

**HIT Policy Committee
FDASIA Workgroup
Transcript
May 6, 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 second meeting of the HIT Policy Committee's FDASIA Workgroup. This is a public call and there is time for public comment built in at the end of the agenda. The call is also being recorded, so please make sure you identify yourself when speaking. I'm now going to go through the roll call and I'll just remind members as I'm going to the roll call, if you're not actively speaking, to please put your phone on mute, so we don't get any background noise. 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 at 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? Geoff, I believe you're on the line.

Geoffrey Clapp – Better – Co-Founder

I guess I was on mute, here.

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

Oh great. Thanks. Todd Cooper? 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?

Esther Dyson – Edventure Holdings, Inc. – Founder

Here.

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

Thanks Esther. Richard Eaton?

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

Here.

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

Thanks Richard. Anura Fernando?

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? 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

I'm 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**

Here.

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

Thanks Drew. Jeffrey Jacques?

Jeffrey Jacques, MD – Aetna – President, Neonatal Solutions

Present.

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

Thank you Jeffrey. Robert Jarrin? Robert Jarrin I believe is on the line. Mo Kaushal?

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

Here.

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

Oh great. Thanks Mo. Keith Larsen?

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

I'm here.

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

Great. Thanks Keith. Mary Anne Leach?

Mary Anne Leach – Children’s Hospital Colorado – Senior Vice President and Chief Information Officer

Here.

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

Thanks Mary Anne. 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

Here.

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

Thanks Jackie. Anna McCollister-Slipp?

Anna McCollister-Slipp – Galileo Analytics – Co-Founder

I’m here.

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

Great. Thanks Anna. Jon Potter? Jared Quoyeser? Martin – oh great, thanks Jared. Martin Sepulveda? Joseph 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?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, P.C.

Here.

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

Thanks Brad. Jodi Daniel?

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

Here.

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

Thanks Jodi. Bakul Patel?

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

Here.

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

Thanks Bakul. Matthew Quinn?

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

Here.

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

Great. Thanks Matt. And I also know that we do have Steve Posnack and Mike Lipinski on from ONC. Are there any other FCC or FDA members on the line? Okay, with that, I will turn the agenda back to you David.

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

Thanks very much MacKenzie. I thought that our initial call was really terrific and again, we have lots of work to do in a very short period of time. The face-to-face meeting has been scheduled for May 30 and 31 and we’ll talk some more later about our plans for that day. What we’re hoping to do today is to talk about formation of subgroups and then discuss the charters for the three subgroups and later in the call we’ll be going through and asking everyone to volunteer for one of the groups. We’ll also spend a few minutes later talking about what everyone would like to accomplish in our face-to-face meeting and then we’ll have public comment.

So again – so for the subgroups, what we’re hoping is that people will be able to have one call before the face-to-face, that there will also be some virtual work that will go on, either via email or via electronic groups. The rules that we’re thinking about is that everyone – we would like everyone to join at least one of the groups, if you want to join more, you can. Again today, think about which of the groups you would be interested in. We elected to form three subgroups in part because that’s the number that we feel would be – agency partners we can support really well and the three – we broke things into three domains. The first group will be the taxonomy group, which will think about scope, and we’ll go through some more about that in the next section of the call. The next group has been tasked with thinking about both risk assessment and also innovation, and our notion is that those two go together well. And then the third group will be asked to think about regulations and levers, which could be used to move things forward in this area. So that’s a brief overview. Jodi or Bakul or Matt, things to add?

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health

No, I think as we get into – this is Bakul, sorry, as we get into the detailed discussion, we can dive deeper into that, but that's really good.

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

Okay. So – and questions from the workgroup members about the subgroups? Okay.

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

This is Patty. My big question is, are you envisioning us having sort of a check in at each of the calls that have now been scheduled from subgroup activity, and so that the knitting together of the sub – will happen in these meetings not outside of these meetings?

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

Knitting together correct will happen in the – I'm thinking will happen in the times when we are together. I mean clearly, there are interactions between these areas and overlap.

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

Yup. Okay. Thank you.

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

Yup. Other questions? So, not hearing any, let's actually move into a discussion of what the subgroups should focus on. And since the last call, we've identified co-chairs for each of the groups and Patty Brennan and Meghan Dierks have agreed to co-chair the Taxonomy Group. Paul Tang and Keith Larsen have agreed to co-chair the Risk Group and then Brad Thompson and Julian Goldman have agreed to co-chair the Regulations Group.

So let's start with the Taxonomy Group and that group will be thinking about what should be inbounds and what should be out of bounds. And again, FDASIA 618 has asked us for a report that contains a proposed strategy and recommendations around a risk-based regulatory framework that pertains to health information technology including mobile medical applications. This group will have to decide, again, what's in and what's out and there are a few options, one of which would be to explicitly limit the scope to known name types or categories of HIT. A second might be to explicitly exclude some types of HIT. A third might be to explicitly state the scope as any software that's usable by patients or providers to create, maintain or access health information. Another option might be to create a scope where the boundary is defined by the IT's functionality. Another might be to scope based on user type. So those are some of the various options, and I think it will be important to think about what's in and what is out. So that's really the task for this group. Patty or Meghan, as you reflect on this, does – what do think and then let's open it up more broadly.

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

Meghan I'll go, but jump in. So it's helpful to see that when we talk about taxonomy we're actually also talking about scope and boundaries as well as maybe some kind of enumeration. And while I think that we'll probably have to iterate to this several times, given how the discussions may go in the other two groups, I certainly see that we should be able to come up with some kind of a straw dog structure fairly quickly for reaction from this group. And I really like the idea of thinking about cases and case exemplars rather than specific products or activities or technical platforms. I also think it's going to be really helpful to think about – to review, and I'm not sure if one of the federal staffers can help us with this, but to review the broader scope of the Act, so that we can understand whether this, the idea and the intention was to address any kind of non-fixed platform of computing, whether it be a smart glucometer or a doc using an iPad to look at Epocrates. Or if there was a real intent to look at, as we heard last week, the sort of

medically serviced and software supported actions and not the information transfer actions. Thank you.

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

This is Meghan, Meghan Dierks. I think one of the things we'll just have to be very attentive to is that – is starting with at least consideration of those parts of Health IT that are already formally regulated and look at how they're regulated, and then move from there into those that haven't yet fallen under the existing regulations. And that would be in the interest of making sure how we think about this and what we decide in terms of inclusion and exclusion, that we don't conflict with existing regulatory frameworks.

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

Great. Other comments or thoughts?

Geoffrey Clapp – Better – Co-Founder

This is Geoff Clapp. Could I just ask a general question?

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

Sure.

Geoffrey Clapp – Better – Co-Founder

Because right now if I was asked, I couldn't answer the question and I get asked a lot of questions about these meetings. I don't have any problem with the people, but what was the process for picking who the co-chairs were for the different groups, because I don't feel like I understand how that happened.

