SMART HEALTH: EMPOWERING THE FUTURE OF MOBILE APPS

HEARING

BEFORE THE

SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

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CONTENTS

March 2, 2016

SMART HEALTH: EMPOWERING THE FUTURE OF MOBILE APPS

WEDNESDAY, MARCH 2, 2016

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON RESEARCH AND TECHNOLOGY,
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY,
Washington, D.C.

The Subcommittee met, pursuant to call, at 10:07 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Barbara Comstock [Chairwoman of the Subcommittee] presiding.

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House of Representatives
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Smart Health: Empowering the Future of Mobile Apps

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

Witnesses

Mr. Morgan Reed, Executive Director, The App Association

Dr. Bryan F. Shaw, Assistant Professor, Department of Chemistry and Biochemistry, Baylor University

Mr. Howard Look, President, CEO and Founder, Tidepool

Dr. Gregory Krauss, Professor of Neurology, The Johns Hopkins Hospital

Mr. Jordan Epstein, CEO & Founder, Stroll Health

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

HEARING CHARTER

Smart Health: Empowering the Future of Mobile Apps

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

Purpose

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

Witness List

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

Background

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

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

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

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

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

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

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

Hurdles and Concerns

Regulatory Agencies

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

Reimbursement

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

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

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

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

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

[5] Ibid.

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

Security Concerns

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

Funding

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

Additional Reading

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

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

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

Chairwoman COMSTOCK. Good morning. The Committee on Science, Space, and Technology will come to order. Without objection, the Chair is authorized to declare recesses of the Committee at any time. Welcome to today's hearing, entitled "Smart Health: Empowering the Future of Mobile Apps". I now recognize myself for five minutes for an opening statement.

There's something we all have, not just us here in this country, but all around the world. The mobile penetration that is growing exponentially every day is very exciting, and it's very exciting when you think about how it's permeated all aspects of our life, but now has the opportunity to help so many aspects. And today we're here to talk about how it can help with health care.

There's an app for just about anything we want to do, from finding the nearest and cheapest gas station to depositing a check, and also, of course, with health care. The rapid growth of this game changing technology, and the data, and how we can amass that, is a reflection of the ingenuity of app designers, and the market of consumers ready, willing, and able to take advantage of what technology has to offer in order to be more personally involved in our own health care, and that of our families.

When it comes to our health, especially for the younger generation, you know, it might be easy to ignore different visits to the doctor, and we obviously want to make sure every does that, but we really want to put that power back in the hands of the consumers. And mobile apps are a really exciting way we can do that, particularly in the busy two-earner families, who run around with so many things going on, this is a great opportunity to really improve quality of life while making people's life easier to get that health care.

You know, it can be difficult to make an informed decision about your health, but with the abundance of health apps, and wearable technologies which cover a wide variety of diseases, and chronic diseases, we can now exercise more control by availing ourselves of that data. The data also benefits those who might suffer from an ailment or a chronic disease. Whether it's cancer, epilepsy, or diabetes, the more data we have about ourselves that we are personally aware of, and how we are going to share and amass that data. I was just at the Milken Public Health Summit that's being held in Washington today, and it was really exciting to see all aspects of health care, but the mobile technology, and what we are going to do there, and how we can amass data, and—for example, they talked about people who have cancer. They said 75 percent of them would be happy to share their information if it would allow them to access data, and get information, you know, for themselves, and for their doctors to see, you know, what they, you know, what they might have in common with other people in the same boat.

So this new revolution in technology can, and should, open up a new revolution, and all of us being very personally engaged and responsible for our own health care, but also more knowledgeable. You know, it's a great education tool, and we don't have to just go in and see the doctor now. We can be a full participant. It may be—sometimes doctors may not like that, but—we had a witness here earlier this year, talked about a book, which I still have to

read yet, which is called "The Patient Will See You Now", turning the whole world upside down, which I think is kind of exciting.

So our witnesses today are here to talk about technologies they have developed, or are developing, to help individuals take control of their own health care. Two of our witnesses, Dr. Bryan Shaw and Mr. Howard Look, have very personal reasons for their endeavors. Dr. Krauss and his colleagues have embarked on some important research using the Apple Watch and the Apple Research Kit, an open source software framework that may revolutionize medical studies. And Mr. Epstein's technology helps people make informed decisions about receiving care at reduced cost. This ability to save a few or many dollars is something we can all support, both on the personal individual level, and obviously at the aggregate level, with the federal government, with that being one of the fastest growing costs in our budget.

As with all new technologies, there are, of course, pros and cons. We'll be discussing them also today. But this kind of research and technology is really exciting, and we want to make sure we in Congress have the kind of policies and help to make sure you could leverage and do this in the best way possible, and have faster cures, as the Milken Institute was talking about today. Faster cures is what we all want. Prevention is obviously another area where mobile apps have a great opportunity.

[The prepared statement of Chairwoman Comstock follows:]

COMMITTEE ON
SCIENCE, SPACE, & TECHNOLOGY
Lamar Smith, Chairman

For Immediate Release
March 2, 2016

Media Contact: Zachary Kurz
(202) 225-6371

Statement of Research & Technology Subcommittee Chairwoman Barbara Comstock (R-Va.)
Smart Health: Empowering the Future of Mobile Apps

Chairwoman Comstock: Since the introduction of the smart phone, mobile applications – or apps - have permeated all aspects of our lives. While there is an app for just about anything we want to do – from finding the nearest and cheapest gas station to depositing a check – our focus today is on health apps. The rapid growth of this game-changing technology is a reflection of the ingenuity of app designers, and the market of consumers ready, willing and able to take advantage of what technology has to offer in order to be more personally involved in improving our healthcare.

When it comes to our health, especially for the younger generation, it can be easy to ignore it at times and make excuses to skip visits to the doctor for regular check-ups and physicals. Whether it's because of family or work obligations, too often we find it inconvenient to go to the physician's office.

It can be difficult to make an informed decision about your health and whether or not you should make that doctor's appointment. But with the abundance of health apps and wearable technologies which cover a wide variety of diseases, we can now exercise more control over our lives by availing ourselves of data that can aid our decision-making process regarding our health.

This data also benefits those who suffer from an ailment or a chronic disease. Whether it's cancer, epilepsy or diabetes, the more data we have about ourselves that we are personally aware of, the more likely we are to be able to receive precise and comprehensive care from our physicians.

This new revolution in technology can and should open up a new revolution in all of us being personally engaged and responsible about our healthcare. I'm excited we can now put more control of our healthcare into our own hands.

Our witnesses today are here to talk about technologies they have developed or are developing to help individuals take control of their own health. Two of our witnesses, Dr. Bryan Shaw and Mr. Howard Look have very personal reasons for their endeavors. Dr. Krauss and his colleagues have embarked on some important research using the Apple Watch and the Apple ResearchKit, an open source software framework that may revolutionize medical studies. And Mr. Epstein's technology helps people make

informed decisions about receiving care at reduced costs. This ability to save a few or many dollars is something we can all support.

As with all new technologies, there are of course pros and cons. Understanding what they are and how hurdles can be overcome is part of the process for change. I look forward to hearing about the challenges our witnesses have encountered and the challenges that have yet to be conquered in order for healthcare apps to become a prominent feature of the healthcare system. This is the kind of research and technology that will greatly benefit people, and it will be helpful to hear your thoughts on what role Congress or the federal government can play to help empower the future of mobile apps.

Thank you all for joining us today.

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Chairwoman COMSTOCK. So I now recognize the Ranking Member of the Research and Technology Subcommittee, the gentleman from Illinois, Mr. Lipinski, for his opening statement.

Mr. LIPINSKI. Thank you, Chairwoman Comstock, for holding this hearing, and to the witnesses for being here today. With well over 100,000 health-related apps available through the Google and Apple app stores, and hundreds of millions of downloads, mobile health apps are increasingly becoming part of our daily lives. The phrase there's an app for that is very applicable to the mobile health environment, and the number of apps is growing daily.

Most of us are familiar with, and may even use, one of the popular fitness apps to track our steps and help us with fitness goals. But some people rely on mobile health apps to monitor serious health conditions. The CDC reports that, as of 2012, over half of all adults had one or more chronic diseases. The treatment of chronic conditions accounts for 86 percent of the nation's health care costs. As people are taking a more active role in the management of their health, they're turning to electronic and digital medial platforms for help. Diabetics can find apps that track their blood sugar levels, cardiac patients can find apps to track their blood pressure, and people that suffer from depression can find apps to monitor their mood.

The great promise of these apps is that they have the potential to contribute to better health outcomes for their users. But whether this potential can be realized depends on the quality and reliability of the apps, and the information they contain. For mobile health apps not regulated by the FDA, there is much greater uncertainty. We don't want to stifle innovation, but there are major concerns that must be considered, including the potential for an app to lead to harm. Inaccurate readings, for example, could lead to a life threatening situation. We also need to consider how to address ownership of data, given that information flows between patients and their app providers. Some of these regulatory questions fall outside our Committee's jurisdiction. However, there are parts of this discussion that do fall within our purview, and, in fact, they're very common themes before this Committee, including human factors research, privacy, and cybersecurity.

The goal for users of many mobile health apps is to live a healthier life. They may be looking to increase their fitness, to eat healthier, or to quit smoking. Some users, as I have discussed previously, are using apps to monitor and respond to potentially serious chronic health conditions. In all of these cases, there is an implicit assumption that the app will influence behavior in a predictable way, and in some cases assist users in long term behavioral changes. But, as an engineer, I know that we—if we do not incorporate human factors into the design and evaluation of these apps, they may not function as intended, or may even cause harm. This is a very important area of research, one where the National Science Foundation has a role, possibly in collaboration with the NIH.

In addition, privacy, and the security of a user's personal information, must be a part of today's conversation. Many mobile health app users trust the information within the app is secure. However, a recent study by a research team at the University of Illinois at

Urbana-Champagne found that many free apps use ad libraries as revenue sources, which many expose users' data to these ad libraries. This is clearly a privacy issue, but it could also be a security issue if the app requires a user to enter personally identifying information and/or sensitive health data. Furthermore, in the case of high quality apps that health care providers incorporate into their patient care, we may also want to give the physicians and nurses access to data being recorded by the apps. This brings up more questions about how to keep the data secure.

We all share the goals of promoting better health care outcomes and reducing health care costs. Mobile health apps have the potential to contribute to these ends, and so it's very important that we continue down this road. As these apps are being developed, we—make sure we are looking at these apps, and make sure that, in the end, we are doing—at least not doing harm, and hopefully we can do a lot of good for people. So there are many important questions that need to be addressed as this technology continues to grow. I look forward to a good discussion with our witnesses, and I yield back the balance of my time.

[The prepared statement of Mr. Lipinski follows:]

OPENING STATEMENT
Ranking Member Daniel Lipinski (D-IL)

House Committee on Science, Space, and Technology
Research and Technology Subcommittee
"Smart Health: Empowering the Future of Mobile Apps"
March 2, 2016

Thank you Chairwoman Comstock for holding this hearing and to the witnesses for being here today. With well over 100,000 health-related apps available through the Google and Apple app stores, and hundreds of millions of downloads, mobile health apps are increasingly becoming part of our daily lives. The phrase, "there's an app for that," is very applicable to the mobile health environment and the number of apps is growing daily.

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We all share the goals of promoting better healthcare outcomes and reducing healthcare costs. Mobile health apps have the potential to contribute to these ends. Nonetheless, there are many important questions that need to be addressed as this technology continues to grow. I look forward to a good discussion with our witnesses. Thank you, and I yield back the balance of my time.

Chairwoman COMSTOCK. Thank you. And I'll now recognize our witnesses. Our first witness today is Mr. Morgan Reed, Executive Director of The App Association. Mr. Reed specializes in issues involving application development relating to privacy, intellectual property, competition, and small business innovation. His expertise and knowledge has been sought by the House and Senate in multiple hearings, and his commentary and insight is a—has been featured on news networks. Mr. Reed received his undergraduate degree in Political Science and Chinese from Arizona State University, and a graduate degree in Chinese from the University of Utah. I am pleased to welcome you here today.

Dr. Bryan Shaw is our second witness, and he is an Assistant Professor in the Department of Chemistry and Biochemistry at Baylor University in Waco, Texas. Dr. Shaw received his undergraduate degree in Biochemistry and Biophysics at Washington State University, and his Ph.D. in Inorganic Chemistry from the University of California, Los Angeles. In 2008 Dr. Shaw's son Noah was diagnosed with bilateral retinoblastoma. While his doctors initially missed his eye cancer, Noah's mother, Elizabeth, observed a white reflection in his eyes in pictures she took, which ultimately helped lead to his diagnosis. Noah is the inspiration behind the Cradle app created by Dr. Shaw and his colleagues at Baylor University, and I'd like to welcome both Dr. Shaw and his son Noah, who's in the audience with us today. And I understand your—I did get to meet your wife, and your other—your younger son also, so it's delightful to have you with us here today.

Our third witness is Mr. Howard Look, President, CEO, and Founder of Tidepool, a Silicon Valley non-profit startup that has developed apps to help people reduce the burden of managing Type1 diabetes. Prior to Tidepool, Mr. Look held technology leadership positions at Amazon, Pixar Animation Studios—might come in handy with the kids here today, right—and as a founding team member at TiVo. In 2015, Mr. Look, who holds a Bachelor of Science degree in Computer Engineering from Carnegie Mellon University, received the White House Champions of Change Award for Precision Medicine on behalf of Tidepool's work. And just last month Mr. Look shared the stage with President Obama during a panel discussion at the Precision Medicine Initiative Summit. Mr. Look's motivation behind Tidepool comes from his daughter, Katie, who was diagnosed with Type1 diabetes five years ago, and I am pleased to welcome him here today.

Our fourth witness is Dr. Gregory Krauss, a Professor of Neurology at The John Hopkins Medical Center in Baltimore. Dr. Krauss is a native of southern Oregon, and received undergraduate training at Harvard College, medical school training at Oregon Health Sciences University, and neurology residency and epilepsy fellowship training at Johns Hopkins. Dr. Krauss is the co-inventor of the EpiWatch app, along with his colleague, Dr. Nathan Crone, who is also a Professor of Neurology at Johns Hopkins. EpiWatch research uses a novel data management program integrated with the Apple Watch and iPhone operating systems called Research Kit. It is the first research app to use the Apple Watch. We welcome you, Dr. Krauss.

Mr. Jordan Epstein is our fifth witness, and he's founder and CEO of Stroll Health, which makes software applications that help doctors and their patients find and follow through with lower cost, best value health care. Prior to Stroll Health, Mr. Epstein worked on a client services team of Merced Systems, sorry, a business intelligence startup. After their acquisition by NICE Systems, he led development of the small and medium-sized business performance management product line, which today is used by hundreds of thousands of people on five continents. Mr. Epstein's clients have included Fortune 500 companies, such as United Healthcare, Kaiser, Delta Airlines, and Chase. Mr. Epstein holds a B.A. from Carlton College, and I am pleased to welcome him, and all of you, here today.

So I now recognized Mr. Reed for five minutes to present his testimony.

TESTIMONY OF MR. MORGAN REED,
EXECUTIVE DIRECTOR, THE APP ASSOCIATION

Mr. REED. Thank you. Subcommittee Chair Comstock, Ranking Member Lipinski, and distinguished Members of the Committee, my name is Morgan Reed, and I am the Executive Director of The App Association. I thank you for holding this important hearing on empowering the future of mobile health apps. The App Association represents more than 5,000 companies and technology firms around the globe, making the software that runs the devices that you wear, and the apps that you love. We are currently spearheading an effort, through our connected health initiative, to clarify outdated health regulations, incentivize the use of remote patient monitoring, and ensure the environment is one in which patients and consumers can see improvement in their health. This coalition of leading mobile health companies and key stakeholders needs Congress, HHS, and NIST to encourage mobile health innovation and support policies that keep sensitive health data private and secure.

Now, traditionally this is the moment in my oral testimony where I would recite some interesting numbers about the industry, talk about jobs created and niches filled, but I'd like to break from tradition and instead tell you a story, one that is likely to be relevant to all of you, and is certainly relevant to a huge chunk of your constituents. Nearly everyone in this room is either caring for aging parents, or knows someone who is. Now, imagine your parents are fortunate and living at their own home, but significant medical challenges are beginning to face them. The questions begin, do I get a home health attendant? Do I pay as much as 12,000 a month to move them to an assisted living facility? Do they move into my basement? And how do I deal with the fact that my parents don't want to move into my basement? And a home nurse feels infantilizing. What do I do to help them stay at home and live with dignity?

Well, most of you remember Life Alert. You know, the product with that tag line, help, I've fallen, and I can't get up. That kind of device is commonly known as a personal emergency response system, or PERS. They're great devices, but incredibly limited in what they can do. Now, imagine a far more sophisticated PERS,

packed with sensors that can track blood sugar, blood pressure, heart rate, biomarkers for medication adherence, geo-fencing for Alzheimer's patients, and much more. Sensors small enough to fit into a watch, one that connects to the loved one's phone, an alert device, alert service, a physician's tablet, and a medical record. Suddenly, mom can stay at home, maybe another year, two, or three, all while managing her health. And if mom allows the data to be sent to you, you can be part of the solution, staying in touch, and on top of her needs. And, not insignificantly, your basement can keep its big screen TV.

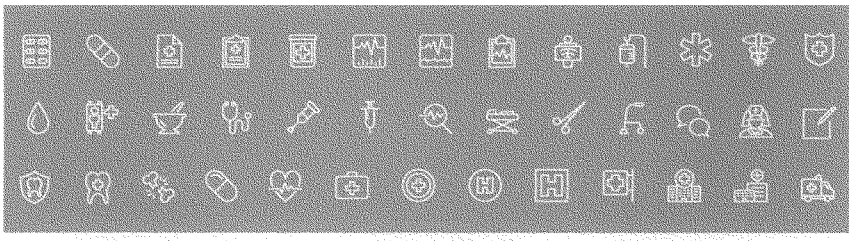
By 2050 there will be 83.7 million Americans over the age of 65, twice the number from 2012. 80 percent will have at least one chronic condition. Without question, this age group's rapid growth will severely strain public and private health resources. Therefore, the picture I painted for you is not a pipe dream, but rather imperative to prevent a cataclysmic economic outcome for this boom in aging adults. Moreover, we're already seeing near real time technology making a difference today. One example that we didn't mention was Airstrip as a model of the potential for connected health care. Its apps and connectivity services allow physicians to remotely view live patient data. Emergency medical staff are able to send live waveform data from an ambulance to the emergency room so that a trauma center or cath lab can be readied by the time the patient arrives. The minutes, or even seconds, that are saved by this technology can make a critical difference in a patient's life.

So what's standing in the way of this dream? What is needed to ensure everyone can benefit from these new innovations? Well, I have three messages for Congress. One, questions about privacy, security, and government regulation have met to create an environment where companies are worried about making devices more medically relevant. And physicians worry about the impact on their practice. The slow process by which HIPAA has been updated continues to delay uptake, and impede investment in innovation.

Two, patients and care providers must know that their information is private and security. Industry best practices around the treatment of sensitive health data, as well as a commitment from government to support these practices, are important to establish trust, and push the industry forward. Moreover, clarifications on government access to data matter, and Congress should be pushing back on any government pressure to weaken encryption, and harm the protections that NIST are trying to establish.

Finally, ensuring that doctors are reimbursed for the use of these technologies will be essential. Currently CMS is statutorily prevented from reimbursing for certain kinds of remote patient monitoring based on some absurd geographic restrictions and antiquated technological requirements that were state of the art 15 years ago, but haven't moved since. Success will come when the technology, trust, and means to pay for it all come together. I ask that Congress help ensure that that happens now, rather than see one more of our family members move out of the home they love because we failed to act. I look forward to your questions.

[The prepared statement of Mr. Reed follows:]



ACT | The App Association

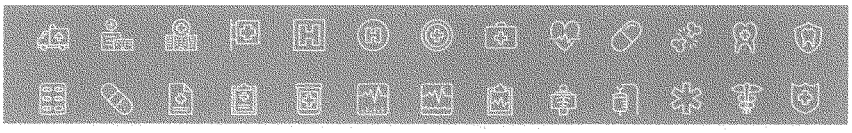
Testimony

of
Morgan Reed
Executive Director
ACT | The App Association

on
Smart Health: Empowering the Future of Mobile Apps

before the
House Committee on Science, Space, & Technology, Subcommittee on Research and Technology

March 2, 2016
2141 Rayburn House Office Building



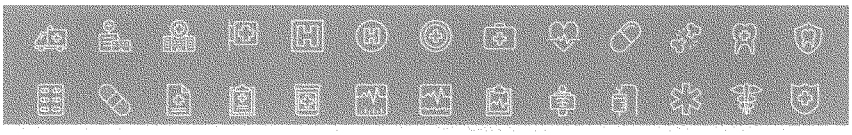
Subcommittee Chair Comstock, Ranking Member Lipinski, and distinguished members of the Committee: My name is Morgan Reed and I am the executive director of ACT | The App Association. I thank you for holding this important hearing on "smart health" and empowering the future of mobile apps.

ACT | The App Association represents more than 5,000 app companies and technology firms around the globe. As the world has quickly embraced mobile technology, our members have been creating innovative solutions to improve workplace productivity, accelerate academic achievement, and help people lead healthier lifestyles.

Additionally, we are spearheading an effort through our Connected Health Initiative to clarify outdated health regulations, incentivize the use of remote patient monitoring, and ensure the environment is one in which patients and consumers can see improvement in their health.[1] This coalition of leading mobile health companies and key stakeholders works to ensure Congress, the Food and Drug Administration (FDA), and Department of Health and Human Services (HHS) adopt policies that encourage mobile health innovation and keep sensitive health data private and secure.

In my testimony today, I elaborate on the following key messages:

- Mobile health apps offer potential to positively transform the American healthcare system. Without improvements to interoperability and reimbursement for using technologies like remote patient monitoring, we risk increased costs, and harm to patients.
- To reach the potential mobile health apps hold, clarity in legal and regulatory responsibility is needed. In particular, guidance regarding Health Insurance Portability and Accountability Act privacy and security rules in the context of cloud computing must be updated.
- While well-intentioned, law enforcement efforts to get access to data on devices and in the cloud pose major risks to data security and to businesses trying to manage data. Complying with both law enforcement and NIST security and data requirements, including recommendations on encryption, create a Hobson's choice for our industry.

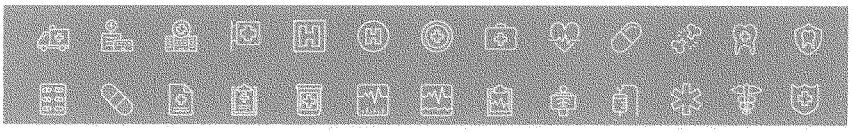


The Potential of Mobile Apps and Health

In existence less than a decade, the app industry has experienced explosive growth alongside the rise of smartphones. As the most rapidly adopted technology in human history, these devices revolutionized the software industry. I urge you to review our recently-released ***State of the App Economy,***[1] which provides further information and statistics on this innovative industry that continues to grow while creating jobs and revolutionizing how consumers work, play, and manage their health. I'd also like to note that small companies and startups have thrived in the mobile marketplace. They currently represent 82% of the top app makers, dominate the revenue rankings, and drive innovation in the mobile economy.

Connected technology has the potential to radically improve the American healthcare system. As Americans have rapidly adopted mobile technology, our member companies have been producing and investing in innovative products and solutions across modalities and segments of the economy, with no stronger an example than healthcare. With 60% of the population already using mobile apps to help track their conditions and make informed choices about their health,[2] mobile-app enabled telehealth and remote monitoring of patient-generated health data (PGHD) continues to represent the most promising avenue for improving care quality while lowering costs. Examples from ACT | The App Association's membership include:

- Atlanta-based Rimidi[3] is a company showing the path forward with its Diabetes+Me app, which has demonstrated better patient outcomes at reduced cost.[5] Goldman Sachs projects that connected health solutions like Rimidi's will reduce healthcare costs by $305 billion.[6] Rimidi uses both the "bring your own device" (BYOD) model as well as connected glucometers to better understand and improve the treatment of diabetes. Physicians are using the Rimidi platform to monitor their patients' glucose levels, as well as to help their patients determine the correct balance of insulin more efficiently.
- AirStrip[4][7] technology is a critical tool to keeping doctors informed on patient vitals while they're still in the ambulance. The company's products use Department of Defense-level encryption that allows doctors to remotely view live patient waveform data from multiple devices and systems on a single mobile screen securely, in advance of the patient entering a hospital room.



- CareSync[8] provides a software platform that digitally connects doctors, patients, and caregivers, reducing the paper chase burden for MDs and delivering better care to happier patients, including chronic care management for Medicare.

Even the indirect benefits of connected health are astonishing. For example, Apple's ResearchKit connects medical researchers with volunteers who want to share health data for scientific study. The platform provides no direct revenues for Apple, but it is revolutionizing how studies are conducted and accelerating the progress of medical research. In just 24 hours after its introduction, 11,000 iPhone users signed up for a Stanford cardiology study. Before ResearchKit, that level of engagement would have required 50 medical centers to each spend an entire year finding volunteers. I will note for the Committee that we recently provided written input to the FDA expanding on the benefits of our members' innovative technologies in the clinical trial setting, which we urge you to review.[9]

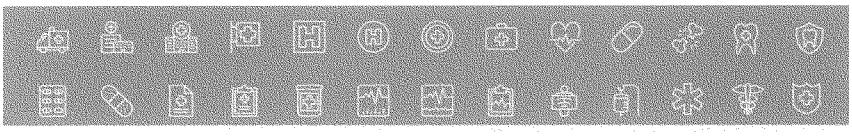
Clearly, we have only seen the beginning of what connected health can bring our country, but we know there is incredible promise. However, there is also incredible need for these innovations that will only increase over time.

