HIT Policy Committee
FDASIA Workgroup
Risk Assessment & Innovation Subgroup
Transcript
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Presentation

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Thank you. Good afternoon. This is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy FDASIA Risk Assessment and Innovation Subgroup. This is a public call and there will be time for public comment. The meeting is being transcribed, so please remember to say your name when speaking. I'll now take roll call. Paul Tang?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Keith Larsen?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Geoff Clapp? Esther Dyson?

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Mike Flis?

Michael Flis – Regulatory Affairs Director – Roche Diagnostics
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Jeffrey Jacques? Anna McCollister-Slipp?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
I'm here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Jared Quoyeser? Jonathan Potter? Michael Swiernik? Jodi Daniel? Matt Quinn?

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Bakul Patel? Are there any FDA staff members on the line? Are there any ONC staff members on the line?

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator
Mike Lipinski.

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

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
And I think Kate Black is on as well.

Kate Black – Office of the National Coordinator
Yes, Kate is here.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
So with that, I'll turn it over to Paul and Keith.

Mohit Kaushal, MD, MBA – Partner – Aberdare Ventures/National Venture Capital Association
Good afternoon, Mo Kaushal here as well, I just joined.

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

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
Meg Marshall's here as well.

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

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

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Well thank you everyone for joining. This is our only call before our full workgroup call tomorrow for FDASIA. Let me ask Keith, is it okay if I go – I don't know who's teed up first. Do you want me to go first; we'll split the time again?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Yeah, because I – you had a lot of new material that I think should – you should cover first.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Okay. We do have a full two hours, so we have more time than we've had in the past. I don't think we'll need it all, but let's see. But we are closing in on our recommendation, our final recommendations to the David. David then will present that current state to the Policy Committee next week; we'll get feedback from them, turn it around with the full workgroup and then produce our final for the September Policy Committee meeting, in the first week. Let's see, could we tee up the next slide, let's see if it's – go ahead. So I guess we're going to go through these, shift until you start seeing the colored slides, the color matrix, and hopefully, I shared the...

Caitlin Collins – Project Coordinator – Altarum Institute
Do you mean the Word documents?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
They were word documents, but somebody asked...and we asked them to post it.

Caitlin Collins – Project Coordinator – Altarum Institute
We can pull up a specific one, but they're all separate because they weren't originally in a slide format.

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

Caitlin Collins – Project Coordinator – Altarum Institute
Which one –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
I send somebody a list, was it Kate? Anyway, I send somebody a list of the order that I wanted to go through this, the first one being the mHealth Nutrition App. It was Kathleen Black asked me.

Kate Black – Office of the National Coordinator
Yeah we got them all in –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Okay. Now if you could go to the second page please. So what I'm going to do is, I took the matrix, the last version of the matrix we had, which was version 2.2, and as I had imagined in terms of how would you use this, put through six exemplars to show how it might be used. And actually the process of trying to fill out the yellow boxes is the value in itself, and so that's why I sent it out last week, in case anybody had time to go through that. And I'll explain how I went through the process and what it felt like or what are the questions that arose, to help maybe you can live through it vicariously. Now, the exemplars I chose were six different ones, I've actually had something like this, five of the six, I haven't done anything with the insulin pump. But let me just announce that these are all made up, so I'm not thinking of any one product so, if there's any resemblance, then it's fictional.

So let's – the first one was some nutritional analysis software, I just gave a super-brief description, just to show you the kind of thing I had in mind, and then we'll go to the matrix. So the exemplar is just basically this standalone mHealth app. You give it some way of describing the food, it could be the UPC, some description of the food that you want to analyze and it comes back and says, well here's what's in it and here's how it fits with your health condition. It could be diabetes, it could be heart failure, it could be obesity. We're trying to – this little app tries to help, how does this food match with your health goals. The target users are consumers and patients. It's a standalone. You would obviously enter in, well I have diabetes and I trend that; so there are a few sort of user specific parameters, but it's not real complicated. So the severity of risk for injury would be minimal. Now if we could page up then to the colored matrix.

So as I went through, I sort of asked myself each of the questions on the left, the first column, and then tried to place it, for this little scenario that I described, is it a lower risk, is it a higher risk or something with greater tension, is there medium risk and so on in between. So the purpose of this product is information only, it's pretty clear what it's supposed to do and how it does it. The target user is knowledgeable, a consumer or a patient and I'm knowledgeable about how food relates to my condition in general. There's a very low probability of harm for using this device as it's an information only. The likelihood of some strange thing happening, oh, it could be a database error or something and that causing harm to me is pretty darn rare. And what the software does is pretty transparent and almost anybody could understand that, how it gets to its conclusion.

And the only person between me – nobody's going to force the food down my throat, so there's a human intermediary, i.e. the user of this software. So there's clearly someone who's knowledgeable about food and its impact on me to intervene. The complexity's fairly – it's pretty mature, I mean we've had nutritional content analysis for ages and the FDA described how to do that. The build is almost trivial, I mean I enter in a little bit about myself, my age, my gender and any chronic condition I have. It's pretty darn easy to use, so the complexity of training and use is very low, clearly less than an hour, for example. And it's used standalone, so it doesn't have to interface with a whole lot of things which can introduce errors or risk. And then it just basically talks via cellphone or wireless to operate.

So as you can see, that vicariously, that was pretty easy for me to go down this matrix and, in fact, describe all of those.

Esther Dyson – Founder – Edventure Holdings, Inc.
Hello this is – sorry. Can I just ask a question, I was – the operator was interrupting me, but, suppose this particular app –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Who is this please?

Esther Dyson – Founder – Edventure Holdings, Inc.
This is Esther Dyson, sorry.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Yeah Esther, I've got just a couple more sentences and then open it up.

Esther Dyson – Founder – Edventure Holdings, Inc.
Okay, yeah, I'm sorry, the operator was interrupting me so I didn't know where you were.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Okay. So you can see, it was very easy for me to walk through these attributes or dimensions on looking at the possible risk of this application, and I felt comfortable and confident, and didn't really raise a whole lot of questions as I thought through this. And you can see from the yellow boxes, it's really pretty much all of the – across all the dimensions, it really lined up, in my mind as someone who sort of went through this, in the lower risk category. And so the bottom line is it all lined up in the lower risk category and it was very straightforward and easy to make those decisions and place that box. That's sort of the lesson learned as I went through this exemplar. So let me go ahead and ask for comments, and Esther, you're up first.

Esther Dyson – Founder – Edventure Holdings, Inc.
Okay thank you, sorry for the interruption. There are two alternative cases that I'd just like to raise as possibilities. One is that you have this app, but it's sponsored by Dr. Oz or some diet company or some company that says the food you should be eating is our special nutrichemical prepared for someone like you.

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

Esther Dyson – Founder – Edventure Holdings, Inc.
And how – so that's the first use case. The second is, the person has celiac disease or something, but doesn't know it, and thinks their safe because they're using this app. So, I just think those two are worth considering and maybe they're regulated some other way, but to me, the commercial sponsored issue is probably the bigger one and the validity of a lot of dietary advice is really questionable.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Um hmm. Okay. Let me address them as how I might respond to those questions and then see what the group thinks. So one, as far as spons – so this describes the intended use of this matrix is to look at the software itself and the implementation of it. It doesn't place any value – judgmental value on the content so long as, and there's a dimension about transparency. So if this content is produced by the USDA, it says that. If it's produced by Dr. Oz or some other foodco, then it should say that and if it doesn't, then it gets dinged for that. So this would not make a judgment on the quality of the data, it does make a judgment on whether you're transparent on where the data comes from and who sponsors it. So it would not make a policy judgment itself on whether that's tainted or not – or biased.

From a celiac disease, then same thing, probably comes in the transparency. It says, look, it's only as good as you enter data or that you know about yourself, and the output is going to become – I'm making this up, so the transparent way said, we are going to take into account the health conditions you enter and match that against the nutritional content of the food you're asking to be analyzed and make a statement based on the ADA, for example. So that's what it would do and of course it would have no claim on anything that you didn't enter, or that you didn't know about yourself. So that's how I'd answer your questions Esther and I'm –

Esther Dyson – Founder – Edventure Holdings, Inc.
Thank you.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
– interested to see how – okay. Other people either comment on my answer or other comments about the use, and this is one of six we're going to go through.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
Paul, this is Meg Marshall. I have a question about your response if you wouldn't mind, and maybe I missed it. I'm afraid I don't have an excellent phone service, but could you talk a little bit about how the expectation for the transparency requirement is set?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Okay, it's a good question –

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
Are you assuming that it happens through consumer protection? I'm just trying to piece that part together.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
There are two pieces. One is, I think both of you are raising, we may have to describe transparency more, okay, so I'll write that down, to indicate what do you have to be transparent about. The two things I was particularly interested in are one, where do you get this know – whatever content knowledge is in your app, where does it come from, and I think Esther points out, and who paid for it. So that's a really good point as well. And then the other is, and what do I do with it to get the output I'm going to give to you. So that's an example of how I might define transparency. And what's nice about transparency is that invokes the authority of the FTC in saying, everybody – every product manufacturer's obligated to live up to the claims that they make, so this is a way of one, making it clear to the user what the vendors trying to make happen in their app. And two, being held accountable, or ultimately the ability to be held accountable by FTC against your claims. Does that help?

