

**HIT Policy Committee  
FDASIA Workgroup  
Risk Assessment & Innovation Subgroup  
Transcript  
June 28, 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. Hi, did someone just join in? Can I ask everybody to please put their phones on mute? Everyone please mute your lines. We have a live line; I think someone is drinking coffee. Okay, 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 the Subgroup on Risk Assessment and Innovation. This is a public call so please make sure you identify yourself for the transcript as well and there is time for public comment on the agenda. I'll now go through the roll call. Keith Larsen will be joining momentarily. Paul Tang?

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

Here.

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

Thanks, Paul. Geoff Clapp? Esther Dyson? Mike Flis?

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

Here.

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

Thanks, Mike. Jeff Jacques? Anna McCollister-Slipp?

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

Here.

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

Thanks, Anna. Jonathan Potter? Jared Quoyeser? Mike Swiernik?

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

Here.

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

Thanks, Mike. Steve Posnack?

**Steve 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. Simon Choi? Is Simon on?

**Simon Choi, PhD – Senior Science Health Advisor, Center for Devices & Radiologic Health – Food and Drug Administration**

Here.

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

Thanks, Simon. Matt Quinn? And for full FDASIA Workgroup members I have Anura Fernando?

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

Here.

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

Thanks Anura. 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.

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

Rob 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, can I just ask everyone to please mute your computer speakers as well because we're getting an echo. And Todd Cooper?

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

Happy Fourth of July.

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

Happy Fourth of July, thanks, Todd. Any ONC staff members on the line?

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

Elise Anthony here.

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

Thanks, Elise. Okay, Keith have you joined the call yet?

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

Yes, I'm on.

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

Great, thanks, so we also have Keith Larsen. So with that I'll turn the agenda over to you Paul and Keith, but I believe Keith is going to be going first.

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

Yes, go ahead, Keith.

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

Oh, I'm going first? Okay.

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

If you would like to, just alternating to make sure you get enough time.

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

Okay, so again, let me just verify we're going for how long today?

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

Let's see.

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

Okay, we have an hour and a half, so if I –

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

It's 1:00 to 2:30.

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

Yeah, so I'll go 40 minutes and we'll watch it from there.

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

And Keith if you're on a speaker phone could you just move a little bit closer to the phone?

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

Okay, is that better?

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

Yes.

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

Okay, I'll just take the headset that might help, is that better now?

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

Yes, much better.

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

Much better.

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

Okay, can you go to slide 4 please? I sent these slides out with a little note, yes can you advance the slides to slide 4? Oh, wait a minute, hold on, okay, let's go back just one slide, okay, thank you, okay now I'm in sync. Sorry for the delay.

Okay, so, and I put this in the e-mail, there are three things – the slide deck is getting longer because it's trying to be comprehensive for our different discussions, but the three main things in the slide deck are a critique of current regulation, you know, how has that effected innovation in particular, not critiquing on any other basis, but what is the critique for innovation. The second one is: What are the specific innovation requirements that we have? And then the third one is suggested framework that would serve innovation.

For today's discussion then we're going to – I ask that we concentrate on the critique of current regulation. I've put some things in there that we've experienced here and, you know, gathering from a few others, but I need to validate that information and then we'll get into the innovation requirements.

For the suggested framework for innovation I also referred in the slides to the regulatory group who is putting together a discussion of that July 8<sup>th</sup> and so they are on, there will be a discussion on that. So, I want to concentrate on the first two points. Can we go to slide number 7 then? Yeah this one.

So, again, what has been the impact of current regulation on innovation? Next slide. The pieces that we're looking at and part of it – okay, so we have the FDA with the medical device regulation which includes labeling, manufacture and practices, and then pre-marketing approval on certain classes of it.

With ONC I put in information about the ARRA certification, Meaningful Use and I included Surescripts in here because of it being enabled by ARRA certification and Meaningful Use and maybe there can be a comment of whether that's fair to put that in or not. The difference is – let's go to the next slide. Actually let's advance to slide 15. So, oh, one back.

Okay, so with the FDA approach, with the medical device regulation again this is just measured against innovation and then we've put in these process controls. I know that we have vendors that have put in these process controls, so I'm throwing these things up for discussion, one is that on the positive side I think that the process controls, the emphasis on process controls allows us also to – I mean, promotes innovation to the point that I can depend on that if I'm using components that were tested this way it gives me some kind of understanding of what that component has been through and so that results in a trust factor.

I think that on the con side is the clarity, you know, who is subject to regulation, I mean, we've talked about this in the Taxonomy Group, and has led to, you know, regulatory discretion but, you know, who is subject to it and then just there is a knowledge barrier of how do I wade through this law and know what I need to do.

And then the Regulation Group has been talking about that it has been geared much to physical devices, I mean that was the early purpose of that law and they've already suggested some adds and subtractions, mainly subtractions to fit medical software. There is also the reference in their slides to the AAMI report where it was trying to, again, look at how do you apply this law to software and that has the different attributes of being virtual and changeable, and trying – and in fact you want to have it configured.

Okay, and then the last issue I put on there is as we talk about progression in software something may start small without regulation, because it's below the radar of regulation, but then at some point because of how it's being used and how far it gets used now I'm trying to apply this, these best manufacturer and processes on something that did not do all that process and how do you make that entry point better.

Anyway, other comments or experiences with the FDA device regulation either positive, negative, any comments on that?

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

Hi, Keith, this is Anna, I guess my sense, and again this is just based on my understanding of things and I could be wrong, but the sense that I have is with devices is that you have to have the FDA review it before it's available which is expensive and makes perfect sense I think for like physical devices like an insulin pump or a continuous glucose monitor, or, you know, a cardiac valve or something like that, but when it comes to software that slows the process of rapid iteration and rapid improvement so you don't see the constant iterations that you get with Apps on the App Store for instance where it's constantly improved based on user input and feedback. It's a very static process that really slows where you could have incremental improvements if it weren't for the regulatory process. Does that make sense?

