HIT Policy Committee
FDASIA Workgroup
Transcript
May 30, 2013

Presentation

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Good morning everybody. This is MacKenzie Robertson in the Office of the National Coordinator for Health IT. Welcome to the HIT Policy Committee's FDASIA Workgroup in-person meeting. This is a public workgroup meeting and there is time for public comment at the end of the agenda today. This is a 2-day meeting; it will be today and half day tomorrow. And I will now go through the roll call. David Bates?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks David. Patricia Brennan? Geoff Clapp?

Geoffrey Clapp – Better – Co-Founder
Here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Geoff. Todd Cooper.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
Good morning.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Todd. Meghan Dierks?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Meghan. Esther Dyson? Richard Eaton?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Richard. Anura Fernando? Lauren Fifield?

Lauren Fifield – Practice Fusion – Senior Policy Advisor
Here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Lauren. Mike Flis?

Michael Flis – Roche Diagnostics – Regulatory Manager
Here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Mike. Elisabeth George?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Elisabeth. Julian Goldman?

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
Good Morning.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Julian. Drew Hickerson?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Drew. Jeff Jacques?

Jeffrey Jacques, MD – Aetna – President, Neonatal Solutions
Present.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Jeff. Robert Jarrin?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Robert. Mo Kaushal?

Mohit Kaushal, MD, MBA – Aberdare Ventures/National Venture Capital Association – Partner
Good morning.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Mo. Keith Larsen?

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director
I'm here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Keith. Mary Anne Leach?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Mary Anne. Meg Marshall?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Meg. Mary Mastenbrook? Jackie McCarthy?

Jackie McCarthy – CTIA – The Wireless Association – Director of Wireless Internet Development
Here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Jackie. Anna McCollister-Slipp?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Anna. Jonathan Potter?

Jonathan Potter, JD – Application Developers Alliance – President
Yes.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Jonathan. Jared Quoyeser?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Jared. Martin Sepulveda?

Martin J. Sepulveda, MD, MPH, FACP – IBM Corporation – Fellow, Vice President of Research
Here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Martin. Joe Smith?

Joseph M. Smith, MD, PhD, FACC – West Health – Chief Medical and Science Officer
Good Morning.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Joe. Mike Swiernik?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Mike. Paul Tang?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Paul. Brad Thompson?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Brad. Jodi Daniel?

Jodi Daniel, JD, MPH – Office of the National Coordinator
Here.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Jodi. Bakul Patel?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Bakul. And Matt Quinn?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Matt. With that, I will turn the agenda over to you David.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Thanks very much MacKenzie. Well, want to welcome everyone; it's really good to see everybody. We clearly have a lot to do over the next couple of days; I'm hoping that this will be very productive. The objectives of this meeting are really for us to get an initial set of ideas around where we want to go and for everyone to meet each other and get to know each other a little bit. One minor housekeeping thing, I'd encourage you to consider choosing the brown-bag option for lunch, if you do that, they'll bring the lunch here and then we can talk amongst each other and get to know each other a little better.

So, to go to the big picture, again, in terms of what we're doing, we do not have to create the framework ourselves, we do have to come up with a set of use cases and a lot of ideas about what the framework should be. And that will then be developed by the agencies over the fall. We do have a revolution in this country right now in health information technology it's a pretty exciting time. If you look at what adoption rates are doing, this is the biggest change that we've had in this market, and therefore I think it's really prudent for us to have been asked to consider the set of topics that we're thinking about now. And we have to deal with lots of issues around HIT broadly, around wireless, around devices and so on, and there are lots of permutations and things will look different as we move forward. And a lot of people in the room have considerable expertise not only in terms of thinking about how things are today, but in terms of thinking about where we need to go. So, the things that we come up with are intended to help take us forward.

Let me just talk through how we elected to structure this meeting. First of all, we'll hear from each of the three groups, and the three groups have already had at least one, and sometimes more, calls. So we'll hear first from the Regulations Subgroup, then from the Risk Assessment and Innovation Subgroup and then we'll have a report out from the Taxonomy Subgroup. Our thought is that the Taxonomy Subgroup is mostly deciding what are the boundaries of what we're being asked to consider and what's in and what's out. And we're hoping that they're group will be essentially done, or pretty much done with their work at the end of this meeting. And Meghan will be presenting, Patty is coming in on an airplane and she'll be here as soon as she can, but hopefully she'll join us by the time that Meghan makes that report.

Then, this afternoon, after lunch, we'll have concurrent breakouts. We felt it was really important for people to have an opportunity to talk amongst each other in groups that are a little less big that this one; this is a sufficiently large group that it's hard to have a lot of conversation. Following that, we'll have report outs with the discussion for each of the two groups, the Regulations group and the Risk Assessment and Innovations Subgroup. For those of you who have been on the Taxonomy group, what we'd like you to do is just pick one of the two groups, you can go to whichever one seems more interesting to you. At the end of the day, I'll wrap up, we'll have time for public comment and then tomorrow we left the agenda relatively open.

We think that there are likely to be some things that will come up today that we'll elect to discuss in some more length tomorrow, but we'll start by – I'll start by recapping things from today and then we'll spend some time talking about crosscutting issues. Much of the discussion in the subgroups is focused on the fact that you can't really think about risk without thinking also about a regulatory framework, and vice versa. So, that'll give us an opportunity to perhaps bat around some things that go cut across multiple domains. And then we'll finish up and think about where to go next. And again, remember that we do have a hard finish line and we have to have a pretty robust set of draft recommendations done by early August. So, lots of work, I know its summertime, everybody's busy, but really appreciate everyone's effort around this. So that is the overview of what we're going to do today. Any questions about that? If not, perhaps we could go right into the subgroup update from the Regulations Subgroup, which will be from Brad and Julian.

Jodi Daniel, JD, MPH – Office of the National Coordinator
David, can I –

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

Jodi Daniel, JD, MPH – Office of the National Coordinator
Let me just make one comment. I wanted to let folks know that we did open up a docket, we put a notice in the Federal Register to solicit more public comment and input, which will come to the agencies. If we get input, we will share it with the Committee, so that it can help inform your thinking and discussion, but that just posted, it published today. So, you may be – just in case anybody sees that or hears about it, we just wanted to make sure that other folks who are not able to participate on this committee have an opportunity to provide their input as well to our thinking.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Thank you Jodi. And we've talked about repeatedly the notion that there are lots of people who have thoughts and input that will be of value to us, but did not get a chance to sit on this committee.

M
Could you, can you send that out to the group so we could forward it around to people and increase awareness?

Jodi Daniel, JD, MPH – Office of the National Coordinator
Sure, we can do that.

M
Thanks that would be awesome. Thank you.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So, are we going to be able to pull up the slides on the screen? Everyone I think has a copy of – great. Julian and I haven't had a whole lot of time to talk about this, so we're going to try and double-team it in our presentation as we go through this. But it occurred to us one of the most perhaps valuable thing we could focus on in our 10 minutes is how to – how we hope to interact with the other two groups. Because if we can leave this 2-day meeting with a clear charter for each of the three groups, knowing exactly what we need to do that doesn't overlap with the other two groups, to me that's a very valuable process objective. So we're going to give a little bit of background of what we're trying to accomplish in the Regulations Subgroup. Then we're going to use that as a springboard for talking about what we might do versus what the other groups do. And then we're going to pose some specific questions to the other groups that we hope you'll give us feedback on over the course of however long it takes to get that information.

So, let me just start with a little bit of basics, and I apologize for this sounding perhaps elemental, but it's important, I think, to say. And that is, from the Regulations Group's standpoint, we consider ourselves, I guess, to be problem solvers. We're not philosophers, we're not theorists; we take our charge as trying to help identify regulatory solutions to a problem. So we have to start with that problem, the whole point of regulation is to address some sort of weakness that exists out there, not to exist on its own. So, what we want to do is have clear what our responsibility is versus the three agencies. So as David just explained, the three agencies are the ones writing the report, it says so right in the legislation, I lifted this from the legislation.

What the Regulation Group does relative to the agencies are these two things that were included in the webpage that was used to set up this committee. So I cut and pasted those and put these here. So the Regulations Subgroup, and I underlined, I don't remember if that was in the original or not, but underlined factors and approaches that could be included in a risk-based regulatory approach. So not the approach itself, but factors that feed into that, to avoid both – or to adequately protect safety and to avoid duplication. So, peeling the onion just a little bit more specifically, in our case is to focus on patient safety, that is, what regulations are absolutely necessary to protect whatever patient safety issues the Safety Committee tells us exist, o, I'm starting to segue into what our role is versus the other roles, while minimizing any side effects.

So people talk about using innovation, or using regulation to foster innovation, I've never heard of any regulation that fosters innovation. Regulation hopefully, at its best, doesn't stand in the way of innovation. Standing in the way of innovation is a side effect that we want to avoid. So for those of you clinicians, I mean, this is very much like in cancer research, trying to find the most specific therapeutic approach to treating the cancer, while not hurting the rest of the body. So, we're going to be laser-like focused on the safety issues, what the narrowest thing is we can do to address those safety issues without traumatizing the rest of the body.

So, it's really analytically a 2-step process. The first is an evidence-driven process of figuring out what the problems are that need to be fixed. Are there safety gaps that need to be fixed? Are there specific areas of duplication that need to be fixed? Are there specific ambiguities that need to be addressed? And I'm highlighting the evidence driven aspect because I spent a fair amount of time reading the literature, as the rest of the PowerPoint shows, and most of the rest of the PowerPoint is for this afternoon, and the literature isn't all that robust so far, on really identifying the problems that need to be fixed. So it seems to me that's our first order of business is agreeing what the problems are that we're trying to fix. And then, using those problems as the launching off point to talk about solutions, or particularly regulatory solutions.

So during one of our first discussions, someone made the comment, we really ought to make sure that we're using the committee to its best advantage, given the group that's assembled. And it is an impressive group that's assembled. But it got me thinking, well what is the group assembled and what can that group do? Well, by statute that group was assembled on the basis of economic diversity that is, representing a lot of different aspects of the public, from patient groups to provider groups, to venture capital folks and so forth. The strength of the group is in its diversity of viewpoint. The group was not picked, and I don't mean to burst anyone's bubble here, sorry, but the group was not picked as regulatory experts. We're not regulatory experts; that's not what we know. There is an area of regulatory expertise that's called administrative law; people spend their whole lives studying it. They work at OMB or they work in the agencies or they work in academia, they work any number of places, but they are really gurus on regulatory policy. We are users of regulation, not experts in regulation.

We also don't, just as a matter of political science, have any authority to speak on behalf of industry. Industry didn't elect us to this group, right. So, we can't act as though we have some legitimacy or some authority to make regulatory policy. Instead, we're kind of like a focus group that Coca-Cola might assemble to figure out whether we like Coke or Pepsi better, and then they'll take that input to figure out what they're going to do. So what that translates to is in our group, we're going to treat it more like a focus group, we're going to start with the question of, where are the problems? You're the users of regulation, where are the problems? Where are ambiguities you don't understand? Where in your daily life do you experience duplication that needs to be eliminated? Where to you see costs that the regulation is imposing that are out of whack or unjustified by the safety issues that are trying to be addressed.

