

**HIT Policy Committee  
FDASIA Workgroup  
Transcript  
April 29, 2013**

**Presentation**

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thank you. Good morning everybody, this is MacKenzie Robertson in the Office of the National Coordinator for Health IT. This is the kick-off meeting of the HIT Policy Committee's Food and Drug Administration Safety and Innovation Act Workgroup, also known as the FDASIA Workgroup. This is a public call and there is time for public comment built into the agenda. And the call is also being recorded, so please make sure you identify yourself when speaking. I'll now go through the roll call. David Bates?

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks David. Patricia Brennan?

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin-Madison – Project Health Design National Program Director**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Patricia. Geoff Clapp? Todd Cooper?

**Todd Cooper – Breakthrough Solutions Foundry, Inc. – President**

Good morning.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Good morning. Thanks Todd. Meghan Dierks?

**Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Meghan. Esther Dyson? Richard Eaton? Richard, I know you're on the line. Anura Fernando? Thanks.

**Anura S. Fernando. MS, MD – Underwriters Laboratories – Principal Engineer, eHealth**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Anura. Lauren Fifield?

**Lauren Fifield – Practice Fusion – Senior Policy Advisor**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Lauren. Mike Flis?

**Michael Flis – Roche Diagnostics – Regulatory Manager**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Mike. Elisabeth George?

**Elisabeth M. George, MS – Philips Healthcare – Vice President, Global Government Affairs,  
Standards & Regulations**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Elisabeth. Julian Goldman?

**Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Julian. Drew Hickerson?

**T. Drew Hickerson, JD – Happtique, Inc. – Assistant General Counsel & Senior Director, Business  
Development**

Present.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Drew. Jeffrey Jacques?

**Jeffrey Jacques, MD – Aetna – President, Neonatal Solutions**

Good morning.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Good morning Jeffrey. Robert Jarrin?

**Robert Jarrin, JD – Qualcomm Incorporated – Senior Director, Government Affairs**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Robert. Mo Kaushal?

**Mohit Kaushal, MD, MBA – Aberdare Ventures/National Venture Capital Association**

Yes.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Great. Thanks. Keith Larsen?

**Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director**

I'm present.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Keith. Mary Anne Leach? Meg Marshall?

**Meg Marshall, JD – Cerner Corporation – Director, Government Health Policy**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Meg. Mary Mastenbrook?

**Mary Mastenbrook – Consumer**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Mary. Jackie McCarthy?

**Jackie McCarthy – CTIA-The Wireless Association – Director, Wireless Internet Development**

Good morning.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Jackie. Anna McCollister-Slipp? Jonathan Potter? Jared Quoyeser?

**Jared S. Quoyeser, MHA – Intel Corporation – Healthcare Industry Manager**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Jared. Martin Sepulveda? Joe Smith?

**Joseph M. Smith, MD, PhD, FACC – West Health – Chief Medical and Science Officer**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Joe. Mike Swiernik?

**Michael Swiernik, MD – MobileHealthRx, Inc. – Chief Executive Officer and Founder**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Mike. Paul Tang?

**Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and  
Technology Officer**

Here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Paul. Brad Thompson? Jodi Daniel? I know Jodi's on the line.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator**

Here. I'm here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Jodi. Bakul Patel? Bakul's also on the line. And Matthew Quinn?

**Matthew Quinn – Federal Communications Commission – Director, Health Care Initiatives**

Hello.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Great. Thanks Matt. If there are any ONC staff members on the line, if you could also please identify yourselves.

**Michael Lipinski, JD – Office of the National Coordinator**

Mike Lipinski.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Great. Thanks Mike.

**Steve Posnack, MHS, MS, CISSP – Office of the National Coordinator**

Steve...MacKenzie, Steve Posnack, ONC.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Great. Thanks Steve.

**Bakul Patel, MS, MBA – Food & Drug Administration – Policy Advisor, Center for Devices and Radiological Health**

MacKenzie, this is Bakul. Bill Maisel and Jeff Shuren are here as well with me.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Great. With that, I will turn to Dr. Mostashari for some opening remarks first.

**Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator**

Thank you so much. Very pleased to be joining you all today. I'm Farzad Mostashari, I'm the Director of the Office of the National Coordinator for Health IT and we emphasize more the health and the information than the technology part. If folks could go on mute please, I'm getting some echo, great. We really believe that technology is a critical tool, it's just a tool, but it's a critical tool, to help a healthcare system that's poised for transformation in how care is paid for and delivered, in how patients engage in their own health and healthcare and recognizing that this field, health IT, is complex and quickly changing. HITECH, the HITECH Act, part of the American Recovery and Reinvestment Act, established this office and two federal advisory committees, under the Federal Advisory Committee Act and the Health IT Policy Committee, of which this is a subgroup, has been giving us recommendations on a policy framework to support the development of the option of a nationwide health information infrastructure.

And these committees and their members, some of whom – some of you have been serial participants, have dedicated really an unbelievable effort and time, and this history of this Federal Advisory Committee that you're joining is really an impressive one. The committees, their members, and their many working groups have really laid the groundwork and the policy framework for everything we've done in health IT, and they've done it in the public. All of the committees meetings are available through live webcasts and we've met on the average every other day one or another workgroup or committee meeting for the past three years. And I have no doubt that this workgroup will continue in that tradition.

The issue here is obviously of great significance. We're really seeing the potential for information technology to improve healthcare and the consumer experience in a way that we've seen in every other aspect of our lives, but not yet in healthcare, to the extent that it could, but that's changing. People are literally taking their health into their hands in, through a variety of means, mobile devices in particular being an incredible tool for empowering consumers to take control of their health, their health care, their health care finances. And it's a big part of ONC's strategy in consumer eHealth to increase patient's ability to access their own data through things like the Blue Button and through our policies.

But, we recognize that with every technology, there are risks, as well as benefits. For example, the ubiquity and connectedness of mobile devices create concerns for privacy and security and new technologies, we have to make sure that they also provide assurances around safety. But to do so while balancing, as the legislation that kicked off this effort recognizes we need to be balanced in a risk-based framework. The likelihood that the risks are going to be realized, the impact of those and we really want to get the best advice from you, as we draft our approaches, in coordination with the different agencies, to avoid any duplicative or overlapping regulatory requirements, and to have the greatest possible innovation, as well as protecting patient safety.

So, it's a tall order, but I think the key things that we have learned at ONC has been, one, to be transparent and open and inclusive, and this process is a big part of that. To keep our eye on the prize, in terms of what the destination is that we're all shooting for while keeping our feet on the ground, recognizing the realities as well. To embrace market-based approaches, but to make sure that we also protect the little guy, as we do so. And to put the patients in the center, and their interests in the center of everything we do, that's paramount. So, those are our principles and I welcome you to join us on this in a coordinated approach, with all of you and with our sister agencies. Let me turn it over now to Julie, are you next?

**Matthew Quinn – Federal Communications Commission – Director, Health Care Initiatives**

It's actually going to be Matt, Farzad.

**Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator**

Okay. Great.

**Matthew Quinn – Federal Communications Commission – Director, Health Care Initiatives**

Well good morning everyone, oh, go ahead – good morning everyone. This is Matt Quinn. I joined the FCC three weeks ago as Director of Health Care Initiatives from my prior work at NIST and AHRQ, where I was working on measuring and improving the usability of health IT. Something that I learned in the work there is that the introduction of new and innovative technologies into the healthcare systems, and into people's lives, holds real promise of great benefit, but it also introduces new potential risks and hazards. And a key trend in health IT is the movement from wired devices to those that are wireless, and that's a trend in our lives as well.

Most healthcare organizations today, just in the past couple of years, now have doctors, nurses and other healthcare professionals interacting with clinical systems via wireless devices. And many patients or people view, access and share data about their health and healthcare via mobile apps. The intersection of wireless spectrum and health IT brings with it great opportunities for leaps forward in workflow efficiencies, capturing and gaining value from data and empowering and connecting people with the healthcare system in their communities. That's why we're seeing the levels of investment, entrepreneurship and energy in this space and in this marketplace. But it also highlights and elevates concerns around interference, reliability of access, usability and security.

And each agency that's participating in this workgroup, in the FDASIA process has a unique role and brings different perspectives, expertise and jurisdiction to the table when it comes to promoting innovation and assuring patient safety. FCC's area of responsibility is regulation and authorization of equipment using the radio frequency spectrum. While this is a narrow area of responsibility, our participation and inclusion in a regulatory framework for health IT is vital to smart regulation and regulatory efficiency, especially as the number and types of health IT tools using wireless spectrum grows. We're excited that the workgroup includes representation from both the here and now of health IT leadership, and folks on the leading edge. Together we'll get the advice we need to set the right balance between speeding new health IT innovations to market and ensuring that risks are mitigated before they get there. Thank you so much for your participation. I look forward to learning from you to inform our report. Thanks a lot.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

And Jeffrey Shuren, I believe we have opening remarks from you as well.

**Jeffrey Shuren, MD, JD – Food & Drug Administration – Director, Center for Devices and Radiological Health**

Yes. Thank you. Good morning. I'm Jeff Shuren, the Director of the Food and Drug Administration's Center for Devices and Radiological Health. I wish to add my thank you to all of you for being willing to participate on this working group to help inform us, ONC and FCC, on the development of a regulatory framework for health IT that protects patient safety while promoting innovation and avoiding regulatory duplication. We share your passion for health IT and the benefits it can provide to improve patient care, disease prevention and healthier living. We want to see this field thrive. For this reason, three years ago, we at the FDA made a paradigmatic shift in our thinking about health IT and stand-alone medical device software more broadly. A shift we are still working through and seek your help in getting to the right place, what we call, smart regulation.