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

Yeah and there are different classes of devices, Class I through III and then even in Class III where you have the pre-marketing authorization there is, or approval, there are exemptions to that. So, it doesn't necessarily have to be applied as a pre-marketing authorization it kind of goes to how it's classified.

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

Well, that seems to be the way it works. So, for instance if you have software that goes with the device the software is under the same scrutiny as the device itself.

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

That's true but that's when it's part of the device, you know, if we're talking about standalone software how does it fit into the device classification and then – but, I mean, the issue about the pre-marketing approval is really the issue of iteration.

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

Can I interrupt? This is Robert Jarrin with the Regulatory Group, the Regulations Group, can you guys hear me?

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

Yes.

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

Yes.

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

Great, so Anna, there are a couple of things; one is Class I devices do not require pre-market approval or clearance for the most part. The majority of Class I devices are actually exempt from pre-market notification at all.

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

Right.

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

Pre-market devices are the ones that are minimal potential for harm to the user. So, what the manufacturer has to do is they have to – depending on whether or not they can be exempt they would have to go through the general controls which are available for all Class devices, so Class I, Class II, Class III they all have to fall – that includes establishment registration meaning they have to register as an establishment with the FDA, you have to, you know, list your device with the FDA, you have to abide by certain labeling regulations.

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

Sure.

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

And then there is this very – called GMP, so GMP is really where you get into the quality systems regulations. If you're a Class I device some of those devices, many of them actually, have to go through GMP, many of them – a lot of other devices actually don't have to go through GMP. So, when you're a Class I device if you're low risk enough and you don't have to go through GMP you merely have to register with the FDA, you have to list your device with the FDA and that's pretty much it. You don't have to, you know, notify them and you don't have to go through any kind of approval.

Now if you're talking about Class II devices that's a device where general controls alone are not sufficient to provide what they call reasonable assurance of safety and effectiveness. So, there you have to go through what is a pre-market notification that's what really translates into a 510(k) you have to find substantial equivalents to a predicate device that's on the market and you have to go through the same general controls that I just listed, establish and registration, sustain labeling and GMP, and you may also have to have other special controls which include things like post market surveillance.

And then we get into a Class III device that's where you get into really strict stuff, because, you know, those are devices that support or sustain human life and are of substantial importance in preventing the impairment of human health.

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

Right.

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

So, you know, when you think of it quickly you think of Class I as you have to list your device, Class II you have to ask for clearance, you know, you've received clearance rather and Class III you have to gain approval that's really the easiest way to look at the three of these.

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

Right.

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

So, I would argue that in many Class I devices, which are not, you know, most Class I devices or all Class I devices for the most part, you know, you don't have to go through the same types of scrutiny that you would for a Class II where you require pre-market notification and/or a Class III device where you have to go through approval, some you may have to, but there are very, very, very few.

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

Right.

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

And again it's that idea of which one do we end up classifying software.

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

Correct.

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

Sure, but not all types of –

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

What I would also –

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

Software.

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

I was just going to clarify one more thing, when you mentioned accessories, you know, the issue of standalone versus part of the actual device, if it's part of the actual device, depending on what class of device it is, it's probably – you're probably going to include it in your 510(k) for that device. So, it's not a standalone type of scenario it is part of the device so it's part of your specific product that you're putting through.

If you're creating a software that is outside of your product, you know, you may have to put it through FDA if you're making it available as an accessory which means you're either selling it directly to somebody, you know, or other things which I don't want to go into.

The big issue with accessories though I think, you Anna, said something very important, which is if you're a standalone device and you're trying to sell it or trying to offer it to market and it connects to an existing device that's got another product code the current Reg is that it will up class to that code whatever that code may be.

So, in other words if it's a Class III device that's using a Class I software the Class I software would technically code up and have to go up, well not code up, but would have to be regulated at the Class III designation and that's a little hard to deal with and that is an area that needs to really be clarified by the FDA and worked on.

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

Right.

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

Right and that – exactly and that is what's slowing the innovation of elements of software that have nothing to do with device operations they merely have to do with recording events that track along with the data generated by the device, you know, interpreting or at least displaying the data or relevant things that go along with the data that's generated by the device.

And the way that the current system works is all of that has to be pre-approved beforehand so you get into these three year innovation cycles that leave, you know, basically the second the device is launched its outdated. That our software isn't innovating – is innovating at the same rate as the physical device and that's slowing the route to market for a lot of things that would be very helpful and have nothing to do with the actual device operability.

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

Okay, I'll add that. Other experiences with – I mean, again, what Robert went through I think is important is that it's very hard to say exactly how this impacts without knowing number one is the software under the regulatory discretion first is it being regulated and the second thing is what class is it being regulated at, because again they have different burdens of regulation.

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

Right and the one thing that I would say, Keith, is, you know, as a lawyer when I would think of, you know, a software –

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

Yes.

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

There really is no distinction to me if it's a medical device. A medical device can be, you know, some hard tangible product or it can be software, you know, if it falls under Section 201(h), you know, it is what it is and then we go from there and figure out, you know, which class it is and, you know, other burdens that is has to go through.

You know, these are some of those areas that, you know, I keep bringing up which are, you know, there are ways that the FDA can be a very nimble regulator, you know, and arguably they have not been exercising, you know, that nimbleness in some ways and that might be one of the things that you guys and all of us, you know, really could, you know, hopefully push on is that, you know, some of the things that they can do to be nimble, you know, are important especially when you're thinking about things like software and the accessory rule.

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

Well –

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

The MDDS rule, you know, and I'll cap it, is the MDDS rule, you know, very specifically within the Reg it does state that an MDDS can work with any other class device meaning that if you're a Class I MDDS device you do have to have to register, etcetera and you're not GMP exempt so that's a big deal. You know, however, an MDDS, you know, that transmits, transfers, stores, converts, you know, medical device data from one preset spec to another and helps display it electronically, you know, can work with any other class device and it does not class up, you know, so that's big deal, you know, the FDA came straight out and said, you know, this the way that we intend this thing to work and I think that they can do that with lots of other things.