By 2050, there will be 83.7 million Americans over age 65–twice the amount from 2012. Eighty percent will have at least one chronic condition.

For example, consider the aging population of the United States. By 2050, there will be 83.7 million Americans over age 65—twice the amount from 2012.[10] Eighty percent will have at least one chronic condition.[11] With a large portion living in rural areas or far from loved ones who could offer support, the age group's rapid growth will severely strain public and private health resources.[12]

Advanced personal emergency response systems (PERS) are an example of the technology that can empower older populations and help them live comfortably in their homes years longer than today's norm. Today, a PERS is typically a single button worn around the neck that directly connects to emergency services when pushed—made famous by the line "Help! I've fallen and I can't get up!"

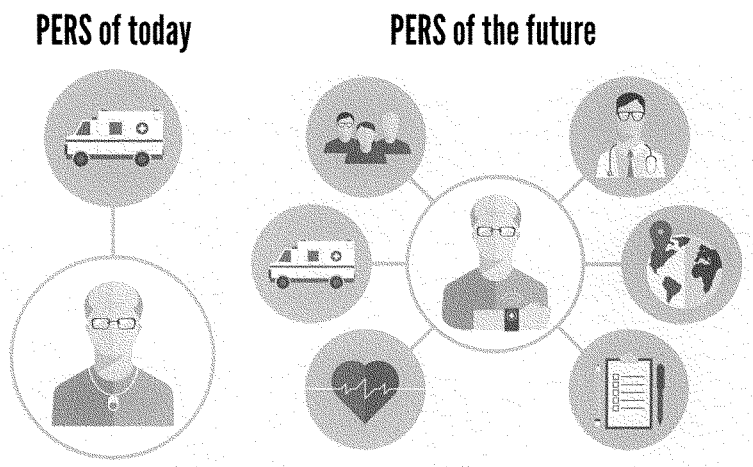
A far more sophisticated PERS will be packed with sensors and enabled by mobile apps that can track blood sugar, blood pressure, heart rate, biomarkers for medication adherence, geofencing for Alzheimer's patients, and much more. These sensors will be small enough to fit in a watch and will connect to a loved one's phone, a physician's tablet, and a medical record system.



Non-wearables empowered by mobile health apps will matter as well, and there are some products already helping our rapidly aging population. For example, the Beddit is a mattress strap that monitors heart rate and sleep patterns.[13]

Even more sophisticated technology, such as the Microsoft Kinect, allows users to interact naturally with computing technology.[14] This innovative solution can be used by physical therapists to allow patients to do therapy at home after a knee replacement, while still accurately measuring flex and strength.

This increasingly connected approach to healthcare will lower costs,[15] empower aging populations to live at home longer, and allow physicians and loved ones to help with care in an efficient way. Individuals and their care teams will also have a more complete view of health information, allowing for earlier detection of issues.



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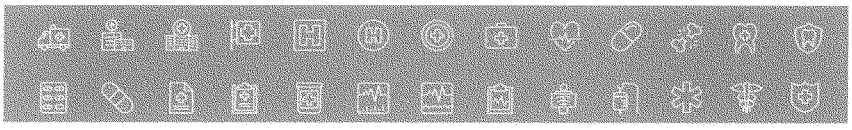


Legal Uncertainty Threatens Health Data Privacy and Security

To reach the potential mobile health apps hold, transparency in legal and regulatory responsibilities is a necessity. Increased predictability and clarity in the expectations and obligations for any organization are directly correlated to increased investment and innovation. Today, there is much room for improvement across a number of important contexts. Namely, mobile health app developers face sustained uncertainty around data storage and the cloud.

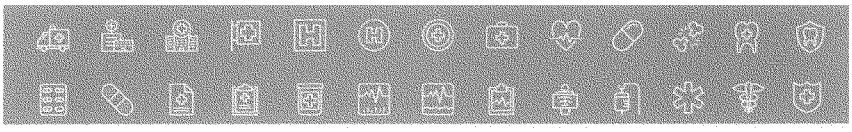
Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules

The Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules provide a set of minimum standards for protecting all electronic Protected Health Information that a Covered Entity and Business Associate create, receive, maintain, or transmit.[16] The concerns addressed by these laws are taken seriously by mobile health app developers, and our members work to meet the letter and spirit of the law.

However, relevant HIPAA privacy and security rules and guidance applicable to mobile apps have not been updated since before the introduction of the iPhone, and the persistent lack of clarity around HIPAA applicability in a mobile environment prevents many patients from benefiting from these services. As a result, many physicians are reluctant to receive health readings from their patients electronically, and hospital systems are discouraged from adopting patient-centered technologies. To date, clear guidance does not exist to explain whether physicians and patients can text or email each other.

To address this need we worked with Members of Congress to attain an explicit, public commitment from HHS Secretary Burwell to work with ACT | The App Association in 2014,[17] specifically to:

- Provide up-to-date and clear information about what is expected of technology companies for compliance with the HIPAA rules, and identify the implementation standards that can help technology companies conform to the regulations;
- Provide more clarity on HIPAA obligations for companies and services that store data in the cloud; and
- Engage regularly with technology companies to provide compliance assistance.



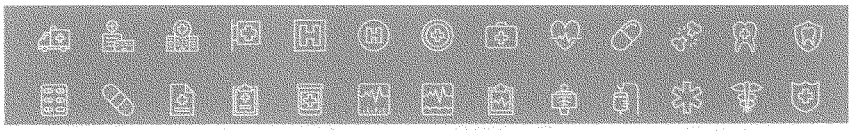
We welcomed these commitments in 2014, but have seen little evidence of meaningful follow through. Up-to-date and clear information about obligations under HIPAA is critical. While HHS has recently issued guidance with specific scenarios which may be helpful in a narrow range of circumstances,[15] more guidance and documentation is needed.

Threats to Encryption in Protecting Health Data and Patient Privacy

No data is more personal to Americans than their own health data. ACT | The App Association members appreciate this, and put extensive resources into ensuring the security and privacy of sensitive health data to earn the trust of consumers, hospital systems, and providers. Fully leveraging technical measures, including end-to-end encryption (defined as a set of mathematically expressed rules for rendering data unintelligible by executing a series of conversions controlled by a key), is a critical element to accomplishing this. For example, the use of encryption is critical to meeting obligations under the above-noted HIPAA security and privacy rules.

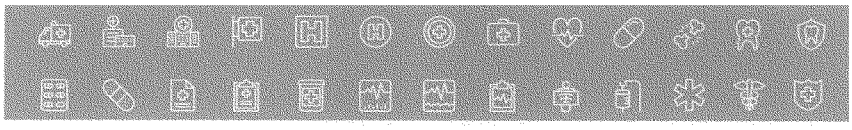
More broadly, encryption enables key segments of the economy, from banking to national security, by protecting access to, and the integrity, of data. Since October of 2009, when the HITECH Act's enactment started requiring reporting of breaches, 1,473 health data breaches have occurred (a qualifying breach impacted 500 or more people); in 2015 alone there were 253 healthcare breaches representing a collective compromising of over 112 million electronic health records.[16] Encryption's role should not be understated – without encryption, entire economies and industries are put at a significantly heightened risk of their data being compromised.

The National Institute for Standards and Technology (NIST) itself currently plays an important role in promoting the use of encryption. NIST's Computer Security Resource Center (CSRC) facilitates broad sharing of information security tools and practices, provides a resource for information security standards and guidelines, and identifies key security web resources to support users in industry, government, and academia.[17] NIST also provides the Cryptographic Module Validation Program (CMVP) that validates cryptographic modules to Federal Information Processing Standards (FIPS) 140-1 Security Requirements for Cryptographic Modules, and other FIPS cryptography-based standards.[18] Further, NIST SP 800-66, An Introductory Resource Guide for Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule, lists HIPAA-related storage security needs, and describes the need to encrypt and decrypt electronic protected health information.[19]



Despite the important role encryption plays, some interests persist in demanding that "back doors" be built into encryption for the purposes of lawful access. We reject such proposals as mandates that degrade the safety and security of patient information, and the trust of patients. Worse still, these "back doors" could create vulnerabilities that are guaranteed to be exploited by state-backed hackers and criminals, furthering the kinds of "ransom-ware" situations, such as that faced by Hollywood Presbyterian Medical Center we all recently learned about.[11] Finally, these proposals also threaten the work of NIST's CSRC to improve data security generally, and specifically in the health context.

In a recent court action against Apple, the Department of Justice has, using the All Writs Act as justification, taken steps to establish an unparalleled precedent that would allow it to compel software modification, forcing any company to re-engineer its code to provide government access, undermining the trust of its customers.[12] Due to the ubiquity of software in our lives, these mobile health apps which rely on strong encryption are directly impacted by such a policy. We are deeply concerned that the government's request charts a dangerous path that would have a grave impact on app makers, and a chilling effect on innovation. We urge NIST to take all steps necessary to protect the role of encryption.



Empowering Mobile Health Apps Requires Interoperability

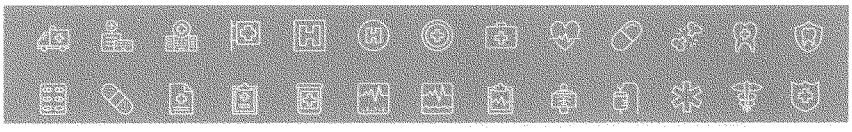
Coupled with electronic health record (EHR) data stored in standardized formats with interoperability facilitated by such means as application programming interfaces (APIs),[35] mobile health apps provide the capability for analytic, as well as near real-time, alerting. The use of APIs to design solutions and platforms for data streams from multiple and diverse platforms and sources (including PGHD) will directly contribute to areas of needed improvement in the healthcare sector, including information silos, data blocking, and deficient patient engagement in care.

The utilization of open and consensus-driven and voluntary standards is a long-standing federal policy that promotes effective and efficient technology and innovation in the global marketplace.[36] Open standards are a cornerstone to interoperability, and will promote innovation in the eHealth marketplace.

To encourage a more widespread adoption of interoperable health information technology, the American Recovery and Reinvestment Act of 2009 calls for the Office of the National Coordinator (ONC) for Health IT, in consultation with NIST, to recognize a program for the voluntary certification of health information technology as being in compliance with applicable certification criteria to meet defined meaningful use requirements.[37]

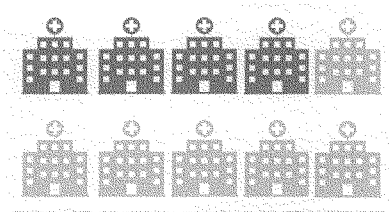
In collaboration with ONC, NIST has developed the functional and conformance testing requirements, test cases, and test tools to support this health IT certification program. While CMS Acting Administrator Andy Slavitt has indicated that the Meaningful Use program's days are numbered[38] and that CMS will not tolerate data blocking or business models that prevent or inhibit the data from flowing around the needs of the patient, NIST should build on its work on standards for health IT interoperability communication moving forward.

Further, technology, standards, and products are available today to facilitate the data exchange of patient data to a clinical EHR, including health reporting network interfaces that establish standards for exchange of patient summaries between remote monitoring systems and certified EHR technologies. NIST houses important efforts to promote standard-based medical device interoperability and communication.



Private-public partnerships have created valuable standards, including: the Continua Alliance's Design Guidelines,[32] Health Level 7 (HL7),[33] ISO 12052 (Health informatics -- Digital imaging and communication in medicine including workflow and data management),[34] and the integrating the Healthcare Enterprise (IHE) initiative,[35] among others.

The use of open APIs and standards for interoperability between providers as well as between remote patient monitoring devices and EHRs—all enabled by apps—is critical to improving patient outcomes. According to research from ONC, forty-one percent of hospitals nationwide routinely have necessary clinical information electronically available from outside providers or sources when treating a patient.[36]

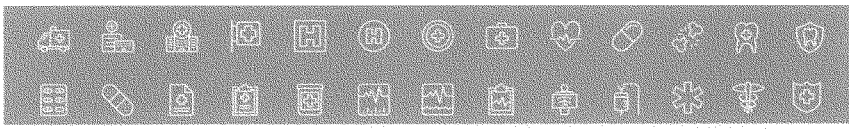


Only 4 out of 10 hospitals routinely use electronically available clinical information from outside providers when treating a patient.

Source: ONC/American Hospital Association (AHA), AHA Annual Survey Information Technology Supplement

It would also enable systemic engagement between patients, health care providers, and other stakeholders. Such voluntary industry standards along with consensus on specifications for interoperability between remote monitoring systems and EHRs already exist, continue to be developed and refined, and are currently available for use in systems and products.

For these reasons, we urge this Committee to work to enable interoperability in healthcare, and supports NIST's role in ensuring the interoperability needed to empower mobile health apps.



Reimbursement's Role in Empowering Mobile Health Apps

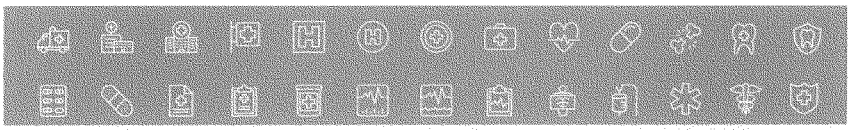
Healthcare providers must now shift from fee-for-service to value-based payments, and the resulting incentives favor outcomes more than procedures. This transition significantly elevates the value of connected health data that comes from remote patient monitoring, chronic condition management, wearable sensors, and apps.

Mobile health apps provide great opportunity to advance patient care, lessen hospitalizations, and boost patient involvement and investment in their own treatment. For example, a connected glucometer that periodically sends biometric data to a monitoring physician's office allows for ease in care management and could also easily prevent an emergency room visit by detecting shock onset early.

Despite the demonstrated value these technologies hold for improving the American health system, statutory and regulatory constraints on Medicare reimbursement for health care professionals' use of telehealth and remote patient monitoring technologies have long been a deterrent to advancement and adoption. Notably, Section 1834(m) of the Social Security Act has resulted in significant restrictions on telehealth services by adding odd and untenable requirements like "originating site" and "geographic" restrictions.[34] In addition, remote patient monitoring is unreasonably restrained by the Center for Medicare and Medicaid Services' (CMS) policy decision to not provide direct coverage for payment purposes.

As a result, Medicare coverage for telehealth is startlingly deficient,[35] while reimbursement for remote patient monitoring is non-existent and denies reasonable reimbursement for the monitoring of patient generated health data that should be leveraged to improve care outcomes.[36]

Despite a lack of support within subsidized medicine, the body of evidence demonstrating the potential benefits of remote monitoring of PGHD continues to grow, showing improved care, reduced hospitalizations, avoidance of complications and improved satisfaction, and greater patient involvement in care, particularly for the chronically ill.[37]



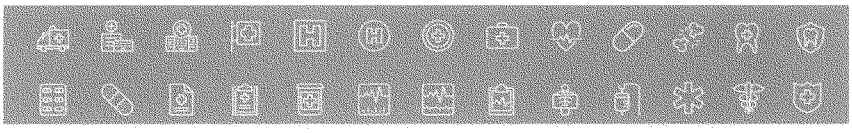
For example, the use of virtual chronic care management by the Department of Veterans Affairs resulted in a substantial decrease in hospital and emergency room use.[38] There is also a growing body of potential cost savings: by the end of 2016, mobile health solutions could represent up to $340 billion in annual healthcare cost savings worldwide.[39]

By the end of 2016, mobile health solutions could represent up to $340 billion in annual healthcare cost savings worldwide.

While ACT | The App Association has continued to urge CMS to incorporate telehealth and remote patient monitoring solutions under the existing fee-for-service reimbursement system to the greatest extent possible, great opportunity exists in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA),[40] including the use of the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs). MACRA will move Medicare from a quantity-based reimbursement payment model to one that is quality based. We are deeply engaged with CMS as it plans for MACRA's 2019 effective date, and welcomes the opportunity to work with Congress on these issues.

It is for these reasons that we are a leading supporter of the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act,[41] a careful and balanced approach that would lift Medicare's arduous limitations on the use of telehealth, enable the use of remote patient monitoring technology for patients with chronic conditions, safeguard that new payment models will incorporate connected health technologies, ensure that these advanced solutions are a part of the Medicare Advantage program, and address discrete issues associated with the treatment of Americans who suffer strokes and who require dialysis treatment.

I should note for you that we are not addressing these reimbursement issues in a vacuum. Today, ACT | The App Association leads a diverse—and growing—coalition of more than 90 companies and associations that reside across the medical and technology communities which convenes on a regular basis to discuss the convergence of the healthcare industry, ways in which stakeholders can work together, and which advocates for these policies based on detailed consensus views.[42]

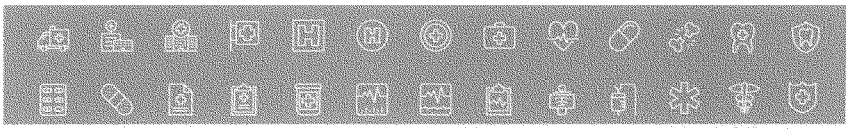


Federal Agency Coordination is Key to Enabling Mobile Health Apps

To realize the full potential of a mobile health app-enabled "continuum of care," the coordination of key federal agencies is essential, and I commend you for addressing this important topic in today's hearing. NIST, the Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC), HHS Center for Medicare and Medicaid Services (CMS), HHS Office of Civil Rights (OCR), and the Food and Drug Administration (FDA) all play key roles in empowering the future of mobile apps, and Congress' continued focus is and will be needed to ensure that federal agency coordination remains top of mind.

In ACT | The App Association's experience, agencies impacting mobile apps in the health space have some room for improvement in their coordination activities. As just two examples:

- Section 618 of the Food and Drug Administration Safety and Innovation Act (FDASIA)[13] requires that the FDA, in consultation with ONC and the Federal Communications Commission (FCC), develop a proposed strategy and recommendations on a risk-based health information technology (IT) regulatory framework. While this proposed strategy was released in draft form in April 2014[14] and a later public forum was held in May of 2014,[15] it has not been finalized to date, and we have seen little meaningful coordination amongst FCC-FDA-ONC resulting from it..
- While CMS has commenced regulatory activity towards the 2019 implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)[16] which Congress has explicitly stated is to embrace remote patient monitoring of PGHD in evolving Medicare, ONC has separately announced that it will develop a policy framework for identifying best practices, gaps, and opportunities for the use of PGHD in research and care delivery through 2024.[17] Both of these significant activities—which ACT | The App Association is supportive of and invested in—are overlapping yet not in coordination.



Agency coordination will not only help avoid duplicative or conflicting regulations and parallel efforts, but will help agencies ensure that inquiries into opportunities are informed. NIST occupies a unique role in the federal government as a coordinator of other agencies. For example, in addition to statutory roles related to electronic health records,[28] standards coordination,[29] and information security standards and guidelines for federal agencies,[30] NIST leads the development of the NIST Cybersecurity Framework[31] and the National Strategy for Trusted Identities in Cyberspace (NSTIC).[32]

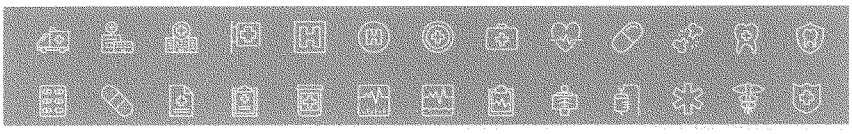
We are committed to working with this Committee, NIST, and other federal entities to explore new ways improve coordination and improve governance structure towards empowering mobile health apps.

Conclusion

Mobile health apps offer incredible benefits to the American healthcare system, but they will not reach full potential without a careful and coordinated effort between Congress, Federal agencies, and private stakeholders. As discussed above, without meaningful action to address important issues such as interoperability and reimbursement for using technologies like remote patient monitoring, we place countless patients' quality of care in jeopardy.

It is also important that clarity in legal and regulatory responsibilities be provided. Specifically, guidance regarding HIPAA privacy and security rules in the context of cloud computing must be updated, and the ability to use strong encryption should be protected. Finally, efforts to ensure close Federal agency coordination should be prioritized.

I thank you again for the opportunity to present testimony about the extraordinary mobile health app ecosystem. I look forward to our continued work together and pledge our support to help advance measures that empower mobile health apps.



End Notes

1 "Connected Health Initiative." Available at: http://connectedhi.com.

2 http://actonline.org/2016/01/04/act-the-app-association-releases-latest-app-industry-report/

3 Get Mobile, Get Healthy: The Appification of Health & Fitness Report, Mobiquity (2014). available at http://www.mobiquityinc.com/mobiquity-white-papers?ref=mHealth-report-2014.

4 http://www.rimidi.com/.

5 Lindsey Valenzuela, Lucienne Ide, Michael Jardula, Mena Salib, Jade Le. "Early Results Support Efficacy and Clinical Efficiency of Diabetes Management Decision Support Software for Blood Glucose." Annual Diabetes Technology Meeting, San Diego, CA, October 2015.

6 Roman, D. H. & Conlee, K. D., "The Digital Revolution comes to US Healthcare," Goldman Sachs (June 29, 2015), available at http://www.scbio.org/resources/Documents/Internet%20of%20Things%20-%20Volume%205%20-%20The%20Digital%20Revolution%20comes%20to%20US%20HC%20-%20Jun%2029,%202015%5B1%5D.pdf.

7 http://www.airstrip.com/.

8 http://www.caresync.com/consumers/index.php

9 See comments of ACT | The App Association regarding the Food and Drug Administration's Request for Comments, Using Technologies and Innovative Methods To Conduct Food and Drug Administration-Regulated Clinical Investigations of Investigational Drugs (Docket No. FDA-2015-N-3579) (filed Dec. 28, 2015), available at http://actonline.org/wp-content/uploads/ACT-Comment-to-FDA-re-Clinical-Trials-122815.pdf.

10 "An Aging Nation: The Older Population in the United States," United States Census Bureau (May 2014). Available at: http://www.census.gov/prod/2014pubs/p25-1140.pdf.

11 "Healthy Aging: Improving and Extending Quality of Life Among Older Americans," Center for Disease Control and Prevention (2009). Available at: http://www.cdc.gov/nccdphp/publications/aag/pdf/healthy_aging.pdf.

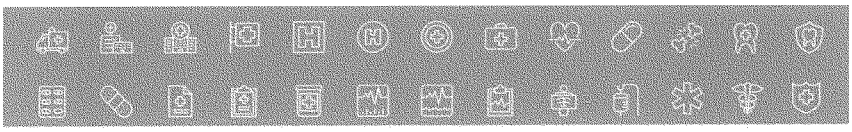
12 "Housing an Aging Rural America: Rural Seniors and their Homes," Housing Assistance Council (October 2014). Available at: http://ruralhome.org/storage/documents/publications/rrreports/ruralseniors2014.pdf.

13 http://www.beddit.com/.

14 https://dev.windows.com/en-us/kinect.

15 "The Boomer Challenge," Hospitals & Health Networks (January 2014). Available at: http://www.hhnmag.com/Magazine/2014/Jan/cover-story-baby-boomers.

16 45 CFR Part 160; 45 CFR Part 164 Subparts A and C.



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

18 http://hipaaqsportal.hhs.gov/a/pages/helpful-links.

19 https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf.

20 http://csrc.nist.gov/.

21 http://csrc.nist.gov/groups/STM/cmvp/.

22 http://csrc.nist.gov/publications/nistpubs/800-66-Rev1/SP-800-66-Revision1.pdf.

23 E.g., http://www.engadget.com/2016/02/19/hospital-ransomware-a-chilling-wake-up-call/.

24 http://www.apple.com/customer-letter/answers/.

25 The Center for Medicare and Medicaid Services (CMS) defines an API as "a set of programming protocols established for multiple purposes...[that] may be enabled by a provider or provider organization to provide the patient with access to their health information through a third-party application with more flexibility than often found in many current 'patient portals.'" 80 FR 16753.

26 See OMB Circular A-119 Revised, Federal Participation in the Development And Use of Voluntary Consensus Standards and in Conformity Assessment Activities (rev. Feb. 10, 1998), available at http://www.whitehouse.gov/omb/rewrite/circulars/a119/a119.html.

27 45 CFR Part 170 Subpart C.

28 http://www.nist.gov/healthcare/testing/mutestmethod.cfm.

29 http://www.continuaalliance.org/products/design-guidelines.

30 http://www.hl7.org/implement/standards/index.cfm.

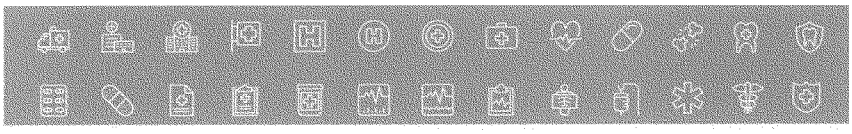
31 http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=43218.

32 http://www.ihe.net/About_IHE/.

33 https://www.healthit.gov/sites/default/files/briefs/onc_databrief25_interoperabilityv16final_081115.pdf.

34 See 42 CFR § 410.78.

35 For example, according to the Centers for Medicare & Medicaid Services (CMS), Medicare telemedicine reimbursement totaled a mere $13.9 million in Calendar Year 2014. See http://ctel.org/2015/05/cms-medicarereimburses-nearly-14-million-for-telemedicine-in-2014/.