To us smart regulation means applying the tools available to the FDA, based on using a risk-based approach that achieves the often complimentary goal of protecting patient safety and security, and facilitating innovation. Smart regulation also means recognizing when not to regulate. Many types of health IT, maybe a medical device is a matter of law, but we firmly believe that we should not enforce FDA requirements on most of them. You can see that philosophy on full display in our mobile medical apps draft guidance, which Bakul Patel and CDRH will discuss in more detail in a few minutes. Under this draft policy, we would only actively regulate the proverbial tip of the iceberg. We have heard loud and clear how important it is to issue the final guidance quickly, to give app developers the certainty they need that we won't enforce requirements. It is our goal to issue that guidance very soon.

At the same time, the FDA has long regulated various types of stand-alone medical device software by applying a three-tier set of oversight tools, based on the level of risk. For example, we've cleared over 75 mobile apps since 1997 and we have long regulated some stand-alone medical device software with clinical decision support functionality, such as computer-assisted detection devices and make recommendations to a radiologist as to which areas on a radiographic image, such as a mammogram, may be a tumor, and thereby warrant additional testing or treatment. And for many years, we have engaged with national and international standards development organizations on establishing standards for medical device software interoperability, to help optimize the potential benefits of health IT, but to do so in a way that assures patient safety.

As part of our shift in thinking, we are also revisiting how we approach stand-alone medical device software generally, focusing more on assuring that appropriate processes for software validation and verification are in place, and less on traditional pre-market review, including the review of software modifications. We believe that even for many types of stand-alone medical device software we do regulate, we need to apply a lighter touch, that appropriately takes into account the business models for and the lifecycle of software development and maintenance. We seek your insights to assist us, along with ONC and FCC, to develop a regulatory framework for health IT that best utilizes our collective regulatory tools, authorities and expertise to promote innovation, protect patient safety and avoid regulatory duplication.

As part of this effort, we seek your input as to factors the FDA should consider when determining what types of health IT that are medical devices we should and which types we should not actively regulate. For example, which types of stand-alone medical device software with clinical decision support functionality we should, and which types we should not actively regulate, based on level of risk. In addition, for those health IT that are medical devices, but which we have decided as a matter of policy not to actively regulate, or regulate only in part, how to best leverage the available tools, authorities and expertise of the other agencies, if at all, to protect patient safety and facilitate innovation. Again, thank you for taking part in this important undertaking. We look forward to working with all of you over the coming months.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Great. Thank you very much. I'll now turn the agenda over to David Bates, the chair of the workgroup, for his welcome.

**David Bates, MD, MSc – Brigham & Women’s Hospital & Partners – Senior Vice President, Quality and Safety**

Thanks so much. So, I also want to thank everyone for taking time from their busy schedules and for being willing to serve. We have, as you’ll hear, an extremely talented group with expertise in lots of different areas and my experience has been that workgroups like this one have been able to make major contributions. I recently served on the IOM committee, which is one of the inputs to this process, as did several others on this group, and that experience made me realize how important a wide array of perspectives is in this domain. So, to briefly review our charge, we’ve been asked to think about types of risk, factors or approaches that could be used in a risk-based, regulatory framework and then approaches to avoid duplicative or overlapping regulatory requirements.

Some of the things that we’ll be covering include a scope, so we’ll be thinking about what should be considered health IT, then work on a patient safety risk characterization, think about what the issues should be around innovation, and then address the area of regulations. Fortunately, we don’t have to actually develop the framework that will be done by the agencies. That being said, we have a very aggressive timeline. We’re planning for an in-person workgroup in D.C., which will probably be in late May, at some point. We may elect to identify some subgroups between now and then, to work...to tee things up for us. We have a major deadline August 7<sup>th</sup>, when the final workgroup recommendations have to be presented virtually to HIT Policy and September 4<sup>th</sup>, we’ll do an in-person presentation of the final workgroup recommendations and then what will happen is, between September and January, the agencies will actually prepare the strategies and recommendations for public comment. They have to – and then a report has to be issued by the end of January.

So the implication is that we have a lot of work to do between now and August 7<sup>th</sup>. We’ll probably elect to do a lot of this in small groups, as this is a big group and it’s hard to make a lot of headway in big groups. I’ll note that lots of materials have been sent out, many of you likely have reviewed them already, but if you haven’t, please do so. We’re going to try and reach consensus, when possible, though I recognize there are a lot of complicated issues in this area, and that may or may not always be possible. So, our goals for today are to go through introductions, to hear from the agencies. Let’s let the group react to our charge and ask questions of some of the agencies, and perhaps begin to think about how to do some of our work between now and the face-to-face meeting in May. So, with no further ado, maybe I’ll just provide my own introduction first.

I’m the Chief Quality Officer at Brigham & Women’s Hospital and the Chief of General Medicine here. I’m also the Medical Director of Clinical and Quality Analysis for Partner’s Information Systems. And I’m the former Board Chair of the American Medical Informatics Association. We want the introductions to be pretty brief, about 30 seconds ideally, as there are a lot of us. So, MacKenzie, could you take us around?

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Sure. Can we move to the next slide? There we go, okay. So, Patricia Brennan.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin-Madison – Project Health Design National Program Director**

Thanks very much. I’m a professor of Nursing and Industrial Engineering at University of Wisconsin, Madison. And I direct the Project Health Design, which is an initiative supported by the Robert Wood Johnson Foundation and California Foundation, to create new and novel personal health information tools and to move the concept of personal health records from a data repository to a platform for action.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Patricia. Geoff Clapp.

**Geoffrey Clapp – Better – Co-Founder**

Hi, yeah. This is Geoff Clapp. I’m an entrepreneur in health IT, started getting 5-10K back in the early ‘90s and worked with Rock Health with a number of health entrepreneurs, obviously dealing with a lot of these issues in the regulatory space and just actually launched my next start-up as well. So, that’s me.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Geoff. Todd Cooper.

**Todd Cooper – Breakthrough Solutions Foundry, Inc. – President**

Good morning. So I have about many, many years in the medical device informatics interoperability space. I am, among other things, co-chair of the Joint Working Group ISO/IEC that developed the 80001 standard and guidance documents. I'm head of delegation of ISO TC 215 on health informatics and I've been fairly engaged in a number of different standards bodies like the IEEE, HL7 and IHE.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Todd. Meghan Dierks.

**Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center**

I'm Meghan Dierks. I am faculty in Division of Clinical Informatics at Beth Israel Deaconess Medical Center and have done research and operational work in the area of systems analysis, systems interoperability and looking formally at risk analysis of this type of – these types of systems.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Meghan. Esther Dyson.

**Esther Dyson – Edventure Holdings, Inc. – Founder**

Hi. Esther Dyson. I'm an angel investor in a lot of healthcare start-ups as well as other areas. I'm on the Board of 23andMe, which does direct tumor genetics and of Oxeva, which is an mHealth company. I'm also an investor in Omada and a bunch of these other – with the hat of an investor who wants to make this marketplace work.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks. Richard Eaton.

**Richard M. Eaton, JD – Medical Imaging & Technology Alliance – Director, Industry Programs**

Good morning. I'm Richard Eaton. I'm the director of Industry Programs at the Medical Imaging & Technology Alliance, or MITA. We are the leading trade association representing diagnostic imaging equipment and radiation therapy equipment. Our association also represents producers of radiopharmaceuticals. Our manufacturers not only produce medical devices, but also produce a wide array of software products, PACS, RIS, HIS and the list goes on. We are delighted to participate in this group. It's going to do a lot of important work and we thank you for inviting us to participate.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks. Anura Fernando.

**Anura S. Fernando, MS, MD – Underwriters Laboratories – Principal Engineer, eHealth**

Hi. I'm the Principal Engineer for Medical Software and Systems Interoperability. I've worked in the development of risk-based standards related to software and also associated regulations, as they've been adopted into different regulatory environments across a number of different industries, alternative energy, industrial control, automotive, consumer appliances and most recently, medical. We're also currently working with the Association for Advancement of Medical Instrumentation, AAMI, to jointly develop a standard, which is starting off as AAMI/UL2800 for interoperable medical device interface safety. And we also appreciate the opportunity to be here and work with all of you.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks. Lauren Fifield.

**Lauren Fifield – Practice Fusion – Senior Policy Advisor**

Hi everyone. My name is Lauren Fifield and I am the Policy Advisor for Practice Fusion, a provider web-based and free technology to patients and doctors, including an electronic health record. I serve on the executive committee of the EHR Association, so an electronic health records trade group, as well as a leadership group. And I am now in San Francisco with Practice Fusion, but was formerly also in this role, among others, with athenahealth, which is a Boston-based EHR provider as well.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Lauren. Mike Flis.

**Michael Flis – Roche Diagnostics – Director, Diabetes Management Systems, Regulatory Affairs**

Good morning. I am the Director of Diabetes Management Systems, Regulatory Affairs for Roche Diagnostics and I've been involved with pre-market registration activities in the USA and Europe for over 20 years. I have served as AdvaMed's blood glucose workgroup leader and am currently a member of Continua Mobile Health Regulatory Coalition. And I volunteered to join because I'm hoping that we can lead to a fair, reasonable and predictable regulatory environment for these products. Thank you for the invitation to participate.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Mike. Elisabeth George.

