of care and cost for the Veterans Administration. And we are on the VA website as a Blue Button partner listed there. Veterans can go there and link to our app and download our app from iTunes or Play Store.

Mr. COFFMAN. Please.

Ms. CASUCCI. Great. So as industrial engineers, these are certainly concepts and ideas that are very near and dear to us. So our goal of designing this, what we set out to do is really to try to reduce these costs of redundant or rework care, if you will. So what we try to do from the quality perspective is really improve the comprehension and the understanding of what that care process is and what the steps—not only what the steps are you have to do but why you should be doing them. And what we hope to do from that through our assessment portion of it all is to understand not only what that level of comprehension is but what are the other constraints that are in this individual or this family's situation that could prevent them from enacting this level of care that was prescribed. So if there are conditions where the informal caregiver is a working adult with their own family, there is clearly scheduling conflicts that need to be considered. So if we can take all of this into account in the beginning, then we can get this much better and more hopefully attainable care plan at that initial discharge, preventing all of these adverse events and effects coming in once those plans are not really working out as they were intended.

Mr. COFFMAN. Thank you, Mr. Chairman.

Chairman COLLINS. Thank you.

Ms. Hahn, do you have some follow-up questions?

Ms. HAHN. I do. And if you will indulge me, I was just thinking, especially when I was listening to Mr. Portela talk about cardiac patient, I was thinking about my own father, Kenneth Hahn, who was a county supervisor in the 1960s in Los Angeles, and his heart doctor came to him one day and said, "Mr. Hahn, how would you like to save a life a day?" And my father was, like, "Great. As long as they are registered voters." No, my father said, "Yeah, how does

it work?" And he said, "What we have discovered with a heart attack patient is this golden hour. Right? If we can get to them in the first hour, we have a chance of saving their lives."

So his idea was to train firefighters to be allowed to inject the drugs where they were instead of waiting until they were transported to the hospital. My dad thought it was a great idea, and at that point it took legislation because obviously a nonmedical person was not allowed to administer these drugs. So it was passed by the California State Assembly and Legislature, and our governor at the time was Ronald Reagan. And Ronald Reagan was going to veto the legislation because at that point the AMA was against it, the nurses were against it, because again, you were taking something that was in their jurisdiction; you were giving it to these firemen. And my dad said, "Let me talk to Governor Reagan before you veto this." And so he flew up to Sacramento and he said, "Let me give you one last opportunity to understand what this is about." My dad explained it. Governor Reagan said, "Let me ask you one question, Mr. Hahn. Would these ambulances, would these mobile paramedic devices, would they be allowed to cross jurisdictional lines or would they just be assigned to certain cities?" And my dad said, "No. The point is they are at a base hospital. Whoever is closest is dispatched to the heart attack victim." And Ronald Reagan said, "Kenny, I am going to sign this." And my dad said, "Gee, what changed your mind?" And he said his own father in Beverly Hills had a heart attack and his mom called an ambulance at the time in the 1960s. The ambulance came from Los Angeles and it stopped at the Beverly Hills property line and turned around and went back without relaying the information to anyone else and his own father died in Beverly Hills.

And so sitting here today, this is a great political satisfaction for someone like me who is new around here to think, gee, 45 years later, something that my dad actually championed—it was the Paramedic Program—and here we are 45 years later and I think— of course, that was government. It is very exciting to hear small business people, what I think we are on the verge of something as dramatic and life changing, lifesaving as what my dad championed in the late 1960s, which became our paramedic program.

And I will let you speak, but I was thinking the latest Pew Research Center said 56 percent of U.S. adults own a smartphone, but that still leaves a lot of people in this country, about 45 million people who will not be able to access your applications because they do not have a smartphone. And I know my district that I represent in Los Angeles is a poor, minority district, and a lot of those folks cannot afford a smartphone. How do we embrace this, help you to succeed, try to support you? And how do we not leave behind 45 million Americans who, by the way, probably are the ones that have the medical conditions probably that would exactly need this kind of help with their health care in general which would save money and be more efficient? How do we not leave them behind?

Mr. PORTELA. Well, so a lot of important points that you made. And what I would like to address first is that, of course, the vision he had. And of course, what we need to look at is that many times we learn a lot from what happens on the military side because we worry, of course, of what we are going to do in rural communities,

but many of the things that we are doing in health care today and technology come from the military side. And we have to look at the model in the theater of operations.

Prior to coming to AirStrip, I did 10 years of technology into the military health system. I deployed systems in every military base throughout the world. If you look at the theater of operations, the battlefield, that is where a model like this will have a significant impact because you have a medic that is not a physician but they need to be able to take action right there. But if you can really provide the access so the doctor can make a decision, so if they have to inject something or if they have to perform the procedure, now they are going to have use in telehealth. They are going to be able to have this doctors working with those medics to be able to save those soldiers. So I think that is an area we can start immediately. We have the right regulation for diagnostic quality. We have the right regulation for security, for the DoD, and then really bring those models into the private sector supporting underserved communities.

Now, the issue about people opposing an idea like that because they did not want the firefighter to make the decision, now we go back to what we were saying at the battlefield. You can have now somebody remotely really helping on an emergency where something like that has to happen. As far as this group helping us and how we can have more adoption on cellular phones and smartphones, well, we are the silent partner of the patient. We support the caregiver, so I am more about the physicians being able to get access to the data for all the patients anywhere at any time. So anything that can support caregivers to be able to do care coordination through mobile coordination, I think it is the area where we need the most help. And reimbursement on the Medicare and Medicaid side is very important for that.

Mr. BURROW. Thanks for that question. It is true that not everybody has a smartphone, although that is changing rapidly. In communities that have disadvantaged individuals where economics may not be there, we have been amazed at how many people, particularly of the younger generation, do, in fact, have smartphones. And as we have all learned, more people use smartphones now to access the Internet than use the PC. This is extraordinary. We have just gone through an amazing inflection point there.

So what we observe—this is anecdotal—is that individuals who accompany their mother to the hospital and they have a smartphone with the record on the smartphone, this is an extraordinary thing for individuals who might not be able to answer the questions—what are your medicines? Who are your doctors? What are your problems? And even individuals who do not speak English, if they have our record in English right there and they can show it to the doctor, this is really, really something. And so we think that this kind of technology is very important for the communities that you are referencing.

Mr. BROPHY. We have seen the proliferation of the mobile technologies is exploding. Even as it has already reached this inflection point it continues to go up, up, up, and a solution like ours can not only run on a smartphone but also on tablets, mini-tablets, anywhere that there is wireless where we have supported the applica-

tion. Often the insurance companies will provide the device themselves to the populations, whether it is to children with severe asthma or senior citizens with heart conditions if they do not have a smartphone of their own because the expected cost savings are so significant, the cost of the device pales in comparison.

We also designed a solution so it does not require pervasive Internet; it requires occasional Internet, and we have scenarios where users that do not have access to every day Internet go to a library, to a school setting, to their local restaurant and upload the data. So there is a variety of approaches we have used.

In terms of what could help looking to the future, I would just underscore that bandwidth is beautiful and a nation with great bandwidth is a strong nation today.