36 Medicare considers CPT Code 99091 ("Physician/health care professional collection and interpretation of physiologic data stored/transmitted by patient/caregiver") as "bundled" into payment for other basic services (e.g., an office visit provided the same day or other services incident to the service provided) and therefore does not currently make separate payment for 99091.

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

38 See Darkins, Telehealth Services in the United States Department of Veterans Affairs (VA), available at http://c.ymcdn.com/sites/www.hisa.org.au/resource/resmgr/telehealth2014/Adam-Darkins.pdf.

39 See SNS Telecom, The mHealth (Mobile Healthcare) Ecosystem: 2015 – 2030 – Opportunities, Challenges, Strategies & Forecasts (rel. Sept. 2015).

40 42 U.S.C. 1305.

41 S. 2484 (introduced Feb. 2, 2016). Companion legislation introduced as H.R. 4442 (Feb. 3, 2016). See also Letter from ACT | The App Association to Senators Schatz, Wicker, Cochrane, Cardin, Thune and Warner (sent Feb. 3, 2016), available at http://actonline.org/wp-content/uploads/ACT-Ltr-of-Support-for-CONNECT-for-Health-Act-020316.pdf.

42 E.g., Joint Comment to Senate Finance Committee's Chronic Care Working Group (Jan. 26, 2016), available at http://actonline.org/wp-content/uploads/Coalition-Letter-re-Senate-Finance-Chronic-Care-WG-012916.pdf.

43 P.L. 112-144.

44 FDA, FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework (Apr. 2014), available at http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm390588.htm.

45 79 FR 21473.

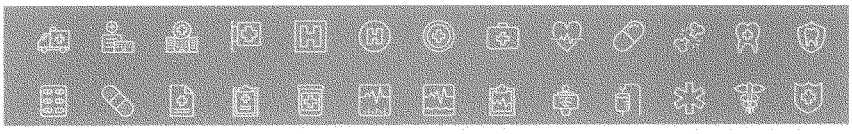
46 42 U.S.C. 1305.

47 https://www.healthit.gov/policy-researchers-implementers/patient-generated-health-data.

48 NIST's roles in this context have been articulated in both Federal Health IT strategic plans (2008–2012 and 2011–2015) and in the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act (ARRA) of 2009.

49 Under the National Technology Transfer and Advancement Act (NTTAA), NIST manages assigned responsibility to coordinate federal, state, and local technical standards and conformity assessment activities, as well as coordinates with those in the private sector.

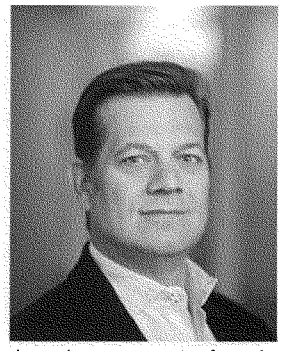
50 Title III of the E-Government Act of 2002 (P.L. 107-347).



51 http://www.nist.gov/cyberframework/index.cfm.

52 http://www.nist.gov/nstic/.

Morgan Reed
Executive Director



Morgan Reed is a widely known and respected expert on the government impact on technology innovation. As ACT's Executive Director, Morgan specializes in issues involving application development relating to privacy, intellectual property, competition, and small business innovation.

His expertise and knowledge has been sought by the House and Senate in multiple hearings while his commentary and insight is a major draw for news networks including Fox Business News, MSNBC, CNBC, CNN, and ABC. He is consistently quoted in the trade and popular press, ranging from the Wall Street Journal and the Washington Post to Ars Technica and Slashdot.

Morgan has authored and contributed to several white papers dealing with applications development and government, including "A Crash Course on Open Source" and "A Software Developer's Guide to the DMCA." He was part of the developer team for the Linux Router Project (LEAF), and remains an active Apple and iOS licensed developer.

His recent work has focused on outreach to app developers to address concerns about privacy in the mobile marketplace. As Congress and the FTC have devoted considerable efforts to rewrite and update online privacy regulations, Morgan has traveled throughout the country to encourage developers to adopt self-regulatory measures, implement privacy policies, and improve data transparency.

Morgan has been appointed to serve on the Advisory Council of mHIMSS, the mobile Health Information Management System Society. mHIMSS serves the health IT community by supporting efforts to embrace and harness the power of mobile health to improve care and control costs. The health care community is seeing dramatic advances in remote care aided by growth in the smartphone and tablet industries.

Morgan has also leveraged ACT's resources to host innovation workshops across the country. Organizing events with venture capitalists, business leaders and attorneys, he helps to foster innovative new technologies by helping new emerging businesses manage their intellectual property. An organization called Innovators Network emerged from these events and is now comprised of more than 2,000 members.

Before coming to Washington, Morgan worked for a Taiwanese trading company specializing in the manufacture of technology products for the U.S. market. He served as managing director of North American sales, handling bilingual contract negotiation. During his time abroad, Morgan gave lectures in both English and Chinese on various aspects of U.S.-China trade, including building and maintaining long term partnerships in Asia. His expertise on Chinese business practices is regularly sought throughout the administration.

Chairwoman COMSTOCK. Thank you. And I now recognize Dr. Shaw.

TESTIMONY OF DR. BRYAN F. SHAW,
ASSISTANT PROFESSOR,
DEPARTMENT OF CHEMISTRY AND BIOCHEMISTRY,
BAYLOR UNIVERSITY

Dr. SHAW. Chairwoman Comstock, Ranking Member Lipinski, and distinguished Members of the Research and Technology Subcommittee, my name is Bryan Shaw, and I am a Professor of Chemistry at Baylor University in Waco, Texas. Thank you for inviting me today to testify on our health care app, Cradle.

I want to tell you the story of Cradle, and show you how it works, because I believe doing so will help you continue to make wise policy. Cradle is an acronym for Computer Assisted Detector of Leukocoria. What is Leukocoria, and why would we want to detect it on a smartphone? Leukocoria is simply white eye. It is a white pupillary reflex. You can see an example of Leukocoria on your video monitor. White eye is a symptom of several pediatric eye diseases, including the aggressive childhood eye cancer retinoblastoma, and much more common, but less serious, conditions such as refractive error. One in 80 children will present with Leukocoria because of some type of eye disorder. This picture is of my son Noah at three months old. Noah's Leukocoria was caused by a 9 millimeter tumor in the back of his eye. The Cradle app alerts a parent to the presence of this type of picture on their smartphone. The Cradle app also harnesses the phone's digital camera and LED to convert the smartphone into a crude ophthalmoscope to help a doctor directly examine a child's eye for a white pupillary reflex.

Although the appearance of white eye might seem obvious in a picture of a child with eye disease, and although white eye can be observed by a doctor when shining a conventional ophthalmoscope into the eye, white eye often goes unnoticed and undetected for months, for years, by both doctor and parent. These delays can blind, and even kill, children. I know this fact from personal experience. My son Noah, who inspired my team and I to invent Cradle, was born with retinoblastoma tumors in both of his eyes. Noah's pediatrician never caught the Leukocoria during any of his routine eye exams, but his mother did, using her digital camera. Tragically, it was too late to save Noah's right eye, but doctors were able to salvage his left eye with external beam radiation and systemic chemotherapy. We later learned, to our horror, that Leukocoria had been showing up in our pictures for months, ever since Noah was 12 days old, and had we noticed Leukocoria then, we likely would've saved both of Noah's eyes.

Unfortunately, our story is common, but Cradle is beginning to make it less common. Since its release for the iPhone in October of 2014, and for the Android in July of 2015, Cradle has prevented vision loss in other children all across the world, and it's done so at zero cost. In two of my favorite cases, parents used the free Cradle app to catch retinoblastoma so quickly, so early in their children, that the children did not require chemotherapy, they did not

require radiation. They didn't require removal of their eye, or eyes. They only required laser treatment, and they have good vision.

Very quickly, I would like to do a little show and tell by showing you a video of me demonstrating the video ophthalmoscope mode of Cradle on my 7-year-old son, who's in the audience today, and also as a control on my 3-year-old son, who does not have retinoblastoma. If we could see that video?

[Video shown.]

That's the end of the video.

In closing, the Cradle app demonstrates the humanitarian, entrepreneurial, and innovative potential of mobile medical apps. Cradle was created by basic scientists and students in their spare time, with no prior expertise in conventional health screening, other than witnessing its failures with Noah. We were able to provide Cradle to parents quickly because there were no regulatory or cost barriers in our way. Cradle cost under $20,000 to create. We provide it to the world freely. Cradle has already reduced health care costs around the globe. We are now pursuing funding for the clinical validation of Cradle, and plan to apply for regulatory approval. I would be happy to answer any of your questions on Cradle. Thank you.

[The prepared statement of Dr. Shaw follows:]

Written Testimony of Dr. Bryan F. Shaw Regarding the CRADLE Medical App.

Summary: 1 in 80 children will exhibit "white eye" or *leukocoria* (Fig. 1) as a symptom of a variety of eye diseases. A free medical app developed by Greg Hamerly, Ryan Henning, and myself at Baylor University can help parents and doctors detect this symptom, which can be tough to spot (Fig. 2-3). The app is known as "CRADLE" (**C**ompute**R** **A**ssisted **D**etector of **LE**ucokoria) and since its release in 2014 for the iPhone (2015 for Android), parents across the world have used this free app to save their children's vision and life, for example by quickly detecting "white eye" associated with the aggressive cancer retinoblastoma. Doctors in the U.S., Germany, and Guatemala have also taken advantage of this free technology and are now testing CRADLE in urban and remote clinical settings as an alternative (or compliment) to the ophthalmoscope. My colleagues and I are now optimizing CRADLE and testing it under different clinical settings. We know that CRADLE works, but we want to know how well it works. The largest obstacle in the initial development of CRADLE, and its ongoing optimization is receiving funding. The development of CRADLE has relied on financial support from private donors and from Baylor University.

Pediatric Eye Diseases are Widespread and Difficult to Detect. Each year in the U.S., approximately 500,000 children will develop or will be born with various disorders of the eye, including refractive error, retinoblastoma (cancer of the retina), pediatric cataract, Coats' disease, persistent fetal vasculature, amblyopia, strabismus, and myelin retinal nerve fiber layer. Catching these disorders early can prevent vision impairment and in the case of retinoblastoma, death. The cardinal symptom of these disorders will often be *leukocoria*, a white pupillary reflex that can appear in a photograph or can be observed by a doctor when shining a light into the child's eye (Fig. 1). Unfortunately, leukocoria can go unnoticed by a parent and often goes undetected by a pediatrician.

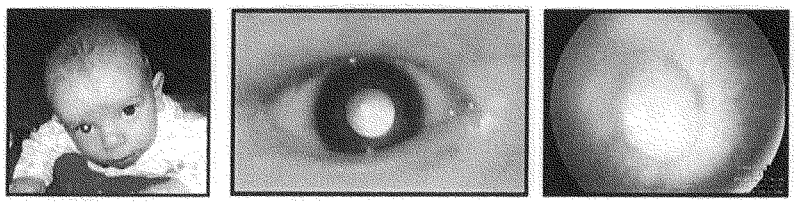


Figure 1. Left and center images: an example of leukocoria in a child with retinoblastoma (taken by mother before diagnosis). Right image: fundus photograph of the same Rb tumor from the same eye in left and center images (collected by an ophthalmologist after diagnosis). Images donated by Bryan Shaw.

My own family's experience with the challenges of screening for eye disease cost my son Noah most of his vision, nearly cost him his life, and has cost our healthcare system hundreds of thousands of dollars dealing with the results of his late diagnosis. Noah was born with aggressive retinoblastoma tumors in both of his eyes. Doctors were not the first to detect these tumors: Noah passed all of his eye examinations at 3 days, 1 week, 2 weeks, 1 month, 6 weeks, 2 months and 3 months. It was his mother's digital camera that detected his tumors at 3 months old. An ophthalmologist confirmed the diagnosis a few hours after Noah's mother informed his pediatrician about her observation of leukocoria. Noah would go

on to receive systemic chemotherapy, would lose his right eye, and would receive ~ 30 cycles of radiation treatment to his left eye.

Although Noah's mother noticed these pictures when he was 3 months old, we found later that leukocoria had been occurring in pictures since Noah was 12 days old. Noah's ophthalmologist predicted that, had we diagnosed Noah in the first month of life, only laser- and cryotherapy would have been used, without the need to remove the right eye or irradiate the left eye. Studies suggest that my family's experience (including our pediatrician's inability to detect Rb, *ab initio*) is common.

After realizing that doctors and parents need better tools to screen for leukocoria in children, my colleagues and I at Baylor University, Greg Hamerly and Ryan Henning, invented CRADLE. CRADLE has been available on Apple's App Store since October, 2014, and on Google Play since July 2015 under the name "White Eye Detector".

How CRADLE Works. CRADLE (Fig. 2) searches pictures on the smartphone's hard drive for examples of leukocoria. CRADLE can also convert the smartphone into a computer-assisted ophthalmoscope by activating the LED and video camera. In this live-video mode, CRADLE software analyzes each video frame for leukocoria (in real time), constantly tracking each eye and positioning green boxes around normal eyes that exhibit red or black pupillary reflexes, while positioning red boxes around eyes that exhibit white pupillary reflexes in one or more video frames. We have also incorporated CRADLE software into other photographic devices, including an inexpensive ($16) LED Webcam (Fig. 3).

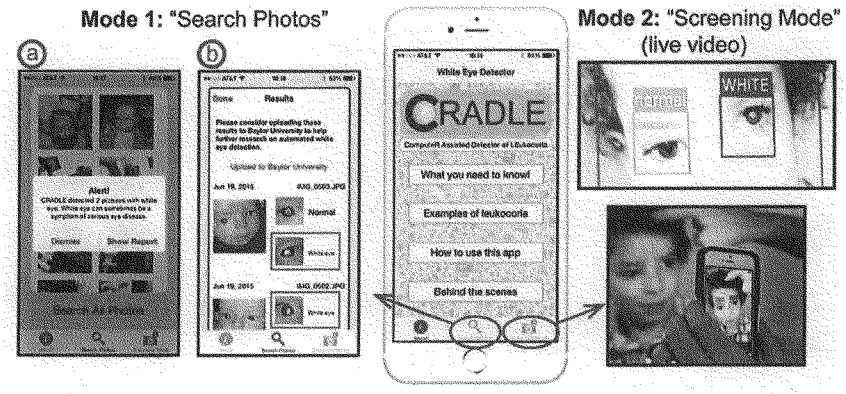


Figure 2. **C**ompute**R** **A**ssisted **D**etector of **LE**ukocoria (CRADLE). The free CRADLE smartphone/tablet app is listed in Apple's App Store and Google Play as "White Eye Detector". The app operates in two modes: "Search Photos" (Mode 1) and "Screening Mode" (Mode 2). Far left: "Search Photos" mode. CRADLE can search all images stored on the device (or single images, via "tapping") for leukocoria. Far right: "Screening Mode". In screening mode, the smartphone becomes an improvised ophthalmoscope and tracks and tests the eye in real time. Note: the user needs internet access to download CRADLE, but not to use it, i.e., CRADLE software is saved to (operates independently on) each person's smartphone. Images donated by Bryan Shaw.

CRADLE's Global Impact. In less than 18 months, and without forming any type of corporation or organization to market or promote CRADLE—we are just a group of academics who put an app on the web—CRADLE has received ~ 45,000 downloads on all continents. It is most popular in Germany, where it has received 20,000 downloads. In 2015, two families in Germany used CRADLE to detect rétinoblastoma in their children long before doctors detected the disease. Retinoblastoma is an exclusively pediatric eye cancer that affects 8,000 children each year, usually striking the developing retina before the 2nd birthday. Retinoblastoma will kill 4,000 of these children, and it will diminish the vision of survivors. In these two German children, CRADLE caught retinoblastoma at such an early stage that the children only received laser therapy, and these children were able to keep both of their eyes and will survive. Germany's premier network, ZDF reported this story, which can be found on the link below (you can translate the text of the story into English using Google Translate):

http://www.zdf.de/volle-kanne/praxis-taeglich-app-als-fruehwarnung-vor-augenkrebs-39098494.html?tabNo=0

There are other examples of how CRADLE has helped children receive diagnoses of tough-to-spot eye diseases. This link in PEOPLE magazine describes a few examples:

http://www.people.com/article/dad-creates-app-detects-eye-cancer-children

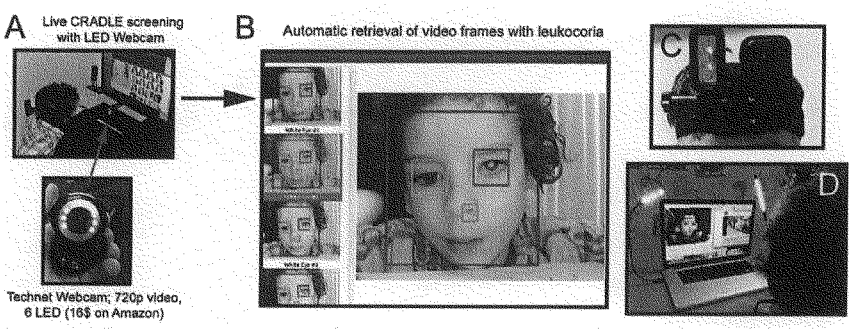


Figure 3. Different types of hands-free/live-video versions of CRADLE tested on retinoblastoma survivor with regressing tumors. A) A webcam equipped with 6 adjustable LEDs is used to screen for leukocoria in sitting position. B) This version of CRADLE removes and stacks leukocoric video frames in real time (allowing clinician to examine or store frame in the patient's electronic medical record). C) A POV "GoPro" camera with LED attachment. D) Laptop version of CRADLE using screen camera and USB-LED. Scanning the Rb survivor (left side of laptop screen) while his eye tracks cartoons (right side of laptop screen) allows testing at multiple optical axes. Images donated by Bryan Shaw.

Obstacles Encountered in Developing CRADLE. The largest obstacle we have encountered while developing CRADLE is receiving funding (e.g., from NIH) to further develop, optimize, and test CRADLE in clinical settings. We are hopeful that we will eventually receive funding. Receiving funding to clinically validate CRADLE is necessary for the development of this technology. We know that CRADLE works, but we want to know how well it works. We want to know: what is the smallest size tumor it can detect? Are tumors in the periphery more difficult to image than centrally located tumors? We want to test its efficacy at detecting other eye diseases. How early can it catch Coats' disease and cataract? What is the minimal refractive error that it can detect? Is CRADLE more effective and easier to use than the ophthalmoscope? Should doctors use CRADLE with the room lights on or off? How well does it work in outdoor settings? What are the optimum usage parameters? We also need to translate the text and instructions in CRADLE into every language possible. We want to receive FDA approval for CRADLE, in hopes that pediatricians will feel more comfortable recommending CRADLE to their patient's guardian. Four million children are born in the U.S. each year, and we cannot possibly reach out to all parents, year after year, in terms of advertising CRADLE. We can, however, reach all pediatricians in the U.S.—there are only ~ 30,000, with low turnover—and we believe that FDA approval will increase the chances that pediatricians recommend CRADLE to guardians of their new patients.

My research team and I have received little resistance from the oncology and ophthalmology community. Pediatric ophthalmologists and oncologists from Dana-Farber Cancer Institute, Massachusetts Eye and Ear Infirmary, Baylor College of Medicine and St. Jude Children's Research Hospital have enthusiastically become part of our research team, either by co-authoring peer reviewed studies regarding CRADLE, or collaborating as co-investigators on our grant applications to fund the clinical validation of CRADLE. Ophthalmologists and pediatricians whom we have no formal collaboration with have contacted us and informed us that they are testing CRADLE in their clinics across the world.

We have not encountered complaints of issues of privacy from our users. CRADLE has been designed so that it does not upload your pictures to us for analysis, rather it downloads itself to your phone, and you search your own pictures. This design also lets the user operate CRADLE without internet access (although internet access is needed to initially download CRADLE).

Biography of Bryan F. Shaw:

Bryan Shaw is an Assistant Professor in the Department of Chemistry and Biochemistry at Baylor University, in Waco Texas. He received his undergraduate (B.S.) degree in Biochemistry and Biophysics 1999 from Washington State University, in Pullman Washington. He received his Ph.D. in Inorganic Chemistry from UCLA in 2005. From 2006 to 2010 he worked as a post-doctoral fellow in the Department of Chemistry and Chemical Biology at Harvard University. In 2010, he began his tenure-track appointment at Baylor University. Some of his notable awards include the National Science Foundation CAREER award, and the Ruth L. Kirchstein National Research Service Award. The bulk of his research focuses on protein biophysics, and developing lead compounds to inhibit the self-assembly of proteins linked to amyotrophic lateral sclerosis.

In September, 2008, Dr. Shaw's son, Noah Shaw, was diagnosed with bilateral retinoblastoma. Noah's doctors initially missed his eye cancer. Noah's diagnosis was initiated by Elizabeth Shaw, Noah's mother. Elizabeth observed leukocoria (a white pupillary reflex) in pictures she took of Noah. Elizabeth reported her observation to their pediatrician and Noah was diagnosed that afternoon by an ophthalmologist. Noah endured months of systemic chemotherapy, removal of his right eye, laser photoablation, cryotherapy, and multiple cycles of proton beam radiation to his left eye. After this ordeal, Bryan and Elizabeth learned that Noah's leukocoria had been showing up in pictures since he was 12 days old, i.e., months before Elizabeth first noticed leukocoria. This entire experience inspired Dr. Shaw and his colleagues at Baylor University to create CRADLE (ComputeR Assisted Detector of LEukocoria), a free smartphone app that helps parents detect leukocoria in digital pictures, and helps doctors detect leukocoria when performing the red reflex test in conventional and unconventional clinical settings.

Chairwoman COMSTOCK. Thank you so much, Dr. Shaw. And I think if that video is available for us to put up online, I think all of us would love to do that, and share that with everybody. And thank you so much.

And Mr. Look, we'll now hear from you.

TESTIMONY OF MR. HOWARD LOOK,
PRESIDENT, CEO AND FOUNDER, TIDEPOOL

Mr. LOOK. Thank you. Chairwoman Comstock, Ranking Member Lipinski, and distinguished Members of the Subcommittee, thank you for inviting me today. My name's Howard Look. I'm the founder and CEO of Tidepool, a non-profit open source startup from Silicon Valley. We're building software to help people reduce the burden of managing Type1 diabetes.

My story starts five years ago, on a family camping trip. Our daughter Katie had unzipped the tent three times in the middle of the night to go to the bathroom. The next morning she was throwing up and we thought that she might have the stomach flu. Two days later we were told that, along with weight loss, these are the classic symptoms of Type1 diabetes. Katie's immune system had begun attacking her pancreas, the insulin producing cells in her pancreas, and without insulin, she simply couldn't metabolize the energy that she needed to survive. My kids call me their geek dad. At the time my daughter was diagnosed, I was VP of Software at Amazon. Before that, I was VP of Software at Pixar, and I had been on the founding team at TiVo. I knew software and user experience, but I knew nothing about the challenges of health care.

Our family quickly discovered what everyone who lives with Type1 diabetes knows. It's a challenging and burdensome disease, requiring hundreds of decisions per day, and constant vigilance. Managing Type1 involves calculating precise doses of insulin, a deadly hormone, based on food, hormones, exercise, illness, and more. Not enough insulin, and you run the risk of ketoacidosis, or contributing to long term complications, like blindness and kidney failure. Even a little too much insulin and you risk severe hypoglycemia, or low blood sugar, which can lead to seizure, coma, or death. Said another way, effectively managing Type1 diabetes is all about meaningful, real time access to data to make the best dosing decision possible.

The most popular insulin pump and continuous glucose monitor, these are two devices critical to successful diabetes therapy, come from different manufacturers, and they're incompatible with each other. The software that comes with most diabetes devices is closed, proprietary, and hard to use. It's a little bit like owning a digital camera and being forced to use the terrible software that came with it in order to view your pictures. To make a long story short, I found lots of other people who felt just like I did, and we founded a non-profit, open source startup called Tidepool. Our mission is simple, allow every patient to liberate their own health data from their devices, and in doing so, catalyze an ecosystem of applications to help them more meaningfully engage in their own care. It's still early, but we've already made a tremendous impact. Nearly all device makers have made their data protocols available, and our free applications are currently the only way to visualize data

from the most popular insulin pump and most popular glucose monitor in one place at one time.

This is our web application called Blip. It lets you see diabetes data from multiple devices. Here we have data from an insulin pump, continuous glucose monitor, and a finger stick meter, as well as contextual notes from your mobile phone. This is another mobile app called Nutshell. It lets you keep track of what you ate, along with the insulin dose that you used, and shows how your body reacted to it so that you can make an even better dosing decision the next time you eat the same thing. And this is a prototype of a mobile application that shows real time blood glucose values combined with location services, allowing parents to know that their child is safe no matter where they are. All of these are examples of a robust ecosystem of applications that can exist when health data is liberated, and the patient can choose how the data is used.

Tidepool is not the only patient-led initiative using data to improve standards of care for people with Type1 diabetes. Our family also used Night Scout, an open source project that allowed us to keep—to see our daughter's blood sugar remotely, keeping her safe when she was at a sleepover. And finally my daughter now uses a do-it-yourself system based on an open source project called Open APS, for Artificial Pancreas System. Her devices now work together to automatically deliver insulin based on a software algorithm, allowing her to receive safer and more effective therapy than the usual standard of care.