So that's how we're going to structure the workgroup is first use it as a focus group to really understand the problem and from there, it's a launching off point to talk about the solutions. And I'm also fairly passionate about the fact that we do stand on the shoulders of giants and we have six or eight weeks to do what we're supposed to do and we can't possibly act as though there's no information out there and everything is going to be something that we come up with. There's a whole bunch of work that's been done to date, and it would be inappropriate for us to act as though that wasn't there. So in the session this afternoon, for example, I've gone through, okay, I'll admit, an associate of mine went through a lot of reports and tried to synthesize answers to some of these specific questions taken out of a lot of these different reports that have been out there. And I've listed the reports in prior meetings and I'll have that list this afternoon. As a starting point for what we anyway have seen out there, then from there we fill in the gaps. What hasn't been analyzed in the literature so far, what are they missing, what does our experience tell us hasn't been adequately addressed? We'll sort that out and we'll end up presumably giving that to the three agencies for consideration.

So now, I'm segueing from our mission to how we'll interact with the other two groups. And I put this together; this is a reframing of the like seven questions that the agencies came up with in that very first one-pager that we received. I reframed it to be a little bit more conceptual, by topic. And so I also used the color fonts, hopefully you can read the green, it's in your handout if you're having trouble on the screen, to show the difference between what the Regulations Group presumably, and I'm saying this out loud for anybody to challenge, right, so if I'm getting this wrong, tell me I'm getting this wrong. But the green stuff is what I perceive the Regulations Group to work on; the black stuff is what I presume the Safety and Innovation Group to work on.

So the first one, patient safety not fully protected, so the patient safety group will come to us at some point and say, here are the 16 patient safety issues related to HIT that we see. We would presumably take that list, look at the regulations and say, is there a good alignment; do the regulations cover those 16 risks adequately? Are they over-inclusive or under-inclusive, right? So the difference between one and two is number one asks the question, are we regulating too little, number two asks the question are we regulating too much. And presumably we can do both at the same time, we can over-regulate and under-regulate, if the regulation isn't sufficiently targeted at the risk. So it all starts with our friends on the Safety Committee telling us what those risks are, then we line up the regulations to see how focused they are and how good the coverage is.

Then third, the Safety and Innovation Committee tells us where the risks are to innovation. And we take those risks to innovation and look at the regulations and say, are they over-inclusive, is it like a cancer treatment that maybe kills healthy tissue as well as canc – I'm going to stop with this metaphor at some point, but is it over-inclusive and it kills off innovation when it shouldn't. So then, we're going to be looking – and there's a timing issue here, right, because we need that input as soon as possible to get started. So the last two are the ones that fortunately don't depend on patient safety and innovation, these are right out of the statute and it is, are the ambiguities? We can start that today, and in fact, that is our agenda for this afternoon, are there ambiguities that impede compliance or just add uncertainty into the mix. Or is there regulatory duplication that wastes government resources, which in this day and age is a real sin, or frustrate the compliance because you have "A" telling you to do something and "B" telling you to do something else, and you don't know which to follow.

So I picked those two at the bottom, and proposed them to Julian, because it seems to me it's something we can dive into in our subcommittee because we don't need to wait for the input of the other committees in order to be able to start to think that through. But, we need the input of the other committees to do the first three. And so we're going to have to figure out some way on a real-time basis or whatever to be getting information from that committee, as to what those risks and innovation issues are.

So what's our conceptual approach? Well I'm a lawyer, so obviously I'm going to argue about things like what the word "is" means. But – so my first question is, what does safety mean, because it isn't intuitive what safety means. We're talking about software, which in some cases might be standalone software, it sits on a computer and all it does is display something on a screen. So what does safety mean as we're looking at a screen? So number one, we're going to need to know from the Taxonomy Committee, are we talking only about standalone software, which has a big impact on the safety considerations, or are we also talking about the connective software that links to medical devices where the safety issue might be much more real. So would networked medical devices, the FDA category of MDDS and so forth, is that in scope or out of scope? So Taxonomy Committee needs to weigh in on that, because that defines what kind of safety we're talking about.

And then there's two other flavors of safety that are potentially applicable to standalone software. The first is, if the software doesn't do what it says it will do. Now there are easy cases where the software doesn't boot up and it's just worthless, right, it doesn't do it. But there's more insidious cases where the software claims to be able to help you make a certain decision, and it isn't truly wired or programed in a way that will literally help you make that decision. So, there's failure to meet the claims associated with software and could that produce a safety issue.

And then finally is the information presented wrong in some regards. So what does that mean in the information we're talking about. Well, there can be factual errors. It says the medical data is Brad's data when it's actually Julian's data, right, that's objectively false and could lead to treating Julian or Brad incorrectly. I should have put in here from FDA language, false or misleading, because you can also have language that's presented in an ambiguous way, the user misunderstands what it's suggesting and doesn't act appropriately. Then you can have wrong advice, so it's not factually wrong, but the advice on some objective standard is not the right advice for the software to be given. And then you get into a really slippery slope of talking about subjectively what's the best advice, when you get into CDS, talking about what the advice might be, how do you measure that issue? So there's a lot more.

So we – again, I'm not trying to answer these questions, I'm posing this framework because I hope the Safety and Innovation Committee looks at these things and comes back to us and says, in our considered opinion, safety means this, so a framework as well as specifics. So another element to this, when we consider things like safety. Everyone here I know well understands that there's been a historical manual system to all of this stuff, then there's that automated system that we're focused on sitting on top of that manual system. When it comes to risk, again, this is for the Safety Committee, are we allowed to compare the relative risk of automated to the pre-existing risk of the manual? So maybe there's risk associated with automated, but it's actually far less risk than the manual system it replaces, is that relevant? Can we consider that in what we're doing and in the weighing of the recommendations that we're trying to make?

And then above that automated system is a private system of oversight. So you have certifications and other non-governmental organizations that add a layer of assurance, because they're willing to offer a system for oversight. And then regulation fills in the gaps above that, whatever the private system can't adequately address in the way of the risks below it. Everyone's doing pyramids these days, so I had to do a pyramid.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Brad let me just check in with you –

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
I'm out of time?

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Yeah, you're well over.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
We started early though.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Yes.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
We are not over on the agenda yet, right? I have 3 minutes, the agenda says until 10. All right, I'll do whichever you want.

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
Oh, actually, I guess I'm off. So keep going.

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

Farzad Mostashari, MD, ScM – Office of the National Coordinator – National Coordinator
You get that time back – you get those 20 seconds back.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yeah, can I have those 20 seconds back? No, so the risks of the manual system, I'm not going to go through all of these, you guys know all of these risks. But in each of the main areas where HIT is being used, it's being used because it's designed to help healthcare, it's designed to help improve healthcare. I'm not going to go through this slide either, other than to say, as I said before, we stand on the shoulders of giants and three years ago at the FDA did a very comprehensive analysis of risk, presented it to ONC, it's in the public record, and I found a lot of useful stuff there. Again, that's not really for our committee to look at, it's really information for the Safety Committee to consider.

So what do we need from the Safety Committee? Number one, we need to understand generally their conceptual approach to risk. Some of the questions that I previously posed, we need their guidance as to how they want to approach risk. Then we need specific safety risks that include explanations for how they arise. Because in order for us to do a good job on our side, on the regulatory side, we really need to understand the origin of the risks that the committee has identified. And the same with regard to innovation.

From the Taxonomy Group, I thought about doing two concentric circles for the Taxonomy Group, because it seems to me the Taxonomy Group has a two-step process. The first question is: What is in scope for deliberation of this committee? What are we considering or even looking at to decide whether it should be regulated? Then there's an inner concentric circle which is, what merits regulation? Those circles are not the same. We're going to cast the net more broadly and look at stuff, and then presumably come up with a smaller subset of what gets regulated. For our standpoint on the Regulations Group, in order to really get going, we need to know the outer circle and we need to know it relatively soon, because when we look at duplication, regulatory duplication, when we look at ambiguity, is UDI in or out? I really don't care, but I need to know if UDI is in or out, because it's a completely different regulatory approach. And so if UDI is in, then we've got to do some work on UDI. If UDI is not within consideration of this group, then I'm not going to worry about it. So we need to understand what is within the scope long before we need to understand what is regulated. I yield the rest of my time to my co-chair over here, Julian.

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
In the 11 seconds that we have left, I'll just say that it's I think noteworthy that many of the words that Brad used talked about system. And so we're really, I think it's important for us to recognize we're not talking necessarily about a medical device in isolation or one health IT application connected to "a medical device in isolation." It is the complexity of the system that's really, I think, bringing much of this challenge to us. And there are ample examples, I would say not well surveyed and compiled over the years, but ample number of examples of where the safety issues are the result of the problem between the interfaces and across the systems. And we recognized early in our discussions that we really wish we had more data, and moving forward, we have to consider a plan that will allow us to continue to collect data and understand this problem, even as we move forward with proposed solutions. And I'll stop there.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Thank you. Paul and Keith?

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
All right, thanks, David. Our group is initially entitled Risk and Innovation, and the way we've decided to look at it, is really there's a risk – there are two kinds of risks. There are risks that the software device can impact patient safety in a deleterious way, and there is also a risk of regulatory approaches to innovation. So that's the kind of way we're approaching it. This is the first of multiple iterations, we've had a call, but we're going to be doing more work, as David mentioned, later on this morning or this afternoon, and then get back with you, incorporating some of the more work that we do in the workgroup. And then we'll keep iterating on that until we achieve our goals.

So we've put together sort of dimensions of patient safety risk. This is just the starter set, we'll undoubtedly expand or change this, but we're looking at it from a purpose use. I mean, if it's something very innocuous, then there's not much risk in it. We look at the patient harm risk, everything from the magnitude to the ability to mitigate ant risk, and I'm going to go through this in a little bit more detail in the following slide. The complexity of the software obviously affects risk. How is this used, in integration with other components, hardware or software and the network connectivity?

So we started off with a matrix, we have a matrix framework for the risk to patient safety and one to the risk to innovation, and Keith's going to go over innovation one. So just to give you a heads-up on where we're headed, at least in our initial discussions, they are clustered by the colors. And the first one is looking at the purpose of the software and who is the intended user, and that can help you think about the risk of that piece of software. It could be anything from just information only, which has a very low risk to something that's automatically deciding on its own, in a sense. Think of and intelligent IV pump or the automated electrical defibrillator. Those things act as a black box and they do something that potentially is life threatening. So that would be in the higher risk category.

The intended user could be someone who is professionally licensed to understand and to act on this information, presenting a lower risk. On the other hand, it could be giving outright advice to a patient, a consumer. That might be posed as a high risk. The kinds of risk can be measured by the severity of the risk, the number of people exposed, the likelihood of the situation even arising and the ability for some human to intervene. So in terms of severity of risk, there could be something very, very low probability of happening, or something that – of causing harm or it could be something that an error of commission or omission, could be life-threatening consequences.

The number of people exposed clearly affects the total amount of risk of this piece of software. It can be relevant to a very, very small population of individuals or it could be a large group, such as all diabetics, for example. That certainly bears on the risk of this particular piece of software. The likelihood of it happening, it could be once in 100 years in a specific situation, lower risk. Compared to something that is very common, the condition or the situation where the software operates, which would pose a higher risk. And finally, the ability to mitigate the harmful condition. If this is a licensed professional, skilled in this kind of information, and the software is transparent on the way it's calculating or doing its task, that's a situation where you might have lower risk. Compared to a closed loop situation where there's no human intervention taking place and it's a black box.

The complexity of the software has to do everything from the way it is designed and developed, to the way it's implemented, to the way it's ultimately used. And those three things affect the risk of the software and how it poses potential harm to an individual. The fourth one is the use in a more comprehensive software and/or hardware system. If it's a standalone product, it is specific in what it does, it doesn't interact with anything else and it gives out a very easy to understand piece of information like blood pressure, very low risk. On the other hand, if it is by design meant to be in part of a larger system and you can't exactly tell how it's going to be connected, that could pose a higher risk. And finally the network conductivity. If – again if it's wired, entirely controlled wireless spectrum, you know how it's going to be used versus the other, where it may be living in an unregulated piece of the spectrum.

