

**HIT Policy Committee  
FDASIA Workgroup  
Transcript  
July 2, 2013**

**Presentation**

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

Thank you. Good afternoon everybody, this is MacKenzie Robertson in the Office of the National Coordinator for Health IT. This is a meeting of the HIT Policy Committee's FDASIA Workgroup. This is a public call and public comment is referenced on the agenda. The call is also being recorded, so please make sure to identify yourself when speaking. I'll now go through the roll call. David Bates?

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

Here.

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

Thanks David. Patty Brennan? Geoff Clapp? Todd Cooper?

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

Good morning.

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

Good morning, thanks Todd. Meghan Dierks?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center**

Here.

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

Thanks Meghan. Esther Dyson?

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

I'm here. Good morning.

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

Thanks Esther. Richard Eaton?

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

Here.

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

Thanks Rich. Anura Fernando?

**Anura S. Fernando, MS, MD – Principal Engineer, eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories**

Here.

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

Thanks Anura. Lauren Fifield?

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

Here.

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

Thanks Lauren. Mike Flis?

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

Here.

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

Thanks Mike. Elisabeth George?

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

Here.

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

Thanks Elisabeth. Julian Goldman?

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Hi, I'm here.

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

Great. Thanks Julian. Drew Hickerson?

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

Here.

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

Thanks Drew. Jeffrey Jacques? Robert Jarrin?

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

Here.

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

Thanks. Mo Kaushal? Keith Larsen?

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

Here.

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

Thanks Keith. Mary Anne Leach?

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

Here.

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

Thanks Mary Anne. Meg Marshall?

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

Here.

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

Thanks Meg. Mary Mastenbrook? Jackie McCarthy?

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

Here.

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

Thanks Jackie. Anna McCollister-Slipp? Jonathan Potter? Jared Quoyeser? Martin Sepulveda? Joe Smith? Mike Swiernik?

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

Here.

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

Thanks Mike. Paul Tang?

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

Here.

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

Thanks Paul. Brad Thompson?

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

Here.

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

Thanks Brad. Steve Posnack for ONC?

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

Here.

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

Thanks Steve. Bakul Patel?

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

I'm here.

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

Thanks Bakul. Matt Quinn? Okay, are there any other ONC staff members on the line?

**Elise Anthony – Senior Policy Advisor for Meaningful Use – Office of the National Coordinator**

Elise here.

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

Hey Elise.

**Kate Black – Office of the National Coordinator for Health Information Technology**

And Kate Black as well.

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

Thanks Kate. Okay, with that I'll turn it back to you David.

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

Thanks very much MacKenzie. So, we'll be spending the bulk of the day today going through the Risk Assessment & Innovation Subgroup's update, and then the Regulation Subgroup update. I want to note a couple of things. One, MacKenzie sent out a document which includes a list of exemplars/use cases, which I put together based on our face-to-face meeting. These are by no means exhaustive, people should feel free to add additional ones or to change these, but I would encourage everybody to take a look at them and perhaps use some of them as examples that the Risk Assessment and Innovation Group and the Regulations Group in particular might want to consider as whether the sorts of things that you're addressing would deal with these cases. I also just want to note that today ONC announced the publication of the Final Version of its Health IT Patient Safety Action and Surveillance Plan, and I'll just ask – it just came out just now, but I'll have MacKenzie send it around to the workgroup. A number of the recommendations in the group will relate to what we're doing in some way and the Regulations Group will be talking a bit about post-market surveillance, and this report builds on some of the recommendations of the 2011 IOM report on Health IT and Patient Safety and provides a roadmap around mostly post-marketing work and it talks about collaboration between PSOs, providers and developers, some tools and resources. There are also comments around research and development of tools and guidance, and discussion of beginning common formats. And I haven't had a chance to really go through it in detail yet, because it just came through on the transom, but I think it's another input for us. Any questions about that before we launch into what's going on – launch into our report from the Risk Assessment & Innovation Subgroup? Okay, so Paul and Keith, over to you.

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

Okay, thanks a lot David. Keith, do you want me to go first or do you want to go first?

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

Why don't you go first, the last time we did it, I took too much time.

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

Okay. I think we have 50 minutes, is that correct David? So I think –

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

It is.

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

– what we'll do is take about less than 10 minutes each to update the group. So I'll first – do you have – is it going to be shown Caitlin?

**Caitlin Collins – Project Coordinator, Altarum Institute**

– document?

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

Hmm.

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

Let's see, it's not showing yet.

**Caitlin Collins – Project Coordinator, Altarum Institute**

Which document are you looking for?

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

So this would be, let me try to send it to you –

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

Well here's one, this is Risk Assessment, Patient Safety and Innovation.

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

Well, so Keith, why don't you start that and then I will send Caitlin a separate document. Will that work Caitlin?

**Caitlin Collins – Project Coordinator, Altarum Institute**

Okay.

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

Okay. Thank you.

**Caitlin Collins – Altarum Institute**

Thanks.

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

Okay, as Paul expressed, we have 50 minutes I think on the agenda to do this, so how we wanted to divide up the time is use 10 minutes each just to present our slides, so that would give us 20 minutes, and then have a 30 minute discussion, so that we want to emphasize more on the discussion than on the slides themselves. The slides here are – there were two presentations that were sent out today; one is background slides that have more slides, and then these presentation slides that are really a few slides out of the other slide deck. And so I'll concentrate on just the presentation slides, given the timeframe and be able to then – I'll present and then I guess Paul will present and then we'll open it up for discussion. So next slide.

Again, this is just our charter and just emphasizing that what we're trying to do is get a new regulatory framework for health IT that promotes innovation and protects patient safety. And so it's really a risk-based regulatory framework for health IT. Next slide. As we looked at that then, the approach that we're trying to take is one is to examine the results from current regulation. We've had current regulation, we've had experience with it and in the spirit of open discussion and using results to guide us in our future, we thought that that would be a good exercise. Second is to look at specific innovation requirements that would be generated by looking at the different levels of care – well, different levels of use of the software. We have general requirements that were outlined in the IOM report appendix D and in the full report that that refers to, that compared different industry. But we also had specific requirements stratified by the source of innovation. And the last thing on this work product approach is thoughts on what is that new framework that promotes, again according to the charter, promotes innovation. Next slide.

Okay, again the IOM report describes the governance role as being the only body able to provide policy guidance and direction to compliment, bolster and support private sector efforts and to correct misaligned market forces. What that's describing then is really a shepherding role versus a defining or a leadership role. And it's a way to correct the market and let the market then apply transparency and market forces to what comes out. And so we used that as we talked about current regulation. Next slide. The question is really what is the impact on innovation from current regulation? Next slide, one slide – next slide after this one. So the key ones that we really have to work with are the medical device regulation and certification regulation. Next slide.

In the background slides, again there's more detail on these things, and I would invite feedback on all of those things. But as we look at it, we're going to compare it again to this what the IOM report talked about was increased stringency decreased innovation, increased flexibility meaning the defined number of implementation paths to meet compliance increases innovation and information, if I'm promoting more information in the marketplace, it increases innovation. And then if I have measurement specificity, then I can decrease innovation. Next slide. So comparing these two approaches, medical device regulation is really primarily a process control. It describes how to create things and you have a pre-marketing approval in some cases, but primarily you're looking at how things are made and the regulations that shape the products. In the certification regulation, we really have a product definition. Best practice is defined and best practice then is translated into feature definition and feature definitions then are specifically measured with test cases that are very specific. And in some cases – well, and what you have is really pre-use approval because you have to have certification in order to qualify for meaningful use.

The impact of these two systems is varied, too, on innovation. Again this is measuring on innovation. One is that medical device, that type of regulation can be positive when combining software from different sources, because it increases the trust value. There is a lack of clarity of who's in, who's out or who's been regulated and who isn't, and as we talked about, that's kind of the flipside of regulatory discretion. There is an entry impedance here on clarity of the requirements and the process. There's an AAMI report that's been referenced by the regulatory group to try to reduce that. But there is a current – there's a specific issue about late-entry into the process. If I have existing product, and now I become in instead of out, what is my – there's an entry impedance to now have a documented process where maybe there was not a specific documented process in creation of that. There's continued overhead, a heavy process versus agile development and if fully applied to HIT and local implementation, it's really devastating to the market. And again, that's blood bank example. The regulatory avoidance is you try to disqualify for more regulatory inclusion.

With the certification regulation, it really reduces flexibility because what we have is a defined best practice, even where best practice may not be known. And in the case of the current certification regulation, it did have, I think, the unintended consequence of empowering private regulation. In other words, other regulatory – private regulatory agencies, in this case I'm talking about in conjunction with ePrescribing, and it encourages compliance innovation, because they have a specific test and they work to the test. And then the regulatory avoidance response is control each feature and test script. Next slide.

Again, lessons learned from this is, and these are conclusions to be debated, obviously. Certification regimens should be avoided; they narrow creativity and innovation by either design or measurement. They channel energy into working to the test and they channel the discussion into definitional terms rather than meeting the market needs. Again, Steve from ONC talked about this that he's constantly bombarded with what does this mean specifically – what does merge mean in med reconciliation; it becomes very much a definitional argument or discussion. Transparency of results to replace certification. Instead of certification, a suggestion is that we use this transparency that David was talking about before having a transparency learning system really would enable the market to self-correct. National goals seems to work, JCAHO, Meaningful Use, they set a stan – they set a goal and on their own, if they were – if they let flexibility in meeting that goal, they really then set a problem agenda not a product agenda and they do change market forces. Okay, next slide.

The next question we said is, looking at the different ways that we – where we have innovation, what are the requirements? And there are a lot of slides in the background on that, let's just go to the following two slides. This one's really a repeat; let's go to the next slide. If you look across all the different requirements and accountability model, when we looked – what was outlined was both what are the innovation requirements and then what is the accountability model. Again, it's definition of process, not end product. National and international standards. If we're going to have a standard, try and make it international to help companies that are vending this software that have to work in multiple nationalities. National interoperability standards. This is – I've heard debates both ways from people that they hurt innovation or they encourage. I think that they encourage it from the standpoint of lowering the entry cost because they can plug in, I can participate in a larger process if I know what – the interoperability standard. But there's been some discussion on that. Encourage configuration and extension. I mean, this is primarily the biggest, I think, difference between a physical medical device and HIT is actually we encourage configuration and customization so that the software is useful to support processes in the point of care and also solve problems. And so we're encouraging configuration and extension. The transparency of product and results, the ability to experiment, and I've talked about this a couple of times, that I'm able to experiment with known providers – well, knowledgeable providers and be able to understand the impact of my configuration and extension. And then the last one is local control, local accountability. We talk a lot about these products at a very high level of being manufactured, but where they have great impact and where we've seen in the few reports that have been on patient impact, negative patient impact. It also has to do how the system is configured and locally extended. Okay, next slide. A few more and then I'll turn it over to Paul.