This kind of innovation is only possible when patients have access to their own health data in real time. Real time is a far cry from requests for health data that are fulfilled within 30 days, or that come on paper, or by downloading PDF or Excel files. Medical device companies have the power and ability to publish their device data protocols now. Cloud data services can make that data available to users securely, using modern methods like OAuth and REST APIs. There are no technological, security, or privacy barriers. There are only barriers of fear and uncertainty. We've heard companies say, we're worried about what people will do with the data, or we're worried that people will present the data out of context. Positions like these serve to perpetuate existing standards of care, and limit what an open and vibrant ecosystem of liberated data can achieve.

From a regulatory standpoint, the FDA has been extremely pragmatic with guidance documents like MMA and MDDS. They've been supportive of non-traditional quality systems that enable a lean and agile startup like Tidepool to iterate quickly, and we look forward to continuing conversations with the FDA to support non-traditional trials in n-of-1 studies based on distributed and patient-led projects, and to discussing labelling requirements that would allow device companies to publish their data and control protocols without fear of added liability.

To summarize, engaged patients should not need to outsmart the very companies that they depend on in order to achieve safer and more effective therapy. Their data should be readily available. The ability to foster and catalyze patient-led innovation and personalized engagement through mobile and web-based health care applications exists today. Thank you.

[The prepared statement of Mr. Look follows:]

Written Testimony on "Smart Health: Empowering the Future of Mobile Applications"

Committee on Science, Space and Technology, Subcommittee on Research and Technology, U.S. House of Representatives

Howard Look, President and CEO, Tidepool
March 2, 2016

Key points:

- Empowered Patients, Citizen Science and Patient-led Innovation is real. We need to embrace it and encourage it. People empowered to do their own research and development fosters patient-led innovation, which leads to safer, more effective care. NOT embracing this is a greater risk to safety and effectiveness because it slows down the the pace of innovation. Examples of patient-led innovation:
    - Nightscout: Access to Dexcom CGM data led to thousands (if not tens of thousands) of people with diabetes, as well as their parents and loved ones, having the peace of mind that they are safe. The community that formed around Nightscout, CGM in the Cloud, provides additional support to engaged patients and their families.
    - Bigfoot Biomedical: A commercial venture building a closed loop "artificial pancreas". Early prototype development prior to forming the company was based on access to Dexcom CGM data and the ability to control Medtronic insulin pumps.
    - OpenAPS: An open source implementation of a closed loop system based on the same access to Dexcom CGM data and control of Medtronic insulin pumps. Even in early form, it clearly leads to safer and more effective treatment than the usual standard of care. There are currently dozens of users and active contributors of the project, and growing quickly.
    - Tidepool: A non-profit organization that has built an open platform enabling access to diabetes data from devices and an ecosystem of applications to emerge to cloud data.
- The White House, Congress and the FDA should not limit the ability of citizens to develop and use their own medical devices as they see fit.
- The White House, Congress and the FDA should ENCOURAGE Citizen Science and Patient-Led Innovation by compelling device makers and software to openly publish their device communication protocols and data access APIs.

    - To overcome concern of liability, law/regulation can make it clear that as long as data and control protocols are correct, accurate, and timely, that what the end-user does with it causes no liability back to the device originator.
    - Law/regulation can also make it clear that data and protocol specifications is a labeling requirement.
- Patients should always have access their own health data, including real-time data generated by devices connected to them (e.g. a CGM or insulin pump) or implanted in them (e.g. an ICD). Patient access to data from devices or clouds should not be limited.

Cloud data providers should:

- Use REST APIs or other well-known APIs mechanisms to expose real-time access to data (any mechanism is fine, but in 2016 we encourage REST APIs; better mechanisms may emerge in the future). Electronic/software access to data key to innovation. It's not good enough to say "you can download a PDF or CSV."
- Use OAuth or similar well-known authentication methods to allow patient-driven access to data.
- Using mechanisms like OAuth and REST APIs will encourage an interoperability an ecosystem of devices and applications to emerge. This will lead to innovation in areas that we can only imagine.

Device Makers:

- SHOULD use well-understood authentication and communication protocols that are based on tried-and-true cryptographic techniques. Don't invent something new.
- SHOULD NOT depend on "security through obscurity" to keep your device safe. Firmware will be reverse engineered, and communication protocols will be sniffed.
- SHOULD permit users to be able to get data off of their device. Do not use "security" as an excuse for not making it possible for data to be extracted from your device by the end user. You can have secure access by end users while still publishing your protocols.
- SHOULD publish control protocols for your device.
    - Doing so does not change its intended use; you can (and should) make it clear which interfaces support intended use and which interfaces are presented for research and development purposes only. This fosters patient-led innovation and better care. It is the responsibility of the third

party using the interfaces to make sure that it does not adversely affect the intended use of the device.
    - You SHOULD NOT limit access to device data because you are "worried about how people will use the data."
    - You SHOULD use well-known authentication and encryption mechanisms as well as data transport protocols. Use standards where possible.
    - You SHOULD NOT limit access to a device by its user using cryptographic techniques.

Also, devices makers COULD do these non-intuitive things that will also spark patient-centered innovation:

- You COULD allow your device to be flashed with new firmware, by the end user, in the field. This will encourage further innovation.
- You COULD publish your source code. This leads to greater inspection and safety.
    - You can still protect your intellectual property if you do this, though it would be nice if you gave your IP away.
    - [1][2] ... free and open code gives users the ability to independently assess the system and its risks. Bugs would be patched more easily and quickly, and it would remove the dependence on a single party.

Regulators SHOULD:

- Seek ways to encourage Citizen Science and Patient-led innovation.
- Allow device makers to publish the data protocol and device specification of their devices without that changing the intended use of the device. Liability to the device maker ends with documenting the protocols and ensuring that the data and protocols are accurate. Once the device maker shows that the data is correct, accurate, and timely, it becomes the responsibility of others who use the data and control protocols to ensure safety and efficacy.
- Place no restrictions on "N of 1" studies - empowered patients who design and implement their own studies are a wealth of knowledge and research.
- Allow employees of device companies to opt-in to small-scale trials.
- Make it clear that documenting a Do It Yourself project is not the same as distributing a medical device.

Impediments. These are the impediments that have have prevented efforts from doing more:

- Device companies not being willing to openly publish their device data protocols, or only making them available under terms of confidentiality or limitations on use.

- Companies being concerned that "we don't know what people will do with their data." By contrast, companies should wonder "I wonder what wonderful things will do if we DO give them access to their data!" Some examples:
    - They will invent software that enables them to track their child's blood sugar while at school or on a sleepover, reducing the risk of nocturnal hypoglycemia and increasing quality of life.
    - They will invent devices and systems that do a better job of maintain blood sugar that the usual standard of care, and reducing the risks of hypo- and hyperglycemia.
- Companies being concerned that by making data available, that their competitors will take that data out of context or make inappropriate claims, e.g. "Your insulin pump causes more episodes of hypoglycemia in children than mine does."
- Companies feeling like they "own" the data, and not being willing to let patients use it as they see fit. Or companies not wanting to make the health data that they store available without being paid.

In summary:

- We need to shift the thinking from "We are worried about what people will do with this data" to "We wonder what incredible and wonderful things will do if we DO give them access to their data!"
- Patients should not be required to "outsmart" the very companies whose devices and services they depend on in order to receive life-saving therapy by reverse engineering the devices.
- Instead of seeking ways to limit what an engaged patient can do, we should seek ways to empower them. Along the way, we will also inspire and engage other patients who might have otherwise thought that the usual standard of care was as good as it gets.
- The avalanche of patient-led innovation and citizen science has begun. We need to do everything we can to foster and catalyze this revolution.

References:

[1] https://opensource.com/life/10/8/how-open-source-community-could-save-your-life
[2] http://www.softwarefreedom.org/resources/2010/transparent-medical-devices.pdf

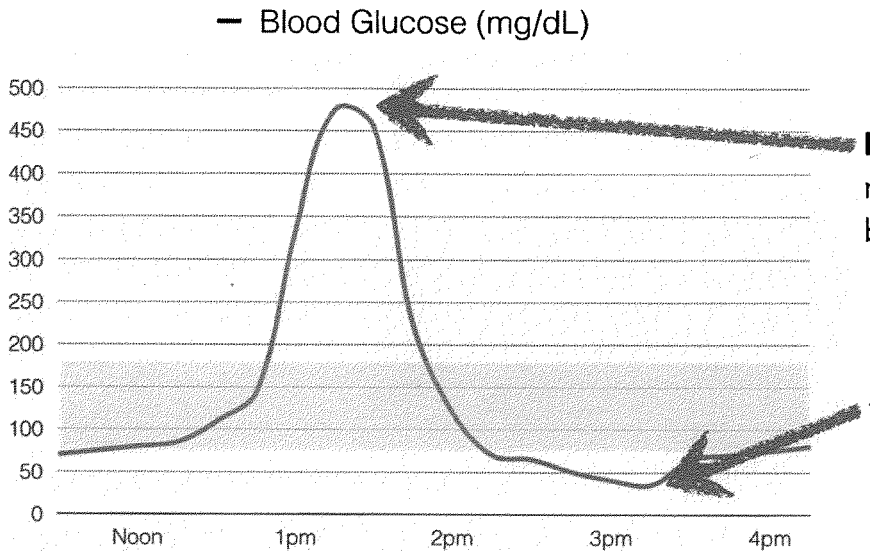
TIDEPOOL

Howard Look
President and CEO, Founder

Testimony before:
Committee on Science, Space and Technology
Subcommittee on Research and Technology
U.S. House of Representatives

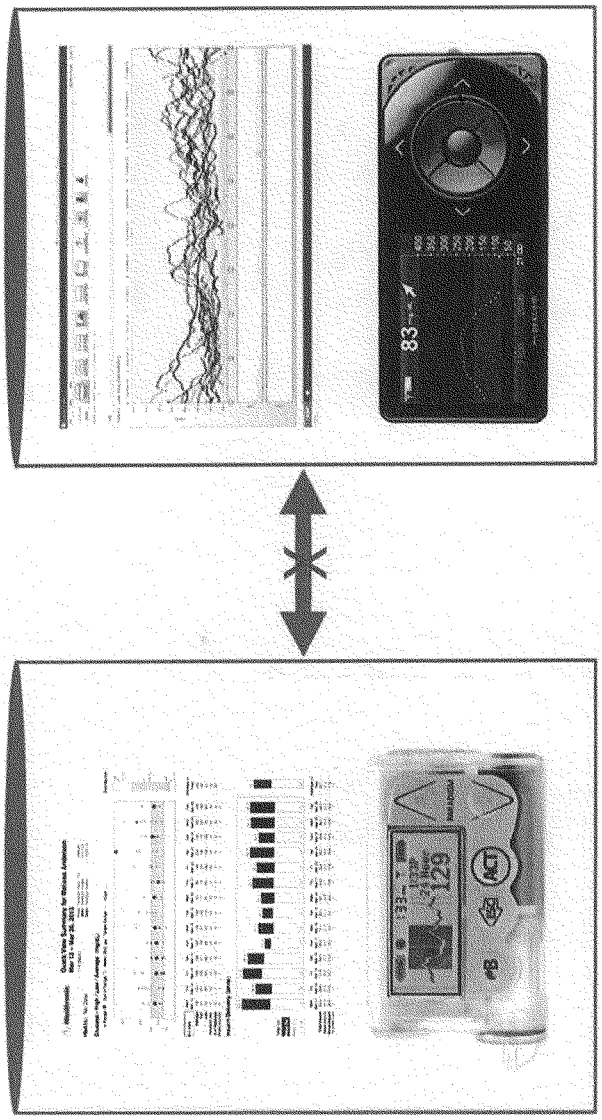
March 2, 2016

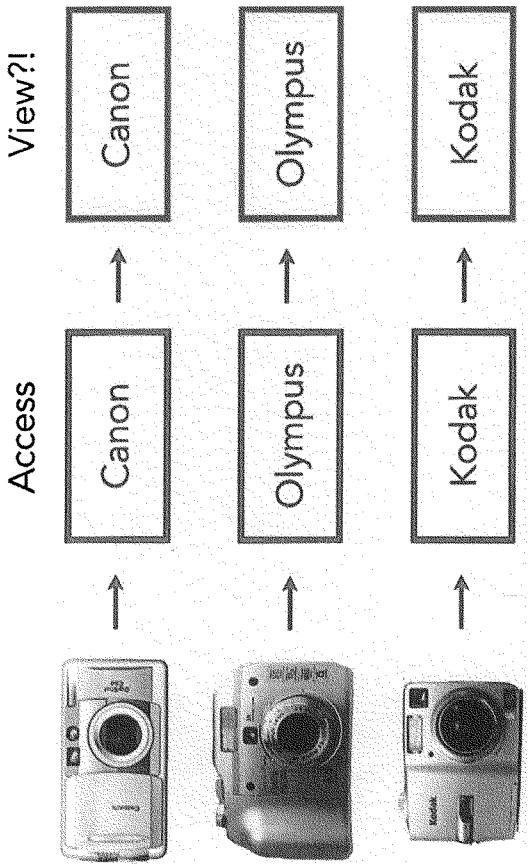
Katie Look
First Day of 6th Grade, 2011
(5 days before diagnosis)



Long term complications:
nerve damage, kidney failure, blindness, amputation

Acute, short term dangers:
cognitive impairment, seizure, coma, death

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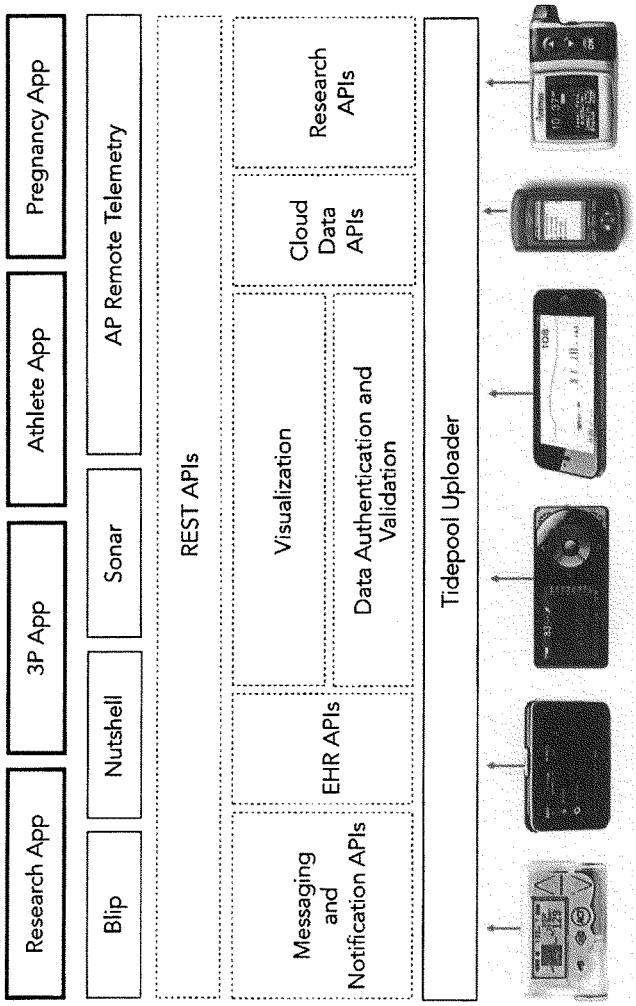
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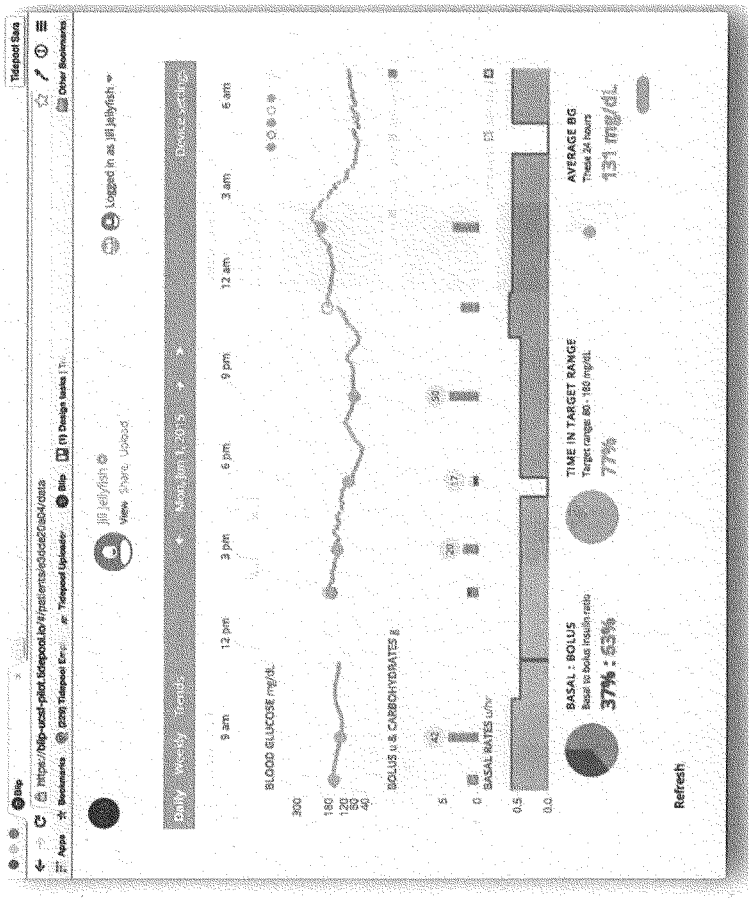
3P App
Athlete App
Pregnancy App
Blip
Nutshell
Sonar
AP Remote Telemetry
REST APIs
Messaging and Notification APIs
EHR APIs
Visualization
Data Authentication and Validation
Cloud Data APIs
Research APIs
Tidepool Uploader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Basal to bolus insulin ratio
37% : 63%
TIME IN TARGET RANGE
Target range 80 - 180 mg/dL
77%
AVERAGE BG
These 24 hours
131 mg/dL
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with 15 chips & salsa
after ballet
Apple Juice before
and horchata
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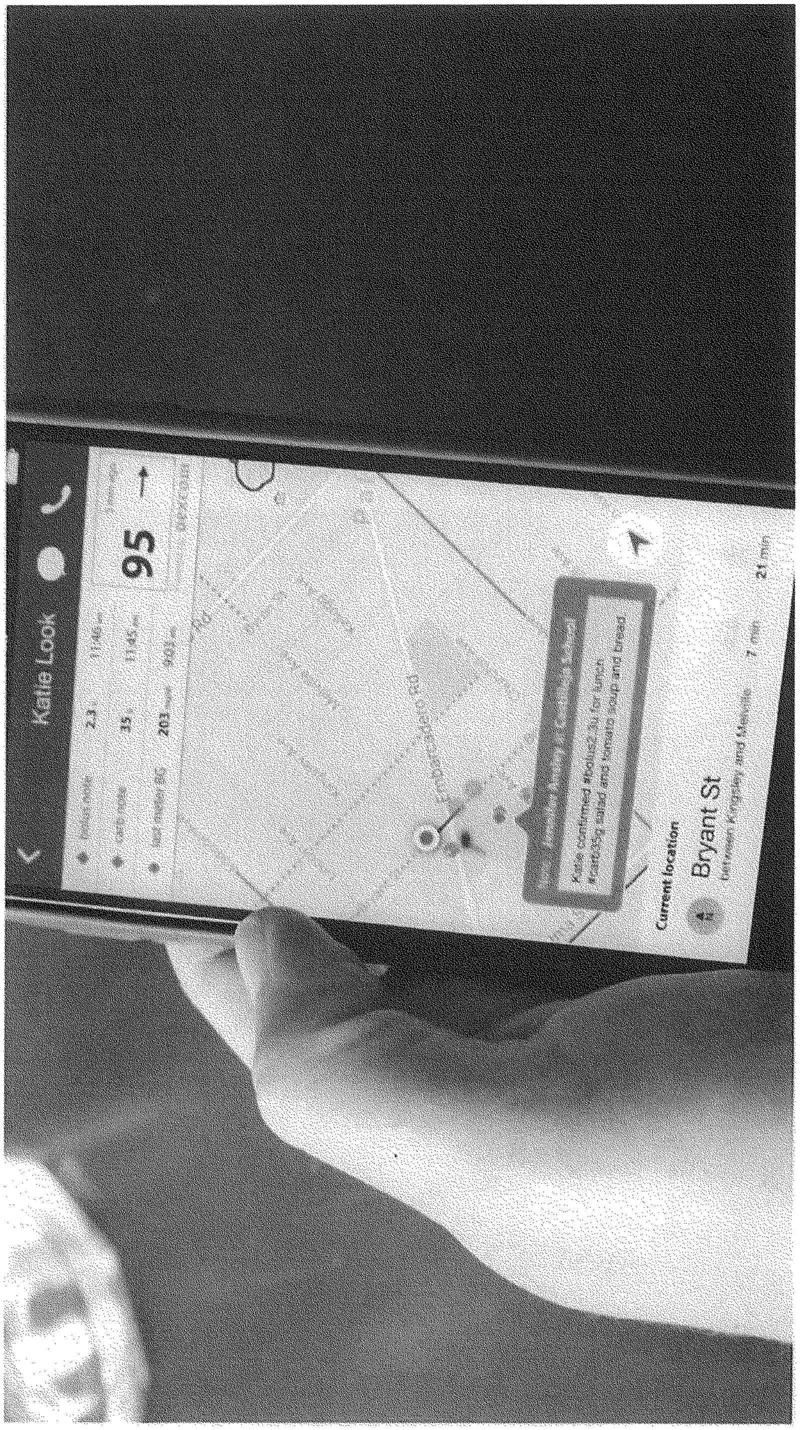
Running on park

Nutshell


Katie Look
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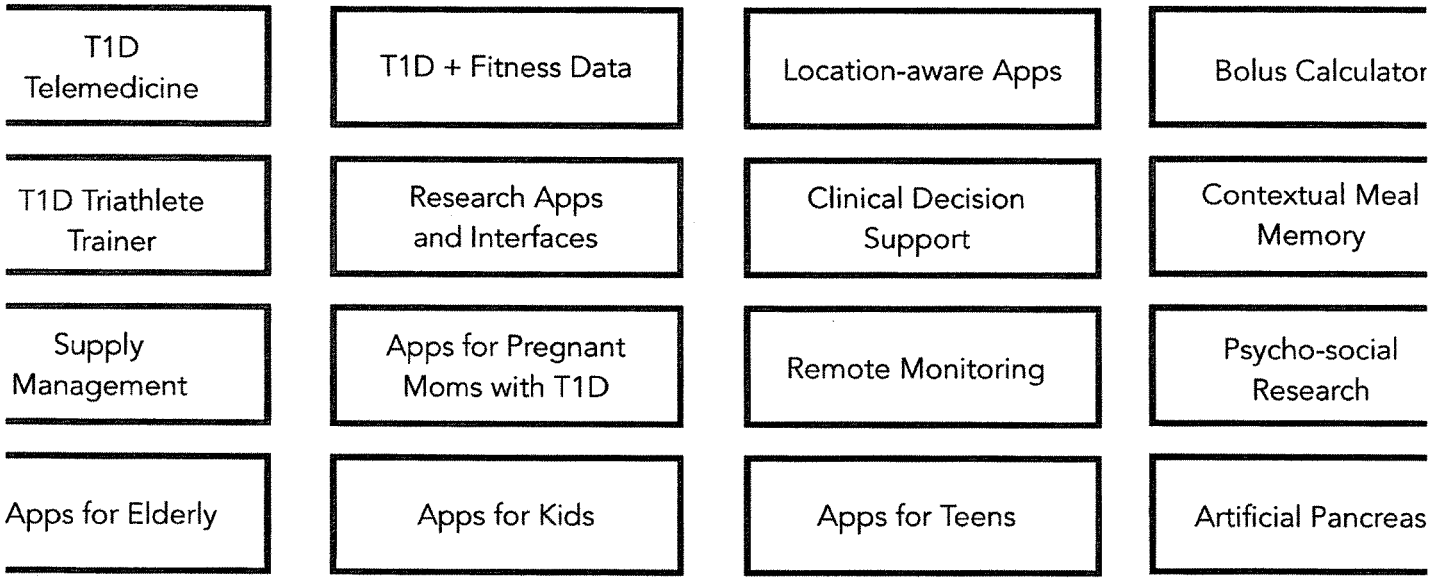
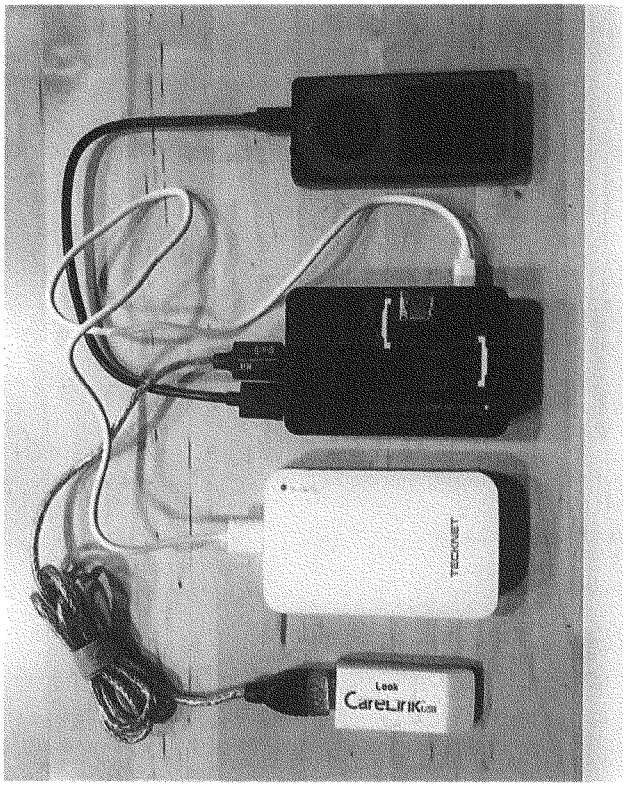
A Type 1 Diabetes Application Ecosystem