So this is, sort of again, these are not things that prescribe regulation, but these are the attributes of a system and its risk of harming patients that one would consider in applying regulations. That's what the subgroup's going to be discussing further this afternoon.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director

There are a lot of slides in a short amount of time, so I'll just cover these. I think it's already been expressed is that the purpose of this committee is not to write regulation or respond even to specific regulation, but try to give frameworks involved that will guide the development of regulation. The sources of innovation as we – and so what I'm going to present is just some of the thoughts that we've had in the calls that we've done so far. The sources of innovation are really varied or what the IOM report referred to as the SocioTechnical system. And so you have everything from developed software on the top to something that's very non-predictable of how the user combines different technologies on their own. And where they're applying even devices and software that were not intended originally for medical use, but applying them to a medical problem.

So it's very tempting in this, as we talk about solving problems with regulation, to go to the top of the list there and target people that are making devices or making software, while ignoring some of the other issues. We've all talked about this, is the regulation appropriate to the problem? And this is a core issue that we're trying to address. As Brad was talking about, the point of regulation is to solve problems. But it's also being able to say, what are the problems and what are the real risks, not the imaginary risk? And then have regulation address those things. We've talked a little bit about kind of a medical paradigm, because many of us are medical people. And as you look at the medical paradigm, the first thing is that you do no harm and so that you concentrate on those things that prevent harm and then as you go forward, then you try to think about things that will maintain or restore wellness.

As we look at regulations and applying this same type of paradigm, the things that we can most easily agree on are probably things that cause apparent or predictable probable harm. As we look at the regulations and the target of the regulation and what kind of problems they're solving, many times we see though not just concentrating on what causes harm, but also then trying to inject into that best practices or a determination of best practices. And whenever you do that, it starts to limit innovation. This slide is just going to the issue of the partic – or how you do the regulation and how you do the implementation of those regulations. As Brad was talking about, all regulation starts with good intent, it's looking at a particular problem; it's trying to solve that problem in a regulatory way. But as we try to implement that and measure it, the measurement in fact, can negate that original intent. And so when we look at the regulations, it's not just the regulation or the intent it's trying to do, but how is it measured? And we all kind of are ascribing to Deming, that if you can't measure it, you can't manage it. But then it comes back to a governance issue of who should be managing these things and where does the governance lie?

This thought came out a lot in our different discussions and came out today, it's again is that the status quo is not always the safest state. I mean, what we're comparing is that we're trying to – in all cases we're trying to make the world better with the innovations that we're doing. We are trying to make it safer for patients, we're trying to make medicine more efficient and cost-effective, and so as we look at that, we really have to balance the risk – well, we have to balance the problem that we're trying to solve with the risk that we're doing. I'm going to continue on in the metaphor with oncology medications. If we just looked at the risk of oncology medications, none of us would use them. So what you have to do is say, what is the intended purpose and what is the benefit, as well as the risk.

So we'll talk about, in our group, try to enumerate the risk to innovation – I'll just, because I'm out of time, I'll just do a couple of these very lightly, but we'll also talk about how do you promote innovation with regulation. And how do you set up incentives such that you're getting to a more perfect state. And so in that case, we're looking at really – oops – three things, the regulatory interventions, how they do their measurements, and then looking at what those two axes, what is the impact on innovation. And we have some starter sets on that, but we'll continue those today. Thank you.

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

Thank you both. Those were terrific. We could talk a lot about those now, I'd encourage everybody to make a few notes; I've made a few notes about things I'd like to talk about. But next we're going to hear from the Taxonomy Subgroup, from Megan, and we will pass you the clicker. And then we'll spend, after this presentation, we will have some time to just talk about this at some length.

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

Okay, thank you, Dave. I am Meagan Dierks and I'm presenting on behalf of the Taxonomy Subgroup. I just want to acknowledge the members, Richard Eaton, Elisabeth George, Drew Hickerson, Mary Anne Leach, Meg Marshall, Mary Mastenbrook, Jackie McCarthy and then from the federal agencies, Jody

Daniel, Bakul Patel and Matthew Quinn. The Taxonomy Subgroup had two hour-long teleconferences with quite a bit of exchange of information and ideas back and forth via electronic mail and what we hope to do today is present some synthesis of the subgroup's deliberations. And I think it's fair to say that I hope to achieve at best, maybe some ability to exclude some things, to sort of make the task for the larger workgroup a little bit more manageable. At worst, just generate some good discussion and some points for the remainder of the group here to talk about and maybe pose some considerations that you haven't previously thought about. But I think that we might be able to provide some scoping at the end of this.

So, Patty Brennan is not here at this time, she'll probably be joining us fairly shortly, but she was also a co-chair of this group. So I want to start by just kind of stating a few things. We did a good amount of organization before we began to talk about scope. The first was to just agree upon what we thought the output – the anticipated output of the charge of our subgroup was. And we agreed that this was to help identify the scope of health IT that should be considered or included in deliberation by the full workgroup, as the full workgroup helps to develop and handoff then to the federal agencies recommendations about a risk-based regulatory framework.

I want to make one sort of emphasis here and that was that I think it's possible that when we were charged with the task, the understanding was that we would provide a list of the specific types of health IT that would be in and out of scope. But the good news, in my opinion was that the group talked about other dimensions of health IT that we feel are part of the whole scope discussion. So we're going to talk about not just the types of products, but also other dimensions that we think are important and we'd like you to include that in the deliberation. So again, the Taxonomy Subgroup's scope – one precautionary word, that the Taxonomy Subgroup's scope should not be misinterpreted as being a final recommendation for what should be regulated, that's really for the larger audience, including those on the line.

We thought it was very helpful to just remind ourselves of some of the statutory definitions of health IT. And we didn't feel as though we wanted this to restrict our consideration of scope, but we thought it was important to acknowledge what's out there and what is ultimately framing the larger discussion. So the Social Security Administration defines health information as any information, whether oral or recorded in form or medium that's created or received by healthcare provider, health plan, public health authority, employer, life insurer, school, university or healthcare clearinghouse and that relates to past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual or past, present or future payment. So this is very broad and this was important because it is out there and yet it helped us define a few things that we might consider out of scope, and we'll get to that in a few minutes.

So the second important statutory definition was that – that comes from the HITECH Act and here, just as a reminder to the group, this defines health information technology as meaning hardware, software, integrated technologies or related licenses, intellectual property, upgrades or packaged solutions sold as services, that are designed for or support the use by healthcare entities or patients for the electronic creation, maintenance, access or exchange of health information. And I think this definition is kind of unique in that it talks about a few things that might not have previously come into scope, aspects about licensing, aspects about upgrades, which gets to the issue of maintenance of products, and the product lifecycle. And then this concept of solutions sold as services, so one has to consider or broaden one's perspective to go beyond what is traditionally sort of an installed piece of software and instead get to the whole service aspect of it.

And then the last statutory definition that was helpful to us, as we began to define scope, was that that comes from the medical device regulation. And again, just a reminder that the definition of a medical device is any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or similar or related article, including a component part or accessory, and I'll get back to this, that's recognized by the National Formulary, Pharmacopeia or a supplement to them, is intended for the use in the diagnosis of disease or other conditions or cure mitigation, treatment or prevention of disease in man or animals, or is intended to affect the structure or function of the body of man or animals and which does not achieve its primary intended purpose through chemical action. And I'll truncate it there, because I think we've gotten to relevant things. But I think here, some key words that came into discussion or play was this idea of component, part or accessory, and that will come into the presentation on scope.

So after we sort of revisited the statutory definitions, we then talked a little bit about what the options were for scope. And I'm going to show you what we deliberated. There were a number of options, potentially many more that didn't even come to discussion, but this was very helpful to us. The first was to sort of narrow the scope to existing technology. So if we had already conceived of it and produced some type of a product, should that be the scope. And we felt reluctant to do this, in part because of the rapid evolution of technology and we want to make sure that any kind of boundaries that we might knowingly or unknowingly create around this scope recommendation wouldn't be too constraining, and would have sort of an open endedness and be capable of managing future unforeseeable technology.

The second approach would be to take a very exclusionary focus, meaning not talk about what's in scope but at least try – strive to define a few things that are explicitly out of scope. The third approach would be to be very prescriptive and inclusionary, meaning focus mostly on creating a list of what's in scope and anything that isn't on that list is implied to be out of scope. The fourth option was to really stick with an existing statutory definition focus, meaning really focus on what is already stated as a software usable by patient or providers to create, maintain, access or exchange health information. That would be sort of a little bit of a bias towards the HITECH Act, or maybe exclude explicitly those products that currently and without argument meet a definition of a medical device. And the notion here, particularly for the second aspect, was sort of attending to the recommendation that we try or strive not to be duplicative or create or setup – set ourselves to make recommendations that would potentially be at odds, orthogonal or contradictory to existing regulations around things like medical devices.

The next three sort of scope option considerations that we discussed were a user type focus, meaning create a scope that's really based on a user typed, and I'll get into a little bit of the discussion about user types. But that would be, do we only think about the user as being a licensed, credentialed healthcare provider or do we want to be more broad and consider it consumer type – what's often considered consumer type products that are acquired, used exclusively in the hands of a public health individual without any direction from a licensed or credentialed healthcare provider. The next was about functionality or intended use, and this really became a huge – I think a huge influence in our deliberations, which was what is in or out of scope should really heavily be influenced by what the functionality and intended use is and even include sort of foreseeable misuse. So, we'll talk about that. And then the last would be a risk-harm focus. Now the problem with this risk-harm focus, this was – the idea here was to create a scope that was based on the potential for injury or harm that might be associated with a failure, malfunction, or foreseeable misuse. This put us in a little bit of a bind because it's a little bit of a chicken and egg scenario. In other words, do you define your scope because you already anticipate there could be some risk and then that enables the risk group to talk about the risk framework, or vice versa? But we thought it was helpful because one could make some very cogent arguments that it's easy to take things totally off of the table for discussion if one can't in any way envision a harm to a patient through even misuse of a product.

Now I'd like to say we picked one of these, the good news is we picked several of these. So there were a number of ways in which we actually formulated what we hope is useful framework for what's in scope and out of scope. A few additional organizing principles that we used, we felt and the larger group may debate this and we may change direction, but we did feel it was – that from the outset, we wanted to sort of be platform agnostic. And what this means is that we felt that it was probably not a good idea to define the scope based on something such as the wireless versus wired, mobile versus fixed and installed versus software as a service. And in part we were anticipating that risk probably is driven less by these, although it could shape either greater or lower probability of an adverse event occurring or harm occurring, that those in and of themselves didn't really tell you that something was completely free of risk or full of risk.

And the second sort of organizing principle was we really strive very hard to avoid creating a list of specific examples and instead tried to be generic in our thinking about it. And even when it came to eventually coming up with a few product categories, kind of creating a category based more on a general function or intended use versus a specific example of a product that currently exists. And that was again, in an effort to not paint ourselves into a corner for future technologies. The last sort of organizing principle was this idea of part/whole that if a component or part would be in scope, then we should make the assumption that the whole is in scope. I don't know if that's – we can elaborate a little bit more on that, but it was to not bind ourselves again by a small accessory or component being in scope but then the whole product being deemed out of scope.

So I mentioned at the very outset that we may have misunderstood our charge as being beyond this, we didn't restrict ourselves to the product category in scope and out of scope, but instead, we addressed issues of what kind of user type, who the developer or manufacturer type might be and how that might shape scope. What phases of product lifecycle and conditions of use. So these are all things again that we're not necessarily going to be perspective about them, but we want that to be in scope in the discussions by other two groups and by the larger workgroup.