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

Okay. Other people that have – is there anyone on the phone that has again worked under these approval processes and can give experience?

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

Keith, this is Mike Flis.

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

Yes?

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

I also wanted to draw attention in 1997 FDA published a guidance document to help manufacturers decide when they needed to report modifications in the design of a Class II device and that document has been extremely helpful because it allows companies to make well over 90% of the changes without having to report them to the government before you implement them in the market. I've heard that FDA is interested in updating that document, but so long as such a document is in place there remains a great deal or degree of freedom in the types of changes you can make and how quickly you can make them without the burden of receiving FDA clearance before you can put that modified product in the market.

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

Okay, thank you. Okay, any other comments on the FDA Regulation? Let's go to ONC the next slide. ONC is a little bit different than FDA because the motivation is really to find outcomes, you know, and this is my take on the motivation is that the government is funding a capital improvement to healthcare practice therefore there is an obligation to promote good products therefore we get defined best practice.

The fact that I've collected and experienced is that the assumption of known best practice where it's not known has an impact on innovation because now I've narrowed what the practice can be and the cases that I've put out there earlier on the e-mails are again where you see even something that starts off with kind of a more fuzzy best practice by the time you get to the test behaviors you've really specified a very specific implementation which promotes a working to the test or compliance what's called in the article a compliance innovation.

Well, let's just stop there, I mean, as people have worked with the certification process has it worked for you, has that – what impact has it had on your innovation?

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

Hi, this is Mike Swiernik.

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

Okay?

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

I think what I've seen is that the EMR companies have I guess regressed to the mean maybe because the certification process of course said you have to be here at a minimum and in some cases a lot of them are already there and in some cases the stuff that they had to do was completely new, and so there has been a concern and I think it's a legitimate concern that a lot of the EMR companies that have had to get certified haven't done a lot of innovative work just because they've been spending their time meeting the certification requirements and getting their customers to meet them for Meaningful Use, so that's been an issue.

And then if you're not an EMR company and not directly subject to this certification then what it means is that there is a lot of – but your market is the same sorts of customers than the affect has been, from what I've seen and what I've heard others have seen, is that the providers aren't genuinely that interested in what you have to offer just because they're so focused on meeting the new Meaningful Use and certification requirements and the work that goes there given their limited resources.

I think there are certainly customers that have already made it and for them the Meaningful Use is less difficult and so for them they're interested in those things, but I think the vast majority of people I see are really just questioning whether they're going to meet Stage 2 and all that. So, that's been what I've seen from this.

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

Yeah and –

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

And this is –

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator for Health Information Technology**

Go ahead.

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

Go ahead. This is Anna, just to echo that I would say that there is a perception and I'm certainly not with an EMR company so I don't want to speak on behalf of the industry, but there is certainly a perception that they're now shooting for the least common denominator where these companies are making lots of money and have extensive resources, but that's not going to further innovation, they're just sitting around waiting for the next definition of Meaningful Use before they start looking at ways to innovate.

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

So, I think there are two –

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

That's the perception, whether or not that's the case I don't know.

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

Well, I want to call a couple of comments out of there. I think that – and I'll add these. Again, the EHR companies and, you know, I've talked to some of them and they really are "well, we'll get to that after Meaningful Use, after ARRA." I mean, it has soaked up their attention. You may – I mean, if I were defending the certification I'd say, no, that's exactly the intent is to bring everyone to a common level of competency, you know, because we're supporting this, but it does have a deal that it diverts.

The second comment that Mike made that I'll add in there is – and it rang true because I can see how it's affected our own organization is that you really suppress Non-ARRA work even in the hospitals because they're scrambling to meet the Meaningful Use and any cycles you have for implementation, training and everything else is consumed by ARRA. And then Anna's – do you want to repeat your comment? I didn't get it all the way down, Anna.

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

Oh, sure and again I don't work for an EMR company so I don't want to speak for them and I don't, you know, interact with them, you know, I don't work at a hospital system, but the perception is that there is now, especially for the big players in the market there is an acceptance of the least common denominator that they are making –

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

Okay, well the other comment I wanted on that, I know what it was, I just put one word, is that – and this is really in – is that people looked at Stage 1 they said, I can make it, Stage 2 they're not so sure, in Stage 3 they don't even know what it is so it's that policy uncertainty that's really effected a lot of the development and planning too.

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

So, Keith, this is Paul, I wonder if I could make a contextual comment here?

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

Sure.

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

I certainly understand the – there is a difference between bandwidth and innovation constraints, so Meaningful Use is a floor, just contextually prior to HITECH only 3% were even classified as comprehensive EHRs that were in existence and none of those would have met Meaningful Use Stage 1.

So, to go from essentially 0 to over 50% of EPs and more like 80% of hospitals in 3 years is phenomenal I think. Did that require to have a floor come up and essentially only specify the lowest common denominator, yes, that's part of the – one of the pros and cons of regulation, but I think the existence proof where regulation was needed was the private market wasn't getting us there.

What's important is so much of what we need now care coordination, HIE is a network effect and a network effect only comes into play when enough of the people have fax machines, to draw an analogy, so yes it's true that to get all of us providers from having almost no tools to exchange data and having no hope of coordinating care to one where we're, you know, do you have light at the end of the tunnel to be able to do that was something which caused a lot of effort to be expended in that direction, is that good or bad, I think it clearly consumed bandwidth. I don't know that it prevented innovation. Do you see what I'm saying? I'm trying to make a distinction.

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

Yeah.

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

I don't think the ramp up and really raising the ante of the entire playing field is possible without consuming bandwidth, but I don't think that you cannot innovate on top of that and I notice lots of existing proof for that.

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

I guess my comment, Paul, was, I think it clearly has had the effect if you say that we need to go...we need to accomplish X and in fact what I'm going to do is give you an incentive program so I'll help you finance getting to X effect and if you don't then I'm going to penalize you. I mean, you catch everyone's attention so they will respond.