**Elisabeth M. George, MS – Philips Healthcare – Vice President, Global Government Affairs, Standards & Regulations**

Yes. I'm Elisabeth George and I'm with Philips Healthcare. We're a healthcare company that is global that makes home health, as well as hospital equipment including imaging, defibrillators, patient monitors, and electronic health records. My role is Vice President of Global Government Affairs, Regulations and Standards. I've been in the industry for more than 30 years in quality and regulatory with close to 20 years in software devices, including software only devices, with significant work partnering with the FDA on many advisory committees and panels. And I also am an active industry representative in the Organization MITA, for Medical Imaging Technology Alliance, as well as AdvaMed and a number of standards organizations, including AAMI, ANSI and the International Standards Group.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Great. Thanks, Elisabeth. Julian Goldman.

**Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare**

Hi. This is Julian Goldman. I am a practicing anesthesiologist at the Massachusetts General Hospital where a lot of my work, a few years ago, involved the development of the operating room of the future with Mass General and a large team of folks including people like CIMIT, the Center for Integration of Medicine and Innovative Technology. I have a fellowship in medical device informatics from over 20 years ago, before we actually had a name for it.

I'm currently the Medical Director of Biomedical Engineering for Partners HealthCare System where my responsibilities include assessing the risk management of medical device integration for hospital IT systems and the EHR. I direct a program on medical device interoperability at CIMIT and Mass General Hospital, which is focused on improving patient safety through safe systems integration, really at the boundary of Health IT and medical devices. And I'm involved in a number of standards development activities including, for example, Chair of ISO TC 121, user Vice Chair of ASTM F 29 and involved with a number of standards and safety committee activities with AAMI, UL and Chair of the Use Case Working Group for the Continua Health Alliance. Thank you for allowing me to participate in this working group.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Julian. Drew Hickerson.

**T. Drew Hickerson, JD – Happtique, Inc. – Assistant General Counsel & Senior Director, Business Development**

Good morning. My name is Drew Hickerson. I'm the Assistant General Counsel and Senior Director of Business Development for Happtique. Happtique is a start-up company that provides software solutions to hospitals, healthcare professionals and other health enterprises, to assist in integrating mobile technology into patient care by providing mobile application marketplaces, mobile app and digital content prescribing technology. And we're currently launching a private, voluntary certification program for health apps to identify those that meet certain standards in the areas of privacy, security, operability and content. Prior to joining Happtique, I served as an in-house attorney with Happtique's parent entity, which is the business arm of Greater New York Hospital Association. The Greater New York Hospital Association is a trade association comprised of roughly 250 hospitals in the tri-state New York area and the association's core mission is to help hospitals and other healthcare providers deliver the best patient care in the most cost-effective manner. We're very pleased to be participating on this workgroup to identify appropriate strategies and recommendations to ensure safety and promote innovation throughout the entire continuum of care. So thank you.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Drew. Jeffrey Jacques.

**Jeffrey Jacques, MD – Aetna – President, Neonatal Solutions**

Yes. Good morning everybody, I'm Jeffrey Jacques. I'm the president of Neonatal Solutions at Aetna's Healthagen Division, a newly launched business that we picked up in January that combines mobile technology and coaching to support parents and their children through the NICU experience in the first year of life. I'm an internal medicine specialist by training and joined Aetna through the acquisition of a start-up company called ActiveHealth Management about eight years ago. While at ActiveHealth, I headed up our provider collaboration in support of Accountable Care and PCMH, as well as our population health analytics and our personal health record product. Prior to launching Neonatal Solutions, I was the Chief Medical Officer at Healthagen, which is our healthcare incubator. It's an honor for me to represent Healthagen and Aetna as part of the working group and thank you for having me.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Great. Thanks Jeffrey. Robert Jarrin.

**Robert Jarrin, JD – Qualcomm Incorporated – Senior Director, Government Affairs**

Hi there. I'm an attorney and I serve as Senior Director of Government Affairs for Qualcomm Incorporated. I help direct the company's policy, regulatory and legislative affairs in the area of wireless health and life sciences. I'd like to thank the three agencies for inviting me to join. Thank you.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

All right. Thanks Robert. Mo Kashul.

**Mohit Kaushal, MD, MBA – Aberdare Ventures/National Venture Capital Association**

Hi, good morning, and a pleasure to be here as well. ER physician is my background, was previously the Director of Health Care at the FCC, now a partner at Aberdare Ventures where we invest in early stage companies within this space. Of relevance within the smart devices space. We're investors in MC10 as well other sort of more classical healthcare IT companies.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Great. Thanks. Keith Larsen.

**Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director**

Hi, I'm Keith Larsen. I've worked in medical computing since 1976 at Intermountain Healthcare. My background is pharmacy by training. I've worked as a medical informaticist in developing our own clinical software including decision support and CPOE, as well as vendor software integration. I've been a director of informatics at some of our adult hospitals and our Children's Hospital, and I also had a three-year experience developing medical software as part of a vendor environment. Thank you for inviting me into this working group.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Keith. Mary Ann Leach, have you joined the call? Okay, moving to Meg Marshall.

**Meg Marshall, JD – Cerner Corporation – Director, Government Health Policy**

Good morning. This is Meg Marshall. I am a Director of Health Policy with Cerner Corporation. Cerner is a health information technology supplier; we sell our solutions globally including electronic health records. We have several of our solutions are actively regulated currently by the FDA. Cerner is a supporting collaborator of the Bipartisan Policy Center Health Initiative and I am on the executive committee of EHRA. And I would also like to thank the three agencies for the invitation to join.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Meg. Mary Mastenbrook.

**Mary Mastenbrook – Consumer**

Good morning. I am Mary Mastenbrook and I'm a consumer representative to the workgroup. My background includes experience as an FDA investigator, a manager of regulatory affairs and quality assurance. I've started small businesses and I assist others in starting small business. Most recently, I've worked with a start-up that provides a wireless accessory for the consumer market that also includes an app. And I appreciate the opportunity to bring the consumer perspective to the workgroup.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Mary. Jackie McCarthy.

**Jackie McCarthy – CTIA-The Wireless Association – Director, Wireless Internet Development**

Good morning. This is Jackie. I am Director of Wireless Internet Development at CTIA, The Wireless Association. And we're a trade association representing all facets of the commercial wireless industry from the network operators, otherwise known as cell-phone carriers, to device manufacturers, chip manufacturers and operating systems. And I look forward to bringing the perspective of the commercial wireless industry and wireless ecosystem. Thanks.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Jackie. Anna McCollister-Slipp, have you joined the speaker line yet?

**Anna McCollister-Slipp – Galileo Analytics – Co-Founder**

Yes, I'm here.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Okay, thanks.

**Anna McCollister-Slipp – Galileo Analytics – Co-Founder**

Hi. My name is Anna McCollister-Slipp and I am Co-Founder of a company, an early stage Health IT company called Galileo Analytics. We do visual data exploration and advanced analytics of complex health data, such as electronic health record data, registry data, really any kind of data. But I got interested in this business and I'm involved in this committee in large part because I'm also a Type 1 diabetes patient of 28 years. I do a lot of advocacy on areas related to medical device data, data standards, interoperability and the need for innovation in medical devices and interoperability between

medical devices and healthcare apps that you can get on your mobile phones and other things. And the role development will play in developing things like better comparative effectiveness research and outcomes based measurement for those of us with Type 1 diabetes and lots of other diseases. So thank you very much.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Anna. Jonathan Potter.

**Jonathan Potter, JD – Application Developers Alliance – President**

Hi, this is Jon Potter. I am President of the Application Developers Alliance. We are a trade organization that started about a year ago and we currently have 2500 app developers and 115 companies that are members. We obviously are interested in this space and a lot of associated health and medical working groups and I am pleased to be here and thank you very much for the invitation.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Jon. Jared Quoyeser.

**Jared S. Quoyeser, MHA – Intel Corporation – Director of Vertical Segments for North and South America**

Yes. Good morning everyone. This is Jared Quoyeser from Intel Corporation. I am presently Director of our Vertical Segments for North and South America. Vertical segments include healthcare, federal, education, energy and financial services and retail. Previous to that role, I was our Director for Healthcare for North and South America and then previous to that role, was Worldwide Director for our cellular and handset group and driving strategic relationships and engagements with service providers on a worldwide basis. I actually came from healthcare beforehand and spent time at Sutter Health, MD Anderson and also at Columbia HCA. And thank you for the invite.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Jared. Has Martin Sepulveda joined yet? Okay, moving to Joe Smith.

**Joseph M. Smith, MD, PhD, FACC – West Health – Chief Medical and Science Officer**

Good morning. Hi, this is Joe Smith. I'm a cardiac electrophysiologist engineer. I've been in the medical device space for about 25 years, I'm embarrassed to say, prior leadership roles at Guidant Corporation, Boston Scientific and J&J. For the last three years I've been the Chief Medical and Science Officer for West Health. That's an initiative, which includes a medical research organization, an investment fund, a policy center in DC and a small business incubator. We're passionately devoted to trying to lower the cost of health care and see that mobile wireless technology creates a fabulous opportunity, provided we get a lot of the details right, notably medical device interoperability a part of it. Delighted to join, thanks for having me.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Joe. Mike Swiernik.