So again, the regulatory group raised this question, looking at the three agencies together, what is a better way to regulate HIT? So these are the thoughts on that final framework. Next slide. Again, I think we have to assume good intent on people that they're interested in patient safety, they're interested in solving problems and that we need innovation to solve problems and we need to encourage more, not less, participation in this sector. So going with that, next slide. Again the IOM report suggests a shared learning environment focused on shared learning, and that's really what we're suggesting should be the final structure to encourage innovation. Next slide.

The impact of that, again going back to the report on what fosters innovation it's really increasing information in the marketplace. And then pre and post-marketing information sounds like report that was published today addresses some of that concern. Having a common reporting format so that the data is shareable and having providers and vendors contribute to that and open access. And having a structure and environment that's non-punitive, it's learning. This is much like what we hope to have in medicine when we publish articles about practices that we do in hospitals and in clinics and procedures that we think will enhance patient care, and we open up our results for examination. I think there's one more slide.

So really the final slide is this idea that in current regulations, we have many times defined solutions, slow response to innovation and problems and opaque results. We don't know what the results are that everyone has had, and it really discourages participation, so much of our taxonomy discussion is again, well who's in and what's out. If we have a learning environment, then we're encouraging multiple solutions, continuous innovation and continuous measurements of results, and encourages participation in that type of environment. I'll stop there and have Paul do his slides and then we'll open it up for discussion.

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

Great. Thank you. Caitlin, could you go to my slides please?

**Caitlin Collins – Project Coordinator, Altarum Institute**

Sure, let me put that up right now.

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

This is transitioning over to the Patient Safety Risk. So we've talked about how to try to encourage and not impede innovation. The balance measure then is we want to have the flexibility that Keith talked about, but yet we want to be responsible in terms of protecting patient safety. Can you go to the second page first for just a moment?

This is just to set up, if you look at the preamble on the second and third pages are definitions, which I think the group found helpful. By the way, we're closing in, we're feeling pretty good about the matrix that I'm about to review for you. The preamble sort of sets up how do we expect this framework to be used. So one, it's really an enumeration of various important factors, probably not exhaustive, but a lot of the key things that we think everyone should be aware of, cognizant of and take into consideration, both in implementing this or using this particular product or software and in thinking about what regulatory, if any, tools to apply.

The framework by itself doesn't weight, it doesn't provide any calculus for how you'd come up with a single risk score. The reason's because we found that the software itself and how you implement it and use it is so complex that you can't say, oh, this box, a little bit like Keith said, instead of a physical device, it's a software system that participates in a broader software enterprise is really hard to say, here's an exact score and here's where you would – here's the regulatory tools you'd apply. So it's really how you would consider what things you'd take into account when you think about regulation. It's really – it characterizes the relative risk, so as we talked about before, it doesn't say low, it doesn't say high, it says lower or low-ish, it says higher risk because this is part of this complex calculus and serves more like directional guidance only. And for everything we say, they'll be exceptions. If you could go to page 1 now Caitlin.

You recall this colored matrix, that probably most important thing, which actually could earn you a bye, is looking at the purpose of the software and it's intended users, and this has been updated since our last – certainly our last full group meeting. The purpose could be at lower risk as providing information only in a very transparent, clear way to targeted users who are knowledgeable about the product and its use and can safely use the product. That will change from the licensed terminology we used last time, because this clearly can be a patient, a consumer can be knowledgeable and can safely use information about calories, for example. That's an example you say, gosh this just does not sound like it's going to be one of these 510 (k) kinds of products. So, it could be as simple as – so you know exactly what the manufacturer's declaring what it is and you're held accountable for what this does and who should use it. On the other hand, if you have black box things or things that are doing "licensed kinds of activities," like diagnosing or providing treatment advice directly to a lay person such as a patient or consumer, that would be a higher risk situation and you probably anticipate and expect that more stringent regulations could be used to protect public safety.

The next set of blue rows, and these are all dimensions, deals with the risk of the software itself, it's everything from – if you go wrong, what's the risk to the patient. It could be very low probability of harm, like if you're providing calorie counts, or it could be life threatening, if you're controlling an insulin drip or an automatic defibrillator. The number of people exposed sort of tells your entire space, is it a common thing that a lot of people could use, or really a very small sub-segment of the population would even be exposed to such a software contained essentially in the devices. If something went wrong, what's the likelihood – well, what's the likelihood of a risky situation of something going wrong could arise? It could be rare, very precise set of circumstances that this risky situation would arise, thinking about the Swiss cheese model of safety, or it could be common, like it just really is going to happen in a user or a patient's routine use. Likewise, if the human has a chance of knowing what's going on inside the software, what data does it use, what knowledge does it use, how is it combining it, you can really – you the user can really understand how its performing its calculations, if you know exactly what's being used to calculate a BMI, it's fine and people can use common sense to say, well, that makes sense.

On the other hand, if it's a black box and you actually don't even know what data's being used, and there are certainly products like that, you are more – you certainly have to rely on better testing and better specification to reliably use this and make sure you're not going to come out with a bad outcome. And finally, sort of the – in the Swiss cheese model, if there's a human intermediary that both understands the output and knows how – is empowered to intervene to prevent harm, that's a much safer, it's a much better condition than if it's closed loop and a human doesn't even – can't even respond until it's too late. So these are not black and white, but these are the ways to think about the severity of the risk of the software itself.

The next set of dimensions in green talk about sort of the implementation of the software. We all agreed, and the IOM Committee was very clear in saying, just not as easy as saying, is a device safe, there's so much that can happen once it ships from the vendor's doors that can affect actually the risk of patient harm. So there's the complexity of the software and the maintenance itself. It can be very mature, and people understand the input, they understand the output and like the weight or blood pressure, people understand that that's less risky than if it's a very complex amalgamation of data and the data transformed into something, and then it puts out a result, that would be a more risky situation. Particularly, which is common, you can't enumerate all the possibilities for all the data that comes in and then be able to test whether the output is both accurate, credible and reliable.

Complexity of implementation, as the IOM report pointed out, is really a huge area that's hard to control. So if the build is limited and it's pretty straightforward, a blood pressure or calorie counter, to make trivial examples, and the safety upgrades can be accomplished easily, because there's some of that, too. Complex software can come out and usually there are still mistakes or glitches or unintended things, but when you have a good surveillance system and you can catch it and you have a way of pushing the information out, versus requiring each and every user to let's say rebuild something, that all is a better risk profile than if the build is very, very complex and takes sophisticated knowledge and experience to produce and there are limited or no guardrails in the right-hand column. And likewise for the training, if it's something that's easy to use, again use the blood pressure versus something that it takes days of training for the end user even to get exposed to the information that they need, that determines how risky it could be from a proper use point of view. So this green section is really after it ships from the product floor, how much is required in order to have the safe and reliable operation of this software.

The next blue area is most of the software doesn't live by itself. If it does live by itself and the output is very unambiguously used and understood, it's less risky. But most software interacts with a few to tens of interfaces, such as an EHR system, and each one of those depends on what's coming in to be well understood by the software and for it to interpret it and put out something based on that information. It's not only based on the data, but it's based on the knowledge that gets incorporated into, let's say, an EHR system. So that is something to consider in terms of the riskiness of its proper use and the way it's connected to things.

Then finally the network connectivity, the standards that are used and the security that's employed certainly affects the risk to the data as it gets passed along and potentially transformed. It could be a very well controlled spectrum, the standards are mature, and security protocols are followed on the left column, versus in an unregulated structure when you don't really know who could be in there and it's full of proprietary interfaces, just makes the whole situation harder to implement this product and also more likely to be exposed to risk for patient safety. Like I say, this is – we've gone quickly over this, the group is feeling like this is fairly mature, we're very open to your comments, but these are an enumeration of things that we could consider either by the end user, by the developer or the folks overseeing this product, such as a regulator from the tri-agencies. And with that, I think we're open to questions and comments on both areas, both innovation risk and patient safety risk.

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

This is Brad Thompson. Keith, in your presentation I didn't see slide numbers, but there was a slide that you had, I think it was titled assumptions, and the very first assumption I didn't capture exactly what it said, but something like, everyone is interested in patient safety. And that assumption sort of caught my eye because maybe it speaks to worldview, but I think a large part of the reason for regulation is that I don't think that assumption is true. What I mean by that is, we live in a complicated world with lots of people and there are bad people, there are lazy people, there are greedy people, there are stupid people; there are all sorts of people who wouldn't necessarily be put into the category of interested in patient safety. And that's one of the reasons that we're here is trying to balance a framework that prevents people who are inclined, for whatever reason, not to take patient safety seriously, keeps them from causing harm to patient safety.

And so, the article that I distributed this morning is kind of making that point that particularly in the area of mobile health, it's kind of a gold rush and whenever you have a gold rush you have a lot of prospectors show up and some of them are great, some of them are not so great and they put out apps that may be very close to fraudulent, making claims about all sorts of things that they do that in fact they just don't do. So, it just concerns me a little bit that we would have as an assumption that everyone is interested in patient safety when I frankly think a large part of the reason for regulation is that we don't, unfortunately, live in that world. Any thoughts?

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

Yeah, I would respond a little bit. I don't want to sound like I'm pie-eyed and Pollyanna on this and that there aren't bad actors out there. I think that though if we take that particular – I think that we need to account for that, but if we structure a whole system around actors that are either in the category of lazy or just trying to be fraudulent, then I think that the impact, in particular, on innovation is devastating, because it really – it is a gold rush on the apps and what we want to do with the learning environment is really shine a light on what are people's real results. It doesn't mean that there's no regulation, there's no entry impedance in getting into this market, I'm not suggesting that, but that it doesn't necessarily have to be adversarial, that the point of working with regulation, because it's in the interest also of good players, not to be upstaged by lazy or fraudulent players in the market. So there is an interest in having a safe market and – but part of that safety is really being able to have less of an adversarial role – and heavy regulation, but having a more open system, more the results are transparent.

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

Can I comment? This is Esther Dyson.

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

Sure.

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

Yeah. I think the issue is, you want to be able to sue people vigorously for causing harm or even for being negligent. I mean, it's kind of like the FCC versus the FDA, if they do something bad, sue them but don't make it – don't create so many rules that everybody's breaking the rules, sue them for the harm they cause, not for not following some incredibly complicated regulation. And if you have a transparent market, you can determine if somebody's doing something wrong pretty quickly.