I think that my personal issue with this is where the floor is defined so precisely and may not be a good solution or in fact is in conflict, you know, with other things. I mean, one of the examples I gave was that in Stage 1 you had to produce an ePrescribed message which would not be accepted by Surescripts and yet the market really is that Surescripts is the broker, so if I'm producing stuff – if I'm producing a message just so I can get certification you did get my attention and you did get my bandwidth but it was really a useless innovation in this case.

So, I'm not saying that we don't have to have these national agendas. I'm just saying as you define best practice in these national agendas you're right you bring up the floor and you did have the affect like you said if more people are using the systems, which is more of an effect of the Meaningful Use part because for instance there were CPOE systems long before ARRA, but the adoption of them wasn't very high. And so the Meaningful Use really changed the implementation, but did it really change the innovation profile of CPOE or better ways to collect orders?

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

Well, I guess we want to ask the question what amount of innovation would be possible in 2014 versus what was possible in 2009 and I think there are tons more companies offering functionality and using data that was simply not even in existence in 2009. So, that's where we need to go from a trajectory point-of-view and in a sense, as I said, I think there was a market failure before this where we wouldn't even have this platform, that's not only a software platform but a data platform upon which to act and that's required, from my point-of-view, for, you know, reform.

Now it may be fair and there may be some recommendations made about how certification is prescribed or defined, that can certainly be improved upon, but I don't know that we want to throw the baby out with the bath water.

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

Okay.

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

Yeah, I would – I don't think anyone – I'm not necessarily criticizing the way ONC did this. I just think it's sort of – we need to at least – by any stretch of the imagination I think it's been an incredibly helpful process, as a patient I'm excited, you know, I mean, this is all very, very good it's just any time the government gets involved to correct, you know, failures in the marketplace then, you know, there are consequences that may or may not be, you know, ideal and I think there is a perception that some of – that there are resources and some of the players that are getting most of the resources are not using them, they're settling for less than what they could be doing with all of the money they're receiving.

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

Well, let me –

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

Maybe that's not an appropriate –

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

Let me give you an example, I mean, in part of ONC is the idea that I have process support for certain medical processes and we measure them, the processes, you know, specific things like stroke or something, okay, so there are two ways that you can approach that as a developer. Number one is that you can say, well this is a use case, this is a use case of many – what I want to do is create a tool set so that the hospital can manage any of their medical processes, you know, that they can meet this ONC specific use case but they can use the same tools to do other things.

A different response is that I know that I'm going to code the stroke process and that's it because I passed the test and if they give me another test then I will code that one too and so you get two responses that one is a long-term and one is a short-term, and so then you get into the timing of the law itself, and are we pushing people to do short-term fixes rather than, you know, improving the base of the software.

The thing I raised, Paul, is that I don't – again, the problem and the failure in the marketplace I would suggest was not so much with the software but with the implementation, real implementation and measured – you know, different efforts before that was really to say that do you have this software where ONC said, do you use this software with Meaningful Use and I think that was the proper incentive.

And so the incentive was really on the implementation. I just worry that when we have a very high-level organization like the federal government defining specific requirements or specific behaviors in software that that has a – it essentially shuts the door on other solutions for that same problem.

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

So, I think –

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

That's the affect I'm talking about with innovation.

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

Yeah, so and that's fair and we've talked about that in these committee's as well. So, I think there may be a way, there may be a better way than software developers coding more – in particular software developers and coding workflow for professionals. So, are there ways to avoid that unintended side-effect and at the same time ensure that the tools have the capabilities needed by professionals to do their job in this new world.

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

Right.

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

It's a very hard way to – it's a big challenge but as I say let's not get rid of the baby let's figure out what flexibility or what guidance we can provide for the certification process. So, some of these unintended side-effects are at least less.

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

Well, and I think that's our mandate is not necessarily to say for instance to get rid of ONC certification.

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

Right.

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

But what we have is with ONC certification and with what we have with the FDA device law we have real examples and we have real experiences and based on that we should be able to take those real experiences rather than talk about it theoretically and say what's worked and what hasn't worked.

Now then we put that back as a feedback in order to get – because ultimately our mandate is to create or to suggest not create, suggest a regulatory framework that applies, that brings HIT more into the – you know, that adapts regulations specifically to HIT, that promotes, you know, as the law says promotes innovation and protects patient safety.

And so using these real examples just like we do, you know, we should be able to look at our results and say did that work or did that not work and so it isn't saying get rid of it altogether but what worked and what didn't work.

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

This is Mike Swiernik –

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

Yeah, go ahead Mike.

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

Yeah, I want to be clear I'm not critical of Meaningful Use I think the goals for it are great and it's the direction we need to go. I think from an innovation stand-point it obviously means that who decides what is innovative shifts from what you might call the market, in other words people aren't identifying problems and fixing them anymore it shifts to the government if you set up a certification process and then it also changes a bit what is decided the areas should be that one should innovate in.

So, in other words my company works loosely in the area of secure messaging but that wasn't even an area that existed or needed to exist necessarily a few years ago and the regulations including HIPAA kind of created that and we've talked about that before.

I think the other, perhaps concern with the certification from ONC is that it's a matter of size and maybe that's the – is what's causing the affect I described earlier where it's kind of sucking all the air out of the room because it is so big and –

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

Yes.

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

It groups whereas there is other certifications out there that are less impactful that we could certify really changing the market as much – obviously here the – are that market be changed, so that was kind of the point of the whole thing, but what we're talking about doesn't necessarily have to do that.

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

Okay.

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

If there is a way to help enumerate some principles on certification to both create the base capabilities – we're trying to deliver tools with base capability to the providers who need to use them, you know, it's not the intervention itself.