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

Sure. So that was done by – with me meeting with the agency heads and basically, given the timeframe that we have to meet, we just attempted to pick people with a range of expertise in these areas. There's going to be lots of opportunity for everyone to contribute to the work that will go forward.

Geoffrey Clapp – Better – Co-Founder

Okay great. It wasn't a specific problem, but more just about transparency of the process.

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

Sure.

Geoffrey Clapp – Better – Co-Founder

Thank you.

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

Yup.

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

This is Jodi Daniel. I just wanted to make one comment based on what I heard; I think it was Meghan say. I think starting with what – understand what's already regulated and moving from there makes sense as far as thinking about scope and boundaries that we're talking about. The one thing I would say is that to the extent that I wouldn't necessarily assume that something that is regulated a particular way has to necessarily continue in that way for purposes of your discussion. Just so that if it turns out that there is something that promotes safety and – better promotes safety and innovation than what is currently being done, it would be good to know that. So don't just – it's just kind of a point to note that we want to make sure folks are not just saying, well that's – regulated this way, let's talk about the stuff that we're not sure of only, that it should be a conversation of all of the above.

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

Jodi, this is Elisabeth. I completely agree because I think that was one of my questions or comments was, when we talk about transition for the products going forward is that we shouldn't assume that just because something's handled today a particular way, that that's how it's going to be handled tomorrow, that way.

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

Hi, this is Meghan Dierks. Those are great points. I think my goal, one of my goals will be just to make sure that we don't make – submit guidance to the larger committee that is directly in conflict with or orthogonal to, it would be maybe recommendations about enhancements to those that are existing. Just trying to avoid –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

This is Anna McCollister-Slipp and I guess one question that I would have is I think everybody who has volunteered to be on this has a fairly decent sense of what has been regulated and what's happening and have a perspective on where things need to go. But I'm just wondering if the staff with HHS or FDA is going to prepare some sort of an overview or have some sort of an overview. Where things stand and the various pieces and their current state of play that we'd be able to start from, so that we could be able to think through what needs to happen, based on a sound understanding of where things are. It just seems to be in so many different places perhaps that it would be helpful to have that as a starting point.

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health

This is Bakul and I think that's a great comment. And we already provided some background, but if there's anything specific the workgroup's desire to have as a path to think forward into their little activities of the workgroup, we would be happy to do that and we may already have those materials and we can pull it together for you guys.

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

This is Matt Quinn from FCC and I'd be happy to provide more detail or other on FCC processes. But I'd also add that agencies that are not currently part of this, specifically FTC, Office of Civil Rights and probably others have some role in the broader Health IT regulation, especially in a broader sense. And so, I think it's going to be an opportunity for folks who have gone through those processes from the product side and from the provider side, to share those experiences too.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, P.C.

This is Brad Thompson. I wonder if there's some way to ask our federal partners and the workgroup chair to sort of maybe map out a little bit of a sequence or interaction between or among the three groups. Because as I'm looking at each one of them, I'm thinking about taxonomy and there seems to be at least two policy drivers that would suggest what is in scope and what is out, one that's been mentioned is, what we've historically regulated. The other one, frankly, is risk. We're more likely to want to regulate higher risk types of software. So that begs the question, what is the risk assessment. And then the risk assessment people to some extent have to ask themselves an initial question, well, risk in what areas. Someone needs to tell us exactly what areas we ought to be focusing on to examine the risks. So it becomes a little bit of a chicken and egg, and in the regulatory group, the taxonomy will drive the scope of the regulatory stuff, is CDS part of the discussion or not part of the discussion, is mobile, and so forth.

So I wonder if there's some master choreography that could be identified that maybe starts something along the lines of this. The taxonomy takes a first rough cut at what's in and what's out, and it's a rough cut and it's a first pass. That gives guidance to the risk people to know where to focus their energies in terms of looking at risk. When they've done their thing and focused and refined that a little bit more, maybe then they go back to the taxonomy people and say, here's how we're looking at risk, here's where we think its greatest and then the taxonomy people start to refine their preliminary thinking. So I mean, it just seems to me like there's some master choreography that could be offered so that we could each do out thing in somewhat of a logical sequence.

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

I think that’s a fair point. The tricky thing is just the very compressed timeframe with which we have to produce a product. And there very clearly are going to be interactions between the groups. I think a large part of what we’ll do in the face-to-face, for example, is to kind of discuss exactly the issues that you just laid out and deal with some of those interactions. We probably will try and have the taxonomy group meet first, because some of the calls that the taxonomy group makes will very definitely affect the other two. And if we had a couple of years to do this, we’d definitely want to employ a more sequential sort of process.

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

David, this is Patty. I wonder if there’s any – if it’s possible to use some sharing type tools like a wiki that would allow everyone to observe the process and comment on it as it’s unfolding. I know that can be sometimes burdensome for people and not everyone will be interested in it. But if, for example, there’s an interest in seeing minutes of a phone call to see how the thinking’s going and to be able to weigh in, a place where we could have those and post those for everyone to read and comment on would be quite helpful, given our time scale. Thanks.

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

Yup.

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

Julian Goldman here. I’d like to perhaps echo or reinforce some of the comments and ask a few questions. Ideally, of course we always want to start with understanding the problem in greater depth and I appreciate the challenge we have, in terms of the compressed timeline. It would seem that really we would start sequentially and start with risk assessment and understanding the scope. But since we do have to deal with the accelerated timeline, it may be helpful if we have help, this gets back to understanding the domains of regulation, the current regulation and what we have to work with.

It may be helpful to have a clearer idea of the possible scope of deliverables, so that we don’t end up running down the wrong trail, working for days or hours on deliverables that are just impossible or not really appropriate at this stage of work. So, I think for everyone to be on the same page of whether we’re dealing with teasing apart existing regulations, proposing new regulations, developing use case examples that can be shared across the groups in order to drill down into the issues. A few things like that might be helpful, so that we’re all on the same page of what to focus on. The other thing –

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

(Indiscernible)

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

I’m sorry; I’ll stop there.

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

No, go ahead. Go ahead.

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

So the other thing is understanding the scope of the problem space. I think we’re all coming into this with a perception of things that need to be addressed to improve safety with health IT and medical devices and I think some of those things have already been surfaced in some various meetings that are well known. But perhaps there’s a really quick way for us to short-circuit some of the linear process by throwing stuff against the wall, perhaps again on a group discussion tool as to what possible solutions could be. Because when working towards a short deadline, it may be that we need those ah-ha insights and those great ideas to bubble up very early as opposed to sequentially. So those are just a couple of

thoughts on this.

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

Sure. So, let me just respond to the first part of that. I think we are expected to produce things like use case examples. We fortunately don’t have to develop the framework ourselves, the agencies are going to do that, but we need to identify the key issues that the framework, when developed, will need to consider. Jodi, do you want to amplify on that?