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
It does, thank you. This is Meg again. So just to – a follow up, and maybe it's just a broader comment, you know that we saw the presentation – the proposal from the regulatory group last week, and I'm not sure that this made it into the conversations. And so it might just be worth an extra eye and potentially –

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

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
– if this is something that we'll work through tomorrow in the full workgroup call, just to make sure that that transcends across appropriately.

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

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

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Yeah, I think what I'll do as a result of this conversation is I will put a draft definition in there so that at least the group will have that for tomorrow.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
Right. It's just more of on the expectation if one says to me – if the regulatory group is proposing that low risk apps have essentially no regulatory oversight through the FDA, then just closing the loop on how – the expectation for the transparency requirements would make it through. So, it sounds like you're saying FTC and we just need to make sure that that's apparent.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
You know, what I was – the analogy I would make is labeling, so transparency equal labeling and you'd have to label about – for the following things.

Meg Marshall, JD – Director, Government Health Policy – Cerner Corporation
Okay, thank you.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
So this is Robert Jarrin. I'm on the Regulatory Working Group and I most certainly can't speak for the entire working group, but I do want to bring something up. This is a great example Paul, by the way, of some of the apps that have been in question –

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

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
– and very specifically, comments made by the FDA at a briefing that was held a year ago, over a year ago where Dr. Shuren himself said that there were a number of low risk apps that would not merit FDA oversight, which they were interested in putting into a guidance document which they'd been contemplating for the last two years. And the examples that he used, one of which was very specifically nutritional guides. They included a number of things including educational tools, medication reminders for therapy adherence, IV drug dose calculators, BMI calculators, diabetes management guides and the example given were nutritional guides or pre-diabetes risk assessors.

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

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
So, it's – I like your example, but at the same time, it goes back to some of the comments that I've been making about our need to identify some of the things that the FDA, ONC and FCC can do today, or that they have promised to be able to do today, currently, which would be able to speed innovation. Because if in fact they were to come out with this guidance document, then these items would actually be through enforcement discretion, as Dr. Shuren put it, off the table, meaning that they would not be enforced, they're medical devices, but they're not going to be regulated because they're so low risk.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So I think what I'm suggesting is this framework helps justify that decision. It would be very consistent with what Jeff said.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
Correct. And I think that the one thing that I like is this tie into other potential regulations or regulatory bodies that also have oversight over some of these, such as what you mentioned with FTC.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Got it. Okay. Thank you, I'll clarify that, too.

Anura S. Fernando. MS, MD – Principal Engineer. eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories
This is Anura Fernando, just a comment on some of the language here. During group call, I think it was Julian Goldman had mentioned that the use of the term hazardous situation, so in the far left column, if we were to replace likelihood of risky situation arising, and I think it comes up somewhere else as well. And we replace that with hazardous situation, then it would potentially remove some of the potential confusion that could be created by having likelihood of risk –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Uh huh, got it.

Anura S. Fernando. MS, MD – Principal Engineer. eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories
– already having a probability component in it.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Okay. That's fair. We use the term injury, in the row above, so that's fine.

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

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Sure. Okay, I'm going to go to the next one, because it's very similar and then so your comments going to apply to it as well. If you could go to the mHealth BP display document and go to the second page please. Okay, so here is a made up device that – oh, okay, so I – unfortunately, I added – so it's not – I'll have to fix that. So I was originally going to do blood glucose and blood – so think of it only as blood pressure, the second part of that sentence. So this basically is a blood pressure measuring device. It is qualified as a home physiologic monitor and the app then displays the blood pressure on the device, the Smartphone, and the users can store the reading within the app, they can trend it, they can chart their blood pressure over time. The user is the consumer and patient, it's a standalone operation and I didn't have a whole lot more to say about that as well.

So if we can go to the colored matrix, I won't walk you through, but I basically went through the same thing and came up with the same conclusion. That is, that in this standalone app, it – people understand what blood pressure is, it says it's going to display for you the blood pressure that came out of this device and do a few things like graph it, and it doesn't give you any advice. You can trend it, it graphs it, it can color code it, but it doesn't do anything more. I'll be interested to see what people think when I mention the word color-coding it, but that's what the app does. It seems to be very similar, it now deals with a physiologic signal from an FDA approved device, so it goes through this connecting the stuff, and it may do something, i.e. graph or color code, the data as it comes out. So that introduces a couple more things. But, as I looked at it, it didn't seem like it would move from the left column to any right column. So let me open that up for comment.

Michael Flis – Regulatory Affairs Director – Roche Diagnostics
Paul, this is Mike Fl –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
This is Anna and I use an app that does exactly this and integrates with a couple of other consumer/over the counter devices. I think this is good. If you could have something that – I mean, another issue that is happening is that we do have some of these, especially a consumer platform, that integrate data from multiple devices. So in the case of the one that I use, it's a Bluetooth blood pressure cuff that also connects with a body analysis scale that gives you lean body mass, muscle mass, all that kind of fun stuff and they're working on a glucose monitoring device as well. So, anyway, I mean in terms of the risk, I think – I don't think that would necessarily change the risk, but I think that's going to be a gro – hopefully a growing area of development, that's many of these applications with accompanying devices.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
And there was someone else who was about to talk.

Michael Flis – Regulatory Affairs Director – Roche Diagnostics
Hi Paul, it's Mike Flis. I'm very pleased that you have this example. And when I first saw it a couple of weeks ago, it included the blood glucose meter and this would stand in contradiction with how FDA is currently looking at these. Anything that's an accessory to a regulated device automatically takes on the burdens and classification of the parent device. So if this was an app that was taking data from a glucose meter, unfortunately it's a Class 2 product, but here in your example you're showing that that's a waste of effort. There's no risk involved, so this essentially challenges FDAs application of their accessory rule to health IT products. I think it's a fantastic example.

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

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
Anna. I know Mike works for Roche Diagnostics in diabetes and as a diabetes patient, I completely agree. I mean I think separating MDDS from other stuff is just not appropriate and there's no need for that to go through a separate approval, and it's become an excuse for – and a real barrier, not just an excuse, for more rapid iteration and development of pretty low risk applications that would correspond.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Okay, other comments and then I'm going to ask a question about it. So the question I have is, this does, I'm not going to address the connectedness, this does, I'll use the word, but I'm using it lightly, it does transform the raw data that's coming from the device, the FDA approved device, into this app by graphing it or color coding it. Do people see any issue with that? I've been told that that causes a different level of sensitivity, in terms of being subject to regulation. Other people knowledgeable about that?

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
Paul, it's Jarrin again. If you were – I'm going to take the example that actually Anna just mentioned, MDDS. If you were talking about a medical device data system, which I don't think that this would be, because a medical device data system can only transfer, store or convert from one format to another, according to a preset specification. So in other words, something like a doc file into a PDF file, and then help display electronic medical device data, that's all it can do. So if it were taking this information and as you say trending it and tracking it, the devil's in the details as to exactly how its tracking it, that could mean that it wouldn't fall under MDDS and be a completely different product code. But because of what you were saying, and what Mike brings up, which is a very good point, this would be treated as an accessory, a very completely different device. I don't think that what you're describing would be an MDDS, because it wouldn't be just simply transferring and storing it and helping to display it, according to what you're describing.

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

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
So it would be a higher classification, plus it would take on the classification of the Class 2 device, which is what we had on our slides as broken at the letter of the law problem. So this is a good example of something that shouldn't – that needs to be fixed, again. But again, it depends on what you're saying because of what exactly is that trending and tracking. That would really help to define whether or not this would be blown out of – for example, if we were talking about an MDDS, but I don't think we are, especially because of the accessory function.