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

Yeah.

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

So this is Brad Thompson. So, like all things in life, this is a matter of balance and that's what I'm suggesting. I'm not suggesting that we treat everyone as a criminal that would be absurd. And everything is a balance in terms of how much protection you put up front versus how much you simply empower a regulator to pursue in the end. But what makes healthcare perhaps unique in Congress generally, is that you can't wait until someone is, to take an extreme example, you can't wait until someone has died before giving an appropriate remedy. The point of regulation is to prevent the harm before it occurs, not simply create a mechanism like our civil law system, for compensating them after the fact. So, we just have to make sure that we have that balance between bells and whistles – regulatory bells and whistles that are designed to keep people from getting hurt and the other side of the coin, ensuring that innovation can flourish. And that's why we're here today, right, because if it were easy, if we could just say, yeah, anyone who wants to, come on in, we wouldn't have much to talk about. But, I just...and I know your mission is to talk about innovation and so that was your focus, and I don't want to take anything away from that, and because Paul's been handling the safety issue.

I guess what I'm trying to draw out is a connection between the safety – the work that the safety sub-team and the innovation sub-team is doing, but point out that safety isn't just the accidental safety, sometimes there's deliberate actions that cause people injury.

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

And I would agree Brad. And I guess, if anything, it's – I was pushing this point in order to raise it to get – to find the balance point, not saying that this is the end result, but it's – and everything that was in my slice is really trying to say, how do we promote innovation? But at the same time I'm not saying, and I don't think there's ever been a suggestion, that innovation is enhanced or it's at its pinnacle when there's no regulation. And that's not either, because then it – like I said, there's an interest in the good players to have the market and regulations such that it enhances good players in the market so that in fact, that they're competing well. So, I'll take your point directly. Thank you.

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

This is Jon Potter. Can I jump in for a moment?

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

Sure.

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

I'm actually a little confused at the idea that we will be contemplating a discussion about bad actors. We've got all sorts of criminal laws to deal with bad actors and people who are intentionally hurting people, I think this entire exercise is around good actors and well-intended actors and it – we cannot regulate out bad actors and bad behavior. There are bad doctors, there are bad – there are people who pretend to be police officers and hurt people, you can't regulate criminal law into every regulatory system and particularly one around health and medical and innovation. So I just think we should frankly take it right off the table, unless there's a very specific proposal about how one would do that, such as is the suggestion that any product that anybody ever brings to market has to be minimally pre-registered, and – but query whether anybody who is a bad actor wouldn't just pre-register with a fraudulent name anyway, I mean. So, I'm sort of perplexed by this whole discussion.

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

Maybe I can help a little bit. This is Brad Thompson. So, the Federal Food, Drug and Cosmetic Act, which is one of the primary regulatory systems that we're citing, is a criminal statute. It is a statute which if you violate any of its terms, your guilty of either one of two offenses, adulteration or misbranding, and those can land you in jail and they can cause you to be fined and criminal penalties and so forth. It is a criminal scheme, it is put in place so that people do not use health technology to further their criminal activity, and its origins go back a hundred years to when the Wild West and so forth, people would stand on street corners and sell elixirs designed to cure anything that ails you, and turned out most of the time it had no valuable properties whatsoever. It was fraud at a minimum and it was mean at a level where people who were sick were putting their reliance on cures which didn't work. So that statute has been in place to protect us from people who would do us harm by selling us products that either don't help us or, worse yet, are unsafe and would actually hurt us. So the whole thing we're talking about really is how that system should or should not apply in the case of HIT. If we lived in a world where every criminal had a big "C" on their forehead that we could just pick them out and say, we'll regulate you one way and we're going to regulate honest people and people who are hardworking and diligent in a different way, life would be very simple. But, we have to have a criminal system in place to protect us that is the essence of what we are doing and what we're talking about in this committee.

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

So David, this is Paul. This is an interesting discussion, but I wonder if it's more appropriate in the Regulations Subgroup. We want to make sure we get enough time for people to comment on some of the things that Keith and I have been teeing up from our subgroup.

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

That's fine, I agree, so let's take it off the table for now.

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

So other comments about Keith's innovation risk framework and the matrix on patient safety?

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center**

This is Meghan Dierks. I have a couple of questions or comments about the matrix that I wanted to open up for discussion. So in looking at the matrix, there were a couple of specific questions that would be great to get some elaboration on. The first is I found it a little bit interesting – so when I look at severity of risk, I'm interpreting that as severity of an injury that would be realized if a patient was exposed to –

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

Okay, fair comment. Yeah.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center**

– exactly. So those – and then the number of people could – I was a little surprised on the number of people exposed that – is it – was it your intention that if you have a software let's say that's quite custom, so that it's actually used to help manage a very small population of individuals, that just by virtue of that specialization it would be deemed lower risk, even if it helps perform or it's functionality related to a particularly life-threatening situation?

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

Um, it's a tricky one, as you alluded to Meghan. So, let's say it does have to do with melanoma of the rectum. So it's a small number of folks affected, would that be different from saying, having software dealing with all diabetics, of which there are a lot in this country, that trying to capture that notion seems like it is worthwhile, but that's for you to comment on.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center**

So it feeds into sort of my thinking around this, which is that often times you – one tries to engage in doing a risk profile, not because one wants to decide to get rid of a product or anything, but that becomes a guideline for the burden of basic controls that you want the developer to put in place. And so when I think about the number of individuals, I would say that make – my intuition is I'd take that out of the equation –

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

Um hmm.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center**

– in part because I would say that if it's got low reliability, but it just only happens to be used on a hundred patients per year, that is exactly the type of product that I would want there to be very good safety controls in place, if it's again got low, in its inherent basic form, has low reliability, poorly designed and then potentially would lead to under-diagnosis or maybe even over-diagnosis with it –

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

It's a good point and that's been raised in our subgroup before. Could I get a little bit more opinion and see if we can get a consensus? So the proposal on the table is whether to strike that row for the reasons that Meghan described?

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

This is Keith Larsen, just one comment. I think that it's interesting to look at this matrix that in the end you kind of have to take it in a whole rather than individual items, because you can only – I'm suggestion that maybe you can find use cases where it doesn't apply for a particular role, but if you took everything that's on the matrix, does it give you an accurate presentation of the risk? In other words, all the factors together rather than single factors.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center**

So, this is Meghan Dierks again. I guess my real question is that I'm always thinking about how this matrix is used and traditionally in regulated fields, whether it's the EPA or Monetary Funds or anything like that, that the risk profile drives the kinds of things one would do – that will be required to mitigate the risk. And so it's almost like I have to think about, well, how do you want to use – I agree that there are multiple dimensions to it, and you want to get the in total feel, but if this drives the categorization or bucketing of a particular design and then further drives then what your expectations would be about mitigation or design control, I struggle with how you'd use it.

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

Yeah.

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

And this is Esther. I raised this last week as well, the issue simply of the opportunity cost or the risk of doing nothing – the context in which it's used, is this an alternative to somebody being okay or are they dying anyway? And I was told that isn't really relevant, but I think for this discussion, we should remember that there's also a context outside a risk, which is how it's – what the alternative is.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Julian Goldman here. Let me perhaps add to the discussion and raise another question or two. Which I think that a part of this issue that's complicating things is that there's an assumption here that risk is related to technology and that is, in a sense, vary within the table. That there are some technologies that are inherently more dangerous than others is what it appears. So, could there be a comment on whether that was one of the assumptions?

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

I can – this is Paul. I can see where you're getting that, but hopefully if you look at the colored clusters, it says, everything from what you intend to do to the software, i.e. technology is included in that, to how you get it ready for use and put it into use, to how – the context in which it's used and the things that are connected, have a bearing. So I guess if you looked at it that way, it doesn't say it's either – it's not only the technology, at least that's the way it was intended to be constructed.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Paul, I'm looking, for example, at the lines that are marked, the two that were discussed which were related to automated decision making, which is the first line, as well as the higher risk end of the purpose of the software, the first – and then the other is closed-loop, where there's no human intervention, which would be in the middle of the thing, ability to mitigate harmful condition. So, if I think through examples of this, could it really be said that just because something is automated or closed-loop that it's inherently less safe than other technology? For example, if you have an insulin infusion system that stops an insulin pump when a child or an adult's glucose drops below a threshold, in the middle of the night, is that really more dangerous because it's automated or closed-loop for safety interlock than a system in which we don't have that and someone sleeps through a hypoglycemic episode.

In a sense, if we look at technology such as a thermostat for managing a home temperature, that's a closed-loop control system that, I think, most people would consider to be quite safe and very unlikely to be a problem under most circumstances. So, on the other hand, another closed-loop control system that might control blood pressure might be considerably more hazardous and more difficult to implement safely. So, I think those are both closed-loop control systems.

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

It's a really good point and good examples and I have a counter-example for you. Remember that these are all just considerations, so let's look at a traffic light, red and green, in the two different directions and it would be – it's a closed-loop system and it would be disastrous if it were possible to be green in both directions. My guess and this is only a guess, that there actually is a regulation that says it has to be designed so there's a failsafe method. So in a mechanical way, there's a relay that it's impossible to basically to have both green. That's – so, it doesn't mean that you don't design closed-loop systems of the kind that you just mentioned, it just means that that's something where you probably need more to think about stronger oversight. Do you see what I'm saying? I think – the right column doesn't say no, just like – the right column doesn't say no, it just says, huh, let's figure out what's the most appropriate way to make sure that's a safe environment. Does that –

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

I think what you're – the example you give supports what I'm saying which is that can't categorize something and simply drop it into the right-most column because its closed-loop control or because it doesn't involve human intervention. It actually depends upon the specific situation, which is the current FDA approach to regulation, which one has to look at the hazard situation and then the risk to the patient and not the core technology in terms of a category of whether it's closed-loop control or not. Some closed-loop control might be quite risky, so to speak, and others may be very benign. So I think you're giving a good example of that same point – others speak to that point.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center**

So – it's Meghan Dierks again. One other observation distinct about this framework versus others that are used in other industries is that it's often times one appraises the risk or assesses the risk in terms of what is the probability of failure, given the design. So it's not really bucketing a particular technology into a risk framework, but says the risk is based on what's the probability of failure, what's the likelihood of harm given the failure, the severity of the harm. And that gets to this counter-argument around not – that would actually solve that question about whether closed-loop goes into high risk automatically or not. It would really –

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

Yes.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center**

– it really is, what’s – given the closed-loop technology and its design, what’s the probability of failure? What’s the likelihood that it would harm someone and what’s the severity of the harm? And looking at all those three that is ultimately what puts it into a risk bucket.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Okay, just – if I may just briefly, to introduce another point. There’s – it’s been demonstrated by the number of technologies that are closed-loop are inherently safer than open-loop technologies that we have today. Because there is no other way to provide the vigilance that closed-loop control can provide. Anyway, I support what you’re saying, Meghan, I think that there’s just a little more richness that if added to the slide could help convey that. It may not be necessary as its being used now, but as you pointed out, I don’t think it’s clear to some of us how this would be used in the future, so probably want to add that somehow, add that iteration. Anyway, thank you.