So, how can we – how can ONC write certification criteria that makes sure that is true and yet allow more innovation, more flexibility within that? I mean, that is the way that they want to do it but are there any other guidance that could be given to help improve the probability of that? I think that's my –

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

Paul, I think part of it is it really is – it's in the application. I mean, again if I take something that at the policy level says something like, again, what we should have is reconciliation of the record, okay, so that's in Stage 2, reconciliation of allergies, problems and medications.

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

Now see that's – it's just medications for Stage 2.

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

Right, but I mean for certification it's all three. See that's another thing that certification leads out in front of Meaningful Use. So, in certification I have to certify all three things. In Meaningful Use I just have to show medication reconciliation. Okay?

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

Okay.

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

So, what I'm saying on there is – so that's a good idea I mean we should say that I should account for the data I'm getting from other sources of care but then when I get down into the test scripts, okay, what I start to do is describe precisely what works and what doesn't work, okay, so I start to say, look it has to be – you can't have tabs, okay, you can't tab between these lists, you know, that won't pass your certification.

You have to have a merge and then there is a whole bunch of stuff telling you what they mean by a merge and what it means to sign off on a merge, well there you are getting very, very specific examples where if you said, look what you have to have as a clinician is the ability to look at these different inputs of data and make a decision about what's relevant to this patient and what we're going to do is have the regulatory or the certification flexibility to recognize that your solution does that without precisely defining what your solution does, because then you really have the federal government writing the development script and that's the part that I object to.

I don't object to that we're trying to promote medication reconciliation I think it's a great idea and if I have a Meaningful Use requirement on that it will get better and it should get better.

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

So, to try to generalize maybe what the group needs to do is think about principles that can be applied to watch out for things like that.

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

Yeah and that's what I was trying to say in the previous things that, well just go to the next slide, is that again as you go down from policy to measurement that's where I think that a lot of this stuff breaks down and so what I would be asking for personally is that someone can look at a solution – now it gets back to this legalistic approach, if I have a very, very precise test script I will get exactly that and every piece of software that's produced will produce that test script.

But what you haven't told me is that your precise definition really is best practice, it's somebody's best thought of best practice but we may not have discovered what best practice is yet. So, you've gone right to the answer before you've had any discovery and that's my objection.

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

This is Mike Swiernik, I think you could maybe encapsulate those in principle that said maybe like minimum necessary to achieve the goal and/or certification criteria that is more goal-based, in other words, does your software or hardware, or whatever create this outcome or achieve this result versus saying, you know, enter the first name in this field and then the last name in that field that kind of stuff which I think is maybe what you were referring to Keith.

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

Yeah.

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

So, this is Steve Posnack from ONC, just to perhaps give a – I don't even know what to call it I want to say appreciation and I'm not trying to be defensive or anything because I understand and I agree with the principle concept which I think would be very helpful for us. I think what Keith is articulating, as I'm listening, is perhaps just a challenge with the way in which the industry had sought clarity around certification.

Any time I am asked to provide a regulatory interpretation with respect to certification I always focus first on the certification criterion and what outcome it expresses and go from there, because folks are doing things in a variety of different ways and getting certified.

Where I think I'm hearing the tension come in is that there needs to be a specific way to test something or, you know, one way that is put forward for products to be assessed and, you know, software to be assessed and if folks are interpreting that as doctrine and the only way as opposed to reaching a particular goal or outcome that's something certainly that we can look to, you know, as we mature these things. But, I guess I would just offer some caution that that's not the philosophy that we take.

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

Well, let me respond a little bit, because I think you make a very good point and it's kind of like the point that Jodi made in one of our meetings which is I have kind of the Janus Effect, the two-face thing, when I say that I don't like policy uncertainty but I don't like being restricted, you know, there is a flip side to each one of these things and I can appreciate that people say, give me a precise definition of how I pass this because it's an all or nothing thing I either pass or I don't pass, and maybe that could be looked at too, you know, it's an all or nothing thing and so give me a precise definition and I will make sure I nail that definition.

Maybe what I'm suggesting is a little bit like JCAHO goes through and certifies hospitals, in other words they look at your solution, okay, they don't have a precise solution in a lot of things but they look at your solution and they're able to make a judgment about it, you know, does that allow, in this particular use case, does it allow the clinician to do a medication reconciliation, okay, and I may not agree with all the ways, I mean, I love getting together with different vendors and everything and say, here's – we all have this problem how did you approach it and we try to learn from one another about how it's best to do that.

I'm just saying that going to a precise test script does hurt us and it's partly our fault because we asked for it that way.

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

Yeah, I mean, you know, just to give you more experience from the rule writing perspective, right, so, you know, we start out with – it could be a general requirement where there is some ambiguity and that drives people nuts.

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

Yeah, right.

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

And they ask for more, you know, like what exactly do you mean by medication reconciliation and on the flip side, which I found most interesting from feedback that we've gotten over the past few years, is that where we intend to remain silent and allow things folks ask us to explicitly state now that we are remaining silent and, you know, other such approaches that we have not said are okay.

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

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

Yes, yeah, I mean, that is what they will write on my tombstone.

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

Yeah.

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

And Steve, this is Anna, I don't think anyone is saying any of this to be critical of what you guys are doing. I mean it's an incredible challenge.

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

Yeah, no, absolutely, I don't take it that way at all and, you know, we are very much looking forward to this process as I know our FDA and FCC colleagues are to hear from all of you about how to better improve A the things that we're doing right now and B what we need to look forward to in the future with all of your stakeholder expertise.

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

So, I mean, this is the central thing and we struggle with this on the objective side too on Meaningful Use. We are running into a time crunch.

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

Yeah we are.

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

But, I think at some point we need to switch into what can we do constructively. I think we understand the problem, we understand the implications of either side, unfortunately, as Steve said, you just cannot – you can't do one or the other. What can we offer constructively to make the next round better?

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

Well, go one slide, just because – okay, no not that one, next one. Again, this is – you know, I just tried to look at, you know, the approach of these two things. Okay, FDA is very much about process control where the ONC is very much on outcomes control, you know, it's not saying how did you get there it's saying this is where you're going to arrive at and I think that that's – first I think that's trickier, you know, that it does constrain the flexibility.