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

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
Although I have to say one thing, the MDDS does allow, if it were an MDDS device, it would allow for being able to work with other class devices, meaning a Class 2 or a Class 3 device. The rule very specifically to MDDS allows MDDS products to do that, but that's a very, very unique aspect for MDDS.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So let me describe what I was intending to test and see if that is consistent with what you just said. So I was trying to hint that it would do more than just reformat the data, it would do something like trend, and it could do something like color code. And of course color code means, well with what directionals and perhaps the user enters in as part of the configuration. But it would be, in a sense, not just displaying the raw data as coming out of the device. So my understanding of what you're saying is that then makes it not an MDDS device, and it would be open to whatever regulatory framework the FDA eventually comes to. So that's why I'm trying to test this app and do people think that this transformation slightly that's done creates any shift to the right columns for the application I described?

Anura S. Fernando. MS, MD – Principal Engineer. eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories
Anura Fernando here again, MDDS has a provision for Class 1 non-exempt, and I'm just wondering – I don't know well enough personally, and perhaps there are others who know, whether those features could be additional risks as Class – that would still allow it to remain MDDS.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
Anura, you broke off for a second there, can you restate that?

Anura S. Fernando. MS, MD – Principal Engineer. eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories
Sure. So MDDS has a provision for Class 1 non – so whether those risks could be considered under special risks, under an installed – name – MDDS.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
I'm going to – again, it's Robert Jarrin from Qualcomm, I'm just going to say, as far as my understanding is the MDDS can perform all intended functions without controlling or altering the function or parameters of any of the connected medical devices or the data coming from those devices. So –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So does wrapping or color-coding constitute changing?

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
That's – it depends. I hate saying it depends, but what you were describing about the color coding and about tracking and trending, that would be manipulating the data. I would say that yes, it does.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
I would agree, I would agree. So that's – so we're testing that definition and declaring, at least the way I filled out this matrix, that it is still in the lower risk category and then subject to how an FDA would want to regulate things that are all yellow in the first column. So that's the question that's being called, and I'm exercising the framework to say, does this accurately describe that application and then FDA or whoever's going to regulate this, or not, can say, okay, with this kind of situation, what would we do. Okay, now I'm going to watch my time, I have a half hour gone, but it was important to establish one side of the spectrum.

Now I'm going to switch to the other side, I think. The next case, if you could bring up the insulin pump please. Now I've made this case up, the product up, and if you go to the second page of it, I'm describing a made up product that has an embedded insulin pump and an embedded in vivo glucose-sensing device. And that the pump decides, based on the input it receives from this implanted glucose sensing device, and according to some pre-defined, programmatic controls you configure, it will determine the output of the insulin pump. You still can add boluses yourself, but as far as your baseline, it is relying on the glucose sensor and the program that it – that's embedded in it. It is user configured to produce some baseline insulin infusion.

That device will obviously transmit its monitoring, what does it see from the sensor, and what have I been doing about it, to some external receiver that uploads this data all to a PHR or EHR. And there's this external commander module that you can then change the programming of the pump and potentially config – re – do some configuration of the sensor. So the target user here is patients with diabetes. The implementation configuration means you have to pair the external commander device with the embedded devices. You have to pair the wireless receiver so that they can receive information and pair it up to the EHR and PHR. You configure the parameters that cause all this communication, and you customize the programmatic control of the output of the insulin pump, based on the parameters it receives – based on the data it receives from the glucose sensor.

So clearly this is in a position, this device is in a position to create life-threatening injury. There are a number of conditions where that could arise, it could to be a software defect from the beginning, it could be some unanticipated condition where the software doesn't accommodate that and with certain customization, you create this unaccounted for condition. It does assume that there is a quality management process that was in place by the vendors of these products and the software, and I have sort of described to you what the software does and what it depends on, and that would all be described to the user. And you can get some kind of readout from the commander module that shows what's going on there. The patient can communicate a signal or let's say press some button through your skin, to shut down the pump, or they can communicate using the external commander module to chan – say stop the infusion or whatever.

This would require at least a high school education, just sort of making up some kind of parameter for saying, what's the complexity and what kinds of educational background the user should have. And there are a number of thin – and then when you want to upgrade or update the firmware or the software, you'd have to go through this similar process that you did for setting the system up. Communicate, you'd have to download something from the Internet down to your commander module, and it would have to wirelessly communicate with the implanted devices. So I'm just giving you background of the kind of device I'm imaging for this exemplar.

So if you go up to the colored matrix then. So clearly, from the purpose of the use it's an automated decision making device. It does provide, essentially diagnosis and treatment, i.e. it's taking the signals in from the sensor, it's deciding something and it is issuing commands to the infusion pump, which is treating the glucose – serum glucose level. And of course, the potential for injury is life threatening. I put in the medium category everything else. It's a potentially hazardous situation, it's unpredictable; it's probably not rare that something bad could happen, but it's hopefully not common. That the software describes generally, what it's doing, and you have a monitoring function, so it's not a black box, for example. And there is the opportunity, but not the requirement, that a human be able to intervene. So it's not a requirement because it is operating on its own and it can without human intervention, but a human can stop it, either wirelessly or by pushing some mechanical switch.

And the complexity is sort of in the in-between column as well, it's not super, super complex, because it doesn't interface with a whole lot of things, but yet it is pretty complex in terms of what it needs to do. And it's limited in terms of it does have to interact – the pump has to interact with the glucose sensor, it does interact wirelessly back out to data display devices including EHR and PHR and it's using unregulated spectrum. So that's approximately what that looks like for this situation. So, comments.

Anura S. Fernando. MS, MD – Principal Engineer. eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories
This is Anura Fernando again. When we look at system complexity and failure modes and use that as a criterion for making our risk decision, I – mental premise and the likelihood will – of how we go about that. When you get into things like programmable component technologies, for example, there are known failure rates, like soft error rates and things like that –

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

Anura S. Fernando. MS, MD – Principal Engineer. eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories
– and the system designer builds in mitigations for those, understanding that those are common types of failures. So it seems that the criteria should be focused on the implementation of risk controls to protect against those types of failures that would then – probability zone, in terms of the risk determination. Could you speak to that a little bit in terms of how the – is vetted?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Unfortunately, I think you're talking on some kind of wireless device that causes you to slip in and slip out. But let me just sort of address – one of the, I think one of the issues that is coming up and why now, in terms of thinking about regulation, is that all of a sudden we have this explosion of apps, but also that means an explosion of app developers. Which on the one hand could introduce a whole lot of innovation, on the other, is it clear that every person that is developing an app has the access to these known failure rates and the expertise to be able to put in place adequate risk controls? That's an open question I'm sort of just posing and I think that's one of the stimuli for why are we rethinking this. Why are the tri-agencies rethinking this approach and how do you deal with quite a different situation than when you have mature companies that have a lot of – access to a lot of resources and a lot of expertise. So I don't know that we can rely on just their process measure, in terms of being able to characterize the risk.

Anura S. Fernando. MS, MD – Principal Engineer. eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories
Thanks. So, in follow – would compliance with standards for example, that require these types of risk controls become more necessary as we move into – level of risk? So should that be factored in.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Again, you're breaking up some. But I think the – what you're suggesting is, there are situations, there are applica – there are software applications that may merit imposing some risk control process that – is that what you're proposing? Suggesting?

Anura S. Fernando. MS, MD – Principal Engineer. eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories
Sorry about the connection, I think it is – when we start moving – world of risk, then looking at, for example, the platform failures in addition to – selves, seems to become more relevant, so should that be more significantly fas – as opposed to just looking at the software piece of it as criticality increases, looking at the whole system?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
I think, based on what I could hear, the answer is yes, that's a conclusion that the tri-agency could decide, hey look, if you're getting more into this yellow on the right, then there may be different kinds of processes that we'd like to see in place. So I think you're coming to a similar conclusion. So this is intended to sort of describe in some way the risk, this framework provides a way to describe the risk, and then you have a number of options, regulatory options to take it, and I think you're proposing, one of those.

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

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Paul, this is Matt.

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

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Your point about the influx of app developers I think is generalizable to the health IT market more broadly –

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

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
– and I think one of the issues that we heard about in the Policy Committee hearings, was it last week, is just the variability of sophistication and rigor of development and QA, etcetera, across the health IT – the EHR landscape, I should say. And some of that's borne out in the mobile versions of EHRs that we're seeing, but just in bugginess of apps – of EHRs that are making it to the marketplace. And the application of user-centered design would be the other place where there's a lot of variability today.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
Hi Paul, this is Anna, and obviously, this is of particular interest to me.