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

So I think what Meghan described, all rows in this – so you could calculate this in a sense, so there is the likelihood of the risky situation arising and there’s the severity of the injury, and that helps you assess. And you could certainly figure out that in some of these cases, the red traffic light, that when you combine that, then you end up with a safe system, even though it’s “closed-loop.” So I wonder, Julian, if actually is there a better word to put in that particular quadrant, or do people not think that the ability to mitigate the harmful condition is a legitimate – a factor in considering regulations?

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

I think it all boils down to the ability to mitigate, I mean –

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

Yeah –

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

– when one creates the risk framework, it’s a tool to help guide how much in your design, labeling, instruction, training needs to be put in place to mitigate. And if you cannot mitigate to a particular point where you feel as though you’ve done an adequate job and the benefits outweigh the risks, then that’s an argument for not allowing that product to be out there or putting really severe restrictions.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

I think there’s another aspect to this that I – that’s causing a little confusion as I read the table, and a little hard to do without a microscope. But, the leftmost column says, ability to mitigate the harmful – ability to mitigate harmful condition.

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

Uh huh.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

So when I read this, I re-read it, it implies that the closed-loop capability is being used to mitigate the harmful condition. I don’t think that’s what’s intended here, is it?

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

No, it is, if you have a closed-loop system where a human cannot see what the output is or control what the output ends up causing to happen, then that is a higher risk, it is something you would pay closer attention to, it does not mean you would not approve this thing. It might mean that you want to make sure that designs incorporate the following condition. Like and the traffic light says, okay, humans aren't going to do this, humans are programmed to respond to red and yellow, I mean red and green, and so I am declaring that all designs have a failsafe way of making the non-existence of two greens ever happen.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

So the – it's just – a well-designed closed-loop control system has to address a whole series of hazardous situations and also open-loop control systems do, so it would pro – again, I think we probably just want to look at another cut. It isn't inherently the closed-loop that's the problem, it's we have to separate out the technology from the hazardous situation and then it's likelihood to produce harm. And then probably – so, it's kind of a classic approach and maybe we can – I know we have a call with a lot of people and we're bringing up, I think, very important issues. I'm not quite sure how to best resolve it or to capture some of the –

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

Would you mind trying to suggest some words there? You've heard the other as well, that yes, it's a close – this matrix is not declaring closed-loop systems as unsafe, it is declaring that you sh...the people thinking about regulation or protecting public safety need to pay more attention to closed-loop systems for which there's no human intervention. That's the only statement that's being made.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Right, and I would disagree with that statement because the closed-loop control system might be extremely low risk in terms of the possibility of causing patient harm. It isn't – a closed-loop system that's doing a minor or trivial automated task, let's compare it to a thermostat, is not equivalent to software, which may be performing a calculation and is presenting the calculation to a clinician, but the clinician may not recognize when the calculation's in error. And that happens, as you know, quite a bit.

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

Okay, not that's in the row above it. So anyway, you have to take all the blue ones together, but feel free to suggestion some words and we'll try to work that in.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Sure.

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

So, that sounds like a good resolution. Other general comments before we go on to Regulations.

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

This is Todd. I just want to echo the same concerns that has been discussed about this and I'll try to provide some input separately along those same lines. I guess my question is, within the overall work of this group, what is the role that this risk assessment table will perform? And one of the key issues here is, as I think Julian and Meghan have talked about, and actually part of the original IOM study, was that you really can't understand risk unless you have that use context information. And as we've said from our beginning meeting, when we looked at the various points on this table, many times as we've just done, you can argue based on different use contexts and sequences of event, whether it's higher or lower risk around the probability of potential severity.

However, I guess one of the key needs here is to provide more of a classification system that will identify levels of concern about specific kinds of software and health software applications that would then enable the appropriate amount of risk assessment activity to be done. And that's very similar to what we have right now in terms of Class I, II and III devices, where we look at a set of characteristics and say, which bucket does it fall into and then depending on that, we understand how much of that process should be applied. I think it would be interesting to look at this, and I don't think it's necessarily a radical change to this, but if we can kind of shift it more towards identifying levels of concern. That would then allow us to drive a classification system and inform that as to how we might – how much of that risk assessment might be needed, when we actually look at these applications.

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

Good point. Thank you.

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

Paul, David, this is Bakul. If I may, I think, I'm just observing and hearing people talk, if I may. I think people are stuck on trying to – not stuck, but trying to figure out how to use this matrix and apply it to particular use cases. And I think David you suggested to collect use cases and walk through that and maybe an approach we should take on next, rather than debating this matrix itself, I think the matrix is really great because it captures a lot of different dimensions. I think what it boils down to is the blue rows where it should be used in conjunction with each other; I don't think it's fair in everybody's mind how that would work. So maybe that's an exercise folks can do in the next call or so.

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

I think that's a good suggestion. I think what we'll do is work with some of the exemplars and then see if we can't approximately put dots on which cells each of the use cases would fall in and then maybe the regulations group can say, hey, okay, well that has the following implications to which of our palette of regulatory tools we might use.

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

So another comment for Keith is, I was struggling, and maybe not struggling's the right word, but trying to figure out. If we take a use case, run it through this paradigm here that the risk framework – the risk matrix here, would there be a similar thing on the other end of innovation that we would want to see that would say, no, even though it's risk X here, does it translate to we definitely need innovation in that area. And that may speak to Esther's point a little bit about what its risk compared to and whether the need for innovation is needed or not needed or we already have an established baseline. And with that combined exercise would also be useful for everybody to sort of see how to tie the dots together.

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

And at one point I had sent out an email looking for exemplars of innovation risk about your comment of tying the two together. Again, the context – what we struggle with on this framework and everything is having the specific context. As was expressed, if I have a dosage calculation and I'm dosing penicillin, it's very different than if I'm dosing an oncology medication. Likewise, if I'm looking at – so, you have to know the context, so the exemplars that we have are all patient risk exemplars that would have to say well, if I have this system, how would it light up this framework so it would raise it to the right level of attention for regulation. And then the connection with innovation is, and now as I choose – or my regulatory tool, what is the specific issue that I'm going to impair innovation and do I – and then you get to balance of the risk.

I mean, one of the examples that was given early on in our workgroup is, and I think it was Anura Fernando, and it was talking about having a big red button on a machine that stopped the process. Now you could say that yeah, that did impair innovation because it has a very prescriptive implementation, I have to have a big red button. But then what you're saying is that the risk of people not recognizing how to stop the machine when there's a problem versus the risk of curtailing innovation in that particular thing, you would say, I'm going to come down on the side of the big red button. So you have to kind of say, okay, so what is the risk, what is the regulation and does the regulation really damage innovation and do you want to make that particular tradeoff? Because the risk is too great, so the risk of the effect is too great, so you do want to narrow innovation, but you don't want to use the same tool for everything, and so context matters.

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

I agree. This is Bakul. I think that's exactly what Esther was trying to point as well.

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

Yeah.

**W**

(Indiscernible)

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

And it would be good to have a couple of exemplars, which do kind of deal explicitly with innovation. I was just opportunistic and basically worked on all the ones that came up while we were going around.

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

Yeah, and again, the example I gave in one of the meetings was about the Hong Kong authority when they were dealing with SARS. In that case they had to respond, they had to go – they had link their patients from all the hospitals in the Hong Kong authority. They had to start collecting data and the risk of the software in that case was measured against the risk of the status quo, which was flying blind in the face of an epidemic. And they made a different – they made different decisions than if what they were dealing with was day-to-day release of software. And so the context in these things – and that's very hard to capture in regulation.

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

Okay. Any last comments before we switch over to the regulations group?

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

This is Meg Marshall. I have a – if you wouldn't mind backing up just a little bit. I have a specific proposal around the population attribute, and really it's more toward understanding and recognizing the downstream effect and downstream uses of health IT. Especially as the industry's moving towards personalized medicine and population health mechanisms, understanding and recognizing that a risk assessment that is performed today may impact a greater number of people during different situations in the future. So, maybe for that particular attribute it could be solved simply by adding the number of potential people exposed or potential downstream effects, something to that effect to kind of capture that as well.

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

That's helpful and I think one of the tentative decisions from this conversation though is I think we're actually going to delete that row, because it, I mean, because it's hard to interpret and the changes as you just pointed out.

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

I still think there could be value in recognizing that as an attribute in the risk assessment. It just may be challenging in trying to articulate how to do it, how do you represent that. But I do think that there's value in understanding how broad an issue could potentially be.

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

Right.

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

This is Mike Swiernik, I have a question for Keith. Keith, you had mentioned open access as one of the principles and I was just wondering what was meant by that, because I think that that can be interpreted a number of ways.

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

Open access, if we're going to collect the data, first it needs to be in a format that anyone – that it's all in the same format so people can get to it. But that it's open access meaning that it's available for review not just by the contributors, but by the people that are using these systems or want to learn about these systems. I mean, one of the things that we talked in a side conversation at Washington is that the class system has been popular and used by a lot of people and really, if you look at it, has very little data and results, it's really consumer perception of the software rather than specific capabilities or results of that software. And so the open access is really to say that as consumers of software, which may be another software that's consuming software. Or if the end user being able to access that database and really seeing what is being reported, what are the things, what are the experiences, not only with the software, but also with the implementation of the software, the context of its use. It's mainly just that it's open for everyone.

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

Okay. thanks. I'll just comment, I think this is a potentially tricky area just because I know that someone had mentioned in one of our meetings about having access to all the data. In other words, any raw data that's generated by an application should be available to someone else, and that's a little bit different than saying access to the data that pertains to the results the application achieved, which I think that's what you're describing. But I think there's – once you get into – if you start going down the road of making all data accessible, then it can cause problems. I know for a lot of startups, being able to monetize their data is basically their only exit strategy, so if you start making all data available, then that's potentially a problem for – from an innovation standpoint as well as competitive. So, I think we have to flesh that out a bit more to specify exactly what we mean.

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

Maybe the definition of what that data is, I mean, because again, you're monitoring – if you're after a specific – I can see what you're saying. That there may be some – I mean, the two barriers are what you're talking about, one is that the data itself has some inherent value that you want to market and the second is that by exposing the data, am I exposing myself to punitive action. I mean those seem to be the two that come up.

