

**HIT Policy Committee  
FDASIA Workgroup  
Transcript  
June 14, 2013**

**Presentation**

**MacKenzie Robertson – Office of the National Coordinator**

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

**David Bates – Brigham and Women's Hospital**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, David. Patty Brennan?

**Patricia Brennan – University of Wisconsin-Madison**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Patty. Geoff Clapp? Todd Cooper. Meghan Dierks?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Meghan. Esther Dyson? Richard Eaton?

**Richard Eaton – Medical Imaging & Technology Alliance**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Rich. Anura Fernando?

**Anura Fernando – Underwriters Laboratories**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Anura. Lauren Fifield? Mike Flis? Elizabeth George?

**Elizabeth George – Philips Healthcare**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Elizabeth. Julian Goldman?

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Julian. Drew Hickerson?

**Drew Hickerson – Happtique, Inc.**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Drew. Jeff Jacques?

**Jeffrey Jacques – Aetna**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Jeff. And if there's anyone that has their computer speakers on, if you can please mute them so we don't get the echo in the background, or just mute your lines in general. Robert Jarrin? Robert. I know you're on. Mo Kaushal?

**Mohit Kaushal – Aberdare Ventures/National Venture Capital Association**

I'm here. Thank you.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Mo. Keith Larsen?

**Keith Larsen – Intermountain Healthcare**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Great, thanks, Keith. Keith, could you go back on mute?

**Keith Larsen – Intermountain Healthcare**

Okay.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, all right, thanks. Mary Anne Leach? Meg Marshall?

**Meg Marshall – Cerner Corporation**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Meg. Mary Mastenbrook? Jackie McCarthy?

**Jackie McCarthy – CTIA – The Wireless Association**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Anna – thanks, Jackie. Anna McCollister-Slipp?

**Anna McCollister-Slipp – Galileo Analytics**

I'm here.

**MacKenzie Robertson – Office of the National Coordinator**

Great, thanks, Anna. Jonathan Potter? Jared Quoyeser? Martin Sepulveda?

**Martin Sepulveda – IBM**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks. Joe Smith?

**Joseph Smith – West Health**

Here, thanks.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Joe. Michael Swiernik?

**Michael Swiernik – MobileHealthRx, Inc.**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Mike. Paul Tang?

**Paul Tang – Palo Alto Medical Foundation**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Paul. Brad Thompson?

**Bradley Thompson – Epstein Becker Green, P.C.**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks Brad. And Steve Posnack?

**Steven Posnack – Office of the National Coordinator**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Steve. Bakul Patel?

**Bakul Patel – FDA**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Bakul. And Matt Quinn?

**Matthew Quinn – FCC**

Here.

**MacKenzie Robertson – Office of the National Coordinator**

Thanks, Matt. And is Jodi Daniel on the line? Okay and Mike Lipinski? Okay. With that, I will turn the agenda back over to you, David.

**David Bates – Brigham and Women's Hospital**

Thanks very much, MacKenzie. So we had our recent face to face meeting, and each of the three groups has had a chance to talk again since then. The goals of today are really to get updates from each of the groups, to have the opportunity to discuss as a broad group issues that have come up within the subgroups, and we'll hear first from taxonomy, then from risk assessment and innovation, and then from the regulations group, and then we'll have some broader discussion. There are a couple of specific topics that I would like to bring up, and we'll talk some about next steps. So that's the plan for today; any questions about that? Okay, so, hearing none, over to Patty Brennan and Meghan.

**Patricia Brennan – University of Wisconsin-Madison**

So I'm going to thank the members of the taxonomy workgroup who got together last week to provide some further refinements. Megan is going to be taking us through a presentation, and we have some very important questions that have to be resolved by us as a group, in particular to do some level setting of our expectations of what the final taxonomy needs to have in terms of detail and explicitness. So Meghan, you ready?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

I'm ready. All right, so I'm going to quickly go through the slides here, which I tried to stick with the format of the last time, and just highlight what came up. So first slide, so the follow-on activities since our face to face were that our group – subgroup reviewed and consolidated the feedback and discussion points that came from the onsite meeting. We actually had an opportunity to review some additional materials that were forwarded to us from – to the subgroup from the Bipartisan Policy Center Health Innovation Initiative. They have a draft work in progress, which is very similar to the task that our subgroup is facing, which is defining and characterizing risks of health information technology. And then lastly, we had a teleconference with additional group level discussion and building on Monday.

So the slides I'm going to go through start with the framework that we presented at the full group that highlight the issues that we either achieved consensus on or added or maybe even retracted or revised. So next slide, please.

So first, on scope dimensions, there was a new thing that we added based on a discussion that came up in the face to face, and that was that we – our dimensions had – we wanted to explicitly state that we did not want to just define product categories, but we wanted to make sure that we explicitly listed in scope user types, phases of product life cycle, who the developer or manufacturer type would be, the distribution model, and the conditions of use. But we also added intended use, and I'll show you where that came into play on the decision tree.

And then I've thrown on the side something miscellaneous. It reflects a comment that was made in the face to face, but I wanted to put it in explicitly, and you'll see it in the subsequent slide. Next slide.

So quickly, user types, that dimension of the taxonomy, we didn't see in our meeting notes any changes from those – the presentation on the 30th and 31st, which was we want to explicitly be in scope discussion around risk and any regulatory framework, independent of whether the user was a healthcare provider, a clinical researcher, a patient who was under care by a provider, or the general public, not under any specific prescriptive care by a physician, but maybe managing their own health. [Audio glitch].

On the product life cycle, we did come up with one additional thing that – we put it into the product life cycle. We wanted this to be explicitly a component of the discussion, particularly around risk, and that was issues having to do with availability and downtime hazards. So those, in addition to thinking about the design phase, implementation, installation, maintenance, recall, end of life, and cyber security, we really want to have on the table for discussion how you want to frame or assess risk and think about a regulatory framework around availability and downtime. Next slide.

I'm going quickly intentionally, so we have time to discuss. On the product life cycle, what we had said was potentially out of scope, and I know there was at least one comment that maybe challenged this, but the group in our Monday meeting came to the consensus that while the concept of end user training can be a control – sort of a control factor that mitigates risk, and could be part of the regulatory framework. The specific way, in which you deliver the training, we didn't want you to get bogged down in that, and thought that would be out of scope for detailed discussion. Next slide.

So the miscellaneous issue that came up, and this reflects a comment – one or two comments that were made on the 30th of May, whether the concept of regulation around privacy should be part of the overall discussion, deliberation of this group, and whether that should be part of the recommendations handed off to federal partners, and we felt that was explicitly out of scope of this. And I just wanted to get that formally down as a recommendation out of our subgroup. So discussion or deliberation about changing HIPAA privacy regulations is out of scope. Next slide.

We had a little – just a little clarification and refinement, and it really more reflected poor presentation of the ideas at the meeting. But on the developer/manufacturer types, we want – we would – the subgroup would like to have in scope consideration of products independent of whether the individual is marketing and licensing and distributing a product with a commercial interest or for free, and also independent of whether it's a private health – you know, a healthcare provider, whether it's a hospital or an individual healthcare provider, which goes beyond your traditional framework of FDA, which tended to regulate registered commercial entities.

We wanted out of scope to be individual – and this was more to just at least set one boundary, and not have other groups get bogged down in this issue of an individual who might make an application for their own private use. We want that out of scope. And also, an individual who might distribute via totally private channel, so limited individuals without commercial interest. So I make an application and I give it to my family. We want that to be out of scope, just really for pragmatic reasons of not being able to develop a good regulatory framework around that, or enforcement capabilities.

#### **David Bates – Brigham and Women's Hospital**

Meghan, what if you give it to your practice? Could you talk about that?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

So I would put that on the left side. As a healthcare provider who develops products de novo for use on patients, even if there's no direct commercial interest. Does that make sense?

**David Bates – Brigham and Women's Hospital**

Yeah. I mean, I guess so.

[Crosstalk]

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yeah.

**David Bates – Brigham and Women's Hospital**

I could put it on either side.

**Patricia Brennan – University of Wisconsin-Madison**

Maybe, though, the issue is clarifying what the commercial – what commercial actually means. Because I can imagine something distributed under open source licensing that doesn't have a monetary exchange, but still has value. And what David's describing, my clinician might give me something she built in her garage for free.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Mm-hmm.

**Patricia Brennan – University of Wisconsin-Madison**

And so it may be that there are other aspects of the in scope, out of scope taxonomy that would be helpful here, like use and the purpose for delivery of care.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Well, so you'll – yeah. So Patty, you didn't have the advantage of seeing the last couple of modifications. So we'll get into that on the – this is – yeah, so my goal here is – we'll eventually get to what the taxonomy group feels is the real meat of what is going to help define in and out of scope, but we wanted to just say that don't – do not exclude consideration or discussion just because you're not going to necessarily sell a product or put a price on it. On the other hand, we acknowledge that it would be challenging for enforcement and challenging to develop a regulatory – a recommendation on a regulatory strategy for every individual who makes their own sort of personal health application. It just wouldn't make – it just wouldn't be feasible.

So I think – so I'm confident that we can, you know, work on the wording, but Dave, I think that your comment about creating applications for your healthcare practice to use, either, you know, in the management of population or themselves, would fall on the left side and be in scope. But I don't know. Maybe you feel strongly it should be out of scope. But we can talk about that. And I think Patty was right in introducing that we still have a lot to discuss today, and I want to leave enough time for that.

**David Bates – Brigham and Women's Hospital**

I just think it'd be good to be explicit about that, because there are an awful lot of things like that. So I – you know, I develop some tool that my practice uses to manage our diabetes patients, or whatever.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

So I think – so, if I am understanding it correctly, it's really important to have it in scope for discussion. And just a reminder, I'm not necessarily saying it's in scope for heavy regulation or regulatory – regulation ...–

**David Bates – Brigham and Women's Hospital**

Right.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

I agree with that. Yes. I agree. Next slide. So, no changes on the distribution model; and again, this is sort of a dimension of the taxonomy where we wanted to make sure that you didn't exclude or – you didn't exclude things just because they may be available just by download, or that they would only be used with intentions – with the intended user being credentialed or something. We wanted it to be broad and include service models, so software as a service model, where it's hosted elsewhere, and not restrict the thinking only to an installed piece of software that is – has an explicit license to a credentialed individual. Next slide.

So a new – so the next dimension was the conditions of use, and our goal here was to – was to not restrict the thinking that it had to be something that was prescribed or used only by a credentialed provider. So included on the list as it was when we presented last week was even if it's independently used by a general consumer, and whether it's used for management of illness or chronic disease, I think we – this slide is a little in error. I think our group wanted to move over health maintenance or fitness. But again, this'll be a point of discussion for today, this question about whether that actually expands the bounds too far.

But what was explicitly added is that if there's a product that's for research purposes on human subjects, we want to include it as explicitly for discussion, simply because it may require some kind of a risk framework and some kind of a regulatory oversight when used for research purposes on human subjects. Next slide.

**David Bates – Brigham and Women's Hospital**

Good point.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

And so it fits – it's now internally consistent, because we had as a user type a researcher. For conditions of use, we didn't have any change here, and the main purpose here was that we wanted you to say, you know, don't get bogged down by real non-foreseeable, willful misuse conditions of otherwise relatively low risk types of functionality, or don't get bogged down in thinking about risk or regulation or discussing it when the product's being used clearly beyond a labeled, intended use. Really stick with intended use, foreseeable misuse, and the foreseeable misuse is through – if through poor instructions or a bad user interface, it's very easy to sort of use a drop down list incorrectly, or something like that. Next slide.

So now we get into really – the real meat of it. So, next slide. Here, we actually just tried to refine a little bit the decision tree approach, and moving from top to bottom, start with an intended use. So again, this is trying to avoid creating a discrete, you know, finite list of specific existing products ...at a higher level... intended use and functionality as well as potential for harm. So, next slide.

So our group spent much of Monday talking about this concept, which was we felt as though to try to – to narrow the scope a little bit, to be a little pragmatic, we thought that at a high level, if one asked the following questions, is this product intended to inform or change decision making around either initiating, discontinuing, or modifying either a care intervention that would be via healthcare provider, or personal health management, and if yes – oh, this is an error, actually. It should be in scope. Apologies there, the 'yes' should do in scope, and the 'no' should be out of scope.

So this is the first level, which is the intended use. Initiate, discontinue, or modify care intervention for personal health management.

**Paul Tang – Palo Alto Medical Foundation**

Meghan, may I ask a quick question?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yes.

**Paul Tang – Palo Alto Medical Foundation**

This is Paul Tang; and what about diagnosis?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Great point. That probably should be added here. I don't – I don't – is there anyone on the call who would disagree? I think that was just a...

[Crosstalk]

**Patricia Brennan – University of Wisconsin-Madison**

Paul, can you...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

You go from your notes. You sit there, the group talks, and, you know, we talked a lot about this. And I went from my notes, and then just tried to replicate it. But yeah, I think diagnosis should be in there.

**Patricia Brennan – University of Wisconsin-Madison**

This is Patty. But can you imagine a diagnosis not also requiring one of these three steps?

**Paul Tang – Palo Alto Medical Foundation**

It – yeah. I was looking – I was thinking about that as I...but just so that people don't have to take any other inference based on what we say, because there are apps on the market that do diagnose, and in fact tell you, you know, where to go. So – but, you know...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

I think it ...

[Crosstalk]

**Patricia Brennan – University of Wisconsin-Madison**

You think it's best to call it out explicitly?

**Paul Tang – Palo Alto Medical Foundation**

Yeah. Yeah.

**Patricia Brennan – University of Wisconsin-Madison**

And I might call out explicitly maintain as opposed to initiate, discontinue, or modify. You might actually determine that you would maintain a therapy.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Okay, all right.

**Patricia Brennan – University of Wisconsin-Madison**

So it may take...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

All good points, so I'll try to – my goal is not to get overly verbose, but to make it so it's – you know, one of the things that's most challenging as we're going through this is to avoid ambiguity, and it's – I've found it to be a very fine line between, you know, being overly prescriptive and avoiding ambiguity. So Paul, I think your comment is good, in that it'll avoid ambiguity, if we can put that in; and Patty, your comment as well about maintaining. All right, so next slide.

So then we get into what we feel are sort of the functionalities and the risk profiles. These are not different from the presentation that we made, which is – and the goal here is to sort of give the group an ability to sort of decide if something is – you know, how could you actually define something as being the lowest of low risk, meaning virtually negligible risk? And so we asked the question whether any foreseeable misuse or malfunction could potentially cause injury by either a delay or failure to present the clinical information at the time of need, present outdated information, or produce a patient/data mismatch. And if it's yes, then really, regardless of those other functionalities, should be in scope. Next decision – next slide.