**Michael Swiernik, MD – MobileHealthRx, Inc. – Chief Executive Officer and Founder**

Thank you. I'm a general internist and I'm the CEO of MobileHealthRx, a mobile health start-up I had founded in January 2012, with the goal of helping to improve chronic disease management in the ambulatory setting. Prior to that, I was the Senior Medical Informaticist at UCLA for nearly 10 years, where I worked on their EMR as well as a variety of research systems. While there, I also directed their Meaningful Use Program and collaborated with the Open End Health Group, which some of you may be familiar with. I thank you for inviting me.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Mike. Paul Tang.

**Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and  
Technology Officer**

Hi. Paul Tang, Vice President and Chief Innovation and Technology Officer of the Palo Alto Medical Foundation, which is a large, multispecialty medical group. In addition to the Innovation Center, I also oversee our EHR and PHR systems. I'm the Vice-Chair of the HIT Policy Committee and Chair of its Meaningful Use Workgroup. I served on the IOM EHR Safety Committee and I Chair the Quality Subcommittee of the National Committee on Vital and Health Statistics and the HIT Advisory Committee to the National Quality Forum, and former Chair of AMIA. Thank you.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Paul. Brad Thompson.

**Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC**

This is Brad Thompson. I'm a partner in a law firm, Epstein Becker & Green and there I work with mostly companies that are interested in getting into the medical device area, so I focus on FDA regulation of medical technology. Probably more relevant, I do quite a bit of coalition and trade association work. So I represent four different organizations that are interested in this space, one is the mHealth Regulatory Coalition with an obvious focus on mHealth and the regulatory aspects. The second group is the CDS Coalition. That group has a similar focus, but obviously from a CDS perspective. The third group is one that's just being launched and it's got an international focus to it, so, we're looking at the same HIT issues, but in the EU and other regions, in addition to the US. And then the Continua Health Alliance. And I'm delighted to be here, thanks for inviting me.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Brad. And our federal ex-officio members. Jodi Daniel.

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

Hi, this is Jodi Daniel. I'm the Director of the Office of Policy and Planning at ONC. I've been here since 2005, when the Office was officially established and was Counsel to the Office before that. I am responsible for our Federal Advisory Committees including the Health IT Policy Committee and have led our efforts on identifying a plan for health IT safety, including the policy work that will be coming out of this effort. I am joined, and you can – by a great team of folks at ONC. I have Steve Posnack, who is the director of our federal policy division, who will – you will hear from shortly, talking about our authorities and activities. And Mike Lipinski, who is a policy analyst in our office as well, and has worked on our regulatory efforts and will be supporting the workgroup.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Jodi. Bakul Patel.

**Bakul Patel, MS, MBA – Food & Drug Administration – Policy Advisor, Center for Devices and  
Radiological Health**

Hi. This is Bakul Patel. I'm a Senior Advisor at Center for Devices and Radiological Health at FDA. My primary responsibility is to create and establish policies for software connected health technologies and imaging technologies in this area. Very glad to be part of this workgroup and thank you all for being part of this.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act  
Program Lead**

Thanks Bakul. And lastly, we have Matthew Quinn, from FCC.

**Matthew Quinn – Federal Communications Commission – Director, Health Care Initiatives**

Good morning everybody. I am the Director of Health Care Initiatives here at FCC. I prior was at NIST where I was working on technical guidance, applying the science of human factors and usability to Health IT and some of our guidance is reflected in the safety enhanced design in the Meaningful Use Stage 2. Prior to coming to AHRQ, I was the healthcare program manager for Teradata and was a product manager for GE Healthcare and worked with Matthew Holt on personal health record start-up. So, happy to be involved.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks Matt. And I think time-wise, I'll just go directly into the next presentation, it was on process and procedures for a Federal Advisory Committee Workgroup. My name is MacKenzie Robertson, I am the FACA Coordinator within ONC and I manage both the HIT Policy Committee and the HIT Standards Committee for ONC. Let me just make sure we're on the correct slide. If we can go to the next slide please. Okay. So, I just wanted to give a brief – back one, there we go – just wanted to give a brief overview of the processes and procedures for this workgroup. The FDASIA Workgroup is...the HIT Policy Committee is a federal advisory committee subject to the Federal Advisory Committee Act, also known as FACA. The Act ensures that advice by the various advisory committees within the federal government formed over the years is both objective and accessible to the public. It also formalized a process for establishing and overseeing these committees.

So the role of the HIT Policy Committee is to advise the National Coordinator, as Farzad mentioned in his opening remarks, on a policy framework for the development and adoption of a nationwide health information infrastructure. The FDASIA Workgroup is a subcommittee, also a workgroup, to the HIT Policy Committee and reports back up to the HIT Policy Committee. The workgroup cannot provide advice or recommendations directly to ONC, the workgroup always reports back up through the Policy Committee. ONC actively...ONC made the policy that all their meetings, all their workgroup meetings would be open to the public. ONC greatly values and encourages public input, so all the workgroup meetings and the workgroup meeting materials are made available to the public. And all the workgroup meetings are posted to the ONC website.

If the workgroup feels that they need additional avenues for public input, we also have the option of doing virtual listening sessions, which are similar format to the working groups where we can invite outside experts to present or give testimony to the workgroup. And we have the opportunity to ask some questions. We also can use the Health IT Buzz Blog posting and post documents that we can get public comment on through our ONC website. Or there is the option of having in-person, day-long hearings where we can gather testimony in-person. The majority of these workgroup meetings will be held virtually and as the Chair, David Bates, mentioned in the beginning, we are planning an in-person workgroup meeting for the end of May. So, more information on that will be forthcoming.

In terms of administrative processes for the workgroup, all the audio recordings for each workgroup meeting will be posted to the ONC website, along with all the meeting materials; I believe it's within a few days after each workgroup meeting. And all the official calendar invites and meeting materials for each workgroup meeting will be coming from the ONC FACA meeting email account. So, if you need to do a quick search, you can just sort through the email from ONC FACA meetings, and those will be all the official correspondence for the workgroup. So with that, I'll take any questions anyone may have.

**Richard M. Eaton, JD – Medical Imaging & Technology Alliance – Director, Industry Programs**

This is Rich Eaton from MITA, just a mechanical, procedural question.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Yes.

**Richard M. Eaton, JD – Medical Imaging & Technology Alliance – Director, Industry Programs**

Do you know when or how the line-up of meetings and teleconferences, do you know when you're going to issue that, so that we can plan our schedules?

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Sure. We have the next virtual workgroup meeting is planned for May 6, from 10 to 12. That appointment should have already gone out last week. The only other meeting that we currently have – that's the only meeting that's on the calendar right now, but we are planning for two additional workgroup meetings in June, we're just trying to find time on everyone's calendars to make that work. So, the only official meeting on the books now is May 6 with two in June and a possible in-person at the end of May. But once we get those confirmed, we'll be shared to send the appointments out to the group as soon as possible.

**Richard M. Eaton, JD – Medical Imaging & Technology Alliance – Director, Industry Programs**

Thank you.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

We recognize everybody's busy and we'll get that out as soon as we can.

**Richard M. Eaton, JD – Medical Imaging & Technology Alliance – Director, Industry Programs**

Thank you very much.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Sure. So David, I believe Jodi was going to do the introduction for the FDASIA 6-18 overview.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Yup. Over to Jodi.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Great. Jodi.

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

Okay, thank you very much. So everybody should have received a one-pager, it is just says FDASIA Workgroup Overview. And David did talk through many of the points that were in here, I just want to highlight a couple of key issues, and then give people an opportunity to ask any questions or pose any comments about the overview. So, this all kicked off with section 6-18 of FDASIA, the Food and Drug Administration Safety Innovation Act, which required FDA to work with ONC and FCC to develop, to draft a report on an appropriate risk-based regulatory framework pertaining to Health IT, including mobile medical apps, that promotes innovation, protects patient safety and avoids regulatory duplication. So we're looking at – those are sort of the three pillars we keep repeating, innovation, safety and avoiding regulatory duplication. FDASIA identified that we were permitted to develop a workgroup in order to get input into this – into our thinking, and this workgroup is, in fact, in response to that call in the legislation. What we're hoping that the workgroup will do is help inform the development of the report.

FDA, FCC and ONC have been working collaboratively in getting this set up. This is a joint effort of all three agencies with joint commitment on our part and lots of staff support from all of us. And there are a lot of issues and things that we need to understand and input and recommendations that will feed into our development of that report. So we are not expecting the workgroup to develop a nice report with a big red bow and all neatly tied up, that's our job as the agencies. What we're looking for is for you all to help us thinking through some of the challenging issues that we need to address, and we need to understand, in developing that framework. So, as David had talked through, as far as the workgroup activities, we would like to have some conversation, and I see it's up on the website now, about the scope that we're talking about and what the scope of this framework would look like. And then focus on the 3 areas that were highlighted in the statute, which is safety and particularly patient safety risk characterization, innovation, what are some things that we need to be thinking about in order to promote innovation and using this framework to do so. And then regulations and avoiding regulatory duplication, and we'd like some input from you all, based on your experience in working with the various agencies and in, on how we can do so in a more efficient way and avoid any duplicative regulatory processes.