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

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
– as someone who uses a pump and a variety of other things. I guess I would just want to walk through some of your assessments here, in terms of the medium risk. And I want to make sure I'm understanding your shorthand correctly. So risky situation arises in greater than 1:100,000 patient years and less than once a year, is that correct?

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

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
Okay, I think that's probably – well, the reality is we really don't know what the current rate is of pump failures, just because we can't access any of the real data unless somebody – unless it happens at nighttime and somebody dies or they go into sort of your DKA, which would require hospitalization. So we don't have a lot of good data to assess the likelihood. It would take a lot of people on insulin pumps to get to 100,000 patient years, just because there are currently, I believe, and Mikey might know the stuff better than me, but I think there may be 3.5-4 million insulin users in the country and only a small percentage of those use insulin pumps. So, again I know you're just sort of – here, but I'm not sure that that's an appropriate representation of the risk, in large part just because we – FDA does not have the authority to collect this kind of data and we just can't judge the relative risk.

In terms of software operates transparently and output is understandable by software expert, if – .for something like this, my – I mean basically the accuracy of the continuous glucose monitor is based on very proprietary, highly guarded algorithm that are very important to the intellectual property of that particular company. So I wouldn't necessarily say that it operates transparently, not that they're necessarily trying to hide something, but those who have better algorithms have better products. So, it probably would be more of a black box, and that's only –

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

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
– one element of the device that you're describing, but it's a critical element since that data will be driving what the actual pump is doing.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
I think that's a very fair comment.

Esther Dyson – Founder – Edventure Holdings, Inc.
This is Esther. Is it possible to do some kind of – the way they do with mattresses and have things jump on them or some kind of testing to get a sense of – without actually having a thousand – a hundred thousand man-years, simply test it physically with some kind of stress?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
The interesting thing is, and this of course is even more at play in some of the things that do more than just determine the pump output, is there are so many parameters that you just actually can't – it's hard to account – it's hard to have comprehensive testing. I would be easier to test this than an EHR for example, but it's still pretty hard, it seems to me, unlike mattresses.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
Yeah, and they do testing in real world and as part of clinical trials and those are currently underway for artificial pancreas/closed loop, which this would be a hybrid of what they're going for. But –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So here's an example.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
– again a small –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Esther, let's say the software programs the pump to deliver high amount of insulin when the glucose is high, and for some reason, the glucose is registering a thousand from the sensor and so it continues to do this. Well they didn't think, gosh, how could get a thousand for an hour – whatever it is, do you see what I'm saying, there are things that you may not test. May I suggest something, given I only have 12 minutes left, should I just go through some of the experience I had with the remaining three scenarios, and then I have actually sort of a proposal to discuss, before the group, as a result of this experience, and see how that sounds to people.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
Sounds good.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So the net one is EHR, and as you can see, I won't go through the description, because I think people will understand sort of what the EHR is, but you'll see from the colored matrix, and my screensaver's come up – is it col – yeah, is that it's all over the board. The experience I had was so much depends. So if you contrast that with the mHealth nutritional app, I found that fairly easy, quick and fairly unambiguous to sort of say, yeah, it fits in this category. With something as complex as the EHR, and particularly with it interacting with so many other systems, but also with such a huge component of build customization, so much depends. It depends on the knowledge, it depends on the expertise, it depends on the user, it depends on the...and so I found myself going through that and can't imagine how you would come up with any kind of a prototypical scoring for a "prototypical" EHR, because there aren't such. So, that's just my take-home message for that experience.

Let me go to the CDS document please, and you can just go to the colored matrix. At a gestalt level, it was more in the middle, and more in the left. Yeah, you can make up a CDS rule that causes it to recommend really strange things that are life-threatening potential, but a lot of it has more options for a human intermediary, for example, and it's a bit more testable, just the CDS component in and of itself. Yet so much is dependent on most CDSs are written by their CDS system, but the author of the content is the user. And so, how much relies on the software versus what the user programs into it, and should the software developer have guardrails? So these are all kinds of questions that could come up in deciding whether a piece of software, what is it's risk for patient harm.

And we'll go through the final scenario, and that's the PHR. And you'll see that predominantly it is in the left column. There's a chance, if the PHR is interacting with CDS or depends on some other knowledge base. And it could even invoke, I think it was Esther that may have raised it, as far as it's got some commercial application and it's got some black box way of figuring out what magic formula you should be eating, you could see how a PHR that has other things, other apps sort of built in – contained in it potentially sponsored by that very company, could cause some risk for patient harm. So, but by and large it's in the left side. So let me throw out an idea, and I sort of welcome people to go through this same exercise. Hopefully the exemplars I sort of picked out sort of exercise the range, the spectrum of things that could come out, clearly not comprehensive, but it just sort of exercises some of the range.

And the lesson I got was, there are some things that are really straightforward, and it's particularly straightforward on the left side, like the nutritional app or just the blood pressure display app that makes it more convenient or provides some storage and memory and portability to it. And maybe, so this is just a hypothesis, it's not part of what we would recommend, but one way that the tri-agency could use this framework is to say, well, when it's this clear, let's stay away from it or have labeling only, just to invoke the transparency. That could be a conclusion of how you would look at these exemplars in this framework.

On the other hand, when things are really way weighted to the right and it really doesn't depend on how many pre-conditions you might put on it, let me think of let's say the insulin pump, which actually isn't all the way to the right. But you sort of like, I would imagine if I were Anna, I'd want somebody to be looking over these companies and what they put out so that I don't have to be worried about everything having to do with this company. I'd have – as Anna, I would have no clue whether this is a one person high school grad that just likes to program. But, not that there aren't smart high school grads, but there – it seems like there are two extremes. And potentially one way to look at this is really the emerging framework, the emerging action for the tri-agencies is let's deal with the two extremes first, and let's do the surveillance function, including reporting of adverse events, for the vast majority of the in-between. And again, I am only saying here's an example, I'm not even – don't think this should be our recommendation, but it's an illustration of how you could use matrix – this matrix to help guide your decisions about making policies related to regulation. Let me open it up for comment on that kind of a proposal, that is, deal with the two extremes and put in robust surveillance function so we can learn – continuously learn about all the things in between that have so much depends in it.

W
This is – go ahead.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
I mean, this is Keith Larsen. I think that, again, it goes along with what we've talked about and what we touched a little bit about in the full group is that, the it depends really has to do with the context that a particular thing is used and then in particular, how its configured.

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
And I think in those cases, again it's, you have a process to do your test cases and everything else, but in the end you want to emphasize the surveillance afterwards because what you get are combinations that, as you indicated earlier Paul, you get combinations that you didn't test.

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
And in development we see that all the time, I mean, we test things, we think that they're perfect, and then you release them for beta and you learn more, because the chaos in the system is more than what you anticipated or what you thought. And then when you make them configurable, you get endless combinations.

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
So even if you're enforce – so it's hard to enforce that you've tested every pathway, because people actually think they have, when they haven't. And so it – because then you're relying again on people anticipating things rather than saying that we're going to learn as soon as it goes in.

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

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
And that's why, this is Anna again, and I have considered developing an application that does something like this, I wouldn't necessarily call it a PHR, but one that integrates data from multiple devices and I've got this other start-up company, so. But I do know people and have friends that are working on different types of applications and they're efforts have been greatly thwarted by their fear of regulation and FDA, as well as a few other things. But, I think it's absolutely critical that we – I mean to Paul – to the issues that – I'm sorry, Keith was just discussing, that's why I think it's important to allow an app store or Yahoo-like rating system to happen, because as these things get released into the wild and patients start playing with it, the bugs are going to appear. It doesn't matter how good you are, you're going to have bugs somewhere along the way. So the bugs will appear but if those who are using it can talk about and share ways that it works better or what does work, what doesn't, what needs to be fixed in the next release and what works great or offer suggestions for improvement. That would go a very long way toward mitigating risk, making the risk that is there transparent and enabling the platform to develop much faster in a much more useful way and ultimately that would help patients.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Because again, I mean just building on this a little bit. When we've talked in the general group about this, and the role of surveillance, what it does is it – you're not necessarily saying you don't have to do a good job before you release it –

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
But it's mainly that as good a job as you give, you need to have a way to measure it out afterwards, and we do the same thing with medications, too. As much as we have the premarketing and development and the reviews, then there's a post-surveillance and it lessens – a lot of the times what you see in regulation is that you do more and more and more, and you're adding time to the process, but not necessarily you haven't really improved the product. There is, at some point, where you're not improving the product, you're just adding time –

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
– where emphasizing a balance with a surveillance program, it doesn't say you don't have to do anything, we'll just find out how it works. But it's saying that you have also a safety net of a good, robust surveillance program afterwards.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
And again, I don't want to speak on the part of – this is Anna again. I don't want to speak on the part of the manufacturers, but I did speak with a couple of medical – of diabetes device manufacturers, just – it's a group that I see more often. And they said that one of the things that's frustrated them and has slowed their ability to iterate and improve their product is that because of the way that they're interpreting the regulatory structure requirements or limitations now, they actually are not able to release their products to patients who aren't in a clinical trial to get input to the data display and integration platforms, until it's already on the market. And once it's there and it goes through the approval process, it's probably going to be at least a couple of years until a new version is created. So, apparently FDA currently interprets that as preapproval promotion or something thereof, something like that, so the current system discourages patient access and feedback at a point at which it would actually make a difference in terms of the product design.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So could I get a sense from the broader group on the thought of suggesting that there are extremes that you feel more confident about what it's saying, in terms of risk for patient harm, and that the large middle ground where you have the yellows all over the board, then it's so context-dependent, as Keith said, that it's hard to design into the framework that's able to capture – be precise about capturing the risk for any given software. But that the biggest recommendation would be robust surveillance as – to develop more data about the risks, the actual risk in the field.