I will talk lastly about the product categories, I'm sorry about the animation here. And I'm going to first address how we framed scope by these other categories. So, we're going to start with user types. So on the left side, what the group discussed and achieved some degree of consensus about was that in scope for user types would include healthcare providers, and this would be an institution as well as an individual healthcare provider. Should include clinical researchers who might use health IT on human subjects. Should include patient use of health information technology, particularly if under the care or direction of a provider. But also potentially, should include the general public user/consumer who are using the healthcare technology under their own perceived management of their health or a particular chronic condition. So, now you see on the right side, we actually didn't identify anything that we would perceive to be explicitly out of scope in terms of user types. I guess we could come up with some, but we thought that – and what we really did here was by user type defining what's in scope.

So the next sort of scoping task and discussion revolved around product lifecycle. And our goal here was to make sure that we got in scope – that we didn't think that the larger group or the other subgroups didn't narrow their thinking only around the design and development of the product, but made sure that you thought about risk, innovation and any kind of a regulatory strategy at each of the lifecycles. So in scope would include the design phase, and we were hoping that part of the scope of discussion includes the use of risk-mitigating design controls, use of standards, development of requirements, documentation and labeling. And again, I just want to emphasize the Taxonomy Subgroup isn't necessarily saying that this has to be part of the answer or the recommendations; we just want it to be part of the discussion.

The second phase of the product lifecycle that we want to be in scope is issues around implementation and installation, and specifically issues that might revolve around configuration management. Meaning do you want to think about risks and think about whether there should be regulatory strategies or framework around upper bounds of configuration complexity when these products are marketed, implemented, or maintained, issues having to do with interfacing with other systems, whether they are currently regulated systems or non-regulated systems, interoperability as a system of systems.

The third aspect of the product lifecycle that we felt was explicitly in scope and we wanted to be part of the larger discussion, was issues around maintenance of the software. And to provide a little more detail, we wanted this to include not just routine updates and upgrades, but maybe maintenance that enhances performance, so the performance tuning maintenance, the defect and safety related corrective maintenance, enhancements and change in the base functionality. It is not projecting here on the slide, but the last statement was also to include in scope thinking around whether or not for safety and for regulation one had to consider the customer relationship, in other words, whether they actually should always have to take corrective maintenance, patches and things like that.

The fourth is related to maintenance and that is we wanted to have explicitly in scope discussion about the concept of recall, when there is a known defect or a known safety-related issue in a product. And what this really touches on is managing the entire install base versus just the index customer who identified the issue. And there is a lot of interrelationship here because that can be very challenging if one offers almost limitless configuration options, it becomes very challenging to know whether the safety issue exists in the entire install base. But it also touches on this issue of whether or not there needs to be discussion of the risks and a regulatory strategy around maintaining a configuration log, by whomever it is that produces this.

The next issue has to do with the end-of-life support. And this would be again to ask that the larger group consider in scope discussion about de-installation of outdated software or de-installation of software that no longer subscribes to what the industry has defined as the standards for safety, so non-conforming products.

The last, which I added, I have to say I don't want to put the words into the mouths of the remainder of the Taxonomy Subgroup is perhaps we might consider in scope, it may move to potentially out of scope, issues having to do with cybersecurity. And I put here, maybe I extended it a little bit too much, but this would be control of personal health information, assuring protection against malware-based risks. And one really has to think, in this day in age, about the installation or use of health IT software in a networked facility and the potential that it could have to propagate to standard medical devices whose risks and controls are thought to be well defined, but could be impacted by the creation – or introduction of risk by the use of health IT.

So I did put something on the potentially out of scope, while training, sort of I think about training, instructional manuals, these manuals as falling into the sort of labeling and the design phase. We may want to consider out of scope defining specific or putting regulation or making recommendations about regulation around the specific method or mode of end-user training.

So the next sort of dimension, and I promise I will get to the actual product categories, but the next dimension that the group discussed, but we wanted to have considered as part of the scope would be who are the developers or I call them manufacturers, but who are the developers of these products. And we thought it was important to consider that because there may be a perception that one has to be a commercial entity, who's in the business of making money off of the software to be considered subject to regulation, but we weren't really convinced that was the case. So we wanted to explicitly consider that what should be maybe in scope for the large group discussion is any entity who develops, markets, licenses or distributes products with a commercial interest, so that's your conventional idea of people out there selling software. Healthcare providers, and this might be an institution such as a hospital or nursing home, or an individual proprietor who might develop a product de novo for use on a patient, even if there's no direct or indirect commercial interest.

And healthcare providers, again institutional or individual providers who may modify the functionality of a previously licensed finished product. We thought that might be important to have in scope because again, there's sort of the out-of-the-box product but the manufacturer of that may make the capability and even market or advertise that one of its features allows one to go in and fundamentally change the functionality or the risk profile. We also considered in scope an independent entity who might develop, advertise or distribute via a public channel product that is intended for general public users, even if there's no commercial user. And so I think there's a nuance here that I want to try to emphasize and that would be even if one offered this for free and made it available for release or distribution or download from the Internet, if it was sort of a public channel that should be considered in scope for discussion about risks and potential regulation.

Now what might be out of scope, I put potentially we could cross that out and say, it's definitely out of scope, but individuals who might develop for personal or private use. We just felt that this was sort of unenforceable, even if one thought it potentially was an area of regulatory oversight, very difficult to enforce. So that's an individual writing their own software for their own health application. Potentially out of scope an individual who would develop and distribute via a private channel, so not making it widely available for download, but giving it to their friends and family members, limited individuals, but no commercial interest. And then potentially out of scope would be independent, noncommercial developers – oh, I'm sorry, that's an error there, that third item; so the first two represent the two that are potentially out of scope.

The next dimension that we wanted to have as part of the scoping was the distribution model. This is pretty straightforward. We thought that in scope would be marketed, licensed, distributed products that are sold in a restricted manner, meaning that sold, but require you to have a credential or a license to be able to acquire it. The next would be in scope would be marketed/licensed/distributed or sold in a restricted, but no credentials required. So in other words, you don't have to be a practitioner, a healthcare provider licensed or credentialed, but it's marketed or sold. And then the third in scope would be made available for download by an unrestricted with or without credentialing. I think this is a little bit of a replication or a repeat of the items on the last. But importantly, again the distribution model, we thought it was important to have it in scope, not necessarily saying something is out of scope simply because it's available under a software as a service model.

The general conditions of use were another dimension that we talked about, and I think what we agreed upon generally or came to some consensus about, was again so that the risk group didn't become entangled in some highly improbable use case scenarios, we thought it was appropriate to put out of scope sort of willful misuse of the software and not kind of discuss or make recommendations about regulation that would address every conceivable odd use of the software. And also out of scope use that's clearly beyond the labeled intended use of a product. But in scope would be the intended use and really should consider the foreseeable misuse. And what is often thought of as foreseeable misuse is that the product it has a well-defined set of bounds about how it's intended to be used, but it's common practice in the provider community that they use it slightly beyond those boundaries. We thought that was appropriate. Or that there's sort of a very common human use error mode that one could envision through its design.

Additional general conditions of use we wanted in scope, certainly those things that would be prescribed, so come under some prescription or recommendation by a licensed/credentialed healthcare provider. Potentially out of scope, and this I think is an issue that probably will have some lively debate is whether or not products whose primary intended use is health maintenance rather than management of a chronic, well-defined condition, whether that's potentially out of scope.

So now we're going to get to sort of what is maybe the more conventional thinking around scope, which is around specific product types or categories. Several members of the group, I think, sort of gave a really good recommendation, which is rather than coming up with a specific list and said maybe come up with a decision tree which is kind of a yes/no. If it has these characteristics, it should be in scope, if it doesn't have them, consider it out of scope, and much of this decision tree approach would revolve around the functionality, the intended use and the potential for harm. Again, I'll acknowledge that it could be this chicken and egg situation for the risk group, but we're hoping that this provides a least some framework.

So I'm going to go back to that original thing, and this again may be good for a good point of discussion at the completion of this presentation. But we did make an assumption and perhaps this was incorrect that again, to avoid the potential for a duplicative regulation, or to avoid the potential to create a second set of regulations that were contradictory to existing ones. That if the product currently met the FDA definition of a medical device, and that would include MDDS, that should probably be out of scope, but I may be wrong here. And I guess our group didn't have a clear sense for whether what's on the table here would be recommendations that we'll move forward to the federal agencies about fundamentally changing existing regulations. But at the outset we thought that if it met the definition of a medical device or was currently regulated as a medical device, out of scope.

So some concrete examples would be blood bank software would be out of scope. Picture archiving systems would be out of scope, because those are currently defined as medical devices and have a set of regulations already wrapped up in them that's risk based. The MDDS, I think, is an area where there is some ambiguity or uncertainty in the outside sort of developer environment. But for those of you are who are less familiar with MDDS, and I'm, please feel free to speak up and correct me if I get this wrong. But I think one way of thinking about MDDS it's sort of middleware software that actually interfaces between a conventional medical device that falls under regulation and allows one to take the data generated by the medical device and either store it or present it again secondarily. The final rule on MDDS was made and that is considered a medical device – a class I medical device. So we sort of, to simplify things said if it's already classified, has a product code and is falling under the medical device, we will consider it out of scope for deliberation.

So the next sort of decision tree approach was we asked ourselves, if the product, again not thinking of a specific example, but thinking about all future products. If the products malfunction or foreseeable use has a potential to cause patient injury, and some examples would be delay or failure to present clinical data or information at a time of need, presentation or outdated information or patient data mismatch, we thought that would be in scope. So again, we're not coming up with a list of specific examples, but saying any future technology or innovation, if it met this definition, we should think about it as being in scope.

The next sort of decision tree question was, is the data or information that would be managed by this product the sole or primary source of data at a point of care, meaning that there's a provider taking care of a patient, that is the only source of data. There's no ability, no alternate source of data or information that could be used for confirmation, that that probably should be in scope for at the least discussion about the risk profile and whether or not that actually required some controls around it to manage the risk. Meaning if the product was just one of a portfolio of tools available at any time of use, then it would be less likely to be in scope.

I think the last decision point in this tree was the question about whether through design or intended use is the patient or provider fully reliant on the data or information to initiate or modify a prescribed intervention or treatment. So, looking at it from a provider perspective, is this product that's presenting me with data or information really pivotal in me init – making a decision about initiating or prescribing treatment or potentially discontinuing it, that's a product that should be in scope. If I'm a patient, if this product is presenting me with information and helping me determine whether or not something my provider prescribed should be stopped or modified, we think that's in scope. So again, consumer product but influencing a previously sort of prescribed intervention or treatment.

And I'm sorry, there was one additional one, which is, through design or intended use is the patient – is this product creating a situation where the patient or provider is reliant on alerting or alarming function about a change in clinical status or the need to initiate. If yes, if the functionality includes that or the intended use includes that, we think it's in scope.

So using that sort of decision tree approach, it was helpful in kind of coming up with things that might be out of scope, and again, the larger group may deliberate and some of these may move to the left. But based on that sort of decision tree, we felt that some things that were definitely out of scope would be software that involves claims processing, software that includes health benefit eligibility analysis, practice management software that really is primarily involved with scheduling of patients or inventory management, tools – software tools that are primarily intended to be used to support healthcare provider communication, and that would be e-mailing or paging.

Population management tools, because while it sort of one could iteratively get down and think that by understanding the population, it might change the way you manage an individual patient. The software itself is really intended to helping you understand a population's risk, a population's need or how effective the general care models you're providing to the population are impacting them. Software that is used for historical claims data analysis to predict future utilization or cost of care, out of scope. And cost-effectiveness analytic software, out of scope. And the thought here is, while the software may help you understand how costly the model of care you're delivering is, it's not fundamentally giving recommendations or shaping the specific intervention. That still resides in the hands of the provider using other tools.