So, it's kind of just a very brief overview. I want to spend just a little bit of time, at the end we talk about a draft timeline. We have a very ambitious schedule, as David noted at the beginning. And I appreciate the commitment of everybody in this group in helping us to meet our timeline. So as MacKenzie has mentioned, we are trying to have an in-person workgroup meeting in Washington, DC for a day or a day and a half in late May, and we're just trying to finalize those dates. We will let you know as soon as we do. The timeline for the work of this workgroup is to have a draft workgroup recommendations for the August 7 meeting of the Health IT Policy Committee. And then – so that we can get any input or questions or think through any more details that the workgroup needs to think through before presenting final workgroup recommendations at the in-person meeting on September 4.

So this is just a few months of time commitment that we're asking of you all, although it will be quite a busy summer. And we have put a lot of staff resources behind that, to help make sure that things move quickly, efficiently and that we have all the material that folks need or would like to support your deliberations. If you note at the end, the September to January timeframe is where we're going to...the FDA, ONC and FCC will be working collaboratively to prepare to take those recommendations that you all have given us and prepare a draft report, as called for in our statute, in order to meet our statutory deadline of January, 2014. We do need to get things through our – that only gives us about two months to write, given the review processes that we will all have to go through in our agencies. And we will be putting that out for public comment. So, while we'll be going back in and coming up with a draft framework, it will be something we will then get further input on, so we expect that we will hear, once we actually pull something together, we will get more feedback at that point in time.

So that's kind of a general sense of our timeline, where we see this workgroup fitting in, the kinds of issues that we hope the workgroup will tackle and provide us input on. And how we plan to take that and turn that into a report and the timelines for that. Just wanted to give a very brief, high-level overview to get people kind of focused at the work at hand, and then open it up for questions and discussion for any thoughts folks have.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Great. So questions for Jodi?

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin-Madison – Project Health Design National Program Director**

Jodi, this is Patty Brennan. Can you give us some idea of when – the nature of a report that you're looking for? Are you looking for sort of background and gray literature perspectives or are you looking for high-level, bullet points and summary, a brief summary.

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

So, I'm going to answer it slightly differently, so tell me if I'm understanding what you're asking. I think what...if you look at the list that's in that one-pager, I think what we're looking for is for folks to help us, not necessarily just understand the literature, but we're trying to tap into your expertise on what are the types of risks we should be thinking about? How should we be thinking about risk? What are some of the critical factors that a framework should address to mitigate those risks? Are there particular activities that can...that we should be thinking about that can help promote innovation? Are there – helping us understand the process and decision points that innovators may go through and how the risk factors may apply. Those kinds of things, so as we're thinking about a draft framework, we understand what is happening in the industry, on the ground, how such – some innovative development occurs and how we can both promote that innovation as well as protect safety at the same time. So, we're looking more for your knowledge, your insights into how your knowledge and our processes might connect. And more so than kind of like landscape overview from literature. Does that help? The other agencies should feel free to jump in, Bakul or Matt.

**Esther Dyson – Edventure Holdings, Inc. – Founder**

This is Esther Dyson, oh, sorry.

**Bakul Patel, MS, MBA – Food & Drug Administration – Policy Advisor, Center for Devices and Radiological Health**

Hi. This is Bakul. Go ahead Esther, that's fine.

**Esther Dyson – Edventure Holdings, Inc. – Founder**

Okay. I was going to amplify the question. In what form is our input most helpful? Will you be sending us drafts to annotate or questionnaires or, it's a large group, so obviously, it's a challenge to make us all useful and it's a challenge for us to be useful. So, just how do you envision this happening?

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Well, this is David Bates. I think our output will probably be a series of PowerPoints, so it will be – it will really be bullet points. And the kinds of things that we're being asked to provide are really examples of issues, within the key areas.

**Esther Dyson – Edventure Holdings, Inc. – Founder**

Okay. Thanks.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator**

... provide commentary.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin-Madison – Project Health Design National Program Director**

That makes sense to me also, that you're looking for some expertise distilled through some critical discussion points as opposed to an extensive treatise on any particular aspect of this.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator**

Correct.

**Bakul Patel, MS, MBA – Food & Drug Administration – Policy Advisor, Center for Devices and Radiological Health**

I'm just going to add one – this is Bakul, I'm going to add one more point to what Jodi was highlighting is, the workgroup represents a broad cross-section of exper – healthcare sector. But also, there's – or our thinking is the workgroup should also be a conduit or sort of avenue for folks who are not on the workgroup to provide their input. And we can facilitate that through various different means, but other folks outside of the workgroup may have thoughts, ideas, should be part of that discussion that the workgroup may have. So, I just want to put that on the table for folks to think through as you have discussions that other folks you may have access to may also have great ideas.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin-Madison – Project Health Design National Program Director**

Thank you.

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

And – I think that's a really important point, thank you Bakul. And like MacKenzie mentioned, there may be ways we can help facilitate that through our blogs or through other kinds of means outside of these calls. The one other point I wanted to make, which David mentioned, I just want to reiterate is about, the most helpful thing to us is if folks can come to consensus on particular issues that you're discussing. Obviously, if there's something where there's a strong alternative view point, we're happy to hear it, but to the extent that you can – that there are points of consensus, that will help us to come up with a framework that meets all the various perspectives of this very diverse and extensive group. So, that would be our hope, is that as you're talking through these things, we can develop consensus, it doesn't necessarily mean that everybody will be 100 percent supportive of the position, but that folks can come to positions that this diverse group can agree to as a way forward.

**Elisabeth M. George, MS – Philips Healthcare – Vice President, Global Government Affairs, Standards & Regulations**

Jodi, this is Elisabeth George, I have a question regarding that. Having been through this on other times for other advisory committees, is there also the option that there could be maybe two alternatives identified? So for example, is if we identified a solution and then we said, but here's an alternative way of doing it, so that maybe you could get everybody to buy into one or the other of those alternatives, so that you could propose that to the committee?

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

Yeah. That's a great question. I mean, I think, this is my personal views and others should feel free to jump in. We want people to think creatively and to help us come up with approaches that we may not have thought through ourselves; otherwise, we could have gone in a room and figured it out ourselves. So, we really do want some good creative thinking. That might mean that at some point you come up with a recommendation that may be a little bit more outside of the scope of how we normally do things. And in that case, you may want to have an alternative to say, well, if that's not feasible, here's an approach that we think will get us pretty close to the same goal, but may have different pros or cons. So, I think that we'll have to see how it goes, but I think in some cases, particularly if folks have a really creative idea that may or may not work when we get into the weeds of it, having an alternative could be a feasible way of going. I would hesitate to have alternatives on everything, because it sometimes can also be used as a cop-out, but sometimes it can be used as a great way forward and a way of getting some agreement on something that may be a little bit bolder, with an alternative that's a little bit more conservative. So, I think that is perfectly fine. David, I don't know, or Bakul, I don't know if anybody else has thoughts on that.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Well, I just ...

**Elisabeth M. George, MS – Vice President, Global Government Affairs, Standards & Regulations – Philips Healthcare**

Just to add to that, this is Elisabeth again, I guess might be is that reach for the stars and then maybe identify transition, possibly ...

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

Yes.

**Elisabeth M. George, MS – Philips Healthcare – Vice President, Global Government Affairs, Standards & Regulations**

... as to how we could iteratively get there, rather than having alternatives.

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

Yes.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

This is David Bates. And just from prior work in this area, I know we will not agree on everything, but if there are some base things that we can agree about, I think that will be helpful to the agencies.

**Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC**

This is Brad Thompson. I have a general question, which is kind of, how out of the box we're allowed to think? Are we required to think within existing statutes or if anything we suggest implicates a legislative change, how do you want to handle that?

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator**

Bakul, do you want to take that?

**Bakul Patel, MS, MBA – Food & Drug Administration – Policy Advisor, Center for Devices and Radiological Health**

Sure. I mean, I would say go back to our foundation...under question, the one-pager that you guys all have, is to, before we get into what changes we need to make, we need to first identify what are the key features? What are the characteristics that are critical? And sort of give a rationale before we get to out of the box and big change as in this, as you know, may not be feasible in a timely fashion. So, like Elisabeth earlier, shoot for the stars, but make sure that practically applicable or implementable for the agencies and for the community.

**Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator**

Yeah, this is Farzad. I agree with that and add that, if we are going to give out of the box ideas, you should recognize that this, the Policy Committee and its recommendations have been something that we have tracked very closely in terms of – and we – the industry expects a lot of impact from these reports. So, to the extent that you give recommendations, you want to go to places where you recognize it's out of the box, to label it as such, and potentially have some – if you want to do that, you can have some meat and potatoes, we know it's feasible, it's within the constructs recommendations. And then to potentially, if you want to go there, to say, now here's this action of if you really – we recognize that this would require legislative change or this would require a very difference in approach. But here's our – this is an out-of-the-box idea, so that the reader can understand what it is and what it isn't. Does that make sense?

**Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC**

Very helpful. Thank you.

**Esther Dyson – Edventure Holdings, Inc. – Founder**

Yeah, Esther Dyson. I'm hoping that there is some opportunity to sort of think about defining risk as well as defining dangers and yeah, yeah, get a little meta, because the switch to individual versus group-based risks is coming rapidly and I think that's something that a lot of regulation – the regulatory framework needs to make a shift to understand that. As we get ...

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator**

Yeah, I think that's a great point and I do think – my thought is that we really need to have a very rich and thoughtful conversation about risk. I think that's going to actually be one of the more interesting areas of focus for us, to think how do we characterize risk? How do we think about risk and how does that impact a framework that we would develop to manage that risk? So, I think that's completely on point and I look forward to that conversation.