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.
Paul, this is Lauren Fifield. I think one, I'd – I guess I have two thoughts based on kind of your experience. And I think one, the sort of difficulty you started to have when it came to narrowing EHRs and other sort of more complicated health IT software types of software, I think also calls out not just the difficult to identify levels of risk discretely, but also that when you take something like an EHR that is complicated and has many different functions. That trying to identify the risk of that product may be nearly impossible. I think it's come up in the bigger workgroup, but that we might want to make sure that we reiterate is that when it comes to software like that, it may be that it's more risk defined by functionality, the very specific functionality within the whole product. And that regulating at the product level or even providing guidance at the product level, just really isn't appropriate for such complex software. So, I think that's sort of one thing that I think I'm glad to see was kind of carried out or acted out in your exercise.

And then as to your question, I think having extremes where on the one hand we can give folks who are trying to innovate on lower risk health I – components of health IT, sort of really clear, simple guidelines as to what they do and do not have to do is really good. And making a really surveillance-heavy, getting data, understanding what patient harm we're trying to avoid, understanding sort of what is happening in those environments is also, I really agree with that approach. And I think the only sort of next step is trying to define where those boundaries are, because I can't imagine going through this exercise for everything out there. And so I wonder if we can create any top-level boundaries to sort of say, okay, this will go into the bucket of surveillance, this will go into the bucket of super-high risk and therefore we do need a regulatory process, and this goes into low risk, and here's what you have to do.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
I think – those are helpful comments Lauren. I think that what you just mentioned was – is the goal of this exercise, is to figure out – it seems fairly straightforward to create the one for the lower risk. That's pretty easy. It's a little bit more challenging to find the other side of the – the other extreme. And then there's this big, this big broad area where so much depends on the multiple attributes. I like your – also your reminder that when we talk about taxonomy, we were really trying to talk about function rather than products. And maybe the way to do this is to look at functions so that you could actually figure out what are the more risky, the higher risk functions in an EHR and help tease that out. And maybe we only pay – so one option for the regulators is to only look at those areas, so actually the CDS is an example of a function within an EHR, and perhaps we need more examples of that – of functions that might warrant greater attention. You notice I labeled the right column higher risk/greater attention, because it's not, by defini – it doesn't automatically label these things as high risk, it just means you need higher attention, like if you have this automated infusion pump.

Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.
Yeah, I think this function approach also aligns a little bit better with real world, because I think in some ways, the sort of OCD neurotic in me loves the risk dimension chart, because I can potentially walk through any sort of health IT or health IT function and kind of start to bucket it. But in the real world, of course you have clinicians who are thinking about their clinical settings, their clinical workflows and you have EHRs and other health IT being designed for those things, for consumers that are patients as well. And I think when you start to think more about function, it's also more translatable to the real world setting as okay, I'm in the emergency room and the clinical function right now is to put this patient on different machines that are going to automatically administer drugs, right. So you can kind of map more easily to function.

It may be that in the background an EHR is running other functions in the emergency department, that aren't high risk at all, but that that EHR may be integrated enough with devices where it's taking different vitals, demographics, whatever information to control the administration of that medication. So again, I think function is more appropriate and the more that we can – we or the agencies, and I think just the industry, can map it back to the actual clinical setting, the better able we will be to leave room for innovation. And if we start to assign technology, specific health IT to function, we're going to start to narrow who can enter that field. Whereas if we start to think more about what's happening in the clinical setting and give people freedom to use different things in those arenas, I think we'll be less likely to also stifle innovation and new things coming into those spaces.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
This is Keith. I mean, to build on that, the thing about function too is that it takes into a little bit of alignment the idea of context. I mean, a decision support system in and of itself is not risky or non-risky, but the problems they apply to –

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
– apply it to may be risky or non-risky. And so what happens then, and again, one of the things that as we talked in the general group is, how do you again take something that – even a particular function like CDSS and really it's the implementation or the problems its applied to that define the risk. And then how do you account for that in a regulatory environment. I mean, how do you hold the company, for instance, that created the decision support tool accountable for its application to a specific problem in a specific hospital? And the answer is, it's a shared accountability, I think. The company has a responsibility to say that the decision support tool works as a decision support tool, but the local implementation has a responsibility to test their application of that tool to a particular problem and to be aware of the risk, and pay attention to it.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So how – I see the usefulness and function versus product, how do we bind context to the function without having this explosion, this combinatorial explosion in terms of number of things you'd have to consider?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
It's again the difficulty, just like you – what I think the exemplars brought out is, if I have a very specific narrow product, whatever that product is, it has a set of defined functions and its – and you know its boundaries and the boundaries are clear. Then it's easier to measure its risk and to think about regulation. When you got into the EHR example, the boundaries became fuzzy and what it's applied to went up exponentially. And so again, it's the idea that we have a combination of both very defined software – I guess this is the boundary Paul. We have some very defined function software where it does one thing or it does a handful of things, it does it well and its very measurable. Much like, again if I have an infusion pump, it has a set of known functions and it really doesn't – I don't apply it to other functions.

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
And then you contrast that with more of a tools approach of an EHR where I can add new data to collect, I can add new forms, new workflows, decision support and reports on and on and what you prove with the product is that each tool works correctly. But then you have to address the content itself, which is the application of the tool to a particular problem. And then what's the obligation to make sure that the content is correct or that – I mean, if I can write the form, for instance, I can write the form in such a way that it could obscure information that a clinician needs to make their decision. So I'm putting at risk patient care, but the person who gave me the form writer, really can't mitigate that risk.

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
It's really me that writes the form.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
By the way, hi, it's Julian Goldman. I joined the call a few minutes ago. My first time on one of these calls.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So let me, I want to transition over to Keith, because we're using up his time. Does the group feel comfortable enough for me to present – essentially give a similar summary, a much shorter summary, that I just did to the wider group and incorporate some of the comments that have been voiced in this call? Do people feel that was worthwhile?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
I think it was very helpful again, to again – it's easier to talk about these things that are very high level, abstract level, but when you get into the exact exemplars, then that's where you struggle with the issues a little bit more.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Um hmm. So was it useful to communicate the experience of what it – what the experience was in going through these six exemplars?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
This is Anna. I think it was very useful.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
I would agree with Anna. I always agree with Anna.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
Yes.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Anna has my vote.

Esther Dyson – Founder – Edventure Holdings, Inc.
Esther agrees, too.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So I'll try to clean it up a bit and as I say, incorporate some of these very helpful comments to present to the larger group for comments. Thank you very much.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
This is Julian Goldman here. I apologize I have neither an agenda for the call today nor do I know what happened before I called in, so please excuse this interruption and tell me to stop if I should. The example that I just heard about infusion pumps and software and EHR, there's actually a very close relationship. One can purchase infusion pumps that have drug libraries and it's up to the hospital to decide which drugs and which limits to put into the drug library, the manufacturer doesn't determine that, they're just providing the software environment to do that.

