

**HIT Policy Committee  
FDASIA Workgroup  
Risk Assessment & Innovation Subgroup  
Transcript  
May 30, 2013**

**Presentation**

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

Thank you. This is Paul Tang and Keith Larsen. We're leading a subgroup on what was called Risk & Innovation and we sort of labeled it risk assessment, one for patient safety and another for innovation. So Keith and I, we're going to lead some discussion in the next hour – approximately hour and a half to further delve into the work we did on the phone call and I was remarking before we got connected that it's really nice to see how well aligned this is with what the Taxonomy Group came up with. So, they talked about the issues that we'd already introduced in our frameworks and as Jodi pointed out, they're in and out of scope has nothing to do with in and out of regulation. And similarly, our risk framework doesn't say a definition. Everything in one column is to be regulated and everything in the other not. It's a way to represent dimensions on how to discuss and all rolls up to ONC, FDA, FCC in saying, hey, here's a way to structure some of your thinking, and it doesn't really mean any – there's no presumption one cell or another. They can come up with that.

And even they are not proposing in January or it's not an NPRM, it's a report about a risk space. So, there's many steps along the way and it's also fair to say there's many steps along the way for the public to weigh in on this process as well as what the tri-agencies propose, too. So the next hour and a half and we'll be sort of fair, I think we'll each limit our discussion to 40 minutes apiece, so we make sure that we give Keith's discussion equal time. So with that – so, I don't have any PowerPoint. Let me list five questions that we should discuss, we may not get to all of them this meeting, but we have future calls to go through.

So one is, do we have the right – we have five clustered dimensions to our framework, our draft strawman framework. Are those the right dimensions, considering some of the conversation we had about taxonomy and some of the other comments. Another question we can go to is the boundary, meaning the lower risk side and the higher risk side, are those qualifiers, those – the text words, approximately the right thing to describe what we mean by lower and higher risk and not prescriptive, though. Third question would be, and I'll write up these questions as we go on the flip chart. Third question would be, and then what do we do with this, is there a weighting we're going to apply to it, like it's one of these dimensions that will maybe when it comes to thinking about a regulatory framework than others, we should think about that. Is there a way to calculate a composite risk for a piece of software, something that fits in the taxonomy that we're to describe? So that's sort of the quantified part of our discussion.

And then finally, and we probably won't get to this today, but will do on other calls is a list and rate some exemplars to test our thinking out to fit. Some of it the Regulation Group came up with some good examples, we can put those through, but come up with some – and the more common the better, I think. We don't want to chase after the – that's why I want to hook these – our course is tied to these risks. Okay, how does that sound as a way to structure our next 40 minutes? So, put a –

All right, so the first question is, of the – now, unfortunately it didn't – do you all have, at least electronically for those of you who have your laptops, for the eye chart one, I thought that it was printed out as a full page one, but – we – maybe you could use your – you could project –

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

Yeah, I think there is a –

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

Great, now if you could back it up – chart.

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

Oh – let me just –

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

Yeah, switch over to –

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

– I'll do it.

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

Okay, so the first question on the table is, do we have the right dimensions? There's five of them there. One has to do with the intended use and user, the next has to do with the risk, the different kinds of risks that could be assigned to that. A third has to do with the complexity of software, and that's not making – not necessarily – way, that's from the development to the implementation to its use. The fourth having to do with its interaction with other hardware and software that it comes into contact with and the fifth is the network connectivity. So those – what do we have to day in terms of are those the right, are there additions, are there modifications and vis-a-vis the complexity comment that was raised, this was non-judgmental, it's just a fact of whether its complex or not. Please.

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

Mike Swiernik, I don't know if they can hear me on the phone, but the – I'm not sure how to phrase it – I don't – I can't quite formulate in my mind, but is this – this includes also post-market concerns, too, right? And is that accurate or is this –

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

Yes, it does. How do we discuss that? I think it's useful to have a separate discussion on that, so let's make sure we use that, let's make sure, we did talk about that on the call, so there's post-market –

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

And the reason I bring it up, just so you have some context, is just that these seem somewhat abstract to think about risk this way, in other words, what might risk be in time where we actually have real data, hopefully that will factor into this.

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

The reason for putting it as a separate topic is, I think we want to do – I think they were thinking about, Congress and FDA were thinking about a prospective way of assessing, but, I think we want to make sure that we also render comments and recommendations on post-marketing, the need for that –

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

Okay.

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

– at some point.

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

C5 micro – Paul, I'm wondering if maybe we can use a chart to compare what risks are accounted for today, that people feel are generally accounted for, of the ones that are identified and then what risks are not well accounted for. Like if you go through the chart –

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

Um hmm.

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

– that may help tease them out on one side or the other, because the post-market question, in some cases it is accounted for in some of FDA's activities, in other cases, it's completely off the radar. And that may identify some of the dimensions for where they may fall. I don't know, that may be helpful –

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

I agree, I mean, I think that is a real important one, and we talked a lot about it in the IOM committee, that's where the whole repository and sharing and NTSC-like risks, all having to do with after its out, that's when we're discovering these things.

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

I guess my question would be, do you feel like we should look, the group – I'm sorry, I'm making my part of the group, we should look at the blind spots or have that be maybe some portion of the focus?

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

I think that's what – that's on the table right now, so, are there any blind spots where – that these five dimensions don't cover? Let's start with that.

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

This is Anna McCollister-Slipp for those of you on the telephone. One question that I have or one thought, and maybe this is included in this, maybe it isn't, but what is the risk of the status quo? Because there's a risk inherent within not innovating as well. Like for instance, when I was reading through the MDDS regs, just in preparation for this, I was a little bit astonished and frightened to know that a GFR calculator for kidney functioning is considered a regulated device, but if you just type in the equation into a calculator app on your phone, that's not regulated. Well the likelihood of me making an error in doing that equation on my calculator is much higher than if I had a predefined app. And in fact, I think I've even created a GFR app through like Wolf Widget, I mean I had no idea that I was creating something that could possibly be regulated. But now that's a very simple calculation, but the risk of getting it wrong, on one hand it's just that it's a measure, you're not – you may or may not be using it to make a medication judgment, but, so.

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

I think it's a valid point. Can I offer another side to offer a spectrum of ways to think about this? I think it's useful to compare to the status quo. The question would be, do we set our – is there different humanly perceived veracity when you stick it – when it comes out of the computer? And speaking as a healthcare professional, when we see it on the computer, we sort of assume it's so, where if we see it on a paper or we calculate it, we sort of have some – it's a level of certainty that we assign, and that's not objective, it's just a human phenomenon. So if we see something, and that speaks to the error of commission and omission, if we see an alert, we're just going to say, it's been programmed to do the – say exactly the way it is, and that's actually part of our downfall, speaking again as a clinician interacting with these things. So that would ask the question, just ask or pose a different question is, is it – should we only compare to what it used to be, the status quo? So, people – Matt?

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

I was going to add, one of the things that Meghan brought up in the taxonomy discussion was the whole issue of cybersecurity and, not so much in the traditional forgot the PHI on a laptop that got stolen from the car, but the real possibility of hacking from outside entities and controlling these or changing these. Imagine if someone hacked into the system and changed the CDS rules, so that people would expect them to fire, but they don't, etcetera. And so, I don't think that's a dimension that's necessarily captured here.

**W**

I'm going to ask, is there a definition of harm? Has the group or is there something to point to that – because it was seen that the cybersecurity would allow a traditional patient harm, which is harm to the actual human itself, rather than harm to financial or privacy or organization or something like that?

**M**

I think that that, the way they write – that you guys do actually – it, focuses on patient harm rather than reputation, financial, or whatever.

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

And Matt – on our call and I did check with Jodi, so, because – the ocean, we are limiting more to physical, well, physical or mental harm to patients, it is that kind versus reputational harm, just its focus.

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

Paul, Meghan Dierks for those on the phone. Whoever – it stimulated a little thinking on my part. So one – I can imagine that one could have a product that by its design and through all of the mitigations, design controls that are in place, it is actually quite safe. But it now interferes with another product and so the harm is actually an indirect, it's not technically that this thing's malfunctioning and causing direct harm but it has the potential, because of misunderstanding of its effects, causes another product to malfunction. So, I don't want to get too far down around the whole, but that does – I think it is a dimension that I haven't heard –

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

It's the same dimension. This is Matt Quinn. It's a – I don't know if you guys have seen the you-tube video where hackers took over the power plant, right, and made the turbines spin so fast that it all blew up. You can think of a context where when that situation occurs, hacking into a – medical networks.

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

Can we put that under, I mean, just trying to keep it at the framework level, we do have integration with other systems.

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

Exactly.

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

I think the – could potentially be a – right? I think that when you talk about the interference, it probably should fit under integration as it exists today –

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

Correct.

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

– at the spectrum level back, back. Right.

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

Correct.

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

Whereas with the integration issue, there should be security – you can argue security's going to be a crosscutting line across all of them, right. What happens when I integrate? What happens when I share with the patient? What happens – you know, across all of these five. So I think maybe the two – the one that you brought up and the one that Meghan brought up maybe one goes in an existing category, the interference one. And we can just – we don't have a sub-bullet under that, maybe –

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

I was just going to do that. So what I've written in my notes is, I think security can fit under that interaction, but I think – so what we're looking, in Steve's words, blind spots, So, that's not missing, we can add that, it still can fit in the category we have. Mike, did you have something?