Again, not different than what we had presented before. Strong emphasis that independent of functionality that was the primary source of data at the point of care or the point of decision-making, and you had no other alternatives for confirmation. We thought that had to be in scope for discussion. Next slide.

And then this, again, is not different than what we had previously presented, which is through the design or intended use, is the patient or provider reliant on this to initiate or modify the treatment? So you've already hit that first decision point down here. If this is really sort of a dependency, it's definitely in scope. Next slide.

So I changed the wording here, and I think here's where Patty and I had a brief discussion or exchange today. We're not really – we're still sort of stuck on these points, which are given the scoping..., and this is following that previous decision tree, these would be some examples of things that would be out of scope. And we – you know, we still remain fairly confident about claims processing, health benefit eligibility, sort of the practice management type things. But after Monday's discussion, weren't able to move over to in scope population management or cost effective analysis.

So we're still willing to talk a little bit today about it, if others have kind of cogent arguments about why that would be in scope. But after Monday, we still left it on the out of scope side. And so those are two issues – the yellow isn't showing correctly, but those are two issues we want to bring up for today. Next slide.

These remain sort of out of scope, which were guideline – just a passive guideline distribution, because just by virtue of presenting it on a webpage really wasn't different than printing it up and having it as a piece of paper. And disease severity scoring algorithms, we kept it out of scope, because they – although we acknowledge they may be misused to change or make decisions about treatment, their clear intended use as stated in the public ... the public literature, it suggests – gives someone a sort of benchmark, what's the probability of a specific outcome, and it's not intended to change the way you deliver care. Disease registries, also wanted that out of scope. Next slide.

So the yellow here should be over health information exchange. There was some talk about that last – in the meeting last week, and again, using the decision tree approach, particularly as health information exchanges incorporate not just a passive – not just the brokering function, but also offer advanced functionalities, and also because there is this issue of patient data matching, and that – and risks associated with a mismatch, or the risk associated with loss of data, if that's the primary archive, we thought that these should be in scope. Next slide?

The biggest issue that we obtained is this very last bullet point. You'll remember perhaps from the presentation on the 30th, we actually had this at the top of the decision tree, and our initial sort of thinking had been, okay, why don't we take off the table things that are already declared and actively regulated by the FDA, so some of the standalone software, MDDS, some of the archiving, such as the PACS system. After the discussion on the 30th and the 31st, and after review of some additional things, this is an issue that I think we probably want to have some – use today as the last opportunity or one of the other opportunities to talk about this.

But we've actually revisited this. So the question is on whether or not in scope for the risk and the regulatory group should be whether to consider or make a recommendation about modifying the traditional framework of regulation for these devices, and propose that there's an – you know, that whatever alternative framework that's put in place for health IT, that they consider transferring some of these products over to that framework. So while this had been out of scope, we want to sort of bring the concept of revising regulatory framework for these existing regulated products back into scope. And the next slide.

This explains a little bit of the group's – the group's thinking around this, why we would want to explicitly enter into scope for further deliberation and discussion and revision. And again, we're talking about products explicitly regulated and those that meet a definition of medical device, but currently through enforcement discretion or the regulatory framework, they're not – that is not actively enforced. Next slide.

The thinking – well, first, some examples. The software only products, the archiving systems, like PACS, MDDS, and some calculators and some decision support software. Next slide. Here's the rationale. We – you know, based on what we've been talking about in the development of the taxonomy, and some of the preliminary work by the – by the two subgroups, we feel like already the boundaries are becoming blurred in a very difficult way, where in some cases nearly identical functionality and risk profiles for explicitly regulated products is – it's nearly identical between those that are explicitly regulated and non-regulated.

And we'll give as the example picture archiving systems, which really from the modality, so you have your x-ray machine and your MRI machine or your PET scanner, that's the end modality. It takes in the data, and the diagnosing physician will examine the image in their viewing station, render the diagnosis, and then it gets stored. The PACS systems are archiving, storing, with some regulation around compression, etcetera. And then ultimately that's then called up and used for a future purpose.

Very similar when you think about it, in terms of functionality and risk profiling, as you would for storing, for example, the critical events that occurred in the hospital during the last ICU stay, which you might store in an electronic medical record, or ... and things like that that you might store. So we feel as though there's already that there's a very blurred boundary with respect to risk profile and functionality. And it may be worthwhile considering, you know, an alternate framework for risk assessment and regulation that is – that addresses all of these products ... in an even way. Next slide.

So particularly on that last point, but also the other revisions that we've made in presenting the slides here, we just want to sort of remind, and then I'll open it up for larger discussion, that what we were trying to strive for was a framework that was able to meet future undefined needs. So that was the purpose of going from sort of functionality and criticality or risk profile and intended use versus stating a specific named product. And that's why we were favoring that decision tree. Next slide.

We want – we wanted to sort of also issue a word of caution, because as we thought about the functionality, there are – there can be really potentially very wide spectrums of use cases, and those span a very big spectrum on risk with a single functionality. And as an example, you could – you could think about a prescribing tool or an alerting function, and you can think of plenty of use cases where if you're talking about a water soluble vitamin or a, you know, a moisturizing cream, that it's got negligible risks. So, one could actually do a...calculation of those things for frequency that really present negligible risk.

But the functionality is still – you know, the code that drives that functionality could in the very next use case be doing exactly the same malfunction with a high risk medication. So it's really critical to think about the functionality across the whole spectrum of possible use cases, and not exclude from consideration something just because you have thought about the low risk use cases.

The second important sort of cautionary note is that thinking forward about products or functionalities that rely on a patient lookup, patient data retrieval, or most importantly, a data-patient matching function, should be really evaluated for the risks of – the risks and the potential for patient-data mismatch. And what that ends up telling us is that there's an awful lot out there that would seem to be low risk because it's sort of simply doing archiving, but all of the risk revolves around whether or not – you know, what happens if you mismatch? Next slide.

This is our last slide, and I think this gets to Patty's point, which is a little guidance from the remainder of the group, perhaps some discussion today, is that we're anticipating, and we hope to have it ready, but I think we're going to need some – just a little more time, to be able to give you some tools. We were envisioning preparing either a matrix and/or, maybe in combination, a little bit more formalization of this decision tree tool, and then a final one-page summary of the taxonomy, the final taxonomy, the process and the rationale. But we are open for guidance from you. Outside of what we've talked about, and maybe the discussion that we stimulated, what specific artifacts or deliverables the other – the others in the group – in the larger group feels you'd like to have from our subgroup.

So I think that was the last slide. I've talked very quickly, but I wanted to leave open time for discussion. So I'm going to stop now and ask members who are on the call about comments, questions, or what points you want to quickly hone in on and open up for discussion.

**David Bates – Brigham and Women's Hospital**

No comments?

**Michael Swiernik – MobileHealthRx, Inc.**

This is Mike Swiernik. I had two – or two comments, questions. One is that in the risk group, we talked a little bit about a system where the only users might be another system, which would be the case for a third party product of some sort, like a decision support system or something like that. So I don't know if that's something you guys discussed, or if you were – or one of the questions that came up in our side was whether we should look at the ultimate use of it, or if – or if that was causing the scope to go too far for that particular product, and we should just look at how it relates to the other systems.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

So that's a great question. Let me make sure that I understand it. So we've talked – we talked about end users as being the human end users, but I think it's possible what you're referring to are if there's – some of these software services where...

**Michael Swiernik – MobileHealthRx, Inc.**

Mm-hmm.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

– information is pulled from source A and then sent and consumed by source B, which then does some processing and then sends the final recommendation or something to the end user. Is that the example that you're – is that an example...

**Michael Swiernik – MobileHealthRx, Inc.**

Yeah, that'd be one example.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yes. Yep. I feel – maybe we did a disservice. I named human users. I feel like that's one of the most important things that needs to be discussed and talked about, because I think that's the future world of a lot of the – a lot of the health IT, is these – are these intermediaries.

**Michael Swiernik – MobileHealthRx, Inc.**

Mm-hmm.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Now I think Bakul is on the phone. Bakul, can you help us a little bit to understand if that type of software intermediary – so it's like a web service or – if you want to call it a web service agent, is that within the context of the MDDS definition, or is that different?

**Bakul Patel – FDA**

You mean – this is Bakul. Do you mean by things that translate from point A to point B, or just move data from point A to point B?

**Michael Swiernik – MobileHealthRx, Inc.**

Well, two examples I can give that are kind of at opposite ends of the spectrum in terms of complexity, one might be a program that simply does math functions, but they say, well, we do math functions for medical reasons. So send us some numbers and tell us what function and we'll give you an answer. And then the other end of that spectrum maybe is a system that – send us a bunch of clinical data, and we will diagnose and come up with a treatment plan for that patient and send it back to you. But in both cases, the user of that service would be another system. There's no direct end user, per se.

**Patricia Brennan – University of Wisconsin-Madison**

This is Patty. Would it be acceptable if we added to the user display – I mean the list of users that we have the – another system?

**Michael Swiernik – MobileHealthRx, Inc.**

That's what I was suggesting.

**Patricia Brennan – University of Wisconsin-Madison**

I think...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yeah.

**Patricia Brennan – University of Wisconsin-Madison**

Around slide 6 was it – is it possible to return to slide 6? Whoever's controlling the slides? General conditions of use, and this was...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

No, keep going back. You want – go back a couple more. I think it's the user...

**Patricia Brennan – University of Wisconsin-Madison**

The slide 4?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Let's even go back to – two more slides.

**Michael Swiernik – MobileHealthRx, Inc.**

Yeah. There were four users, and they were all...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Back two more. Back two more. One more.

**Michael Swiernik – MobileHealthRx, Inc.**

One more, there you go.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

There you go. Okay. Yeah. So we – so we could characterize it as another application or another health information technology as a consumer of – something like that, another system, a subsystem.

**Michael Swiernik – MobileHealthRx, Inc.**

Yeah. And then the other comment I would make is that in one of the slides, I think it may be the next one, you were talking about commercial intent on a number of them, and I would argue that commercial intent is hard to know, certainly from the regulator's standpoint, and easy to lie about, I guess. So...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yeah.

**Michael Swiernik – MobileHealthRx, Inc.**

If it gets you out of regulation, I could argue anything is without commercial intent in the beginning...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

So, yeah.

**Michael Swiernik – MobileHealthRx, Inc.**

And then when I actually figure out I could make some money off of it, I could change my mind.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yeah. So let's – if we can go to slide number – if I can...

**Michael Swiernik – MobileHealthRx, Inc.**

It was one or two right after this.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

It's on the developer – next slide, please.

**Michael Swiernik – MobileHealthRx, Inc.**

It was the developer one.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

There. Yeah. I think – see, here's where I think the wordiness makes it hard to see. I think I was – I think we included on here even if no commercial interest, and for exactly that reason. I think it becomes...

**Patricia Brennan – University of Wisconsin-Madison**

It's on the fourth – the third bullet.

[Crosstalk]

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

The first and second bullet. Yeah, yeah, we're on the slide –

**David Bates – Brigham and Women's Hospital**

What's the slide number?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

No, it's this slide that's being projected.

**Patricia Brennan – University of Wisconsin-Madison**

Gosh, I don't see the numbers for the slides. I'm sorry.

**Paul Tang – Palo Alto Medical Foundation**

It's number 8. Just – you know.

**Michael Swiernik – MobileHealthRx, Inc.**

Okay. And I think – well, for me, I think it doesn't – I think the commercial interest is kind of irrelevant as to whether it's in scope, or if it is, it overlaps with distribution model or distribution intent.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Okay. Completely agree. And so what we did on this slide – I'm sorry, because we don't have the numbering. I should have put the numbers on the slide. What we did was to avoid ambiguity there, or give people an out, we wanted – we explicitly put into scope people who develop, market, license, or distribute, whether there's commercial interest or not. Does that – does that resolve your concern?

**Michael Swiernik – MobileHealthRx, Inc.**

Oh, I actually was just – yeah, maybe I was just looking at that first bullet, which specifies with commercial interest. It doesn't say...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yeah. And then the next one I called out and said even if there's no commercial interest. Yeah. We can improve the wording when we go to give the final taxonomy, whether it's a document or final couple of slides. We'll try to...

**Michael Swiernik – MobileHealthRx, Inc.**

Okay.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

...make it as clear as possible.

**Patricia Brennan – University of Wisconsin-Madison**

So this is Patty. Can I clarify – it was this question, and I think it was David's question earlier, when you – when we – you can tell some of this discussion hasn't even been completely fleshed out between Meghan and I, but when we say commercial, does that mean purchased or paid for or covered under insurance, or does it have some other meaning like something that's enumerated on a particular list of software?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

So this is Meghan. I – when I put commercial, I kind of – and we can – this is good to think about the right word that is the least ambiguous. But my goal was it doesn't have to be money. It's anything that, you know, that people are distributing this for the intent of some kind of a gain. But I wanted to also include people who distribute this widely, and it could be used broadly, even if they want to be – and I say that because there are some nonprofit organizations who may develop software, make it publicly available to consumers with good intention, but just because it – they're nonprofit, they're not getting any clear return or monetization of that, this product should still be subject to some risk assessment, and potentially even some – you know, fit into the regulatory framework.

So I don't know if there's a better word than commercial. I think commercial could mean anything.

**Patricia Brennan – University of Wisconsin-Madison**

Could we try public distribution?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Well, that's on the distribution slide, which is downloadable for free versus...distributed.

**David Bates – Brigham and Women's Hospital**

Yeah. I think we can work on this offline.

**Patricia Brennan – University of Wisconsin-Madison**

Okay. Yeah.

[Crosstalk]

**Paul Tang – Palo Alto Medical Foundation**

So this is Paul Tang. I have a comment on this slide.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yes.

**Paul Tang – Palo Alto Medical Foundation**

You obviously recognized that that last bullet on the left, healthcare provider who modifies previously licensed, quote, finished products, would apply to virtually all of us. And I – just making sure that that's clear, and what you think the implications are, and how it inter-digitizes with the one that's out of scope, the, quote, individual who distributes via private channel to limited individuals.

So in a healthcare organization and they make changes for their very own, installation that could be almost considered in that right side, because it's a private channel, it's only at my organization. But you've modified – you've customized, you've – like is expected, you've built this prod – you've added onto this product. You've configured it.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yes.