The FDA regulatory piece of that is merely that the pump has to perform as claimed by the manufacturer. So if the manufacturer says that you – if you violate a limit on setting or programming the pump that you'll be notified of that, that's the only responsibility they have, it's the hospital that takes the responsibility of putting the correct data in. So similarly, one can have other platforms that allow a hospital to do whatever they wish, right or wrong, correct/incorrect from a clinical standpoint, but what the claim is for the device is that it will just do what it's supposed to do. And you can have general purpose capabilities on FDA cleared devices and allow for any type of configuration you wish, as long as the behavior is understood and the manufacturer commits to that.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Yeah, and I would agree with you Julian. This is Keith. Again, it's the idea that just as in your example, is that the product or the tool works according to design. I mean, if you have a limit then it will perform and it will notify you. But then there's a second responsibility or accountability, which as you indicate, in this case, is the people putting in the information correctly so that the use case or the context of use is correct. In other words, I'm controlling Nipride correctly.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
Yup, that's the practice of medicine is typically how, as I understand how the FDA sees it, and of course, they don't know what –

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Right. But, again, it just – in defense of the manufacturers many times, and we've seen this in the reports that have come out with the harm that EHR systems have done to patient care, and some of those reports you just quite frankly look at, I mean you say it was just a poor setup. In other words, the company, the vendor got dinged, but it was really the setup of this software or the setup of the workflow or the content that really – I mean, if you had an incident like you said with this pump, where somebody was overdosed, you could either blame the pump or more properly, you'd see that, well we put in a guideline that was incorrect.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
And the fact that a good – actually, you've just touched on, I think, a critical point, which is relevant to the discussion that had been going on, which is, the recording of the programming data. Which buttons were pressed and the sequence and so forth, becomes invaluable, because indeed, the programming error may have occurred due to someone's lack of knowledge of how to use the medication, but it also could have occurred because of the user interface problem and an error that continues – that occurs repeatedly because of a design issue. And without that data, it's almost impossible to know.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
But that's where you get – that contributes to your surveillance data and getting at root causes.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
Yeah. Absolutely, as long as the equipment supports that, yup.

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

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
Which is why we should have access to all the raw data from all the – this is Anna, again, if you don't recognize my voice by now.

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

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
Which is why it's absolutely critical for us to have access to the raw data that's being collected. Because a lot of it is already – is being collected. I can't speak to personal – or to electronic health records and their use and a hospital setting and all of that, and that's not my role. But I will say that on the medical device side of the equation, from a patient's perspective, the current regulatory system keeps those human – factors from advancing as fast as they could and should. And that's why I think it's absolutely critical that we create – because it's – I mean, some of the interfaces are better than others, some of the companies invest more into the interface and creating less user error prone interfaces than others. Anyway, but once the device is on the market, getting changes to that form factor or the software that contributes or is part of that, is nearly impossible and it basically just doesn't happen. Because it's too cost prohibitive, it's being a something that's sort of tied to the technology that's already out there and the device manufacturer is generally – on, the people who are designing this stuff are generally moving on to the next iteration of that device, which will probably be on the market in three years.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So I want to just make sure that we make the transition over to Keith's section on the innovation risks, so we don't short him of time.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Okay, well I think that I'll provide a little segue. I think that the discussions that are in the – can you tee up the present – the short presentation there? There we go, that's the ticket. Okay, so, well I'll pick up these same themes that we were just talking about, but I sent out on the 18th of July, a long version and a short version of the slides. What's teed up here are the short version. The purpose of the long version was just to give background. If you attended the full call the other day, there was a pretty robust discussion about PowerPoint slides versus PowerPoint slide notes. And that all of us have done PowerPoint slides and – but if you just hand off just bullet points to somebody else, you don't quite get the richness of the discussion and you're dependent on presenter to do that. The intent of the longer version was really to try to capture what we've talked about in slides and in notes. And then with the short – so that it could be part of the body of the work for reference, after the committee is done and the regulators are looking at the material and doing the real writing of the regulation. The short version was really intended to boil it down to a smaller set of slides that just talks about our recommendations that David could plug into the larger presentation.

If you look at the – let's go to the next slide on the presentation. Okay, so this one, many of the slides in the short presentation are represented in David's slide deck. This one was not one of them. It really went from further down in this slide deck to where it started to show our slides, so it was really was slide 4 that it picked up. Because slide 2 just said why we need innovation, slide 3 said what are the work product sections and then it started talking about the impact on there. So what I want to do is that's kind of book work, let me go and ask really three main questions. One is, with the recommendations that are in the short version, is there feedback on that? We can walk through those recommendations pretty fast.

The next question is one that we were discussing, so there was a segue here, about local implementation, because there was a discussion about that in the full group, and it somewhat at times looked on as a whole, in the regulatory climate. People don't know quite what to do with that part of it. They know how to regulate companies that manufacture things, and because you have just from a fatigue level, there's a lot less of those than all the people that are using the software. But how do you address like just what Julian and I were talking about, how do you address then the actual use of the software on site and do you need to address that? And then the third question, if we get to it is, what do we think in regulation would actually enhance innovation, because all this is taken in context of innovation. So let's go through the recommendations real quick and then let's go to those three questions. So kind of think of those in parallel as you're parallel processing here.

Next slide. Let's go to the next slide. This was just a general thing about the IOM report, Appendix D that – and it's just used here to build on in other slides. Let's go to the next slide. Okay. This one, so the first couple of slides were just looking at the two major ways that we regulate, which is also echoed in the Regulatory Group, although the regulation group was looking at this slightly different, as far as law and coverage. I'm trying to look at it – or tried to consolidate what we had talked about is the impact on innovation and so in this one, we're talking about the FDA. And FDA is largely a process control, meaning that it defines how you're creating the product, it doesn't – outcomes was a bad word here and was suggested to be replaced with – they don't define the product, they really define how you make the product. And there's some impedance with gearing towards physical devices, and that was called out in the Regulation Group. And then people always raise the blood bank use case as FDA gone wild or something, that it had a deadly impact on that industry. Any comments on the FDA medical device regulation?

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
It's Paul. Maybe you can explain how that had a deadly impact on blood bank software and whether that was fear or was it truly the restrictions imposed by the regulations? Because isn't there a lot open to interpretation? So for example, I've heard that every break fixed software update had to be approved, and I'm told that's not actually true. So can you comment – do you see my question?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Yeah, I do.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
How much was it fear versus how much was really required by the regulation, because I'm getting varying input on that.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
And I talked to Bakul about this a little bit, because again, it – I think it would – would it be a good use case to go through. Because I know how it felt when it hit us, which was that we had to go through a validation process, it wasn't just the manufacturer, it really got into this question of not only what the manufacturer had done as far as its certification or its regulatory compliance, but we had to also do a review and a compliance at the local implementation level. Okay, so I think that there was a little bit of difference there in that there really was an intrusion into the implementation of the software as well as the software itself.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
In hindsight, was that truly required in terms of what a contractor might have said? You know what I'm saying?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Yeah, I – I mean, our perception clearly was that it was, and in fact, what we ended up doing – we have – and I was going to get a picture of this. We have file cabinets in one building, just about five file cabinets and they're just filled with all the FDA review of the blood bank implementation at our blood bank.

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
And the perception wa – and again, Bakul has pushed back on some of this, was that we had to – well, that we were actually going through an FDA audit of our implementation. We had to document it and then it had to – one of the things, and it's in our current regulations, too, with ONC and with FDA, is if you make a change, you may have to go through another audit or a recertification. And the problem is that people don't really know where that bright line is, and so the net effect was that not many things changed. I mean, at one point we were being instructed that if we changed out the PCs that were connected to the system, that we had to retest and recertify the testing of that. And so the net effect was that the oldest PCs in the hospital were in the blood bank, subject to things like viruses and everything else, and they were just not being replaced.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Can somebody – Bakul, can somebody comment on whether that's – I mean that was the discussion, so is that true – that would be material, I –

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Well, there's also something I gave David. On the FDA site, there's a meeting that took place, I think it was in 2007, anyway, can get the reference, but it was – the blood bank – there's always the association. So I think it's the Blood Bank Association of America, I'm getting it wrong, but they put together a meeting that was all about what they perceived was the devastating effects of FDA regulation on the software. And so there's kind of a lengthy discussion and what they were saying is that the net effect was that it's left the market with undercapitalized small players, midget players, and that no one else wants to get into that space. And so it's kind of an interesting read on that. And in more general than my own perceptions of what happened here at the hospital level.

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

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

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
This is one of my – so how to admit I don't know all the details about the blood banking software. It's handled by a totally different center, but I have to say that one thing that there is – even in the medical device world, people would complain that just because we need to go through a – because of product changes – the FDA. To some extent, some of those complaints may be legit from a risk to patient standpoint and the technology itself and the effect of the intended use of that particular product, but it's not totally true for all – to make a sweeping statement that some of upgrades are prohibited, because there is actually the law obviously allows you to do routine – and that – without affecting the intended use.