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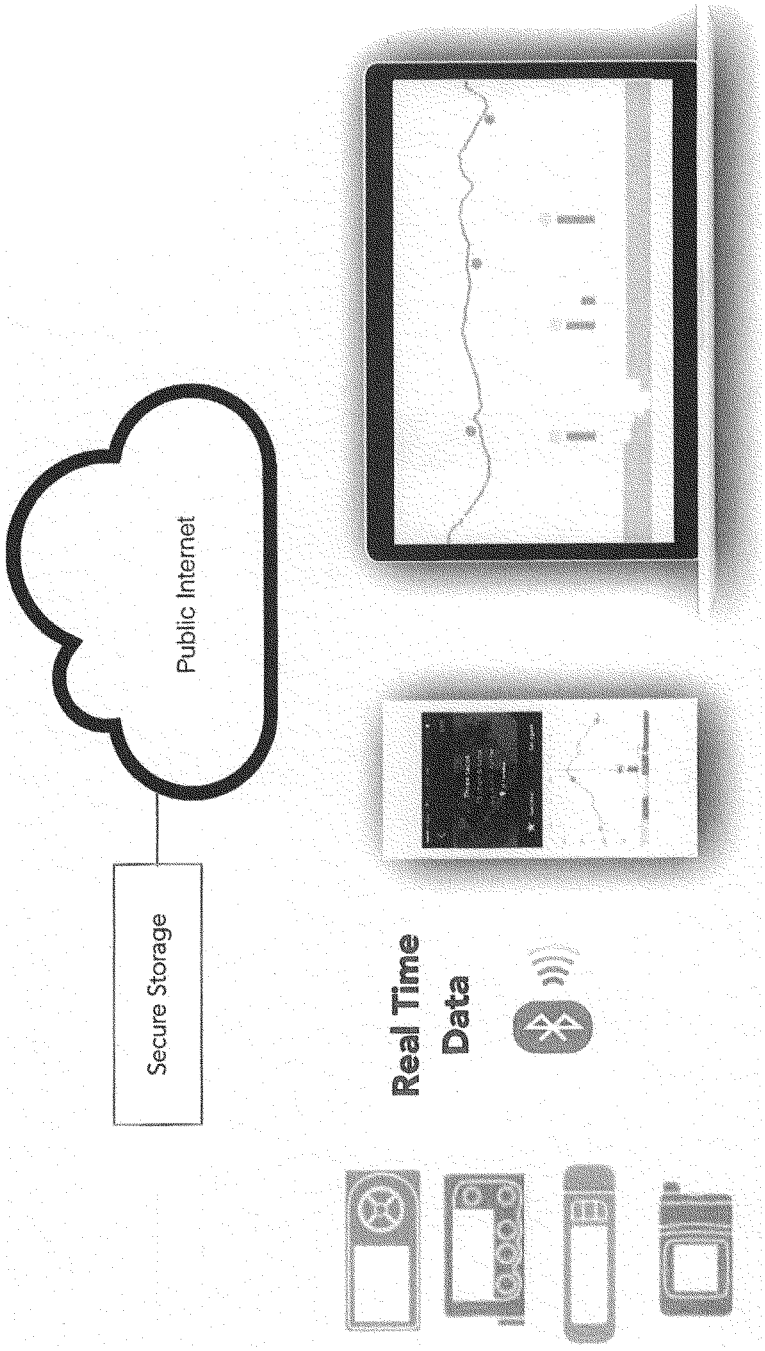
Public Internet
Secure Storage
Real Time
Data

TIDEPOOL

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Biography for Howard Look, President and CEO, Founder, Tidepool

Howard Look is the President, CEO and Founder of Tidepool, a Silicon Valley non-profit startup with the mission of liberating data from diabetes devices and catalyzing an ecosystem of applications that help reduce the burden of managing Type 1 Diabetes.

In June, 2015, Howard received the "White House Champions of Change Award for Precision Medicine" on behalf of Tidepool's work. In February, 2016, he shared the stage with President Barack Obama during a panel discussion at the Precision Medicine Initiative summit.

Prior to working on healthcare challenges at Tidepool, Howard held technology leadership positions in the 3D and consumer electronics space:

> Howard was VP of Software at Amazon (Seattle, WA) and Amazon's consumer electronics subsidiary, Lab126 (Cupertino, CA), where he led a secret software project to develop devices that leverage cloud services.
>
> Prior to Amazon, Howard worked at Linden Lab, where he led the team that delivered the open-sourced Second Life Viewer 2.0 project. "Second Life" is a collaborative, online, 3D, virtual reality experience.
>
> Howard was VP of Software at Pixar Animation Studios, where he led the software development and user experience teams that built Pixar's proprietary 3D animation film-making system. If you wait long enough, you can see Howard's name scroll by in the credits for *Cars*, *Ratatouille* and *WALL-E*.
>
> Prior to Pixar, Howard was on the founding team at TiVo where, as VP of Software and User Experience, he led the efforts that made TiVo as easy to use as it was disruptive.
>
> Howard started his career at Silicon Graphics Computer Systems, also known as SGI. There he worked on numerous projects, including "Inventor", a 3D graphics toolkit, and the O2 Out of Box Experience.

Howard holds a Bachelor of Science in Computer Engineering from Carnegie Mellon University in Pittsburgh, PA. He grew up in Litchfield, Connecticut and now lives in Palo Alto, California with his wife, Melissa Anderson and their three children. His teenaged daughter has T1D.

Learn more about Tidepool at Tidepool.org
Follow Howard on Twitter: @howardlook
Follow Tidepool on Twitter: @Tidepool_org

Chairwoman COMSTOCK. Thank you very much. It was fascinating. It's so inspiring to hear what you're able to do, and—with your personal situation, how you've helped so many, so thank you.

And now I will hear from Dr. Krauss.

TESTIMONY OF DR. GREGORY KRAUSS,
PROFESSOR OF NEUROLOGY,
THE JOHNS HOPKINS HOSPITAL

Dr. KRAUSS. Thank you for inviting me, Chairwoman Comstock, and Members—and for reviewing this important topic in the new era of using personal technology to support health care. I think it might be helpful to start with just illustrating the problem we deal with in supporting patients with epilepsy. So could we show a video, and then go to the next slide? And this is EpiWatch, which we're using to detect seizures and alert caregivers when a seizure occurs to help their family members. And I'll show you a typical patient during a seizure in our hospital.

[Video shown.]

So this is a 17-year-old boy who now—he feels the seizure. 40 percent of people —as their seizure begins—activate a monitoring system. And now the seizure's spreading across his brain. He becomes confused. Now, his father, who's a physician, comes in. He knows something's wrong. Now the seizure's spreading across the brain, evolving into a—here's the staff coming in—towards the end of the seizure—respiratory distress—and so this 17-year-old has seizures like this at school about every two weeks. and they often last up to 10 minutes. And so one need is to have a detector that can warn caregivers of a seizure, and allow emergency intervention to help a patient. An app such as this can also provide a lot of support activity for children.

And so we are developing EpiWatch. It uses Research Kit, which is a novel data management program, that's integrated with the Apple Watch. So the app lives on the watch, and when a patient has a seizure, it can be triggered by a caregiver or the participant, and then for ten minutes it collects data. And these watches have sensors, so it can detect heart rate changes, movement changes with an accelerometer, and it has a gyroscope that can detect changes in position. The advantage of the watch also is every minute we can query the patient to perform a tap test, and let us know if they're alert, or if the seizure's ended. And so we can measure the duration of the seizure, movements during the seizure, and heart rate changes associated with seizures, and with that we're developing a seizure detector.

Now, the question is, how do you collect data like that to make a seizure detector and do research? And so the advantage of Research Kit is that it's a system that allows anonymized data collection from a national participant pool, and allows rapid research to be performed. So the Research Kit has an electronic consenting system where possible participants—they can read about the research on their iPhone. They can be screened based on their criteria, are they the appropriate age, if they have sufficient seizures. They then are tested for comprehension of the research on the iPhone, and then they sign the consent, and then they receive an e-mail with a PDF signed version of the consent. And so you're able to do

mobile e-consenting in a national population very rapidly. And so this is very useful. Once they sign up for the research, they track seizures, and we collect data for ten minutes during seizures, and then encrypted data is transferred to a data system, and transferred to us in encrypted form. And so this Research Kit approach really allows, I think, an explosion of novel research to be performed. First, we're able to study several hundred patients within a month, and capture thousands of seizures rapidly. We can capture seizures from all ages and demographics in the U.S., and we can quickly accumulate data to develop the seizure detector.

And so we're using this research to especially focus on serious seizure types, such as this boy's. So, for example, one in 500 persons per year with epilepsy die suddenly, usually of a respiratory death of cardiac arrhythmia, and that's called SUDEP, Sudden and Unexpected Death of Epilepsy. The majority of this occurs during nocturnal convulsions, and so we're focusing initially on close detection of seizures associated with SUDEP. Could you show the slide? And so this is the data we're collecting during a patient who's having a convulsion at night. They're shaking. You can see on the bottom right, that's their heart rate, markedly increasing several minutes after the seizure, when they're in cardiac distress.

And so this app—the idea is that it would alert patients' caregivers that they're having a serious seizure type. They can then come in, reposition them, stimulate and arouse them to avoid respiratory dysfunction, and perhaps rescue them. And so this is the goal of the research, and we have the advantage that we can actually test prototypes of the detector on the system, and do a lot of research in a large pool of patients very quickly. So we've not moved on to commercialization of this product. That's our—not our goal. The Research Kit is open source, non-commercial software. All our software will be open source, and so we will be able to migrate our seizure detector and app to other platforms once it's developed.

Other questions regarding types of research, and issues of regulation and data security, I think I'll just leave to my written summary. Thank you.

[The prepared statement of Dr. Krauss follows:]

Committee on Science, Space, and Technology, Subcommittee on Research and Technology,
US House of Representatives Hearing on:
"Smart Health: Empowering the Future of Mobile Apps"

March 2, 2016

Gregory L. Krauss
Professor of Neurology, Johns Hopkins Medical Center

Subcommittee Chairwoman Comstock and members, thank you for reviewing this important topic in the new era of using personal technology to support health care. I am a professor of neurology at Johns Hopkins Medical Center and the co-inventor of EpiWatch with Dr. Nathan Crone, the first research app to use the Apple Watch. I would like to describe our app to make several points about issues in supporting innovation and safety in medical applications for mobile devices:

EpiWatch is a medical research app that collects physiological data from sensors on the Apple Watch during seizures from participants with epilepsy. This data is being used in research to create a seizure detector which will use changes in movements, heart rate and alertness to detect seizures and alert caregivers when their family members have seizures.

The app has several novel features:

a) Participants enroll for the research using a novel electronic consenting process in which they review the aims of the research and required activities, and receive study screening and testing for comprehension of the research, all on their iPhones. Those agreeing to participate can sign the consent on their phones and receive a signed pdf consent form via email;

b) Participants' data is anonymized—physiologic data collected with Apple Watch sensors, health information from questionnaires, participants' seizure and pill taking logs—are sent to JHU in encrypted form and stored securely with registration information kept separate from research data;

c) The EpiWatch research uses a novel data management program integrated with the Apple Watch and iPhone operating systems called ResearchKit. ResearchKit supports electronic consenting and encrypted data transfer from mobile devices for research. Apple has no access to the participant registration or research data. ResearchKit requires research app software to be open-access and non-commercial.

The EpiWatch app is designed to collect participants' physiologic changes and responsiveness during seizures in order to collect research data for development of a seizure detector that alerts caregivers when patients might need help. EpiWatch also provides tools that patients with epilepsy can use to keep track of and manage their condition; however, it does not provide direct medical care. Participants submit information about their seizures and treatment and receive brief daily surveys asking if they have had seizures and have taken all their medications. Seizure tracking and survey data are logged in journals that are displayed graphically to participants as feedback on their seizure control and treatment adherence. Other support activities being implemented will screen for problems often associated with epilepsy, including depression and anxiety, drug side effects and quality of life. These activities are designed to

provide helpful feedback on each participant's condition and support additional research in epilepsy. Participants may also choose to share this information with their physician to help manage their epilepsy.

Advantages of research performed on mobile devices:

a) A large anonymized national study can be conducted rapidly that enrolls participants of all ages and demographics;

b) Research data collected on mobile devices can be quickly accumulated to permit rapid development of medical apps which can help patients and potentially save lives.

For example, 1 in 500 persons with epilepsy die each year with sudden unexpected death with epilepsy (SUDEP); we plan to implement risk screening in the EpiWatch app for SUDEP. Our research priority is to collect data for development of a seizure detector that accurately detects the most serious seizure type associated with SUDEP—tonic-clonic convulsions in sleep. The detector could alert caregivers to allow them to aid patients during these serious seizures by repositioning and stimulating them to reverse respiratory dysfunction. We hope the research data collected with EpiWatch will support development of a future version of the EpiWatch app that does not depend on ResearchKit and can be migrated to other devices.

Potential data confidentiality and safety issues with medical app development:

EpiWatch research was implemented with careful review by JHU data safety engineers, a research data safety committee and computer scientists at a medical research server support company. It is important that participant confidentiality be maintained while performing this type of minimal risk research and to prevent data confidentiality breaches. It is also important to the public that medical apps be effective and safe before being used to support patients and that false promises about medical apps not be made. A seizure detector that does not reliably detect seizures might, for example, provide false reassurance to patients and caregivers. Disclosures and cautions about the limitations of medical apps are important in providing medical app support in managing serious medical conditions.

Recommendations on regulation of medical apps: The Supreme Court recently narrowed the patentability of mobile apps, ruling in *Alice Corp. v. CLS Bank Int'l*, that the patent protection for mobile apps is not extended to abstract ideas or simple software representations of existing techniques. This seems appropriate: patents for medical apps should require an innovative application of a new technology representing ingenuity and invention. JHU submitted a provisional patent for EpiWatch based on its novel approach to seizure detection and alerting.

The FDA recently (February 2015) issued a preliminary guidance for regulation of mobile medical applications (http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf). In these nonbinding recommendations, non-significant medical apps are defined as applications that help patients monitor medical conditions, but do not provide medical interventions; non-significant medical apps do not currently require FDA review. Significant medical apps involving medical interventions may require FDA review of the safety and effectiveness of the medical application. The continued development of sophisticated medical apps, however, will require policy development and elaboration of the FDA guidance. Our EpiWatch research app, for example, does not provide medical interventions such as triggering administration of a drug during a prolonged seizure. It is unclear, however, whether seizure detection and alerting falls

into the definition of being a significant medical device when not implemented as part of research. Because of this uncertainty, for example, we did not implement alerting 911 with GPS location during prolonged seizures. This is a potentially lifesaving step, but we did not want to test the FDA guideline during a period of app research and development. Instead, participants are allowed to send a text message to a caregiver whenever the participant begins tracking one of their seizures. This is not as useful because it limits alerting to evolving seizures in which the participant is initially alert. Regulatory review is important to protect the public from unsafe devices, but it also needs to encourage medical app innovations. Regulatory review is also needed to help adjudicate liability associated with use of medical apps.

Medical apps for mobile devices are likely to be segregated into large and small tiers: 1) non-significant medical apps not requiring FDA review will be relatively inexpensive to develop and will probably compete in a broad marketplace based on user reviews and demonstration studies; 2) medically significant medical apps offering sophisticated functions will require much more expensive and time consuming testing and regulatory review. Hopefully, these test and review requirements will not limit medical app development to the major medical device field, as this could slow innovation and narrow the range of disorders supported by medical apps. These issues, such as how to fund significant medical apps for less common diseases, would be helped by direct NIH support of medical app development in each division. It would also be important to determine in which instances insurance could be billed in order to support the development and regulatory costs for significant medical apps.

Thank you for allowing me to testify on the exiting new medical field,

Gregory Krauss, MD

The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University

Brief Biography:

Gregory Krauss, MD is a professor of neurology at the Johns Hopkins Medical Center, Baltimore, MD. He is a native of southern Oregon and received undergraduate training at Harvard College, medical school training at Oregon Health Sciences University and neurology residency and epilepsy fellowship training at Johns Hopkins. He is a clinician scientist who has helped develop many antiepilepsy drugs for various types of epilepsy, performs electrophysiologic research and conducts studies to help support patients with epilepsy, including studies of risks for driving, pregnancy outcomes and drug side effects. He is the co-inventor of EpiWatch research kit with Nathan Crone, Professor of Neurology at Johns Hopkins.

Chairwoman COMSTOCK. All right. Thank you so much, Doctor. And now we will hear from our final witness, Mr. Epstein.

TESTIMONY OF MR. JORDAN EPSTEIN,
CEO & FOUNDER, STROLL HEALTH

Mr. EPSTEIN. Great, thank you, Chairwoman Comstock, Ranking Member Lipinski, Members of the Subcommittee. Thanks for having me. My name is Jordan Epstein, and I'm the founder and CEO of Stroll Health, a startup based in San Francisco that helps doctors help their patients find better value health care. We started with the vision that when you go to your doctor, your doctor should do what's best for you, not just what's easy for them, or what they do for every patient, but what's actually best for you based on your insurance, where you live, and how much you can pay. And that's exactly what we do for 300 procedures.

In radiology today, when a doctor orders it through the Stroll app, we can show a patient what's in network, what's nearby, what their out of pocket cost options are, and, together with their patient, decide the best place to go. On average we save 30 percent, and 86 percent of the time send patients to lower than average cost care. If Stroll, or a Stroll-like tool, could be used for all non-hospital-based health care decisions in this country, we would save the nation $500 to $700 billion a year. That's a lot. So you would think that the National Science Foundation, or the Small Business Innovation Research Program would want to support this kind of research and development, but you'd be wrong. Stroll applied for, and did not receive, an SBIR grant. And when you look at the average age of an app developer versus the average age of a health related grantee, it's almost double. Too many of my generation are spending their time building apps for ads for mobile and texting, and we need to support those of us who choose to dedicate our time to address some of the toughest problems our nation faces.

In developing Stroll, we've come across a number of barriers. The first is we work with hundreds of insurance companies, and the protocols to do that are incredibly complex and arcane. Imagine for a moment if you're on, you know, a U.S. highway, except for—there were no speed limits, and whatever vehicle you wanted to be on, you could. Bicycles, cars, tractors, you name it, right? Traffic would be a nightmare, and that's exactly how the current U.S. architecture, you know, IT health care architecture works.

The second sort of problems that Stroll faced were on the regulatory side. So there's a number of regulations, including the Federal Anti-Kickback statute, that basically regulate how companies like mine, that try to improve efficiency and reduce the cost of care, can be compensated. So imagine again, for a moment, you wanted to buy an airline ticket, except there's no Progressive, there's no Kayak, there's no Expedia, right? You have to call each individual airline, and ask for a price, and what's available, and that's exactly how our U.S. health care system works today, and it needs to change.

The third sort of roadblock we've run into is just—as a small business that employs highly technical, highly skilled workers, we need to offer health insurance to stay competitive. What I don't understand is why I have to choose those plans for my employees. So

imagine again—let's say I wanted to offer a tax free transportation benefit. I could offer my employees a Lexus or a Ford, but only ones that had large cup holders and a V8 engine. That's clearly not best for my employees, right, and it doesn't foster innovation and competition in industry, but that's exactly the sort of decision I have to choose every time I make a health care, you know, plan decision for my patients—or my employees.

So, bringing it back to Stroll, we started with the vision that when you go to your doctor, your doctor can do what's best for you, and five to ten years from now, when you go to your doctor, they'll be able to tell you what's in network, what's covered, and you can leave knowing exactly how much it costs.

I look forward to your questions, and thanks for having me.

[The prepared statement of Mr. Epstein follows:]

Prepared Testimony and
Statement for the Record of

Jordan Epstein
CEO
Stroll Health

Hearing on
"Smart Health: Empowering the Future of Mobile Apps"

Before the
United States House of Representatives
Committee on Science, Space, and Technology
Subcommittee on Research and Technology

March 2, 2016

Chairwoman Comstock, Ranking Member Lipinski, and members of the subcommittee, thank you for the opportunity to testify today to discuss the role of mobile health apps in empowering physicians and patients to make value-based decisions.

My name is Jordan Epstein and I am the founder and CEO of Stroll Health, and for the past two and half years our team has worked to make healthcare easier to navigate and more affordable for the average American. We started with the belief that physicians and medical staff should make recommendations that consider the entire patient's needs, including financial responsibility--not just what is medically necessary and easily obtained by a provider. We realized that without immediate access to helpful information and software tools patients find it extremely difficult to find affordable, available, and high-quality care. Repeatedly studies have demonstrated that patients do not understand how their health insurance works or the metrics that matter in quality. While most want to know how much upcoming care might cost, only a tiny fraction are able to obtain cost information, and even fewer know how to switch to lower cost, better value care providers. And so we set out to build Stroll.

Stroll Health is a startup based in San Francisco. We make HIPAA compliant mobile and web apps used by both patients at home and by providers in a clinical setting. Our first app enables physicians and their staff to electronically order radiology procedures that are in network, affordable, and convenient for patients. To date, our clinical data demonstrate average savings of 30%, and with Stroll, physicians and their staff send patients to comparable quality, lower-than-average-cost care 86% of the time. If Stroll or a similar tool could be used in the decision-making and ordering of all non-hospital health care expenditures with similar effect, we estimate the US would save $500-700B each year.

In my testimony today I will discuss:

1.) **Stroll Health:** Stroll's technology and how it empowers physicians and patients to make value-based decisions.
2.) **R&D Funding:** Funding sources for research and development of mobile healthcare technology, and how the federal government could play a larger role.
3.) **Barriers:** Technological, regulatory, social, and privacy barriers Stroll has faced, and suggestions to improve the future development of technology.
4.) **Health App Market Overview**: Types of health apps, their function, and my beliefs on which should be supported by the federal government and how.

1. Stroll Health

Stroll Health is embedded in the US mobile and health IT landscape. We create technology that integrates with provider workflow, optimizing clinical choice for location of care based on cost, convenience, quality and more. Stroll acts as an easy-to-use tool to discuss, find, and order best

value care for patients and their providers. In real time, we process each patient's insurance benefit, tailor a provider directory to the specific test a doctor is ordering, and personalize the results based on what is in network, nearby, and lowest out-of-pocket cost for that patient. Together with the patient, providers choose what they and their patient believe to be best value care. We electronically follow patients across the care continuum, and track that they receive the prescribed care at the arranged price, in the most efficient way possible.

To do this, we use web scraping and big data to aggregate, process, and store hundreds of thousands of records, create statistical models to regress and smooth missing data, and utilize machine learning and data science to make improvements to our algorithms. Utilizing industry best practice enterprise cloud architecture, we meet or exceed HIPAA security standards. We actively integrate with clearinghouses and insurance companies, follow standardized protocols for communication across electronic medical records and practice management software, and daily deal with the clinical frustrations of missed reports, denied care, and forgotten appointments. To date, we cover more than 300 procedures in radiology, and for those tests alone, there are more than a trillion options that a doctor faces every time she picks up our app to refer care. Stroll processes patient insurance information and doctor preferences in real time, and in a handful of seconds shows the twenty or so options that are personalized to be the best fit for the patient. The doctor is then able to choose a quality, low cost provider together with their patient.

Today, our standalone public patient web app and private provider iOS tablet mobile app are used in the San Francisco Bay Area to find and order best value radiology imaging services. In the future, Stroll's Application Program Interfaces (API) and Software Development Kits (SDK) will be embedded in third party technology used by electronic medical records (EMR), telehealth companies, clinical decision support, and other consumer facing tools and more. With the rise of high deductible and narrow network plans, many patients fear interacting with the healthcare system in any way, including long-term cost-saving preventative care. In a world empowered by price transparency and real-time patient-centered decision support at the time of care, electronic ordering, and round-trip patient monitoring and reminders, we believe we can remove the complexity, decision fatigue, and confusion facing the average patient every day in the US health system. Whether a patient or provider knowingly uses Stroll or not, we hope Stroll will become the standard of care for ordering better value, more affordable health care services across types of procedures and the nation for years to come.

2. R&D Funding

Stroll is in the process of expanding from our clinical pilots in the Bay Area to integrating with some of the largest health systems in metropolitan areas across the country, including Washington D.C. We are also raising our first institutional capital from healthcare and technology venture capitalists across the country. Stroll has been supported to date through private grants and in-kind services from Robert Wood Johnson Foundation, Blue Cross Blue

Shield, Google, Microsoft, Wilson Sonsini Goodrich and Rosati, in addition to private angel investors. In addition, Stroll has participated in programs with some of the top research universities in the world, including the University of California at Berkeley (UCB), Cornell, Stanford, and the University of California at San Francisco (UCSF). Stroll applied for, and did not receive, federal funding via the NSF (National Science Foundation) Small Business Innovation Research (SBIR) program. Stroll never received any information regarding why our application was rejected.