Ms. HAHN. Actually, my facts are that 132 million Americans do not own a smartphone right now. So that is a lot of folks. And even when you look at, for instance, AARP magazine—I am a member, I am not embarrassed—their advertisements are for the Jitterbug. Right? So there is not this, you know, our senior population is not embrace. Maybe the young people are clearly but the seniors, particularly those who are disadvantaged are really considering this probably a luxury that they cannot afford. So I hope we can figure out a way to not leave that many Americans behind as we embrace this new technology.

Thank you, Mr. Chairman. I yield back.

Chairman COLLINS. Well, I want to thank all of our witnesses for participation today. I mean, certainly, what we have seen is entrepreneurship at its best, and I think we do rely on small business. They are 60 percent of the employees today, and will be, I think, 80 percent of the new jobs created in America. And it is that entrepreneurship that we see here is alive and well.

Bringing forth solutions in some cases to problems people did not know they had, but as you have demonstrated today, these solutions are somewhat common sense, but they are only common sense after you discover them. And then as you present them, parents are saying, well, of course I would like to be able to monitor my child's behavior, whether they are diabetic or they have asthma, you know, for the comfort of mind. All of us with aging parents want to be able to know that we know what they are doing and that the doctors know, because they do go to different pharmacies, they go to different doctors, and we all worry about that. What you have done today, I think, has helped describe where this is going, and anytime you are on the cutting edge, which we are today, there will be bumps in the road, but I think your testimony was good and very informative to all of us. So thank you for your time.

I would like to ask unanimous consent that the members have five legislative days to submit statements and supporting materials for the record. Without objection, so ordered.

The hearing is now adjourned.

[Whereupon, at 11:26 a.m., the Subcommittee was adjourned.]

A P P E N D I X

Prepared Statement

of

Mr. Alan Portela

Chief Executive Officer, AirStrip

"MOBILE MEDICAL APP ENTREPRENEURS:

CHANGING THE FACE OF HEALTH CARE."

BEFORE THE

HOUSE COMMITTEE ON SMALL BUSINESS

SUBCOMMITTEE ON HEALTH AND TECHNOLOGY

JUNE 27, 2013

Chairman Collins, Ranking Member Hahn and members of the Subcommittee, thank you for the opportunity to appear before you today to discuss mobile health (mHealth) and current regulations that surround it.

Over the last 20 years, information management and information technology have played a transformative role in shaping the future of healthcare. Current and future innovations in healthcare information technology (HIT) will be no different and they will affect very facet of healthcare including how it is delivered, how it is consumed, how hospitals compete with one another to provide best value and how the healthcare labor force is realigned to meet ever-changing requirements.

The nation's healthcare system is undergoing a significant transformation. The move from an "Episode of Care" (Fee for Service) to an "Outcomes Improvement" (Bundled Incentives and Payments) model is forcing healthcare organizations to look beyond the four walls of the hospital and into a "Patient Centered Home Care" model.

As a result of this change, the attention is moving from the inpatient (hospital) to the outpatient care settings (ambulatory, home, etc.). The focus is turning to all activities around outcomes improvement throughout the continuum of care in order to avoid unnecessary hospital stays and re-admissions.

The model is becoming more patient-centric and, at the same time, the consumer's level of sophistication is increasing the competition amongst providers who are quickly seeking differentiators by acquiring both specialists (primarily cardiologists and endocrinologists/diabetes specialists) and leading-edge technologies that can have a direct impact on chronic disease management. The competition generated as a result of this trend is becoming fierce; payers are embracing ACOs and negotiating lower reimbursement, while providers are aligning clinical service lines with quality and costs.

These changes and challenges faced by the healthcare system have been exacerbated as the Baby Boomer generation is reaching retirement age and 16 million formerly uninsured additional patients that will be added to the system as part of Healthcare Reform. The change in scope (Patient Centered Model), coupled with the current caregiver shortages the industry faces and the move away from generalist doctors to specialists, will mean a great reliance on mobile health and shared-medical technologies. The major driver behind this transformation is the prevention of disease and the management of chronic diseases while reducing costs. Approximately 75% of the US population has at least one chronic disease, with cardiovascular diseases representing three of the top five (COPD, hypertension, cardiac heart failure, diabetes and stroke).

The focus on outcomes is forcing healthcare organizations to concentrate their strategic initiatives around federal and private sector **reimbursement and incentive payment programs** designed to support regional management of those chronic diseases (Accountable Care Organizations or ACOs, Meaningful Use and other similar payer programs). A key initiative is to attract a larger patient

population by tapping into the regional specialist (i.e. cardiologist), partnering with other regional providers as well as the use of social media to reach out to the community.

Hospitals will need help as they move from a fee-for-service to a fee-for-value model since they are the ones leading the paradigm. They've been focused on core operations in the hospital and not so much on the pre-hospital or post-hospital care. Integrated Delivery Networks (IDNs) are back to buying up physician groups as they were during the managed care days, but there is a much different motivation for doing it today. In order to integrate to a more collaborative model, they're going to need the type of technologies that will enable them.

Unfortunately, providers have been significantly reducing personnel in the inpatient areas, with massive layoffs starting in the second half of 2011 in anticipation of expected reimbursement cuts. In our opinion, this is not the right approach to take since it will only make things worse. Our approach is validated by new research from the New England Journal of Medicine suggesting that as hospitals prepare for an additional 16 million newly insured patients in 2014, they should be concentrating on adding more support staff to support specialists. The reasoning is that aside from providing care to newly insured patients, not only within the hospitals but also throughout the continuum of care, hospitals will need support staff to process applications, file insurance claims, submit data for regulatory compliance, and perform other administrative duties, according to the study.

Mobile technology will play a crucial role in the development of new federal and private reimbursement revenue models that can improve the quality of care, reduce costs, prevent job losses and create new, more specialized healthcare jobs.

Today, large integrated delivery networks are exploring reimbursement models focusing on the adoption of technology to improve workflow and generate revenues around clinical services such as cardiology and diabetes. Payers are also following these models, realizing that the shift will occur with or without the momentum created by the federal government around Medicare and Medicaid programs and ACOs. Payers leading the way include Aetna, United, and Humana.

As previously stated, for the past decade, the healthcare industry has faced an ongoing shortage of caregivers impacting physician labor force distribution. Under the new labor model, primary care generalists are disappearing, replaced by specialists who are breaking down work previously done by one person into more specialized tasks performed by experts.

Doctors will no longer be paid by the episode of care, but rather by their expert interpretation of raw clinical data as well as improved outcomes. Relevant data will need to follow the physicians wherever they go, rather than bringing them to the data residing in one central location. At this point, technology becomes essential to support the new reimbursement and financial models. That includes mobile technology, analytics, and cloud computing.

As a result, physicians no longer practice medicine in one location. They are fast becoming mobile professionals, with mobile technology including tablets and smartphones developing as the ultimate tool to improve workflow under the new models.

Labor force changes include:

• Primary care generalists are decreasing by alarming rates.

• Rapid rise of hospitalists, who now account for approximately 40% of hospital admissions (55% from the emergency department and rest via primary care physicians).

• The shift to an ambulatory care model (home) will only add to the shortage since care was primarily provided within the four walls of the hospital.

• Hyper-specialization, which is increasing around new service line reimbursement models (i.e. cardiologists, endocrinologists, oncologists, etc.).

The Rise of the Virtual Specialist

Hyper-specialization requires technology to create virtual environments. The shift of medicine to outcomes improvement and care beyond the four walls of the hospital will add a significant burden to the existing shortage of caregivers. Mobile technology that enables physician virtualization will be critical moving forward.