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

Sure. This is Jodi Daniel. Yeah, for us – it’s helpful for us to understand what the issues are, where there are opportunities. We as the agencies, the FDA, ONC and FCC, as David said, will be developing the framework ourselves, but what we need is as much input from you all to understand some of the scenarios that we may face. Where there are opportunities to promote innovation, where there are the greatest risks, how we can think differently about risks in this space, if we need to think differently about risk in this space. And also kind of if there are things that you all, in your wisdom think should be out of scope, making sure that we understand what those are so that while we’re developing the framework, we’re basing it on what the wisdom of this group is on how far we should take this. Is health information exchange, for instance, in or out? Is CDS in or out, all of that and so we don’t necessarily need this group, particularly in this short timeframe, to lay it all out and dot the I’s and cross the T’s on how the framework would work.

But we do need the group to help us understand where there have been pain points, where we see some of the new technologies changing – being different than what we’ve experienced before in our oversight capacities, and where there are. Particularly when we’re talking about mobile, how some of the different agencies rules or approaches may come into play in ways that we haven’t really experienced, or at least not experienced in this widespread a way to raise the concerns in the past. So I think what’s interesting to me is that this is probably one of the – it’s sort of a new approach in thinking not just about risk and safety, but thinking about – acknowledging that innovation can help improve safety and improve health, and that we need to focus on both simultaneously. And I think that’s an area where this group has a lot to bring to the table in helping us think through how we balance those and how we can promote both simultaneously.

I think use cases are really helpful so that we can better understand when you are putting things forward, what you were thinking about when you suggested them, so that we have a context in putting together a framework. So I think that can be very helpful. But I also want to make sure that we’re not limiting the discussion to the limited things that we know most about today, so that we’re not developing a framework that works today, but may not work five years down the road. So I think use cases are helpful, but not – we should be thinking beyond what – we should be thinking about what might come down the horizon, not just what exists in the present.

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

Jodi, Julian Goldman. Just to jump in for a second, on what you just said. So the use cases, when we work on them within – in some other domains, could clearly be future use cases, not necessarily what we do today. I just want to add that. There’s no reason not include things like that, future workflows, future ideas, enabling innovation.

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

That would be great, actually. I think that’s a very good point. Well said.

Esther Dyson – Edventure Holdings, Inc. – Founder

And so that means there’s a very fine line between imagining new use cases from the taxonomy and imaging new risks, for the risk group, right?

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

Correct. I think that’s accurate.

Esther Dyson – Founder – Edventure Holdings, Inc.

Great. Esther Dyson. Yeah.

Jonathan Potter, JD – President – Application Developers Alliance

So this is Jon Potter of the App Developers Alliance. It sounds like we've shifted the discussion a little bit from one which says please help us understand what is to the last couple of comments which were, let's focus on what we want it to be. And let's be aspirational here in terms of the future of innovation, the future opportunities and not be so tied into the way the regulations work today. Is that fair?

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

I think it is. I think we're being asked to do both.

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

This is Matt Quinn from FCC. I agree completely and I think one of the key goals here is to provide clarity to folks like folks in the health IT industry and folks implementing health IT and folks buying health IT that – around these processes. One thought around innovation, is that innovation in all things is not necessarily good, and from the work on usability, there's been a lot of innovation on what the color red in an EHR means, and having 500 meanings for it isn't necessarily good. And so helping thing about how this can support constructive innovation, but not dysfunctional innovation.

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

This is Meghan Dierks, just one comment about the future thinking. I would say we just want to be cautious not to feel overburdened by trying to think about or conceptualize about all the future typologies of health IT, but more or less just to say, be very open-minded and not be overly constraining if we make specific recommendations, because of the future changes that could occur.

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

This is Jodi Daniel. I think that's a fair point. I think basically we want to make sure that if we're developing a framework, that it is adaptable to things that may come down the pike, so you may want some future use cases to make sure that the recommendations you all are giving us are – can work for future products that may be developed. But, we obviously don't want to put something in place that would be obsolete or would not work for things that are coming down the pike, but I think that's a fair point. We can come up with something that's adaptable without necessarily having to think of every single possible product that could come down the pike in the next few months.

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health

This is Bakul and I would echo that completely. I think it's more thinking about I mean what works, what doesn't work today, what are the things that may be foreseen if you think about five years down the road, that need to work. I think thinking about it from that perspective would be another way to putting the same sort of constraints on or same sort of limits on. So think about it as how – what the framework should have five years from now, also not losing sight of what's needed today.

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

David, this is Steve Posnack from ONC. In listening to folk's comments and Julian's comments as well as Patty's and others, it's sounding to me, and this is just – I'm going throw spaghetti on the wall right now. So we could take a taxonomy approach where we try to come with criteria or we try to come up with some other type of boundaries or you're supposed to identify things. And as the group has been discussing this quandary of sequencing and whatnot, the use case idea seems to me, since folks generally have a feel of what products that they know exist today. And to echo some of the points that Jodi, Bakul and Matt had made already, I think we're really interested in the "why" here. In terms of why people are concerned about the future, and what could be that we could see a year or two or three from now and why people don't think that the regulatory oversight or frameworks that we have today are prepared to handle what could come from an innovation standpoint.

And maybe the taxonomy group could identify a set of use cases, 5-10 use cases or start with 5 and then Ping-Pong those with the other groups to say, how do those jive with the regulations that exist today? What types of risks are considered for those use cases? And then others, you're going to maybe come up with a repeatable process that all three groups can kind of cycle through, where each can work on them with their own little piece; just throwing that out there.

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

I think you're right on. This is Matt. And I think one of the places where it gets a little gray and dicey maybe, is where technologies that, for a variety of reasons, have been isolated, come together. And this is the whole idea of converging technologies and identifying and thinking through what some of the unintended consequences and opportunities that come from that convergence are. So, this is the convergence of medical devices and health IT, convergence of consumer health IT and traditional hospital stuff. And then the idea of these being just pure consumer products, some of them, and some of them not being, I think you're right there, and keeping in mind why we're doing this, not only just to satisfy this Congressional requirement, but also because there's a real opportunity to either facilitate or stifle constructive progress in this industry.

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

This is Paul Tang, wanted to build on some of these recent comments, particularly on the flexibility in the sense of – so I think we want to think fairly independently so that we can have something that's flexible with the emerging technology and emerging way we use these things. So that would seem to ask Patty and Meghan to come up with a really comprehensive taxonomy. And Matt's point was an interesting one, not only of the pieces, but how you might put them in varying ways together, because I think there's new risk when you put things together, as we all know. Then I think, let's say in the risk and innovation area, we'd want to have a framework that sort of looks at risk or innovation in a comprehensive way, so that it can be applied to whatever taxonomy. And we'd have to test it; we might want to test this through the use cases or exemplars that come out of the taxonomy group.

But it seems like if we all work in a more generic – if we work very specifically, let's pretend we had 3 use cases. We all worked on those that probably would, by definition, almost constrain us in our flexibility. So maybe we all need to work fairly comprehensively and make sure we're always thinking of, make sure that this can be applied very broadly to all kinds of, in our case let's say taxonomies. But we certainly in checking our work would apply them to the – think about it in a comprehensive sense and then apply it to some exemplar use cases that taxonomy group comes up with.