More federal research dollars should be made available to app developers, particularly those outlined in Section 4 below. At the time we applied for an SBIR grant, we did not fit neatly into any NSF or National Institutes of Health (NIH) topic area. In the few years since, NSF has created a "Smart Health and Biomedical Technologies" topic, which should simplify and facilitate mobile health app developers looking for government support. Still, there is a disturbing trend in how dollars are allocated, particularly when you look at distribution of age and education across grantees. The average age of a mobile developer is 33[1] and 71% have college degrees, which are both significantly lower than the typical SBIR grantee, particularly related to health technology (the average age of an NIH SBIR grantee is 53). It is important for grant evaluators to recognize that the majority of successful innovators creating the sharing/app economy are young and early in their careers, and that awards should weigh the significance of the change more than the length of credentials. More development of clinically viable apps that improve quality of care, reduce the cost of care, and improve the patient experience is exactly what this country needs. Gifted app developers with experience in other fields should be supported in the endeavor, regardless of age or education.

Private funding alone is not enough. Even socially conscious investors expect a return, and when Stroll started, we did not know how we would make money. My cofounder and I simply believed that this was a problem worth solving, and if we solved it, we would find a way to make a business. Private investors, especially typical app investors, look for two key metrics when determining whether to invest--growth in active users, and revenue per active user. However, apps in the health care market like Stroll's need to be clinically tested, tuned, and studied to confirm efficacy, all of which take time that traditional investors tend to avoid in search of quicker returns. The federal government needs to fill the gap to take best practices and core technology from one field to another, especially in mobile healthcare applications, before they are ready to be commercialized.

In addition, the Centers for Medicare and Medicaid Services (CMS), the Department of Veteran Affairs (VA), and Congress have allocated millions of dollars to innovation and improvements to quality of care, yet very few app developers have received their support or funds to create new apps, nor have existing and independently developed apps received funding to be piloted to later commercial success. Many health systems now have both venture arms to financially back,

1 http://www.onlinedegrees.com/degree360/hot-job-report/december-2013-app-developer.html

and innovation arms to clinically implement and test new technologies. As the nation's largest payer[2], the government would be the largest beneficiary of spearheading this effort.

3. Barriers

While many of the barriers Stroll Health faces are specific to its deep data and provider integrations, none are unique. In no particular order, the following are some of the issues we face, along with recommendations on how the federal government can help mitigate them.

Technological Barriers

Standardization for Machine Readable Plan Benefits and Provider Networks
Congress should mandate standardization for communicating in-and-out of network provider designations and plan benefit specifications that are updated on at least a weekly basis. Few payers, if any, provide such information in a machine readable format, and many payers provide plan benefit information in ways that have non-standard, second-order definitions, leaving benefit experts, patients, and even their own call center staff confused about which benefits apply when, and for whom (examples include designations such as "choice" and "outpatient free standing"). Even for CMS, with some of the most standardized network and plans in the country, it is near impossible to determine which providers are participating, non-participating, balance bill or are privy to the Outpatient Prospective Payment System (OPPS)--all of which, and more, are "in-network" Medicare providers.

Standardization and Electronic Protocols for Utilization Management
Utilization Management (UM), the umbrella term used when a provider has to go through a third party to ask a payer for permission to perform medically necessary services, is an incredibly complex and time consuming aspect of our health system. Many studies suggest that no savings are actually created, and instead simply shift the cost burden from payers to providers. In addition, sometimes necessary care can be delayed by weeks or more, resulting in detrimental outcomes for patients. While I do not disagree that some level of population health management needs to be exerted on providers, the existing method of requiring providers to use separate portals or fax machines for each payer, and make sometimes three or more phone calls as a review escalates from agent to nurse to peer-to-peer is entirely outdated, dangerous, and wasteful. Instead, Congress should mandate electronic UM standards and require payers to adopt them, including Medicaid (and Medicare when it adopts UM standards in 2019).

Interoperability
Every electronic medical record (EMR), picture archiving and communication system (PACS), practice management system (PMS), and radiology information system (RIS) should have standardized APIs for accessing patient information and sharing with other providers as

2 http://www.americanhealthpolicy.org/Content/documents/resources/Government_as_Payer_12012015.pdf

appropriate. Alternatively, such systems could integrate with a health information exchange (HIE) or single, standardized data aggregator, which would then allow easy, standardized integrations. Congress should direct industry to set these standards, and set a timeline for adoption, with penalties for non-compliance. Without such policy, apps like Stroll literally have to integrate with more than 1,000 other software systems in complex, expensive, unique point to point integrations, which will likely never happen and thereby limits the scope and benefit of such apps.

Data Barriers

Electronic Eligibility Data
While most payers have some sort of mechanism for communicating electronically with clearinghouses and providers, many do not, especially safety net, county, Medicaid payers, and many state and federally funded plans like Children's Health Insurance Program (CHIP) and Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA). Apps such as Stroll and others cannot interface with these payers without this data, which prevents their enrollees from receiving any of the benefits of these apps.

CMS Claims Data
While in recent years CMS has done an admirable job of releasing data sets, it still preferentially shares only some of its data, often with researchers and non-profits, and sometimes to private for-profit businesses as well. If de-identified data is safe to be shared with one company, it should be safe to share with all. Today server and sharing costs are so low, there is no justification why smaller companies and app developers have continued to be locked out of this data.

Quality data
While Medicare has made strides in advancing quality metrics and outcomes measurement, there is still little useful data for entire segments of patient care, including radiology. The continued use of outdated and obsolete equipment, or providers without the correct subspecialty, can directly cause inferior patient outcomes. CMS should create more and more relevant quality metrics, and make those easily available to app developers via an API format.

Regulatory Barriers

Health Insurance Portability & Accountability Act (HIPAA)
HIPAA is not designed for today's health IT market where a non-clearinghouse, highly technical organization that sees no patients and has no physical servers goes to market using modular service integrations. The technical standards are relatively easy to understand and implement given today's enterprise security and privacy architecture, but the law needs to be simplified. In particular, with today's complex "app-in-app" and data sharing infrastructure, it is not always clear who should be signing a Business Associate Agreement (BAA) with whom. This can lead to an arduous process of, for example, integrating with an EMR, only to have to obtain

authorizations from each individual provider on a case-by-case basis, even when the total solution is already authorized by the provider with a BAA in place. This problem does not affect just small app providers, but also some of the largest, most innovative, publicly traded healthcare IT companies. While I applaud the Department of Health and Human Services (HHS) Office for Civil Right's (OCR) recent guidance on when HIPAA might apply to apps[3], it needs to make clearer when patient permission is needed, when a BAA applies and to whom, and what sort of communication is permissible to patients without explicit consent.

Gag Clauses, Most-Favored Nation Clauses, and Usual, Customary, and Reasonable (UCR) Rate Clauses

Healthcare providers and payers should be able to share fee schedule, claims, and other data freely with app and other technology providers without fear of legal recourse. However, most contracts that describe fee schedules expressly prohibit sharing data (Gag Clauses). Even without those clauses, many providers still won't share their pricing data because they are afraid that one payer might see lower rates and decide they should also be entitled to them, regardless of their negotiated contractual obligation (Most-Favored Nation Clauses). Finally, some contracts with payers note that if a provider offers lower rates on an UCR basis, that that rate somehow will become the providers new contracted negotiated rate. This inhibits providers from wanting to offer discounts based on availability and more. In order to make healthcare a free market and drive competition, these types of price control provisions should be prohibited at a federal level.

Stark Law, Federal Anti-kickback Statute (Federal AKS), False Claims Act

In every other industry (and indeed for selling healthcare insurance plans), it is entirely legal and indeed beneficial for society for a company to receive remuneration for connecting a buyer and seller (i.e. Expedia), such that efficient markets can be made and competition can determine consumer costs. The Stark Law, AKS, and False Claims Act together do the exact opposite, and are written so broadly as to make illegal to even "offer" to be paid, much less actually be paid, for such market-making activity. In total, these laws create a fear of felony conviction and high fines, and larger companies have added entire legal strategy teams whose responsibility is to validate the appropriateness of their payment schemes within the confines of AKS. In addition, there are 36 separate state-level AKSs that interact with the Federal AKS. Such laws directly inhibit innovation in the field, especially by small mobile health app developers, and such laws should be changed.

I propose the following amendment:

Currently, monetary or other in-kind incentives to providers are illegal. In-kind incentives should be re-defined to make clear that "controlled, two-way" communication devices for the purpose of communicating between providers and payers, so that being paid for new innovation in electronically passing ePHI and improving workflow efficiency in clinics and medical settings are expressly allowed. In addition, businesses and apps should be allowed to be paid for directing

3 http://hipaaqsportal.hhs.gov/community-library/accounts/92/925889/OCR-health-app-developer-scenarios-2-2016.pdf

patients to lower cost, better value care. Ideed this is the whole concept of the modern risk-sharing and accountable care organization (ACO) arrangements. As long as there is no financial influence on the provider for a specific choice, it should be made clear that this is allowed, just as numerous private companies already do this at the employee level. Stroll Health, in conjunction with Cornell University and Robert Wood Johnson Foundation, are currently conducting research on this topic, and funding further studies are recommended on both the potential financial impact from this policy and on clinical pilots of this technology. If effective, I believe that making clear that market making tools are allowed and beneficial will dramatically reduce the cost of American healthcare.

Reimbursement Barriers

As CMS goes, so too does the rest of the commercial healthcare market, and establishing a unified policy on telehealth visits, reimbursement and codes for mobile health apps and devices needs to happen.

Operational Barriers

Small Business Health Benefits
Providing health care benefits is essential to attracting highly skilled software talent in extremely high demand. However, procuring healthcare for a small company is expensive, time consuming and financially inefficient. If a company provides healthcare to its employees it is entitled to a tax deduction for the expense and the employee does not pay income tax on the benefit. But small company employees would enjoy more choice and better value if they could secure their healthcare independently via a private or public exchange. Allowing the company to reimburse the employee or providing a voucher (without such payment to the employee being taxable) would greatly simplify healthcare procurement for small businesses, lower costs and improve portability and coverage for employees.

The current system creates a series of inefficient and negative financial and social consequences, which I outline below:

Negative financial impact from directly providing employee health insurance

1. Businesses pay an additional 3-7% indirectly in premiums to cover the cost of brokers
2. Businesses have to define their own healthcare package and customize benefits for their employees, which complicates the system unnecessarily and adds costs to pay the middle man, human resources staff, and for providers, payers, patients, and administrators downstream
3. Businesses and their employees are divided into smaller risk pools, thereby increasing the insurance risk and cost of insurance
4. Business pay for higher actuarial value insurance than their employees ideally would like (and in most cases, they would prefer to have the marginal healthcare dollar to spend as they choose)

Negative social impact from directly providing employee health insurance

5. Businesses tie their employees' benefits to employment at their company. If the employee leaves, they lose their insurance, thereby reducing liquidity and efficiency in the labor market.
6. Businesses limit the opportunity of plans and payers to only those that the broker or HR department decide to customize in the "best interest" of their employees

I believe that clarifying the Internal Revenue Service (IRS) tax ruling and allowing small businesses to provide employees with a Health Savings Account (HSA) compatible voucher with the same tax treatment as directly providing insurance would help mitigate these issues.

4. Healthcare App Market Overview

The mobile health technology field is incredibly diverse, consisting of the following segments:

- Consumer wearables, fitness, wellness and other bio-monitoring trackers and accompanying apps
- Consumer search, information, and ordering tools
- Telehealth/Digital therapeutics
- Medical-grade diagnostics, remote patient monitoring
- Care coordination, patient communication and payment, and patient medical record apps
- Provider workflow and communication tools
- Clinical decision support

I will discuss each category below:

Consumer wearables, fitness, wellness, and other bio-monitoring trackers with accompanying apps
(i.e. Fitbit, iHealth, myFitnessPal, MapMyRun, Pacer)

These are apps and gadgets used for a variety of cosmetic, fitness, and leisure purposes. These applications provide users with continuous access to health information and quick, easy-to-understand health metrics. However, these products typically lack clinical viability, and physicians often distrust these apps and devices due to lack of accuracy and emphasis on self-reporting. From both a regulatory and consumer threat perspective, I believe that the FDA's approach to enforcement discretion is adequate, and that consumers are fairly warned about privacy and efficacy in terms of use. It is unfortunate that without the clinical evidence of effectiveness, some employers have tied usage of such devices with incentives for healthcare

insurance rebates. My belief is that the marginal healthcare dollar can be spent in a more efficient manner.

Consumer search, information, and ordering tools
(i.e."Uber" for healthcare apps, ZocDoc, iTriage)

These apps attempt to provide quick how-to's, explanations and diagrams, and bookings for healthcare services, and there are two levels in this segment. The first is the general repackaging of material already found online into a user-friendly, easy-to-understand format, requires neither regulation nor federal funding. The second is a much more specific type of application that use big data, machine learning, data science, and statistical modeling to create new insight and value. Because this second segment typically has long development cycles and unpredictable returns, especially in the short term, some allocation of government funding to this category is in the nation's best interest, as it will enable the technology to demonstrate effectiveness and subsequently become commercially viable.

Telehealth/Digital therapeutics
(i.e. Teladoc, Omada, DoctorOnDemand, HealthTap, Pingmd)

Telehealth and digital therapeutics attempt to replace a doctor or provider visit and provide guidance for follow-up steps to maintain weight and stay healthy. Overall, large self-insured employers have been especially enthusiastic about paying for this technology, which has made private funding of such technology in the capital and venture markets relatively easy and frequent. These apps appear to be reaching a maturation of the technology and product features, and there are large numbers of them. I anticipate a market consolidation, largely to the benefit of the average American consumer. Regardless, while reimbursement changes are needed and should be led by CMS, no further government funding is needed for this type of apps.

Medical diagnostics, remote patient monitoring
(i.e. Proteus Digital Health, Eko Devices, iRhythym, Vital Connect)

Monitoring and diagnostic apps and their accompanying hardware improvements propose a net benefit by improving access to care, enhancing the patient experience, and reducing the cost of care. Examples are monitoring programs that can track data such as patient heart rate, vital signs, and blood sugar levels and transmit this information securely to health professionals. Another example is technology empowered stethoscopes that can use big data and machine learning to find trends where a simple scope cannot. It is in the nation's best interest to support such apps with federal research dollars, and more of these diagnostic tools could rapidly come to fruition with a relatively small investment.

Care coordination, patient communication, and patient medical record apps
(i.e. MyChart, The Patient Portal, eClinicalWorks Patient Portal, CareMessage, CareNotify)

An incredibly important part of the healthcare app ecosystem, these applications prevent unnecessary doctor visits and duplicate tests, and strengthen patient compliance to physician recommendations and medications. Technologically, they are not particularly complex, but provider-specific barriers and the diversity of the health IT landscape hinder wider adoption of such applications. A number of the proposed policy changes presented earlier in my testimony might help to remove many of these technological barriers. Due to its low risk and complexity I do not believe additional federal funding is necessary to speed adoption or development of this technology.

Provider workflow and communication tools
(i.e. TigerText, Doximity, Stroll Health, DrChrono, DocBookMD)

This is an incredibly broad category, including EMRs, peer-to-peer texting apps, and more. These applications allow for quick communication between healthcare team members, improving clinic efficiency and flow. In general, I believe sufficient federal funds have been spent on EMRs through the Health Information Technology for Economic and Clinical Health (HITECH) Act. However, while that act has substantially accelerated adoption of such technology,the lack of adequate standardization has interfered with interoperability. Many states have taken it on themselves to create their own HIEs, and it is important that such HIEs should be funded and administered at the federal level, or new regulation and policy should be created to mandate adoption of interoperable standards.

Clinical decision support
(i.e. UpToDate, Medscape, Medcalc, Epocrates, Skyscape)

Clinical decision support apps help physicians make proper diagnosis, perform appropriate tests, and prevent errors. While there are many clinical apps for specific specialties and drugs, almost all focus on medical outcomes but fail to engage patients, improve their experience, or reduce the cost of their care. More apps should focus on value and the total cost of care, and because such projects typically require long development times and clinical trials, government support and funding should be available to speed commercial release and to improve outcomes.

Conclusion

Medical mobile apps like Stroll have the promise to reduce the cost of care, improve outcomes, and enhance the patient experience. While many barriers to adoption and commercial success exist, Congress can adopt legislation that will improve access to data, reduce burdensome regulation, and provide funding to accelerate development and adoption of these beneficial new technologies. Thank you for the opportunity to testify, and I look forward to your questions.

Witness Biography

Jordan Epstein

Jordan Epstein is the founder and CEO of Stroll Health, which makes software applications that help doctors and their patients find and follow through with lower cost, best value health care. Prior to Stroll, he worked on the client services team of Merced Systems, a business intelligence startup. After their acquisition by NICE Systems (NASDAQ: NICE), he led development of the small and medium-sized business (SMB) performance management product line, which today is used by hundreds of thousands of people on five continents. His clients have included such Fortune 500 companies as United Healthcare, Kaiser, Delta Airlines, and Chase. He holds a B.A. from Carleton College.

Chairwoman COMSTOCK. Thank you so much. Boy, this is so exciting, to hear from all of you. I really appreciate your expertise, and all the things you're working on. It strikes me, as I hear all of you speak, and certainly with your personal experiences, that this really is going to require some really different thinking. This is sort of the Uber economy and health care. How are, you know, and I have a number of doctors in my family, and I know oftentimes they're like, well, we have to decide, so—the doctor knows best. And this is turning this on its head a little bit, where we're going to use our knowledge and understanding, but also the technology, which is probably more precise in many cases.

So what kind of resistance, if any, are you—I think—lot of resistance, so that's very helpful. But what kind of resistance are you seeing, if any, hopefully not much, to this kind of thing, and what can we do to assuage that resistance that the medical field might have? Mr. Reed?

Mr. REED. Yeah. I think one of the things we have to consider, it's very easy for us in the technology industry to say, the doctor is wrong, and, you know, be disruptive, and welcome disruption in their lives. But what I've found is that physicians are as frustrated by the regulatory requirements, and the barriers, and the questions about reimbursement as anyone. The AMA had a recent study that showed a 30 percent decrease in efficiency due the way that the failure of EHRs to be interoperable had created, and, frankly, bad user interface design.

So I think we have two real problems that's we're facing with physicians. One, physicians are uncertain about how to accept that data, and the accuracy of the data they might accept. And then, two, what are the liability that extends to them if they accept that data and they don't act on it? And then the overarching question is, if they take the time to review the data, and engage with a patient in that way, how does that figure into their reimbursement?

So I know this Committee's jurisdiction touches on the edges, but we are all frustrated with the physicians, but I think I would speak for the—my meetings with the AMA and others in saying that they're frustrated right along with us.

Dr. SHAW. What I work on, retinoblastoma, it's highly specialized. So pediatricians, ophthalmologists, they actually know peer reviewed studies have shown that mom, then grandma, then dad, are statistically the first people to catch the symptoms of retinoblastoma. And the primary test that the pediatrician uses, shining a light into the eye, this is called the red reflex test. It's notoriously ineffective, and everybody knows it.

So the doctors that we're working with, I mean, they love it. I haven't——

Chairwoman COMSTOCK. Yeah.

Dr. SHAW. I haven't encountered any resistance——

Chairwoman COMSTOCK. Great.

Dr. SHAW. —from the practicing pediatric, or ophthalmology, or oncology community.

Chairwoman COMSTOCK. That's great news.

Mr. LOOK. So Type1 diabetes I think is a great example of this. It's one of the only diseases where you are literally prescribed a deadly hormone, right? If you take too much of it, it will kill you.

There's a shortage of endocrinologists in this country. Most endos see their Type1 patients four times a year for maybe 15 or 20 minutes. The other 361 days a year, the patient is on their own. So most endos love engaged patients. Patients who engage with their data and understand what a fine line it is to deliver good insulin doses do better.

Chairwoman COMSTOCK. And in terms of the data sharing that was mentioned earlier this morning, when we were talking about, you know, cancer patients wanting to share data and get to share that, I guess, you know, maybe we need to have some legal changes, liability changes, but do you think in that area, as we share that data, you're going to see, like, well, this, you know, so this is the, you know, the person who's done the best with Type1 diabetes, not doing any damage, have done these things, so as you're tracking through, you sort of have a goalpost of all these thousands before you that you can stay in the zone to get, you know, the A level of performance from something like this.

Mr. LOOK. By and large, in the world of Type1 diabetes, there is not resistance to sharing data. People understand that by sharing their data, they're doing better for the community. And when there's a large pool of data, it means that not only doctors can see how patients are achieving effective therapy, but you can even start imagining effective ways of computing insulin doses. When my daughter walks into California Pizza Kitchen and orders the five cheese margherita pizza, she should be able to look on her phone and see how did other 16-year-old girls who ordered that same pizza dose for this effectively, and help to come up with a better insulin dose that way. So, by liberating the data, we allow for more engaged patients, and much more effective therapy.

Chairwoman COMSTOCK. And I have to imagine, as a parent, that gives you a lot more peace of mind too.

Mr. LOOK. That's right.

Chairwoman COMSTOCK. Yeah. All right.

Dr. KRAUSS. One interesting thing we found is that, actually, patients want to control their own health data. So when we collect tracking data about their pill taking, or the number of seizures, they actually don't want that to go directly to their doctor. They want to receive it, and then show it to their doctor, potentially, and they're quite willing to come in for appointments and have their device optimized.

But that's an interesting feature, but it's one that we use also, so we want to optimize our graphing, and show relationships between missed pills and seizures. We have a participant, like me, graph so they can see how other people with the same condition, same age are doing. But that was an interesting finding, yeah.

Chairwoman COMSTOCK. Okay.

Mr. EPSTEIN. Okay. So bringing it back to, you know, kind of doctors using apps, we actually make apps for doctors, right? So we've encountered lots of resistance. The first is, as Mr. Lipinski pointed out, there's 100,000 apps, right? So are you really going to ask a doctor to use—no way, right? And so basically, you know, when we talk to doctors, we have our own app, but they're like, put it in the EMR. And really kind of—if you think about the EMR as the sales force sort of model, where you basically stick a whole bunch of

apps—and the doctors don't even know they're separate apps. It's just a widget within the app, right? And so you have, you know, one for blastoma, you have one for, you know, all these different things, right? So that's kind of, I think, where the future is——

Chairwoman COMSTOCK. So we really need to make that just available directly for the patients, and not having any blocking things? Because the doctors can't possibly know all the things.

Mr. EPSTEIN. Or, right, make it easier, so HHS is just putting this interoperability thing, you know, freeing the data to allow doctors to be able to say, look, in my EMR I can control it how I want to control it, with whatever apps that I want, right? So that's exciting.

And then when you think about, again, this work flow problem—so, again, if you were trying to diagnose, or trying to use any of these things, you're saying, I have to do a new thing, right, as a doctor. I used to do this, and now I have to do something else, right? And so that's one of the biggest things that we've, you know, faced, is how do we reduce work flow for physicians, right? And so, I mean, that's——

Chairwoman COMSTOCK. All right. Thank you very much, and I'm over my time, but I really appreciate it. I'm——

Mr. REED. If I could borrow some time from Mr. Lipinski really quickly, I think it's interesting that Dr. Shaw, Mr. Look, and Dr. Krauss all talked about access to data. But one of the problems that we do see is that much of the guidance around remote patient access to data on HIPAA pre-dates the iPhone.

Chairwoman COMSTOCK. Yeah.

Mr. REED. Now, they've done some new stuff, but 2006, for the guidance, iPhone came out in 2007. So as you're considering the places where there's movement, there is room there.

Chairwoman COMSTOCK. Thank you very much. Recognize Mr. Lipinski for five minutes.

Mr. LIPINSKI. Thank you. I want to follow up on what Mr. Epstein had just mentioned about the—how the Office of the National Coordinator within HHS had recently released the final rule on expanding electronic health information, access, and exchange. Now, the rule requires that mobile health app vendors develop apps with an open application programming interface that allows the user to share data from her mobile health app with her electronic health record.

So, Mr. Epstein, is there anything else that you wanted to add on that? Is there anything more that needs to be done on interoperability? I wanted to see if anyone else had any comments on that.

Mr. EPSTEIN. Yeah, absolutely. So, on the app side, I think I can speak for all of us, but maybe not. We all use APIs, right? That's the standard, right? But when you talk to the EMR vendors, when you're talking about, like, Epic, and, you know, these guys, right, that's really the problem. It's not us, right? We want to get in with those guys, right? We want to integrate with the system, right? And it's really, how can we get in?

And so, you know, the current process today, there's both these technical barriers, right, but then there's also—I have to actually go first sell—there's no easy way to do it, right? I have to go through this long contracting period. I usually have to get the doc-

tor or the health system to vouch for me to get into these guys, right? There's no standard process. And then on top of that, in terms of HIPAA regulations and data sharing, as Mr. Reed was, you know, pointing out, the standards are totally unclear for what we're supposed to do.

So, for example, we're integrating with AllScripts and Athena, right, large publicly traded EMR vendors, right? For one of them I assigned a subcontractor, BAA, with one of them, which I think is the correct thing to do, and with the other one I literally have to go doctor by doctor to sign a new contract with every single one of them, which makes no sense at all, right? But it's unclear what we're supposed to do with how the laws are written, so——

Mr. REED. I would say that NIST has a role to play. We all believe that better user interface design is absolutely critical. They have some oversight in it. Originally NIST was powered in part to help with the interoperability. I think we all know there were some misaligned incentives for the EHRs, in terms of creating the interoperability that we all need. We're all exploring open APIs, and there are projects underway to improve it, but realistically I believe that the motivation will have to come elsewhere. The major vendors recently signed a pledge about no data blocking. That's a nice start. We want to see that continue to grow, and an acceptance of either open APIs or other systems that allow for better interoperability.