Today, the biggest challenges in the advancement of Health Information Technology (HIT) are security, limited access to diagnostic quality solutions (FDA cleared or approved) and medical device interoperability. AirStrip has decided to proactively deal with the first two by seeking the highest level of certification for our mobile medical device solutions for security (DIACAP / Defense Information Assurance Certification Accreditation Process / DoD) and for diagnostic quality (FDA Class H, 510K). We are taking this proactive approach because we feel strongly about the need for the FDA to regulate (from both diagnostic quality and security perspectives) mobile applications that handle vital information for remote monitoring systems. Many vendors today are trying to question the need for FDA involvement with an argument around whether innovation is being slowed down or stifled outright. The reality is that the same requirements influenced AirStrip's innovative approach and today thousands of lives are impacted as a result of a partnership between federal and private sectors. Vendors opposing FDA involvement are concerned about the medical device excise tax as well as the strict "Good Manufacturing Practices" regulations without looking at the quality of patient care. We on the other hand do not object to the FDA requirements and involvement, but do not want to be singled out (Excise Tax) for proactively partnering with the Federal Government.

In July 2011, The House Energy and Commerce Committee's sent questions to FDA seeking much-needed clarification on the agency's policy of regulating certain mobile medical apps as medical devices. I was pleased to see the FDA respond to attempts to clarify the "gray area" of the guidance it issued in July 2011. Moving forward, the FDA should immediately release the Final Mobile

Medical Applications Guidance Document and take the following patient safety issues into consideration:

• *All mobile medical device applications displaying near and real time medical device waveforms and parameters data need careful regulation* - Traditionally, the FDA has focused on regulating hardware devices, but companies producing software-only medical device apps or even websites need to be regulated as well. Today, many websites or apps have crept into FDA-regulatory territory without scrutiny by adding features or functionality that position them as clinical decision support systems. For example, a website where vital signs, demographic data or physiological observations are used to power a decision flowchart that guides diagnoses can easily extend out to a mobile platform. That, in essence, creates a medical device that is conducting clinical support, and should be regulated.

• *"Accessories" to primary devices should also be evaluated* - Currently, software "accessories" (as the FDA terms them) to primary devices do not require separate clearance by FDA. Not only could the network go down, but the mobile medical device itself could be overloaded or failing in other ways. The FDA needs to also consider these accessories and potential failure points to ensure that manufacturers have addressed those issues in their testing.

• *Mobile applications capable of displaying mission-critical patient data should obtain security certification levels that go beyond the existing HIPAA requirements and FCC security regulations (Open SSL).* Patients privacy and security are also important to ensure FDA's goal of safety and efficacy of medical devices. The DoD's security certification process should be used as an example and cross-pollinate to the private sector.

The industry is greatly benefiting from mobile applications, but not all applications are created equal in terms of risk. Given the number of applications claiming to exchange or display patient data, the FDA should include many more mobile medical device apps under its jurisdiction.

Our approach to address interoperability has been around complying with interoperability standards - HL–7, Continuity of Care Document CCD and others.

Interoperability of health information has been heralded for decades as a way to make medicine more effective, efficient, and safer. However, the interoperability challenge has plagued hospitals and health systems for longer than any of us care to admit. The industry has largely over-promised and under-delivered when it comes to vendors "playing nice in the sandbox," integrating systems, medical device interoperability and making data across the continuum available in a simple and cost-effective way.

The answer to this challenge is mobility. With today's changing models of care, mobility enables coordination across multiple facilities and geographics, as clinicians increasingly need to make or discuss real-time decisions beyond the bedside. Mobility also overcomes what we've always known as the traditional barriers to interoperability - disparate data sources on the back end and con-

flicting and varied user preferences on the front end. In the race to accountable care, where health care organizations are being forced to figure out how to reduce costs and improve outcomes in record time, mobility is the first and fastest enabler of clinical integration and transformation. Without it, accountable care cannot be achieved.

However, even mobility vendors haven't gone far enough in addressing interoperability. We've attacked different pieces of the puzzle, understanding that we need to prove value and return on investment, but we are ready for the next step. When CEOs and CIOs of major hospitals witness the unifying power of mobility in areas like cardiology and obstetrics, beyond enabling them to make strides around specific quality metrics like door-to-balloon time or patient satisfaction, they are recognizing its potential to achieve clinical transformation throughout the entire health system. I've already seen this start to happen in the health systems I visit every day. This signals to me that mobility has been proven, and the industry is ready to take an enterprise-wide approach. We are entering an era in which health systems view mobility as a necessity for the entire care continuum.

A world where interoperability is achieved through mobility should not only provide secure, near-real-time data about a patient from any source across the care continuum - from admit to discharge and beyond - but it should also offer the "big picture" data health systems need to make broader decisions about their operations and ultimately, their financial future. This will mean that health systems can finally make the shift from focusing on incremental or departmental operational changes to true transformational change that enables them to meet the broader demands of the new healthcare environment - improving population health and addressing pressing issues such as reducing readmissions.

Clinicians no longer work in stationary environments, but rather are frequently required to move across facilities and departments. To provide care to patients regardless of location, physicians need the data available whether they are at the bedside, down the hall or at a different hospital. For now, interoperability will continue to be a challenge in the future of HIT, but it is clear to me where the industry is headed. Mobility is the lynchpin, and we are not far from every hospital and health system's "a-ha moment."

I am often asked by hospitals CEOs and CIOs how they should prioritize mobility when it comes to different care areas. My first answer is to look at your current challenges and strategic initiatives, and then ask how mobility can help you to get there. While I always emphasize the benefit of mobility across all departments, cardiology is where I see the potential for mobility to make the most immediate impact - especially when it comes to improving outcomes and reducing readmissions.

Door-to-balloon time is one of the most significant metrics regarding cardiology. Today, the average in the U.S. is about 90 minutes. But when you equip cardiologists with diagnostic-quality ECGs coming right from the ambulance, they are able to make de-

cisions immediately, saving valuable minutes and giving them the option to bypass the emergency department to send patients directly to the cath lab. I've seen hospitals drive door-to-balloon time down to 35 minutes. On the flip side, a hospital loses $7,500 every time they unnecessarily put together a cath lab team. Thus, the sooner clinicians can identify and communicate a false STEMI, the more savings the health system will see.

More importantly, reducing event-to-balloon time also puts patients in the ICU with less damage to their hearts and who are ultimately "healthier' on their road to recovery. I've seen hospitals shave nearly a day from their post-STEMI ICU stays, which saves anywhere from $1,400 to $2,500 per patient. Over the course of a year, a hospital that cares for 200 post-STEMI ICU patients could see a savings of at least $280,000.

This leads me to cardiology-related readmissions, which are under the most scrutiny with the CMS penalties enacted by the Affordable Care Act (ACA) where hospitals can be docked up to 1 percent of Medicare DRG payments around acute myocardial infarction (AMI) and heart failure (HF). In general, patients who experienced a shorter event-to-balloon time and shorter ICU stay are much less likely to return with complications within 30 days. But there is even more to that story. For one hospital, we looked at 100 ECGs of discharged patients and noticed that a significant percentage of those patients had difficult-to-detect conditions when discharged, and therefore ended up coming back within 30 days. This was because those patients had a heart condition or weakness that was not detected by the physicians on the floor - because not all of them were cardiologists. Electro-physiologists and cardiologists need to be able to review patient data from anywhere to identify issues and prevent patients from leaving the hospital without proper care.