I think that it's interesting if you look at that last bullet there, regulatory avoidance strategies, right? We talk about the medical device it's all about the taxonomy discussion, how do I get excluded where in the regulatory avoidance with ONC it's really how can I make this test script conform to what I already do.

And so, I think it's a harder problem when you get into certification that's all I'm saying and that one of the biggest things that I would make as a principle specifically to ONC, because I think that again, I'm not personally saying throw it out I'm saying – because I think that it's changed the landscape but when it's become non-productive is when the flexibility is lost.

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

But, Keith, we've got to come up with what advice can we render to make it closer, make it better.

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

Certification – I'd say certification like you have regulatory discernment, certification discernment. The second thing is that maybe it's not an all or nothing. I mean, because ultimately what I'm trying to say here, I mean with my regulation is I'm prompting the market in the United States to buy these products, I want to make sure that they're good products, well do I have to – is it just binary and that.

And then if you know that something isn't working respond to it. I mean, we had some Stage 1 things, that example I gave in Stage 1 you had to demonstrate how you modified an allergy alert. In Stage 2 the regulation essentially said, we got a lot of feedback on that, we understand that it didn't work and so we took it out. But people that still hadn't certified on Stage 1 still had to develop and demonstrate that even though ONC itself knew that that was not needed. I think that the flexibility thing and the accommodating of different solutions is what has to be done.

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

Paul, this is Mike, I'm just curious what does the Regulatory Group need from us in terms of what level, like should we come up with like guiding principles or do we need very low levels or a mix like it's easy to come up with the principles and just toss them over the fence, but I'm just curious.

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

They asked for – what I'm getting from them is that they – it really goes to the next discussion what are the specific innovation requirements and the review of the FDA medical device and the ONC is mainly to found – to serve as a foundation of developing what are the specific innovation requirements that we would want, okay, so it isn't an end to itself it's just a means to get to those principles as Paul just expressed.

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

And then maybe some examples of specifics that are problematic?

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

Yeah, yeah.

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

All right, thank you.

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

Yeah and so, you know, these calls are very short, I need to defer to Paul because I've taken way too much time, a lot of the work – I would appreciate that people would look at this and think about it and start e-mailing back and forth, you know, what are those principles that we can derive from our experience with regulation and, you know, how would the world be better, how would we make this better so that we do protect innovation and also protect patient safety and trust in these products that are being produced. Anyway, I'll defer now to Paul. But just please e-mail.

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

Can I ask a – sorry, this is Mike, can I ask a quick question on scope? Are we not including HIPAA in our discussion about regulatory impact on innovation?

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

You know, I think we should.

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

I'll defer to Steve, but I don't think we should, I think that's out of scope.

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

You're saying –

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

The IOM has had an entire study on – I mean, there have been multiple studies on this, I think that's another thing – we have so much to do that I don't think that's a part of our scope and maybe Steve can weigh in.

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

Steve is it in or out?

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

Oh, I mean, my first reaction is that, you know, that it is out.

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

Okay.

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

Just because I think the intent of the statute is to focus on those agencies that have regulatory provisions on Health IT, so, you know, ONC has certification programs for Health IT, FDA has device regulation, etcetera, FCC is in the middle for both. I think, I guess I would be pending available time if you all think that there are other issues that could be raised I think, you know, we'd be able to help you guys – you know, like FTC has been raised as well. Other agencies authorities that could affect Health IT that maybe another chapter or set of slides that get produced that would be informative to us to produce a more comprehensive report or you could recommend that we evaluate that as well. I mean, you know, ONC and FDA, and FCC still need to do the legwork.

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

Yeah, in that we're not – and again, I think that it's interesting, because in the end we're not making specific recommendations for the FDA device laws, specific recommendations to ONC what we're tasked to do is say what is the framework for bringing those together in an effective regulation of HIT.

So, I think we could – you know there are lessons learned from all that, but for this particular problem what we're trying to say is what are the principles that are illustrated by what we've experienced and what principles do we want to go forward with. So, anyway, Paul, you probably won't let me go first any other time, so I understand that.

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

That's an important discussion.

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

And I will now defer to Paul.

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

Alrighty, thanks Keith.

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

Thank you.

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

And thanks everyone for participating. Hopefully, this will be a briefer discussion. I think we're closing in on our next iteration to present back to the full group which I guess we'll be doing July 2<sup>nd</sup> I think. So, let me just quickly go through this and really take your – you know, glance over this as getting to be in its final form and certainly e-mail me back anything that we don't have time to discuss on the phone. If you could go to – if we could move this – I don't – do we have the slides up? Switch over, yes and then go to the next page please.

Okay, so the first thing I wanted to do is just to go over the preamble, a lot of the work has been done in adding the definitions on these two following pages, but the preamble I think tries to set up what is this supposed to do and it's a little bit of like what is our Subgroup doing.

So, it's really that this patient risk framework, that's the topic we're discussing now, enumerates various important factors that influence the risk of software systems to human health, it does not incorporate in and of itself a weighting system, it does not calculate any specific risk score or turn that into the predictive probability if harm happens because we all know how complex that is.

So, really it's enumerating the important factors. So, it's a framework to help anyone, it could be the vendor, it could be the user, it could be the regulator, it could be the policy maker to help assist the factors to consider when you are assessing the potential risk that use of a software system might have on human health.

So, it tries to be a little bit – it does a little bit of relative risk in the form of these columns lower, medium and higher not low, medium and high, and some of the conditions that go into thinking about the risk factors but is not prescriptive on what the “score” is. So, it's really directional guidance and this is something we hope that could be used by the tri-agencies to develop their framework that would guide their thinking about regulation and that doesn't mean “yes regulation” it just means they're thinking about regulations and so for each of these both categories and cells there is going to be exceptions.

So, if we can go back now to the colored matrix and I'll just quickly go over these things just literally in passing and then open it up for any future comments or future work you think we need to do. So, it starts importantly at the top line which is the purpose of the product and who it is used by, the purpose can be anything from information only to where it's making its own decision.