Other out of scope would, I apologize for the typographical error there, disease severity scoring algorithms. Some specific examples would be Apache scores; they give you a sense for what the patient's likelihood, based on a reference population, is of having a specific outcome but should not and are not intended to be shaping the way you manage that patient. Electronic guideline distribution tools that don't change the guideline, just present them to you. And again, the last one might move to the other side, but we felt potentially is out of scope is disease registries.

Now in scope, I'm violating my original principle, which was to try to avoid giving specific example, but given the decision tree approach, these seemed to fall within the decision tree approach. And I can give a little elaboration or we can leave it to the discussion, but EHRs, partly because they now are more than just a repository of historical information. Because of meaningful use, almost all of them involve some additional functionality, such as prescribing and order entry, and independent of whether it's installed or software as a service. The hospital information systems, which are now systems of systems. So, systems that may secondarily present waveforms or trend data that's derived from some other system, we thought that was in scope. Decision-support algorithms, without getting into any details about a definition of what clinical decision support is. Potentially in scope, visualization tools that help you see or send or re-visualize anatomic tissue images, medical images or waveforms. We did put a question mark, health information exchanges, that goes to that original decision tree where it may, in some settings, rural healthcare settings or emergency settings, be the only source of information one has and so is potentially in scope again. We're not asserting that this needs to have regulation, but should be in part of the discussion. And then just thinking sort of forward thinking again, consider things like electronic or robotic patient care assistants. So these are things that consume prescriptive information and then recommend or actually guide a patient in the management of their condition outside of the context of a traditional healthcare provider.

I'm going to stop here, Patty Brennan our co-chair is now here. Before I sort of turn it back to Dave Bates for questions and discussions, I want to ask Patty if she has any comments or retractions she wants to make.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison
No, I just want to express my gratitude towards first of all, the group that worked with us over a very tight deadline and secondly to Megan for stepping, straightening out and presenting so well. Thank you.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Thank you very much, that's a – I think that's very helpful. I have to say, at the end of the day, I feel like there's more in than is out. But that perhaps is not surprising and is appropriate. Questions or comments, can I just ask people to raise your tent if you have a question or a comment, as Paul has done. So, we'll start with Paul and then we'll –

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
Great, thank you Meghan and Patty. Very comprehensive list and especially like the decision-tree, I mean, just as a way of thinking things. And it's gratifying, even though we had to buy time work in parallel, but really I don't know whether you noticed, but a lot of the match – the alignment between how you scoped and how you defined the taxonomy aligns very well with, I think, the risk framework that we proposed.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison
Yeah, I agree.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
So I just have a few questions, and I think it's for discussion. So one, you did call out of scope the methods and modes of end user training and that's probably reasonable, but we did recognized end user training and its use clearly impacts the safety of that software. The other piece is, in your population – you defined as out of scope, population management tools and predictive modeling, you did say predictive modeling for utilization and cost of care. In both those cases, I think you took the perspective of someone outside of the care rendering care, which would make sense. But these tools I think now are used in care, so population management tools are used by care management, nurses for example, in making decisions and predictive modeling also is used to alert the clinician, so actively participates and you could commit errors of commission or omission doing that. And the other piece is a...it could be used by plans for coverage decisions or medical appropriateness, which turns around and affects decisions impacting care. So, it may be comments on that perspective.

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So as soon as you put something out of scope, there are very cogent arguments for getting it in scope. And I'm going to actually make one comment, then make sure that the rest of the Taxonomy Group has a chance to weigh in on this. But, I think one of the things that might have been influenced having it out of scope on the population management is that it's not the sole source. In other words, if one saw a need for an intervention, that a provider would likely still use the standard approaches versus say a specific risk definition or a risk score for an intervention. You may be referring in part to the gaps in care. In other words, some of these population management tools identify where there's a gap in care or there's failure to do a standard preventative thing and if one became reliant on that over time, I think yes, it does pose a risk if the system fails or sort of has a wrong kind of underlying logic for identifying the gap in care.

And then the care management, I think I see a very strong point that if one used software to identify candidates for care management that could fundamentally enhance their disease trajectory and the system wasn't well designed, one would miss those opportunities. So I think those are just my immediate responses to why we might have considered them out of scope, but certainly you make very strong arguments, because they're moving into day to day direct patient care.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
I'd like to just clarify the comments –

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

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
– so one, on the clinical side, it brings up your notion of – or the group's notion of solely relying on and although clearly there's information "in the medical record," the whole – people rely on what's on the screen, in a sense. So that's one point.

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
Yup, point well taken.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
And the other is, and you may not have caught the nuance of using predictive modeling or population management tools, so the payer can almost decide what is covered or not, which turns around and affects the care decisions made. And that's a strong –

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So maybe the only narrowing thing I would say is if it's just used to predict what the cost is, with no – in the end user and they won't modify it, but again, important scope decision.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
I have to say, as soon as you started going through specific ones, I can make a strong argument for many of them –

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
– for and against –

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

Geoffrey Clapp – Better – Co-Founder
So, this is a bit cross-cutting, across all the presentations, so, don't want to take this as a – the last person to speak, it's some kind of treatise on just what you said. It came up several times across several of the presentations, and it's, I don't want to say concerning, but I want to put my opinion into the commentary. But the original medical device definition, written at a time when we can only perceive that doctors would do things as diagnose and treat. HITECH Act introduces patients or providers, that terminology, the "who" part. As we start to introduce the idea that we may be protecting patients from themselves with open data and things like as we start to push that in, the idea of someone treating themselves, there's a bit of an analogy with kind of vitamins versus drugs. And I think we need to be very careful about the point where we're saying, where is diagnose and treat? Who actually does those things? And what – where that scopes the legislation, and what our recommendation would be?

I don't expect everybody in this room to agree on what that is, but as we start to talk about those things, we have a law written quite some time ago is what the medical device definition is and that diagnose and treat doesn't have a who, because we assume we know who that is, right. We've introduced patients directly into this and as I see it start to creep into the fringe this that we need to start regulating how someone may self-administer or self-manage their data, or deal with their own things on decision-making, I think we need to be really careful about where that line actually is. And so we can actually explain how those two things come together. Those are places where ambiguity exists, right. One, the regulations have a pretty clear expectation of what one – of what that scope is and another one starts to introduce this idea. We're kind of mixing those terminologies or in some cases, trying to pull the patient immediately into, well, you're not able to – you aren't able to self – if you're using this just for yourself, that's not covered.

So, it's something cross-cutting and I think that all the groups have to consider about where those lines are and specifically that diagnose and treat. I want to be very – keep going back to that medical device definition and saying, we've got to foresee a world where that's now automated, that's now patient-driven, that's now – and think again about, I can walk into Rite Aid and pick up lots of things that say they're going to help me with my heart. And on the back they say, the FDA didn't actually think about this, because they're vitamins. There are different definitions of those things. We allow that in other industries, let's be careful how far we push with that.

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

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
First of all I would to applaud the great work you guys have done. This is really good; I'm pleasantly surprised by the thoughtfulness that you guys put into this –

Jodi Daniel, JD, MPH – Office of the National Coordinator
– in this short time frame.

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
– in this short time.

W
We're not going to take that personal.

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
So, just a couple of clarifying questions and more for my own edification, whether you have thought through that or not. When you use the word design in your product lifecycle, did you actually mean only design or the creation of the product?

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
We meant the creation, yeah, we didn't want to restrict it to design, so maybe design and development would have been the better –

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
Right, and so that was – and then, I didn't see anywhere in your presentation, and this was maybe on purpose you decided not to include it as part of, but the capabilities of the organization that are the manufacturers or the developers, what's the background, what's the baseline they're coming from? Is that something that should be a part of the discussion? Sort of the structure and the capabilities they may or may not have to develop a product or use a product.

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So, just to make sure I understood, so you're thinking more about the maturity and experience of –

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

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
– an entity. I don't recall that that came up, but it's a great point. I think it's a great point.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison
The conversation, I think, whether that adds to one's confidence in a product or not and whether it should. So, I think it's worth a conversation.

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
The structure, the management structure and the training and you know, you touched upon the training of the users, but training of the people –

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison
– the integrity of the laboratory, the ability to have good scientists available, the materials – process, they're all critical pieces. Whether or not that's characterized by institutional characteristics, or some of the ways demonstrated, I'm not sure.

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
So, I don't know whether that should be part of discussions or not, just put it on the table for other groups to take into consideration. One last thing, I want to just mention or ask a question, is, when you mentioned electronic and robotic patient care as product type, are you referring to also telemedicine kind of products?

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So I didn't put that explicitly on the list, but that's probably something that's going to ultimately be on the scope list, just because it's prevalent, it's already out there, it's a well-defined thing. So yes, add it.

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
And just a note for the Regulations Group, some of the things the Taxonomy Group talked about in the decision tree, to think about stuff like MDDS. And we would be really happy to hear if things are working with those fringe – I would say fringe regulations that exist today, that we may be better at or we should get better at.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Okay. Meg?

Meg Marshall, JD – Cerner Corporation – Director, Government Health Policy
First of all, as a member of the Taxonomy Workgroup I would like to thank Meghan for pulling this together. It really represents some challenging conversation that we had and so thank you. Two notes, and perhaps there are more questions. We speak to the terms regulation and without quite understanding what the definition of regulation is and what that potentially means. And just as a not, regulation does not necessarily mean what we would see from Class 3 FDA device, so perhaps it would be helpful to put our minds around that just a little bit better. We may find at the end of a decision tree for example, a very low risk piece of software, but nonetheless should follow a quality management, similar documentation, or something like that. So I would maybe challenge the group to think along those lines as well.

And again in regard to the decision tree, one thing that we – I know that we struggled with is whether or not it's presented as a binary, that perhaps there's a method where we can weigh the attribute. So as you mentioned, Geoff, if a person is individually using this for maintenance of his own health and well-being that perhaps might have a lower weighting rather than a binary shoot-off that says no, it's a lower weighting that's taken it into consideration with an aggregate. So, just an option.

Geoffrey Clapp – Better – Co-Founder
Yeah, I think that's a fair point. That's more what I'm looking for, I think, you hit the nail on the head. My reaction was a little bit to the binary nature, and again, it wasn't just the Taxonomy Group, I want to be fair, but about sometimes the black and white nature of these things. And we say things like, information to help you make decisions about your stuff, well now we're going to chase down every website that says, you should use Gingko, right. I mean, it's like there's a limit to that and there's got to be a place where we're kind of like – that's why I was trying to use that analogy of vitamins, where there's someplace where we're just kind of like, look, if you want to chart your blood pressure and look up online what that looks like, that's fine. You want to prescribe drugs against that, that's a different thing. And so, I think that maybe it's in the fringe where I'm trying to be, probably not surprisingly.

Jodi Daniel, JD, MPH – Office of the National Coordinator
Let me jump in and remind folks to state your name before you speak, because we do have people listening on the phone and they're doing meeting minutes as well. So, if folks could just try to do that, that would be helpful.

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

Joseph M. Smith, MD, PhD, FACC – West Health – Chief Medical and Science Officer
Yeah. Hi, Joe Smith. So, a couple of points. First, as we think about the intensity of regulation from a provider perspective, I think we may do well to remember that the noisiest part of – and most error-prone part of the administration of care is often times that initial encounter with the patient when we take this wealth of information and distill it and transform it into this digital record that we are then concerned about subsequent errors. And we should be careful not to regulate the subsequent activity to a level of precision not borne by the accuracy of the original data. So let's be careful that the intensity of regulation reflects that the process is always quite error-prone by virtue of the initial source of much of the information that we get.