Mobility also plays a key role in the critical post-discharge period for heart failure patients. They can be sent home with sensors that are constantly uploading ECGs and other data that can be accessed by a group of electro-physiologists and cardiologists, who in turn identify and ideally prevent potential causes for readmission. A two-year study of patients with congestive heart failure (CHF) showed a 44% drop in readmissions through the use of home tele-monitoring. If a patient can go directly to the cath lab rather than the ED because a physician is able to remotely diagnose the condition, then the hospital is not penalized for a readmission under the ACA. And the physician doesn't need to be at a desktop in the hospital to make that happen. Not only that, when an electro-physiologist needs to consult with a cardiologist about a patient, the two can review the same ECG in virtually real-time on an iPad or other mobile device in two different locations.

The benefits of a mobility platform in every department across a health system are too significant to ignore, but with its time-sensitive and care-intensive environment, cardiology represents the most immediate opportunity for mobility to make a positive impact on both patient care and a hospital's bottom line. The management of other chronic diseases (i.e. diabetes, COPD, etc.) via mobile de-

vices should be placed in the same category in order to quickly impact the quality of care.

I am honored to have the opportunity to be a part of the mobile healthcare industry, a partner with the federal government and even more so to be part of the exciting innovations which will deliver better patient care and better patient outcomes, now and in the future.

U.S. House of Representatives
Committee on Small Business
Subcommittee on Health and Technology
Testimony of Ideomed, Inc., CEO Keith Brophy
June 27, 2013

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June 27, 2013

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Chairman Collins, Ranking Member Hahn, and members of the Subcommittee, I am Keith Brophy, CEO of Ideomed, Inc., and I appreciate the opportunity to address you today.

Ideomed is a Michigan-based company with a national focus. Our mission is to solve one of healthcare's most vexing issues: engaging patients long-term in managing their own health and chronic illnesses. Ideomed was launched in 2010 through Spectrum Health Innovations, a business unit of Spectrum Health, a major midwestern health system. The vision was to improve health outcomes through patient daily health engagement. It was a vision driven by real economic need: our nation's growing cost of chronic conditions — by some estimates 75% of every dollar spent on health care — was a catalyst.

I'm also here today as part of the Association for Competitive Technology (ACT), a trade association that represents technology companies involved in mobile app development. Founded in 1998 by software developers, ACT supports companies like us across the world: innovative small businesses that develop mobile apps, whether as a primary focus or, like Ideomed, as part of a broader solution. They help us navigate the laws and government regulations, and they advocate for developers at all levels of government. I am part of a large community of developer members who have benefited from ACT's hard work and resources.

A key player in the early vision for Ideomed was Spectrum Health Innovation's leader Kris White. Before becoming president of Spectrum Health Innovations, she'd enjoyed a successful nursing career and worked her way through the ranks to become a health system executive in charge of patient engagement. Another visionary was Ideomed's technology vice president Lisa Schutte, Ph.D., who brought expertise from her background in healthcare and product development. My own background as a successful transformational technology business entrepreneur, growth team builder, and innovative thought leader in human engagement solutions aligned perfectly with the company's mission.

More importantly, we assembled the current team of more than 30 employees with an eye on diversity of expertise and talent, and brought together people with an innovative, entrepreneurial spirit who are driven to transform health care. The team's collective background spans science, technology, engineering, math, user experience, content and creative design, and healthcare and business development. This team now constitutes one of the nation's greatest concentrations of health information technology expertise for a company our size. But early in our journey there were just a couple of us in a one-room office with a dream of making a difference.
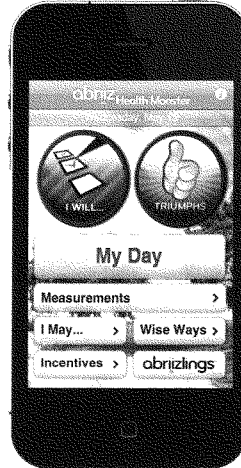
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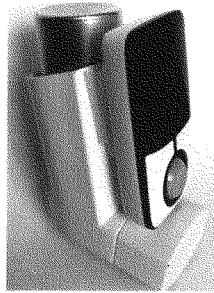
The original prototype: an inhaler sleeve that provided medication reminders and encouraging messages.

Our original product concept was a sleeve device that slid onto an asthma inhaler to provide medication reminders and messages of encouragement to an asthmatic child. Our motivations to make a difference in the realm of asthma were great: 14% of all children in the United States have been diagnosed with asthma, according to the federal Centers for Disease Control and Prevention, making it the number one chronic illness among children and the fifth largest for the population at large. For those who suffer from it, asthma can have a major impact on quality of health and life. It can also be deadly.

In 2010 alone, the nation's emergency rooms saw 1.8 million unique visits in which the primary diagnosis was asthma, according to the CDC's National Hospital Ambulatory Medical Care Survey. We also understood the payer impact behind this condition. Of all ER visits in 2010, almost half — 49.1% — listed Medicare, Medicaid, or CHIP (Children's Health Insurance Programs) as the primary payer, according to the CDC's National Hospital Ambulatory Medical Care Survey. Another 36.9% were privately insured.

By early 2011, we had produced a working prototype of this solution and a manufacturing plan for it. We also assessed how we might apply the same sleeve device concept to a pill bottle. We continued have concerns about how we would get our product to market, including obtaining the FDA Class I or Class II medical device approval our sleeve would require, and how we would continue to innovate alongside the rapidly evolving pace of other consumer technology devices. We also continued to contemplate how our custom device could advance in the future considering the constant waves of innovation that were rippling across the industry of standard consumer technology devices.

Ideomed invested a significant amount in the development of the original prototype and in preparing for the marketing introduction in the face

Abriiz® Health Monster supports a wide range of user types with a number of tracking features that can be configured based on the end user's health focus.
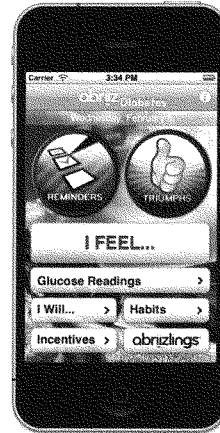
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of these questions. As our team worked to move the solution forward, it became increasingly clear that committing more time and money — required to achieve FDA approval and bring the product to market — would be prohibitive to us as a small company working to build our entrepreneurial survival in a fast-changing market through progressive business success.
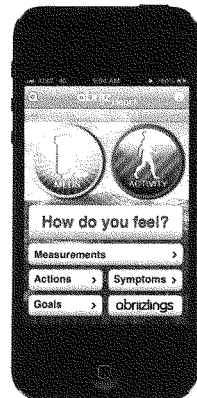
During this timeframe we gained tremendous insights into chronic condition management through our ongoing research, focus groups, and analysis, and developed a philosophy of successful patient engagement. We also recognized an interesting aspect about the ever-improving commercial mobile platforms.