So that created the bottom line, but I'm hearing, and Paul, I think to your point, we need to sort of tease out what's required and what needs to be improved, rather than pointing out just because it didn't work in certain case, it should not – never work. So I really am interested in sort of hearing and I think you said it Keith, that changes need to be there, technology and computers as they evolve, that should be – the framework should allow for some of that, so I'm hearing some of that, but I think to your point Paul, I think we need to sort of dig into what's really the problem and maybe – really, maybe that's not a focus, but also focus on what should be there for health IT.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
And I would agree with that, and you and I talked a little bit about this. Because I think why the blood bank is a particular interest and use case is it's used a lot in these discussions that I've seen some – just some editorials recently, because of these FDASIA group things that are going on, so other people are also adding to their opinions. And they – they're playing this card about the blood bank, regardless if it's legitimate or not, okay? So I think that why it's an interesting use case, because you could tease out – see, because again I'm saying that my perception is, and what I'm backing up is all the documentation that we did, that this actually did go beyond the manufacturer in that we had to document our particular implementation. And that changing anything was not prohibited, but it was prohibitive because of the process that we thought that it's easier to live with a 486 computer than it is to re-document what we did. But again, I think it's – I didn't want to focus so much on the blood bank use case, but because it comes up in conversations, and it's kind of legend, it's really teasing out, well what things really did work and which things did not work, and just learn from it. That was the only thing on that. Again, it's hard to put that in PowerPoint bullet, I could put a little bit more of that in the notes.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
This is Matt. One thing that I think is missing from this pros list –

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

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
– is the necessity that FDA has placed in requiring things like demonstration of quality management systems and demonstration of user-centered design, has had a real impact on the quality and the usability of medical devices. So if you put that between being able to sell your product in the market, developing it and putting it on the market, manufacturers improved their practices considerably. That said, there is the drawback that that takes time and resources, etcetera. But if you look at the use of quality management systems in the quality of products, the variability of manufacturing, etcetera, which are some of the issues that plague this industry, they're much, much better than they were – than before that.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
And when I – I tried to capture that when I compared the two, the slide that compares the way ONC approaches regulation and the way the FDA, I agree with you. I think that – I think one of the things that Paul said earlier in this call is that if we increase innovation, we're really increasing programmers. And you have a hoard of programmers that all say, wouldn't it be cool to work in medicine, well you do, but if you're consuming those products, you want to know that the products are good products, and that they came through a process. So I agree with what you're saying, is that, and I – it's pretty light in that first bullet, it's process control, but it's had a great impact. It's like someone said, well who doesn't think it's a good idea to write down your requirements before you build something or that even to preserve your intellectual property, write down a design. And so I think it has improved things. So I can make that stronger in this thing. Any other comments on that? Do people agree with that, because I agree, I think that the manufacturing process – the user-centered design have been very positive effects on the industry.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
This is Anna. I happen to know of an example, and I'm all for manufacturers doing rigorous user-centered design testing and really spending – and investing in that area, because I think it's critical. But, just, since I know – happen to know this particular case study I ran into a guy recently who I used to know, who now works for a medical device company that does what they're calling patch pumps for type 2. Basically because of this user-centered design change, FDA informed them that they had to incorporate some sort of informational piece or whatever, into the device itself, and they've decided not to reapply – they've got their CE mark in Europe. But they've decided – I mean, it's taken them an additional three years to get to a point where they're comfortable refiling in the US and they've had to go to Wall Street to raise additional rounds of money. So, there are real implications, I mean device manufacturers tend to be smaller than pharma manufacturers, so, I just wanted to raise that as a part of – something that we should at least keep in mind.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
It would be interesting, again, just like the blood bank use case, to really tease out what was the specific thing that held them back. Because again, if you at the user-centered design, at least my perception, doesn't specify specific things that you have to do, it says a specific process of how you get the information and process it in order to make your product rather than an answer to the – what the product is.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
Keith, Julian here –

Anna McCollister-Slipp – Co-Founder – Galileo Analytics
And I can see if I can get in touch with the guy and get more specifics. But, that's the gist of what he relayed to me, it was at a cocktail party, so I didn't really take notes.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Come on, you had a napkin. Bakul, you were going to say something?

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
Keith that was Julian –

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

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Oh, okay. Go ahead.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
I just wanted to suggest that on the left column under pro, you could point out that along with the FDA medical device regulations comes the reporting, the adverse event reporting requirement, which I would consider a pro.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Yeah, and we spent a lot of time on that, so we ought to emphasize that.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
Right. And on the right side, con, it's probably true that it's geared to physical devices, but certainly it has been applied to software. And I don't know the best way to refine the words there, but I think that the notion you're conveying is that its geared to physical devices and it probably needs to be improved for software, some way to make things a bit easier. I don't have specifics to add, I can't help with that. I would add, however, that on the con side, along the lines of what you've been talking about, the MDDS could be a specific example for you in that hospitals fell under the MDDS regulation when that final rule was released, for medical device data systems.

And the cost of implementing a quality system in order to comply with the MDDS regulation is quite high or can be quite high, because of the uncertainty of what the requirements really are. And for a very low risk application such as a very simple MDDS system to be created by a hospital and used to connect medical devices to send data to the EHR, the associated cost in consulting time, document development and process implementation is unbelievably high. So, I just would propose that if you need an example of a con of kind of unanticipated effect of medical device regulation for a simple health IT type application.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
We've experienced that here and one of the things that has come up in a lot of our meetings is, and I know that there's been other groups looking at this, is how do you make these regulations a little bit more user friendly? How do I get involved in this and can you scale, can you scale the regulation to the scope of the product that you're doing – as an improvement type thing?

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
Um hmm. And in theory, as the example I gave you, didn't necessarily have to be that burdensome, but the nature of hospitals not knowing how to – not being necessarily experienced with quality system implementation and the uncertainty that it creates that is the burden there. If there was a simple solution, it wouldn't be as burdensome.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Well again, there seems to be a knowledge gap –

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
Yes.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
– right? Because if you say the FDA's coming, everyone cringes and runs for the corners, they don't want to be involved, rather than understand what it really means and how to get engaged and apply the principles, right.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
Um hmmm.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Let's – if anyone has any other comments, please email them. This slide did make it in to David's deck, so I'll make the updates that people said and I'll reship it to David. Next slide. Okay then, when we were talking about ONC certification, it's really this more goes to innova – I mean, motivation is that we had to certify and I mean as Jodi pointed out, it was part of the regulation that there has to be some certification system. The main – well, let's go to the next slide, I think I can cover it there from our discussions. The recommendation specific to certification type regulation, initially I had put, and it was more my feelings that maybe of the group, because I didn't know where the group was on this, was to avoid all certification systems. My reasoning being that what you're doing is you're certifying an end-product rather than like the FDA approach which is more of how did I get the product and let the product – so the product itself is defined by who's doing the innovation.

After the discussions with this group and other group, this was refined to really say that if you're going to have – that what's needed is the flexibility of compliance. And I don't know how many people here have actually had to make their software work with the ONC thing – test cases, but the test cases are very specific and they really define a specific product behavior. And I see the risk as being, we're freezing in place or canonizing today's answers and essentially taking that off the table for innovation. And so, anyway, there's the three recommendations. Comments? I mean the first one is the one I'm most concerned about, and it's been modified from other discussions, but –

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
How do you do this? So, you have to comply with something, how do you avoid specific implementa – how do you write a compliant test script or something that's flexible and only look at features?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
The example that I would use a little bit would be the way JCAHO does things. They mandate that you do certain things, let's say, med reconciliation, okay? But what they do is then you have a team that comes in and does your certification or your accreditation in this case, and the team essentially sits back and says, okay, so you know what we're trying to accomplish, how did you accomplish it? And you present your solution. And you can be very creative in your solution and you can meet accreditation, but you don't have to have the exact same solution. Where in a specifically written test case, what you have – I mean, using med reconciliation Stage 2 certification, there are very specific things about – that you have two lists, you don't have tabs between the lists. You then will merge the list and you will then certify the list. You're doing a specific process and then questions come up, well, what if there aren't two lists, what if it's just the patient that shows up, I don't have a CDA document and all that stuff. So then you have a lot of these kind of legal discussions about well, what does comply and what doesn't? Where in the JCAHO model, you're really saying that what we need is med reconciliation, these are the things we're trying to accomplish, now show us your solution. That's what I'm suggesting Paul, is that you're defining the desired end goal, but not how you get there nor the product.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
That sounds good. It seems like it's open to the experience and judgment of the auditor, right?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
It is and that's what happens in JCAHO. Now you don't have one auditor, you have a group, and so you get some discussion, but what you can do is you can make your case, right?