**Paul Tang – Palo Alto Medical Foundation**

You intended that to be covered, which seems reasonable, but then how do you reconcile that with the right, the distribute via private channel, since it is private in the sense that only that organization would have the access to it, your ...?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

A good point. Maybe we should take – we have a few options. We could take the bullet on the right off. I want to just sort of re-emphasize that the healthcare provider modifies, I agree, in this day and age, it's –

**Paul Tang – Palo Alto Medical Foundation**

Everybody.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

– Almost unheard of to get a product from – you know, out of the box, and make no changes. The goal of putting it on was just, again, not that we're proposing a specific regulation around it, but that that has to be talked about, because it is – you're right. That's the model in this day and age. And the consideration more around institutions that do modification, have to think about a risk – they have to think about it in using risk-based assessment about how much they want to modify and what implications there are... it in...with respect to having it on for deliberation and discussion.

**Paul Tang – Palo Alto Medical Foundation**

Right.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Maybe we should take the right one off, and the only thing out of scope is if you make something on your own, for your own use, you're on your own.

**Paul Tang – Palo Alto Medical Foundation**

Yeah.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

It's in – it's not practical to think about regulation around that.

[Crosstalk]

**Keith Larsen – Intermountain Healthcare**

But even there – this is Keith Larsen – I mean, it – going back to David's comment, I create something for my use. My colleague watches me use it, says, well, that's cool, let me use it. So then it – the thing grows exponentially, and then we hit this tripwire, okay, where it's now interesting for regulation. How do you address that? I mean, on a practical basis, I think that it – on a very practical basis, I think this is very difficult to do.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yes.

**Keith Larsen – Intermountain Healthcare**

I know we're trying to get scope. But on a pragmatic basis, the person who did a little thing for their own practice is in many cases not even aware that they're treading very close to being – to inheriting the full impact of the FDA, for instance. So again, how do you address a change in purpose as the things goes on, and if – and specifically, if what you were doing, for instance, was applying the regulation as it is now, where – which goes back into the manufacturer of the product itself. You're already there. You're at a manufacturer product. And so practically how do you do this?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

So let me – maybe we could have Bakul weigh in on this. My understanding of the current regulatory framework, and maybe it's easier to talk about, you know, traditional, conventional medical device. If I made something in my garage and I used it on myself, the FDA would have no enforcement – they would – the regulations would not apply to that scenario. And...

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

But you're treating that under practice of medicine, though. Julian here. That's how we describe the practice of medicine.

**Patricia Brennan – University of Wisconsin-Madison**

How you describe the practice of medicine is –

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

We applied the concept of practice of medicine to that one-off device, being built under the oversight of a physician and used on one patient.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Well, I was even trying to simplify and say if I use it on myself, personally, me, there's absolutely no regulatory oversight. And you are right, Julian, in that traditionally, that's fallen under that clause of that's the practice of medicine, and may have not regulated individual surgeons, for example, just using that as an example, from modifying something and then using it on an individual patient. It sort of had to cross that boundary where it was sort of either marketed, advertised, or sold, before...

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

Or used on multiple or possibly once it gets used on multiple patients within a given hospital, or by different physicians in the hospital. I guess that starts entering that gray zone.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yeah. So that's sort of been the traditional – now, you know, if we believe that health IT is different, and that in fact we should talk about whether that model should be, you know, suspended for health IT, then I think that's worth discussion. But that would be – you know, I think that's – that had been sort of shaping the thinking originally around this.

**Jodi Daniel – Office of the National Coordinator**

So this is Jodi Daniel, and Steve Posnack and I have been having a little sidebar back here, and thinking about this, and the question you're asking right now about, well, would – this doesn't seem like it would be something that would be in scope for FDA today, it raises the question of when you're going to the in scope and out of scope, what the delta is from today, and whether or not you're just putting out of scope those things that would be out of scope today, or is there something different that puts something in scope or out of scope for health IT?

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yes, great way of framing it. Yeah.

**Patricia Brennan – University of Wisconsin-Madison**

Are you looking for an answer for that, Jodi?

[Laughter]

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Yeah. I'm certainly struggling with that, because...

[Crosstalk]

**Male**

I thought there was a question there.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

No, I think she's – I think, Jodi, if I'm understanding, you're restating much more succinctly what we're struggling with, which is do we start by saying, look, if this – you know, if a conventional device used by an individual provider on an individual patient was never regulated by the FDA, do we want to sort of use that as our level setting for health IT, or is that different? Is health IT fundamentally different?

**Paul Tang – Palo Alto Medical Foundation**

A different way of asking it would be does this – does this expand or contract at all what the jurisdiction of the FDA is today?

**Patricia Brennan – University of Wisconsin-Madison**

I'm really glad that you brought that up, because I think we do need to clarify whether our recommendations for regulation also presume that the FDA will be the responsible body for that.

**Jodi Daniel – Office of the National Coordinator**

Well, I'm – this is Jodi. I don't – I don't know that – I think that's a separate question. So I'm thinking more of what gets taken off the table, and the question is, are there things that wouldn't be on – you know, within an oversight – regulatory oversight approach that we want to be considered for some kind of a regulatory oversight, or not; or the other way around? You know, like basically, I'm asking a line shifting question. And then how is a different question, because, I mean, even today, FDA exercises enforcement discretion over things that are in scope for them, but they do nothing – they don't exercise any kind of enforcement over, and maybe there's some other way we might want to have some enforcement over that that's not FDA for some of those things that FDA wouldn't take on.

So I don't know – I think it's two different questions. I think it's a line drawing question, but since FDA has a lot of authority, it's a good first question to ask. We may want to ask the same question with respect to other authorities as well. And then if – so this is just the in-scope/out-of-scope line drawing question. And then I think there's a second question, which is if it's in scope, is this, you know, is this an FDA approach? Is this an ONC approach? Is it an FCC approach? Is it an FTC approach? Or is it like we shouldn't – it's in scope, but, you know, there's so little risk or such high impact on innovation that we – that you guys think there should be – we shouldn't take action in that space. So I think it's two questions. It's what the line is, and I think at – you know, a lot of what you've been talking about is close to the FDA line. That's why I raise it. But I don't think that means that we presume that anything that's in scope is – goes into an FDA model. I think that's the second question.

**Patricia Brennan – University of Wisconsin-Madison**

That's very helpful, Jodi. So as I've been thinking about the taxonomy, it is somewhat forward-looking, not just in terms of what's currently regulate-able, but also it should be robust enough for at least a couple of years of innovation. So if we develop dissolve-able computing tools for embedded in a human body in the next three years, we should be able to have the regulation framework be big enough to support that, and not need to be revised just for that.

**Bakul Patel – FDA**

So this is Bakul. Can I just comment? I think the discussion was more about the individual making a product for his or her own use, right? So the question on the table as I see it is should that be deliberated as part of the risk and the regulatory group's discussion? And what I'm hearing is if an individual uses – makes it for his or her own use that that seems to be out of scope. And I think that makes sense, because you are just not exposing a whole lot of people for that product, and you don't intend to, and that's the intention there.

It sort of jives with some of the things that FDA has done, but that does not necessarily mean it's an FDA approach. It's just we should probably be focused on should that be part of the discussion or not. And maybe to change a word here may help to clarify that. And I think, Meghan, you had a comment in response to some discussion to elaborate on that, or Patty, I think you may have done it instead.

**Patricia Brennan – University of Wisconsin-Madison**

So it's gone out of my mind if I had them, but it sounds like what you're encouraging us to do is to think about the scope as it is with some clarification.

**David Bates – Brigham and Women's Hospital**

You know, and one thing I would ask you to do, in addition to what Meghan suggested, is just come up with a few examples or use cases, which would illustrate, you know, kind of both sides.

**Patricia Brennan – University of Wisconsin-Madison**

Yes. Yes.

**David Bates – Brigham and Women's Hospital**

So I think that would help us. You know, one example would be just the example that you just gave. Someone develops something which they just use themselves. I think it would be useful to describe what the issue is if I – if someone creates something in their practice, and then want to give it to other people in their practice. That's something that comes up all the time. And I personally was thinking about using more as a dividing line if I then want to sell it to someone else or start to spread it across other practices. That might be one way of thinking of a place of drawing the line.

**Anna McCollister-Slipp – Galileo Analytics**

Hey, guys. This is Anna McCollister-Slipp, and I guess I have a couple of questions. One, I want to clarify that we're just talking about the scope that will be discussed within the context of the report, not what will or not be regulated, correct?

**Patricia Brennan – University of Wisconsin-Madison**

Correct.

**David Bates – Brigham and Women's Hospital**

Right.

**Anna McCollister-Slipp – Galileo Analytics**

Okay. That's good. I mean, in terms of use cases, for instance, I'm part of a diabetes tracker group that is populated with a lot of people who are much better than I am at writing code and developing new products. But frequently they will share new ways of visualizing diabetes data from their own medical devices with each other. I mean, I suppose if we're just talking about what is the scope of the report, that's great. I mean, that's completely fine. We should probably provide clarity. But I think we just – I mean, I just want to make sure that we don't crack down and keep people from doing that kind of stuff.

**David Bates – Brigham and Women's Hospital**

So I think that's a good example...

[Crosstalk]

**Anna McCollister-Slipp – Galileo Analytics**

There's a lot of really cool innovation –

**David Bates – Brigham and Women's Hospital**

If somebody develops something like that and then they wanted to sell it, that's the sort of thing that I think would be within scope.

**Patricia Brennan – University of Wisconsin-Madison**

Right. I would agree with that.

**Paul Tang – Palo Alto Medical Foundation**

It's almost like the FDA...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Again, I think it's...

[Crosstalk]

**Paul Tang – Palo Alto Medical Foundation**

It's once cross state boundaries, which is your own sphere, and then it becomes open.

**Anna McCollister-Slipp – Galileo Analytics**

Well, what if I had a patient group and I, you know, charged \$30.00 a year for people to be part of this group and distributed it to all the members? Would that be selling it? You know, as one of many things that I did?

**Paul Tang – Palo Alto Medical Foundation**

I think so.

**Patricia Brennan – University of Wisconsin-Madison**

We – remember, the taxonomy has a number of different components, so while it might not – something might not become eligible for regulation under one component, might come on the other – so for example, I would think if – if as part of a – of a membership fee you provided people with a service or a software, then you've moved the distribution model to something that becomes – makes it – brings it under regulation.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Oh, so Patty, this is Meghan. So just to follow up on that, so I would say one – you know, you might meet those checkboxes, but then ultimately, you want to go through your decision tree, because if the visualization is very low risk, then the – you know, having gone through the tree, it might be totally out of scope, or it might be in scope, but that, you know, then the regulatory group makes recommendations that it's, you know – depending on where it is in that spectrum, maybe the most it needs is a good instruction manual.

**Patricia Brennan – University of Wisconsin-Madison**

So, Meghan, we might –

[Crosstalk]

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Or good labeling.

**Patricia Brennan – University of Wisconsin-Madison**

...early on, that any entity that is being considered under this is actually described by multiple dimensions.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Correct.

**Patricia Brennan – University of Wisconsin-Madison**

And so it is – it is the composite of the description that leads one to be able to make a conclusion about the regulation, not its performance on any single one.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Well, so – and I do want to do a quick time check, so Dave, just cut us off if you feel like we need to move on.

**David Bates – Brigham and Women's Hospital**

Yeah. So I'm going to move us on in a couple of minutes, but this has been a really good discussion, so I've – and we had some flexibility. That's been fine.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

So just to respond, Patty, I was – so my – you know, my thinking is, I – you know, we kind of wanted to have a lot of – we wanted dimensions in scope, so that ultimately, the – for the other subgroups, didn't just narrowly and on product functionality, that they also – that they didn't exclude something because it was, you know, a downloadable versus software install. So that was one of the purposes there.

But I would imagine that if you check off – if you meet some of those dimensions, but then you get to that final functionality and intended use, and you're not a sole source, there's no conceivable harm to the patient if it malfunctions, it's not really going to change therapy, then, you know, that's sort of – I guess you could still have it in scope, but it's hard to make a case that that – you know, that that would then ultimately – that you could shape any recommendations around it. Does that make sense?

**Anna McCollister-Slipp – Galileo Analytics**

Yeah. I guess – I guess from my perspective, for instance, I use, you know, a free access to visually – a commercially available visualization software platform that's very well-known. It – and you know it works for me. I play with it when I have time to see different patterns. If I decide to make that available to friends, I guess that would be not within scope. If I decide to make that available to an online group where we've all paid \$10.00 a year to pay for server space or something, then suddenly that becomes within scope.

And I think – I mean, I think clarity on these kinds of things would be absolutely essential. I just want to make sure that we're talking about what is within the scope of the need for clarification as opposed to what needs to be regulated or not.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Okay.

**Paul Tang – Palo Alto Medical Foundation**

Was that a question?

[Crosstalk]

**David Bates – Brigham and Women's Hospital**

Okay. I think it was more a comment.

**Paul Tang – Palo Alto Medical Foundation**

Okay.

**David Bates – Brigham and Women's Hospital**

So Meghan and Patty, do you feel like you have what you need to...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

So I was taking notes. I think one of the most important things I heard was that example or use cases will be very helpful for, you know ... these dimensions. I really – it's not for want of – we – it's not that we haven't tried, but we are striving to get some kind of a useful tool, and whether it's a matrix or a refinement of the decision tree, we will have that. But I think I took good notes. It does sound –

[Crosstalk]

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Like we may have to have another meeting...

**Patricia Brennan – University of Wisconsin-Madison**

I think I have an idea about how to present the use cases also, so that...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Okay.

**Patricia Brennan – University of Wisconsin-Madison**

What I'd like to propose is that let Meghan and I work this through together, so we'll meet sometime early next week, perhaps, and then we'll get it back to our taxonomy workgroup for an email round robin, and then send it back in time for the meeting on the 20...

**Paul Tang – Palo Alto Medical Foundation**

Twenty-seventh.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Twenty-seventh, okay.

**Patricia Brennan – University of Wisconsin-Madison**

Yeah.

**Paul Tang – Palo Alto Medical Foundation**

Can I add one consideration for the group?

**David Bates – Brigham and Women's Hospital**

Sure.

**Paul Tang – Palo Alto Medical Foundation**

This is Paul Tang. On population management, just quickly, most population management tools are designed to influence your decision making, so you might check and see whether that's really...

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

We didn't get a chance to get to that, but that was one big thing that we couldn't really get any consensus on. So thank you for stating that again, and we'll – it probably will come in scope.

**Paul Tang – Palo Alto Medical Foundation**

Thanks.

**Anura Fernando – Underwriters Laboratories**

This is Anura Fernando. One more comment, going back to the beginning of the discussion, also. When we modified slide 4 per the original suggestion to add other systems of user, we – could also take a look at slide 11, where it talks about use conditions, and consider introducing the concept of indication for use as well as intended use, since when we have a device being introduced into a broader system context, from the intended use, we're looking at a specific device attribute, but from the indications for use perspective, we're looking at the role of that device in the larger system context.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

Okay.

**Anura Fernando – Underwriters Laboratories**

Thanks.