Consumer trends and technology advances in mobile devices — mp3 players, smartphones and tablets — and rapid consumer adoption of them offered tantalizing possibilities. The adoption and use trends were hyperbolic: as of June 2013, smartphone penetration in the United States is at 61%, according to Nielsen, and people were relying on the mobile devices

Abriiz® Diabetes joined the product lineup in early 2013.

more and more for an assortment of tasks. Why not have health-related tasks as one of them?

We shifted strategy, leveraging the explosive growth in consumer adoption of smart device and mobile technology and refining our business focus with awareness of the requirements presented in the Patient Protection and Affordable Care Act (PPACA). In less than 6 months, the Abriiz ("ah-breeze") web- and mobile-based engagement platform was born. Our aim was to make the stewardship of one's health a breeze.

Abriiz® Heart, which targets elderly heart failure patients, debunked the myth that seniors wouldn't adopt mobile device technology.

This bold step allowed us to enhance the adherence, awareness, and engagement motivators we could surround an individual with through the mobile experience. We made it our mission to inspire individuals to steward their own health, rather than taking a policing or enforcement approach. Our goal was to make the experience valuable, easy, and fun where it was appropriate to do so. And most of all, to make it matter.

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A wide variety of industry studies clearly show that sustained engagement can drive better health outcomes. Studies have also demonstrated that a care management based multi-modal approach can have a positive impact on adherence and outcomes in chronically ill populations. Ideomed blended these approaches. We recognized the need for an enhanced system to assist care managers in supporting larger populations, accessing real-time patient compliance data, and engaging patients in their own care for ensuring long-term success.

Defining a replicable and scalable approach to "patient engagement" that simultaneously supported the care partner's existing efforts became the central focus behind the development of the Abriiz technology. We integrated various aspects of engagement and adherence science: tracker/reminders, incentives, repetitive motivation and education, self-monitoring, connected monitoring, positive social engagement, badge-based gamification, and more. The experience we offered to patients at the mobile level also connected to insurance companies at the web level, with the ability to involve families as well.
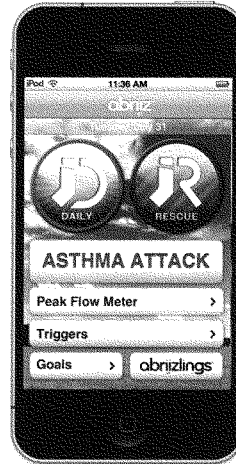
Ideomed's cornerstone product, Abriiz® Asthma, provided a template for first-in-class user experience and brought our proprietary engagement science techniques to the interface level. Features such as the Dashboard, (web view shown at left) gives case managers and care partners a hub for sorting and viewing patients' daily tracking details in a scalable manner.
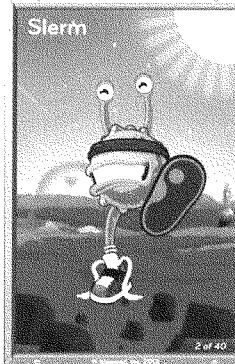
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The initial iteration of the Abriiz web application was designed for insurance company case managers and, optionally, parents of the pediatric asthma patient. Insurance companies purchase the solution to drive better outcomes in their member populations.

The "care partner" tailors the mobile experience to the individual by creating medication reminders set for the exact time a dose should be taken. They can also create goals and incentivize the child to achieve them; for example, adherence to a medication regimen daily for 2 weeks is rewarded with a pizza party. If a patient or their guardian chooses, they can share account access with other care partners such as grandparents, school nurses, or other members of the broad care team, or "care web." That care web becomes a powerful engine, helping the patient stay engaged, while acting as a safety net to catch early warning signs of a flare-up or need for an intervention.

The mobile app, which connected to the care manager's web account, was initially designed for children and has an interface that was styled to address usability issues unique to a pediatric population. The app also features a built-in game designed to encourage use: as the child tracks and demonstrates adherence, they earn badges called "Abriizlings," critters that interact and respond in the mobile interface.

We intentionally started our Abriiz journey with populations perceived to be the toughest — managed Medicaid provider populations often in disadvantaged social and income circumstances. We were warned that making a measured difference in these populations would fail for a variety of reasons: lack of internet access, lack of interest, inability to protect the devices. All of these warnings turned out to be overstated myths; our experience has illustrated this repeatedly as we continued to build success data.

Originally designed for pediatric users, Ideomed has found that the "Abriizlings" in our app-based game hold universal appeal.

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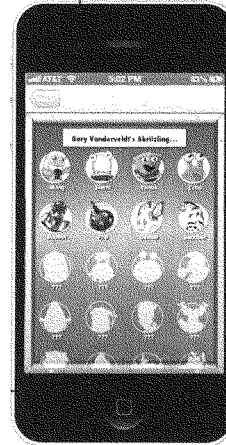
Studies show that well-controlled asthma leads not only to better health outcomes, but significant cost savings in management of the disease. A 2011 study in Annals of Allergy, Asthma & Immunology showed that the costs of very poorly controlled asthma were more than twice as high as asthma under better control; those costs dropped as the status of their asthma control improved.

Abriiz has consistently demonstrated positive results in the field. Three early clinical trials showed a drop in emergency room visits during or after using Abriiz as well as other positive impacts. This suggested cost benefits as well, and we began to collect data in these areas.
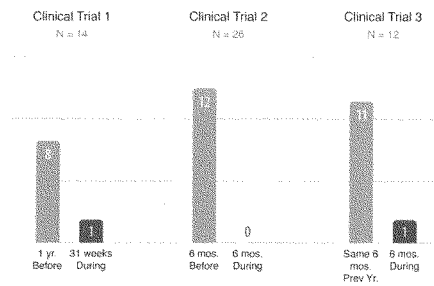
The results suggest Abriiz does all we'd hoped, and more. It upended assumptions — ours and others' — about whether we could successfully engage with more challenging populations, such as managed Medicaid. Why not apply the platform's principles to other chronic conditions, ones that present the same challenges as asthma? We started with heart failure at the end of 2012.

We ran into new traditional thinking myths, including the oft-stated assumption that older populations would not use mobile devices on a sustained basis. Our first usability study with a home health heart program debunked that myth also; the average number of days on which seniors used the mobile application exceeded 80% over a 6-month period.
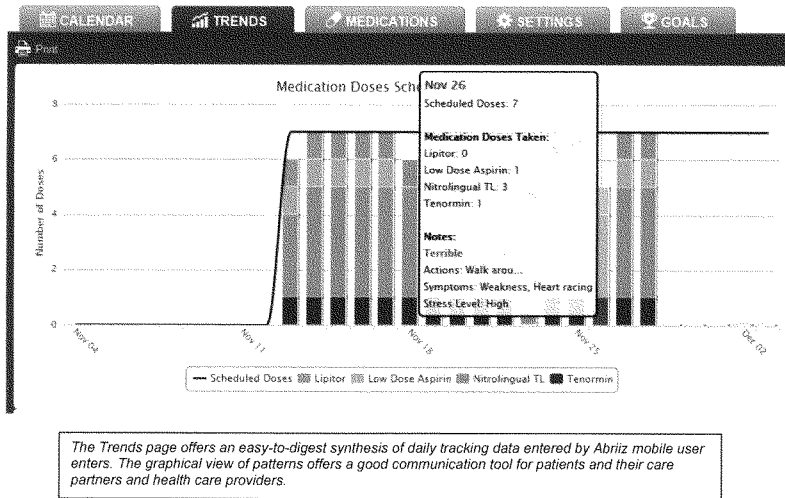
Based on these encouraging myth-busting experiences, we continued to expand the suite. The Abriiz portfolio now includes solutions for diabetes, palliative care, and multiple conditions/co-morbid condition management. We have more products and integration capabilities in the works.