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

Yeah.

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

Okay. So, terrific discussion, more to follow. Let's move on, and now over to you Brad and Julian.

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

So, this is Brad. I think I'm supposed to go first, we're going to tag team this. If you wouldn't mind pulling up the presentation and then can you give me the ability to move it forward, Julian and me both the ability to navigate.

**Caitlin Collins – Project Coordinator, Altarum Institute**

I can.

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

Thank you. So this presentation, being a little bit tongue in cheek, I wrote on here it's a report of the typist because no one in our subgroup has even seen this presentation in its current form. This is basically something that Julian and I wrote last night, after the subcommittee regulation group's call yesterday. So I just want to make sure that no one misinterprets what this says. So, really this is an important juncture, in my estimation, for coordination and I listen very carefully to the discussion of the Safety and Innovation Working group because we're getting pretty far along in the process and we're all kind of I think naturally starting to converge a little bit. Converge at least in the sense of focusing now on regulatory specifications or what the regulations should ideally do, because that ultimately will be the work product of the whole working group.

So, we've been trying to follow very closely the developments of the matrix that we just went through, the development of the factors that were identified as important to innovation and I think – on the one hand, I think it's important that we be careful not to duplicate each other's work. And I wonder, and I'm speaking purely personal, I haven't even talked to Julian or anybody else about this, but I wonder if we aren't reaching to point where we need to set the subgroups aside and start doing the work collectively, as a whole, for the whole workgroup. And the reason I say that is because we've kind of gone through a natural logic here, we started with us having emphasis on taxonomy and defining things. We've spent a good bit of June really figuring out the elements of innovation and the safety issues, and now in July, we kind of need to, as a whole group, come together on a set of regulatory specifications that we can recommend to the three agencies. So, I wonder if we aren't sort of getting to the point where we need to have a discussion among all of us, more than the subgroups.

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

Well –

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

The process –

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

Yeah. Let me just jump in Brad. This is Dave. We – our calls are already set up and the – so, we do have two more calls of the full group before we have to present our recommendations. But, I mean we're clearly getting to the point where we need to be synthesizing some more, but I think both your subgroup and the risk subgroup have a little bit more work to do, and then we'll be done with the subgroups. So that's really where we are with that.

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

Well I know we have a lot of work to do, I mean we have a number of calls scheduled, and I'm going to outline kind of what that plan is. My nervousness is that to some extent we seem to be doing some – examining some of the same questions as the Innovation and Safety Subgroup, which isn't a bad thing, except if we go in different directions, it makes the synthesis more difficult at the end. So the process that we're following, and I'm just going to cover what we're doing basically over a one week period and then after that, we've got a few calls scheduled to try and produce a deliverable. But, so yesterday we focused on examining the three regulatory systems, ONC, FCC and FDA, to identify deficiencies and primarily that's what we're going to be reporting on today is the work from yesterday.

We carved out the whole issue of reporting and cutting across all three agencies, because we thought number 1, it cut across all three agencies and number 2, we thought it deserved its own focus and own meeting. So, Julian is going to lead that discussion tomorrow. And then also tomorrow, as directed by the statute, section 618, we're going to be examining the ambiguity in the three regulatory systems and then we're also going to be examining the duplication among the three. Those again, we didn't pick those, those were identified in the statute as important elements. And then the fourth meeting in this cluster of meetings is going to take a step back and say, okay now that we've been down kind of in the weeds looking at each individual regulatory system and looking for gaps and looking at how – what its impact is on innovation and so forth. We're going to ask ourselves well, is there a big picture better alternative for how to do all of this? So we're going to try and make sure that we step back and take that bigger view into account.

So yesterday or leading into yesterday I should say, kind of the lead in the end of June, we began by examining the work of the Safety and Innovation Subgroup. We read their materials in order to understand them as best we could. Several, I think, members participated or at least listened in on that subgroup's activities to try and understand. Because as we've been saying all along, that really is the foundation for what we think we're supposed to do in the Regulations Subgroup, is take those principles that the other subgroup is identifying and sort of build the regulatory specifications around that. We then also held five sessions, either 90 minute or 2-hour sessions on the regulatory systems of each of the three agencies and then we had a wrap-up session that was on sort of all other federal and state regulation as well as private industry efforts to address safety in the area of HIT.

So we tried to be as comprehensive, and those were more presentations and discussion. We always tried to save some time at the end for discussion, but there was a lot of presentation in those, a lot of slides developed. If anyone's interested, we obviously have those slides, and you can take a look at them, but we really spent some time trying to understand them, because each member of the subgroup kind of came from a different perspective or different background and needed to learn. In my case, I really needed to study ONC and FCC, because I just wasn't very familiar with them. So the questions that we examined yesterday are these, and I'm not going to go through all of them, they should be hopefully self-evident. Basically what we're trying to do is figure out if the regulatory systems, regulatory schemes of each of these three agencies are too much, too little or just right. And to ask ourselves more nuanced questions as to whether they're appropriately focused or whether, as per the statute and use principles of risk-based regulation in order to make sure that they have a light enough touch on areas that do not deserve heavy regulation. And likewise, making sure that there weren't safety gaps, that there weren't issues that could cause someone harm.

So that was the scope and so what we did is we created some tables where we basically listed the issues that need attention. And the first table is about FDA and we'll have a separate table for each of the other two agencies, and we have kind of this short hand classification process of "A" or "B." And the difference is, obviously you can read, that "A" means that the regulatory requirement is ambiguous and "B" means broken, which is not a very elegant description, but let me explain kind of what that means at a more intuitive level. By broken we're referring to a regulatory element that is codified in some way, written in some way, it might be in a statute, might be in a regulation, might be in a guidance, but a written requirement that does not fit well or frustrates the purposes of HIT. So, some existing requirement that was not well designed, or I should say, was not designed with HIT in mind. It might have been well designed from the perspective of a traditional physical medical device, but wasn't designed well from an HIT perspective.

The "A" refers to ambiguity, which can be an equally big problem, but it's a problem of a different sort, where you have a general requirement that's expressed, but it leaves quite a few questions figuring out how to apply it or to implement it from an HIT standpoint. So, it's not that it's inherently a bad requirement or a requirement that can't work for HIT; it's just that in this case FDA hasn't taken the time to really explain how that requirement applies. And ambiguity is a big issue, it's called out by the statute, we're going to have a portion of the meeting tomorrow focused on it. I'm not going to spend much time on it today, because we haven't really talked about it, it's for our call tomorrow. But these materials will give you some indication of what we're thinking. So I'm just going to go through the "B's" today, because that's what we talked about yesterday.

So kind of the first three or four items on this slide, really, most of this slide, is focused on issues that define the scope of FDA regulation. The next slide will focus on the mechanics of how FDA regulation works on those things, which come within the scope of FDA. But this is issues about the scope of FDA regulation. The first one is the basic threshold requirement that to be FDA regulated, there has to be a disease-related claim, the medical device definition turns on whether the intended use includes a disease-related claim, somehow in the cure, mitigation, treatment of disease. All right and there's an ambiguity, I'm not going to cover that now, but there's a concern that a lot of claims, and here it probably has more to do with mHealth than the broader HIT environment. And as you recall from the statute, mHealth is called out as a very important component of what we're supposed to be focused on. This particular item, my perception is, is really more driven by mHealth than by EHR or some other areas.

But in mHealth, there are a lot of apps where the claims around them may reference a disease, but it references it in such either a casual manner or from such a well-established manner, that it really doesn't create the kind of risk that merits FDA regulation. So, for example, you might have a mobile app that is used by a person to count calories and basically manage their diet. Well, in promoting that app, the developer or the vendor might say, this would be very useful, for example, if you have diabetes or if you are obese. And most of you probably know that two weeks ago the AMA decided that obesity is formally recognized now as a disease. So you've got an app that really is – maybe an elegant calorie counter or maybe it marries it up with exercise that you get or whatever, maybe not much substance to it. But by merely invoking the disease, arguably it falls within FDA regulation. We would say, that is an aspect which is inappropriate, it results in overregulation of certain apps, and as a result, it's a requirement that should be fixed, meaning it should be carved out for low risk disease claims.

The second issue is the accessory rule, and there the history is in order, I think I've explained this in the past. But, there's a decades old rule at FDA that if you sell something that accessorizes a medical device, it is regulated in the same manner as the medical device it accessorizes. So, if you sell something to be plugged into a medical device, it would be regulated in the same manner meaning, for example, the same classification, the same level of FDA regulation. Well, in mHealth again, this is more of an mHealth issue, I think, than larger HIT issue. There are a number of fairly generic, fairly low risk products, for example, a cable that might have a USB port on one end or a micro-USB port on one end and a proprietary – not a port, but a plug on one end and plug that maybe goes into an Apple iPhone or whatever it might be, and it's just a basic cable. And you have low risk technologies that are fairly simple, that might be nonetheless used in mHealth, for example, to create connectivity and they may not fit into an existing FDA classification. They may not fit in, for example, the MDDS the medical device data system, because they'd be involved in more than just a transmission of the data, there's some analysis involved, or something like that.

So, that's a second issue where we're concerned that the law, as presently written, is deficient because what we would – I shouldn't say we, this isn't final work product so big caveat there. But proponents of this would say that FDA should adopt more accessory classifications to down-classify, not exempt, but down-classify low risk accessories. So the only other "B" item is at the very bottom of this slide, which is post-market requirements for networks. And this is an area I think well understood or well-known where we're moving to a system where the network is common and the original design of the FDA regulatory system was to focus on individual components. And those components would have a risk profile associated with them because you would know the intended use and you would know, for example, what other products it might be paired with, and if something goes wrong with that device, you would have post-market obligations. You might have an adverse event report that you have to file, you might have to do a corrective action, you might have to remove it from the market or fix it or do something else. And the problem is, when a network hiccups it's our experience that it isn't abundantly clear which component is, so to speak, at fault for that network hiccup. And so all of the cascading post-market requirements become very unclear, because folks might be pointing the finger at each other saying my system or excuse me, my component worked just fine, it was yours that caused the problem. When in fact, it might be that the two worked – intended to operate together and so there's kind of equal blame or equal non-blame on both parties. So the system, in our estimation, doesn't work well – the FDA regulatory system doesn't work well in that networked environment where it seeks to impose singular responsibility where, in fact, shared responsibility might be more appropriate. So those are the three areas that we identified as, using the pejorative term broken, that's probably not the best term, but areas where something we think needs to be fixed.