**Meghan Dierks – Harvard Medical Faculty, Division of Clinical Informatics**

All right, thanks. Sorry, Dave. We'll hand it back to you.

**David Bates – Brigham and Women's Hospital**

Okay. No, thank you very much. So next we'll hear from Paul and Keith, over to you.

### **Paul Tang – Palo Alto Medical Foundation**

I think we'll go – whatever slide is loaded – we had two different slide decks, so whichever – okay, that's mine, so I guess I'll go first. David, what kind of timeline would you like us to follow?

### **David Bates – Brigham and Women's Hospital**

Oh, so I think we have about 45 minutes.

### **Paul Tang – Palo Alto Medical Foundation**

Okay. So I'll go first. You'll recall that this is the risk group, which talking about, one, patient safety risk, and the other is risk to innovation of regulations. And Keith is covering the latter, and I'll be covering the former. This – what you have in front of you is an update – we had a call yesterday, and here are some changes, and they're not all the changes that we made, just because we had the call yesterday. So one of the important things that is a to do for me is to go in the first column and write out some definitions, which will I think help elaborate on what we mean, and answer some questions.

One of the requests from the face to face was to fill out the medium risk, just to give some more information about what – you know, what kinds of things you're thinking about, and so that's a major part of what's in front of you.

So I'll just highlight some of the changes. Under purpose of software product, this was raised earlier in this call. One of the things I added was the lower risk, the transparency, the notion. So you can escape lots of things by not saying a word and just putting it out there, and we didn't really want that to happen. A big part about being transparent on who – what the use is and who the users are, intended users are, is then that could invoke some other agency enforcement capabilities. So if you promise something, the FTC can come down on you if you are not delivering on that. And likewise, if you are not saying it's used for some purpose, then use for that purpose would be off-label use. So there are some things that the FDA could be invoked.

But anyway, so the transparency should be clear about what's the purpose. So we have the boundary of its information only to its making its own decision on the right, so the medium is that it does make decisions, make recommendations, but it's to the user.

The intended user, I put an F there now. Mike Swiernik also raised earlier this conversation, the user could include another system, but a clinical decision support system or a drug database system doesn't – doesn't relieve itself – the vendor of its responsibility just because it went to another system before it got unadulterated or it got exposed to the user. If you're making the decision that was generated from a decision support system or the drug database, you still should be covered.

So we did add, based on the face to face meeting, the notion of not just license, but your credential to do the – to absorb the information that's being delivered and to act on it. On the very right, if you're making diagnoses or treatment advice directly to the patient, it seems that a higher risk, and so making recommendations but not necessarily diagnosis or treatment in the – is sort of in the medium risk category.

The next cluster has to deal with the attributes of risk, can be very low probability of harm to life-threatening, so the medium risk would be potential non-life-threatening adverse event. Number of people exposed, some of the requests at the face to face was put some numbers on it, so here's just an attempt, less than 100 versus greater than 1,000, and then something in the middle.

Likelihood of risky situation evolving, also try to get some number. The medium risk was sort of – to capture the notion, well, you know, we really can't predict, but it's going to happen every year, kind of a thing.

Transparency of the operations; it's both the transparency of the – how the software operates, but also, and here we go invoke content again, which was brought up at the face to face and the call, the content providers, like drug databases, should be made transparent by the system where it's being exposed or presented, and so that you understand, well, how did they get this information, and can gauge for yourself what's its level of reliability, and what's your trust in that system?

### **Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

Can I ask for a clarification on something that you just mentioned before, or save it for later...

**Paul Tang – Palo Alto Medical Foundation**

Sure. Yeah.

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

If it's better later. This is between recommendation – between diagnosis, treatment, and recommendation.

**Paul Tang – Palo Alto Medical Foundation**

And that's a fine line, and all these things are gray. So if you are making a diagnosis, if you're making treatment decisions, those are pretty spelled out in terms of medical boards. That's covered by licensure. You could imagine other recommendations like wait it out or ..., and I understand that's gray. But, things that are maybe less clearly invoked by the medical licensing boards and that was the intent for hedging there.

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

I – yeah, I can't – I mean, I don't want to belabor the point, but as I think through the recommendations that I give patients and advice I give, and I can't think of any that fit into that category offhand.

**Paul Tang – Palo Alto Medical Foundation**

Okay. Well, we can work on the wording, but the two bounds are it's like totally giving it to someone who's licensed to understand it and act on it versus giving it to somebody who's not necessarily equipped, like a patient, to understand that advice.

**Patricia Brennan – University of Wisconsin-Madison**

So Paul, this is something I think we're going to have to spend a little time on.

**Paul Tang – Palo Alto Medical Foundation**

Sure.

**Patricia Brennan – University of Wisconsin-Madison**

Because I'm not clear how you would decide who would make that decision.

**Paul Tang – Palo Alto Medical Foundation**

Well, this would be part of the transparency. So if I'm a vendor, I say, this product is for use only by licensed physicians that deal in some area, okay? Versus – and I'm disclaiming that this shouldn't be used by consumers. Then you're at least making it clear what your intent and what's the level of expectation of the recipient, the user.

**Patricia Brennan – University of Wisconsin-Madison**

Right, that's what I – I want to come back to that.

**Paul Tang – Palo Alto Medical Foundation**

Yeah. We sure can. Let me just sort of try to get through this. Then the transparency and the software operations, making clear not only what the output is, but the calculation that went into that output, that got revised as a part of the subgroup's call, so that it can be understood. The – giving the user the best chance of understanding what's going on. The black box is totally operating in a vacuum. The user is clueless. You're just hoping that the right thing is coming out. And it generally is. That's what a product is for.

But in the middle, then, you might have transparency, but it takes a software expert to understand it. So that's sort of a middle of the road, versus something that it's clear that the user, end user, should be able to understand what's going on, to be able to judge its reliability.

The ability to mitigate harm, clarified this, now. The human intermediary is part and parcel. It's just part of the chain. It goes from this device or software right to a human, who can act and could prevent any harm from misunderstood or foreseeable adverse output, to something that is on the right side closed loop, and there's no chance for a human to intervene. It's basically controlling the IV pump, and you'd have to sit there and watch the dials and make – and – to see what's going on.

Then medium would be, yeah, it's accessible. It's in plain daylight. I understand what's being put out, and I understand what's going to happen next. And if I so choose, but I do have that opportunity. I, a human intermediary, could get involved and mitigate any changes. But they're not a required part of that chain. That's what I meant by not routinely involved.

The next cluster has to do with the complexity of the software, its maintenance, its implementation, its upgrade, its training, and its use. That whole chain of getting complex software or software in the hands of the user, so the complexity of the software and the maintenance, which was added with the meeting, is that it's not only is the application mature, it's widely adopted. People understand this. This is not brand new. And so those would be things, attributes of software, even if it's complex, that's in the lower risk profile. In the higher risk, it has a lot more transformation going on, and a lot more – and it's a lot harder to test, is this operating as designed, and is it operating safely? So that's the far end.

So in the medium, you may have medium complexity, but you have test procedures that can fairly deterministically say, hmm, this is operating as designed, and it is operating in a safe risk profile.

The complexity of the implementation and upgrade, it can very straightforward, you know, you plus this thing in. It's supposed to put out a blood pressure. It does that. There's – you can do it in kilograms or pounds – wrong one. But millimeters of mercury or something else, it's pretty straightforward, whereas on the other side, you can pretty much get this thing to do whatever you want, present it the way you want. That may be a good thing, but if there are no guardrails, you can get into trouble very quickly if clinicians that are savvy are not involved.

And in the middle, you have fairly complex software, but there's guardrails programmed to really watch that you don't do anything really, really bad that could induce life-threatening risk. And the training and use, it's either really easy, it's a blood pressure, or it's really complex, and the user interface can definitely influence both the interpretation and the safe use of this product. We're familiar with that. Formal training may take days, several hours, where in the medium risk, it would be arbitrarily less than hour. So it's not that complex to use.

The next part is its participation in a broader system. It's either standalone – now we changed this as a result of conversation, both at the meeting and the call. It's – standalone – well, being connected to other systems isn't necessarily a bad thing, because there's actually some redundancy and check and balance and context that can be provided. So that's the caveat here. So it's – so instead of saying a standalone is only – the only safe product, standalone or things where there's redundancy created so that there's a minimum – it reduces – it actually reduces the single point of failure. That was a point that was brought up, so that's been added.

Whereas if there's less stuff going in, and the output of your software can certainly be misinterpreted or misused, that's the foreseeable misuse that Meghan was talking about, then you've got to be careful. And it just – it's a higher risk. Doesn't mean you can't do it, but you got to be careful. And the medium would be small number of interfaces, well-described and well-adopted interface. You sort of know and – know what you're expecting, and you get it.

The network connectivity goes from wired or tightly controlled spectrum to an unregulated spectrum, and the middle point is it's unregulated, but, you know, we've got long years of track record here in use, and no interference has been reported.

So let me go back and first tackle the question that was raised in terms of – I totally agree, it really does – it's just the same discussion we had with taxonomy. We need to make sure that both the purpose is adequately disclosed, so that we have labeled, protected, understood, and accountable purposes, and what might be deemed off label uses, and that people have an understanding of its – of that off label use, and then who are the intended users? The question came up in our call, what if you have more than one? Well, you would actually go through that decision tree and say, oh, for the licensed, credentialed professional, here's the risk profile. But this could also be used by a patient or a consumer. You'd have to look at it from that point of view, too.

And if the vendor chooses to label that product for use of – by consumers or physicians or clinicians, then you'd have to pass all those tests or have the appropriate disclosures, disclaimers, or regulation. And certainly open to participate with the taxonomy group in terms of fleshing out whatever else needs to be fleshed out there. Other questions or comments?

**Patricia Brennan – University of Wisconsin-Madison**

Paul, I guess – this is Patty. It's not clear to me how, beyond a vendor asserting this can be only used by this person, how we would have that person demonstrate that knowledge base. And I'm thinking right now about nutrition advising. You know, most health professionals, physicians, nurses, pharmacists, don't know enough about nutrition to give deep nutritional advice. So if – I mean, when we're getting into micro-nutrients and all that other stuff. So if we have the FDA say this is – I mean, sorry, if the manufacturer says this is – this should be used only by a licensed physician, nurse, pharmacist, dentist, how would – how would that manufacturer know that that was within that group's knowledge base, and would there – I mean, is your vision that – I know...but is it your vision that that would be something that the person would need to demonstrate for the regulation?

**Paul Tang – Palo Alto Medical Foundation**

No, I think – so licensed folks certainly have a scope of practice and a knowledge base that's written out in some code, right, by the boards, professional boards.

**Patricia Brennan – University of Wisconsin-Madison**

You know, I think it's to a greater or lesser degree that – yeah, let's – but, I mean, because a physical therapist, for example, would say that we don't get – we don't have the knowledge for mechanics – so, I mean, it's really a professional turf issue, I guess is what we're getting down to.

**Paul Tang – Palo Alto Medical Foundation**

Yeah.

**Patricia Brennan – University of Wisconsin-Madison**

And I guess – and I know we're not going to resolve that in this phone call, but is your thinking that the developer would say, this is the constraint, and that we would just take their word that that knowledge base should be present in that group?

**Paul Tang – Palo Alto Medical Foundation**

Right, I think so. I think the major thing is to be used by someone who is at default not trained in that. So should you – let's go back to the diagnosis app that we talked about when we talked about taxonomy. So here's a – you plug in your symptoms and it spits out a diagnosis. You might say, "Huh, well, okay, if a physician's going to use that, then that's okay." And then they market it to here is how you can, you know, avoid, you know, just get your problem solved simply. That would require a lot of assessment, I think.

**Patricia Brennan – University of Wisconsin-Madison**

Well, I think that – I think a lot of the – you know, there's a pretty large group of people who believe that license – that the knowledge base of some of these issues, and let's stay away from things that are clearly very regulated, like narcotic prescriptions, but the license base for prescribing PT, for example, isn't really contained within licensed health professionals only. And so we need to be careful from a patient advocacy perspective that we not diminish the rights of patients to have access to something, or that the risk be defined simply by licensed versus unlicensed.

You know, I'm quite concerned – I think about...going back to the issue of – or the diabetes people saying that there's a clinician view on the data, and then there's a patient view on the data, and even though the clinician view may be more informative or easier for people to use, it's because of regulation by FDA that clinicians are essentially failing in their practice if they allow a patient to have access to that view of it. So we could really be setting up an increase of problems for patients to have access to the right tools by allowing developers to simply say you have to be a licensed professional to see this.

**Paul Tang – Palo Alto Medical Foundation**

So I guess the goal, and I'll just give one person's perspective, is in order for – if your intent, and probably is, in many cases, the intent of the developer to make this more widely available, then what they're saying is, gosh, if you're promoting this for use by patients or consumers, then I think you ought to up the – up your sense of responsibility and accountability how you present information, make sure it can be understood by that target group, and can be safely used. And that's not a bad thing.

**Patricia Brennan – University of Wisconsin-Madison**

Paul, I actually think it's – that what we have to worry about is nefarious constraints, that things would be defined ... purview of professionals, when in fact you don't necessarily have to be that way. So in – and I'll stop in a minute, David, because I'm sure you need to go onto other things. But we have the potential within this group to really disrupt the flow of knowledge and information in healthcare, which to me is a really positive thing. We want people to have access to safe tools, but we want to stimulate innovation around them, which might actually mean that you may start consulting your iPhone instead of your physician when you have a urinary tract infection.

So I don't want to build into the regulation something that allows privileging of a professional class when in fact we have – we may not necessarily be intending to do that. And so I guess I'll leave it as a task for your group to balance the way that we assure safety and minimize – or explicitly characterize risk without necessarily privileging a professional class of health providers.

**Anna McCollister-Slipp – Galileo Analytics**

Patty, this is Anna, and I could not agree more enthusiastically with what you just said. I mean, I think it's going to be somewhat problematic if we try to predetermine or recommend that ONC or HHS tries to predetermine what is and is not appropriate for one audience versus another, or what is and is not appropriate or helpful in terms of how to visualize something, because then it becomes very prescriptive, and what works for me as a patient may not work for somebody else. You know, if you have, you know, parameters on what works for visualization, for data visualization, for instance, then what happens if the person is blind? Does everybody have to be able to see it in the same way? Does it have to work for every audience? Or are we going to create a mechanism by which lots of people can develop lots of different ways of showing or viewing or tweaking the display?

So anyway, thank you for that. I think...

**Patricia Brennan – University of Wisconsin-Madison**

Yeah.

**Anna McCollister-Slipp – Galileo Analytics**

I wholeheartedly concur.

**Patricia Brennan – University of Wisconsin-Madison**

I appreciate that.