We're poised to enjoy incredible success. We've expanded our customer ranks across the midwest and nation. We've won a number of awards recognizing Ideomed's leadership and innovation. We even came full circle on the device front. We're now integrating, rather than custom building, a wide variety of devices used in monitoring personal health metrics — wearable devices, scales, glucose monitors and more.

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We're united with health care providers and health insurers in our shared mission of saving lives and improving population health. And our solution addresses one of population health management's most difficult to solve issues: how to move the needle on behavior change in chronic condition management, how to develop an integrated care web to drive change and to drive engagement, and ultimately, how to persuade individuals to effectively take the wheel for their own health journey.

The Trends page offers an easy-to-digest synthesis of daily tracking data entered by Abriiz mobile user enters. The graphical view of patterns offers a good communication tool for patients and their care partners and health care providers.

Abriiz represents a new breed of health applications. The application does not dispense any medical advice nor replace the role of any clinician. Rather, it extends the insight of the clinician and it inspires the human behavior and empowerment of the patient. This is a winning combination.

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We look to a future of possibilities and touching lives, and peer ahead to anticipate the emerging guidelines which are not yet present for our industry. Ideomed welcomes governance, guidance, and regulatory partnership in shepherding a new era of patient-driven health care through mobile engagement.

As we build out a mature, effective, and highly integratable solution suite, we highlight the value of quick clarity in governance to innovative emerging businesses such as Ideomed. We are vigilantly careful about building solutions that are of the highest caliber for our users, and which simultaneously protect their data to the highest standards. Our success has been shaped by our ability to turn on a dime, to take this patient vigilance forward, to turn assumptions upside down, and, ultimately, to empower individuals with the ability to steward their health with the care and connectedness of a broader team, whoever might be part of that team.

It is important to remember the impact laws and regulations have on small businesses. I thank the Committee for placing the spotlight on developers like Ideomed who are working hard in a very competitive industry. With the possibility of unintended consequences disproportionately affecting small businesses, it's important for Congress to move carefully when making changes that affect health care mobile technologies.

These are transformational times in American health care, and we are proud to be an engine of that responsible transformation.

huMETRIX®

Testimony of Christopher R. Burrow, M.D.

Before the

Subcommittee on Health and Technology

Small Business Committee

U.S. House of Representatives

Hearing on

"Mobile Medical App Entrepreneurs: Changing the Face of Health Care"

June 27, 2013

Chairman Collins, Ranking Member Hahn, and distinguished subcommittee members, thank you for the opportunity to appear before you today to discuss mobile medical applications and their impact on the U.S. health care system. My name is Dr. Christopher Burrow, and I am the Executive Vice President for Medical Affairs at Humetrix, a small, woman-owned business in Del Mar, California. Prior to my current role at Humetrix, I was an executive and founder, respectively, of two California start up biotechnology companies that developed new cardiovascular disease diagnostic tests. As a physician-scientist, I have two decades of experience both as an attending physician in Nephrology/Internal Medicine and as a molecular biologist. Humetrix's CEO, Founder and President is Dr. Bettina Experton, a former California Public Health Officer who conducted groundbreaking health services research on the impact of managed care on the frail elderly in the Medicare and Medicaid programs. Humetrix is a member of the App Developers Alliance, an industry association dedicated to meeting the needs of developers as creators, innovators and entrepreneurs, and we appear here today on their behalf.

Leveraging Patient-Facing Technology to Improve Health Care

Founded in 1998, Humetrix has been a pioneer in the development of mobile technology. At Humetrix, we believe that tools and mechanisms that enable increased engagement by patients and their caregivers have the potential to transform the delivery of health care. Indeed, over the last fifteen years, we have developed numerous mobile applications that enable consumers to engage with the world around them in new and innovative ways.

Despite the significant progress in electronic health record (EHR) adoption made as a result of the Health Information Technology Economic and Clinical (HITECH) Act (included as part of the American Recovery and Reinvestment Act (ARRA) of 2009), essential health information is not readily accessible by patients in today's provider-centric health care system. In 2011, only 31 percent of physicians were capable of exchanging a patient's health information with another provider.[1] Given that the average Medicare beneficiary sees seven providers a year, the odds that all of a given Medicare patient's providers are able to exchange records could be as low as 2 in 10,000. A typical physician treating a Medicare patient must coordinate care with an average of 229 physicians in 117 practices.[2]

The gaps and limitations of provider-based health information exchange solutions - through which one EHR system connects to another EHR system, either directly or using supporting tools and technical infrastructure - present a particularly critical challenge for the Medicare population because these patients often transition between care settings and may see multiple providers to address their chronic care needs. Recent data shows that one in three Medicare patients are discharged from a hospital to a long-term or post-acute care setting.[3] In many cases, little to no information follows the patient to their new care setting, as the vast majority of these facilities do not use EHRs and have no means of electronic exchange, EHR-based or otherwise.

A lack of appropriate information at the point of care may also negatively impact health care outcomes and increase health care costs. Experts estimate that, in any given year, a lack of accurate, comprehensive information about a patient's health status and treatment results in the needless duplication of laboratory tests, imaging studies and avoidable medical errors. In its September 2012 report, *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America,* the Institute of Medicine (IOM) recommended equipping patients with tools that deliver "reliable clinical knowledge" so that they are able to fully participate in their own care, stating:

> "Health providers should place a higher premium on fully involving patients in their own health care to the extent that patients choose. Clinicians should employ high-quality, reliable tools and skills for sharing decision making with patients, tailored to clinical needs, patient goals, social circumstances, and the degree of control that patients prefer . . . CMS and other payers should promote and measure patient-centered care through payments models, contracting policies, and public reporting programs. And digital technology developers and

[1] Federal Register, Volume 78, Number 45 (March 7, 2013), pages 14793–14797 http://www.gpo.gov/fdsys/pkg/FR-2013-03-07/html/2013-05266.htm

[2] Pham HH et al. 2009 Primary care physicians' link to other physicians through Medicare Patients Annals of Internal Medicine 150: 236–242 and Pham HH et al. 2007 *Care patterns in Medicare and their implication for pay for performance NEJM* 356: 1130–1139

[3] Federal Register, Volume 78, Number 45 (March 7, 2013), pages 14793–14797 http://www.gpo.gov/fdsys/pkg/FR-2013-03-07/html/2013-05266.htm

health product innovators should develop tools to assist individuals in managing their health and health care." [4]

My testimony today will demonstrate how Humetrix is using a federal initiative called "Blue Button" to realize the IOM's vision of consumer-centric care. By enabling patients to access to their own health information at the point of care with an easy-to-use mobile application, Humetrix's solution is free many of the challenges encountered by current provide-centric, system-to-system health information exchange initiatives. We believe that leveraging consumer-driven mobile technology at a large scale could transform health care by serving as a powerful care coordination tool and improving patient safety.

iBlueButton as a Case Study

The Federal Blue Button initiative was launched by President Obama in 2010. The idea was simple: given patients access to their own health information using an easy-to-identify symbol that could be adopted and used by any organization holding valuable patient date - a blue button. The initiative saw results quickly. Just three months after its launch at the Department of Veterans Affairs (VA), more than 60,000 veterans had already used it to download their personal health information. Today, more than 100 million Americans have access to Blue Button data through the VA, the Department of Defense (DoD), the Centers for Medicare & Medicaid Services (CMS), or a private health plan.