I think the notion of context, and Meghan I think you brought out very well, this notion of criticality or dependency on a single pivotal point of information. I think that's terribly essential as we go forward, because it is always the case in the practice of medicine that you get erroneous bits of data that you dismiss in light of a context, which is then much more integrative. And that concept of the provider being that point of integration I think's essential to keep track of as we go forward.

I had a question as we talked about one of the things that we're going to be careful to regulate is visualization of information. And I can well remember getting faxes of patient records and EKGs in the middle of the night. And we are so much better than that unregulated platform, it brings me back to Brad's point, can we look at risk relative to where we've been as opposed to some notion of new absolute risk. Because it would be particularly unfortunate to over-regulate a process, which replaces one which was much more error prone and much less regulated and so, I would not like to see us hit with a hammer the progress while we allow the error to run free.

And then lastly, this notion of regulating user modification of this technology. So I come from a class 3 world as an interventional cardiologist and we make up our tools every day as we go, in some of the riskiest part of healthcare delivery. And we appreciate that opportunity because we value the personalization of that approach to the end user, to the specific circumstance. And so it would strike me as incongruous to regulate more harshly the adaption of a particular user interface when we allow interventional cardiologists like myself to mess with the tools that change the way the body works, right, so I'm looking for some congruity of regulatory oversight. Thanks.

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So, those are great points and maybe the best way of sort of responding is to just say that by saying in scope, it wasn't necessarily we thought you had have specific regulation around that. Just that the discussion and the recommendations that we handed off to our federal agencies would be incomplete if we hadn't considered how are you going to address that, which I think really is this innovation. It's sort of the cusp of innovation, which is that you conceive of and identify entirely better ways of doing things only through modification of the existing sort of standard approach.

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

Michael Swiernik, MD – MobileHealthRx, Inc. – Chief Executive Officer and Founder
Hi, Mike Swiernik. So you guys had mentioned in your organizing principles this concept of part and whole and how if part of it falls under the regulation that all of it should and that it's kind of related to what I think an accessory might be defined as. And so my concern with that, which is more of a general concern, it's not just in this, is just how viral I guess that makes the regulation in that if you regulate one piece of it that everything else that touches that becomes regulated. And the concern there is in my prior career, I had a number of examples, unfortunately, of vendors who had FDA regulated software that for instance wouldn't update from Windows NT because they considered that to be part of their – what was regulated, and that may be a clarity issue, we didn't know.

But a lot of modern software, especially mobile software, is built on a framework of services that interconnect and a lot of that is, I guess commodity software, it's not something that's medical, it's just out there available for anyone to use, and it may be best of breed. So forcing someone who's regulated to create their own version of whatever that is in a sense may be a get back to some innovation risk there. So, I just wanted to mention that as a general concern and we should be aware of that.

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So similar to, I think it was the last set of comments, I think our goal here was just – not necessarily to say that that should shape the specific regulations. But that if we're considering kind of something as a part – that if we consider something in scope that's a part of a bigger thing, the bigger thing should be in scope. You do raise a very important point that I think is, I hope that we talk in more detail about and that is what I think is its current state, but probably going to become even more prevalent, which is the development of software that calls other softwares to do things. And so maybe the overarching principle that I hope is in scope is, our recommendations or our deliberation around risk should also address this idea of the master/slave relationship. And if in fact there are – there in the future are regulations around one versus the other, what framework will enable us to sort of reconcile that and assure that there's ongoing patient safety, so it's that master/slave calling type relationship.

Geoffrey Clapp – Better – Co-Founder
This is Geoff again. I think architecturally, especially in modern software development, it would be bad idea to think master/slave, because in many times you're one or the other, and then we're going to go back into ambiguity. So I think that in a specific use case it will work, but in the grand use case it won't. There are a lot of times were EPIC is the master and there a lot of times, well, EPIC is never the slave. But, that's a different story. So I think that I would be careful about that analogy because I don't know that it will extend well into the pathways that we currently look at where most systems are playing both roles. In fact business development wise, it's really hard sometimes to know which one you're going to be and where the money actually is, even – so –

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison
So again, I think my perspective is that our discussion and our thinking would be incomplete if we didn't kind of think through those kinds of scenarios.

Geoffrey Clapp – Better – Co-Founder
Sure.

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

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
This is Brad Thompson. I could tell in your remarks you've already kind of gotten some feedback on whether the exclusion of FDA regulated software is an appropriate exclusion and I just wanted to add some thoughts to that. So I am guided by the statute and the statute directs a report to be written at the end of this year by FDA joined by ONC and FCC. I don't know why Congress would want FDA to write a report on only software – or FDA to write a report on only software that FDA didn't regulate. It seems that Congress specifically intended that FDA regulated software be within the scope. The statute also does not say that we want to report on unregulated HIT, it says we want to report on HIT. And if we were by the way going to exclude all regulated software, there's a lot of other regulators that are involved. The Federal Trade Commission regulates all software, so we'd have to sort of exclude all software.

So I don't understand the impetus behind the exclusion of FDA regulated software. Secondly I'm afraid that adds a lot of ambiguity because when you got to the actual what is in scope, several of those items are within the statutory definition of a medical device. FDA is on public record for years saying electronic health records are a medical device. They choose not to actively regulate them to this point because they perceive that they're to be low risk. But they are a medical device. You identify decision-support software, FDA is on public record as saying some portion of clinical decision-support software is regulated, in fact, they've been regulating it for quite some time. They've been accepting 510(k)s for clinical decision-support software. A number of the other categories you have heavy components of MDDS in them, which is FDA regulated obviously.

So, it creates some confusion for you to say on the one hand, we're excluding FDA regulated software on the other had to include a list that has a lot of FDA regulated software. But more fundamentally, I don't think the statute anticipated this committee to be only focusing on unregulated software, that wouldn't seem to jive with the language of the statute.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Let me just comment that my take on this was that we were being asked to assess both, but to address the bulk of our response to the things that are not regulated today but Bakul, let me ask you to weigh in around this.

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
To Brad's point, I think the intent of what Meghan was trying to get to is to that area of what is health IT, answering the question of what is health IT? I don't think the statute intended to talk about pacemakers or knee implants or some things like that. So there are – I mean, there are CAD software, that software that does diagnosing and points people to the right point on an image. That's been regulated. I don't know, I think the question for the group is, is that something that should be on the table or not? I think for MDDS, that's why I mentioned earlier that that may be a fringe area that we should think about differently. Some types of clinical decision-supports are using terminology very broadly, as everything medical device because the definitions are too broad, may not be very inclusive or exclusive. Using

broad terminology as clinical decision-support, which means many things to many people, may not be very inclusive or exclusive, so maybe peeling that onion layer a little bit would sort of help.

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

Michael Flis – Roche Diagnostics – Regulatory Manager
Thank you for the presentations, I think this is been very helpful in preparing us for how we'll make contributions this afternoon. I thought it was very insightful to remind us of the MDDS regulation and how we might be able to build some thoughts around that. But as we move forward and we think of the regulations that are in place that could be helpful to us, it may also be appropriate for us to look at regulations that are in place that actually should be revisited and may be either stricken or significantly rewritten. And at this moment I'm particularly thinking that in the year 2000, FDA wrote a regulation for the limitations of exemptions and that was based on their sense of what the risks were for medical devices at that time. And they looked at anything that was related to diabetes management and said it would require regulatory oversight including 510(k). Well thinking of today and all of the hundreds and hundreds of mobile applications that have been made available for the people managing diabetes, no one would really expect that to be covered by 510(k). That's an example that that regulation is no longer applicable to how we want to conduct ourselves. Thank you.

Geoffrey Clapp – Better – Co-Founder
This is Geoffrey, a clarifying question about that? Is the argument that because there are so many it shouldn't be regulated, because there are thousands of them or it shouldn't be regulated for some other reason for diabetes?

Michael Flis – Roche Diagnostics – Regulatory Manager
I think we have historically make decisions on regulation based on the intended use of the products.

Geoffrey Clapp – Better – Co-Founder
Sure.

Michael Flis – Roche Diagnostics – Regulatory Manager
And if you have a regulation in place that says anything that is related to diabetes management is automatically subjected not just to regulation, but a certain degree of regulation. That's not in step with all the variety of products that are now available for disease management.

Geoffrey Clapp – Better – Co-Founder
Okay. Thank you. What I was hoping you were saying was the variety and the legislation saying all versus just that there's a lot of them. So, I just wanted to be sure. Thank you.

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

Anna McCollister-Slipp – Galileo Analytics – Co-Founder
Hi, Anna McCollister-Slipp, Galileo Analytics, and I'm actually here with two different hats. I'm a health IT entrepreneur that works with big data and electronic health record data, but I'm also a Type I diabetes patient who uses four medical devices, that are approved by FDA and a whole bunch of mobile apps and consumer devices to manage my disease on an ongoing basis. So, I guess one of my questions was already addressed by Brad, that is I would love to get some clarification on the scope. I feel like if we aren't taking a fresh look at what is currently regulated by FDA, that we may be missing a really big part of the boat. Just because this – I mean, the sense of that I got about what this committee or what this working group is designed to do is to look afresh and say, this is a field, this is a potentially incredibly helpful, challenging field that needs to be thought out from a new perspective.

How do we approach that from a regulatory policy perspective? Is there a framework that will work that both protects patients when that's needed and enables innovation and doesn't stifle innovation and doesn't try to pre-determine what it is that can be done or can't be done, because we'll never figure out what that is in advance. I mean, everybody, there are a million good ideas out there and if we try to pre-define that ahead of time we're never going to get there. So I think it would be great to have some clarification on that because I feel like if we limit ourselves to those things that aren't yet regulated by FDA, then that's a very piecemeal approach with limited effect or limited utility.

Secondly, in the taxonomy, this is a very specific issue, you mentioned that analyses done with electronic claims data would be out of the scope and there was no mention in that specific context of electronic health record data, although there were other references to different things within the context of electronic health data. So I was wondering if that was just a, you didn't add claims, EHR retrospective historical analysis used to look for trends or if that was just – if there was a specific reason why those two, there was a distinction made?

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So hopefully this will help with the clarification. So what was in scope was the investigational use of healthcare data on human subjects, so that would definitely be in scope whether you were using claims data or EHR dated to do that. But it was influencing specific, well-defined human subjects. I think the only, you always get yourself into trouble when you put something on a list, but the idea behind putting historical claims data was really software that helps one understand what happened in the past in terms of health service utilization. That was I felt off the table or out of scope. Although Paul brings up good points, it depends on just where you then use that analysis, so we may revisit that. But the HER studying patterns of utilization within an individual patient for example and that informing or affecting your choices about treatment, I think would be in scope, because it's influencing decision-making and choices about interventions on an individual patient.

Anna McCollister-Slipp – Galileo Analytics – Co-Founder
Just to raise a concerned flashpoint, and I don't really know where I would come down in terms of the policy perspective on this to be completely honest. But, as a patient and a health IT entrepreneur, we have done a lot of work and the whole notion of a learning health system, which is the great hope of all of this health IT, all of this data whether it's electronic health record data or medical device data or clinical guidelines or registry data. Whatever the clinical trial data, all of this coming together and creating applications that sit on top of it that help inform and create an evolving ecosystem of data turning into knowledge. And I think that for us to try – again, I would be concerned if we try to pre-define what was and was not enabled from an innovation perspective within that context. Because once you start doing that, you're putting limits on what could potentially happen and flourish, once a lot of really smart, creative minds get access to new data, new analytic capabilities, new visualization technologies etcetera. So again, I'm not the regulatory expert fortunately for everybody, but I would like to voice that concern. I mean the whole promise of all of this effort is that we're going to create this new ecosystem that takes data and turns it into knowledge that – and if it's everybody within the system from patients and providers to payers, etcetera. So, I think that's one thing that we need to keep in mind, not just the micro uses of all of these individual applications, but sort of the macro big picture of where all this is going and how what we do with this working group, how that fits into the overall strategy of where we're going as a society. And do we want to put any kind of undue limits on where that could go? And within that context, how to manage the risk appropriately and define it in such a way that it doesn't limit innovation but actually fosters it.