And the next thing we're going to do is focus on the "A's" of where there's ambiguity. And I'm not going to cover that today, because we haven't as a subgroup, gone through that and I need to get the subgroup's views. So at this point I want to turn it over – oh, I'm sorry, there's one more FDA thing. I apologize. Quite apart from the individual legal-based shortcomings, there was a more overarching concern about FDA in the way it administered its program. And again, this is focused mostly on mobile medical apps, and it derives from in part the fact that mobile medical apps sort of cut across a lot of different aspects of the Center for Devices, and even beyond the Center for Devices into the Center for Drugs has some role with it as well, when the app is to be used with a drug. So, the issue is that we've been hearing about companies, for example, that call to try and get clarity from the agency about whether the agency requirements apply to their particular app, for example, and it's not uncommon to get inconsistent reactions, depending on who you talk to at the agency. And more generally, the guidance that was proposed just about two years ago, July 2011, has not yet been issued and people are waiting on the clarity from that final guidance.

So for all those reasons, the sub-workgroup felt as though there needed to be identified as a weakness, the current system for really providing information, regulatory information to entrepreneurs in order to help them navigate either the decision of whether they're regulated or not, or once they're regulated, navigate the internal FDA processes. So, that's it for FDA and I want to turn it over to Julian. Julian, are you able to drive your portion of it?

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Thank you Brad. So, I'll continue with just a few more slides and then we'll go to the Q&A, or at least the Q. So on this slide we've outlined a number of topics related to ONC where attention is needed, and again, the same categorization. The first was mandatory elements – sorry, there was a noise in the background, mandatory elements. And as you can see, this addresses the point that the ONC program does not include capability in law enforcement and the mandates that exist have been related primarily to financial incentives, which is a different structure fundamentally than exists within the FDA, and also, I believe, within FCC. Brad, did you want to add anything to this?

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

No, uh, uh, thank you though.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

So, next we have assurance of safe configuration. This is another topic that came up in the working group with specific examples and it's condensed over here, that –

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

Julian, this is Elisabeth. Are you going to have access to those slides, because right now we're still seeing the FDA issues on the screen?

**W**

No, I see ONC.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

I – right, I'm viewing the same thing everyone else is viewing, so I think you may have, Elisabeth, a buffered slide on your –

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

Okay.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Now if that was patient information, you'd be looking at all data and it would potentially –

**W**

Yeah, great example of what could happen –

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Yeah, you'd be looking at the old –

**W**

If this thing is not regulated, right –

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

– screen, patient is flat lining and you're not – yeah.

**W**

Exactly. All right. Thank you. I wish to tell you that I didn't do that on purpose guys.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Oh, actually we planned it, we had a few more surprises – Okay, so the next is assurance of safe configuration. Now again, as Brad pointed out, this has not been thoroughly vetted with everyone, but tried to capture the discussions that we've had. And in this case, it's been pointed out that an EMR or EHR, a number of – many different software systems, as we all know, can be highly configurable and may be configured or may need to be configured specifically to meet certain needs and requirements, especially to meet certain safety requirements. It's been studied and documented that there are approaches to the implementation of EHRs that might be safer than alternative approaches, and Dr. Bates pointed out an example, nicely pointed that out and related studies that support this contention. So currently there does not seem to be a means to address this, to ensure, for example, that the configuration is performed correctly in a manner that will support safety or not inherently provide barriers to safety. Dave, do you want to add any comments to this?

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

No. Thanks.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Moving on to the next one, coverage of interoperability issues. With a little hesitancy really in labeling something like this, surely ONC or really identifying the best fit on slide for agency, but it happened to start at least at this one. And this is the discussion of interoperability that we just had the other day, that there is somewhat unclear, incomplete responsibility that it has been expressed on a number of occasions that the ONC, this is the ONC's purview to address interoperability when it involves certified EHRs and medical devices. And so therefore, simplified here in the slide is the HIT medical device interface and that's the FDA's purview is to regulate medical device interfaces, but again, in a way that's similar to the conversation we had earlier on this phone call, as an attempt to attach something to technology as opposed to its function. And you can give an example here, and there are certainly many others, that you can have the same medical device, such as in intravenous infusion pump, and that same device could be installed in the same hospital or the same environment or home in which it could be connected to another medical device or to a server or it could be connected directly to an EHR. And that connectivity could include wireless connectivity or a wired network infrastructure. It could include a server or have a direct connection. In other words, there are many different ways for the architecture to be implemented and for the connectivity to be established. So how – so we have an inherently ambiguous and nebulous situation in terms of the regulatory pathway and very specifically, for example, which agency would receive reports of problems and who then is responsible for resolving these issues. I'll move on to the next slide at this point, let's see if my control works. It does.

So, moving on to FCC issues where attention might be needed. This – again this captures several of the conversations we had, the first is linkage to FDA reporting. The FCC pointed out that they have regular meetings with the FDA to discuss issues, especially with wireless communication, but I assume not exclusively related to that. And the point that's been brought up is that it just isn't clear to the public how that communication occurs. It isn't necessarily transparent and therefore there isn't an opportunity for the public to understand the state of the discussion and communication and also to provide input. The next line item is also linkage to FDA review and that is that there's a perception that FCC and FDA do not coordinate their review process and that there are different issues that come up, manufacturers have to get – issues that come up that are different within each agency. And I think has been discussed now at several meetings.

The next item is linkage to FDA regarding conformity assessment. And this addresses – this speaks to the issue that the FDA can be faced with the need to perform an assessment of the safety or efficacy of medical equipment, and yet there are not widely adopted standards for the performance of those devices with regard to their – especially their wireless communication, including coexistence with other wireless communication technologies. And that the adoption and existence of some standardized tested measurement criteria would be helpful apparently across both FDA and FCC. And then the final section on this slide is post-installation surveillance and here the topic has been again discussed on several occasions that spectrum management is quite difficult in healthcare settings, identification, diagnosing and resolving wireless coexistence or electromagnetic compatibility problems that affect health IT and medical device performance is quite a challenge. We don't have widely available standardized testing tools, there isn't a way to share that information publically when there are problems that are identified and therefore both identification and resolution of the problems are a significant issue. A number of organizations have been discussing this lately, there are activities with AAMI, for example, and others that are struggling with these issues and we've heard from within the group and the agencies that probably need attention and therefore it has an "A."

Let's see, I think, we'll go to the next slide now to talk about the bigger picture and I'm going to hand this back to Brad.

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

Well, okay. Basically we wanted to then not just look at each of the three agencies, but look across the three agencies, and this is – so we have big, bigger and biggest. And this is kind of going one level up, to look at the three agencies together to see if there are gaps across the three agencies, and that still needs us next – on the 8<sup>th</sup>, to look at the biggest picture, which is kind of, ignoring the three agencies altogether and looking at what the regulatory options are. But in this biggest area, or bigger area I should say, the main gap we focused on is the reporting of safety issues. And several people really seized on this, identified this as the biggest gap across all three agencies, that we really just don't have the data. We did not go into this in any particular detail because we carved out, as I said before, a whole session that will occur tomorrow, when we're going to talk about nothing but this. So this is kind of a placeholder until we have that deeper discussion that Julian's going to lead tomorrow.

So, that's basically what we're going to do tomorrow, a deep dive into reporting as well as starting to prioritize some of the issues that we identified. We take as kind of an implicit direction that we have that whatever we come up with in the way of work products has to be prioritized, because we can come up with a thousand items, areas that need clarification for example and a few areas of duplication. And we can come up with a whole slew of issues more generally, but we kind of assume that the agencies will want us, at the end of the day to start ranking them in order regarding where the biggest bang for the buck would be in terms of making improvements. So, we're going to start that process tomorrow. And so with that, I think Julian and I would be happy to try and field any questions or we'd be delighted more generally to hear any comments.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**  
Absolutely.

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

Okay, so questions for Brad and Julian?

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

This is Keith Larsen. First I agree with Brad, on my presentation too, it reflects the typist. I mean, we're going so fast on these things that our review process many times is whoever touches the presentation last it really reflects what they heard. The other thing is, I would endorse what Brad said is that as we see things – I mean, there are two comments. There's the comment that these things are converging, which means if they're converging, it also means that they're doing some redundant work, because there – we're groping towards more of a consensus. And so the meetings that David outlined I think will be very helpful.

I wanted to comment on one thing is that when the gaps with the ONC certification process, the first one was that it's broken because it doesn't have the enforcement of law and instead it participates in an incentive or a disincentive program, because there are incentives with Meaningful Use and then a disincentive of penalties – eventual penalties. Julian, would you comment that how would a certification process ever be a law enforcement issue? Because as Brad talked about, is that the purpose of the FDA was to be a criminal statute and with the certification process, we're saying – for instance, would it be criminally negligent if you did not perform med reconciliation exactly as the certification process said and I'll hold for comment.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Since you directed the question to me, my answer will be brief which is, I think that's an excellent question and I don't have an answer for you. I think it's a discussion that we should have.

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

Yeah, I did a – the intent of it was two regulations were quite a bit different and it's interesting when you try to marry the two, which is probably what we need to do.

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

So I don't remember who made the original comment, we discussed – several people I think chimed in, but I'll give you my own perspective, at least what I thought I was hearing. Which is that not so much that someone was saying, well, it's a weakness we ought to fix it by changing it to a mandatory system. But simply to recognize that at the end of the day it's a primarily voluntary system and voluntary systems have limits as to what they can accomplish. So, in that sense, it isn't designed, the whole certification process is not designed for example, to catch the people who are maybe deliberately trying to cut a corner, for example, or deliberately trying to do something to overstate a claim or whatever they might be doing in order to make money, at the expense of safety. So, it was just – I think it was raised more in the context of simply a limitation of the whole ONC system, that it wasn't designed to be a mandatory system.

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

Okay. Appreciate that feedback, thank you.

**Anura S. Fernando, MS, MD – Principal Engineer – eHealth – Medical Systems Interoperability and mHealth – Underwriters Laboratories**

This is Anura Fernando. I think I may have been one of the early folks to raise the issue also. And one of the things that I wanted to put out there for consideration is when we look at sort of the authorities of each of the three agencies, when we compare the fact that ONC is really voluntary regulation versus FDA and FCC being more mandatory, it creates at least that theoretical gap of systems getting out there without having a minimum set of requirements for safety and effectiveness around them. And so as we look at the boundaries of this authority or the boundaries of what constitutes a medical device under FDA's purview versus an HIT system under ONC's purview, for example. The safety and effectiveness issues could potentially be considered to extend into health IT, just from the perspective of safety and effectiveness, so that we can best leverage where there is a greater degree of legal enforcement authority.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Julian here. I think there's another point that we should make. We've taken an approach which has been I think clear to everyone, that right now, as we look at the slides that we've been looking at individually at each agency, and we've been – as we've talked about in the meeting altogether that one can go from one direction or another, either from looking at what's possible within each agency's purview and structure. Or one can look at this in terms of what are the needs of the larger system, what do we need going forward in terms of the requirements of a regulatory framework. In other words, what's it that we need versus how do we do it? And I think that to some extent the group has moved back and forth between how would it get done and what's possible versus what do we need and what's the larger vision?