Humetrix recognized the transformative potential of Blue Button data early on and saw an opportunity to build on Federal initiatives by leveraging the extraordinary power of mobile devices, particularly smart phones and tablets. Current data shows that 61 percent of American mobile phone users, or 139 million individuals, have a smart phone.[5] Increases in smartphone usage for health care management have been seen in all demographic and ethnic groups, including the 55+ age bracket.[6]

As greater numbers of consumers become increasingly comfortable using their mobile devices to securely conduct sensitive transactions (e.g., online banking and other e-commerce transactions), health care will need to adapt to meet consumer expectations. Humetrix believes that the most efficient, cost-effective mechanism of health information exchange relies on mobile technology to ensure that patients and their providers are able to securely access their medical records whenever and wherever they need to. As such, we have created the iBlueButton iOS and Android apps to provide patients and caregivers with easy, reliable and secure access to their health record, as maintained by both private and public payers.

Humetrix began its development of the smart phone iBlueButton app series in Spring 2011; we have been continuously upgrading

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[4] Institute of Medicine, *Best Care at Lower Cost The Path to Continuously Learning Health Care in America* (September 6, 2012); Mark Smith et al., editors. National Academies Press.
[5] Available here: http://www.nielsen.com/us/en/newswire/2013/mobile-majority--u-s--smartphone-ownership-tops-60-.html
[6] Available here: http://www.pewinternet.org/Reports/2012/Mobile-Health.aspx

our apps since that time to provide ever increasing utility to our end users. In June 2012, Humetrix entered the Investing in Innovation (i2) "Blue Button Mash Up Challenge" sponsored by the U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC). The goal of this challenge was to inspire developers to create an easy-to-use, patient-friendly application that combined Blue Button personal health record data with other data sources designed to improve care, improve health and reduce costs.

After a rigorous peer-review process by a panel of patients, vendors, and developers, ONC announced that Humetrix was the winner of the i2 Blue Button Mash Up Challenge. Humetrix's iBlueButton application transforms the beneficiary-level claims data currently produced by CMS into a secure, user friendly, longitudinal health record that can be accessed on a mobile device and exchanged by patients and providers at the point of care.

Because CMS makes up to three years of claims information available to each of its beneficiaries, the Medicare Blue Button record is often unwieldy and of limited utility to a patient or their physician; for even simple cases, the record can easily reach dozens or even hundreds of pages in length for a single patient.

However, once a record has been generated, iBlueButton transforms the hard-to-understand list of coded claims in the Medicare Blue Button record into a patient friendly, 3-year longitudinal clinical record. This comprehensive health record can be viewed directly on a smart phone or tablet, and contains a patient's key health information such as problem and medication lists, as well as a detailed history of all the patient's health care encounters, including inpatient admissions, outpatient visits, imaging services, labs, and procedures. Medicare beneficiaries can review their information, annotate their records with additional details, and look up information about medications and potential adverse reactions or medical problems using MedlinePlus, an online reference resource maintained by the National Library of Medicine. Medical records are stored on the smart phone using state of the art encryption, and cannot be accessed by others in the event that the smart phone is lost or stolen.

In addition, the iBlueButton app also enables the patient, or their caregiver, to securely transfer the Blue Button record to a physician's tablet running the companion iBlueButton *Professional* app. Using the iBlueButton *Professional* app, the provider is able to view the patient's records, as well as any annotations made by the patient about their medications, potential side effects they may be experiencing, and their medical conditions.

The iBlueButton app is currently available to consumers directly from the iTunes or Google Play stores, providing millions of fee-for-service Medicare beneficiaries and/or their caregivers the ability to have mobile, secure, immediate access to critical medical information.

Realizing the Potential to Change the Face of Health Care.

Humetrix believes that existing mobile infrastructure and increasingly ubiquitous mobile consumer devices must be leveraged to provide patients and their caregivers access to essential health information at the point of care. Indeed, tremendous benefits could result from strategies that enable better exchange of health information in the health care system using the Blue Button record. Providers could use the record to identify previous misdiagnoses and medications prescribed in error, as well as other misinformation. They may also use the comprehensive information contained in the record to eliminate unnecessary tests and prevent adverse drug reactions, which result today when a new prescription interferes with an unknown existing medication. Patients may even use the Blue Button record to detect fraudulent or erroneous claims, and break down existing language or health literacy barriers.

The real-world impact of this technology was highlighted by Christine Bechtel, former Vice President at the National Partnership for Women & Families, during her March 20, 2013 testimony before the House Energy and Commerce Committee's Health Subcommittee. She relayed a story told by a woman who experienced the true value of Blue Button, and iBlueButton in particular, when caring for her father, a Medicare beneficiary:

> "The hospital had an old record showing he had a diagnosis that required him to take Coumadin, which is a blood thinner. And because I had the [Blue Button] data in my hands, I could show them that he was no longer on that medication, and that truly was instrumental in saving his life. Within hours of his discharge he fell and suffered severe head and arm lacerations that would have been life threatening had he been on Coumadin and would have resulted in a readmission within just five hours of discharge." [7]

To ensure that these benefits are realized on a large-scale by patients and caregivers across the country, policies and regulations should be structured to support continued innovation in mobile health technology. Many organizations, including the App Developers Alliance, have established principles and policy recommendations for the fair regulation of mobile medical apps. These principles may be informative as policymakers continue to consider how to support mobile access to health information as a key component of improving the safety and cost-effectiveness of health care.

Furthermore, additional work must be done to educate consumers and providers alike about the value of consumer-driven health information exchange using the Blue Button record. Although significant progress has been made in certain patient populations, including veterans, intensive outreach and education efforts are needed by Federal and private payers alike to ensure that their beneficiaries have access to and understand how to use technologies like iBlueButton. Likewise, large-scale provider outreach is needed to train providers on the value of using these technologies at the point of care and to provide them with the information needed to educate their patients on the use of mobile apps for management of their own health and health care.

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[7] Available here: http://www.nationalpartnership.org/site/News2?page=NewesArticle&id=38627

In closing, I would like to thank Chairman Collins, Ranking Member Hahn, and all of the members of the subcommittee for the invitation to testify today about this important topic. I look forward to answering your questions.

Mobile Medical App Entrepreneurs: Changing the Face of Health Care
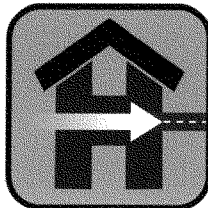
Testimony of:

Sabrina Casucci, MBA

PhD Candidate and Entrepreneur

Buffalo, New York

Before the

Committee on Small Business Subcommittee on Health and Technology

June 27, 2013

Chairman Collins and distinguished members of the Subcommittee, thank you for the invitation to participate in today's hearing. My name is Sabrina Casucci and I am a PhD Candidate in Industrial and Systems Engineering. As a PhD candidate my recent research has focused on modeling healthcare processes. As an entrepreneur, I seek to apply this theoretical learning to develop more effective healthcare delivery solutions. I am honored to represent a talented team of fellow graduate students from the University at Buffalo Department of Industrial and Systems Engineering.