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

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
Thank you, Julian Goldman here. I'd like to go back to address the discussion about risk assessment, patient safety and innovation. And in the presentation, there's a table, which despite my brand-new reading glasses, I can barely make out. However, I can make out some of the key points in here. And I think it's worth asking about and thinking about the notion that the complexity of technology is somehow aligned with the hazards and the resultant risks. It's almost an easy assumption for us to make that more complex equals more hazardous. However, if we take something very simple, such as the conversion of weight in pounds to or from kilograms, in some systems there's very little risk associated with an incorrect conversion and yet there are cases of significant patient harm in settings such as chemotherapy dosing for example, and that could be deadly. So simple calculation that a high school or elementary school student can perform and all of us would consider to be trivial in fact could be deadly.

And conversely, we can look at the vision that many of us have that more automation of things that are done today clinically could be lifesaving. And we can even take the exact same technology with two different medications. So we can have a technology in which an infusion pump could be stopped automatically if the patient starts to decompensate from the medication being administered, and let's say that medication is morphine and the patient has respiratory depression. It's possible to stop the infusion before they have respiratory arrest, at least theoretically so and there have been products that have done that. So the risk to that patient of that system failing in such a way that stops the infusion prematurely is very low risk to the patient, especially in a healthcare setting, and if a healthcare provider is called as part of the solution.

But conversely, if the almost identical system is used to interrupt or adjust the dosage of something like epinephrine and there's a minor error in the software or the system, it could be lethal, conceptually. And so, in other work over the last few years we've had a fairly large working group looking at some of the safety implications of interoperable systems, especially multivendor or heterogeneous interoperable systems and teasing out where the hazards might arise. And one of the things that we learned early on, which kind of surprised us, we only realized after sitting down and thinking about this is that we cannot make the assumption broadly that risk and complexity of technology are aligned. They may be and they may not be, and it depends upon the specific intended use and many other factors. Things that are considered routinely in, for example at FDA assessments for new product. And so I just want to be careful that we don't incorporate without additional critical thinking and teasing out of these issues, we don't incorporate this as a kind of notion that becomes almost an assumption that's always correct. So those are the observations I have and would love to hear, maybe we can discuss that or can disagree or whatever. Thank you.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison
So I think a lot of the things that you bring up, the interoperability issues definitely in scope and I think we would be remiss if we didn't explicitly address those in terms of both the risk, innovation which it's a lot of putting together subsystems that brings out new functionality. So that definitely is in scope. But I think the other point that you bring up is that it can be very hard, even if you decide something's in scope, it's all about the conditions of use. And it's just one of the challenges, and I think that's why even if you thought – even if you examined in detail existing regulations, they're challenging to apply to software. I mean, we have to – hopefully this group will come up with some ideas and some recommendations about maybe entirely new ways of assessing the risk that are more applicable or more relevant to those really diverse functionalities in software.

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
Yes, and for example in the table, it points out that as you move from left to right, lower risk to higher risk, and we go from human in the loop to an automated system. But we know there are human in the loop systems that are very high risk, and we as humans just don't perform very well, and there are automated systems that would be markedly safer, especially when used in the constrained scope. So that – it's understandable to take this approach and it applies a certain areas, it just starts to fall apart a bit when you tease out the specifics.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
(Indiscernible)

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
Yeah, this is Todd Cooper. I just wanted to agree with the assessment of the eye test chart and say that I know in a lot of discussions that we've had around the standardization and risk assessment, we might use this as a tool to get at criteria and principles. But we really try to use it only as a tool and not formalize it going forward because it ends up taking you down a very narrow path of thinking, as opposed to really identifying what are the true issues there.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Great. Elisabeth?

Elisabeth M. George, MS – Philips Healthcare – Vice President, Global Government Affairs, Standards & Regulations
Elisabeth George with Phillips. One of the things I did want to remind us of is that at the very first kickoff meeting we did all say that nothing was out of bounds, that we needed to think outside the box. And working for a medical device company that's had to do 510(k)s for software for more than 20 years, I would love to see the potential opportunity that maybe some of those products might be down scoped or put into one of these creative alternative methodologies that we are trying to create here. So I hope that, as Anna mentioned as well is that I think we should consider that just because the FDA regulates it today, they may regulate it for me, but they may not regulate it for somebody else sitting around the table.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
That's a good point. Mo?

Mohit Kaushal, MD, MBA – Aberdare Ventures/National Venture Capital Association – Partner
Good morning, Mo Kaushal here. I'd like to echo some of the previous points, especially Brad's. So I understand the intellectual exercise to figure out what's in scope, what's out of scope, but I think to an extent innovation's always going to outpace regulation. So in my vantage point, I've see a range of companies and my paying point is to think through, are they going to be regulated or not. And many of them don't fit within the discussion of the specifics in scope or out of scope. So again, I urge us to think a little bit more in terms of Paul's framework and maybe get some consensus around having a much more generic description of the value proposition of what we are looking at and agree on the specific risk factors of those buckets. And I think this is a great start and then really focus our discussion on this piece versus very specific use cases. Thank you.

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

Joseph M. Smith, MD, PhD, FACC – West Health – Chief Medical and Science Officer
I'd like to provide an echo chamber for what Julian was saying about the notion that complexity can provide safety as opposed to create additional hazard. I think the IOM report was pretty clear that the information that's required to take care of patients now largely exceeds the time and bandwidth available by the average clinician and we're going to need aids. And so unless we recognize that there's a safety adjunct associated with that complexity, as opposed to just another hazard, I think we're going to largely miss the boat.

So Meghan you brought about the notion that interoperability is in scope, I think we have a tremendous value that can accumulate when the information is available to create a learning health system and we've talked about the safety benefits of having data in context. So when we say interoperability's in scope, do we mean it's something we'll think about or do you think we have what it takes at this particular opportunity, which I think is relatively unique in the next several years, to enforce the value proposition of interoperability in the final rudiments of a result from this committee?

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So all of the above. I think it would be a huge omission if we didn't at least talk about and then forward as part of our recommendations that this has to be part of risk assessment or consideration. The issue with interoperability that I've personally experienced as a healthcare provider is that there's sort of this black hole, meaning that you have component "A" that has a very well defined design and in its independent design has been very thoughtfully – the risks have been very thoughtfully mitigated. And same with "B," but when put together and there is a malfunction there's almost, one doesn't even know how to manage that and one doesn't even know where the accountability rests. So understanding that interoperability is a huge promise I think for the future, the discussion and any kind of thinking about a risk-based approach to regulation has to address that. And we may not get the answers, we may not even get good recommendations to offer but it has to be sort of put dow – at least explicitly listed as an item that we are tabling but has to be revisited in the future.

M
To push us if I could, I would say that, and not to get too philosophical, but a value proposition for government is to step in when there's a market failure. And so as we talk about what is the problem we're trying to solve with the regulation, one could posit that a problem is that we have a safety hazard that results from non-interoperable systems and that since we have not seen a market-based solution, this may be one of those unique opportunities were government can bring unique value.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Thank you. Jonathan?

Jonathan Potter, JD – Application Developers Alliance – President

Thank you and thanks to everybody who's done really good work. Somebody described this group at the beginning of the day as a randomly collected group of folks without – some with great expertise and others without. I would put myself in the category of random and interested and excited, but not a lot of expertise. But with our membership in the App Developers Alliance, a whole lot of folks who are interested in the market and are struggling to figure out how to be successful. I am challenged by the idea of when the practice of medicine ends and when the regulated world begins. And when a physician comes to one of our member companies and says, which they do frequently, I've got an idea, I want to build an app. Am I building something for a doc who's going to use it in his practice, and is probably going to share it and might write about it, and it might be peer reviewed when he writes about it, or it might not be. And what are my obligations? Now presumably I can get an indemnification and all sorts of things like that, but thinking about it holistically, where does that fit?

And Joe Smith talked about the docs in the OR manipulating the device, well presumably the device is already pre-approved, right that hard device, that physical device, but his use of it wasn't. And I think that that's something that we have to be very careful of is when we are encroaching on the practice of medicine and what does that mean? And there I've hit the limits and I'm back into the random category.

I'm also struggling with the idea of big data and the value proposition, the opportunity of innovation using big data and how we regulate electronic health records and patient records. And whether we can promote, if you will the anonymization of those and that the public dissemination of those in ways which creates tremendous opportunity for innovators who can figure out things to do with the data and solutions and opportunities and trends and ultimately can practice medicine based on that. And are we hyper-protecting for patient privacy, are we hyper-protecting for other reasons electronic health records, which could actually be – just as the government has made a huge move, the federal government, into pushing more of its data to make it available to problem solvers, are we limiting ourselves by over-regulating and for what reasons health records? And will anonymizing them, and admittedly the 12-year-old might hack right through that anonymization scheme, we all know that is true with everything we do, but are there ways that we can push that. And I think there might be ways that the government can promote innovation and promote research and solutions.

The last thing that I would say is, an example that I've used before and some of the people in the room have heard this before is, when do we go from basic information that is very legitimate to walk around with on a Xeroxed piece of paper, but because it's in an app, suddenly becomes a medical device. And my favorite example is the concussion diagnostic app that every single football coach should have, because 90 percent of football coaches don't even have a trainer and 99 percent of them certainly don't have a physician. And so when the kid comes off the field and he's groggy, is it a bang in the head and he can wait 5 minutes and go back in, or do you need to send him to the hospital? And what's that 10 questions that every doctor knows, because he probably learned from the first year of medicine, in medical school, but I don't know. And literally it was a ditto sheet when I was kid. Ask them to hold three fingers from 2 feet away and if he says it's three that's good, if he says it's four, sit him down. And if he says what fingers, send him to the doctor. Little simple stuff like that that you create real solutions for real people, but because it's in an app, because it's on a smartphone, is it diagnostic software? You tell me. Is it an

FCC regulatory thing, because it's either right or it's not. Or it's good enough or it's not, and should we just say, you know what, if it's consumer facing at some level and it's basic at some level, just let it go. So those are my random, uneducated thoughts and I look forward to the rest of the day. Thank you.

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

Jodi?

Jodi Daniel, JD, MPH – Office of the National Coordinator
Thanks, Jodi Daniel. So I want to play a little bit off of what Jonathan was just talking about. And what's still a little bit confusing to me about this discussion is, I'm going back to the definitions that the Taxonomy Workgroup presented at the beginning, and in this decision tree about does a product currently meet FDA definition of medical device. I feel like there's still blurring of, is it a health information technology versus healthcare technology and then is it health information technology or is it just helpful consumer information. And I feel like trying to get, and I realize there is blurring of lines between all of those, but trying to get some clarity of are there things that are off the table, not because of how they're used or where it is in the lifecycle, but because it's not really health information technology, it's something else. It's a pacemaker, it's a – I don't know. Although some things that may fall within FDA definition of device, like MDDS, maybe that is health information technology.