Mr. LIPINSKI. Anyone else? Go ahead. Can you pull the mic a little closer?

Mr. EPSTEIN. You know, turn it on. You know, basics. Yeah, sorry. So everyone is talking about interoperability between EMRs and apps, right, but there's also another type of interoperability that's not talked about very often, which is also incredibly important, which is interoperability with insurance companies. And there needs to be standards there. It's a—literally that highway analogy that I told you is how it works today, and it—it's almost—it's so difficult for a company like mine, that's trying to say, look, what is your benefit, where can you go, how can I help you, and the insurance companies don't want to do that.

And that—it's the same interoperability problem, actually, for doctors talking to those insurance companies with a—what's called a prior authorization process. You have to literally go—with phone calls, right, with—you have to get the nurses, you know, back and forth—you have to do a peer to peer with physicians, right? This is all just standards. This should be in the API connection. I should be able to ask you, and you should be able to tell me electronically, and we're done.

Mr. LIPINSKI. Thank you. I just—very quickly, before I get to my next question, I want—so here's my blood glucose monitor, and here's my pump PDA. So I'm looking forward to looking at and trying out Tidepool, although it's a lot of information to put in there. And it's a matter of actually getting myself to do that. The issue that is—you talked about——

Mr. LOOK. We try to make it easy, so——

Mr. LIPINSKI. Connect——

Mr. LOOK. —you know——

Mr. LIPINSKI. But it still takes time. The issue with connecting these two, which you said you have done—the issue, as my endocrinologist has told me for a number of years, is a liability issue. There's no technology issue whatsoever, so—but that's something beyond where—what we can do here, but I just wanted to mention that. And—before I ask my last question on price transparency. Again, Mr. Epstein, you—it's been, you know, I've been trying to do this for the 12 years I've been in Congress, is get to more price transparency. There's been some work that's been done—requirements that have been done at the federal level. How do you get the prices? The providers don't want to provide the prices. And then you have—the insurance companies have their, you know, the rates that they negotiate. The insurance company has a different rate with the hospital. How'd you get at this?

Mr. EPSTEIN. Yeah. So the long answer is talk to me afterward and look at my written testimony, but the short answer is it's really not easy at all. We work directly with providers. We try to get fee schedules. We try to get claims data. Again, there's, you know, gag clauses, and all sorts of, you know, most every nation clauses, all—and these contracts they sign with insurance companies, all of which, I think, should not be allowed. In California, for example, gag clauses are not allowed, so I think at a federal level there's more that we can do there.

But basically, you know, the way that you have to do this is you've got to get—first, what's in and out of network, and there's no standards on that right now for insurance companies. There need to be, right? Because, you know, just as an average patient, like, where do I go? Come on, guys, right? And even if you call your insurance company, they can't tell you. So there needs to be standards there. And then when you get to the fee schedule component, you know, there's lots of companies, like Castlight, like my company, that look at claims data that try to process these things, that write statistical models, but it's just not easy. It's really a complex problem.

When you look at the—kind of the scope of what Stroll does, you know, for an individual doctor trying to make a decision, there's more than a trillion options, with a T, trillion, when you're trying to figure out where a patient can go that's best for them. So it's really not an easy question.

Mr. LIPINSKI. Thank you.

Chairwoman COMSTOCK. Thank you. And I now recognize Ms. Bonamici for five minutes.

Ms. BONAMICI. Thank you very much, Chair Comstock, and Ranking Member Lipinski, for having this informative hearing. This topic is—in this Committee, we're frequently reminded of the challenges of regulating and legislating around technology, because the technology advances so much faster than the policy. And the example about HIPAA, you know, it was back when we had landlines and pagers. You know, it's really time to update a lot of these things. And there's some great examples from my home state of Oregon.

Dr. Krauss, I saw you spent some time at Oregon Health Sciences University. I, last fall, met with some entrepreneurs from OHSU. They developed Provata Health. They got a grant from

NIH, and it's a wellness digital health program. And they're using it with Oregon's public employees, educators, and families, and seeing tremendous progress and improvements in nutrition and physical activity just through the digital health program. For example, the Portland Fire Bureau said they're saving about $1,000 per firefighter just because of using this. So there's a tremendous amount of potential. The director of the OHSU Knight Cancer Centers Institute on Melanoma Research, and a cancer biologist there, Dr. Sancy Leachman, and the biologist, Dan Webster, created an app to help users track moles for science in melanoma. So there's just a tremendous amount of potential. And as we look at ways that we can help patients receive better care, and improve diagnoses, it's really important for us to look at the potential here, and evaluate these tools.

I really appreciate your innovation and, you know, Mr. Look, and, you know, your personal stories about—Dr. Shaw, how you stepped up and filled this need. I serve also on the Education Committee, and I have founded and co-chair the STEAM Caucus to talk about the importance of integrating arts and design into STEM so that we have an innovative work force, and creativity, and innovation. So this is yet another example of where design is important. I know that—I think the NSF, their Smart and Connected Health Program goal, is to help transform the health care system to one that's more reactive.

One of the largest, as you know, health information technology conferences is happening this week, and focusing on some of the behavioral aspects of these apps. So can you talk a little bit about the design, and how important it is that these apps be useable, and how has design played in your design—how has design played a role in your development of apps? Who wants to start? Mr. Reed? Mr. Epstein?

Mr. REED. So, very quickly, I use an example of AirStrip. It is a vendor that actually puts live wait forms in the hands of physicians on a screen. Like, this—it is amazing in its ability for a physician to actually quickly go through, look at live wait forms, spin out, pick something in particular, look at the event, move it on, transfer it to another doctor, all on their iPad, while the patient is still in the ambulance. And so the design of that is critical.

Notice what I didn't say. I didn't say pull down menu. I didn't say a login screen, followed by a pull down menu, followed by a sidebar, followed by a pullover. It's got to be touch sensitive——

Ms. BONAMICI. Right.

Mr. REED. —obvious in its usefulness, and responsive in its design.

Ms. BONAMICI. And, Mr. Epstein, I know you say something in your testimony about removing the complexity and decision fatigue, I think is what you said, and confusion facing the average patient in the U.S. health system. So can you expand on that, and how your app has changed a person's management of their health care?

Mr. EPSTEIN. Certainly. So if you look at—I was just talking to Providence Health Care. I was at that large conference in Las Vegas yesterday, right? And so if you look at the average number of clicks that would go through to ordering a radiology procedure, it used to be 20. 20 clicks, right? So now it's four, with Scroll. And

so when you think about, you know, just, you know, what you have to do, it needs to be easier. And when you think about, like, login screens and things like that, that's actually required by HIPAA. So, you know, we should think—and do you know what—the first thing that—when I go talk to hospitals, you know what they ask me? They say, can you make it an auto login?

Ms. BONAMICI. And? Yes, Mr. Look?

Mr. LOOK. So a lesson I learned working at TiVo, an easy to use consumer electronics device, is if you don't make it simple, and approachable, and intuitive, it will fail. A lesson that Silicon Valley has taught us is you have to iterate. You have to try something, test it, try it again, test it, try it again, test it. We've tried to apply both of those to everything we do at Tidepool. Design is at the core of everything we do. Our UI design lead, Sarah Krugman, has been living with Type1 diabetes since she was six years old, so she has empathy for the people that she's designing for, and then she gets to iterate, and try and try again. One of the challenges is the regulatory structure tends to be design up front, test, release, not iterate, try, iterate, try. So I do think we can do more.

Ms. BONAMICI. Right. And, real quickly, I mean, we also talk on this Committee a lot about cybersecurity, and data breaches, so are you all convinced that we can do this, and protect people's privacy, but still make everything more efficient, more usable? Because, you know, it's not like we're logging in to buy a plane ticket or something. You know, this—health issues are sometimes really urgent, and we need these things to be easy to use. Are you all convinced that we can do this and protect privacy?

Mr. REED. Yes.

Mr. LOOK. Yes.

Mr. REED. Yes.

Mr. LOOK. 100 percent.

Dr. SHAW. Yes.

Mr. REED. But I would point out that yesterday we had a hearing in the House Judiciary Committee where we had FBI Director Comey and Cyrus Vance basically take a swing at the idea of the kind of security that we're all talking about. And we are all confronted with the reality that, on one hand, you have Comey saying, well, I don't know about this encryption stuff, at a certain level. And yet NIST is telling us in order to protect the patient privacy and health that we must engage with high level cybersecurity elements, like encryption. So we asked Congress to make sure they're giving us the right message, and make sure the solution makes some sense.

Ms. BONAMICI. Well, I look forward to working with my colleagues in breaking down some of those barriers. I yield back. Thank you, Madam Chair.

Chairwoman COMSTOCK. Thank you. And I now recognize Ms. Esty for five minutes.

Ms. ESTY. Thank you, Chairwoman Comstock, Ranking Member Lipinski, for this really important hearing today. To Mr. Look, with a brother who has Type1 diabetes who's also a triathlete, this would improve his life. I'm going to make sure he gets on board. As a mother who took many, many pictures, Dr. Shaw, I think empowering consumers, parents, to really use technology to look for

things—as the one who checks my husband's moles—I mean, we are starting to take pictures. And we talk about this. Like, I should be taking pictures, because you're only going to get in, you know, it takes you 2 months to get in and see the doctor. So, for all of you, it is critical that we do this, not just to save money, but to save lives, and to empower Americans to lead healthier lives. It can't be about going to see your doctor and fixing the problem after the fact. How do we keep ourselves healthier for longer? And I think we're all committed to that, because that's the goal, not more health care. It is healthier lives. So I want to thank you all for your work.

In Connecticut we're doing a lot of work around stem cell research, personalized medicine, all of these things that are going to be so important. And when I think about the privacy issues, we're using our fingerprint to open our phone. That kind of is a personal identifier that ought to be able to unlock these things pretty quickly. So it seems to me we should be able to solve that problem, I hope, in ways that meet the tests that we are being challenged with otherwise.

Dr. Epstein, you had—in your testimony you talked about—Mr. Epstein. I know, I—as somebody who grew up in Minnesota, I figure, Carlton, I'm just going to elevate you to doctor. You're—it's the spillover effect of all the doctors around you. You talked about how when you applied—when Stroll applied for—to receive federal funding through SBIR you were turned down, and you went elsewhere. You went to the private sector. Now, these programs are up for reauthorization. Can you talk to us a little bit about—what should we be looking for? What should we, as Members of Congress, be doing about critical roles in federal funding, which we fight for every single day in this committee on basic research, and yet you are raising some really interesting and troubling questions about whether we're going after it the right way.

Mr. EPSTEIN. Great. Thank you. Yeah, so I'm all for those programs, and I think, you know, there's two questions. One, is there, you know, enough money for those programs? And then the second is, you know, is the money going to the right places, right? You know, I think probably the answer is no to both of them, right? But, you know, I won't talk about the absolute management of the money. But in terms of—especially, you know, for app developers, right, I think it's great that we have, you know, a number of doctors, you know, that are here that have, you know, tens of years of experience. But there's also, you know, people with, like, you know, a couple years out of college that really have great ideas that don't, you know, need to make very much money, right, that really just want to make a difference.

And when you look at, you know, what $150,000 can do for this country, like, you know, let's say, you know Stroll is not successful, right? Let's say there were 100 Strolls, right? That's, what, $15 million, right? We're talking about $500 billion that, you know, how many bets do you want to make? And I think it's worth taking those bets, so, you know, and I think it's really, you know, how those programs are administered, and who is reading those applications, right, and who has the experience to say, like, is it—do we believe this person can do it, and is it a worthwhile endeavor?

Ms. ESTY. Thank you, and I may follow up more on that, because I think that's exactly where there is a role for federal government. We have a market failure, because if you're trying to save money, it's not clear who's going to collect that money, and the apps are designed for free, and you're not going to charge people to use them. So we do have a real compensation issue, and incentive misalignment. So I think—the other issue I wanted to ask all of you about was this question about iteration. And we run into that all the time in this Committee. You know, the legislative process is designed to be slow, and yet technology is moving very, very fast. And so we have, you know, we're dealing with agencies who are struggling who have 15-year-old systems, to say nothing of trying to deal with apps.

Any of you want to talk to us a little bit about how, as responsible policymakers, how do we think about, you know, what can we responsibly look to do to vet ideas and technologies, and yet not be so far behind the curve by the time we approve them? So it looks—Dr. Krauss is getting ready to go. Please.

Dr. KRAUSS. Well, yeah. The reason is is—one thing that's very important to us is that there's a real marketplace of these apps. And we do want very safe and effective apps to come out. And I don't know that there's enough focus on that in many of these areas, particularly with significant medical apps. And so we are very sort of engaged with this idea of using a research approach, using mobile devices to collect data, build prototype systems, test them, and only then release it, and we hope that that's encouraged. And I think this sort of Research Kit approach is helpful in that regard.

I think it would be very helpful if there were administrative add-ons to NIH grants for rare diseases to fund apps in those areas. That'd be very helpful. And general encouragement of app development with FTA, which, you know, they've been helpful, but everything's in a preliminary stage. Thank you.

Mr. REED. I'll quickly explain what he—one of the things that he mentioned there at the end, which is a solution, or at least a—something that the FDA is trying, and that is the development of this risk triangle, where they came out with the guidance in 2013, and declared that apps that posed essentially no risk to patients, or something that would not require a 510(k), a review—regulatory review process, that applications that moved into the middle category, which they refer to as a regulatory discretion area, were ones that they felt had low likelihood of patient harm, but yet probably still fell under the purview of the FDA.

And then, finally, the obvious ones, which is if you have an app that, either through marketing, or through the technology that you're trying to do, creates a real risk to patients, then yes, this needs to go through a formal process. So far several applications have gone through the FDA, and have passed 510(k). At last count—I don't believe anything has been pre-market approval. I don't recall a single app that's done full pre-market approval. Everything has been 510(k). If I'm wrong on that, I'll correct it in my written. Thank you.

Ms. ESTY. Thank you. Appreciate all of that. And did you have a comment?

Mr. LOOK. I was going to suggest, I do think we need to find a way to disconnect the riskier components of technology, where you would want to actually do a deeper testing release cycle from the parts of applications where you should be able to iterate quickly. Like, even—something that visualizes blood glucose data, I should be able to release software multiple times per day to help find the best way to present that to my user. So it's a matter of where the risk is.

Ms. ESTY. Thank you very much, and I think we'll follow up to get a little more precision so we can pass that through to FDA, and we can look at it in our own legislation to try to provide some of that—your help, and that guidance. Thank you very much.

Chairwoman COMSTOCK. Thank you. And I now recognize Ms. Clark for five minutes.

Ms. CLARK. Thank you so much, Chairwoman Comstock, and Ranking Member Lipinski. And, really, what an incredible panel. Thank you for being here. Thank you for the work that you're doing, and trying to help us help you. Last night I had a great privilege. I have three Weston, Massachusetts High School juniors who won the STEM app contest, and they—Dr. Krauss, you'd be interested—developed neurological testing that could be done on an app and give real time information, be able to be done remotely, and also measure things that couldn't be measured on a paper test. So the speed, how many times, where did things sort of fall apart for patients. Really interesting stuff.

And I was thinking about them, and, coming from Massachusetts, where we really have a hub of innovation, one of the things that I am hearing from companies in my district is that, as they are worried about technology and app development sort of falling into the regulatory no man's land, they're seeing the lack of clarity really causing the VC community and investors to pull back. They don't trust the regulatory atmosphere, so they don't know how to play in that field. And I wondered, to any of you, what were some of the questions that investors asked when your companies were getting started, and what were some of the biggest pushbacks? And what are you sort of hearing from the landscape around investors?

Mr. EPSTEIN. So—I'm going through this process right now, so I, you know, I've had 80 conversations in the last 2 months, so I feel like I can speak pretty—so we're not FDA regulated, so that's not something what we're worried about. And, in fact, on the regulatory side, that's—the biggest sort of fear, like, just—like non-rational fear that investors, you know, talk to me about is really just about what is the future of this market, in the sense that, you know, are apps going to win, right, or are these big, you know, EMR vendors, right, basically going to, you know, rule the ship? Like, is there a role for a company like Stroll, that makes this very, very important, but very, very small, in terms of the big, you know, scheme of health care, right how do we fit into this, right?

And basically, if it's not going to be the case that we can integrate, and it's not going to be the case that we can, you know, distribute through these channels, right, then we're not going to win, right? Then an investor doesn't want to invest. It doesn't matter how great the idea is, right, and then they walk away.

Ms. CLARK. Yeah.

Dr. KRAUSS. We have more of an academic model, where we've, like, aligned ourselves with Cure Epilepsy, that was founded by Susan Axelrod. And so we're applying for grants, we're collaborating with them and their scientists, in terms of patient experience, and what we want to include in the app, and then we will develop a non-profit kind of model for release of this app.

Ms. CLARK. Yeah. So it just doesn't come into your world, the private investor.

Dr. KRAUSS. Well, it will eventually, probably——

Ms. CLARK. Yeah.

Dr. KRAUSS. —but we basically want to get it right, and use Research Kit, do research, really optimize the system before then—we turn to commercialization.

Mr. LOOK. So my company made a crazy decision to be non-profit, even though we're in the middle of Silicon Valley, in part because of this, in part because we wanted to focus on the unique needs of Type1 diabetes, and not have to be pulled into the—a broader market that had to show a return. But one of my board members is one of the leading health care VCs in Silicon Valley. We spend a lot of time with the device makers that are trying to raise funds from VCs, and this is a real issue. Why would a VC give money to a medical device company that's going to have an 18 to 24 month PMA approval cycle, when they can give that same money to the next software only social network, and get them out the door quickly. So it is a real problem, and I do think it hinders innovation in this area.

Ms. CLARK. Great.

Dr. SHAW. In the case of retinoblastoma, you know, my vision is to get this app into—I can dream big. There's nothing with dreaming big. But my vision is to get this app into every parent's phone. There's 4 million babies born a year in the U.S. I—you know, and every year it's a new set of parents. And I can't reach them, right?

Ms. CLARK. Right.

Dr. SHAW. But there's only 30,000 pediatricians. I can reach them, and they don't have low—they don't have high turnover, right? So I actually want to be regulated. I want a pediatrician to feel comfortable with our app. And I think if I get some sort of regulatory approval, and we, you know, we put it through all the tests, that that will happen.

It's so cheap—what we're doing is so inexpensive. I mean, I just don't know if we would—this is probably bad to say, but I don't know if we would need any more money, other than what an NIH R–1 could give us.

Ms. CLARK. We won't hold you to that.

Dr. SHAW. And I, you know, it's all free, open source, no ads, or anything like that. So—I haven't got to the business side yet. I should get all your cards.

Mr. REED. Well, I think, to try to given you some perspective, we have a connected health initiative, which engages with hundreds of these companies, and three things come to light. If you have to spend time in your pitch meeting explaining why the VC doesn't understand HIPAA correctly, it's a problem.

Ms. CLARK. Yeah.

Mr. REED. HIPAA becomes one. And oftentimes HIPAA isn't the problem. It's the education around HIPAA. The number of HIPAA consultants that, frankly, have it wrong is remarkable. So HIPAA is the first. The second is the FDA questions, which—I think it's important to give some credit where credit is due. The FDA, from 2013 on, has really tried to step up their game. Now, they haven't—there are still auditors in the field that seem to have not gotten the message from on top, but that's a problem.

And the third, and the most important, is reimbursement. The realize of anything where you're selling to a physician or a health care system is if they don't see the monetary tie back to it, then you don't get the purchase. I see lots of companies that get angel investing, Series A financing, and then never get mezzanine. Because that's the moment where you have to walk in to your funders and say, here's my sales projection.

Ms. CLARK. Yeah.

Mr. REED. And the regulatory barriers, with no reimbursement model, with liability increased for physicians, how do you make that—how do you close that purchase when the other end of it isn't sure, as we've pointed from Research Kit, is it going to be effective? Is it going to reduce cost? Is it going to actually increase liability? So there are multiple regulatory threads that form through this, and ultimately it creates a barrier, really at that mezzanine financing level that we see.

Ms. CLARK. Great. Thank you. I'm well over my time. Thank you.

Chairwoman COMSTOCK. All right. Thank you. And I now recognize Mr. Swalwell for five minutes.

Mr. SWALWELL. Thank you, Madam Chair. Thank you to our panelists, and, Mr. Look and Mr. Epstein, I'm familiar with your landscape. I represent the East Bay out in California, where so many of these apps have been created, are being developed, and being used by my constituents, and other folks in the Bay Area. We are many of the early adopters.

With these apps—one question I have, you know, speaking about just HIPAA, and privacy, is—it's an exciting time. You know, people are experimenting with different ways to tackle many of the health conditions that plague us, or allow us to live more healthy lives with better preventative measures. But, you know, in—it's—as we know, in the Valley, and the Bay Area, companies take off, companies crash. That's just kind of the culture of our environment.

But when an app company at least gets off the ground and starts to get some users, and then, say, it crashes, what happens right now with the data of the people who have, you know, hoped and trusted that that company's going to be around, and that they're going to have a relationship with the company? But now, you know for whatever reason, it just didn't survive. Do we have laws around what happens with the data? And what is your experience in the community of what happens with the data? Is it destroyed, or is it still kind of out there on a server that is dormant? Open to anyone who wants to take——

Mr. LOOK. I can answer from the perspective of Tidepool. I think this is why it's so important for end users, patients, to own their own data, and for the companies that house that data to be stew-

ards of that data. And, finally, for those companies to say, here's how you get access to your data at any time. Whether it's by downloading it in a simple text format, or—JSON is the, you know, wonderful modern way of storing data, or providing APIs so that you can say, at any time, you may get your data from our system to someone else's system. Companies do go away. We need to expect that that will happen, but it also needs to be possible for the end user to always have access to their own data so they can take it wherever they want.

Mr. SWALWELL. Sure. And, Mr. Epstein, if you could address that, and also just tell me, in your statement, that private funding alone is not enough to drive innovation in mobile health technology. What could the federal government specifically do to help enable investment in mobile health technology?

Mr. EPSTEIN. Great, thank you. I'm actually glad you asked that one, to address something that Ms. Clark said. But—so there's a class of apps that you can develop for $20,000, which are very important, right? Then there's a class of apps where you have to hire data scientists, right, you have to work with huge sets of data. It takes years of development, right, and you cannot do that with just, you know, my team, you know, working on their own. You need to have funding, right, and investors don't want to invest in that, because they look at other apps that are, you know, texting or whatever, and say, look, I can deploy that in two months and see growth. And I'm saying it took us two years to develop Stroll. It took us two years, no product. two years, right? That's not something that most investors want to invest in, especially when I don't know how I'm going to make money, and I don't know if it'll work.

And then—but—and then briefly, for the death of apps, just—again, this is where I may now be misinterpreting HIPAA, but there's—you're supposed to keep data for seven years. You—the—who you sign a HIPAA contract with, they can destroy that—you—they can request that you return and destroy that data. I have no idea what happens when a company dies.

Mr. REED. He—Mr. Epstein is right. There are provisions of HIPAA, and the Office of Civil Rights, OCR, at HHS deals with these questions every day. It is an ongoing thing. It's funny, Congressman Swalwell, we were just doing our sharing economy event together, and these same questions of what happens to data is something that rides throughout our new modern sharing economy. I think in the health care space—you've heard from all of us that—the idea that the patient owns their health data is a thematic element that I think we would all agree to. It's different than where you traveled in your Uber or your Lyft. It has a certain level of—personal nature to it that I think is critical.

Mr. SWALWELL. Thank you. Yield back.

Chairwoman COMSTOCK. Thank you. And I now recognize Mr. Palmer for five minutes.

Mr. PALMER. Thank you, Madam Chairman. Mr. Reed, according to a report from the Health Research Institute published in December, 32 percent of consumers reported having at least one health app on their mobile device, which is double from just a couple years ago. Given the increasing prevalence of health apps, what are developers doing to ensure that consumers don't begin to see apps as

replacement for their physician? And I find this particularly interesting the context of, typical male that I am, I tend to self-diagnose.

Mr. REED. First of all, you're right. As a fellow male, I can tell you that we are a terrible species when it comes to my wife, when you go to the doctor, it says who's your primary care physician? Most men before 40, and even after 40 in many cases, what a primary care physician?

Mr. PALMER. Yeah.

Mr. REED. I go to the doctor when I'm hurt, and that's the primary care that I get, from that perspective. I worry less about people using apps to self-diagnose. I'm more concerned with them finding applications that actually engage them in a way that they don't do what we, as typical males do, and then ignore it. You know, one of the Members of Congress who was here earlier spoke about checking her husband's moles. That's an interesting concept, but there it is, right? We look to others to engage with us in a way that gets us involved.

And the reality is that my dad loves to watch World War II shows on the History Channel. If there was some way that an app engaged with him in the same way that the History Channel does on World War II, he might be better about monitoring his Type1I diabetes. So I think that we're looking at the ways to make these more engaging, and from a user design perspective.

But I think replacing the physician isn't the problem. How do we get the person to the physician in a timely fashion so that they're not as sick?

Mr. PALMER. Anyone else want to say thing? I've got a comment on this, and I think where technology might lead us on this, is that—you do these EKGs, is there any possibility at some point that, instead of plugging in earphones, you plug in something that you've tapped on—you're on the stationary bike or whatever, and—and in the context of self-diagnosis, actually—again, from a male perspective, well, that's just heartburn, actually go see a doctor when you need to? Mr. Epstein?