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

Yeah. On our call I brought up the issue of content and where that fits, and I think Anna, you mentioned something about this and some people mentioned it this morning. I feel like there are a problem currently where, and I don't mean to pick on specific industry, because there are a number of examples, but where an EMAR vendor can say, we don't provide decision support and that means we're not regulated, you the provider have to build it all yourself. But a GFR application, which is very brainless, it's all of a sudden regulated, so it's – but I think looking at this, it could be under complexity of implementation if content is included as part of build. Because that's really what it is, is that you're forcing the providers to build this rather complex thing within your tool. And in a way, this might correct that, because if the vendor provided it, then the build becomes much less complex. It might bump it up in other areas, but maybe that's a balance – point, we need to – I don't know if that was the intent, but –

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

Good point. Jeff?

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

Yeah, I just – under the – I don't really see this happening. There is a creation, and I think because we have innovation, as part our group, we think about creation, but I think we need to add maintenance under complexity of software –

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

Yeah. Exactly right. Yeah, I put, I think it was Meghan that – so I put maintenance under that, and then complexity of implementation I added upgrade, because that's on our – the user side. So, I've added some of those notes, because it was all of that conversation. Mary Anne?

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

Paul, this is Mary Anne. Under, maybe this fits under post-market surveillance, but, there's an issue of transparency, I think, in reporting. When do we know there have been known issues with products. So, for instance, if you go the Better Business Bureau, you can see there's been 527 complaints on XYZ vendor. It would be great as a provider if I could be more informed about some of the known reported issues.

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

Or you can imagine, this – whoever replaces up in 5 years, having the same conversation. I mean, future policy –

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

Yeah, but we did it. Other blind spots, then we'll go to the next question. Meghan?

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

So, I'm not sure I'd call it a blind spot –

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

Okay.

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

I know in other industries, when I've done formal risk analysis, one dimension has been the detectability of the failure. I don't know where that would belong, but you can get kind – require a little more mitigation when failures go undetected for a period of time.

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

So, it was listed under, but I think it's with a different bullet so it's under ability to mitigate hostile conditions, it's – intermediary and the software transparency –

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

There it is.

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

– but I think that there may be another way of calling that out.

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

Okay.

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

Because that's where we really get blindsided.

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

Bakul brought up, and it's actually – I don't think it's a blind spot as compared to the current regulation, but it might be a blind spot in our – in this framework is, organization. I think that's probably sort of the organizational maturity.

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

Um hmm.

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

I think generally having that kind of organizational – what would have ended up being in your – management documentation in 510(k) for example. That might make sense as part of the framework as well, which I don't think we kind of have today, which is the participants, all right, so like is their organization actually set up in a way, is there organizational maturity, organizational development. He brought that up in the meeting and it felt like that was worth at least talking about again.

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

So would that belong with the implementation and the training and use?

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

I don't know. I struggle with a place to put it, because it's more like everything from your management review process, to your org chart, to your – like is this one person in a garage, not just metaphorically but literally. Or is it – we have tons of things to show that big organizations make just as big mistakes, I'm hoping there's nobody from Guidant or Boston Scientific in the room, but I mean –

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

Right.

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

– we can – so I'm not sure – I'm not saying that that gives you more credit, but I wonder if that's one of the legs of the stool, which is like, is there – there's an organizational maturity. It doesn't mean they're not new, but have they done the things to organize themselves for success.

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

In a sense that brings up the notion that it's a different problem, one, I think we're trying to look at the result of product – a software product, and the other is the danger, and this was brought up in the IOM report, of its use, everything from you have to have a sophistication in the organization. So we can figure out how to state that and it's probably like in a preamble. We're talking about how to make safe products, there's safe use.

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

And even now in the organizational thing, if we just like, keep doing what you're doing –

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

Yeah.

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

– I mean sort of, the regs are pretty clear on that, at least the FDA side, so we're not saying we'd take it out.

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

Just to be clear though, your organization, and this is Meg Marshall, your organization comment is around the developer –

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

Yes, manufacturer.

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

– not around the implementer or the provider.

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

Oh, okay –

**M**

I'd rather it do both.

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

It could both, I was pointing to the manufacturer – just be – I mean I'd love to take credit, it's a good point, but I can only say – I was only back on manufacturer. But if you think it's really smart, I'll take the other side.

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

So Geoff, this is Meghan Dierks, so I think what Bakul was pointing out that was unique about software is that in traditional products, it's really hard for someone who doesn't have an infrastructure and a certain amount of just historical experience to be able to build a thing, whereas software's quite different. It is relatively easy with very few resources to create something. So, it just creates conditions where it is possible that someone with less experience, and I'm making no assertions about a relationship between years of experience and quality, but it is possible. And so I think that was the point that you were –

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

Yeah, because I'm going to argue, we need to skate where the puck is going, I say that as an East Coaster who still plays ice hockey, so if technology doesn't work – but, that – so I can say East Coaster here, I'm not in California anymore. You've got to make that analogy in California or they're like, what are you talking about ice hockey for. With 3-D printing, I can print a gun today, so I think the analogy that software's easier than hardware, I think developing good software is just as – and I that we shouldn't make analogies that one's easy and one's hard. Hardware is becoming easier than it ever was and actually writing good software's a lot harder, especially in complex systems. So, I think that's – that assumption was true at one point. I think if we start to think about regulation as going – organizational maturity is going to be important, independent of what you build. I think saying kind of, oh, a couple of people can build software in a garage, some people can build hardware in a garage now, too. And they'll put it up on Kickstarter and get the million bucks in a week. So, I think that it's a fair point, but it's one more about where we've been, not about where we're going.

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

So I'm going to move us along, so we can get enough feedback so that we get give that back to the group. Because we're going to be open like Meghan was to group discussion, and we just want to make sure we reflect on the thoughts so we can get it out there.

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

I'm sorry to keep bothering – Julian and I were talking about one more mention I think that might be different –

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

Okay.

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

– is the level of dependence that people have on whatever it is that's being used, whether or not they can stop using it, potentially. Because – and maybe for those of you that work with EHRs, you could go back to paper, I mean that would be – if your system went down, but in general, if there's an issue, you may or may not be able to turn it off. With an app, you may be able to stop using it as a kind of protective mechanism. I think that fits – I didn't know if that fit under the row with the ability to mitigate, because that seemed like a little bit different type of mitigation, as opposed to, I really depend on this, I can't stop using it. We were kind of using the analogy of like the Dreamliner, right. FAA found that there was a battery problem, they grounded all the flights, so no one could use the plane. In this case, you may not be able to stop using what it is that could be potentially causing harm.

**M**

You call that Microsoft.

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

I think –

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

We won't make any jokes about blue screens –

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

I think we can work that into mitigate, but it's an important point. So let's – can you put up the matrix?

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

Okay –

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

Why don't you F5 – bring it to the presentation mode, it's a little bit bigger.

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

Paul, this says current slide.

**M**

Paul, is it deliberate that you put the purpose and the intended user up at the very top, because that seems to be a great approach. Because a lot of things we're talking about, if it breaks, what would be the harm to the user, really comes down to what was the purpose of the software to begin with.

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

So the current – primary or secondary screen, its full screen as a reverse.

**M**

If you go to view, I only know this from failing –

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

Yeah, innovation is –

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

I'll flip that down for a second –

**W**

If we're going to talk about the complexity of training, do we need to talk about the adequacy of testing or the –

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

That's part of implementation, though –

**M**

That would be part of maturity model –

**W**

– or compliance with standards, if it's a security issue, it's got to be compliance with NIST, right, so –

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

Okay, so where I'm going with this is, have we described the dimensions in the text of the lower and higher risk columns? This doesn't have to be – but have we given people the right idea of what we were shooting for?

**M**

I think somebody was giving a suggestion about –

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

Paul, this is Mike Flis. From a manufacturer's point of view, I was hoping to try to define the terms over-the-counter and prescription device more here as –

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

Say that again please.

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

I hope to see the terms over-the-counter and prescription device as differentiators as well.

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

– for proposed use – I mean, if you put in your 510(k) that you need to have a doctor review that you're going to get prescriptions. So maybe we should call it out under the user?

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

And it goes towards training, because if it's a prescription device, as a manufacturer you're conceding you are incapable of providing adequate directions for use, you've got reliance on the healthcare professional. There's so many legal precedents of what that means.

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

– start putting OTC and prescriptive –

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

I think that's covered under intended user, is that right? Because that's the counterpart to prescription versus OTC.

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

Yeah.

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

Yeah.

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

I think what you – because I like what you're saying, I would argue that you're saying like, there's intended user, but then there's a different role, right, which is also the kind of how it got there.

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

The patient may actually benefit from if they don't get access to the device until they go through a training program and there's a licensed healthcare practitioner who executes that training.

**M**

You know how to use this.

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

Yeah, and the manufacturer's simply incapable of providing that training.