**Bradley Thompson – Epstein Becker Green, P.C.**

If I can – this is Brad Thompson. I'm struggling with this discussion a little bit because it flies in the face of what I'm – what I'm familiar with. So I come kind of out of an FDA background, and the idea of prescription status is decades old, where we say that a given product is only safe if used under the supervision of a licensed physician, that that means something, that that credential, what they're expected to know, means something, and the product isn't safe unless it's used under their oversight. And we have corollaries to that in lots of different areas beyond the straight up prescription in the medical device area. There are all sorts of technologies that are targeted at people with specialized knowledge, because that knowledge is necessary for the product to be used safely and effectively.

So what we're talking about is a – is an old, old, old concept of factoring in the skills and abilities of the user in the calculus for whether something is safe and effective or not. So – I mean I get that we shouldn't overdo that. By all means, we shouldn't overdo that. But all I'm hearing is sort of the, to me kind of bare, obvious observation of what we've been doing for a long time in most areas of product related to medicine.

### **Patricia Brennan – University of Wisconsin-Madison**

Well, this is Patty, and I guess we're suggesting that that might need to be thought of a little differently, not only in terms of licensed professionals, so for example, things that are privileged for the use by physicians may also need to be or could be effectively used by a nurse practitioner or a physician's assistant or a clinical psychologist. And I realize licensing issues vary. But the idea that we would label a professional class versus another really opens up a lot of complexity. So I don't expect nurse practitioners to do surgery. On the other hand, a lot of nurse practitioners do stitch up small wounds. So there is some flux.

The bigger issue is that when we're talking about – I mean, a fundamental part of this act is to assure safety while stimulating innovation, and that of necessity requires us to rethink where the locus of knowledge resides in healthcare. And there may be certain things that should only be used by a physician, and I get that. And there may be things that could be widely used by everyone, and I'd like to promote that. But I think to codify some level of credentialing really opens up an enormous issue of who's going to make a decision about what knowledge base that is.

And while I agree that there are laws in every state, our read on those laws is that they actually are not very specific about knowledge, and in fact, have sometimes restricted patients' access to things that they would be perfect capable of handling, perhaps even better than blankly given physician, because it might be the purview of only a subset of physicians. Most of the physicians I know do not know what to do if somebody approaches them with an erection that lasted more than four hours. They don't know what to do with it. So...

### **Elizabeth George – Philips Healthcare**

Patty, this is Elizabeth, and I think one of the things that I was also going to mention is that we need to be cautious with that, because in fact, I know from a radiological tech standpoint that, you know, I think everybody assumes or would hope that they're all certified, but in fact, in most of the states in the United States, there is no certification required for the person that's doing the radiological tech work on you. So, you know, I think it's going to be really hard to say that certification is required for software, when in fact it's not even required yet on some of the actual electromechanical medical devices.

### **Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

So I'm listening and having trouble to bring this down to examples that are traceable for me. Julian Goldman here, and maybe, Brad, I'm saying something that you might say. This is for me still – I can understand in a general and abstract way, but it's still a bit too nebulous for me in terms of specific applications where we run into a problem like this. And maybe it's just I'm not thinking of it, and others who are having this conversation have a whole catalogue of obvious choices, but I'm having trouble seeing it. Are there any specific examples that prove the point?

### **Paul Tang – Palo Alto Medical Foundation**

Can I just try to maybe clarify, because ironically, I think we're after the same goal, you know, what Patty was talking about, and Anna, and where we might be thinking of this proposed solution in two different ways; so the proposed solution, having these two categories, is so that FDA does not get into looking at information only applications for patients. That's basically to get an 'opt' out.

At the same time, not to burden the folks, okay, we make radiation systems, advising – planning systems, and they're obviously to be used by people who know about radiation, and oncology and radiation therapy, and not have to prove that a patient – a consumer could use this. You see, in that sense, it gets the burden of regulation away from these obvious, you know, extremes, and it allows for the innovation that happens in the hands of a radiation oncologist, while not impeding the patients' access to information that's basically for information only.

That's what this was designed to solve. Ironically, I think you're interpreting it in a very different way, but that's the intent. Because if we open – if we do not clarify the on label purpose of the product and the intended user, it seems like we open up looking at all uses by all people for all things, and that brings everybody to a standstill, I think. That's the problem we're trying to solve.

**Patricia Brennan – University of Wisconsin-Madison**

Maybe, Bakul, you can help us take a step through this, because there is – we don't want to add more regulatory burden on the FDA. It's just not feasible to do this. And so – and we don't every one off to have to go through a three-year regulation cycle. So are there ways to say least restrictive language or most – you know, most essential, must occurs, in a regulatory structure? I'm not asking you to answer that right now, but if you can help us think that through.

What we're – what I think the report that Paul presented is trying to do is to identify where the risk could be, and maybe if I keep thinking about this like we think of the taxonomy, that is, it's not saying these are the highest risks or lowest risks, but in order to appraise the risk, we need to know about was...

**Paul Tang – Palo Alto Medical Foundation**

Right.

**Patricia Brennan – University of Wisconsin-Madison**

Was this intended for use by this or that? Maybe that would be helpful.

**Bradley Thompson – Epstein Becker Green, P.C.**

Bakul, are you there?

**Bakul Patel – FDA**

I'm here. Can you guys hear me?

**Patricia Brennan – University of Wisconsin-Madison**

Yes. We can hear you fine. Thanks.

**Bakul Patel – FDA**

Can you hear me now? I was just switching phones. Sorry.

**Patricia Brennan – University of Wisconsin-Madison**

Okay. I was just say – I don't want to derail the whole conversation, but I remain concerned that if we – if – with the language that's in the risk structure that refers to licensing credentials, is actually going to have possibly two outcomes that we're already seeing. One of them is a – the two outcomes that are not desirable. One of them is that defining a certain technology as the purview of a given profession without really having either the understanding of the diversity within that profession, or the possibility of that knowledge base existing in other professions.

And the second is the over-privileging of professional users to the – to determine of lay people. And in that case, I'm giving – I gave a specific example of when – the visualization of diabetes information through some of the glucometers and the insulin pumps has a patient view and a clinician view, and the clinician view is more informative, but the clinician's unable to share it with the patient because it's not FDA approved for patient use. It's approved only for clinician use.

And so are there ways we can embed in this risk appraisal process the possibility of a framework that says least restrictive or that it doesn't – that doesn't in some way bog us down with having to really understand the knowledge base of each clinician who's actually going to use a product. I have a nursing license, but right now, I can tell you, I am clinically unsafe, and so anything that said okay for use by a nurse, I still shouldn't use.

**Bakul Patel – FDA**

So I think you are raising – I mean, the discussion, I was listening to the conversation, and I think it raises a point which may be just applicable for trained users versus untrained users. And I'll explain that a little bit, because trained users can do certain things. I think licensing may be a different aspect. I think what Brad was mentioning earlier was – and I can think of – I was thinking of corollaries in other areas, a service professional only they can service certain equipment. Okay? Maybe because he's trained in that area to look at – and like in health IT case, I would suggest maybe backing up from – at least for the discussion's sake, backing up from the concept of license, and then maybe thinking about it from the trained perspective, trained versus untrained perspective.

I also see this as an opportunity for recommendation from the group of trying to understand patient preference as part of the learning system, as how can we actually get that. Because I thought – you're pointing out in terms of visualization of data, it may be okay for Anna, but may not be okay for others who may not be keen on looking at – visualizing data in a certain way. So, just thoughts for you guys to think about.

**Patricia Brennan – University of Wisconsin-Madison**

That's helpful.

**Keith Larsen – Intermountain Healthcare**

This is Keith Larsen. I was hearing the question a little bit different, and maybe you can correct me, is because we're making criteria for inclusion/exclusion or level of regulation, there would be an unintended consequence of people declaring that their software is only for use by a trained physician, because it reduces risk and may reduce then regulatory oversight. I mean, that's the way I heard this statement. Is that a correct interpretation?

**Patricia Brennan – University of Wisconsin-Madison**

Wow. That's not quite where I was going, but I see how you got there.

**Keith Larsen – Intermountain Healthcare**

Maybe it's too convoluted, but – but again, it's kind of like what we said before. If you – if we regulate something that a patient uses for health maintenance versus wellness, you know, if it has a different regulatory profile, does everyone raise their hand and say we're doing wellness? You know, and so that – I mean, in the context of this discussion, that's what I was – I was most worried about. I agree with Brad. There are some things that are only intended for physician use. But if you make a different regulatory oversight based on the level of the clinician that's using it, which may be legitimate, do you actually have the unintended consequence that you're now excluding the use of certain software because people are trying to get more of a lighter load on regulation.

**Anna McCollister-Slipp – Galileo Analytics**

Exactly, and, I mean, to sort of comment as a patient on Brad's earlier statement, and I don't mean in any way to be attacking, but we've got to revisit – when it comes to access to data and access to information, particularly that's relevant to me, that I generate, or that my family generates, or friends, or loved ones, I don't see any need to restrict that to somebody who's a physician, regardless of what it's about, whether it's blood glucose or tumor size.

I mean, I'm not going to choose to have – to do surgery on myself if I have an iPhone app that reads something and shows me this – the location of a particular tumor. But it could be interesting and helpful for me to kind of get my head around what it is I have. Now I have – as – on the flip side, as a diabetes patient, I make decisions literally 24/7 about how much insulin I should take, and it depends on a whole bunch of different factors, from what I've eaten to, you know, hormonal cycles to the weather, in some cases.

And for the medical device manufacturers to restrict access to certain data points because I'm a patient versus a physician is completely the wrong paradigm, if we're trying to encourage people to take responsibility and empower them to manage their own health conditions. And, you know, I think there's still a lot of – a significant amount of a patronizing attitude within the healthcare – within the healthcare world that is discouraging and infuriating.

Now what I want to do with my diabetes data is completely different than what my father, who has type 2, wants to do with his. But he's not going to care about what I need to do with it, because he doesn't think that – that's not his interest, and his disease isn't that complex. But it's just...

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

Well, now, now, now, now, you really don't need all that data.

[Laughter]

**Patricia Brennan – University of Wisconsin-Madison**

Who dared to say that?

**Anna McCollister-Slipp – Galileo Analytics**

Thank you. I mean, and you have no idea how many times I've heard that and other people within just the type 1 diabetes community have heard that. I mean, if I were Hugo Campos, I'd probably be doing a sit in on the White House gate. But...

**Patricia Brennan – University of Wisconsin-Madison**

Actually, I think I have a solution to this particular one, if I can submit – propose it as a friendly amendment to the risk group. And that was when you talked about transparency of the software, if we could just – of the software operation, if we could just add transparency of the software operation and the data to that line, it might – would it address what you're thinking of, Anna? I mean, if we just, as a byproduct of making the data transparent, oh, you got the data?

**Anna McCollister-Slipp – Galileo Analytics**

Yeah. I – if that fixes it, that's brilliant. I mean, I just think there should be no data generated by an individual, whether that's EHR data or whether that's medical device data or medical app data, that is not accessible by that individual or somebody that they want to access it. It just...

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

Well, despite the fact that you gave me the opening and the opportunity to be condescending and patronizing, which I enjoyed for a few seconds, I happen to agree wholeheartedly.

**Anna McCollister-Slipp – Galileo Analytics**

You sound like...

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

I happen to agree wholeheartedly with you. My 88-year-old mother receives all of our lab data from her physician. She then calls me at night and reads values to me. And some of them she understands enough to realize when her kidney function starts to deteriorate. Other things, she doesn't understand at all. And I can't fathom why we have an approach, have a system, where we do restrict data. Sure, there are some patients for whom – in whom they should not know, under certain conditions...

[Crosstalk]

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

You know, potentially bad news. But for the most part, it's really – it's just an old construct from a different time.

[Crosstalk]

**Anna McCollister-Slipp – Galileo Analytics**

And I would say even the bad news needs to be out there as well. I mean, you know, people aren't going to choose to take on something that they have no capability or interest in understanding. And...

**Paul Tang – Palo Alto Medical Foundation**

Can I just ask where on these words that you're seeing anything about restricting access to data?

**Patricia Brennan – University of Wisconsin-Madison**

Oh, no. Paul, I was just suggesting we make explicit on the line about transparency, about software operations, that we make the transparency around software operations and data.

**Bradley Thompson – Epstein Becker Green, P.C.**

So I think we need – this is Brad Thompson. We need to parse this a little bit more specifically. And what I mean by that is when I gave you my analogy of prescription status, what prescription status means is that before a patient can have something, the doctor has to sort of team with them and say, "It's okay." The data area is a little bit different. But – so I don't think any – or at least I'm not saying that patients shouldn't have access to data, any data.

But there's a question of having direct access and having access in tandem with a physician. And this is a very big issue in genetic counseling, as you know, that with all that genetic data that's out there, that tells me, you know, my likelihood of developing this disease or that disease, and so forth, and all the complexities around that, and all the uncertainty around that, there's an argument to be made that when people get that data, it ought to be with professional advice, so that they don't go off and make changes that would be maybe potentially harmful for them.

So I would – I would never say that a patient should not have access to data. The question is, should they have it in tandem with someone who can help them understand what the data mean?

**Paul Tang – Palo Alto Medical Foundation**

But can I just go back to this – the first green area?

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

Yeah.

**Paul Tang – Palo Alto Medical Foundation**

And help me understand how we even got to this discussion, which doesn't look like it's covered in this – in this – there's nothing in this matrix that precludes that. So let me read it again, and I did add something I think that may help. So intended user, I said licensed, credentialed professional, comma, if appropriate. So let's go back to the data.

**Patricia Brennan – University of Wisconsin-Madison**

That didn't help me.

**Paul Tang – Palo Alto Medical Foundation**

If it is information only, it's told what it's for, it explains what it does not do in a transparent, clear way, and it's intended user is a patient which does not have to be licensed, this would be in the column of lower risk, that does not prescribe or prohibit regulations. The FDA would use that information to say, well, if I look at this ..., I'd say this seems like a low risk – lower risk kind of proposition, and they would decide whether or not it invokes any kinds of regulatory thought. So I don't see where any of these words prohibit or even impede access to data. But that's where – so maybe I'm lost – I've gotten lost in the...

**Patricia Brennan – University of Wisconsin-Madison**

There are two things that I think would be helpful. One of them is to remove any qualification around who is – who's going to determine who's appropriate, licensed, credentialed, and eligible. That language would have to be stated very – as clearly as possible, because I think that that's where we can actually have nefarious actions come in.

And the second is that I think that when we talk about transparency, the data do have to be accessible and visible and explicitly mentioned as part of the risk framework. Otherwise, it's risky – it's riskier when the data are invisible, because we don't know if they're the right data. There's no way of tracking that the algorithm was operating on the correct patient, etcetera, all the other things. So I think that the explicit statements in the risk framework for things that encourage open access to data are critical for managing the risk.