The intended user and here's an important change I made in the text to try to accommodate a lot of the comments we had about, you know, user and knowledge, etcetera, so now on the lower risk is that targeted user are knowledgeable and can safely use the product so that doesn't talk about license anymore, it says people who should be able to understand this and use this appropriately that's a pretty – that's a good space to be in to something where we're really, this software is contributing to diagnosis or treatment advice directly to patient and you can see how that is performing almost a licensed service.

Then the blue area is the next category and it tries to think about the various attributes of risk from this varied risk from very low probability of harm it's like the Class I we heard about in FDA to life threatening potential when you have the software operating your AED or your internal defibrillator. The number of people who might be exposed to the software, clearly if it's going to be affecting a large percent of the population you have to be really careful and likewise it could be affecting a very small number of people but providing high benefit you've just got to weigh that.

The likelihood of the things we're describing could be really rare, it's certainly possible but really rare or it's just going to be common and we understand that either we need to incorporate that in our thinking and incorporate that into whether we regulate this or not and what kind of regulation is required.

Transparency we talked a lot about it's the software operations, the data and the content providers, if you know exactly what's going in and you know what the software is trying to do and you're able to deal with that that's a better situation than when it's operating as a black box and when you have a human intermediary that is knowledgeable and empowered to prevent harm and is required that's certainly less risky than the closed loop situation.

The next group deals with, and Keith has referred to this many times, it's implementation, it's not just the lines that code it's really how we get it to its intended user and its intended use. So, there is complexity in the software itself and maintaining that. There is complexity in the implementation and every upgrade is almost another kind of implementation and the complexity of getting it to the end user, equipping the end user both the training and its use.

And the next dimension is how does this piece of software sit in the bigger context? It could be part of a device, a single standalone device, it could have interfaces with other devices, it could be clear in what it is supposed to measure and produce or it could be less clear and less predicted, or it can be one of 50 things that are connected and you've got to make sure that it's going to deliver, be as sure as you can that it's going to be delivering the anticipated output. And then the way things get wired up and the security that's attached, and I think I forgot to add, that impact the risk of a piece of software lying somewhere in the system.

So, that's just like a – you know, obviously just a 50,000 foot glance at this and then as I say added some definitions that I think we went over the last time. So, let me just open it up for comments and work you think we need to do.

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

This is Mike Swiernik to me this looks good.

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

Thanks, Mike.

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

I think the definitions really added to the whole document.

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

That's good. I'm trying to give people at least a hint of what we've been, you know, steeped in and hopefully – and we will get to test this again with the larger group.

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

Yeah, this is Anna, I think this is kind of getting there so and I would agree with Keith I think the definition in the preamble is very helpful.

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

Thank you.

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

See that's the general struggle that we have with these artifacts, I mean, PowerPoint's and grids don't give the depth of understanding that – I mean, these write ups really help. Good job.

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

Paul, this is Mike Flis, I find the table very helpful along with the definitions but I wonder will – let's say the Regulatory Group then be looking for guidance from us as to how to use the information in the tool, is there some type of flow chart that should go along with this that if you've got a product that has some aspects of low risk and something that's high risk how should that impact the regulatory decision.

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

That's a good comment, Mike. So, I hope, and I've turned this over to the Regulations Subgroup, I hope one they try to apply this that's what they said they were going to do with it and then we'll get questions just like you're posing.

We could – as you can see there is, I don't know how many, permutations there are for this, it's impossible to describe them all, but hopefully you could – if there are kinds of stringency there are many dimensions of a regulation, if there are – in the stringency dimension you could see, well I would probably be thinking about that in the right-ish column groups and the more you end up of these dimensions here in the right side the more I'm probably tempted to think of stringent regulations, the more in the device classification scheme the more I'm thinking about Class III without prescribing a calculus which I don't think you could apply-y to each and every piece of software and similarly the more you end up in the left side of this matrix the more you're happier with the – you know “Class I” kind of approach.

So, I'm putting it in quotes because the Regulation Subgroup is going to come up with, well, okay, could it be just certification or could it be just accreditation of behavior, or could it be just labeling. Those are different kinds and they have different amounts of stringency and assurance and that hopefully would fit on that left and right side of this column. Does that make sense Mike and then we'll get feedback from them and say, well, actually could you make some tweaks and maybe get – be more fine grained in this area or is this enough?

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

I think that's helpful. Thank you, Paul that was what I was hoping to hear.

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

Okay, thanks.

**Esther Dyson – Chairman – EDventure Holdings**

Hello, this is Esther, can you hear me?

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

Yes.

**Esther Dyson – Chairman – EDventure Holdings**

Great, okay, I'm sorry I seem to have issues with the phone. Just really briefly this is a great chart, extremely useful, the only thing that's not here, I'm not sure how relevant it is if you're looking at cancer drugs or something, but the notion of the reward, in other words, trading the risk off against could this be very useful for someone who is terminal anyway versus this is something to improve acne or something.

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

Yeah.

**Esther Dyson – Chairman – EDventure Holdings**

So, it's the reward side of the risk equation.

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

It's a great comment, it's been raised, I think it is exactly what you said, which is there is – if you think of cost benefit, there is the cost and there is the benefit, and those are two pieces and often we divide them and that's how you get value and that's how you get, you know, judgment.

I think what we're trying to describe here is the quote cost, it's really not cost, but it's the risk side of the equation and then wherever you end up you can decide either leave the individual, you know, it could be an informed consent kind of a situation or if it's so imbalanced, you know, the risk is just so great then you might have some kind of regulatory or even say it's not approved besides thinking of benefit as another, it's another characteristic of the product.

**Esther Dyson – Chairman – EDventure Holdings**

Okay, I mean whatever, I might put on here, but as long as we're clear that that's a really important issue because –

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

Of course.

**Esther Dyson – Chairman – EDventure Holdings**

The reward is key here.