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

Okay. So it's sort of a credentialed user, so that – had an element to that, got it. So, it's information versus doing it on its own in a black box. And it's a qualified, credentialed, trained user versus anybody who has access to this. Does that sort of illustrate the dimension pretty well? Yeah, and the severity of the risk is like spitting out the weight, now that was actually...the one we just tested, spitting out the weight, people know what a weight is, they know what to do with it, there's actually face-validity testing, even a consumer would know, I'm not 200 pounds, so they would know when it's broken. So that's the not – it's pretty low probability that that's going to harm someone versus putting out the dose of a vasoactive or chemotherapeutic agent, has a life threatening potential.

**M**

Paul, you currently have it as one row, but I would separate severity and probability into –

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

It is, this is the probability. So one is – when something goes wrong, what's it going to do to you –

**M**

As how bad it is –

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

Yeah, not much or potentially life threatening, although all of them as – in. How many people are even exposed to it. You're only using this when you're hiking Mt. Everest versus everybody's using it. What's the likelihood? So, you know what, yeah, you know I mean exposed if there's a sunspot and the grid is down, then this could have an effect on it, it's just not happening, versus you know, the sequence of events of the individual single point of failure, pretty common, that's what that dimension's supposed to be. And then the ability to mitigate. If someone's standing in there and they know exactly what the machine is telling them, that's transparency, and it's not a critical like all systems down is unlocked or is it like the thing is doing it and I don't know what it's doing and it's doing it on its own. So those are some of the bounds of that. Does that cover sort of the risk of software on human condition? Mike

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

The last – Mike Swiernik. The last one, ability to mitigate, in my mind it may be almost two lines, one which is more what's described here as transparency that the – whatever you were worried about has occurred and then there's the mitigation one with – and that may be also not just your ability, but what mitigation do you actually – like what are you –

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

– accepting. Like can I just pull the switch and it's off.

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

Exactly –

**M**

What's your options?

**M**

Yeah, right.

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

Yeah, have I figured this out or –

**M**

Standardizing the risks.

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

So can I observe what's happening versus just these idiot lights and then can I quickly do something about it.

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

Right, or the software –

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

And that the intended user can do that. Versus a patient, they see its – wrong, but it takes a doctor. Great.

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

Jared Quoyeser. Is there a quantifiable measure of rare risk to comment and a higher risk?

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

Um, I put that just to start discussion, but we would have to probably discuss what rare is.

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

There's a good standard for that – (indiscernible)

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

Okay. That's if we do need it Geoff.

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

Mike made this point earlier, I'm sorry – Flis? Mike Flis made this point earlier, I just thought I'd – I think the first two are so important and probably if you think about the decision tree, which I thought was really nice what your team did with the decision tree. That I mean, you mentioned it, I'm thinking in my head the weight one, as soon as you said weight, I'm thinking, oh CHF patient, pound and a half, they might still think, yeah I weigh 201, but it's going to make it totally – of their Lasix. I wonder if we almost pull them out of the table as part of the decision tree and say like, depending on where you go from these, this is the way to read the rest of them. Because those first two are so much bigger than the rest of them in terms of how they guide our thinking, that when presented in the table, if you were to just give this sheet to someone else that wasn't in the room, they're immediately going to do the same thing we're doing which is like, oh, but what about this or what about that. Whereas I think we've all kind of acknowledged those two things set the context, what's the purpose and who's it used for? I wonder if there's a way to just present it – or pull them out. I'm not saying we should do that right now, but, because they're not equal to the rest of the –

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

So can I do that at the next question, which is the weighting?

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

Totally fine, sure. Sorry.

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

Meghan.

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

Just an additional perspective. So, in the days when I used to try to define design control, it always came to, what's the thing that's going to mitigate the risk? And so it was helpful to break I think what you have as two categories, this is just my personal – help to break it in the following way. What's the probability of fail – of the system malfunctioning? What's the probability that given the malfunction, it reaches the patient? And then the third is, what is the severity of the harm, given that it failed and it reaches the patient? And it may sound pedantic, but it does actually then tie directly to how you go about mitigating. You don't just say, just because all three of those are possible, that you'll never clear the – so you're never allowed out there. It just means that it calls for more. Sometimes it may just call for better labeling and training, sometimes it calls for actual physical design controls, but, that has been helpful to me in the past, in breaking that, I think what you have as two categories into three –

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

So what are the two?

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

So I – what is the probability of the system malfunctioning or being misused?

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

This one –

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

Right.

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

The second is, given the failure, what's the probability that it reaches the patient?

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

So are you proposing to link these more tightly than thinking that you can, in an orthogonal way –

**M**

They're different dimensions.

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

So it's funny, I don't think about linking, I think about those two things actually could break into three distinct categories – three distinct dimensions. And I don't want to make it seem as though we're adding, but it can – help, because sometimes something can have a moderately high probability of misuse, but it rarely reaches the patient because it's very obvious right when it happens, and it never reaches the patient. In other cases, you can have kind of a low probability of failure, but it always reaches the patient because it's kind of hard to detect, and yet the severity of the harm, given what it is, it's a GFR calculator, the severity of the harm has a very kind of lower bound.

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

So I think what you're saying is these are the right sub-dimensions, but you're saying that you actually have to weigh each of them tied to a specific scenario, specific use cases.

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

I think that it becomes easier to kind of assess what mitigation you need to put in place, because you will have a lot of cases where it's a higher probability event, but the severity of the injury is just low, given the kind of things that the product –

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

So I think – so here's how this was intended to be used, and let me see if that addresses your question. So we get, instead of talking about generalities, we put through an exemplar, a use case. And we go, okay, let's think about how often is this likely to happen, oh, and if that happens, what's the risk? And of if that happens, is someone standing in the way to prevent the harm? For each use case you'd always go through that exercise, so does that –

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

I think that – it's a little bit like our kind of nuance says, SOAP is applied to what we're going to talk about versus where if you're saying, what's the likelihood of – very important to say, what's the probability that the failure occurs in a product is distinct from what's the probability that the patient will be harmed, given the failure. And the third thing is, okay, if the patient gets harmed, what are the – what's the severity? If it's very minor, you can't possibly envision a scenario where the patient has a high severity of injury –

**M**

Let me give you – worksheet.

**M**

There's a really good FDA worksheet –

**M**

I was going to give you –

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

It's from the FDA –

**M**

So how often are your GPS things wrong?

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

Fairly frequent.

**M**

How often do you not catch that you shouldn't drive off of the cliff to your demise? Not very often. And so that's, I think, an example of separating the –

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

The failures occur –

**M**

The failures occur fairly often –

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

– but the probability that it –

**M**

– but the probability –

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

– it leads to harm –

(Multiple speakers speaking over each other)

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

I'm not sure if I'm understanding what it is you actually changed, because I think this handles that condition – for every given use case, I was assess how likely it is to happen. If it happens, what's the severity of that potential risk and who does it occur to and who could intervene to prevent it from reaching the patient or harming the patient. So, I think these –

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

I think you've got it all, I think in other industries you've got a little bit more specific about a term they use, so they would decouple – so they'd take the word risk, and break it into probability of occurrence and –

**M**

Severity.

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

– severity of harm –

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

Maybe I can work with you to pick up the language –

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

– so eventually –

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

– but I think the concepts are there, right.

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

I think they're all there, I think they're all there.

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

Mike?

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

Yeah, Mike Swiernik. I think also what you might be referring to Meghan is there are several scoring systems I've seen that are very specific, like project management has one that's exactly this. And what you're talking about is kind of like why we focus on bar-coded medication administration versus the physician errors, because physician errors almost always get caught, but giving a med doesn't get caught, so there's scoring things in that.

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

And one gets mitigated through design control, the other is harder to – it's very –

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

Exactly, but there's a calculation that you do. So if we're just saying general framework, this works, but if –

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

I think you've got it.

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

Okay. It looks like we've had two things queued up for question 3, meds.

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

If you wanted to close that out, I'm not sure –

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

No, no, I mean it's going to actually feed into the next question.

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

So, have you accounted for the intended user's acceptance of risk in there somewhere? So, as a user who's interacting with a product, I may recognize that the risk may be high or low and that may – so my expectations may be lower?

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

Umm. Hold on. That's an interesting, and I'm writing it down because I think we need to somehow say where does that fit in. Does –

**W**

Well, it's acceptance of risk, not just tolerance of risk, right?

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

No, conscious acceptance.

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

Yeah.

**W**

– of responsibility and accountability.

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

So –

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

Isn't that more an issue of control, it's sort of like the issue that you were talking about with the GPS. Well I can look at the GPS and say hey, there's a cliff that the GPS doesn't register, I probably don't want to drive off that in most days. But, if it's one of the Google cars where they drive themselves, that's going to kind of bother me if the GPS is running it. I mean, I'm not going to be like multitasking with my computer and realize the GPS was wrong after I'm driving off the cliff, so I want somebody to make sure that GPS is really onboard. Similarly, like with an insulin pump, I currently control my dosing. Little errors in dosing can have big, sometimes fatal consequences. When I control it, I can deal with this, with an automated system or the closed loop, which we're getting fortunately closer and closer to, I sort of – that, makes me a little nervous.