Our team members are: Dapeng Cao, Theresa Guarrera, David LaVergne, Nicolette McGeorge, Judith Tiferes-Wang, and Yuan Zhou. Dr. Li Lin, a professor in the Department of Industrial and Systems Engineering at University at Buffalo, SUNY, is a valued mentor in on our ongoing development activities.

Our group of young entrepreneurs are translating our individual healthcare and technology related research into a mobile solution that will make hospital discharge planning a more effective and efficient process. Ultimately we seek to reduce readmission rates by facilitating communication among patients, their family, and clinicians, improving patient and family preparation for post hospital care and ensuring continuity of care with community based care providers.

I would like to briefly discuss the critical aspects of our work, including the fundamental problem of readmissions that we are trying to address, our mobile solution, and the difficulties that we will face on our development journey. The need for improved tools that fundamentally address the issues inherent in existing healthcare processes is great. Increased governmental and industrial support for start-up organizations and health care researchers like us is needed, as is increased federal support of interoperability standards that enable communication between different Information Technology systems.

The discharge planning process is a critical step in acute patient care. However, the inherent complexity of existing processes and the lack of a standardized approach often result in undesirable outcomes for the health care system and the patient. As a result, nearly 1 in 5 Medicare patients are readmitted to a hospital within 30 days of their initial discharge. This negatively effects individual patient health and places a huge financial burden on the US healthcare system. Potentially avoidable readmissions of Medicare patients are estimated to cost more than 17 billion dollars annually. Despite recent efforts to reduce readmission rates and costs of care, annual readmission rates have remained relatively constant.

The effects of poorly executed care transitions on the patient and their family is equally important as studies have shown that more than 40% of high risk elderly patients have experienced one or more problems post discharge, including readmissions. Further, patients and their families often feel frustrated, confused, or otherwise unable to manage their care.

Our solution connects personal mobile devices with Health Information Technology to improve patient outcomes and reduce

healthcare expenditures by redefining the patient discharge process. Our systemic approach provides personalized tools for patients, their family, and clinicians that enable informed decision making and improved continuity of care.

Solutions like ours can make a significant impact on healthcare in the US. Mobile solutions can connect fragmented care processes and improve continuity of care, both contributors to improved patient outcomes and reduced care costs.

The idea for the Discharge Roadmap app was developed, in part, due to my own personal experiences. In the past few years my mother has served as an informal caregiver for several elderly relatives, most of who are older than 90 years of age. She has had to manage her own career and health needs as well as the complex needs of this generation. When three relatives were recently and simultaneously hospitalized she spent countless hours on the phone and missed several days of work to ensure their post discharge care needs were met. Navigating three different discharge processes was an arduous task and it was clear that better solutions should be possible.

The opportunity to develop a tool that addresses these difficulties came in November of 2012 when GE Healthcare launched the Health Quest competition. Teams were challenged to develop new mobile healthcare apps that would improve the hospital experience for patients and their families. The competition presented the catalyst needed to develop Discharge Roadmap, which we believe will fundamentally redefine the discharge planning process.

As a start-up organization we know there is a long and difficult journey ahead of us. However, there are many groups of talented and dedicated researchers and entrepreneurs throughout the US working to develop solutions to these complex healthcare problems. The opportunity to (i) positively affect healthcare in the US, (ii) reduce readmission rates, (iii) lower healthcare costs, and (iv) alleviate the anxiety and burden of discharge planning for patients and their families, compel us to overcome these challenges.

In order for technology-enabled solutions, such as Discharge Roadmap, to succeed, the solutions must be able to communicate with existing hospital information systems. However, the current lack of a unified data structure and communication protocols severely limits this communication ability. Improving interoperability will ensure that healthcare providers can choose a solution that best fits the needs of their patients, and not just the needs of their current health information technology systems.

As a start-up organization we are in the early stages of developing our mobile solution and are eager to continue the process. We believe our app will alleviate the burdens imposed on patients, their families, and clinicians in this critical process. We seek to make a meaningful contribution to reducing readmission rates by providing patients, their families, and hospital based clinicians with a clear communication channel and by improving continuity of care with community based care providers.

June 25, 2013

Chairman Chris Collins
Subcommittee on Health and Technology
Committee on Small Business
2361 Rayburn House Office Building
Washington, DC 20515

Chairman Collins:

We appreciate the Committee's efforts to bring attention to the important field of medical apps. The Association for Competitive Technology (ACT) is an advocacy and education organization that represents mobile application developers, including medical application developers. We represent over 5,000 small and mid-size IT firms and advocate for public policies that help our members leverage their intellectual assets to raise capital, create jobs, and innovate. Our organization was founded in 1998 with the commitment to foster an environment that allows small technology companies to flourish. Our founders believed that the greatest innovation occurs in nimble companies like these and our board of directors has always been exclusively comprised of small business owners.

It is important for this Committee to address mobile health as so many of the companies creating mobile health apps are small businesses. According to a recent study by ACT, 78% of developers are small businesses and a vast majority of those are businesses with less than 10 employees. These small businesses are located in every state, from New York to California and everywhere in between.

Small business app developers add significantly to the American economy. According to a report commissioned by TechNet, the U.S. app industry contributes more than 466,000 jobs to the economy. This year, estimates put the global revenue of the app industry at $25 billion. As America is recovering from recession, app developers have a significantly lower unemployment rate and higher wages than the national average. App development is an area where small business is thriving.

Beyond contributing jobs and revenue to the economy, mobile health app developers provide health assistance to consumers in a way traditional medical services cannot. A physical therapist can build an app helping a patient across the country to rehabilitate from a specific injury. A doctor in a rural area could use mobile apps to keep in touch with patients scattered throughout a large geographic region. A consumer can use a mobile health app to track symptoms and be better informed when they go to their doctor.

Every month, more and more Americans are turning to their mobile devices and medical apps to make better health care decisions. With one in three Americans owning a tablet and

Association for Competitive Technology

WASHINGTON, DC | 1401 K Street NW | Suite 502   BRUSSELS | Square de Meeus, 35   www.ACTonline.org
Washington, DC 20005 | P +1.202.331.2130 | F +1.202.331.2139   B-1000 Brussels | Belgium | P +32.(0)2.513.0524   www.innovators-network.org
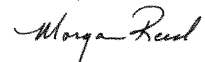
smartphones outselling feature phones, mobile devices are positioned to efficiently allow Americans to increase and improve doctor-patient communication, streamline the marketplace, and reduce medical costs through easy transfer of information. The field of m-health is starting to take off.

Understanding the risks involved in the medical profession, the industry already has mechanisms to ensure the quality of medical apps. For example, ACT member Happtique founded by the Greater New York Hospital Association created the Health App Certification Program to review and certify apps that physicians can prescribe. Happtique's efforts have helped improve users' confidence and trust and allow many to enjoy the benefits of mobile medical apps.

Mobile app developers are creating small business jobs, helping to improve the health of their consumers, and reducing the cost of health care through better communication and marketplace streamlining. In this important and growing area, we hope this Committee will ensure the protection of the small businesses that are responsible for innovation in medical mobile technology.

Thank you for addressing this important issue.

Sincerely,

Morgan Reed

Executive Director