**David Bates – Brigham and Women's Hospital**

And I think another way of handling this might be to make a statement, for example, in a preamble to say that patients need to have better access to their own data. I think – I think we all agree about that.

**Paul Tang – Palo Alto Medical Foundation**

Yeah.

**David Bates – Brigham and Women's Hospital**

Okay. So this has been a good discussion. Keith still has a presentation.

**Paul Tang – Palo Alto Medical Foundation**

Yeah.

**David Bates – Brigham and Women's Hospital**

So unless there's strong objection, I'd like to go ahead and just move on to that.

**Martin Sepulveda – IBM**

Hi, guys. This is Martin, Martin Sepulveda. I just want to make the following observation. And I find myself in this situation very often, and that is that those of us who are sitting around having these discussions are highly unrepresentative of the total population that we're talking about. So I think it's important that we frame this in a way that recognizes that things like literacy are really important in how people use information that's made available to them.

Now I'm completely in the camp of an individual should have access to any and all information, you know, that pertain to them as an individual, including in health. But I think that the suggestion that a couple have made, that it ought to be done in the context where people understand that they may need, you know, to discuss something with someone before they act, is very prudent, particularly in the context of the observation that we're a highly – we represent a highly skewed and small component of the overall population that we're talking about.

**David Bates – Brigham and Women's Hospital**

Point taken.

**Anna McCollister-Slipp – Galileo Analytics**

And just, again, and I don't mean to sound flippant or whatever, but I would – as a patient who's been frustrated with the lack of innovation and listened to manufacturers blame FDA and regulatory intractability as a result, I would say that's a very patronizing attitude. It's a very common attitude. But it's very patronizing. And I guess there's a lot at risk if we choose to go that direction in terms of a lack of innovation, in terms of a lack of patient empowerment, in terms of the inability of individuals who want to be engaged in their healthcare to be able to make decisions using the best data possible, particularly if it's data that they generate with a medical device attached to them. So, I mean...

**Martin Sepulveda – IBM**

Well, with all due respect, that's not what I said.

**Anna McCollister-Slipp – Galileo Analytics**

Okay.

**Martin Sepulveda – IBM**

Like what I'm...

**Anna McCollister-Slipp – Galileo Analytics**

Then I'm sorry for misunderstanding. I just want to make sure that...

[Crosstalk]

**Anna McCollister-Slipp – Galileo Analytics**

We don't create a regulation that's designed to set people at the lowest common denominator.

**Martin Sepulveda – IBM**

No, that's not what I said. In fact, what I said was it needs to be done in a way that, you know, provides the flexibility for people like you to do exactly what you just described, but it should not assume, by the same token, that there are others, you know, who at least ought to be aware that they, you know, should consult some other resource, right? And ... to take action. And if you feel – and to do that in a way that if you feel, you know, you've got all of the capabilities to be able to act on action, then, you know, by all means, we need to empower you to be able to do that.

But, you know, some of us sit in circumstances where we see, you know, lots of people, well-intended, you know, who are presented things in ways that they act on, and they're the ones to tell us, you know, I wish somebody had told me that. And I think we need to sort of factor that into the consideration.

**Patricia Brennan – University of Wisconsin-Madison**

This is Patty. I appreciate the differences in these opinions, and I think that the caution that you're raising, about the need to put things into context is really critical. I – unfortunately, the constraining it to requiring a clinician engagement is out of the reach of many people who lack insurance or who are cared for in public clinics, where the resident of the week has seen them, and no one knows who's responsible next. So I think we have a situation where it'd be good – someone referred to the privilege of all of us, to be appropriate stewards of the privilege we have, we need to make sure this regulation indicates a shift in access to data may require concomitant outreach, education, public information, about the need to align and engage clinical conversations in a better way, and maybe even to look at payment reform.

Because when I have a clinician say I get paid for a physical, I don't get paid for a conversation, I worry that that clinician may never have a conversation that you're hoping is going on.

**Martin Sepulveda – IBM**

Thank you. That's perfect.

**David Bates – Brigham and Women's Hospital**

So with that, let's move on to Keith.

**Keith Larsen – Intermountain Healthcare**

Okay. Can we bring up the slide? Okay. I'll go through a few slides. Our discussion was recent. It was yesterday. So these slides haven't been changed since then. But I'll hit some points, and then open it up for discussion. Can you put up the next slide?

One of the things that I came out of Washington – the Washington meeting, and just from general conversation, is I think – we should at least look at what are our current assumptions. And assumptions that I think we're making on innovation is – and risk, is number one, I think we should assume that everyone is interested in patient safety, because we're all patients, and we all have family members who are patients, and we all use healthcare. And so it's just not the purview of regulation or the vendors or anything. We have it all up and down the stack. And ultimately, those who provide the care to a patient are vitally interested that the rules they use are safe, and are giving them what they need.

Second is that we need innovation to solve problems in healthcare. I mean, I've worked in hospitals all my career, and when we're trying to solve problems in hospitals, many times we look at what kind of IT tools can we apply to it, and so there's a real role for health IT.

So – and the third thing is really need to encourage more, not less participation in this innovation and in this sector, that we really do a very general but significant harm if the end of the regulatory approach is that the price to pay to get into this sector or to contribute to the innovation in this sector is so steep that people just don't go into this work, and so those are kind of assumption that we're working on. Next slide.

We've talked about this a little bit in the taxonomy and in the last discussion, is that innovation and risk comes all up and down this type of thing. And many times, we end up, again, talking about developed software, but I like the phrase that the locus of knowledge is – or the focus of knowledge is at multi levels. And so it's a very complex system, and the tools that we've – that we've used primarily on the regulation have been certification and process definition. And so how do you apply this to the whole thing? Next slide.

This is a revamp – I know I'm going through a lot of slides at once, and then I'll – we'll stop and open it up for discussion. You know, when we were in Washington, we talked about the standard approach and a reverse approach, which is the standard approach, is that I identify risk, I respond with some kind of rules, and then I try not to harm innovation. And we talked about the opposite, which was I'm really trying to create a system that promotes innovation, because ultimately, in the long run, that's going to reduce patient risk rather than increase patient risk.

I have to address specific items of patient risk, and then I want the regulation to be minimal to address the patient risk. Many of our discussions today have felt like it's expanding rather than trying to be a minimalist approach. Next slide.

So then we talked about the difference between a legal framework and a learning framework, and this goes back to, again, the meetings back in Washington. And the learning framework is really predicated on transparency. And it was interesting, when you had a – just a – we just had a robust discussion about transparency on patient data, and the need for transparency. Well, what we're talking about here is how does transparency play into this learning framework for software? Let me get the next slide.

As we look at this, the – this is really – and we just didn't come up with this in a meeting. I mean, the IOM report that we're addressing really did talk about to encourage innovation and shared learning environment, and it really outlines an approach that is focused on shared learning, maximizing transparency, being non-punitive, and identifying the appropriate levels of accountability and minimize burden. It's really an accountability model and a learning model. And this is also echoed in the bipartisan presentation or report where it talked about creation of a learning environment for safety in health IT. So, next slide.

As we look at then the IOM report, you know government's role was defined there as the government in some cases is the only body able to do the following: provide policy guidance and direction to comply – to complement, bolster, and support private sector efforts. And second, to correct misaligned market forces. But both of that talks about tweaking the direction. Next slide.

When we come down to our – one of the things that I've struggled with, and I think the group has, is what exactly our work product that we end up with? And there are these five types of things, which is a general framework for analysis of proposed regulation. It's very reactive. It looks at things that are outlined in appendix D of the IOM report and the broader report of that. So it's really a principle of preserving innovation type approach.

The next one was the critique of current regulation with exemplars. I did send out an email earlier this week trying to outline, you know, what regulatory – what regulation looks like when you're kind of a consumer of it. But it's, you know, using those exemplars, just like David was trying to get us to use patient safety exemplars to validate and to extend our thinking as use cases.

Number three, regulatory development process, take kind of a process recommendation of how do we insert in the process of creating the regulatory product the insertion of consideration of innovation.

Fourth one is specific regulatory implementations. Again, that's much like number two, is look at what are the types of regulatory interventions, like certification, like process monitors and that, and what is their impact on innovation? And then one that we started in Washington was where Bakul was saying, well, what are the – what are the requirements that we need to meet to preserve innovation, specific requirements? Looking at the development of a regulatory product, much like we develop any software product is where we put the requirements, in this case for functionality, best practice, patient safety, alongside of requirements for innovation, and try to create a product that in this case is regulation.

As we looked at these – the other thought in here is that it – all five of these are more of – they're a little bit reactive, and they're trying to put a framework, but they're accepting to a certain extent the model as it exists. An alternate way of looking at that is what we were talking about and what was seen in the IOM report. Why don't we go back to that last – the last slide? And then we'll open it up for comments. Is that maybe instead of trying to be this reactive report of saying here's things that work and don't work, try and say, well, maybe the model for this is just wrong, and that the transparency model – again, what we're trying to do is enlist – if we assume, again, that everyone is interested in patient safety – now, of course, there's nefarious players that will not be, but that's really not what we're talking about. We're talking about the general thing where people are interested in patient safety.

So actually go to the last slide. I'm sorry. No, not last – yeah, before this, the very last of the different – of the whole slide deck. Okay. The idea that if we assume everyone's interested in patient safety, and so what we want to do is foster innovation so that we can have patient safety, but we want to make sure it's safe innovation. I personally keep coming back to this transparency model, that if we have transparency, what we're really saying is we're saying the government should do what it does best, which is organize, and create and correct market forces.

So having no barriers to sharing of the data, you know, remove the artificial barriers; having a repository of the data, then post-marketing surveillance and just transparency again. And I think that's what's being called for in the IOM report, because if you – if you do that, what you're really trying to do is – it is an accountability model rather than a control model. And you're making it a way that hospitals or anyone interested in patient safety have a way of evaluating the products that they end up using, either singly or in mixture.

And so there's – again, and now I'll open it up for discussion, there's really two ways to approach this. There's this way of looking at regulatory interventions and try to make some comment on them and give some guidance, or there's the idea of do we just talk about a different model that really covers the regulation itself, you know, the regulatory model itself, and which one could be most effective to meet patient safety, and also encourage people to give us better products. Any comments?

**Bradley Thompson – Epstein Becker Green, P.C.**

So this is Brad Thompson, and I'd like to kind of approach this from – so I'm on the regulations group and to some extent – to a great extent, we really want to use your work product. We really want to use your work product to inform what the regulations group is going to do.

So as a – as a consumer of your work product, what I'm – what I'm really hoping you tell us is in some prioritized sense, what the most important attributes are, or features are of innovation that need to be protected. And I'll give you an example, because it's easier to speak in examples than it is in generalities.

You had a slide a couple back where you had several of these, and I'm sure there's a lot more, but one of the things you might say, for example, is from – for innovation in HIT to really flourish, developers need the ability to really tinker and use real human data, albeit maybe on a small scale, in order to be able to develop their HIT innovations, that for innovative software, it is terribly important to have a model which allows for nearly constant updating of the software to reflect changes in the IT ecosystem, to reflect changes in user needs or wants, to reflect changes in whatever might be driving it.

You might tell us, for example, that health IT by its very nature is an incredibly collaborative activity. So one of the most important things to us is that we be able to work – have a coder, developers, work side by side with clinicians, who work side by side with others, and you might describe how that works. You might say that one of the most important things in health IT is to preserve the innovation that occurs at the user level, in addition to the developer level.

And I'm sure you could list 20 such things, and so what I'm really hoping, apart from anything else you might do, is that you tell us on the regulations group what those most important elements are, and most importantly, maybe, that you prioritize them or rank them to give us a sense of which is truly the most important, because then what we would do in the regulations group is take that intelligence, take that work product, and go through some of the things that we're looking at in the way of regulation, and then rank the approaches that we're looking at.

Well, you know, the innovations group told us that the very most important thing that they do or need to be able to do is use real human data, you know, even if just a small subset. So does the model that we're developing accomplish that objective? Just go right down your list to make sure that what we're coming up with in the way of regulatory specs in is – is in as much as we can make it perfect synch with what you're doing, and, you know, from Paul's discussion earlier on safety, that it hits on all of those risk factors that the safety part of your collective work product is addressed as well.

So I'm just – I'm focused on the interface between our two working groups. That would be really valuable to us.

**Keith Larsen – Intermountain Healthcare**

Okay. Thanks. I mean, that would be like the innovative requirements idea...

**Bradley Thompson – Epstein Becker Green, P.C.**

Yes, the last on the list here.

**Keith Larsen – Intermountain Healthcare**

That...talks about. Yeah. The last on there, to say, these are – these are things that we're trying to preserve.

**Bradley Thompson – Epstein Becker Green, P.C.**

Exactly, yeah.

**Keith Larsen – Intermountain Healthcare**

Okay, other comments?

**Patricia Brennan – University of Wisconsin-Madison**

This is Patty. I really like the balancing of safety and innovation, and I think that's really important to be considering. I think that it would be helpful to know if your group has had some conversation about whether you think there currently barriers exists to innovation because of safety constraints, first of all, and secondly, if there's – if you've had any discussion about what safety constitutes in this area. Is it safe use of the entity? Is it no harm in the care process, no delay in treatment, that type of thing? Thank you.

**Keith Larsen – Intermountain Healthcare**

Okay. Let me address that a little bit. I mean, the interesting thing is the IOM report said that in our information about contribution of software to patient harm is very small, and maybe in – maybe is inhibited by – in our transparency in all this.

But when we – when we went around the room, and Brad in their group, when they presented in the last meeting, and then I saw it again in the taxonomy presentation, really, what we come down to are things like bad data, you know, and it's bad data because it's showing data on a wrong patient. It's malformed presentation. It's somehow I got confused on which patient I was working on, or it's things like what Julian was talking about, sampling rate. But it's all this data that, again, is supporting human decision making, whether it's making the decision, or not and there is calculations in that.

That's – if I look at a regulatory approach, so far, it's how do I get to that in a certification process, unless what I do is prescribe precisely what the sampling rate is, what the standard for a sampling rate is, or how the data should look on a particular screen, and at that point, you're missing opportunities, because someone may have thought of a better way of doing it, because you're trying to get at a particular issue using a pretty blunt instrument.

And then how do I get that with something like a process control that says it will somewhere along the line – I mean, if you look at the process control, a lot of it's about making the development of software transparent to the stakeholders, so that they can do some of this correction. But they don't address precisely these patient safety issues. So, you know, it goes a little bit back to what Brad is saying, is that what are we trying to preserve and what are the models of regulation that will preserve that and encourage actually – not just preserve, but encourage more people to get involved in this area?