The reality is that a lot of people die from overdosing because they dose themselves wrong or not a lot of people, but 1 in 10, 1 in 20, have died from hypoglycemia, but – and the studies for the artificial pancreas are much safer than that, even though limited, but it's the perception of risk and comfort with control. I mean, if we try to control everything that goes into my calculation for my bolus, we're going to be regulating the entire economy, including sidewalks. But, if we are just focusing on this one thing that I have no ability to control because it's on a black box, then that's appropriate.

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

I just – differently though, if I'm reading it – I think that's a great example that you made. I think the other half of it, though is, should there be the ability, I wish I could remember who brought it up, because it was somebody else's point from the session, I'm just rehashing. Should there be the ability to say, I'm willing to accept more risk or how do we share risk in the process? So the flip side of control is the ability to say, I'm willing to try that thing, drug, device, whatever and what, as we start to think about patient's empowerment in the process, what is the communication of risk than the ability to accept. They can say, like either option – I have to opportunity to present them to you, so see if the other –

(Multiple speakers, different conversations)

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

Right, which is an issue of control, do I take a plane, am I afraid of flying or am I afraid of driving? I mean you're more likely to die in a car –

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

– you have a choice, what I want to make sure is we don't get to the point where you say, you only get cars.

**W**

Yeah and –

**W**

Exactly, exactly.

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

What I'm going for is giving the consumer the adequate information to be informed to make that decision on their own. So are you labeling appropriately so that you know there's a 75% chance it's going to drive off the cliff, I would take a plane, you know, something like that. But – so it's more around the information and perhaps labeling of it.

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

I was going to echo exactly that, is the ability for a user to detect doing good or bad or consequences of what's going to happen if I take an action based on a number that shows up in front of me, that's more important. And I was going to flip that around and say, is this something from an innovation perspective you guys need to think about, patient education or information for a particular instance, educating people why you are so comfortable dosing yourself, but you know that so many people who die because of hypoglycemia and hyperglycemia. You've got some people who don't know how to dose themselves, so is that something you need to get our thoughts.

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

Just working on that – the view that I’ve never used a pump or whatever, but a lot of them now have these built-in bolus calculators based on sort of algorithm, but, that I’m assuming is regulated by FDA. I usually ignore those things because they also don’t know what my exercise level is then, what I’ve eaten, the num – I mean, they don’t incorporate any of that stuff, but that’s a regulated decision. I have complete control to override that, so, I’m much more comfortable making a decision on my own than I am with a pre-defined thing, because I have control.

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

So I’m going to move. Yeah, Mike?

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

Mike Flis. When I’ve been in other conversations about risk management with software, I’m a guy that’s never used the word harm and software, because software never harms a person. It contributes to harmful situations and if we can teach ourselves to think of what type of regulations do we need for harmful situations, it could restructure that table.

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

Well I don’t think we’re saying that software harms, there’s a risk – that software introduces a risk for harm to happen.

**M**

Same thing. I think it’s the same.

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

Creates a situation.

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

So we have two minutes before I’d like to move to another topic that I think everybody’s been itching to talk about the whole way, but here’s one that did come up in the discussion just this morning and wanted to get your feedback on. So this is the interaction, so it completely – stand on a scale, it doesn’t talk to anybody, let’s assume it doesn’t right now, you get it and then you get something that you understand and it’s transparent and you have face validity test. Compared to almost all the other things we do down to the act of read the scale, has more chance of introducing things that pose a risk when – to the user or operating with that information. Do those words adequately describe this spectrum we’re talking about, this dimension? When we drill down on it, it’s going to be tough to start defining which side of the spectrum it’s on, but let me get your thoughts. Mike.

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

Mike Swiernik. On this one I could play the devil’s advocate, I’m not sure I believe this necessarily, but, one could argue that this would be covered under the other pieces of this without even needing to exist on its own. Just because the using it as part of a broader system of multiple things really gets to the complexity of its operating, complexity of implementation, and maybe unfairly called out the fact that it’s part of a networked environment in a way that makes it more prominent than it should be. And maybe it’s a weighting issue or something, but, it strikes me maybe this is duplicative and be punitive to those that – for instance, if I was a weight scale, I’m de facto going to be part of another system and therefore suddenly I’m rated higher on this scale than –

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

Not necessarily.

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

– well, if I was a connected weight scale.

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

Connected and you could be misinterpreted. So, you're absolutely right that getting pulled out was implicitly assigning a higher weight might go to this next discussion, but let me get peoples sense of that. Does calling it out, this whole system integration, as a risk, is that warranted?

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

So, I would second what Michael said, which is, I think it's more – this is much more a part of intended use, so, if it's networked – and again it has no use if it's a network scale for weight loss versus for CHF versus something else. I think this is part of its intended – how we plan to use it versus the fact that you connected a piece of software to a person's piece of paper, that I'm still going to give my doctor or something else, like I think this – we should roll this sort of under kind of intended use. The fact that it was connected by any particular means, I think it's too specific and it would be better to roll it up underneath intent.

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

So just to clarify, it wasn't just by virtue of connected didn't earn it a higher risk –

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

Understand.

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

– it was a number of things, so let me hear it, because it did come up at our call, so somebody brought it up.

**W**

I was going to say, the only time an interface or a connection or conduit is of concern is when the data is transformed somehow.

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

Sure –

**W**

If there's just a connection and its transport, it shouldn't really have any impact on harm. But if the data is transformed, advertently or inadvertently, it could impact harm.

**W**

Now what do you mean by data's transformation on that?

**W**

In other words, the value going from here on a device to here in an EMR, if it just goes through a conduit, that is no transformation is involved, I'm not sure that would pose risk. But if it's something where the data's transformed from analog to digital or back, then I think it poses risk, which is why – kinds of things are regulated, right.

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

But even if it's X-file to – technically MDDS –

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

This is Bakul. I'm sorry, I was just going to say that – I mean, when Geoff was talking about his weight scale on a dialysis machine, weight scale at home, presents two different connectivity risks. So, I think there's, and if I'm reading too much into it, just stop me, there's the concept of intended use when you have two benign objects get connected to make something bigger and as a part of a bigger system, or two very deadly objects when you connect together just becomes totally benign. I think you can have the scenarios that can occur, I don't know if it's getting at that, but, I'm just going to put it on the table for people to react to, to think about when you have the sum of all parts create a different risk profile when you – when as opposed to being on its own.

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

So who's next?

**M**

Go ahead.

**M**

I think the scenario that we're trying – if you have a weight scale and you're using it for itself, it's not a medical device, it's not subject to regulation any –

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

You know what, let's switch examples because I think we're spending too much time on something that people have a pretty clear understanding. Let's talk about a pharmacy system and an EHR, so now say what you're going to say.

**M**

– because regulatory decisions tend to be made on the system rather than the components. So whatever we're talking about, you take a component that is unregulated, make it an integral part of a system that is being used for disease management, health authorities have an interest.

**W**

So, I might be reading a different dimension in this. I'm actually thinking that when you take two systems of any sort, two engineered systems, even when they're manufactured by the same – or even designed by the same company, but two different – my experience, and this is a – experience, you have very unpredictable outcomes. Sometimes they're completely fine and there is no – sometimes you have very unpredictable – and it's not – you cannot predict the performance and safety profile from the independent safety profile and design. It's just...it's been my experience. But I would argue that I think you bias towards the assumption that it would more often increase the risk. I think it's unpredictable and maybe by virtue of its unpredictability, that puts it in that higher category that you –

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

Final comment Jonathan, we'll move on to the next –

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

I shouldn't be final. But, in the consumer electronics world where I come from, we think about accessories, right, and accessories are so often plug-and-play. And we've talked about whether it's a device we talked about yesterday was simply an accessory transmission of data back to a pre-approved device, right. So, is a dongle simply an accessory that makes the collection of the information that is then just transmitted over to the already approved device or is the iPhone being used simply as a transmitting device. So the dongle is my electrocardiogram, which just delivers it to the iPhone, which delivers it back to the laboratory or the hospital or whatever it is with the big device is reading it. And in that – in the context of an accessory, which has a limited purpose, I think the regulatory issue, the risk issue is does the accessory work correctly, is it transmitting accurately? If the system breaks down but it isn't the accessory, that's obviously an unintended consequence and should have been checked, but I don't think you have to judge and regulate the accessory based on the system itself. So, if one of the Class 1 or Class 2 or Class 3 is the accessory necessarily the same level of regulatory review or is it simply is the accessory doing what it's intended to do?

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

I'll give a counter-example, because I was – of what you and Mary Anne spoke of, so we had an accessory, we had a conduit that's supposed to transmit from a device, a regulated device to our EHR and it –

**M**

Did not –

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

– wrong data it started filling up our records –

**W**

It actually changed the data –

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

– it changed the data, and they were not regulated, so we had no way to – we could only beg them to look at the situation. So, it's something I completely did not expect to happen, it's a conduit and now we have that data in our EHR. But anyway, so let's move to the third one which you all were anxious to talk about and I have three minutes, because I'm – we're honest with each other –

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

Paul, can I make probably a very bold statement and probably overstepping here, I'll feel you, in this morning's conversation, a lot of people are focusing on the end-goal of where the regulations would be, can I ask you guys to stop that?

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

Yeah.