**Richard M. Eaton, JD – Medical Imaging & Technology Alliance – Director, Industry Programs**

Jodi, this is Rich Eaton. I had a question. You have the list here of workgroup activities, my question is, was this listing meant to be sequential in terms of what we will tackle in order, or not necessarily so?

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

So I would say – this is David – not necessarily, we'll definitely have to have a lot of parallel processing.

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

I will say also that this was what we came up with as a straw man for the workgroup activities. This was not meant to be set in stone. If folks look at this and say, you know what, you're really missing some sub-bullet here that we should be focused on; this was really to give a flavor of the work. As the workgroup is talking about details, I expect that things will come up that we didn't anticipate or didn't think about, so this is more of a guideline than a Bible.

**Bakul Patel, MS, MBA – Food & Drug Administration – Policy Advisor, Center for Devices and Radiological Health**

I would agree with that. This is Bakul. This was just initial thoughts of interest as we were thinking about the framework, what information or data or thoughts the workgroup can provide. So, there may be more to it, there may be less to this; I think the workgroup should agree on the areas. And there can be parallel activities, think about it as parallel activities that the group can sort of take on.

**Elisabeth M. George, MS – Philips Healthcare – Vice President, Global Government Affairs, Standards & Regulations**

Jodi, this is Elisabeth again. One of the things that came up in mind for me when I thought of this process was, is that no matter what the end-game ends up being, someone is going to need to transition to that end-game. Whether it be someone who is presently completely unregulated or inversely, someone who already has say a 5-10K and may we have to go backwards. So I guess one of my questions would be we need to capture somewhere those thought processes with whatever we identify as the way forward.

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

I think that's a great point. And that may be another stream of discussion. I think it's a great point.

**Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare**

Julian Goldman here. As I think through the different areas of the risk characterization and balancing that with innovation and the value of regulation, I realize that sometimes when we get into a discussion about risk or rather frequently when we get into a discussion about risk, we look for data. And risk can sometimes be assessed through first principles, things that we know are dangerous, or that may be or hazardous. But, when it comes to Health IT and the use of Health IT and medical devices with Health IT, it seems that we – the community has been struggling to find data about events and issues. Whether it's erroneous data from the medical device that shows up in electronic health record or a problem with a decision-support component or a problem with the device interface, so that when a device is connected to a Health IT system, the device may fail. And all these things have been documented, but the documentation is scattered, very little of it is available. And I wonder how the organizers are thinking about and how we'll move forward, if there will be additional data or source of data or a way for us to perhaps characterize and document these challenges and the implications that not having data imposes on developing a framework.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

This is David Bates. One of the charges of our – the IOM Committee that reported on this area was to summarize the data, and as Julian has suggested, those data are quite incomplete and relatively scattered. I think we probably will not be gathering additional data in this process, given our time frame, and we'll have to make some suggestions, recognizing that we don't have all the data that we would really like.

**Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare**

And suggestions may include a better approach to handling data collection in the future, I suppose.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Absolutely. I think that's one of the key things that we should be thinking about.

**Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare**

Thank you.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin-Madison – Project Health Design National Program Director**

David, this is Patty. If – this may be – you may need to redirect this question to later but, there have been several risk models advanced at the federal level, Homeland Security has some, the power industries have some. Are you – should we be thinking about this from those perspectives or should we be looking at a different models of risk completely?

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

I think that's also a great point. I think we should bring it up when we get into talking in detail about which risk models we should consider.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison**

Perfect. Thanks.

**David Bates, MD, MSc – Brigham & Women’s Hospital & Partners – Senior Vice President, Quality and Safety**

I’m just watching the time and we’re a little bit behind schedule. I think it might be time to go into the Agency 101’s from ONC, FCC and FDA, if that’s okay.

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

Great. Can we go to the next slide? Up, I think there’s one before that. Okay. So, each of the agencies thought – we figured that everybody has their own expertise on this group and that everyone might not know all of the different agencies authority and activities that may play into the discussion and the thinking of this workgroup and the framework that comes out. So what we wanted to do was just take some time to do a little, a little bit of level setting for folks on what each of the three agencies are currently doing and what our authority is, even if there isn’t a current activity going on in that space, so that you all can think about creative approaches to address some of these issues that we’ve been talking about. We’re going to just do a quick run through. ONC, I think ONC, FCC and then FDA, to talk through this, to help folks have that context and then we can take some questions and then move on. So I’m going to turn it over for ONC to Steve Posnack.

**Steven Posnack, MHS, MS, CISSP – Office of the National Coordinator**

All right. Thanks a lot Jodi. So, I am Steve Posnack, as Jodi introduced earlier. Can you go to the next slide please? One of the many voices from the federal team that you’ll be hearing and interacting with via email. So, I am the Director of the Federal Policy Division at ONC and responsible for the publication of our regulations, basically serve as kind of our Editor-in-Chief now at this point. So ONC was originally created by an executive order in 2004 and then formally codified in statute as part of the Stimulus Bill, or the ARRA, American Reinvestment and Recovery Act. Within the Recovery Act, there was a large bill called the HITECH Act, I’m giving you all the acronyms, the Health Information Technology for Economic and Clinical Health Act and so the HITECH Act gave ONC specific authority related to Health IT certification.

And our authority is really two-fold. We have the ability to administer voluntary certification programs for Health IT, and there’s a little quote of our statutory authority there from Title 30 of the Public Health Service Act, the XXX there wasn’t a placeholder that is the title that we have. And then we also have the authority to adopt standards, implementation specifications and certification criteria for health IT. So, generally we go through a regulatory process, adopt certification criteria that so reference different technical standards and implementation specifications that health information technology needs to meet. At the present time, we have been administering a certification program for electronic health records. Some of you may have heard other folks on the call reference meaningful use. We implement our certification program and authority to support the EHR Incentive Programs that are run by our colleagues at CMS, which provide incentives to Medicare and Medicaid, certain eligible providers under those programs.

And I also wanted to throw in here that Congress was so helpful in giving us a definition of Health IT and, so you can see, I’m not going to read it off to folks here, but we have a definition in the HITECH Act with respect to what Congress had intended Health IT to be defined to be. And just to give folks a sense of how broad our authority is relative to the voluntary certification programs that we could set up. So while we currently are implementing certification programs for EHR technology specifically, we would, through issuing subsequent regulatory actions, be able to create other voluntary programs for Health IT, where it would be useful to stakeholders. So I will jump to the next slide.

So current activities. As I mentioned, we administer the ONC Health IT Certification Program. In response to the Institute of Medicine's report on Health IT and Patient Safety, which we commissioned in, I believe, 2010, they issued a report to us in 2011 and gave us a year to issue a Surveillance and Action Plan relative to Health IT and Patient Safety. We published a draft plan in this past December 2012, and we are actively working on working to finalize that plan. I believe it was part of our materials, reading materials that we sent out, so would encourage folks to give that a quick read to see what the Surveillance and Action Plan includes. And as you've already heard, we do regularly communicate and coordinate with our colleagues throughout the department at FDA, AHRQ, CMS, many other federal agencies on the intersection of health IT and patient safety. So that's a quick whirlwind tour of ONC, our current authorities and current activities, and I will turn it over to Matt, from FCC.

**Matthew Quinn – Federal Communications Commission – Director, Health Care Initiatives**

Great. Thanks Steve. Next slide please. So, unlike Office of the National Coordinator for Health IT, healthcare is not in FCC's name, but I hope the next few slides will help clarify where FCC plays and provide a good level set in our involvement in healthcare. Next slide please. And so the FCC was established in '34 and charged with regulating interstate and international communication by radio. About 1700 folks, attorneys, engineers, economists and folks like me, that are et al. We have a lab in Columbia, Maryland, where we do some of the product testing and certification, authorization, as well as some other technical things. Next slide.

So FCC areas of responsibility. At the top of the list, FCC manages non-federal spectrum, and what this is used for is promoting access to airwaves for medical devices, radio services that support Health IT and apps. We also run a rural healthcare program, as part of the Universal Service Fund, where we subsidize broadband for healthcare providers, public health organizations and this promotes telemedicine adoption. We work in broadband advancing wire line and wireless communication, and a lot of this can be – a lot of the...where we see this going can be found in the National Broadband Plan, which is available at the link in your resources. Next slide.

So there are licensed radio services that we're all familiar with, broadcasting, satellites, private wireless, commercial mobile, etcetera. Next slide. And what FCC really is concerned about here is, interference control, so frequency, power output, bandwidth/channels, spurious emissions. Where FCC generally has not regulated is in performance, reliability, compatibility and we strive to be technology neutral. Next slide please. And then there's a whole world of unlicensed devices, generally short range devices. And examples of these are everything from your Bluetooth headsets and keyboards, to wireless baby monitors. I checked mine last night and there is an FCC symbol on it. The medical camera pills that are now going around, pool cover controllers, diaper wetness sensors, etcetera, etcetera. And, next slide please. Again, the focus on this is interference control. And these are generally low enough power and strength that they're not causing that, but that's one of the things to look at here. Next slide.

So, FCC operates an equipment authorization program and it's a multi-tiered program where many devices are actually self-declared. Most transmitters must be certified by the FCC or telecommunication certification body, and equipment may not be imported or marketed until certified. There's a really good link here, and, being at the agency for three weeks, this was the first place that I looked, at FCC.gov Office of Engineering and Technology/EA. Next slide.