**Patricia Brennan – University of Wisconsin-Madison**

So like I understood...

[Crosstalk]

**Bakul Patel – FDA**

I'm sorry. This is Bakul. I was just going to pose a question to the group. Do you think specifying product, you know, health IT features, either through certification or through regulation, would ...or innovate or enhance innovation? Because I can see an example, if we tell health IT to do visualize – data visualization a certain way, and that's a requirement from – as a part of regulation, there may be many other ways to visualize that data. Is that something the group has thought about?

**David Bates – Brigham and Women's Hospital**

This is Dave. I think it's actually done both. It's – well, forced people to innovate in many ways, because there were many functions that most of the vendor systems just did not have, and that they would not have gotten around to, so they've had to build them.

At the same time, I think it's also inhibiting in many ways because people are essentially sort of so focused on those criteria that they're sort of – it's like they're teaching to the test. The vendors say, “You know, we're going to do these things, and we can't do anything else, because we have all these things to do.”

**Keith Larsen – Intermountain Healthcare**

I think that – echoing what you're saying, Dave, I think that they can do both. I mean, if I look at – at some point, there was a consensus that med management – patient safety is enhanced if we have management of the med right from ordering through dispensing through administration, with tools like barcoding and that. And it really freed people – I mean, it freed the vendors from the certain standpoint, because they know that – you're engaging the market forces again. Okay? This has become something that is important, so we're going to create systems in this space.

And so you encourage people by essentially saying here's the problem, now solve it. I think where it becomes inhibiting is when the description of them – of the solution is really part of the certification process, because in that case, what we're saying is that the group of individual who put together this certification really do know best practice, and the best practice has been found, and the only – the only thing we should do now is just conform. And that's where I think that there's a real inhibition of innovation, because it's an answer, and it is an answer that is being canonized, but is it the – is it the right answer? And you're really precluding the conversation to find other answers.

[Crosstalk]

**David Bates – Brigham and Women's Hospital**

Good discussion. Is that – did someone have another comment?

**Matthew Quinn – FCC**

Yeah. Just a quick one from Matt to bring attention to something that's different in certification rules this time around, and that is that in the past, certification rules have been mostly functional, need to have this function or that. And for the first time, the safety enhanced design piece and the quality management systems piece have really sought to add, you know, does this stuff work as it's supposed to, or was it developed in ways that are rigorous?

And the safety enhanced design requires developers to describe their process, what standards they use, whether it is NISTIR 7742 or something else, for including user centered design. And second, to report on the – using the common industry format for summative usability testing, the results of the usability – summative usability testing for the medication – the functions and certification associated with medication management.

And so there is no judgment as to the result of those tests, other than by the general public, which as part of certification we'll get to see those. And there is no prescribed three-part test, as was something else that we developed at NIST, and published technical guidance on. But at the same time, you know, that's a piece in saying it's – we're making that information available. And I hope that that describes something a little bit different than the traditional certification around functions. And the quality management systems are very similar.

**Keith Larsen – Intermountain Healthcare**

Well, again, I mean, part of it is a transparency issue...

**Matthew Quinn – FCC**

Yeah.

**Keith Larsen – Intermountain Healthcare**

That it makes it more transparent on how the – how it was created, and what standards and other things they used to create the thing. Do you think that that – you know, and I agree that those things raise it up, but when I do a certification, it's somewhat binary, right? It's either certified or it's not.

**Matthew Quinn – FCC**

Right, it's really – unless you don't fill out the form...

**Keith Larsen – Intermountain Healthcare**

Yeah.

**Matthew Quinn – FCC**

And – I mean, you know, with the quality management systems, you can have no quality management system and say it, and you still pass. But, you know, it's a start and a foundation on which to build, potentially. And, you know, if I'm evaluating systems, you know, and I look through that available information, now I can look at the ones that, you know, vendors have said no, we don't have a quality management system, or, you know, we wrote, you know, the first chapter of *The Wizard of Oz* in our summative usability testing form.

**Keith Larsen – Intermountain Healthcare**

Mm-hmm.

**Matthew Quinn – FCC**

You know, that should say something.

**Keith Larsen – Intermountain Healthcare**

Yeah, it does.

**Matthew Quinn – FCC**

And that is there. But it isn't the rigor that, for example, FDA would use in asking for evaluation. They would judge those forms and make their binary judgment, you know, on whether to move forward or not based on that. Just some perspective on, you know, something that's already in the works.

**Keith Larsen – Intermountain Healthcare**

Okay. Good.

**David Bates – Brigham and Women's Hospital**

Okay.

**Keith Larsen – Intermountain Healthcare**

Other comments?

**David Bates – Brigham and Women's Hospital**

I think we should – we should wrap this up, because I do want to give the regulations group some time.

**Keith Larsen – Intermountain Healthcare**

Okay.

**David Bates – Brigham and Women's Hospital**

And as Brad noted, they've been kind of waiting to hear what's coming out of risk and innovation, which is why I let this discussion go on a bit longer. It's been good. But let me hand things over to Brad and to Julian.

**Keith Larsen – Intermountain Healthcare**

Okay. Thank you.

**Bradley Thompson – Epstein Becker Green, P.C.**

Julian, are you still on? I don't know if we've lost him or not. It's probably 4:00 AM.

**Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

I'm still – I am still here. It is 4:00 AM. It's been a heck of a lullaby.

**Bradley Thompson – Epstein Becker Green, P.C.**

Yeah. Well, if – Julian and I have not had a chance to talk since our last meeting, this was only Wednesday. But what I thought we might spend our time on this afternoon is more the process that we're going through than the substance, because as a group, we really haven't reached even very many substantive recommendations yet. We're still in a – in a process standpoint.

So I just put together a few slides to sort of outline what we're doing, and basically, in the month of June, what we're doing is kind of leveling the knowledge throughout the regulation subgroup. So, some of us come from an ONC background, some from an FCC background, and some from an FDA background. And we're using this month to go through the regulatory requirements of each of the three agencies and study how they apply to HIT, the pros and cons, the good fits, the bad fits, really trying to understand all of that. And that's kind of our month of June.

What I'm going to do is kind of show you how we've done it so far with FDA, because we started with FDA. We took two 90-minute meetings in order to cover the FDA topic. We're going to do ONC and FCC next week. I think both of them are scheduled for next week. We've got two two-hour sessions, I think Wednesday and Thursday, or something of next week.

So I'm going to show you how we've done it with FDA. I'm not going to go through all that we did, because there's no way we have time. I'm just going to sort of show you by illustration how we approached it. And I'll show you from there. Hopefully, it'll make sense.

Before I get too deeply into it, though, I thought this might be an appropriate time just to make sure that we're all kind of level in our understanding of what FDA does regulate. And so I developed this kind of from a patient-centric standpoint, thinking about devices and those that actually touch the patient as kind of on one level, and then moving away from the patient to make sure everyone has the same general understanding of what FDA regulates.

So the first category I called classic medical devices. I made that up completely. That has no meaning to it, other than it's what everyone naturally thinks of when you say a medical device. So things like pacemakers that are actually implanted, but also monitors and infusion pumps and so forth that are tethered to the patient, and even ultimately the operating table and wheelchairs used to move the patient around. All of those things are clearly sort of the classic medical devices.

The next level away from the patient are those things that work on patients – on human specimens, or patient specimens, and they come in two general flavors. The first is lab equipment, big analyzers that sit in a central lab and work on a lot of specimens at once, and then those that might be handheld or otherwise used at point of care, or in the home, things like a blood glucose meter or INR meter or other things that can be used, either by the patient or by someone in a – in a physician's office, for example.

Moving one step away from the patient further, you get to the sort of HIT connective tissue issue, and this is where – connective tissue, I'm not being literal, but this is where you start moving more into purely IT, which might in some sense be viewed as a standalone, not resident on a pacemaker, but for example, MDDS is a category we've been talking a lot about. MDDS is itself a fairly narrow category. You know, it's only for retrieval, storage, display, or conversion of data from devices. If it analyzes the data, then typically it's in one of the other – the first two categories. If it analyzes pacemaker data, it's treated with the pacemaker. If it analyzes blood glucose data, it's treated with the blood glucose meter. But we have this level of HIT which is really designed to move data around, and then LIS, I should have spelled that out. That's laboratory information systems, same concept, but taking data from a laboratory. But again, now we're sort of in the HIT realm.

And then finally, the furthest away in a sense from the patient is standalone software, which can come in any number of flavors. CAD is a classic example. Those of you in – who have a background in radiology are very familiar with this. It's software that might look at a medical image, for example, and circle on the image a suspicious dark area or light area or whatever it might happen to be, and direct the radiologist to study that more carefully.

You have CDS software that basically is an aid in some manner. It reminds people about taking drugs, or it's a calculator for any number of clinical purposes, or maybe even it does cancer treatment analytics. I put EHR there because FDA has said that EHR is technically a medical device, but not actively regulated by FDA.

And then in the low right hand corners, when you get farthest away kind of from the patient, and you're looking at HIT, which is unregulated by FDA, and a lot of what, you know, I heard in the taxonomy committee fell into that category, clearly outside of the FDA realm, so it's unrelated by FDA, but still HIT by the definition that we're collectively developing.

So I just visually depict this, and I've got the patient at the bottom there, and show kind of as you move away from the patient, the layers, the – excuse me, it's the third and fourth layers, being HIT layers, that we're discussing in some manner; and then the green layer, being that which is outside of FDA's realm. So the blue, various shades of blue, FDA, green, non-FDA.

And then I drew this red circle around it to emphasize a point that Julian and others have really emphasized, which is where some of the greatest risk might be is actually at maybe the dividing line between FDA jurisdiction and not, whatever it is outside of FDA jurisdiction. And so that dividing line becomes a source of risk that we have to consider. So that's, again, just to sort of level set, make sure that we're talking about the same things.

So in our work, what we're doing is trying to look at the regulatory requirements through the prism of different health IT use cases to see whether we're fitting a square peg in a round hole, or a square peg in a square hole, just trying to assess how good that fit is. And we came up with this, you know, very high level, simplistic green/yellow/red to show kind of the spectrum from clearly does fit to red, clearly doesn't fit, and yellow being something in the middle. We haven't done too much of that yet. I'm not even sure we'll make sure of it in the end. But it's something that we're – that we're considering, and I'll show you kind of how this ultimately gets used.

When we got to the use case area, we really had a lot of different use cases that we could talk about. Members of the group identified a range. We initially started talking about mechanical ventilation weaning, because it was a classic example of CDS. But, you know, it's fundamentally different from a mobile app that might be a consumer mobile app, and the risk profile is completely different. Maybe the innovation issues are different. I don't know. But it really presents a different set of issues. And we've got the interoperability issue, which to some extent is maybe that red circle that I drew around FDA, but it also could reside other places. It could reside in the hardware. It could reside in some of the outer reaches of the blue area on the previous diagram. But there are important issues embedded in interoperability.

And then, you know, a number of our folks are involved in the AAMI work, and pointed out that there's a great classic use case potentially available to us for PCA, and I have the link – the link there.

We ultimately decided to set that aside for the present time, start to dive into the regulations, and then after our kind of appreciation of those regulations had risen somewhat, go back to the use cases to figure out maybe which ones we need to draw upon to illustrate whatever the points are that we're trying to – that we're trying to make. So we're holding this in abeyance presently.

So when we went through this exercise, one of the things that I tried to keep track of is themes that I was hearing from our members of the regulations workgroup about what makes HIT different, and therefore, when we look at the regulatory issues, what we need to keep in our minds when we're trying to interpret these regulations to see if they fit, don't fit, or are someplace in the middle.

And I've come up with this list of themes so far from the discussion. I'm sure we can add to it. And this is an area where, Keith, to go back to my prior comment on, for example, the innovations work, I would love to take your list that you guys might develop of important aspects of innovation that need to be protected, and add them to this list, because the way we're using this list is to sort of test the regulatory system to see whether it fits HIT. So I want to add those, and I want to add what Paul was going through in the way of risks. I want to add that here as well, to make sure that we're – that we're carrying that work over and using it as our prism, as our way of looking at – of kicking the tires on these – on these regulatory systems that we're considering, the FDA, ONC, and FCC, and whatever else we might come up with.

So I'm not going to go through all these in detail. You know, we've got the systems element, which makes HIT different from many classic medical devices. We have the needs of the end user to modify. We have the very virtual nature of the manufacturing process itself that makes it hard to pinpoint. We have the virtual nature of the software itself, and a lot of the regulations contemplate physical product. And so that becomes an issue of interpretation.

So what we've done, and we did it for FDA purposes in about 30 slides, is we went through and we identified the regulatory requirement – so this is just a not quite random example, 801.4, labeling, and it defines the concept of intended use. And we looked at the definition, and we said, okay, what's the purpose of the definition? That's the purpose of the risk mitigated, or purpose or risk mitigated. Sorry. And then we said, okay, you know, in HIT, what are the unique issues that FDA needs to make sure that it – that it addresses in some manner, where HIT is different from other medical devices, or at least the regulated HIT is different? And we listed them.

So, for example, you know, for HIT it seems as though the intended use evolves constantly over time. Well, you know, for most medical devices, that is true, but I would argue it's more true with some HIT than it is with other products. So that's something that FDA has to think about when it's taking this concept and applying it in their regulatory scheme.

So literally, we went through, and we had 30 different slides, and I'm not going to – I've only got 2 of them, I think, here. The other one is the so-called quality system, and most of you have probably heard of this. This is a set of regulations, a rather lengthy set, it's like 25 or 30 regulations that basically tell manufacturers how to make product.

Well, they were written for the most part with physical product in mind, not as much with standalone software, although standalone software has been regulated by FDA for decades. But clearly, the emphasis seemed to be on physical product.

So here, the reason I included this example is because this is where our committee said, okay, you know, there's a group out there, AAMI, that's done an enormous amount of work on this specific question. They've looked at the quality system, first in the context of MDDS, and they've asked themselves, which of these apply in the case of HI – of MDDS? And that group, which was a very interdisciplinary group, FDA participated, a lot of industry people participated, they came up with these five subparts as being the cornerstone, as it were, of a quality system for MDDS. And now AAMI is going to work on a broader HIT analysis.

So to us, you know, rather than reinvent the wheel, I think we're going to use that as a starting point and see if it's something that we can – that we can support. So, for example, I have to check on the derivation of this slide. These are a bunch of sections that – and I'm cautioning, I'm not sure it's the AAMI committee or if it's individuals that we consulted on the AAMI committee – that said, you know, these were areas where either they just didn't apply because they clearly related to physical product, or they had limited application to when software is used. And in fact, I think most of them are more limited than zero application.