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

I'm saying it bluntly because in this group, I would really ask you guys to think about, when you come up with these examples, when you come up with these dimensions, think about does it really matter to the patient. And if that is not – if you guys cannot come up with an example that it matters to the patients or not matters to the patient, then we should probably not talk about it. Let us get to the – I'm really feeling that we're talking – spending a lot of time about assumptions, maybe false assumptions, that we intend to ask for 510(k)s for all of these things, no. Can I say "no" more clearly? No, the point here is health IT, we get it, we all get it. Steve's here, ONC gets it, FCC – it's different, we get it, we need to figure out what's different, we need to figure out where the risk points are, we need to figure out what those risk points actually do and then we can talk all day long about you know, what's the best approach to go about doing it. So, I just wanted to get it off my chest.

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

So Jodi and Bakul, is that it? Let's – okay, we're not in the regulatory, we're not writing the rules. They have all the stories they need, literally, and they have all the flexibility. So that's sort of the main thing. So, the one that you wanted to talk about is waiting. Are any of these, we've had some challenges of whether something really is at the top and we've had something that says, should be subsumed by something. Are any of these five standouts? Are any of these five trivial? Thoughts.

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

I mentioned earlier, I think the first two are head and shoulders above the rest.

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

Okay, that's the green and blue cluster –

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

Oh, no sorry, the first green cluster.

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

The first green cluster. Okay, so you think they stand out.

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

I agree with that, Jared, the first two.

**M**

I think definitely.

**W**

I say first three.

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

First three colors or first three –

**W**

The first three rows.

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

First three rows, okay Michael.

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

I think I disagree, I think the second block of the blue ones, which I'm sorry, I'll assume what the reg – if there's a calculation that it does to determine risk, I think that would wind up being the most important thing, is whatever came out of that, which would subsume all the rest of them I guess. Because you could, I mean, even if it's whatever high risk in one of the first two, but when they do the calculation it's fully mitigated and the real risk is zero, then who cares, you know, that one.

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

So the flip argument, for the exercise, would be – would it be possible to actually not do the second part if the first is low enough? So, I –

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

I don't think – I think you'd still – I think you'd still have to – well –

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

– you would, but today it takes five minutes, right. I mean because this process already exists with the FDA. I mean, you already go through that blue block today, any – a Class 2 or greater, you're going to go through that block anyway, severity, likelihood, all those –

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

Go back to the patient –

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

– I believe that is if the devil –

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

– user, like Meghan, of these complex systems and all of these have caused us potential or actual harm to patients because of these dimensions, so I'm more aligned with Mike in saying these are really important things to think about. And all of them obviously past this one, clear to me, it's in EHR, we're supposed to use it – but, it's all the other things that got in the way and caused very strong –

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

But that starts with the assumption that it got to you, and the reason I'm trying to put the first one out there as the first thing is, I think it's a whole class of things that should never get to someone like you.

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

I, I –

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

They're never regulated. Are you going to take the steps from my FuelBand and do anything with that?

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

No, but the things that do are appropriately being used by the right intended people are posing risks, not deliberately obviously, it's because of a lot of the things that are covered in those dimensions, and we just –

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

I agree, I'm just saying in the whole scope of things, it probably shouldn't get to that point.

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

So you might be using that in the algorithm saying, if it's a steps calculator, then it never has to go – so, you might be looking at decision tree –

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

Then we agree, as long as it's up front, I'm – so we already agree. It may even echo one of Bakul's points; I'm glad you went first. And you didn't tell me to mute the phone at the appropriate time, on the record – so, I think, at least for me, on listening to the conversation already is, there's not a presumption that we would be regulating something. And so maybe what we're talking about in terms of what the level of – as an outcome, what the level of oversight we expect would be. And that I feel like is what folks are – like in your situation you would say, an accessories should be – the level of oversight over an accessory should be “X” as opposed to a – device would be “Y,” which would be greater. And that's the type of outcome that we're struggling with, I think, juxtaposing with the levels of risk, is that at the end of the day, I was kind of trying to draw on my own little signature here. At the end of the day you come up with a level of oversight, and it may be no federal entity does anything, and Drew's not here, but people depend on Drew and Haptique to do something to them. And that's the level of oversight that – and I'm looking at it from the perspective of, at least the 3 of us here, I'm pointing to Bakul and Matt, at some point will translate this into some form of writing into a proposed strategy and risk-based framework. And the risk-based framework to me is at least the levels of gray of oversight that are applied to your different scenarios.

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

Okay, so I'm going to do the do unto others rule, and so I want to make sure that the same amount of time – so –

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

Give your partner – give Mike his –

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

If you set aside the potential risk as a comp – from a patient's perspective, if the company's done an excellent job of building in a diverse and redundant control mechanism, and done the verification and validation testing to show that no harm will come, even though it is a really innovative product which had been – if they hadn't done that, there wouldn't be harm, well then there's no risk involved. So, while it's not on the table, it's diversity and redundancy of those control mechanisms can overcome a lot of potential risks.

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

I agree, I would totally agree with you Michael. I mean, so that's one-step again towards closer to the solution of what risks exist or don't exist and what controls exist to control those risks. So, one thing I noticed, and I'm going to shut up right after this, is, some of the – in the table, I saw risk identifiers and risk mitigators on the same line items. And I was confused by the fact with the traditional way of looking at risk as saying, and where's the risk and what mitigates it rather than thinking about here's some lists of risk that could occur or sources of risk, you may think about, and then here are some mitigation factors. Maybe a way to slice it is think about where the risks emerge or could potentially emerge and think about where the potential mitigations either are in place or are doing redundancy or whatnot, other things. And then whatever balance comes out of that would be something that you could recommend as a control that, oh, that's not been done consistently or that needs consistent, or I'm just giving you an example. So that may be an approach to think about as you think about the likelihood and the consequence and then think about what the mitigation factors could sort of solve those consequence.

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

So can I just clarify. Did we move toward a weighting system or, I heard two different things? I heard that there were some that were some that were greater than others and then I heard that they were all equal. Is that –

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

I don't think there's consensus about diminishing the number, but, that's what we have to talk about further and it would be lovely to get some more input from the rest of the workgroup. But, we didn't have consensus here, that's clear – if anybody disagrees –

(Indiscernible)

**M**

There is time tomorrow, too. Because tomorrow, as David mentioned, is somewhat unstructured, so if this is a salient point that we feel everyone should have an opportunity to discuss in depth, lobby David to have that as part of the agenda tomorrow.

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

So just going back, this is Keith Larsen. Going back to your last comment, I mean, the thing I struggle with this discussion is we have a matrix to assess risk, as you point out Geoff, it's quite a matrices to assess risk. Okay. So what's different? Okay, so on one hand we're not talking directly about regulation, okay, and especially not in a binary way of regulate or to not regulate. So, if we're looking at the risk, I mean, what is our added value of even having a discussion unless it's to say that here's a risk and somehow correlate it with an approach to regulation, not necessarily the regulation itself, but an approach. Again the idea that if something, and it's kind of like what we were talking about before, is that if I have something that could harm the patient, could happen and – but the way I mitigate it is not to – I mean because now I throw the regulatory levers, right. So I'm going – am I going to pound the manufacturer with good manufacturing processes? Am I going to make the risk transparent to the intended user so that they share in the risk and they're a knowledgeable user? Am I going to certify it? There are a lot of different levels and I think that maybe our work product is not just the risk of what is the most – what's the appropriate way to address the risk, not with a specific regulation, but the regulatory approach.

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

Right.

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

Do you agree with that?

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

Yeah. I want to know where the risk arises, what are the causes of those risks and then we can – you guys can talk at length about what should be the best way to control them. And maybe there's no control needed, buyer be aware or whatever the –

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

Or maybe the control is –

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

Or is it – yeah, sometimes it's just noise, you can't –

**W**

What we talk about doesn't seem practical or feasible if you're talking about data that comes from patients or families, it's inherently incorrect or there are just sources of data that aren't correct and so some of what we talk about as risk, it isn't going to be feasible to mitigate it.

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

Right.

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

At least that there's some – you address it in a completely different way. Because again, the easiest way, and I was trying to make this point this morning, the easiest way is to attack the manufacturing process.

**W**

Not necessarily.

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

That's a way, it's not always the case.

**W**

That's one way, it could be –

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

No, but you have a pretty good control of it is what I'm saying. You don't have control over which tools the particular user picks up and uses together. So if you look at it where you have control and where you don't have control, and yet, you may be introducing risk, like you say, you combine two things and all of a sudden they're lethal or they're even more benign. But – so how do you make this system sensitive to risk, making the right people sensitive to risk or respond to it.

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

This is Matt Quinn. One of the things that – I think that there are more sources of information on what's actually happened in health IT and specifically EHRs, and we're thinking about it. I know that IOM spent a lot of time thinking about this, there's evidence in – reports from over the years, there's evidence, ECRI did work for the state of Pennsylvania, and the sources of error are around human error or use error, human factors, workflow, patient identification, I mean, there are big buckets of these that are known. And then, that's on professional use type stuff. On the other side, there are probably – what are the sources of information we should be thinking about for consumer use type products, and that's a whole different dimension. But maybe part of this discussion should be what are current sources of information, how can we enhance those to inform current what we think are risks and what they could be, and then moving forward so that there is transparency. So if, for example, human factors issues disappear with user-center design or whatever, and they no longer become a focus, maybe that – and other areas emerge with something else, that we would have a feedback mechanism to support that. So, each manufacturer currently, for example, has a call center – reports, each hospital probably has one, too.