**Elisabeth M. George, MS – Philips Healthcare – Vice President, Global Government Affairs, Standards & Regulations**

Matt, this is Elisabeth. I have a very quick question.

**Matthew Quinn – Federal Communications Commission – Director, Health Care Initiatives**

Sure.

**Elisabeth M. George, MS – Philips Healthcare – Vice President, Global Government Affairs, Standards & Regulations**

You mentioned interference control, and if I understand it correctly, it's interference that those devices cause on other devices, correct?

**Matthew Quinn – Federal Communications Commission – Director, Health Care Initiatives**

Correct.

**Elisabeth M. George, MS – Philips Healthcare – Vice President, Global Government Affairs, Standards & Regulations**

Okay. I just wanted to make sure that people understood that, because I know from a medical side that in the...specifically the unlicensed area, that's always been a topic of discussion for us.

**Matthew Quinn – Federal Communications Commission – Director, Health Care Initiatives**

Absolutely. And you can think about it in the context of inside the healthcare enterprise, but then even broader ones, for example, there are some issues with telemetry software and aircraft test pilot tracking that are on the same spectrum. And, although they're completely different power and not likely to cause interference, these are FCC kind of issues. So why does this matter? Spectrum is the oxygen that wireless broadband needs to thrive and the proliferation of hungry devices and consume apps and all of these national purposes, including healthcare and Smart Grid and telemedicine and public safety, are...it's the same spectrum map. And there are some pretty innovative things going on here at FCC to potentially free up more bandwidth and more spectrum for wireless. Next.

So, FCC and FDA have been working together for many years and there's ongoing collaboration and consultation on the guidance for wireless medical apps, EMC, RF safety. Next slide. And in July of 2010, unprecedented joint statement of cooperation in this area. Next slide. In addition, the FCC has been working with the private sector, through its mHealth Task Force, Dr. Goldman and Jared are two of the Chairs of that. And they published a great report, that I'd recommend that everybody check out at [FCC.gov/healthcare](http://FCC.gov/healthcare), released in September 2012, that really established a set of recommendations that we hope will help mHealth technology become routine medical best practice within five years. One of those was hiring a permanent director of Healthcare Initiatives to really coordinate and lead these initiatives, and that's me. Next slide please.

And so in addition to this, FCC has done things like granted waivers for various medical devices, adopted rules to expand spectrum for medical implant communications and service, and created medical device service. There's a whole set of rules to provide spectrum for medical body area networks, nerve stimulators to restore motion and there is some discussion of a test bed as well. Next. So this is my contact information. If you have more questions, please feel free to reach out to me and I'll work with Julie Knapp, who is the Chief of the Office of Engineering and Technology here, and we can answer your questions. Thanks.

**Bakul Patel, MS, MBA – Food & Drug Administration – Policy Advisor, Center for Devices and Radiological Health**

Next slide please. This is Bakul. Thanks Matt, thanks Steve. Let me just walk you through a brief, or a high-level overview on what FDA gets its authorities from, our vision and then as Jeff mentioned earlier in the call, how we've been changing our approaches as we move forward and looking at technologies going forward. So let me, next slide please. Let me share with you, what we are really focused on, next slide, is assuring patients and providers have continued access to safe, effective and high-quality medical devices. That's the foundation, we start from there. And also at the same time, providing people with access to science-based information about products and healthcare products that exist out in the marketplace. But most importantly, not forgetting medical device innovation is also a key for healthcare to continue to be on this trajectory it has been in the last several years, last many years actually. Next slide.

Oh, three more, yes. Which leads us to our vision, is back to access, patients having access, having US, the world leader in regulatory with medical device innovation. We also at the same time, creating processed and programs that actually does device approval and clearances in a timely fashion, safe and effective medical devices and providing the science-based information that needs – that provides the needs to the patients, providers and consumers that gives confidence to folks when they use technology in the healthcare area. Next slide please. So this is where we get the definition of a device, in section 201 H of the FDNC Act. And I want to read through this. It's basically products that are intended to use for diagnosing a disease or other conditions, that cure, mitigate, treat or prevent is considered medical device. Next slide.

So let me just distill that further. Medical devices are any product that does not achieve its principle intended purposes by chemical action or being metabolized. So, we have – the medical device world is very heterogeneous, it ranges from a simple tongue depressor or a thermometer to a very complex robotic surgery device and everything in between that which has information from one point to another, providing easy access to diagnosing, gaining access to treatment, etcetera, fits into that. Next slide gives you a good perspective on the various range, and we put this together to just show how many products can range from the low end of the spectrum to the very high end of the spectrum. Next slide.

So this also includes devices – medical device also includes software. The three types of software as we categorize them as software in a device, as so many of the products in the previous slide contain software, as you can imagine. And then you have software that are used in manufacturing processes. And then you have software only as devices and here are some examples. Next slide please. So when Jeff talked about earlier there are different types of software-only devices that provide you information, provide you ability to diagnose, provide you and tool that can take you from the data that's collected from a person or physiological signals and translate it into something meaningful. Networks like laboratory information system or IT systems that provide connection between the labs and the provider is also one of the things that we regulate. Next slide.

So all the products that we have – I showed you earlier, the medical device amendments of 1976, created a – gave us a three-tier, risk-based system that gives you Class I low risk, Class II moderate and Class III higher risk products, and gave us also tools with the philosophy that you can use the tools and mix and match and use them within those big, broad buckets of Class I, Class II and Class III types of products. Not all products in Class II typically require a premarket review, some products don't, and some products require just special controls. So that's an example of how we tailor our regulatory tools and regulatory tiers, which is right for the technology and the risk that poses to patient safety. Next please. So here's an example of the current activity.

We proposed in 2011 a mobile medical apps draft guidance, which proposed a policy for looking only at the tip of the iceberg, like Jeff mentioned, which focuses on only a very small subset that will provide the same confidence as you – that you would want from another medical device that's currently regulated. And in the policy we also clarified that very simple tools like patient self-management and other things that may even meet a definition of a device by law, we would exercise enforcement discretion towards those type of mobile medical apps or technology in that area. We also, in that guidance, we also clarified there are certain things that don't even meet the medical device definition, and we clarified those are the things that we would not have oversight on. The point here of the policy was to focus only on a very small subset, and looking at benefits and risks of other types of products that exist in this technology space and making sure that we are applying our oversight only to those that actually could have a value-add from our oversight. Next please.

Here's what we proposed – in a couple more clicks, yeah. Here's what we proposed in the policy. We're focusing on the tip of the pyramid that you just saw, is apps that are either an accessory to a regulated medical device or those that transform into a regulated medical device. Let me give you a couple of examples of that, an app or a combination of app and a mobile platform that converts, transforms into an EKG machine, it's still an EKG machine regardless of the platform it resides on. So that's the policy we put together here, or we proposed it. The accessory part is, if an app or a contrivance or a product that controls the blood pressure cuff or controls another machine or another medical device, we would be overseeing as the policy proposed. I wanted to share with you that this is the focus that we are proposing in the Draft Guidance. Next please.

Here's our current thinking. FDA's approach has been, for the last three years, toward a smart regulation, focusing on only a small subset of technology that can – that would pose high-risk to patients, and also using our tools that are appropriate for the technology that may not necessarily fit our traditional Class I, Class II, Class III risk bucket that are the categorization that we have had. We are also looking at relying heavily on the quality systems providing that assurance that products, when they are made in the technology space, come out with – come to market with some foundational good practices. Some examples, in 2011 we also had a down-classification for medical device systems, where we actually said things that transfer, store medical device data would not require any premarket submission. So by default, when...without that classification, those types of products may either be classified as an accessory or by itself, if there is no classification exists, will be considered very high risk. We took this proactive approach and said we would consider all those types of functionalities to be Class I, where you don't need any premarket submission.

The mobile medical apps guidance also focused on a very similar approach which said, we are focusing on a very small subset that's similar – that if it appears in a mobile platform, that's similar to a previously regulated device. We'll only focus on that, while recognizing that there is a lot more benefit that may happen in mHealth area where no active oversight is required at this time. Next. So in conclusion, we recognize the importance of balancing patient safety while facilitating innovation in this exciting area, not only mobile apps, but also in health IT and we're open to hearing the workgroups input. But, keeping in mind, we also have many tools that we've been using in a risk-based fashion for many years that we've also planned for the area – even for the areas that we regulate, we plan to apply judiciously. I will – we can take questions at this time, but that was the last of my slides.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Why don't we take questions for about five minutes before we get into next steps.

**Esther Dyson – Edventure Holdings, Inc. – Founder**

This is Esther Dyson. Could you define what you consider to be risk? I mean, there's the risk is electrical interference, but presumably there's some kind of notion of patient risk. And how much of the risk to the patient, risk that the patient will, risk that the information will be used badly. If you could go through that a little bit, it would be very helpful.

**Bakul Patel, MS, MBA – Food & Drug Administration – Policy Advisor, Center for Devices and Radiological Health**

So, I think for health IT as a technology – I'm sorry, this is Bakul – I would want that rich conversation to happen in the workgroup. But, for health IT, we recognize there are different types of risk that can emerge, and I'm not sure whether I'm answering your question or not, but that's our current thinking is the workgroup should debate, as one of the items that's been proposed in the one-pager.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

This is David Bates. I think it would be all those types of risks, but that will be sort of job one for the group that focuses on that area. Other questions?