Lauren Fifield – Practice Fusion – Senior Policy Advisor

To that end, and this is Lauren Fifield, I think one of the really important sort of parts of taxonomy is not just identifying the different types of technology that exist, the different types of technology that could be, but also considering the user and the setting. One of the – I think that I'm in part glad not to necessarily be chairing a workgroup, I'm sure it's going to be very challenging. But I am a little concerned about representation as consumer and ambulatory end-user in that the ways that technology is used in different care settings, whether it's by providers or by consumers, really can have an impact on how it's used, what types of technology those end-users want to consume and need to make their work and lives better. So, I hope that kind of throughout the subgroups, that particularly in consideration of taxonomy, there's really a focus on again those different settings and as many of the chairs tend to come from sort of larger care settings, academic institutions.

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

I think it will be really important to consider an array of settings.

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health

So, this is Bakul and I don't know whether we completely answered Brad's original question of how to coordinate efforts. And as I'm listening to the conversation, I'm thinking an approach could be that the three workgroups could start off thinking about what exists today, and when we have our face-to-face we can bring that together and sort of do some cross-pollination from – for example, if taxonomy group

identifies new technology or new area, use setting, etcetera, that creates the risk in certain area or promotes innovation in certain area, it could be shared with the risk group. Or in compliment to that, if they've identified regulations, either they're present or missing or required, they can be shared for that area. So I think it's going to be a little bit of iteration, on the other hand, if you think if the other groups find out that absolutely these type of – certain technologies or certain use settings should be discussed or should be in the scope of the taxonomy, they should be able to do that. So I think that cross-pollination or coordination, at least that was the way I was thinking would happen at the face-to-face meeting and also formalize it at that point.

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

So this has been a terrific discussion. I agree with what Bakul just suggested. Let's move on to Risk Assessment and Innovation. And here we're thinking about the kinds of things that the risk group would think about would be to identify some of the types and magnitude and likelihood of risk that can be posed by health IT. Identify some of the critical factors that a framework should include to address those risks and then categorize some of those critical factors and the impact of them on safety and innovation. From the innovation side, to think about some of the factors that promotes innovation and come up with examples. To identify some factors if the framework – which if the framework doesn't include them, could inhibit investment and innovation. And then think about some of the process and decision points for innovators and think about how the factors apply to each of them. So, how does that sound?

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

This is Paul Tang. I think that sounds reasonable. I think what you're charging us to do is identify ways to think about risk and ways to think about innovation and then try to balance the two, because not always, but sometimes they may be in conflict. So I think you mentioned the types of risk, the magnitude of the risk, the likelihood of harm arising from potential risks. In the discussion of the taxonomy, we talked about participants in the development and use of the device or software. So that's distinct from the developer to the people who implement, we got a lot of this from the EHR Safety committee and IOM. The users have a role, the patients may have a role and some oversight body organization might have a role. And how – and the risk would also be somewhat balanced or counterbalanced by the ability to prevent or mitigate risk. For example, if you have a human intermediary, which is one of the things the FDA has been relying on, that would, even though there's some risk, that would somewhat mitigate the risk in its actual use. And I guess we'd look at both intended and unintended use, sort of off-label use, I guess, to try to get our arms around a risk profile for any given piece, device or software.

On the innovation side, we'd want to understand what are the critical success factors to innovation. The agility of changing the design, you can see how too agile certainly doesn't give any stability to the people who are trying to use it, but waiting years to enhance something would certainly negatively impact innovation. So how do we measure that, the breadth of impact, the disruptive influence? Some of these things are key attributes of innovation, but can certainly pose a risk. When we talk about innovation, is it a technology innovation, is it a process innovation, does the technology require a process innovation. What does that do to the existing way patients are cared for, for example? So the FDA has a quality management system, is there such a thing as an innovation management system that sort of makes sure risk – in thinking about risk is incorporated in the innovation.

So I guess is there – so once we figure out how to come up with criteria or a framework to assess risk and understand innovation, the critical success factors for innovation, is there some sort of calculus for balancing that, that the FDA or the public at large can use? Right, if we came up with a flexible framework then what I imagine we might do is test it against exemplars that the taxonomy group comes up with and I guess what you're saying is we would do that perhaps at the face-to-face meeting. And then try to adjust and then go back and do our homework to try to make sure that the things that we uncover in that iteration get addressed. Keith, I don't know whether you have other thoughts or – we haven't discussed this before.

Keith G. Larsen – Medical Informatics Director – Intermountain Healthcare

Yeah we haven't talked yet. This is Keith Larsen. I agree with – I think the comment earlier about the context of uses is an interesting one because again it goes back to that sociotechnical notion in the IOM report of how these thin – what is the context of use as we think about innovation in particular and safety. A lot of the innovation that we're going to have to address will be done by the users of the systems. I know as I look as we – as these tools get out there, one in fact the notion that you see in ARRA and everything is the idea that you have a tool set that you can address processes, which means that there will be innovation right at the end-users. And there will be the technical innovation, but there will be also process innovation and how those two work. And then the earlier comment about convergence of technologies is an interesting one, because we know that our users mix technologies, what they're trying to do is solve a problem and they'll do their own alchemy of how they're going to mix those technologies to solve their problem. And so having a framework that addresses both risk and innovation, where it's easiest to control, on the production of the software, but really extends into how people use it and how they implement it, I think will be critical.

Lauren Fifield – Practice Fusion – Senior Policy Advisor

Keith, I think –

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

This is Matt. Go ahead, I'm sorry. I was going to say where software production and implementation come together is in providing guidance and limiting configuration options. So, for example, it's possible to put an engine in a car, install it in a way that will blow up, but there are some safeguards in place that won't allow you to do that, at least without hammering pieces of it off. Anyway, sorry.

Lauren Fifield – Practice Fusion – Senior Policy Advisor

Keith, I was just going to say – this is Lauren. I think those are really important points in terms of sort of considering beyond just the technology, and I would say to the group, another thing to consider, and I guess in this way I'm representing the views of Silicon Valley, is do we want to try to provide recommendations for what exists not in technology alone but in medicine. Or do we want to try to envision a world where the delivery of healthcare is quite different and not constrain where and how technology could be used based on what we know, but based on how things could be different. Right, so it's sort of creating a framework for what is versus creating a framework for something entirely different or the potential for something to be entirely different. I think it's something to establish or potentially establish as a goal, because if you're sort of creating a framework for what exists, the end product is going to be much different than how a potential entrepreneur might be thinking about developing a technology, which is to change how something is done.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

And this is Anna McCollister-Slipp and I would completely echo the previous comment. But I don't necessarily think that's just a view of Silicon Valley, I think it's also the view of, speaking as somebody who's an HIT entrepreneur as well as a patient advocate, there's lots of room for innovation. And there's also a risk inherent with slowing things down so much that innovation doesn't happen; there are consequences and risks of not acting or not developing new technologies. So, we want to make sure that we're not – that we're setting standards for transparency, but not necessarily limiting the creativity of thought and development, that risk and innovation are balanced in a way that's transparent, but isn't prescriptive.