**M**

I'm trying to think of this whole exercise in terms of what the final output is going to be, in terms of – it sort of seems to me that if we're not prescribing particular regulations, which we have been cautioned not to do, and warned not to do – what we really –

**M**

The lawyers are listening, stop.

**M**

– aren't we talking about prescribing types of approaches, types of analysis, what approaches to analysis, isn't that actually really where we're trying to go here in terms of where this report is going to – because we're supposed to give factors, not regulation. So what is the proper approach to assessing risk? What is the proper approach to any of these valuables? I think that's kind of the direction where we're going, isn't it, or am I wrong?

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

Yeah, I don't have a particularly clear view of that either. What is – for the people who are in the room, who are going to be actually writing something based on whatever advice to give, then what would your ideal outcome of this discussion be?

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

So, this is Bakul and I again say, to some degree, if I was trying to create a framework, I would like to know what's important, like, some – can I use the analogy of – is really horrible, but to just say, I want to make this cup and the people say, it needs to hold 8 ounces. I need to know 8 ounces, holding 8 ounces is important for the framework. I need to know that. I need to know, patient safety issues are happening in this area. Innovation is needed in this area. Need – people need to have whatever, redundant systems, people need to have X, Y, Z, those are really, really important. If this group came back and told the feds that, I think it would make it really, really useful for us to go, yes, we'd better think about a way that the framework captures those important things. I think that's really key. And so for us to talk about how – because all the current systems don't work in our work, that's why I'm not very interested because it's not telling me what's important, you're just telling me there are issues with the current system.

**M**

So, feedback loop, right. Everybody who's doing HIT should have a feedback loop, it should almost, I mean, from a marketing perspective, if I was an investor, if I was program – a product developer, I would want it. But from a regulatory perspective, it's critical because that's the way problems surface the quickest, is through the feedback loop to the trusted source, which is usually the manufacturer. And sometimes it can be automated, right, the exception reports could not only kick out to the provider if it's provider-based thought, it could kick out to the manufacturer. So then I would ask you and others who are more practiced in this, what's the right way to make that feedback loop actionable, right, is it important – I used to do CPSC work. And in the Consumer Product Safety Commission world, I'd get a phone call from a general counselor of a retailer who'd say, we got three complaints, one might have been an actual injury, of course these are people who touched – do I need to report this to the Commission and to rat myself out? And the answer was always, forget about the law, in fact, forget about the Commission because they're a paper tiger, they've got nothing, what they've got is the Washington Post. Do you want to read about it in the paper, or would you rather get that sign up preemptively at the display counter that says, hey, by the way, we're recalling this product and we're going to lean on the manufacturer and things like that.

So the feedback loop then becomes, what do you do about it. They got complaints, is it that the agency wants to be able to improve the situation, does the agency have a tolerance for innovation and for the feedback loop and the product iteration. But the agency says, we don't need the feedback loop for purposes of enforcement against you, we need the feedback loop for purposes – or we, the community, needs the feedback loop for purposes of patient care improvement. Which means, get the word out that there's a problem, which means, don't fight with us about whether you're in trouble, work with us to get the word out. And how do we – and is there a safe harbor, for instance, I would argue that as a, I used Microsoft as a joke before, but we all talk about it in the software world, right version 0.1, right. Most product manufacturers have never in their lives had version 0.1 or 0.9 and announced this as in imperfect product. But in software we do it all the time because we have a very rapid feedback loop and a very rapid release schedule, it's not just once a year any more – QuickBooks 2013, no its QuickBooks January, you know, and it's constantly – loop. And I do QuickBooks on the web that's for every business I've ever run, I use QuickBooks on the web. And so the feedback loop and the iterative process of the product, how can – I mean, that's something that I would think is critically important to know and whether I'm going to hide it, whether I'm going rat myself out, how I'm going to discuss it with my customers. And are you going to be a trusted partner by accepting that innovation leads to, what's the right word, failures, right as we talked about in the other room, as Lauren talked about, and that failures lead to success. So there's a –

**M**

Right –

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

So tell me if this is helpful, this type of – way of thinking, and I know it is only addressing some of the categories that's health IT, but in my experience as an end-user I found that it's really important to be able to configure a system to my unique needs, to my unique workflow. So, it ultimately loses a lot of its value and its functionality if I can't do that. But that's what makes it so difficult and that's what makes it so different from a traditional medical device in the traditional risk framework, which is that it's much easier to manage risk around something that has one design and with the exception of a material failure, it's probably going to operate exactly as you – factoring in there is a real limit to how much you can change that. So, the challenge here is, there is this paradox that to make it effective for patient care, you make it so di – you make every one of the single products so different it becomes really difficult to a priori know what the dimensions of risk are. So that's, I think, why –

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

So what I'm hearing – this is Bakul – what I'm hearing is, it's important, and I'm latching on to what's important here, it's important for users to configure the product, I'm not going to use the work customize, configure the product to make it useful for their scenarios. I think that's a great thing –

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

That's a reality, if we don't – that –

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

– that's reality.

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

That is a reality, and yet, then what it means is, you never have one product. Every implementation is a different product –

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

– including the platform –

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

– and so the framework has to address that.

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

No, again, I think it – again, I think this is interesting. I like where we've started off again is, what is our final work product and why does it make a difference, right? Because I was trying to struggle with risk and innovation, so, taking over a little bit the privilege of being a co-chair, I guess, what is our final work product in regards to innovation. I don't think these are separate things, because again, if I take what you were saying Bakul, is that what are we trying to preserve? Which things should, when you consider regulation, do we want to preserve in the innovation space while we're guarding or addressing risk? Is that a right statement?

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

I think we need – so, I may twist your words a little bit. We want to preserve innovation because it – we all recognize it's needed and necessary and better for healthcare. So, for me innovation – risk is a thing that you can easily wrap your head around and sort of manage it, mitigate it, transfer it, etcetera, etcetera, right? Innovation is a sort of antithesis of risk where you may – you may not use traditional tools to mitigate or manage, but you may. And I'm thinking out loud now, you could think about for products to aerate quickly, you use sort of the feedback mechanism or the post-market mechanisms or surveillance to say, deal with not the norm, but deal with bad actors or special causes that may create patient issues. So bring patient angle from the innovation perspective, what – because as you know, we can't argue innovations as good or bad, right, it's good. So let's figure out when innovation goes bad how do we manage patient safety.

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

Okay, but it is printed – it is turning it around because at first, I mean, we're to address it two ways, one is that what we're trying to do is define patient risk –

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

Right.

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

– which leads to regulatory intervention and do no harm to innovation.

**M**

Right.

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

Or what we can say is a guiding principle is that we want to have innovation because we believe that in the overall, not in a particular instance, but overall, it's going to actually give better patient safety because we will address issues that – in medicine. And so if we turn it around that way and say, what we're trying to do is do safe innovation –

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

Right.

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

– okay, which is a different way of saying, how do we regulate this to be safe and not harm innovation, we turn it around and we say, how do we do safe innovation?

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

Right.

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

And so what are the things that are important to us in innovation and then how do we mitigate the risk issues so that we're not increasing patient risk, but preserving innovation. It's the opposite of –

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

Different way of thinking, yeah.

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

I mean – another thing just for a second, because one of the things that you kept saying too is that – or I've heard is that we're not tied to the current paradigm. It's not whether to apply the medical device – what things to apply the medical device thing, which is where we get expansion or contraction of a recurrent paradigm, right.

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

Yeah, but I – this is Bakul, this is for folks on the phone, when I say current paradigm, we have this classic system of Class 1, Class 2, Class 3 –

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

Right.

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

– let's not talk about that. The underlying systems – underlying tools that we have in place, like somebody mentioned, the – system regulation, the correction and removal notification to the agency. That doesn't say that the vendors cannot do correction removals, it's just like when you cross at the second threshold, you tell the agency so they can alert others if they're having the same issue. I mean, those are the kind of fundamental things that are in place, you have a good complaint-handling system that is very benign, but it's very powerful.

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

Right.

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

You need to be able to answer to your customers when they come back and they have no recourse to go anywhere. I mean, look at those tools, I mean the certification that ONC offers has similar powers, so take away what's the big shell –

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

And it has similar impact in innovation –

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

– so take the shells away and look at the tools, the conformance of that, and understanding that it's different, it needs sort of a different way of thinking, so fit it in. And then say, that add – we have a risk in this area, innovation needs in this area, this – if you put two or three of these together or one of this together, you may actually get a better outcome, so you can move the needle. So, think about it from that perspective is what I would suggest.

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

Well and Mary Anne and I were just talking about this a little bit on break and kind of thought about it this way is that we have kind of a legal framework right now, and if we're talking about frameworks, it's really focused on regulation, meeting the regulation. Even like you mentioned with ONC and certification, I mean, whenever we go through a certification, or try to, imagine if we're going to be successful or not with that certification, it's a very legalistic discussion, okay. Will this meet the reviewer's guidelines? Okay, and you get a lot of this compliance innovation, which means you have a lot of activity with no movement forward, its sideways movement. And then, how do you change this around into more of a learning framework, because with a legal framework you have prevention of known risks, but you have to know them, it's kind of like Paul and I were talking about, it's the underwear bomber approach to risk, right. Some guy shows that – on his underwear, now we all check our underwear, okay. And until they come in hats, then we'll have a hat bomber and then we'll respond to that.