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

And an important component of that is who gets to make that decision. I mean, I guess I would argue it's an informed consent by the person who would undergo the risk actually which is in this case the patient.

**Esther Dyson – Chairman – EDventure Holdings**

Fair enough, that's helpful, thank you.

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

Thank you. Any other comments? So, the group is comfortable with me presenting this version to the full Workgroup next week whenever that is getting any further comments. It sounds like we need some more discussion on the innovation side so it sounds like we're in for another call anyway, is that your sense Keith and everyone?

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

Yeah or at least – or we need to have some rounds with e-mail but those haven't been too successful. When is our full group meeting, its next week?

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

I think it's the second.

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

It is the second, it's July 2<sup>nd</sup>.

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

Yeah, it would be hard to call in before then. What I'll do is I'll put the notes in from today and if people can look at those and concentrate on – because what I want to do with the time that we have in the full group, because they're always truncated, is go right to – rather than discuss the existing regulation because that's a means to the end, what are the – what are we trying, you know, what are the lessons learned and so what are the requirements.

So, if you can look at those other slides then I'll add a couple slides for the lessons learned from the first discussion and then just help polish that, but given the time in the full group it would just be on so what are the lessons learned and specific requirements for innovation. Okay, because we won't have time for another call between now and Tuesday.

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

Okay, sound like a plan? And MacKenzie is it already known how many calls of the full Workgroup we're going to have after the second?

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

I know there is another planned for July, let me see if I can pull up –

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

Oh, maybe the 16<sup>th</sup>.

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

Yeah, I'm not sure if they were going to make plans for August yet but let me pull that up.

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

–

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

– in August, right?

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

There is a meeting on site on August 7<sup>th</sup> right?

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

That's the Policy Committee meeting that's not a Workgroup meeting.

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

Okay.

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

So, the FDASIA Workgroup right now there is a meeting on July 2<sup>nd</sup>, there is a meeting on July 26<sup>th</sup>, a meeting on August 1<sup>st</sup> and a meeting on August 13<sup>th</sup> that's the Workgroup. We also have the HIT Policy Committee meeting where the Workgroup will be presenting recommendations most likely from the Chair if not a couple of other Workgroup members yet to be determined, but the full committee meetings are August 7<sup>th</sup> and September 4<sup>th</sup>, but those are not Workgroup meetings.

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

Okay, so the 7<sup>th</sup> of August and the 4<sup>th</sup> of September those are the Policy Committees and I'm assuming that people can come and observe if nothing else is that correct?

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

The meetings are open to the public, we just can afford to travel everybody in on the contract, so you're more than welcome to attend in person or virtually we just won't be able to cover travel funds for all the Workgroup members.

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

Okay, fair enough. Do we know which people need to be at those meetings yet?

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

No, that hasn't been discussed yet, but I believe we already sent out the calendar appointments to the full Workgroup that has the call in information on it just to get it on your calendars.

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

Yeah.

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

So, if someone could just check your calendar to make sure you have August 7<sup>th</sup> and September 4<sup>th</sup> I believe I requested that they send the appointments to you.

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

And then, yeah I see the other one on the 13<sup>th</sup> for the call too and some of the other ones. Okay.

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

Are we ready for public comment?

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

Yes.

## **Public Comment**

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

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're listening via your telephone you may press \*1 at this time to be entered into the queue. We have no comment at this time.

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

Okay, so this is MacKenzie the next time the group will be discussing or getting together will be at the full Workgroup level which is July 2<sup>nd</sup> and the call is at 12:30 p.m. Eastern Time. I don't know if Paul or Keith if you had any closing remarks.

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

Just a question, at one time we said that we would have this Workgroup meet today and then we have another one further on in July, was that set up already or another call?

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

For this Subgroup?

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

Yes.

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

Let me check.

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

Okay.

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

There is another call for this Subgroup on June 28<sup>th</sup>.

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

Wait a minute that's today.

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

Wait a minute it's July.

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

That's today.

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

No there are not any other Subgroup calls planned for this group.

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

So, it looks like we need a couple in July?

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

Yeah at least one more.

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

Yeah.

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

Yes.

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

One before the...whatever the 26<sup>th</sup> full group call?

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

Yes, yeah, because we don't have – I mean, we have a full group call next week and then the next one is – we have on the 26<sup>th</sup>, so if we could pre-date that either the week of – well, we have the week of the 8<sup>th</sup> through the 15<sup>th</sup>.

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

The other thing we might want to try to schedule is after the full – after the Policy Committee meeting in August we probably need to get together.

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

Yes.

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

Or possibly need to get together in support of the full Workgroup's reconciliation of the Policy Committee's feedback.

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

So, Paul –

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

This is Mike Swiernik, is it possible to have a mailing list set up for whatever e-mail communications we want to have, because I just counted there are 70 people included on the meeting materials, maybe that's appropriate but last time we tried it a bunch of people got dropped inadvertently and it was a little bit chaotic.

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

So, this is MacKenzie, we usually reply all to the appointments but hearing your comment if it's not working I can send around a shortened version of the Subgroup list, but we also do have a lot of full Workgroup members that have been calling in so I don't know if it's best just to do the full Workgroup member list as opposed to the Subgroup.

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

Do all the, you know, assistants need to be getting this stuff I guess is one question?

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

If they don't I can cut them out and just start one e-mail chain and if we require alter that.

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

Yes.

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

We can have just the members on it.

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

Yeah, I think that might be useful, because we get all these rejected e-mails and stuff like that anyway.

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

I'll send that out today so we can just reply all to that.

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

Okay, that would be great.

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

Thank you.

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

Well, thank you everyone, on behalf of Keith and myself for your active participation in this discussion and I think we are making progress. We'll get some more comments next week and go for the next iteration.

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

Thank you.

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

Thank you.

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

Thanks for all the work you guys are putting into this.

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

Thanks, everyone.

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

Have a great weekend.

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

Thanks, you too.

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

You too, bye-bye.

**W**

Thank you.