Jeffrey Jacques, MD – President, Neonatal Solutions – Aetna

This is Jeff Jacques –

Esther Dyson – Founder – Edventure Holdings, Inc.

This is Esther Dyson. I'd like to second that and also add, in terms of risk mitigation, it's important to include things like education – the sort of the investment in education so that within 2 or 3 years the risks are dramatically lowered because lots of people know something. It's important to look it not as a single device, but as something that is social and spreads.

M

Absolutely.

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health

This is Bakul. I'm sorry, Jeff, you had something –

Jeffrey Jacques, MD – President, Neonatal Solutions – Aetna

Yeah, I just wanted to add that I think, I mean, I completely agree with the original comment and the follow up comment from my colleagues. I think I would just also add that context of use of the innovation, how it's incorporated either into the life of the consumer or the workflow of the provider or the deliverer of care or the person touching individuals I think is also very important. We should also think about risk attendant to whether or not it's incorporated in how it's used, and I just think that that's something we should really be very mindful of as we consider the risk and innovation.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

So, this is Bakul. I was just going to say that I couldn't agree more, I think that's why it's important to focus on the foundational elements, it could be factors that affect risk, factors that affect innovation. Those foundational elements will probably be more valuable for us to consider as federal partners to consider into – that goes into the framework that we can develop, that not only considers all the points that people talked about and how it's used, where it's used, what technology, and how it's implemented, etcetera. But focusing on the foundational elements would probably give you – give us a better sense of what levers we should use and pull.

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

This is Rich Eaton. I had a question, I guess. One of the things we've been struggling with in our association is defining HIT in general, and if you look at the definition of HIT under the HITECH Act, the definition's extremely broad. And I guess I was wondering whether that should be the starting point, especially for the taxonomy group. We may not end up, in terms of a regulatory framework, encompassing the implications of how broad that definition is, but it's something I think we should take a look at and hopefully that will be a starting point and we'll move on from there. So I just wondered if there are any thoughts about that.

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

I think that – this is Dave Bates – I think that's exactly what we'll ask the Taxonomy Group to at least try and take on.

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

This is Meghan Dierks. I have a question to pose to the group and that's whether in the Risk and Innovation Group you want to also address strategies or actual approaches to prospective – prospectively measuring the risk, because that sort of drives what you'd expect from the producer of the technology in terms of design controls or other mitigating strategies. And then the other side of the equation, which is, thinking about and making recommendations about how to monitor sort of the post-market risk, which is there's – to some extent you can anticipate risk just based on design and the intended use, but then in the post-market, that's where you see the actual thing – the actual risk and hazards. And the question is what strategy might we recommend for doing that post-market surveillance?

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

Right, so this is – go ahead.

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

This is Paul Tang. I really like that suggestion. I was hoping that this calculus for balancing the risk and the innovation would be – could be applied prospectively, and then it would also give the message of how we can monitor its impact. But, it's a good suggestion, certainly has a down – in the drug area.

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

This is Dave Bates. I think it’s actually really important to explicitly address both and in a call that we had, which was not a call of the full group, a couple of people expressed concerns that unless we explicitly focus on that, that we might not cover both. So, I think that’s a very important comment.

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

Julian Goldman here. I strongly support that, and I think that’s really part of the challenge we’re facing here, as we started the call and discussed the need for use cases and the lack of data and clarity that we had on what the needs are and where the current problems exist, are in part related to the fact that we don’t capture, in a sense, the post-market surveillance site of health IT and medical device use; not comprehensively and not horizontally. If I could, I just want to reflect on what I heard with regard to some of the discussion of the hazards.

Whenever we think about hazards, say with a medical device or with a clinical procedure, we know that there are theoretical hazards or known hazards, and then, of course, there’s that likelihood part of the equation which determines whether it’s truly risky or not and then we look at a way to mitigate those risks. But every time that exercise is undertaken, we have to think about the scope of the system in use. And I think, as I’m on this call and thinking about what we’re all talking about. I think the biggest change historically has to do with the scope of the system in use. And until we, I think, until we really start to drill down and understand that, we will have difficulty understanding the issues.

For example, if someone enters a patient weight and makes a kilogram/pound error in an EHR during the entry, if there’s an option, and if another person reads that data and acts on it, they may make a kilogram/pound error. If – and that’s the scope of use and as a human being there and that’s a problem with perhaps training, education and the display quality, human factors and the interface. But if that data is now used to automatically program an infusion pump, and now we start to cross the boundaries of communication and interoperability of these systems, we have a different scope of use that may require a different approach to risk mitigation. And this all starts with a scale that sends its data automatically to that health IT system, which then goes on to send it to an infusion pump, we’ve not changed the scope again. And then, of course, if the wrong person steps on the scale, we’ve now changed it again. And it gets to the points that were made before about education and so forth and so on. So I think the scope is, in my mind, one of the biggest challenges here, in order to then understand how to mitigate the risks and to facilitate innovation. Because it’s the uncertainty of risk mitigation that drives up the cost of innovation, when manufacturers don’t know what they have to do or who they have to speak to.

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

This is Matt Quinn. That’s a wonderful point and one of the things that we don’t want as an unintended consequence of this is that the prospect of combining systems, so truly good things can happen when there’s interoperability, but if all of the regulatory incentives are not to do that, because of uncertainty or whatever, then we’re really shooting ourselves in the foot.

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

This is Anura Fernando. I’m sort of following this line of thinking so far, and also tying back to some of the earlier comments that were made regarding risk management and innovation. It seems like if we were to consider what the current baselines are safety, and look at where those exist and compare them to areas where there is no baseline of safety currently because technologies don’t exist to provide for that particular clinical workflow. Then we could look at equivalent safety where there are existing baselines and use that equivalent safety model to help somewhat constrain innovation. And where there is no baseline, we could look for expanded or less constrained innovation, but perhaps with additional functions like increased post-market surveillance.

Michael Flis – Regulatory Manager – Roche Diagnostics

Hi, this is Mike Flis. I was wondering if there’d be an opportunity for us to take advantage of the work that’s already been performed by organizations that have written and published international standards? There are documents that are available to us describing processes from medical device manufacturer risk management for assessing usability and establishing software lifecycle processes. And these standards are acknowledged by FDA and other health authorities around the world.

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

I think that there certainly will be – I think that’s the sort of thing that we need to identify and point to and ask that they be considered in a risk framework.