And it's very prescriptive, it inhibits transparency because like we're talking about with the reporting, why doesn't everyone report? Why do some of these companies put in fact clauses that say, you don't talk about what you see? Okay. I mean that's – they're legalistic, where if you flip it around, say, can you get a learning framework where you have open transparency or the sharing of knowledge, it is an acceptance of risk pattern and – but the shared also accountability for the risk. Go ahead.

**M**

I think Jared was before me, but I wanted to make a point.

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

Kind of lost the flow – when I originally raised my hand, but we'll get back to it because –

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

Thinking about what we want out of this, or at least what would sort of gel for me is an understand – for this group specifically is an understanding of the sources of risk and causes of risk across the spectrum of the taxonomy, so, because it's different, and across these dimensions as well. And then approaches or ways that currently exist or could exist to measure them, so that we can learn from them both pre-market and post-market, and then, to think about those sources or causes of risk and mitigating factors.

I'm not talking about regulations or rules, but ways, if you're an organization that says, hey, we're having – people are misusing this or people are turning left instead of right in this tool, what are mitigating approaches that are grounded in evidence and experience. So, for example, things like the Joint Commission, things like training, things like – I mean, there's a whole array of these things that are grounded in evidence that – how do I develop software that doesn't have bugs? Well, you do QA. How do you make sure that people can use it? You do usability testing? These are approaches that – and it's free of regulation. And then once we have those mitigating approaches, the other group, with our help, can think about levers or approaches to ensure that they're applied. And some of those could be regulation, some of them could be voluntary, some of them could be somewhere in between. And does that sort of frame – I think that would deliver to us something that would be actionable and much easier to write than –

**M**

That's where I was going with safe harbor idea is that the business process that happens in the software companies and the app developer companies is built around frankly sometimes putting crappy stuff out on the market. Now obviously in the healthcare world we shouldn't be putting crappy stuff out on the market, and it's never, of course, really crappy, but we know it's not as good as it's going to be.

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

– it's going to be when it comes out, right.

**M**

And it's amazing – how long did Gmail – data, right? It was like two years, that's a little – Google's on my board, I should be gentle, but it was a long time. And so, whether it's version 1.0, 1.2, how you iterate, do you make a grand announcement because you're so proud of the new features or you – I mean, how many times do you get on – it's often with Microsoft with the OS, where you do the weekly whatever's, the updates, and you get critical, install this one now. The question is, is that a red flag that's going to create pressure and oh my god, the lawyers have to get involved before I put out that critical alert or even that not critical alert. Or is it going to crea – or should we do it, because that's the way we do it, and is the agency going to be our partner in saying, oh yeah, get it out, if you figured something out, go, go, go, fix it, hurry. And we're with you and we're not going to shoot you when you fix it.

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

What would help us as users, this is Mary Anne, is transparency in testing –

**M**

Oh yeah –

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

So I have evidence of your testing, and particularly, I have to speak to my colleagues in pediatrics, things are not tested in pediatrics, but we use them in pediatrics, and we don't always get the wording that we shouldn't use it in pediatrics. So we actually have some FDA devices, sorry it's not the approved devices, that are causing harm, but because of the way we're using them in pediatrics, and there's no alternative –

**M**

Are they connected?

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

They are not.

**M**

I mean, that is beauty of connected devices, right, is –

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

Right, but they’re standalones.

**M**

The source of this –

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

So adequate testing, I mean, just going back to Meghan’s point, of transparency and evidence of adequate testing.

**M**

Well I can’t tell you how they approved it without adequate testing, but that’s a different story.

**M**

They approved it, not for pediatrics though. I mean –

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

That’s a separate use case, Matt. So, I go back to we know what some of these sources of risk are. Jim Walker’s ARHQ Hazard Manager Project. ECRI did a great study with the state of Pennsylvania. We have MOD reports, we have the IOM research; we have lots of stuff that says, here’s where there are problems, are there other sources of data to fill out this whole taxonomy of systems and these different dimensions?

**W**

So, I have – we should get it out there because reality is that the manufacturers of – and I’m speaking too broadly, the manufacturers of the systems that go into hospitals, high volume, a lot of critical and complex things, their complaint database has way more data than the public is even remotely aware of. So the issue there has –

**W**

Same thing with the devices –

**W**

– it probably is, but I’ve less – experience with that, and so that’s one of the special issues around health IT is that the recent history has shown that there seems to be a barrier between the knowledge that the manufacturer gains from the complaint-handling and the ability to disseminate that or the willingness to talk about it publically. And that’s a problem.

**W**

Yeah, and maybe that’s what – I kind of liked where we were going before and think of it an amalgam of a variety of different things, but Keith I think articulated it probably most clearly is, what do we need for innovation to work? And then think about that within – what – I mean, we know a lot from other industries as well as healthcare, what are the things that make innovation happen? Because innovation ultimately, whether it’s small innovation or big innovation, it’s going to be better for everybody – pardon?

**M**

Business model –

**W**

I wouldn't say a business model, but what are the things that we know – data standardization, standard interconnectivity, whatever the case may be. Rapid prototyping, rapid testing, feedback loops, transparency on mistakes, ongoing updates, etcetera, etcetera. There are people who've looked at this and who studied it, what are the parameters that we need within – for innovation to happen and then pull back from that and say – I mean, and I'm not the regulator. But pull back from that and say, okay, of all of these things that are out there that we know need to happen for innovation to thrive, where are the elements of risks that warrant a regulator stepping in and saying, we need to provide oversight to this part versus that part. It just seems to me like a much more practical way of addressing it.

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

I'm just going to add a little bit and then I'll yield. I think don't, when I said think about innovation and risk as just an example, as maybe opportunities for the feds to look at those needs for innovation to happen and say, this is where we create a different definitive need –

**W**

Right.

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

– also, so it's not about patient safety only, it's not about risk only, it's about, can we create a need for a spot or an area that's – that could be a regulatory way of sort of saying that here's a way we can promote.

**W**

Right. And I'll say – go ahead.

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

Well, I'm just doing a time check, because Paul's kicking me. He's the bad cop, I'm now making Paul a bad guy. I'm just looking at my –

**M**

I'd like to just add another comment and then it leads to a question. So we've been talking a lot about commercial innovation and commercial products innovation and maturation of an organization to manage a product in commercial availability. There's a lot of innovation that happened from the groundswell, there are organizations – there are software organizations hiring their own application engineers, their own – to develop products for the great space of what they see need to be successful moving forward, collaboration, physician to physician collaboration, physician-to-patient collaboration. Is that in this too? Is this going to be a part of it? Is this a regulation – define the risk there?

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

So does it – represent risk?

**M**

Because that's the speed that innovation is using.

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

We had it on the scope meeting, remember it had developer and I said the developer might be a healthcare provider.

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

No, and I come from a healthcare organization, we've always done our –

**M**

Absolutely.

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

But let's switch that to what Bakul asked us for, which is it would be important for us to have the ability to iterate on small scale and tests for user experience. It would be important to include patient in that process. There's a ton of gray area in both of those places right now. So from what you've – what I understand that you asked us for, those are the first two things we should be writing down, which is, it's probably important that the regulation allows for those things, and it is probably important – and I'm putting probably because I'm also using the word regulation, which I know is giving you hives at the end, but –

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

I'm getting them anyway –

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

– it would be important that we involve patients in that process as well. I mean, the whole reporting on a pure consumer standpoint –

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

I think that you are totally spot on, but it has to be flexible enough, because the current model is quite cumbersome, meaning, you have to apply for permission to do and invest – what really you're talking about is an investigate or an experiment really.

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

Sure.

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

Yeah, so I think that you could make a strong case, and in many cases need more flexibility than the traditional approach –

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

So I think that's where – if we can all agree as a group, because if anything's obvious from the phone call and all these things it's like driving towards consensus through conversation's not going to happen. If we can get to a list of these five, six, a hundred and six, I have no idea, of the important things and then say, we think an organizational IRB is enough, right, at a certain scope. We think here are some things where we think it's not flexible enough, that we could start to drive to things that we could probably get closer to agreeing on. So, on everything, there's nothing that we've talked about that doesn't exist today, right, there's risk frameworks, there's all of the others, scoring for example –

**M**

Consumer reporting –

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

– there's consumer repor – we've done them all, right, everyone around the table has done one or all of these things. So I think what we need to do is drive to here's what's important, at least that's what I'm hearing for, and then here's what we think we might want to see be better. So I think your comment is spot-on, which is, I think that's the next level to drive to is. If we think it's important organizations can develop their own stuff and do like Naomi's doing in Boston and stuff like that, and we think IRBs are great, we think this isn't great. We think here are some things we think or we think it's important this is more flexible, might be the framework for us to driving to meaningful feedback versus this consensus like conversation, we're just not going to get anywhere on the path that we're on right now. So, I'm going to steal your framework and just so we can start with what those important things are and then drive with they're important and today's good enough or they're important and – because there are also places we might say, this is important and don't touch this, this works, here's some feedback on that –

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

And you may want to add, if there's no patient risk here –

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

– no patient risk, important, don't worry about it, yeah.