Mr. EPSTEIN. I'm not sure if I have anything intelligent to say on that.

Dr. KRAUSS. I have a comment. One function we're putting in our app is screening for risks for sudden death with epilepsy. And so you will get a red light, green light, yellow light kind of meter, based on your risk, based on assessment of your tracking of your seizures, and your pill-taking, and the type of seizures. And so that sort of feedback will go to the patient, and then it will guide them to go see their doctor.

Mr. PALMER. I should've——

Dr. KRAUSS. But we don't give that data to the doctor.

Mr. PALMER. I should've give you a little more background on this, because I just visited a cardiovascular group a couple of weeks ago, and people who have pacemakers, they have the ability, on their phone, to have their heart monitored by their phone, that if they have an irregularity, not only does it inform the patient, but it communicates with the doctor's office. So the technology is moving in a direction where, you know, to a—in a positive way. You could self-diagnose to get an alert that you need to seek care.

Also, it may also give us an opportunity to avoid over-diagnosis. Do you see any opportunity there?

Mr. REED. You know, you're jumping to my favorite topic, which is the world of wearables. We actually did a study of 99 days of—we looked at 25 different wearables. And you're completely right. The reality is, starting with sports med, you see companies like Under Armor already beginning to look at it. But how do I turn the shirt that you wear into something that helps you keep track of your health? I think I see at least two Apple Watches here at the table. And if you look at the back of this watch, it's exactly what you said.

Mr. PALMER. Um-hum.

Mr. REED. It's a platform for sensors. The back of it is a whole row of sensors. And what you're discussing, sir, is exactly where I think all of us will end up being, and that is how do we incorporate wearables into giving better diagnosis? We're still on the road to that. There are regulatory barriers. But that is, I think, a big part of our vision.

Mr. PALMER. Thank you, Madam Chairman. I yield back.

Chairwoman COMSTOCK. All right. Thank you, and I just want to thank all of our witnesses for a great hearing. It's so exciting, about the possibilities here, and what you all have created and are doing, and how we need to make sure we're getting out of your way, in some cases, and in other cases figuring out how we can clear some of those roads for you. So I would invite the witnesses to continue to keep in touch with us, give us any thoughts or ideas that you might have for additional areas we can focus on.

So the record will remain open for two weeks for additional written comments or questions from any of the Members. And so, again, thank you so much. And since there are—well, there's only two of us left here, but since there are 435 of us, Dr. Shaw, I did want to say my dream is to get this in every parent's phone. As the grandmother now of three children, I can tell you, three parents, I'm going to get it into their phones, but share it with my constituents. I think this is the kind of thing we can all start sharing. We can do this organically, virally, however we can do it, and help you share this mission. And God bless, it's wonderful work.

Dr. SHAW. Thank you.

Chairwoman COMSTOCK. And this hearing is adjourned.

[Whereupon, at 11:34 a.m., the Subcommittee was adjourned.]

Appendix I

Answers to Post-Hearing Questions

ANSWERS TO POST-HEARING QUESTIONS

Responses by Mr. Morgan Reed, questions submitted by Chairwoman Comstock

1. **The day is fast approaching when a smart phone app or a wearable and/or implantable device will be capable of warning a patient about the imminent onset of a heart attack or stroke, summon an ambulance, notify the patient's physician, and transmit a stream of medical information en route to the hospital.**
    a. **What does all of this portend for the traditional doctor-patient relationship? Will patients who have grown up with smart phones in their hands eschew traditional primary care?**

ACT | The App Association agrees with you on the promise that a seamless and connected "continuum of care" presents to American patients, particularly those suffering from serious conditions such as chronic obstructive pulmonary disease (COPD). Powered by apps on mobile devices, these new capabilities offer countless benefits, including the transmission of vital signs as part of care plans for chronic disease patients' electronic health records (EHRs); the transmission of important medical device data, text and images for specialist diagnoses such as X-rays, Magnetic Resonance Images (MRIs), and computerized axial tomography (CAT) scans; video conferencing for telemedicine or training; and, as you discuss, timely access to emergency medical provider services.

Contrary to any worries that technology will undermine the doctor-patient relationship, technological advances will allow physicians to have greater insight into what is happening with their patients outside of traditional doctor's appointments. The doctor will benefit from receiving more accurate data more often (sometimes even automatically), lending to a more effective and personalized care plan for each patient. Second, increased connectivity will enable the same practitioner to identify trends in the patient's health and to communicate bi-directionally with the patient about it, which has been clearly shown to aid in mitigating ongoing issues (such as the heart attack you mention in your question). Third, by aligning a care plan with newer generational tendencies, namely the "mobile first" trend exhibited by younger Americans, patients can naturally become more engaged with their own health trends and care plans, which has been shown to greatly improve patient-sided proactivity in making healthy lifestyle choices.

2. **The power of big data is enormous – with new generations of monitoring devices, we can gather unimaginable quantities of health and medical data. Can you talk about how we might be able to use this information to provide better medical care to individuals, and in what time frame we might expect "big data"?**

ACT | The App Association agrees that the power and potential of big data represents a massive opportunity for the American healthcare system at large. As health systems shift to cloud-based systems, doctors will find that their practices naturally lend themselves to big data analytics products and services which can help them identify health trends in patients based on data from numerous patient-generated sources. As these data streams become more common, the efficacy of healthcare will naturally improve in correlation.

However, in order to fully integrate the benefits of big data analytics into patient care widely, the U.S. government will be required to adopt a shift in policies on a number of fronts to facilitate physician uptake. In our testimony, we discuss several key areas of need in this context. Without these changes, it is very difficult to give an accurate timeframe for when, as a society, big data analytics' benefits will be widely realized. ACT | The App Association is committed to working with the U.S. government and stakeholders at large to reach this goal.

3. **The generation of data from health apps and precision medicine raises some profound questions about big data and its implications. Has the App Association considered the larger issue of who ultimately owns or will own the personal data that health apps are inevitably going to generate? Should Congress anticipate one day needing "Big Data Rights" legislation?**

Without question, big data stands could transform the health-care sector. ACT | The App Association believes that where practicable, companies should provide their users with the ability to access, delete, and correct the health data they collect or maintain about their customers, unless the data is otherwise available directly to the customer. Already, we work closely with our members to ensure transparency in the use of health data.

ACT | The App Association urges Congress to proceed cautiously when considering legislative approaches to big data and consumer rights. Already, the Federal Trade Commission and Department of Health and Human Services' Office of Civil Rights play prominent roles in the protection of consumer data. App makers take their legal obligations related to data security and privacy very seriously. Further, industry-led voluntary codes of conduct have proven a very effective means to ensuring consumer data protections. Therefore, before drafting new legislation, Congress should look first to the robust body of existing laws and regulations related to data security and privacy, as well as industry-led voluntary codes of conduct, to address consumer rights in the big data context.

4. **Your testimony emphasizes the need for encryption and references the work conducted by NIST (National Institute of Standards and Technology) in promoting the use of encryption. Are the NIST encryption standards sufficient, or do they need to be updated or strengthened in any way?**

ACT | The App Association greatly appreciates your raising of the importance of encryption, which we discussed in our testimony. As we discuss in our submitted written testimony, NIST plays a critical role in the functioning of the digital economy through its work on cryptography. ACT | The App Association believes that the transparent and iterative process employed by NIST in developing its standards has resulted in an effective body of work.

As we noted in our submitted testimony, we urge Congress to ensure that encryption's role in the digital economy is protected. To that end, Congress should ensure that NIST's role continues and is protected from unreasonable and shortsighted calls to degrade encryption.

Responses by Dr. Bryan F. Shaw

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON RESEARCH & TECHNOLOGY

"Smart Health: Empowering the Future of Mobile Apps"

Dr. Bryan F. Shaw, Assistant Professor, Department of Chemistry and Biochemistry, Baylor University

Questions submitted by Rep. Barbara Comstock, Chairwoman, Subcommittee on Research & Technology

1. It is reasonable to predict that mobile medical apps will improve the doctor-patient relationship and will not eschew traditional elements of primary care. Doctor-patient relationships will be, in my opinion, improved because mobile medical apps will improve the ability of patients to detect and recognize symptoms and improve their ability to effectively communicate symptoms to their doctor. One of the most important features of the doctor-patient relationship is the communication of symptoms to the doctor by the patient. If this first step is not taken by the patient (or caregiver), then no treatment can be provided. The improved detection and reporting of symptoms, made possible by mobile medical apps, is especially probable for pediatric diseases. Infants cannot verbally communicate the symptoms of their health conditions, which creates challenges in screening and detecting pediatric diseases. Several mobile medical apps, such as "Poop MD" and "CRADLE" (i.e., The White Eye Detector) can be used by parents to screen their children for symptoms of rare and common diseases that occur in the first months or years of life, and are often difficult for doctors to detect.

When predicting the impact of mobile medical apps on healthcare, we must remember that people want their symptoms explained in the form of a diagnosis and they want to be treated. Mobile medical apps are therefore not likely to eschew traditional primary care because, first and foremost, a smartphone app cannot diagnose or treat health conditions; only doctors can do that (for now—and I do not see this changing any time soon). It is important to remember that mobile medical apps are not the first piece of healthcare technology to help consumers manage their health. The widespread incorporation of new pieces of consumer-based healthcare technology has been occurring for decades, without damaging the doctor-patient relationship. I view the smartphone in the same light as these other pieces of technology that consumers have used to monitor or improve their health, e.g., the digital or mercury-based thermometer; blood pressure monitors; band-aids; body mass scales; blood glucose detectors; over-the-counter ibuprofen or Tylenol for lowering fever. Patients still need a doctor to help fix or treat their health problems. In conclusion, I predict that smartphone-based diagnostic and screening tools will promote contact between doctors and patients, not diminish contact.

2. The power of big data has great potential for advancing epidemiology, but "big data", collected or transmitted by mobile medical devices, will not necessarily lead to broad, transformational improvements in human health (of the magnitude that, for example, synthetic organic chemistry—in particular asymetric synthesis—transformed pharmacology, or computer science transformed radiological imaging). It is important to

remember that humans have been social creatures and sharing information about themselves long before the invention of the mobile medical app or social networking platform. Mobile medical apps will make collecting and sharing information easier. Assume, for example, that everyone wears an Apple watch and decides to share their heart rate for a "big data" cardiologic study. We could monitor the heart rate of 300 million Americans all at once! So what? This type of data is already collected at regular checkups (e.g., once a year). At some point, increasing "n" presents diminishing returns. Can I simply learn the same information by studying the blood pressure of 2,000 subjects in a conventional epidemiology study? The data would be much easier to manage and I might be able to reach the same conclusions. Collecting data is not the "end all, be all" in medical science—in fact it can be the easiest part. One has to understand the physical, chemical, biological or social mechanism of the phenomena that are producing the data; the things that are causing the observed phenomenon to occur in the first place; and discerning cause from coincidence in any biomedical correlation is one of the most important parts of interpreting these data. Moreover, we already have a good handle on the incidence rates of diseases and the prevalence of social, racial, ethnic and geographic health disparities.

3. By the year 2020, it is predicted that there will be six billion smartphones in use. Thus, the human being to smartphone ratio is rapidly approaching 1:1. To put this number in context, there are only about one billion automobiles in the world. I would be more worried about people having limited financial or physical access to transportation to get to a doctor, than I would their access to a smartphone for health monitoring. Apps are also now downloadable on smart TV's. That being said, can elderly individuals operate smartphones effectively? I am not an expert on geriatrics, but these devices are very user friendly. I do know that children are good at using smartphones. I am the father of a three year old and an eight year old and they are both experts at navigating my smartphone (albeit for finding the right apps for gaming and cartoons). The three year old is able to navigate the device even though he cannot yet read.

Responses by Mr. Howard Look

HOUSE COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY
SUBCOMMITTEE ON RESEARCH & TECHNOLOGY
"Smart Health: Empowering the Future of Mobile Apps"

Mr. Howard Look, President, CEO and Founder, Tidepool

Responses to questions submitted by Rep. Barbara Comstock,
Chairwoman, Subcommittee on Research & Technology

1. The day is fast approaching when a smartphone app or a wearable and/or implantable device will be capable of warning a patient about the imminent onset of a heart attack or stroke, summon an ambulance, notify the patient's physician, and transmit a stream of medical information en route to a hospital.

a. What does all of this portend for the traditional doctor-patient relationship? Will patients who have grown up with smart phones in their hands eschew traditional primary care?

Mobile phones and the internet have already forever changed how people educate themselves about medical conditions and seek out medical care. This empowers patients and long ago changed the traditional model of healthcare. The answer is clearly: Yes! People who are comfortable using technology will use it in marvelous and compelling ways to ensure that they are receiving the best care possible.

Does that mean that some people will never go to a primary care provider? Possibly, but the traditional primary care role will still need to exist. At a minimum patients need a doctor to write prescriptions. Many patients will also still find great value from in-person, personalized care that only a primary care doctor can provide. That said, we should also embrace the notion that many people will want to use remote, telemedicine and personalized care delivered through mobile and other internet-based applications.

2. The power of big data is enormous — with new generations of monitoring devices, we can gather unimaginable quantities of health and medical data. Can you talk about how we might be able to use this information to provide better medical care to individuals, and in what time frame might we expect "big data" care?

The era of "big data" and precision medicine is here today. Consumers can already sequence their genome to better understand their unique background and risk factors. Companies big and small, from Google to Tidepool, already have the ability to analyze vast quantities of data in order to find trends at both a population scale and an individual level.

With respect to Type 1 diabetes, Tidepool's primary focus, better care can be delivered when both patients and providers are empowered with insights into their diabetes therapy. At an

individual level, we can help people achieve better therapy by being able to provide them with insights over vast amounts of diabetes device and therapy data. This is already "big data" by historical standards. When that data gets aggregated with other patient data, we can provide even more insights. For example, I imagine my daughter being able to walk into a pizza place with her friends and, using her iPhone and a Tidepool mobile application, say "show me how other 16 year old girls with T1D and my same metabolic profile have computed safe, successful insulin doses for items on the menu here."

It is this era of big data that truly enables precision medicine.

3. What are the implications if consumers need smartphones to take advantage of health apps? Is there a risk of excluding a segment of the population toward whom these apps are directed, such as for instance frail, elderly individuals who may be less technologically sophisticated?

As with any new product capability, there will be people for whom it is inaccessible, either because of cost or because they aren't ready or willing to adopt the new technology. 75% of the US population uses a smartphone and this will continue to grow over time. That said, it is highly unlikely that a smartphone application will be the exclusive mechanism by which someone is able to receive appropriate care.

4. Can the Tidepool apps be used to help people with type 2 diabetes and gestational diabetes? And thinking more broadly, are there potential applications of your apps for other diseases?

Like any good startup, Tidepool has limiting its focus in order to do a few things well and not spread ourselves too thinly. Tidepool has focused on people with insulin-dependent diabetes. 100% of people with Type 1 diabetes are insulin-dependent, thus this has been our prime focus. Between 30-40% of people with Type 2 diabetes require insulin. Approximately 15 percent of women with gestational diabetes require insulin.

The general approach that Tidepool is taking is applicable to other disease states. We are building an open source software platform that gathers data from devices and stores it in a secure, cloud-based system. Our applications, and other applications written by 3rd party developers, can then access that data and present it in applications that help provide safer and more effective therapy.

We encourage others to take advantage of our freely available software source code and adapt to their needs. Our source code is available at github.com/tidepool-org. Other data-intensive disease states could certainly make use of our software platform and applications as a starting point for their source code.

5. Why did you decide to form Tidepool as a non-profit rather than a traditional start-up company? What have been the advantages and disadvantages of your model?

When Tidepool was formed in 2013, the question of "Who owns the data from a diabetes device?" was still an hotly debated topic. At the time, if we had chosen to be a for-profit entity and then gone to the device makers and said "We'd like to you to make the data from your devices available to us, because we think that data has value!" they would have said "Yes! We agree! That data has value and therefore we'd like to keep it in our closed, proprietary ecosystem." By being a non-profit, Tidepool could credibly say to the device makers "You don't own the data. We don't own the data. The patient owns that data. We are here to help liberate it so that the patient can receive better therapy when using your device." That strategy worked: The Tidepool Platform is now compatible with 100% of commercially available insulin pumps and continuous glucose monitors in the U.S. diabetes market.

Tidepool also chose to be open and non-profit because it's the best way for us to make a difference for people with diabetes. We are here to help the industry make a great leap forward. We are building a platform and great apps that can help everyone, and being open and non-profit allows us to "do the right thing" and help the industry as a whole in a non-competitive way. We are giving away all of our intellectual property for free. We are not in this for the money; we are in this to help reduce the burden for people living with Type 1 diabetes through our technology.

Responses by Dr. Gregory Krauss

April 11, 2016 – Responses for Dr. Krauss

Dear Chairwoman Comstock,

Thanks you for permitting me testify in your March2, 2016 hearing titled "Smart Health" Empowering the Future of Mobile apps." I responded to the four questions you forwarded:

1) We developed a research medical app called EpiWatch that alerts caregivers when participants with epilepsy have seizures and tracks seizures and pill taking. Patients report that the medical app increases their control over the management of their disease; they also report in a survey that they would like to decide when to share medical information with their physicians and to not have their medical data transmitted directly. Tracking seizures and comorbidities such as depression, for example, help patients monitor their epilepsy and to identify problems such as the presence of drug side effects. Patients can then choose to share this data with their physician in the traditional doctor patient relationship. Seizure tracking data provide valuable feedback to patients, which they can share with their physician. Patients, for example, are often unaware of common mild seizure drug side effects such as dizziness and drowsiness; identifying symptoms with the aid of the app can alert patients so this can be addressed during clinic visits, thus, enhancing patient physician interactions.
2) We agree that medical apps can gather large amounts of valuable clinical data on patients' medical conditions which can be analyzed to assess seizure management and health outcomes. Protecting private health information is critical and we collect data in a secure, carefully constructed research framework. Participants with epilepsy receive study screening, they then sign research consents on their smart phone and provide research data collected on their Smart Watch and iPhone with anonymized coding of participants' identities and encrypted data transfer. This research data system protects confidentiality as part of minimal risk research. Our EpiWatch research app collects biosensor data during seizures and tracks patients' seizures, therapies and co-morbidities. We are using this data to develop individualized seizure detectors, emphasizing detection of serious seizures. The app provides helpful feedback to participants on common co-morbidities such as anxiety and shows them how seizure triggers and pill taking can influence their seizures. These relationships can be studied in a national group of participants with rapid recruitment for the study.
3) Medical research using medical apps on mobile devices requires accurate patient consenting, confidential use of personal health information and careful delivery of medical information to enable patients to improve disease management. The ResearchKit platform permits research to be done on mobile devices with e-consenting on an iPhone, encrypted data transfer to a secure server system and IRB monitoring of study protocol effectiveness, data security and study safety. Seizure tracking data collected anonymously on a Smart Watch is being used to develop a seizure detector based on individual changes in heart rate, movement and responsiveness during seizures.
4) Parents and other legally authorized representatives can help children and individuals with cognitive impairment participate in the research. EpiWatch requires that adolescents with epilepsy complete the study screening and comprehension testing; their parents then review the study and complete the consenting process. Caregivers can help activate the seizure tracking

app during seizures; they can also assist children, impaired individuals and non-technically savvy individuals operate the research app. Smartphones (and soon "smart watches") are widely used, even in developing countries. Our study demographics are surprisingly broad across adult ages, ethnicities and income levels. The data we collect can be used to develop a seizure detector which can then be used on multiple future Smart Watch platform; these are likely to decrease markedly in cost after this initial launch year. As smart watch use increases, app based medical research participation should be possible in both developed and developing countries.

Regards,

Gregory Krauss, MD

Professor of Neurology

Johns Hopkins University

Responses by Mr. Jordan Epstein

Prepared Answers to Questions Submitted by Chairwoman Comstock
for the Record of

Jordan Epstein
CEO
Stroll Health

Hearing on
"Smart Health: Empowering the Future of Mobile Apps"

Before the
United States House of Representatives
Committee on Science, Space, and Technology
Subcommittee on Research and Technology

April 6, 2016

Response to question 1:

For many healthy adult patients, the idea of a "check up" is becoming a thing of the past. Instead of forming lifetime relationships, patients will expect software in the cloud to warn them when to visit a care professional, and will expect those professionals to be convenient for them. Online, urgent care, "Uber" for a doc or nurse, "minute clinic", there is a rapidly growing supply of more convenient primary care alternatives. Patients are demanding access and speed, and triage among care delivery to the most available and least costly (and least credentialed) is occurring and will continue to do so. While this should reduce costs in the long term, this will necessarily extend care to multiple systems and providers, further weakening any relationship with a particular primary care physician.

All of this moves primary care physicians away from their traditional role as the first point of entry into the healthcare system, and away from their role as "quarterback" or "gatekeeper". Without this role, for managed care organizations in particular, it may be difficult for closed networks to successfully manage where patients seek care. Even if such organizations provide the same types of technology in controlled systems, patients will still use their own tools at their convenience. As such, I see a new role emerging as a "care navigator", which helps patients understand their data and manages patients across the growing continuum of virtual and real care providers. While I think it unlikely that primary care physicians themselves will adopt this role, it is possible that together with their staff they continue to be the shepherd of their patients lives.

Regardless, there will always be uncertainty in medicine, and always the need to voice opinion, build a care plan, and take trust in following through. These all need and will need real physicians, and while some minor cases may be solved via other means, in the next five years I still expect most diagnosis of medical issues will be delivered in person by physicians or nurse practitioners. In ten years, technology likely will be robust enough such that diagnosis of routine conditions can be done via software. In the long future, much thought needs to be put into the ethics, policy, and liability around machine diagnosis, prescription, and case management.

In all cases, the relationship with the primary care physician will move to more and more individual case management of potentially severe cases, for which care path is uncertain and which necessitate either additional diagnostics or an in person visit. There will be a need for these primary care physicians to have access to the data provided by these sources in their EMR, and the tools to be able to easily incorporate these into their care decisions. Early versions of such connectivity and tools are already being tested, but given the long testing and rollout cycles I expect such tools to be clinically ready and the standard of care in 10 years.

Finally, to be clear, while much of this technology applies equally to infant and child care, I do not expect relationships with pediatricians to be disrupted anytime soon, especially for first time parents.

Response to question 2:

Big data has the potential to impact almost every aspect of medical care, from identifying when a patient is abnormal, filtering through abnormalities to identify potential illnesses, and then distinguishing among illnesses to identify best care paths. On the business side, big data can also identify most costly patients and providers, create mitigation channels, and proactively monitor to see if solutions are cost effective and implemented.

At the same time, there are significant policy, implementation, and clinical barriers to making big data reach its full potential. The question of open information, protections, and who owns data all need to be addressed, particularly with regards to genetic data. Interoperability needs to be addressed at both EMRs and insurance companies if innovation is to occur at any scalable level.

Today, many companies are using data to monitor population health, and sending automated reminders and texts have been shown to improve outcomes, especially in terms of reducing readmissions. In terms of actually improving quality and accuracy of medical treatments, in the next five years, I expect real results to emerge from projects using mobile technology (like Apple ResearchKit), big data (like IBM's Watson), and projects surrounding stores of genetic data. In ten years, I expect clinical adoption and best practices to emerge around using this data.

Appendix II

Additional Material for the Record

STATEMENT BY COMMITTEE RANKING MEMBER EDDIE BERNICE JOHSNON

OPENING STATEMENT

Ranking Member Eddie Bernice Johnson (D-TX)

House Committee on Science, Space, and Technology
Research and Technology Subcommittee
"Smart Health: Empowering the Future of Mobile Apps"
March 2, 2016

Good morning, I would like to thank the Chair for holding today's hearing. Today we are examining mobile health apps and the challenges to bringing this technology into wider use. While there may be some regulatory challenges to mobile health app technology, this Committee looks forward to considering the related technological, security, and funding challenges.

The panelists here today are closely involved in the development of this emerging field. These are really exciting and potentially life changing technologies. These mobile health apps and the people behind them represent the kind of innovative technology this Committee works to support through good science and technology policy. The apps developed by our witnesses are also either HIPAA compliant or developed through rigorous university-based research. Unfortunately, however, the apps we will be discussing today represent only a small segment of commercially available mobile health apps.

The mobile health industry is a multi-billion global market and is projected to grow larger as more and more people use them. However, the research behind many health apps is not very strong. In the U.S., federal regulators have taken several mobile health apps off the market that were determined to be deceptive to its users. Online reviews, in many cases, are the only source for potential app users to determine the efficacy of an app before they download it. This should not be the case when users' health, and possibly even their lives are at stake. There is a role here for both private sector innovation and more basic research and development at our nation's great universities and federal laboratories. For example, the National Science Foundation's Smart and Connected Health Program is already supporting important work in this area. Its goal is to accelerate the development of innovative approaches to healthcare to move healthcare away from a reactive environment to one that is preventative, proactive and evidenced-based, focused on well-being rather than disease.

Mobile health technology is moving healthcare management forward at a fast pace. Strong partnerships among federal agencies, universities, and the private sector can help address the barriers and minimize some of the growing pains in mobile health app development. I appreciate our witnesses being here today to share their insights into the innovative technologies made possible by such partnerships.

Thank you Madame Chair, and I yield back the balance of my time.

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