Keith G. Larsen – Medical Informatics Director – Intermountain Healthcare

This is Keith Larsen again. I think that the interesting part about risk is, probably the easiest part is regulation or measuring risk with the production of the software, where you have these international standards and others for creating the process. But then when we look at innovation, I think the innovation that we have is, we have the innovation at the manufacture of the software, but we really have innovation at the user level. And it was interesting, an earlier comment about configuration, do you constrict the configuration of the system in order to make it more predictable and what success will we have in trying to address or to constrain innovation of use of these systems. So I think the innovation we’re talking about and the safety is not just at one part of the process, but it is in the context of use. And as we’ve seen, just in our own use of technology personally, we extend the original intent of any technology to address the problems that we’re trying to do and how do you put in a framework to address that type of innovation and support it.

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

Hi, this is Joe Smith. I really like the notion of putting innovation and risk in the same format. I’m perhaps a little concerned about this, the phrase we’re building about constraining innovation, and I’d like us to, as we think about that, think if that’s really a goal of the process, and I would hope it isn’t. And this notion of end-user innovation. I’m reminded of the fact that a scalpel is a really sharp thing, and if we thought about all the risks, we might not approve it, when, in fact, it’s the innovation by the end-user that turns that into a very effective innovation for therapeutic benefit. So I would like us to think about, as we talk about a risk format, that we don’t get exuberant about preventing innovation at the end-user because I think actually that’s where this technology often has its greatest value.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

This is Anna McCollister-Slipp. I would completely, completely agree with that. I mean, we can’t second guess or try to predict all of the potential end uses of all of this technology. And I think it’s incredibly important for us to think about what is a framework for the things that we can control, how can we set up standards that need to be adhered to and that are very transparent and very adaptable. But we can’t just, taking as a type 1 diabetes patient advocate, what is risky for me is not the same thing that’s risky for a 75-year-old type 2 diabetes patient that has difficulty seeing or somebody else who’s blind. I mean, we all might want to use the same technology, but the interface and the risk of using the interface incorrectly are completely different for three different audiences. And if we try to second guess what is going to be appropriate for each of those three, and develop regulations accordingly, if it were too prescriptive, we’re just going to completely stifle innovation and as a result, important developments that typically would be easy from a technological perspective, just aren’t going to happen. There will be a standstill, and there’s a risk involved with that as well, because that will keep progress from happening, which could be very important to the disease management for each of those individuals.

So, I mean, we need to be clear, we need to be transparent; we need to set up standards. But I think if we try to second guess all of the potential ideas and uses, whether it’s end-user or some innovative app developer in Des Moines or Silicon Valley, then we’re going to fail miserably and really limit the development and innovation that we could be seeing in this country.

M

This is –

Esther Dyson – Edventure Holdings, Inc. – Founder

This is Esther Dyson. This is Esther. Can I make another point, which is, that we now live in a world where there’s a personalization in medicine, there may also be the personalization of risk preferences. In other words, people now regularly fill in consent forms, and I know sometimes – badly done. But you can actually have different populations that may have different risk profiles and to the extent we can put that into our thinking as well, I think it would be helpful.

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

I think that’s a good point. This is Dave Bates. I’m just going to move us along. The discussion has been terrific, but I also want us to finish on time. Let’s move on to the regulations area. Thinking of tasking this group we’re thinking about current areas of regulatory duplication, ambiguity, oversight confusion, some of the areas of regulatory success and best practices. Flip side of that, regulatory gaps around safety and innovation needs, some of the relative strength and weaknesses of our current regulatory structure, some strategies perhaps to improve efficiency and avoid duplicative regulatory processes. And then to identify non-regulatory activities that should be considered, that might also have an impact. So, let me just ask Brad or Julian to reflect on that.

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

Julian, I know you’re going to have to leave in a little bit, you want to go first.

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

No, I’m okay for a bit longer, so Brad please, after you.

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

Okay. Well, I’d love to talk to Julian about it, we have not discussed it and I think the way the agency, it’s agencies, plural, has laid out – have laid out the agenda sounds pretty good to me in terms of the scope and charter of what we’re to do. My mind immediately starts to leap to the how question. How are we going to get a consensus? And getting a consensus is as much art as it is science, because we have a lot of great ideas, some of them are fairly different. So I guess I start with a couple of things. One is that I’ll go back to my puzzlement a little bit, that I’m struggling with, which is a lot of what we’re going to do on the regulatory side needs to be informed by, in fact, I’d say driven by what the other two subcommittees are going to be doing. For example, we’re very sensitive to taxonomy, if you tell me a given category of software is in or out, that could have potentially significant implications on which regulatory scheme we’re even talking about. But more than that, really all of the discussion we just had about risk and innovation, that’s what the Regulatory Group is supposed to do, is sort of listen to that discussion and then come up with regulatory features, not a holistic framework, but regulatory features to accomplish those objectives. So, if for example the other group says, the most important thing to facilitate innovation in medical software, I’m making this up, is the availability of pizza. Then in the Regulatory Group, we’d have to think, well how do you adopt a regulatory feature designed to make sure FDA doesn’t over-regulate pizza and therefore stifle innovation in software. So, I’m going to be really interested and I’m going to want to try and figure out some way to closely follow the discussion in the other groups, in order to make sure that we’re building our stuff on their foundation.

Separately from that, I’m a firm believer that we stand on the shoulders of giants and by that I simply mean there’s been a tremendous amount written and a tremendous amount of thought given already to these topics, so one thing certainly out of the gate that I could imagine us doing is simply compiling some of that. Now I’m very mindful, David, of your urging that we get going and that we don’t turn into an academic and debate things endlessly, that we drive toward a conclusion by the first of August. But I really think that step would facilitate rather than hinder that. I think bringing a little bit of the past discussion into it will save us reinventing some wheels. So, just getting the word out to the public in general that we’re interested in articles and papers and so forth, thoughts about what’s working and what’s not working, so that we can compile it and take a careful look at it, will speed up the process and help us arrive at consensus, which may not be a natural thing for us to do otherwise. So those are the things going through my head and I’m really interested in Julian’s thoughts.

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

Thanks Brad. I made a few comments earlier that I think are applicable to the regulation aspects, so I won’t repeat those. And I think Brad said 90% of what needs to be said already. I think what I would add is something that pertains to some of the discussions we heard. There is a concern being expressed, appropriately, that the solutions are not overly prescriptive, that they don’t end up saying how large a typeface should be or something like that, and that things should be – we should end up with solutions that are applicable for the future and support innovation. And I think that that’s an important point, that fits right into a discussion of regulations, because well written regulations, like well-written standards, are not overly prescriptive and do not inhibit new design and innovation.

For example, in the case that was discussed a few minutes ago, the idea that someone with poor eyesight requires a different user interface than someone else, than the teenager. Then the way to address that is – typically the poor way to address that are through requirements that talk about testing eyesight first on everyone who ever is going to use the system, and then having some prescriptive guidelines. But when done appropriately, the issues about the importance of being able to read a display in order to use something safely might be all that is addressed. And so we see this with standards that are risk-based all the time, they're done quite well typically and I would expect that whatever work comes out – or recommendations come out of the group, they would be informed by those approaches. And as Brad said, we'd be standing on the shoulders of giants who have already considered this for years, to avoid overregulation or overly prescriptive regulation.