**Michael Swiernik, MD – MobileHealthRx, Inc. – Chief Executive Officer and Founder**

Hi, this is Mike Swiernik. Is the definition of an accessory also something that's going to be looked at by the workgroup?

**Bakul Patel, MS, MBA – Food & Drug Administration – Policy Advisor, Center for Devices and Radiological Health**

If the question's to me, I think we – as you guys define the scope of what is Health IT. And as you think about that, you need to, from that perspective, look at what should be or should not be included as part of a traditional device medical, medical device accessory is something that FDA is already looking at defining and refining, how we approach that. But as far as health IT is considered, I think you, the group should think about how that should, how that plays into the equation at all, if it does.

**Michael Swiernik, MD – MobileHealthRx, Inc. – Chief Executive Officer and Founder**

Thanks.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin-Madison – Project Health Design National Program Director**

David, this is Patty. One of the questions that I have for Bakul is, has to do with whether it would be possible for you to generate a few model cases or prototypes? Because right now I'm afraid we'll get too quickly stuck into things that we currently can see and it would seem that for these regulations to be useful, especially to be stimulating the industry, we don't want to be anchored just in what we see now. But, for example, an implantable defibrillator that exports a waveform and a series of event notices to a smart phone. The defibrillator's already being regulated, so what the risk and appraisal around the safety issues, is it at the point of what's received in the smart phone, which is not truly a medical device, since the device is in the person, but actually serves more, if I understood it correctly, software device.

**Bakul Patel, MS, MBA – Food & Drug Administration – Policy Advisor, Center for Devices and Radiological Health**

I hate to do this to you guys again, but I think these are the exact type of discussions, as information gets shared and exchanged, or the traditional infrastructure of information technology, I think the group should think about, what type of touch points or risks. As you – if you can imagine, that may arise from having that information transferred from one point to another, when it's not relied, could not be relied upon or relied upon from a benefits versus risk perspective.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison**

Got it. So you're asking us to provide you with some exemplars, even fanciful ones would be helpful to do more rather than fewer.

**Bakul Patel, MS, MBA – Food & Drug Administration – Policy Advisor, Center for Devices and Radiological Health**

Yes.

**Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator**

I agree.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Okay. So not hearing any other questions, let's move into next steps. As you've heard, this group really includes an impressive level of expertise around a whole array of issues including standards and regulation and interoperability and innovation. It includes people from industry, both on the big side and on the small side. It includes provider organizations, consumers, people from the wired world and the wireless world. I'm really looking forward to meeting everybody in person, as well as virtually. Virtually is nice, but it's nice to meet in person. Again, as Jodi emphasized, because of the involvement of the three agencies, we will have lots of support in this process.

We do have a big problem in front of us, these problems are sometimes referred to as wicked problems. So there aren't really going to be perfect solutions, we need to come up with solutions that will work in the marketplace. We will need to take the problem and break it into meaningful chunks. That will be kind of the key next thing that we'll do, and we'll be considering how to do that. You have the straw man in front of you around that, but we're thinking that it will probably be important to have a group that'll focus on clinical systems taxonomy and think about what is HIT, what's in, what's out. Another group will probably focus on safety and HIT risk assessment; Bakul has given us a number of examples just now. We'll probably have a group work on innovation, they'll be work to do around regulations, and what the options are there, what the various levers are. And then there are also a number of mobile specific issues.

So those are some of the areas that we're thinking of as potential chunks. If anybody has a specific issues that they feel we need to address, we want to make sure that they do get addressed or somehow fit within one of the chunks. And I'd encourage you all to send any suggestions to me and/or any of the agency leaders. I also ask you to be thinking about specific people or groups that are not included in the workgroup that you think we need to hear from in the process, because it will be helpful to line that sort of input up early. And as both Bakul and Jodi noted, we'll be getting input from individuals outside the workgroup. We do want to expedite that. So those are what I'm thinking of as the next steps. Any questions about that before we go to public comment.

**Todd Cooper – Breakthrough Solutions Foundry, Inc. – President**

Hello, this is Todd Cooper. What is your process for dividing up the group? Will you be putting out these proposed sub-teams and then looking for volunteers, are you open to recommendations or ideas about different sub-groups? What's the process going forward?

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Probably both of the above; typically we have asked people from within the group to self-identify. And then sometimes we'll also ask people who are not necessarily part of the workgroup to participate in some of the subgroups, so that's an option, if we feel like we don't have sufficient expertise.

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

Yeah I think one thing, we will – this is Jodi Daniel – we will debrief after this call and I'm going to expect to...that you will be seeing more emails, either directly from David or from MacKenzie Robertson, who is our FACA lead, on both materials to review or more activities that are coming down the pike. So please kind of keep up on the emails. We'll try to keep them concise, but we will try to follow up with some more concrete input on areas that – or ideas of how we want to structure this. We could go back and forth on email on some things in between meetings. So, we're just kicking this off and we have lots of different options and ways of organizing. Some of it will depend on David and his preferences and then feedback from the group. And as he said, we can do it lots of different ways and we are open to any input, feel free to reach out to us if you have some, on how we can do this. And we expect that there may be some areas where we do want to have smaller groups to try chew on some things and propose them back to the larger group.

**Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director**

Hi, this is Keith Larsen. So, do you anticipate that you'll set up these workgroups, I mean these subgroups between now and our next call or between now and like June calls?

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

More likely between now and June.

**Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director**

Okay. So next week is more of a full group meeting then.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Correct. Correct. But as I'm looking at the schedule, I already feel time pressure and we just had our first call.

**Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director**

Yeah.

**M**

Agreed.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin-Madison – Project Health Design National Program Director**

David, this is Patty. There are two thoughts that I've had. One of them is that if I'm not mistaken, I don't recall there's any major communications vendor on our participation list, so there's no Charter or Comcast or Verizon. And I'm not sure that they necessarily would be on the workgroup, but it would seem to me an important part of the process to engage – maybe there's other communications and the FCC could advise better on that. The second is that there is a fairly large group at University of Pittsburgh that does threats, security threats and analysis for network-based communications and again, they may be useful as informants or perhaps as participants. But the conversation and the comments to date seem to focus really more on the front-end aspects of risks, like what's the patient touching? What's the clinician seeing? As opposed to some back-end risk issues like, is the network transmission secure? Do we have a way around south New York City if there's another flood?

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Good points.

**Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC**

This is Brad Thompson. I was just going to explain that the telecommunications firms are members of the coalitions that I mentioned before and I plan to go back to them ...

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin-Madison – Project Health Design National Program Director**

Okay.

**Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC**

...a and get their input. That's not to suggest they shouldn't have any additional input, but...

**Matthew Quinn – Federal Communications Commission – Director, Health Care Initiatives**

And CTIA's involved, too.

**Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC**

I will be working with them.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison**

Yeah, okay. Thank you.

**Matthew Quinn – Federal Communications Commission – Director, Health Care Initiatives**

This is Matt Quinn from FCC. We noted that CTIA is involved as well, and that could provide some of that input.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin-Madison – Project Health Design National Program Director**

That's good. Thank you.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Great. Okay. Well thank you all, this has been a great conversation. I'd like to have the operators, if they would, go ahead and open up the phones to public comment.

**Public Comment**

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

So, before we go to public comment, I just wanted to remind members of the public that we're going to limit the comments to two minutes per person. And that they are just public comments, the workgroup does not need to respond directly to each question or comment that's presented. So operator, can you please open the lines?

**Rebecca Armendariz – Altarum Institute**

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press \*1. Or if you are listening via your telephone, you may press \*1 at this time to be entered into the queue. We have no comment at this time.

**Operator**

We do have comments come in from Glen Hill from Siemens. Please proceed with your comment.

**Glen Hill, MS – Siemens Healthcare – Senior Director, Quality and Regulatory Compliance**

Yeah hi, my name is Glen Hill from Siemens. I just wanted to comment to Bakul and Jodi's offer to open it up for input to other workgroups, So, as part of the Bipartisan Policy Center Workgroup, we've been working on the proposal for the regulatory framework. And we have two active workgroups right now, one is developing a proposal for process standards for Health IT and the second one is working with ECRI and other PSOs on a possible...looking at a potential reporting system for a learning health system. So that's just two inputs as well that we would be happy to work with the FDASIA Workgroup on.

**Rebecca Armendariz – Altarum Institute**

We do have another comment from Janet Marchibroda.

**Janet Marchibroda, MBA – Bipartisan Policy Center – Director, Health Innovation Initiative**

Hi. Yes, this is Janet Marchibroda. Thank you for your leadership and we commend HHS for putting together this workgroup. My comment to the workgroup and to the agencies is this. I know that there are at least two documents that you all are working on, the FDA Guidance on Mobile Applications and the ONC Patient Safety Action Plan, and there have been public statements about the timing of the release of those two documents. I also saw that the scope of work of the workgroup appropriately so, is going to weigh in on issues that may have an impact on those two documents, not sure. And the comment is, we hope that the workgroup, the workgroup and the agencies, will consider the timing of these various documents to enable the workgroup and the public process associated with it, to appropriately inform those two deliverables from the federal government. That's my comment.

**Rebecca Armendariz – Altarum Institute**

We have no further comment at this time.

**David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety**

Okay. Well thanks very much everyone, and we will be talking again soon.

**MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead**

Thanks everybody. And just as a reminder, our next meeting is May 6 from 10 to 12.