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

– you have no need to touch it, no need to promote it, no need to control it, good as is. So, that's good to identify and mark it up, too.

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

But even if there is patient risk, I mean, it goes back to this feel of governance, as we do – I mean, my own experience is we do a lot of our own development. We value configuration, we value that we're going to be able to put out decision-support modules tomorrow, that we thought of today. And that we – but we have a process to gauge patient risk and to mitigate patient risk and to look at that as a local level rather than a national lever is – and have it recognized as a method. A canonized method is really a network, because again, it says that you're meeting the need, and I tried to list the things as people are talking about, the need for turnaround time, but also meet the need of safety. Because no one's saying I want to innovate at the expense of patient safety.

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

Right.

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

Okay, so, I think we should assume that everyone is good –

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

I think we invented that a long time ago, called IRBs and –

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

Yeah, yeah, yeah. So, better use some of those things.

**M**

The innovator also needs to know that there's a clear, predictable way to get from point A to point B –

**W**

Exactly.

**M**

– that balances patient safety, also encourages innovation. That balance is very important to be struck, if that balance is not struck – kill innovation. I've heard this from a lot of companies.

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

But it doesn't have to take a long time. I mean, one of the use cases that I threw in the slides is, I had some interaction with the people in Hong Kong. When they had the SARS epidemic, they had something – a problem that they didn't have anything – that hit them from left field, okay. And you had, in this space – a short space, and I can't remember exactly, it was like weeks, they connected all of their hospitals, they were sharing information and they were collecting information about the epidemic, because they had to do it. And so they obviously had to – they had a process to create the software, but they didn't necessarily make it a barrier, they were able to innovate and address that problem and respond to their problem and start directing their resources.

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

To go back to the – approach, we can assume with perfect 20:20 foresight that things that we don't perceive are risky, especially in the hands of consumers, are. But I mean, let's just use a couple of examples. OxyContin was released, who would have thought that people would grind it up and sniff it? Or recently, who would think that someone would drink an entire bottle or two of cough syrup, mix it with Kool-Aid and get high off of it and Lil Wayne almost died, right. And so, these are examples where a consumer product is different –

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

You're supposed to say your name before you talk, because I want to make sure – of Lil Wayne –

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

But, I mean these are examples and the reason is, there needs to be a different framework for feedback for all of these data sets so that we could say, oh my gosh, people are now hacking into these systems and doing something that's not anticipated and is now risky. Versus the absolute need for better transparency about what's going on with not just individual products, implementations of those products, combinations and permutations of those products, in the professional marketplace. So think about this as a data-driven approach to understanding risk and then thinking about what those buckets of risks are, that we discover how to mitigate them and then think about regulatory approaches or not.

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

If I may, this is Meg Marshall. I think one comment that I'd like to make is essentially the group is moving toward an industry standard around the manufacture of health information technology, and if I were an innovator, and I do hear this. And I do emphasize, that if I'm an innovator, I'm going to be very concerned about my potential risk and will I be defending this product and the sales in a tort case. Or on the other side, if I'm a user of the product, do I need to pursue a tort claim on this. So traditionally, that builds up over years with case law and others, we're trying to approach this in a very accelerated fashion, so the more – and the more data sources are definitely very helpful, but it doesn't necessarily mean that there has to be a piece of regulation or a piece of legislation behind it. It's all, I think, moving toward and documenting what that industry standard is. So, in regards to the innovative product, I would welcome that type of a guidance, it's not something that I would shun away from and I don't think it's any additional – not necessarily any, but I don't think it would be an additional cost, I think that that would be part of doing business.

**M**

It's the trade-off between the understanding where the risk lies, the mitigating factors and then the next step, which I think is the collaboration between this group and the Regulation, in saying, okay, so the mitigating factor for reducing, I don't know, manufacturer error, is that everybody who wants to manufacture health IT has to be a – has to do ISO 9000 and this and that and eight other things, which is going to impact innovation. Those are the sort of trade-offs that are – should not be part of this discussion, but should be part of the next step. Unearthing what those risks are and describing them and thinking about a way of pre, during, post, across the lifecycle and across the taxonomy is where we should be, I think.

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

Well, this is Anna McCollister-Slipp. I mean, toward that end, I mean, just as somebody who's again, approaching this with two different hats, one is a Health IT entrepreneur on the big data side, but also as a patient with type 1 diabetes with four different medical devices and a whole bunch of consumer stuff that I use. The thing that matters most for me and for other people with complicated type 1 is patterns and seeing data from all of these different devices come together in one spot. Nobody does that because everybody says it's FDAs fault or it's HIPAAs fault. I mean, the current scheme, and I'm not blaming FDA, in fact, support people who answer my telephone call on the technical support line frequently get informed that it actually is not, in fact, FDAs fault, but it's just the companies decision and they've been told to say it was FDAs fault. But, the companies use FDA as the default reason for not doing simple, innovative development. So for instance, I have a continuous glucose monitor can only be downloaded using a Windows platform, I have an Apple. So, I have to go out and buy a Windows operating system, install it, much to my great chagrin and sorrow, onto my Apple, and then run that. I mean, without that, then I have no access to any of the long-term data; they blame FDA for that, I kind of think that's a crutch.

I mean, I can't find a straight answer of somebody who knows a couple of people at FDA, knows a couple of people in the industry. Now I use a pedometer as an activity monitor, accelerometer, one industry person said they wanted to attach one of those to a pump so that the two would be integrated in one, they said FDA would not let them and something about FCC. I don't know. I mean, there's so much lack of transparency that everybody is afraid to innovate. I mean I looked at the possibility of creating a dashboard as like my spin-off separate company, just for me and other people like me who want to look at all these patterns together so I can make my own decisions about my own treatment. Nobody really will go there or do that and invest in it because it's so murky. So, I don't know what the answer is, but I can say that the current environment, whether it's FDA's fault or not, is that – or FCC's fault or whomever, when it comes to interoperability is that it's not happening, and as a result, we get lowest common denominator interfaces that ultimately don't meet anybody's needs.

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

I blame Lil Wayne, first of all, for that – but, so, I think that –

**M**

CNN.

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

Yeah, Matthew Quinn –

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

(Indiscernible)

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

So I've seen the crutch thing as well, I mean, we've got a couple dozen investments that are – that do that kind of thing, but I've also seen people use an excuse, I've seen both sides of that. But I think this brings up one of the things, if we're going to talk outside the box, if we're not going to talk about regulation, I think one of the interesting things we should be thinking about on the innovation side, is are there economic levers that can be pulled. Because there are a lot of people at this table, you're – people on your team are living it every day with carrot and stick with the EHR. Because there was a statement said earlier like, well if there are problems, people will solve them.

Well, that's not totally true, because most of those problems don't have good business models behind them, they're not financially interesting, right. We've got half a dozen companies that do the dash-boarding stuff, nine of them will die and if you count the math, that means I'm counting on three living that just are also going to die. So what are the economic levers that we could talk about in this group to say, hey, here are some things we think are important that are innovative things that we think could – that could be done. And we might just ask for, because there's more than just three parties at the table, the economic levers that could be pulled through all kinds of grants, through all kinds of different vehicles. Or even just saying like these are problems we want solved, maybe doing it the way Todd does it, maybe doing it the way Farzad does it, there's a whole bunch of different things that I think should be on the table for this group, especially because there's innovation as part of this group, to say, it's not just regulation, it's boy, are there other things that are models we could get from Green text? Are there models we could take from existing just health data about economic incentives to solve some of these problems or to highlight them, like the creation of the registries for some of this? Yeah, safe harbor things or stuff like that, might be another way to approach it rather than just carrot and sti – I mean rather than just stick, but also carrot.

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

I do need to call time. We're going to give Geoff the last word – so –

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

– by the way – Matthew. My mom might be listening –

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

So, incentives. Does anyone have a final comment because I guess we're being called together by –

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

Keith, I didn't want to lose Anna's comment here. I think, and I'm very tuned to reading behind the scenes what she's driving at, really asking us – asking the system whatever system we end up with, to create some sort of way to, and I'm being very tactical, some sort of way to capture all the – requests that comes and becomes very public, that it doesn't become the least common denominator. I think that's a good way for us to think about. I don't know if you were hinting that, but I think that's what you were going to, I called these people, they hear me but they try to blame somebody, FDA included, but really if we removed – if there was no FDA to blame, what would really happen? Would it take 12 months to come up with the next iteration of the products or one week, how important it is? If there's no business need, will they let you do it –

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

Well, and that's right, I think that sometimes the FDA, if it's – HIPAA – because they don't see that there's business here.

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

Right, but if the system created the populous to tell everybody that this is needed, I think it educates everybody in the cycle.

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

Right. If you just create, this is what it is, it's very clear, it's very obvious, then I as a patient can go to my CGM manufacturer, huh uh, there's the rules, you guys aren't doing it because you don't want to and create a movement to get this CGM manufacturer to do it.

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

That's another way of looking at regulations as a feedback loop to think about –

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

Exactly.

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

Okay, than you everyone.