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

Okay. Additional thoughts from the group?

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

This is Patty. This may be a broader question or broader issue, but I found the conversation about 15 minutes ago discussing whether we were looking at risk related to the non-use of technologies or the healthcare risk as opposed to the technological risk and important and frankly and unanswered part of our conversation. It won't be answered in one session, I understand, but it seems to me that trying to put some structure around the different types of risks we're looking at was a step toward that. And then then appears to address some of the regulatory issues also. So if we presume that the regulatory context outside of the technology is going to continue, for example, that you must have a nurse practitioner or physician to prescribe certain kinds of controlled substances, we'll look at different kinds of regulations for devices than if we make some conjectures that other practice-based regulations can change. So it's more of a comment I guess than a question. One of the things that will be useful for all three of our groups is to define what's on the outside of the boundaries that we presume – and what we presume about that. Whether certain changes in other regions in healthcare or other regulations in healthcare may actually lead to invalidating something that we're proposing or strengthening something that we're proposing. I hope that sounded coherent. Thank you.

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

Additional comments?

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

This is Anura Fernando again. Just one other consideration for the group is that for a couple of reasons, one being that we have an environment now where manufacturers are complying with largely internationally based standards for safety and performance and other aspects. And then secondly, from a technology perspective, the types of systems that are emerging seem to really be somewhat unconstrained by geographic boundaries. So when we talk about telemedicine and things like that, it seems like we're really getting into global communication systems and so forth, being able to enable these types of clinical capabilities. And so considering those two things, while this is a US Agency focused activity, it might be of benefit to look at what's going on with regulations internationally. For example, there was recently a proposal, I believe, to look at interoperability under the Medical Device Directive in the European Union, and there are many other related activities like that, that may help at least seed our group with ideas.

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

I think that's a good point.

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

This is Paul Tang. I just want build a little bit on what Patty was just mentioning. So, our charge is to avoid regulatory duplication, but we want to think broadly, it's not just the regulation by the three agencies but if there are activities that can mitigate risk, such as the ONC certification program is one. I think Patty also mentioned so there's professional board accreditation and licensing, as well as the ABIMs, American Board of Internal Medicine and the subspecialty certification. There are many other things that hold some of our users, like the professional side, accountable and so we can rely on those to do their job and not try to be all encompassing. So I thought that was a good comment that she had, just thinking of the various non-FDA regulatory levers there are to mitigate risk and to prevent risk.

Mary Anne Leach – Children's Hospital Colorado – Senior Vice President and Chief Information Officer

This is Mary Anne Leach. I just had a question for Brad or Julian about the features of the regulations that we might consider. Would any of that include how these are implemented? I think we all share a concern about time to market, is that a feature of this or is that really more under the purview of the FDA, for instance, in actually executing against the regulations.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, P.C.

Well, I'll take a stab at that. I'm interested in Julian's thoughts too, but – so to my way of thinking, feature is simply a discrete unit or an element of a regulatory system as opposed to the whole system itself. So what you just described sounds to me like it could easily be encompassed within a comment that the working group might develop on features that would be very useful. Implementation is often a very important key to the success of a regulatory approach. So I would think that would be very much in scope. I was just trying to differentiate features from coming up with a holistic solution, that's really the purview of the agencies.

Mary Anne Leach – Children's Hospital Colorado – Senior Vice President and Chief Information Officer

Okay. Thank you.

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

Julian, does that – your thinking?

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

I have nothing to – I'm not – it is, I'm not sure if that – was that the question, is did we –

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, P.C.

So did I not understand?

Mary Anne Leach – Children's Hospital Colorado – Senior Vice President and Chief Information Officer

No, as I understand it, that potentially how this might be implemented would be the function of this feature framework we might develop in the Regulations Group.

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

I think so.

M

Absolutely practicality and feasibility of actually doing this should be a consideration.

Mary Anne Leach – Children's Hospital Colorado – Senior Vice President and Chief Information Officer

Thank you.

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

Okay. So what I’d like to do at this point is to just have MacKenzie take us through the group and ask people to volunteer for one or more groups. If you can’t decide at this point, that’s okay. We do want to end up with moderately balanced groups, so there could have to be a little bit of work on that at the back end if everybody wants to be in one group or another, but I hope we won’t have to do very much of that. And MacKenzie, are you on and could you take us through?

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

Sure. Do you want me to just go down the roster and poll people?

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

Yes. Well why don’t you skip me, because I’ll be on whatever group is short.

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

Okay. Patty Brennan obviously will be on Taxonomy. Geoff Clapp? Would you like to be on Taxonomy – ?

Geoffrey Clapp – Better – Co-Founder

Innovation and Risks and the Regulatory one please, so the second two.

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

Okay. And, excuse me, Todd Cooper?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

The same Risks as the primary and then the Regulatory.

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

Okay. Esther – Meghan Dierks we have as Taxonomy. Esther Dyson?

Esther Dyson – Edventure Holdings, Inc. – Founder

Sorry, Risk and Innovation please. Sorry, I was on mute.

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

Sure. Okay. Richard Eaton?

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

It’s very difficult to choose, they’re all extremely important. I guess at this stage Taxonomy and Regulations.

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

Okay and I put you down. Anura Fernando?

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

Regulations as primary please and Risk and Innovation as secondary.

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

Okay. Lauren Fifield?

Lauren Fifield – Practice Fusion – Senior Policy Advisor

Regulations primary, Risk Assessment/Innovation secondary, please.

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

So, Regulations primary and Risk and Innovation secondary. Okay. And Mike Flis?

Michael Flis – Regulatory Manager – Roche Diagnostics

Risk Assessment and Innovation please.

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

Okay. Elisabeth George?

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

Taxonomy and Regulations.

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

Okay. Julian Goldman?

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

I'm certainly – Regulations obviously –

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

Ah, never mind, you're on Regulations.

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

– unless I can opt out of belonging to that group.

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

– Regulations. Drew Hickerson?

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

Taxonomy as primary and Risk and Innovation secondary, thank you.

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

Okay. Jeffrey Jacques?

Jeffrey Jacques, MD – President, Neonatal Solutions – Aetna

Risk and Innovation primary, Regulations as a secondary.

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

I'm sorry, what was your primary?

Jeffrey Jacques, MD – President, Neonatal Solutions – Aetna

Risk and Innovation.

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

That's your primary and your secondary is?

Jeffrey Jacques, MD – President, Neonatal Solutions – Aetna

Regulation.

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

Regulations, thank you. And Robert Jarrin?

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

Risk Assessment as my primary and Regulations as my secondary. Thank you.

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

Okay. Mo?

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

Hi. Risk and Innovation as primary and Regulation as secondary.

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

Okay. Keith Larsen, we already have you assigned. Mary Anne Leach?

**Mary Anne Leach – Children’s Hospital Colorado – Senior Vice President and Chief Information
Officer**

Sorry. Taxonomy as primary and Regulations as secondary. Thank you.

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

Thank you. Meg Marshall?