And it's a little dangerous for us to get caught up at any step along the way to say, because this is the way it is, these are the current – this is the current system, that we shouldn't open ourselves up to envisioning what the future system should look like, the end state, with a future regulatory framework that addresses the safety needs in health IT. So the fact that currently there's a characterization as you saw on the slide about the incentive-based approach of ONC versus the alternative approaches, doesn't mean necessarily, at least to my understanding – by our leadership needs to provide clarification. That doesn't necessarily mean that this is the constraint that we have to do as the future. In theory we're supposed to identify the needs and gaps and then the next phase should be looking at a solution pathway. So I would offer that perspective. And Brad, did you want to step in on this, and Dave, any comment on it?

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

No, I think you did a nice job.

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

Yeah, and this is Keith. I would agree with that too. I think it's very useful looking at these current regulations and we were trying to do the same thing from innovation. But again, I would endorse what you said Julian, is, at the end, we're not simply saying well, here's "A" and "B" and we're picking "A," we're trying to come up then with the regulatory framework that really could address this, this whole area. So, I appreciate the comment.

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

Yeah, and this is Dave Bates. I agree with that, I think we do have an opportunity to recommend things that go outside what any of the three groups are doing now, if that's really what's needed. On the other hand, the more we can stay with the frameworks that are already developed, the better off everybody's going to be and I think we now have a much better understanding of all three of those. Other comments?

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

And I think – This is Elisabeth. I think one of the things I actually saw in one of the feedbacks that Steve Posnack sent out earlier today was that it was even the concept of leveraging aspects from all three. So I think we've talked about looking at who gets something, one or the other or the other. Or coming up with something totally new, but there may be aspects that we could leverage portions of all three of the groups and I think again that at least one of the commenters made that suggestion in their comments that they submitted.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

I think that's been our working assumption, at least it's been mine. And then I think the other working assumption is we don't know if that will be enough.

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

So, other comments or thoughts for the regulations group?

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

Just a question, on slide 11, where it has the bigger picture slide, and I guess this is teeing that up for the discussion tomorrow, is that correct?

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

If you're on slide 11 – I'm looking at 11, we actually started that one –

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

...the bigger picture –

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

– yeah, the bigger picture we actually started yesterday and the issues we identified on slide 12 is the one that we identified at the end of the call yesterday, which is just the reporting issue, but – so we're going to go – that was bigger, we're going to go biggest next.

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

Just one of the questions in your first bullet on the bigger picture, fails to address some particular safety risk. As you've reviewed the regulations themselves, can you comment on how specifically they address patient risk directly now, in their current form?

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

Well, it's going to depend on which specific type of software we're talking about. If it is, for example, an FDA regulated mobile app or MDDS or any of the other software that FDA regulates, you have a variety of systems in place for premarket review when that's required or adverse event reporting even when premarket review isn't required and quality requirements and so forth. So you have a wide variety of FDA requirements that apply to software that FDA regulates. The lower risk software that is still part of HIT that FDA does not regulate, really then you're talking about ONC and you're talking about the certification process. And there, I mean, in my mind you're raising a good question of whether the certification process is really designed to address safety or is it designed to push functionality out into the marketplace because the marketplace willing to use that functionality. I'm just not sure that it does a very thorough job of ensuring the safety of it, but sort of by definition or by construct, it would be lower risk to begin with.

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

Yeah.

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

Did I do a fair job of answering your question or do you have a...

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

Yeah, I mean, I guess it's something that I'm struggling with too because with the FDA regulation, it's really putting in process measures. But if I took – you had a nice summary slide in Washington about types of risk, and – that you and Julian put together, like I'm showing the data on the wrong patient, okay, let's just take that exemplar.

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

Yes.

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

I should catch that if I follow good process outlined in the FDA, I should have test cases that ensure that I don't get that along with all my other requirements –

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

Um hmm.

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

– nut there's no specific efficacy or measure of that particular type of thing, nor is there in ONC. So, I'm just – I'm trying to think how we address specific patient safety issues within these regulations. I mean in post-marketing, if somebody was having a problem, you would pick it up in post-marketing. But, the measurement of that in the pre-marketing or even in the certification model, I think it would be difficult.

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

You're raising a great question.

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

I'm just wondering myself how I would approach that, I mean, I know how I approach it when I do my own software, because we put test cases specific for that. And we look for how our software could end up – all of the weakness points, but I don't know how you'd push that out to a regulatory level and have a consistent measure of that. Anyway, it's more of a just a musing than it is a question.

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

Well no, I understand. And in part it's the pre-market versus post-market and as I say, tomorrow we're going to dive deeper into at least the reporting aspect of the post-market control so that if there were a safety signal, hopefully if the reporting systems are robust enough they'll pick it up and be able to address it that way. But pre-market, this is really a place where I think the current system at least makes the choice not to have many obstacles for lower risk software pre-market. It simply does not impose much of a burden to bring new HIT to the market if it's not within the definition or the gambit of what FDA regulates. And so, it's a great question I don't have a really good answer for.

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

Thank you.

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

Okay, other questions or comments to this group? All right. So, hearing none, let's move on. So I just want to thank everybody. This has been a lot of time and effort over the summer. As Brad noted, we are coming into crunch time so we need to have things continue to take a little more shape and we'll be starting to try and synthesize things in the background, together with the workgroup chairs. The Taxonomy Group will be coming back to us with a refined presentation, which is going to include some illustrative examples. Patty couldn't be on the call today, but that will be – we'll have that at our next call.

In the Risk and Innovation Group, Paul got some suggestions about how to refine the risk assessment framework further today. And for both the risk framework and for innovation I think it'll be helpful to consider those in light of some of the exemplars. For the regulations group, that group is going to come up with suggestions about which regulations should be eliminated or duplicative, what new regulations, if any, are needed. Which fall into the purview of any of the three agencies versus not? Two questions I would ask you to consider, which you haven't talked about too much is, should we suggest requiring registration of products? And a second would be, as you talk about the safety reports, what sort of resources are needed if the PSOs, Patient Safety Organizations, are going to share data, so that there's a national resource? And would that be a valuable thing. I'm not sure if that's in the ONC report that came out today, I kind of – I tried to scan through it rapidly and I couldn't figure that out. But that's been something that we've not had, which has been a relatively big gap.

So again, our work product will be a PowerPoint, it can include both bullets and visuals. The initial finish line is on August 7, but we'll finalize it in September. Again, it can be backed up with appendices and it does need to be supported by exemplars or use cases. So, let's see, from a timeline perspective, we do have an administrative call tomorrow at 4, which just involves the members of the agencies and we'll be talking through timelines. But our next call as a group is July 26. My hope is, for that call, to have at least the beginnings of a draft PowerPoint, which people can then react to, and then we'll have another call on August 1, which is just a few days later. So those will be important calls, and then the presentation will be on August 7. So, let me just stop there and we can ask some more questions about logistics and/or more general discussion.

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

So, with these meetings – I mean, this is Keith, sorry. We've independently put together these slides, when the final work product comes out on August 7, for that presentation, is that – so it's a series of PowerPoints or will we –

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

It'll basically be just –

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

(Indiscernible)

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

It'll be one PowerPoint, which I will present to the HIT Policy Committee –

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

Okay.

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

– and I'll have to meld the recommendations from the individual groups. I will try to again have a draft version of that ready for people on the next call that we have as a group.

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

So on the July 26?

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

Yes.

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

When we see the draft? Okay.

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

Yeah.

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

So we want to make sure we have materials in to you before then so that you can create the draft.

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

Exactly.

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

Okay.

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

I mean, my plan is to start working on that in the background. I'll obviously be working with the subgroup chairs, but want to get as much input as we can from the full group.

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

Okay.

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

David, this is Brad. Could you explain more about the purpose of making the August 7 presentation to the HIT Policy Committee? It's a little confusing to me because the statute is pretty specific about the group that needs to develop these recommendations and it provides pretty elaborate guidance and directions to the composition of that group, and that's how this workgroup was developed, I mean, constituted. So what is the purpose of presenting it to this other HIT Advisory Committee?

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

So, this is MacKenzie. I'll step in. The workgroups themselves can't produce any recommendations. So the Policy Committee is the only entity, according to the Federal Advisory Committee Act that can prepare recommendations to send forward to the National Coordinator, and in this case, to FCC and FDA as well. So the workgroup itself can't, according to FACA, produce any documents, they only give information up to the Policy Committee. So in order to be in compliance with FACA, the Policy Committee is ultimately the ones that will be sending forth the recommendations.

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

Okay, so I gather someone made a judgment at some point to rather than make this workgroup a FACA Committee to use that FACA Committee, but it's confusing to me. Is there some scenario where what this group develops might be changed on the basis of what this other group, whatever its formal name, this HIT Policy Committee, that our work product might be changed by that group?

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

So Jodi, I don't know if you're on the line as well, but Paul you can also feel free to make any comments. But, we do have members of the Policy Committee on this workgroup. So once the recommendations are shepherded up to the Policy Committee, both Paul and David are full committee members and they would be providing any additional comments. So there is a chance that the committee could provide additional thoughts or additional areas to consider that would then be sent back down to the workgroup to further deliberate on, that's the thinking of having the initial set presented to the Policy Committee in August, for then the final set to be presented in September. I'm not anticipating a great deal of additional comments, but it is possible.

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

So this is Jodi. I am on the line. So to that, so yes, the workgroup recommendations do go through the full Policy Committee. The Policy Committee is charged by statute to – Policy Committee to provide comments and the recommendations on policy related to health information technology. And so it is possible that there are folks on the Policy Committee who will say, well, in light of these other things that are going on, and come back with questions or request for the workgroup to think about something a little bit more based on their kind of broader perspective on health IT policy. And Brad, I would be happy to talk offline about how we came to creating this as part of the Policy Committee, but one of the factors is that there is a statutory – the Health IT Policy Committee was mandated by statute to address policy issues. And typically we don't create multiple Federal Advisory Committees that have overlap in jurisdiction, so it is within the jurisdiction and so it seemed like the appropriate place to put it. But I'd be happy to discuss that offline.