So we're going to – we're going to build on that work of that other group, and see how FDA regulation applies in the case more broadly of HIT.

So here is a way of potentially summarizing what we're doing. So here are – you can read from 801 to 898 are basically the medical device regulations. And what we've done – and by the way, there's a caption here at the bottom that says this is basically my work product, not the committee work product, because I haven't – you know, I haven't tried to take a vote or haven't tried to get concrete feedback on any of this. So don't treat this as committee work product.

But, you know, about a third of them seem to fit very naturally to HIT. About a third of them or maybe more like 40 percent of them required some clarity or adaptation or, you know, FDA might have to publish guidance in order to explain how they – how they're to be applied to HIT. And then two just didn't apply at all, but it didn't create a problem. These are things that just wouldn't be applicable to HIT. So the red's kind of misleading. It's not that they need to be changed. It's just that they wouldn't apply.

So we're going through that. We've gone through it with FDA. As I said, we're going to do it with ONC. We're going to do it with FCC. And then in July, we're kind of going to shift gears, and we're going to kind of become more “big picture.”

So the first thing we're going to do, and this is where we really need, you know, the input, and this is going to be the very first week of July, where we need the input of the innovations and safety sub-workgroup to start, you know, okay, we've been through each of the different sections. Now for each of the three agencies, are there risks maybe that Paul and his work have identified that are not addressed by these agency requirements? So is – are the regulatory requirements under-inclusive?

Second question we're going to ask, are they over-inclusive? Is it too much? Are we, to Paul's point about, you know, not to go beyond what you need to do, have them narrowly focused: we're going to look and make sure that they aren't overdone? Then third, you know, and this – we really need the innovation stuff, have the needs for innovation been adequately protected? So we're going to go through these regulations that we've just studied and ask ourselves, you know, how well they do at protecting whatever Keith and his group says need to be protected.

And then we're going to ask ourselves the net question. Is there a better way than these existing ways to do this? So that's the task, you know, at the beginning of July, after we've done the agency by agency review of all the regulatory requirements. Then we're going to go just one step bigger and say, okay, now looking at all three agencies together, how does it work? So the big picture was each of the three individually. Then the slightly bigger picture is all three together.

And the statute, section 618, asks us specifically to identify key ambiguities in the regulatory scheme and areas of duplication. We've already taken a preliminary pass. We did that at the face to face meeting. I've been charged with putting together a list based on the discussion from that. And then the group is going to prioritize those. So areas of ambiguity, areas of duplication, and then changes to the regulatory requirements needed to address safety or innovation. So at that level, we're going to answer that question.

Then kind of at the very end of the day, we're going to make sure that we aren't, you know, just seeing the individual trees. We're going to step back and look at look at the whole schema that we've just been through rigorously, we've kicked the tires, we've looked for ambiguities, we've looked for duplication, we've looked for areas where innovation is being infringed upon, we've looked for areas of regulatory overkill, under-kill, all those things on that checklist.

We're going to step back and say, "Okay, is this the best way to do it?" That'll be the ultimate question that we ask ourselves, and then it'll feed into the final work product that we'll be developing I presume in the second half of July, which is big picture, what should the goals of the agency be for the regulatory specs as they consider revisions to this entire regulatory process, areas of duplication that need to be resolved, regulatory elements that need to be changed, and ambiguities that need to be clarified. As I read the statute, we are basically charged with coming up with those elements in our final work product. So that's what we're working toward ultimately. And I'd be happy to take questions. Julian, how did I do? Do you have other points you want to make? Julian, I don't know if you've got us on mute.

**David Bates – Brigham and Women's Hospital**

Or it's possible he's fallen asleep.

**Bradley Thompson – Epstein Becker Green, P.C.**

Wouldn't blame him.

**Paul Tang – Palo Alto Medical Foundation**

He's in China.

**Bradley Thompson – Epstein Becker Green, P.C.**

Yeah. Well, anyone? Comments, questions, or concerns about any of that?

**Anna McCollister-Slipp – Galileo Analytics**

This is Anna. I just wanted to say, I think this is really, really helpful, and a great framework and method for really thinking about it. And – so thank you. I think it's really, really helpful. And thanks to all of the subgroup chairs. You guys are doing all the hard – heavy lifting. It's easy to send out opinions and give examples, but you guys are doing the heavy lifting.

**Bradley Thompson – Epstein Becker Green, P.C.**

Very kind.

**David Bates – Brigham and Women's Hospital**

This is Dave. Let me just make one comment. It might be that there might be some activity that would need to be done by someone who's not one of the three agencies, too, and I think that should be something that you should think about.

**Bradley Thompson – Epstein Becker Green, P.C.**

Well, we talked about that, particularly in the context of the duplication, because we asked ourselves, for example, if an agency duplicates a state, you know, regulatory requirement, or a product liability, or whatever, so it's unnecessary because other laws, other agencies already covered it, that that's fair game. But we limited ourselves to the three agencies because the way section 618 is written, this is all feeding into those three, for them to basically come up with their collective strategy. So we felt as though it would be out of scope, for example, for us to say the FTC should change what it's doing in this way, because they're not at the table. They're not here to talk about it or participate.

**David Bates – Brigham and Women's Hospital**

Okay. Any other comments?

**Keith Larsen – Intermountain Healthcare**

Brad, this is Keith Larsen. You said that there were some of the slides that you considered that were not in this deck, you know, that – is that true, and could I get a copy of those so that we can –

**Bradley Thompson – Epstein Becker Green, P.C.**

Absolutely, it's 50 slides, so... it's 50 not including the number that I just showed you.

**Keith Larsen – Intermountain Healthcare**

Yeah.

**Bradley Thompson – Epstein Becker Green, P.C.**

So the slides that go through the FDA requirements and include our notes. So, absolutely; I'm happy to – I'll do that as soon as we hang up.

**Keith Larsen – Intermountain Healthcare**

And then we can start feeding back on a more informal basis, you know, some of the information that you need about what's important for innovation.

**Bradley Thompson – Epstein Becker Green, P.C.**

Yeah.

**Keith Larsen – Intermountain Healthcare**

If that works.

**Bradley Thompson – Epstein Becker Green, P.C.**

Yeah. That'd be great.

**Keith Larsen – Intermountain Healthcare**

Okay.

**Joseph Smith – West Health**

Yeah. Hi. This is Joe Smith, and if only to prove that I stayed on the call the whole time, I felt like I needed to say something. So Meghan Dierks and I were having a little bit of email traffic around and issue that's come up a couple of times in the course of conversation today, and that's this funny transitional area between what people – what manufacturers make, what stores distribute, and then the kind of tailoring or tinkering that happens at the – you know, at the coal face, where the work's actually happening.

It's been brought up as, you know, kind of the hotbed for innovation. That's where kind of these changes turn into learning opportunities, where we understand how to do things differently. And it also comes up when we think about in or out of scope for regulation. I watched earlier where we almost folded everything that, you know, a doc can do to an API or an interface into that which we will consider for regulation.

And to me, the parallel between, you know, federally regulated processes for manufacturers making stuff and then the practice of medicine, where you can tinker and tailor and alter for local benefit, I wonder if that parallel doesn't apply here. And it speaks to when we say, you know, that we're going to look at the three government agencies to regulate it, we have to realize that there's a lot of regulation about the stuff that happens very locally. And when you think about the parallel to the practice of medicine, there's, you know, hospital boards and local review boards and state practice – state medical boards that review all of those kind of tinkering that people do to create new procedures that are not federally regulated.

And I just wonder, as we do this – as we talk about scope, maybe there's stuff that's in scope for regulation, but out of scope for federal regulation, and it brings up this notion of local control and local review and local regulation, and gives space for that. I wouldn't want to see us get too overarching in our central planning efforts, and not leave room for the local regulation that will allow some latitude, flexibility, and innovation.

**Keith Larsen – Intermountain Healthcare**

I think – this is Keith. I think that the...is, again, I think the local regulation goes right down to institutions that are consuming this, and their responsibilities, also. But – so I'm assuming that as we talk about this, that we're defining the appropriate role for the structure at the federal level. Is that correct? Without defining other layers, but –

**Bradley Thompson – Epstein Becker Green, P.C.**

Right. I mean, we can only, as I understand it, really, from the statute, we can only input to the three agencies as they develop their sort of overarching approach. And to some extent, we have to take the state regulation as a – as an environmental factor. It's either there, not there, it's robust, not robust. It is what it is, and so when we're looking at duplication, if it's there, if it's robust, then there's no reason to duplicate it. If it's not there, we can't really say it should be there, because we don't – we don't really have a mechanism or a vehicle to accomplish that, not through the process of section 618.

**Matthew Quinn – FCC**

This is Matt. Maybe another way to look at it is to, before we get to the regulatory piece, to just back up and look at the risk piece. And so, for example, you know, there are risks that we'll discover, either proactively as part of this, or through mechanisms for learning from what's going on in the field. You know, for example, a situation where customization is going on, you know, for example, in hospitals, and it's, you know, medical errors or things that are occurring, to have the mechanism in place to track that.

Anyway, all of the risks won't necessarily be mitigated, or the best lever – the best carrot or stick isn't going to be a federal one, and certainly not a federal one wielded by, you know, the three horsemen of the FDASIA here. And so maybe that's a place where as we look at this – there's an interface between risk and – the risk workgroup and the regulation workgroup, and we might not – maybe a good way to look at it is to call out the risks that are addressed and identified in the other group, but aren't really well-managed or mitigated by recommendations in the federal regulation to these three agencies. So maybe gaps...

**Jodi Daniel – Office of the National Coordinator**

This is Jodi Daniel. Can I – one thought here is that while it is the three agencies that we're talking about, there is a broader context, which is I think what people are trying to say. You know, there is...

**Bradley Thompson – Epstein Becker Green, P.C.**

Yeah.

**Jodi Daniel – Office of the National Coordinator**

...FTC. There are state rules. It would be helpful to the extent the group has awareness of other things that may mitigate certain risks, to make those – you know, to include those in your thinking and in your report back to us, so that as we're thinking about the federal agency approach, we have that as context. Because there may be things we leave off the table because FTC can do that, even if we don't take the action – you know, even if we're not setting the role for FTC, it would be helpful context. Or if there are state rules that, you know, kind of govern how a hospital might implement an EHR system, or something like that, or – you know, some other processes in place that provide context or that may impact what we would do, because, you know, there's already some other mechanism. You should bring that to our attention.

But I agree, we're not necessarily going to be saying states should regulate in this space, because we don't really have a mechanism for making that happen. So I think it's helpful as context, so that we don't go do more than we need to do, or put forward a draft framework that goes down what we need to do, but, you know, I don't think we necessarily can direct state action. So I think more contexts, and making sure that we are, you know kind of developing something in the broader context.... Does that help?

[Crosstalk]

**Joseph Smith – West Health**

Yeah. That's great. I was – this is Joe again. I wasn't in any way suggesting that we mandate what states do, but rather, we provide latitude for what local control can best do.

**Matthew Quinn – FCC**

Yeah. That makes a lot of – this is Matt. That makes a lot of sense, but to call out where things – where risks are being mitigated by – or where more appropriate mitigation mechanisms would be then by the three agencies. So for example – I mean, you know, throw in the Joint Commission. Throw in lots of stuff that exists today that is a risk mitigation mechanism. That doesn't necessarily have to be the federal government.

**Joseph Smith – West Health**

Right, thanks.

**David Bates – Brigham and Women's Hospital**

Meg Marshall, are you still on the phone?

**Meg Marshall – Cerner Corporation**

Yes, I am.

**David Bates – Brigham and Women's Hospital**

Do you want to just say a word about the EHR code of conduct statement?

**Meg Marshall – Cerner Corporation**

Well, I'm certainly not prepared for that right now, but I'd be more than happy to forward a copy on to the workgroup. David and I had discussed this earlier, and essentially, the Electronic Health Record Association came together and created an industry code of conduct to address these types of – to address several issues, in addition to patient safety; and a code of conduct, a voluntary code of conduct that may be adopted by any EHR developer. So I'm certainly more than happy to share that document itself, and an accompanying FAQ document. And I could facilitate any discussions with the EHRA that the group would like.

**David Bates – Brigham and Women's Hospital**

Yeah, that'd be great. It was – this was just announced this week, and it addresses a number of the issues that have come up as – been identified as problems previously. And I think it relates quite a bit to some of Keith's remarks today. Okay.

So the hour is late, and we need to get to public comment soon. Great discussion today, we covered a wide range from the – from all three groups. In the next session, I think we'll try and plan to get a near final taxonomy set of – set of recommendations. We'll hear some more from the risk and innovation – the risk and innovation group, and have, again, the regulatory group discuss a bit about where they are. And I will be in touch with each of you in the – in the interim to talk about the specifics about what I hope we will cover then. And I think we will reserve some time next time to talk about a few more general issues.

But a really great discussion today, and at this point, I think – I think, MacKenzie, it would be good to go to public comment.

## **Public Comment**

### **MacKenzie Robertson – Office of the National Coordinator**

All right, Operator, can you please open the lines for public comment?

### **Operator**

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

### **David Bates – Brigham and Women's Hospital**

Okay. Well, any other – any other comments from the – from the group?

### **Paul Tang – Palo Alto Medical Foundation**

Dave, this is Paul Tang, one quick comment. We did – I think every group has talked about exemplars, and you had that exercise at the end of the face to face meeting. It might be useful to have a – sort of a repository of some exemplars that we could all draw upon, just to test each of our frameworks and thoughts.

### **David Bates – Brigham and Women's Hospital**

Yeah. I think that's a great suggestion. I actually have been thinking the same thing, and have a very rough set of notes that I've taken around that, and been meaning to go through and clean it up a little bit. But that's very helpful and then we'll need to refine it and expand it and so on.

### **Paul Tang – Palo Alto Medical Foundation**

Right.

### **David Bates – Brigham and Women's Hospital**

Any other thoughts?

### **Patricia Brennan – University of Wisconsin-Madison**

And I know that I've – I owe a couple of you guys some case studies. I had a puppy health crisis this week, so I've been a bit distracted, but anyway, I will get those to you.

### **David Bates – Brigham and Women's Hospital**

Okay. Great. Okay. Well, thank you all. Have – great call, long call on a weekend. Thank you especially, Julian. Get some sleep, a little bit. And we will be talking again soon.

### **Julian Goldman – Massachusetts General Hospital/Partners Healthcare**

Sure.

### **Meg Marshall – Cerner Corporation**

Thank you.

### **Patricia Brennan – University of Wisconsin-Madison**

Thanks, everybody. Have a good weekend.

[Crosstalk]

### **David Bates – Brigham and Women's Hospital**

Bye-bye.