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

I guess Taxonomy as primary, Regulations as secondary. And is it possible; is there a mechanism for just sitting in or receiving an invite for the Risk Assessment Group?

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

Sure. Once we decide all the different workgroups, I can make sure – we can have the appointments go out to the entire workgroup if that’s what everybody prefers.

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

Yup, sounds good.

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

Otherwise we can just do one offs like this. Mary Mastenbrook?

Mary Mastenbrook – Consumer

I can do either Taxonomy or Risk Assessment, wherever you think I would best be suited.

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

Okay. Jackie McCarthy?

Jackie McCarthy – Director of Wireless Internet Development – CTIA – The Wireless Association

Taxonomy and Risk and Innovation, please.

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

Okay. Anna McCollister-Slipp?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Hi, I’d like to do Risk and Innovation as primary and Taxonomy as secondary.

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

Okay. Jon Potter?

Jonathan Potter, JD – President – Application Developers Alliance

Risk and Innovation primary with Regulations secondary please.

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

Okay. Jared Quoyeser? Jared, are you on the line still? Okay, Martin Sepulveda I don't believe is on the line. Joe Smith?

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

So I would say Risk Assessment and Innovation although I'd really like it to read as Innovation and then Risk Assessment, at least that would be alphabetical order. And then secondary would be Regulations.

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

Okay. Mike Swiernik?

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

Risk and Innovation primary and Taxonomy secondary.

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

Okay. Paul and Brad, we already have you assigned as well. So I can follow up with Jared and Martin separately. But what I'll do is put the list together and then send it out to everyone, just for final confirmation, since we have primaries and secondaries.

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

All right. So thank you all. This is certainly an enthusiastic group. We didn't ask everybody to identify two, but it will help to have lots of perspectives. So the plan again is for each of the groups to have a call before the face-to-face and then to do some virtual work, and there are a variety of mechanisms for supporting that. And then we would like to have the co-chairs make a straw man presentation at the face-to-face. Our plan is to take the first day and divide it into relatively equal chunks to focus on the three areas, taxonomy; risk and innovation and then regulation and then we'll spend a part of the remainder of the second day talking about reconciling these. I recognize that there are lots and lots of interactions which have come up many times, in the point that Brad made that there really are very profound interactions. And then we'll figure out what the next steps are. So that'd the overview for the face-to-face. Jodi or Bakul or Matt, do you want to amplify on that?

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

No. This is Bakul. I think this is really good. One last thing is, like David mentioned earlier, that when we have the full – we do want to make sure that the three groups are balanced, so just to make sure that everybody – the groups have equal representation or balanced representation. I think we want to make sure of that. One quick other point is, I think this may be a good point or if you haven't already started, is to start interacting with each other, sort of bounce ideas off each other and as you set up your workgroup, it may be a good point to start now.

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

This is Matt. Thanks to everybody for your enthusiasm and your perspectives on this pretty daunting task, but one I think that's really going to be impactful. I was going to say that based on some of the conversation, if we can start sharing, in addition to the resources that we sent around, items that we think are useful that are pertinent, etcetera. Are we going to have a SharePoint or someplace where we can share those, or just email them to the group, because I think there's a lot out there? We don't want to be constrained to that, but certainly we want to learn from what's already out there, stuff from AHRQ, stuff

from NIST, stuff from other places.

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

So this is MacKenzie. We do have a FACA portal is what we've used to send out the workgroup scheduling polls. There is a resource to that that has a resources pad that we can upload documents to, so if you just want to send materials to me, I can make sure that they get added to that and we'll include the link and the email out that confirms all the subgroup memberships.

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

Great.

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

That'll be really helpful as it will help do what Brad talked about in terms of just beginning to assimilate the backdrop.

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

And this is Jodi Daniel. The other thing I wanted to add is that we do have a lot of federal staff that will be following along with these workgroups and can help either pull together the materials, straw men, kind of summarize what they've heard and try to put together some options or proposals, any of the like. We have – we do have the support to do some of the analytical staff work behind the scenes at the request of the chairs or the subgroup. So, and we will have folks on each of the calls to help follow the discussions and help to support the chairs in bringing the discussions to greater consensus and convergence.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Hi, this is Todd. I know have a couple of questions. Well, the face-to-face, the way you outlined it, it wasn't clear or it seemed like we will not have separate breakouts at any point for the different groups, we're meeting plenary the entire time, is that true?

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

That's what we're thinking about now, although the schedule is not yet made, we're really open to discussion about that and if it would be helpful to have breakouts, we could consider that. What do you think?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

I mean, it depends on how things line up, but especially for the primaries, I would take some time to give the co-chairs and their small subgroups time to deliberate and then maybe bring that back into plenary, even – I think that would be beneficial. But, it's a good topic for the co-chairs to think through. My second question is, as was mentioned earlier, there's a large amount of work going on, especially international standards groups. But that always poses a problem because often times that group or the distribution of those materials is really constrained to that working group. Are there any thoughts in terms of how we might be able to manage providing some of that material into this discussion?

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

I think the best mechanism will be to send the materials to MacKenzie, she can post them on the shared resource, and if you could provide some text as to what to include and maybe also send a note to the relevant co-chair, that would be – about what the relevance of the particular materials, I think that would be helpful.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Right. Okay. So what we would have to individually do is get permission beforehand to be able to provide that information into the working group.

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

Yes.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

From the appropriate parties. Okay.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

This is Lauren Fifield. I have a question and I know that sort of outside of the workgroup real life proceeds, the FDA has medical mobile apps guidance kind of waiting in the wings. And the ONC is responsible for a patient safety surveillance and reporting plan, and I was wondering how should the workgroup consider sort of those ongoing activities, will there be sort of dynamic feedback or should we ignore those activities? Just how should we think about kind of again, thinking real world, obviously work going on in the standards committees and outside, how should we think about that?

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

Jodi or Bakul, do you want to take that?

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration

Yeah. I think – this is Bakul. Should think about those activities as complimentary and whatever the recommendations from this workgroup can be used to either enhance the existing work that’s going on or inform other people, like outside of the two agencies, the FDA and ONC, of what things to be considered. Create the needs for where controls need to be in place, considerations need to be in place, etcetera. So that’s how I view it as.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Thank you.

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

Okay. Other thoughts or comments? Okay. Hearing none, well this has been a very rich discussion. Any last thoughts before we go to public comment? All right, MacKenzie, could you open the phones?

Public Comment

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

Sure. Operator, can you please open the lines for public comment?

Caitlin Collins – Altarum Institute

Yes. If you are on the phone and would like to make a public comment please press *1 at this time. If you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. We do not have any comment at this time.

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

Okay. Well thank you very much everyone. This was a really productive call and we will be in touch shortly.

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

And this is MacKenzie. Before we sign off, I just wanted to make note that two more appointments have gone out for the workgroup calls, we have one scheduled for June 14 and June 27. So please make sure you have those on your calendar.

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

Thank you again everyone/

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

Thanks everybody.