Like I said, what we had in the past – I expect that there'll be a rich discussion and that there will be questions and comments and thoughts, and maybe some additional thoughts that the workgroup hadn't considered, that will get tossed back. And we'll have some workgroup meetings between August and September to talk through whatever feedback we get from the Policy Committee and then provide final recommendations. Part of the reason we have full Policy Committee members on the workgroup is because they are sort of bringing the expertise from the full committee into the workgroup discussion and vice versa. And so David as the chair, who is also on the full committee, will be the person who reports out the recommendations from the workgroup. And folks on the Policy Committee who are used to working with David will listen to what – his representation of what the workgroup recommendations are. And typically the Policy Committee does have a rich discussion, but often defers to mostly the expertise of the workgroup, and I expect in this case, particularly because of the diversity of issues and stakeholders, that there would be a great weight placed on the expertise and the full discussion that has occurred here.

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

So this is – guys, this is Robert Jarrin. So, I've always kind of questioned this because the statute's pretty clear on its face that the Secretary of HHS acting through the Commissioner of the FDA, in consultation with ONC and so forth, will post this thing on their website, and then of course the Secretary may convene this working group of external stakeholders. But it's not in there that it would fall under an existing FACA. I always kind of wondered why we were put under an existing FACA when, in fact, this is calling something to be created completely separate and distinct from existing FACAs, for the sheer purpose of section 618.

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

It was an administration decision on how we thought it was most efficient to do it. I guess, it is in fact the way it was set up and it was a joint decision of the various agencies and of the department on how best to do that.

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

So this is Brad, I welcome input from everyone, I mean, we're going to go here into public session and public comment in a moment, certainly I'm anxious to hear from anyone thoughts as to how to make this work product better. What made me concerned is the notion that sort of after we're done with what we're doing, that this HIT parent committee could somehow unilaterally overrule us and recommend something different, however big or however small, from what we came up with. That's what was concerning me and I just wanted some clarity around the likelihood of that happening. I would welcome their input, as I said, I welcome everyone's input.

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

Yeah, I think as Jody has noted – this is David. I think it's very unlikely that that will happen. Typically there is a really good discussion, often some issues are brought up that we perhaps didn't highlight enough, they'll make some suggestions to us. That's what I would expect to happen. And I just would also note that our input really then goes to the agencies and then they have to do the really heavy lifting of developing the actual framework.

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

To be sure, I respect and understand the agency role in it, but it's the intermediate role of the parent committee that has me nervous.

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

Sure, I find that worrisome as well and all due respect to Jodi and the reasoning for the agencies to do this, I realize that ONC had a very well thought out, established FACA, or two FACAs, but the intent of Congress was not to put it under another FACA. The intent of Congress was to develop this recommendation, this report and to give the authority to HHS Secretary to be able to trigger this external stakeholder working group, so I really don't see it that way.

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

So Jarrin, but the HHS – Secretary of HHS has a lot of discretion on how she chooses to set up and administer her programs. And all I can say is this is the decision that was made and I understand people's concerns about it and, quite frankly, all three agencies are sitting on these committees and all the subgroups and so we're hearing all of the discussion and we're the ones who are going to put together a report. So I'm not – I understand the concern and – but we're here, we're listening to what everybody's saying, we're listening to recommendations that are being made here, we'll be listening to recommendations of the Policy Committee and it is – this is how we set it up. It's not – I'd be happy to have a conversation offline, I don't think it's necessarily a great use of committee time to talk through the decision that was made months ago.

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

Sure. So, other comments about other areas, things that we might need to make sure to flesh out or finish up over the next few weeks?

**Anura S. Fernando. MS, MD – Principal Engineer – eHealth – Medical Systems Interoperability and mHealth – Underwriters Laboratories**

This is Anura Fernando. I just wanted to understand the path forward a little bit better. So are we going to be taking the Risk and Innovation group – I'm sorry, subgroup I should say and use that to sort of mold what the Regulatory Subgroup is doing in terms of making recommendations on how the regulatory path should be established?

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

So we'll be putting together really the outputs of all three workgroups, so we'll start with the Taxonomy Group, which will help delineate things and then bring in the work products of the other two workgroups.

**Anura S. Fernando. MS, MD – Principal Engineer – eHealth – Medical Systems Interoperability and mHealth – Underwriters Laboratories**

So the Taxonomy Group, does that then ultimately define the scope and then the regulations that are addressed fit under that scope and then the recommendations relative to the regulations are based on this balance between risk and innovation as determined by that subgroup?

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

That's basically the – yes.

**Anura S. Fernando, MS, MD – Principal Engineer – eHealth – Medical Systems Interoperability and mHealth – Underwriters Laboratories**

Okay. Thanks.

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

Can we tease that – this is Brad. Can we tease that apart just a little bit more because we had this discussion a month or a month and a half ago when the Taxonomy Group was really kicking it off, as to what the significance was of what they were defining? And at the time my understanding was that they were defining the scope of what we in this working group would talk about, not the scope of regulation. So now that we've talked about it, it would seem that the definition of the overall approach that the Taxonomy Committee has developed is somewhat out of date, because it was meant to define what we would discuss. But when we get to our recommendations, I assume we have to sort of come up with a new taxonomy, a new set of definitions that marry up to what we think ought to be regulated in some particular manner. I'm not sure how I – I don't have a mental picture for how that fits together.

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

Well, the Taxo – the task that we gave the Taxonomy Group was to really define the scope of which things we should be thinking about here in terms of both risk and regulation and to set some boundaries. And their work will apply to basically the boundaries of our recommendations in the other areas. I mean the boundaries are clearly somewhat fuzzy, but I think that they will still apply.

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

David, I'm struggling. We can go back and we can get the tapes as to what was exactly said, but – so to come up with one kind of monolithic taxonomy that is one scope of what ought to be discussed on its face doesn't answer the question of what is the scope of what should be regulated. For example, we have three agencies involved in this, that scope, I assume nobody on this phone call would say that that scope defines what FDA should regulate, for example. I assume that most people would have to really take a look at it and think about if there were a regulatory program that we recommended be created, if it would apply to all of that, certainly all of that in equal measure. Because the whole point of this committee is to find a risk-based approach and the taxonomy definition is monolithic, it's what –

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

Brad, this is Elisabeth. I thought, and I was on the Taxonomy Group, I thought just as you said, that we were defining the total scope of everything that fell under HIT and that step two would be using the risk process, we would determine where each of those items fell. And then using the regulatory scheme, we would define which things, based off of risk, had potentially no regulatory oversight and no regulatory scheme at all, all the way up to the higher risk that may have the most rigorous regulatory scheme. So I think what David said of what we defined in the taxonomy isn't changing, I don't think it is. I think we've still defined what was the superset of everything that fell under HIT, and that using risk we would determine where things fell and then using the regulatory schemes of process, which regulatory scheme they could fall under.

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

Yeah, that's very much the way I've been thinking about it.

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

I'm sorry, it must be that my brain's already on the Fourth of July because when I looked at that definition, it doesn't tell me for example – and then I try and marry it up to the FCC requirements, I don't see a connection between what the Taxonomy Committee did and what FCC ought to do in its various programs for approving new emission transmitting devices, for example. Or what FDA ought to regulate in any of its various classifications. I don't see the interconnections between any of those regulatory schemes and the system that the Taxonomy Committee came up with. I thought all the Taxonomy Committee did is sort of tell us what we ought to spend our time thinking about during this three months. But once having done that, I don't see the continued role of those definitions.

**Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center**

Well this is Meghan Dierks making comment on what I thought the Taxonomy Group was charged with and what I think we did. I – just to restate, I believe the Taxonomy Group looked at the dimensions of the task in front of us and we also took under consideration the need to look beyond what one could conceive of as existing products. And hand that off so that we made sure that as the risk and regulatory groups thought about things, they thought about it broadly along the various dimensions. But it wasn't my understanding, in fact, I think we were pretty clear about the limitations if we were to come up with a specific list of products, nor was it our understanding that from that specific list that the other groups would almost take a prescriptive approach. Meaning, state given this list, apply this framework and use the following as a guideline for the specific regulations or regulations that you think should happen. So, I just wanted to – as far as the time spent by the Taxonomy Group, I wanted to kind of say, that that was our perspective on this.

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

Sure. Thank you.

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

So, I appreciate that. But so, I'm just getting very tactical now, very, very tactical. So I'm picturing David writing this report and whatever we in the Regulations Subgroup hand off to David would be regulatory specifications. And I don't have, to my knowledge as I sit here today, and we've got a lot of work yet to do, so maybe it'll come up, I don't have any cross-reference in our regulatory specifications to the definitions of the Taxonomy Committee. It was helpful, what the Taxonomy Subcommittee did, because it told us what to look at during this three months. But those definitions don't get – so far, haven't been incorporated into anything the Regulations Subgroup is doing.

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

This is Paul. I guess I would have seen it as a next logical step, I'm not sure that I think it would have – it would influence your deliberations right now. But I guess I did see a sequence of taxonomy trying to talk about the scope really of our report and they made some discussion about well why would this be more likely be in than not, we had a group discussion. That then formed our space that we – within which we'd operate. We also didn't specifically necessarily say, oh, well applying it to all those things and not the other things when we came up with both our patient safety risk and our innovation risk framework, but are expecting it to be applied by your group when you come up with the palette of regulatory tools, use exemplars that would come out of the defined scope of the Taxonomy Group. To me that does all make sense and I'm not sure it would have been very useful to have them spend that time to really think thoughtfully go through various kinds of HIT products, if it weren't to put a scope around our reports. It doesn't – justice to anything, but it's part of this whole thinking process. So, it seems consistent to me.

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

Yup.

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

Well, it may be consistent, but from the drafting standpoint it isn't connected. It defined what we looked at, what exemplars we considered in scope, what exemplars we would consider out of scope. But when we get down to the level of saying, okay, so here's a regulatory recommendation, not a system but a feature, it isn't – as I sit here today, we're not done, but as I sit here today, it isn't incorporated in anything that we are doing.

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

Okay. So Brad, it would be helpful over the next couple of weeks if you could connect it to the things that you're doing. I'm sorry, we're out of time and we need to go to public comment. MacKenzie, could you open up the lines?

## **Public Comment**

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

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

### **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 public comment at this time.

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

Okay. Thank you very much and thank you all. Enjoy the Fourth. Some of us have another call tomorrow, but take care and thank you again.

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

Sorry, and this is MacKenzie. I'll just bring to everyone's attention that we did send around a link of the docket that we posted for public comment. So that was sent around this morning at 9:30 if you guys just want to take a look at that as well.

### **Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

Okay, thank you.

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

Thanks everybody.