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Where if I have a very specific script, what I'm doing is, I'm checking boxes. And what you will get is every manufacturer that wants to be in this market – you'll either suppress the market or what you'll do is every manufacturer will start to do things the same way and – which doesn't really – it precludes doing it a better way is all I'm saying.

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

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
So that's what I mean, increase of flexibility of compliance. Go ahead, I'm sorry.

Esther Dyson – Founder – Edventure Holdings, Inc.
– Sorry, it's Esther, just – the whole point is have you allowed for innovation and improvement. To the extent we can add some concreteness to these very – to these sort of general useful suggestions that would be helpful.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Okay. In the long version I talk – I put that in the notes about the more of the JCAHO model that the more knowledgeable your certifiers are, and the more flexibility they have, I think the more innovation you have. If you try to tighten it down to be a very specific script, then the net effect is anyone can be an auditor, but you're ability to really have a better answer goes out the window. You have – you've been given the answer, it's like a test case in quality assurance. ONC has written the requirement and now I'm just running the test case to see if you met my requirement, but my requirement's very specific.

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

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

Anura S. Fernando. MS, MD – Principal Engineer. eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories
Quick comment, I just wanted to indicate that there are strong parallels here to what's currently done with the medical device safety standards. The reason they moved to the direction of risk-based standards using ISO 14971, for example, for risk management was to allow for greater innovation and then allow for that innovation to be reflected in – requirements as opposed to prescriptive requirements. And so going back to the earlier presentation in the first hour, part of the benefit – language, for example the use of terms like – and so forth with those standards is that it may be helpful in taking some of the product domains that aren't currently falling under those standards. So, EHRs for example, and aligning them with those risk management philosophies so that – around the whole system becomes consistent.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Okay. Other comments? I mean the other two bullets, the last one is just the two things I think are the staging effect of ONC is, you can't see where you're – the endpoint is and so it's harder to plan and then, just what we're talking about before, the recertification criteria. You have to report, but you don't know if that's going to trigger recertification. Okay, next slide. I mean, we're almost out of time. This just compares the two approaches, again, and their impacts. Please, if you have comments, email them and I'll incorporate them and try to – and then get them to David. I just want to go to the next – let's go, next slide. Lessons learned, which kind of repeats or summarizes those other things and it's what we've talked about before, the certification process, the transparency of results and the national goals. And then there's a discussion there of JCAHO.

I wanted to get through to – let's go to the next slide. That other question that I – next one – let's go, okay, these two slides which was really trying to get to this issue that we talked about a little bit earlier about how do you apply regulation or should you apply regulation and what should be its nature? On a national level, where you have less sources of like manufacturers, you have – and things that you can do on a broad level versus. The next slide is really what is the local control and local accountability? Because this came up in the discussions in the full group and it goes back to what Julian was talking about, what we were talking about earlier is do we see a role of regulation at the local area. And even when we were talking about the blood bank example, one of my perceptions is that, and this is my personal perception, I'd have to really dig through and prove it, that there was an intrusion into the local implementation of a software. So, how do you – and a suggestion here is that you have local control and you have local accountability, not a federal regulation control, unless it's on a process basis. But you do have an accountability for the configuration of your own software. Ideas on this; this is one of those three questions I wanted to get to. Is it sufficiently obscure?

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
No one knows what I'm talking about.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So you're saying there's local control, local accountability, how – who would "regulate or certify – who would oversee this?"

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
I'm – what's local accountability, I can give you an example. What we do right now is that we test out content as much as we test out software. And we run quality assurance tests on it and – because we want to know, especially – and again, kind of going to your risk matrix, if we know that the context of use is going to be that we're calculating an oncology drug, for instance. We do a lot of test cases around that rather than if we were bringing in Micromedex and an Info-Button, something that has less impact on patient care. But we feel – we've set up – earlier when – because FDAs been talking about regulation of medical software for I don't know, three decades that I've been working, somebody would come from the FDA and talk in AMIA. And one of the responses we did here is try to show that if you did something locally with – we have a clinical information systems review committee of physicians, and we have to present our findings as far as our quality assurance and medical efficacy before we go forward with things. So we don't submit it to anyone, it's a process – it's more of a process.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
But who makes – so from a patient protection point of view, who makes sure that your organization or any organization does that?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
No one does right now. And you're right – so, is there a national interest or regulatory interest that this process be set up, but can you introduce the process without – and give the accountability to the execution of the process locally. And I guess that's what I'm trying to get is a compromise between those two interests. I mean, even manufacturers – I mean if you talk to the different EHR manufacturers, they're concerned that a bad implementation of their product can do harm, because the content – these are tools and I can do harm with the content. So it's in their interest to have a robust review of the content locally so that it just doesn't blow back on them that they had a bad product.

So, I don't have an easy answer Paul, I know what we do here and I know that we weren't mandated to do it, but that it seems to work and we take the accountability for our own content. Could that be audited? Could that be – if it was something that we had to give all the way up to a national review, that would really curtail innovation or it would – at least it would slow things down. Can you give a local accountability and monitor a local accountability?

Anura S. Fernando. MS, MD – Principal Engineer. eHealth, Medical Systems Interoperability and mHealth – Underwriters Laboratories
This is Anura Fernando again. I think, just from a very broad, regulatory perspective, there's already precedence for this. And if you look at the electrical system in your house, it's under the purview of the National Electrical Code at the national level, but there are local geographic considerations and so forth and local implementation and control, and there's a localized regulatory structure that supports that. So I don't think this is an unreasonable request or anything.

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

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
This sounds like, Julian Goldman here, it sounds like a proposal for – that's similar to the Office for Human Research Protection, that's used for IRBs.

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

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
And I – and that's certainly a non-trivial recommendation.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Well is the other possibility that you recommend that private accreditors – because this is sort of a process, and I guess JHACO could see that you have this process in place and working.

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

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
Does that make sense?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Yeah, because again, when you – when you're showing medical process you're giving evidence of your process, how did you do your P&T Committee? What were the decisions? How did they come to them? But you're not mandating particular decisions, you're mandating the process and you show evidence of the process.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
I think our struggle is that FDA regulate – or even ONC regulates vend – developers but they don't regulate the user, even though for these complex software, the users do have a major role and so, what would have to change in order for the protection to include other influences over the risk?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Right. Because I mean, you just take Julian's example again. If I – if my process is I have somebody that – an unknowledgeable person about medications put in all the guidelines, just by looking at some literature, versus having somebody create the content and then I have a review process of that. It's a different process. And yet the manufactured product's exactly the same, it's really the implementation.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
In a sense that is con – much of that is controlled these days or managed through, as you mentioned, something like the Joint Commission, which looks at processes for accredited hospitals –

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
That's – it's an interesting idea that JCAHO, part of their process review would be how do you manage your implementation of a software tool? Because now the software tools are becoming pervasive in the hospitals, they do impact just as much as any of the other processes they look at. Well, we've gone over. I hate to throw out a big subject like this, but then – and then right at the end, but if other people have comments, please email them. I think that this will come up probably tomorrow, because it was hit in the last full group meeting, too. And anyway, are we supposed to open up for public comment?

Public Comment

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Yes. Operator, can you please open the lines?

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
We've left everyone speechless, huh? There you go.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Keith and Paul, this is Michelle. I have a logistical question. David sent me slides for tomorrow already. Do you think that you'll have any changes to those slides and if you do, could you copy me on them as well, so we can possibly update David's presentation before tomorrow?

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Okay. Can you send David's presentation and then – rather than give these slides to then try to find their place in David's, we could just give you targeted updates.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Sure, I think they're already going to get sent out through the ONC mailbox, so you'll see those coming, and then we'll send out an update.

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Will those come out today though, so that we have time, because it's tomorrow morning, right, tomorrow morning for us in the West.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Yes.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
So if you can send it out as soon as possible, we'll update our relevant sections and I guess –

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Okay.

Paul Tang, MD, MS – Vice President, Chief Innovation and Technology Officer – Palo Alto Medical Foundation
– tell you which slides, so you can –

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Yeah, because we start at 6 in the morning for Paul, so he probably doesn't want to get them at 5 in the morning and have to work on them. Just looking out for you Paul.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
He works all hours of the night.

M
No sleep for the FDASIA –

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare'
That's right.

Michelle Consolazio – Federal Advisory Committee Act Program Lead – Office of the National Coordinator
Okay, we'll share with you, thank you very much.

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

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

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

Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare
Thanks to everyone for their comments and discussion.