So I feel like there's still – I still have confusion in this conversation about kind of what's in and out of scope based on what the thing is that we are talking about and is it health IT and therefore in scope or not, regardless of who's using it or how it's being used. And then I think the other thing that I am having – I feel like there's a little bit of confusion about is, is it in scope for discussion or should it be regulated? And I think those are two conversations, I think there are going to be things that are in scope for discussion of this group where we say, you know what, that is health IT, that is within scope of this group. But it's so low in risk for the risk innovation group, that we don't think that the federal government needs to do anything about it, to Jonathan's point. So yes, it's health IT, yes it's diagnosing, maybe it's a diagnostic tool, but there's no risk to this. There is no – and maybe FCC should make sure that – maybe there is a role for FCC as far as if the product information's accurate and it serves the function that it's being claimed to serve.

So, just a couple of line drawing questions that I have that I think would be helpful to get some more clarity on from some folks and areas where I just wanted to clarify, I think that there may be things that yes, we should say are in scope and then dismiss them from the risk, because risk is low. So, yeah, it might be in scope but we don't need – the federal government doesn't need to worry about those things, but at least if it's in scope it's something that we may want to at least keep on the radar screen. So if in fact the risk of changes, based on some of the discussions that the Risk Group is having about the different dimensions, maybe it does eventually fall in scope. So, just cautions of not to just assume that if it's in scope, it's going to be regulated and oh my gosh, that's scary. It could be in scope and still you guys can say, it's in scope, but don't look at the stuff right now. Not important, not risky, not a problem.

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
I just want to thank you for I think summarizing what I think the Taxonomy Group took as our – what we were striving for, which wasn't to say this needs regulation, this doesn't, but this should be part of the discussion so that no one, at least at the end of this, there weren't glaring omissions.

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

Lauren Fifield – Practice Fusion – Senior Policy Advisor
Hi, Lauren Fifield from Practice Fusion. A couple of points I'm sort of well-timed, at least with what Jodi and Meghan just pointed out. I guess for the group, I'm having to remind myself over and over that in and out of scope doesn't mean regulated versus not. I keep having this sort of visceral knee-jerk, oh, in scope, oh God, 510(k), for all that's going to be regulated all the time. So, just sort of reminding myself that in scope is really just for us to consider and then eventually potentially to have the agencies consider, or at least that's how I see it.

I think another point which is unrelated to what Jodi said, but I don't want to let the conversation go without going back to it, it's this concept of regulating a part versus whole of software or health IT. I come from a background in web-based technologies where it's a single instance of software that's deployed to all users. And so the concept of regulating as a whole this platform that continuously changes, in my current experience every two weeks, for one particular release we may touch upon something that would have a high risk to patient safety, may be ePrescribing functionality. Whereas in another part of the release, two weeks later, it could have an impact maybe on our market share, how well we're integrated with billing, but certainly not patient safety. And so I really think given the proliferation of different technologies that aren't these sort of packaged software pieces that we really consider functionality as a risk and functionality components less so than pieces of software, sort of maybe taking away – taking steps away from our kind of device regulation brain.

I'd also say in that, I'm also having to remind myself that regulation doesn't necessarily mean regulation a la device regulation. So that's my other sort of visceral thing I keep doing which is, oh, regulation means "X." Regulation means – first of all, we have no idea, we're not going to decide it, but it does mean for us, whatever we recommend, right, so that's on us. So, that's two. And then three, I think in terms of risk, I know that Joe had mentioned this and we don't really have much of a baseline of risk. The reality is, I'm going to die no matter what and so when I go into a health setting, we're really just prolonging the inevitable, and I'm not trying to be flip, but what I am saying is that, I may make a mistake and overdose myself. A doctor may make a mistake that has nothing to do with technology. And I would really empower us to think of technology not just as a threat to patient safety, but as a way to help improve patient safety. So again, it's not to say that health IT is not implicated in adverse events or couldn't be, but that I think as more as a tool, more as an empowering factor in mitigating patient safety risks than that I would think of it as a threat.

And along similar lines, maybe renegade lines for this group, I also think that risk isn't always a bad thing. I know that for my grandfather who had cancer, he was willing to take any risk possible to prolong his life but also to have a good quality of life. And so particularly as we are looking at the health system to address cost and access, it may be that we don't all have the ability to pay for the highest priced and nicest devices. But that I may be willing because I'm in a remote care setting, I may be willing to take the risk of using an otoscope that's attached to my iPhone because it's cheaper, I don't want to bring my kids to the ER and it's going to cost a lot. And so I think maybe it's going back to sort of an empowering the consumer, empowering providers to empower consumers, but allowing for risk in some way, may be a sandbox within a regulatory framework or also just saying that a tool in a regulatory toolbox is to not regulate and to allow for some risk-taking, because innovation is ugly. It's actually based in failure, it is the result of failure after failure after failure and so, I think risk is very inherent in innovation. So, I'll be quiet. Thank you.

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

Geoffrey Clapp – Better – Co-Founder
Lauren that was great, I was going to tell Matt that he should regulate every two weeks anyway, but since you were so good, I'll back up to Matt's case. It's a combination of kind of what Jonathan and Joe said, and I'm not a doctor, nor do I play one on TV, so I really appreciate hearing your point of view Joe and everyone else who has one. This is again a kind of a high-level thing as we break into subgroups this afternoon. There's a tension in the room, there certainly was a tension on our phone calls between please be really specific so I can check off these boxes and do things. An example of that would be, HIPAAs pretty good at saying, this is what it means to secure data. Here are the 18 things, do those, that's what it means to have secure data. Pretty easy to say whether this is anonymized or not. It's still amazing to me how many people have a conversation with me and say, oh no, no, the picture we stored it on Amazon in clear text. No, the Amazon, that's one of the 18 things that's on the list.

But that's part of the tension and I think that as we each break into our subgroups, we need to consider how much ambiguity we want to have for the reconfiguration of things like that. And I have a specific question for you Joe at the end of this, because I want to learn from you on this. And the – I want to be check the boxes, no, no, I really want to know, I really do. I want to check the – I want to be able to check the boxes and know that I'm cleared, right. There's a natural tension in what we're being asked to do, and I think across the three groups, if we split up in and have very different points of view on what want to do there. We at least need to bring that back to us about are we representing more of the check box, just do these things we can automate the whole thing and yes you're cleared, no you're not or are we looking for a bit of ambiguity to allow for some of that reconfiguration. Because Joe, I'm not meaning to put you on the spot, I am very serious about this.

Are there things that you see that allow you to have that ability to reconfigure, which it seems like a dirty word, I mean it's more like make the tool you work for you, yeah that exists today that want to make sure that we do not lose? Because I think in moving toward a checklist manifesto if you will, we lose the possibility of empowering people like you to do those things. And I'm just wondering if there's anything specific that you know of. And again, I don't mean to put you on the spot, but I think there's a lot of value in that area between the two parts of the Venn diagram of this checklist approach versus in the fringe, in the risk, as Lauren said very eloquently, how do we allow for people to do that? So, I don't know if you have any additional specifics or follow-on, or if I put you on the spot, I totally apologize, but I thought your comment was very apropos.

Joseph M. Smith, MD, PhD, FACC – West Health – Chief Medical and Science Officer
I'm happy to be on the spot. So, we should have lunch because we don't need to occupy everybody else's time. But I think we do have to be careful to allow for innovation at the coal-face, at the interface where care is occurring. It's often times that's where the problems are recognized and where the most creative solutions arise. And so we've got to be careful to do that. And the notion that in scope is regulating what an individual does with their individual software I think is quite concerning.

Geoffrey Clapp – Better – Co-Founder
I do have a follow-up question for you though, which is, how do we learn from people like you? So I phrased the question specifically because I knew I was going to have this follow up and I apologize for that, but part of the thing about – has the feedback loop. What's a feedback loop, because again I can't say it any better than Lauren did, that kind of this innovation is rooted in failure. How do we legislate or provide in such a way, the ability if you say, hey by the way, I connected these two wires, horrible example, I'm joking. But I connected these two wires and this was 10 percent better. Is there a way for us to provide an innovation framework for that kind of thing – like that comes out of clinical regulation but is actually kind of the same way we do would do recalls or anything else, but in a positive way.

Joseph M. Smith, MD, PhD, FACC – West Health – Chief Medical and Science Officer
So at risk of making this – connecting another dot, in an interconnected network environment that this technology pretty much uniquely affords an opportunity to, that notion of what did someone do and how are they using it, that can be available. If in fact we build that in up front and we require the notion of interoperability, it's something we can have visibility to those changes, not visibility with the point of limiting them, but visibility with the notion of creating this learning healthcare system that we all fundamentally believe in, is the value proposition for the technology. So I think here today is an opportunity for us to take advantage of the opportunities that this technology uniquely affords.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Let me just do a time check. With 10 minutes until lunch, I have a couple of things I want to do between now and then. So everybody else who has your card up, I'll try to get to everyone, but please be brief in your comments. Matt?

Matthew Quinn – Federal Communications Commission – Director of Health Care Initiatives
Matt Quinn, FCC and I just wanted to say that I'm not surprised at the thoughtfulness of the work that this group has done.

M
Wow.

Matthew Quinn – Federal Communications Commission – Director of Health Care Initiatives
Let me start by saying that something that Mo said really struck me, innovation will always outpace regulation and whether that's in financial markets or whether it is in campaign-finance reform or any of these things, that really the role of regulation is to encourage innovation that creates value and to prevent innovation that causes harm and dysfunction. So, innovation is a two-edged sword in many cases. So another thing I wanted to up, and Patty, Meghan and I were discussing this a little bit, I think that we should be very careful about being platform agnostic. Platform matters and wired systems and wireless systems both have different potential risk profiles, but also different potential regulatory profiles. And so as the FCC license spectrum, private spectrum is regulated by FCC, both licensed and unlicensed. And so issues like interference and quality and reliability of the connection can be really important in terms of health IT systems and them communicating with each other, etcetera.

But in addition to that, there are human factor issues inherent to moving things from a smaller screen, whether it be truncating things or limiting functionality that's different than the full-screen, double screen, giant screen, high resolution version of that. And then there are also security issues that we need to think about that are inherent to wireless or different in wireless, as well as bring your device kind of issues. So how we fit this into taxonomy, risk and regulation I hope is something that we discuss a little bit, but I just wanted to raise the issue. Thank you.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Thanks. Let's see, Mike.

Michael Swiernik, MD – MobileHealthRx, Inc. – Chief Executive Officer and Founder
Mike Swiernik. I just want to offer one example which I think ties in, maybe part of the part and whole discussion, the in and out and also definitions and what Jonathan I think was alluding to. Which is right now there's kind of an unnatural rift in the mobile health world between what would be considered health applications and what are considered wellness applications. And in the last couple years, I've been working on chronic disease management in the mobile health world. And that rift is kind of a significant problem, which is that you've got all these wellness applications where patients track their exercise, their diet, and their weight and all of those things, and then you've got the health applications to help manage diabetes or hypertension. And we all know that's a major part of cost for healthcare in this country, so, I don't think the rift is completely due to regulation, but I think a lot of it is due to regulation and will continue to be as long as that's – they're considered separate. So when we talk about in and out, I want to make sure that whatever regulation eventually comes out of this, what I would hope we would see is something where they're both in the same bucket and it's easy for them to at least interoperate, if not become one in the same, so that we don't continue to have that rift. Because right now consumers, if I want to track my multiple chronic diseases, I have to enter my weight five different times because it's relevant for all of them, but – so that was just an example that we might think about.

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

Richard M. Eaton, JD – Medical Imaging & Technology Alliance – Director, Industry Programs
Rich Eaton. One thing I've been struggling with and I think probably others have to is, our starting point of the HITECH definition of what is HIT, which is extremely broad. I think our task has to proceed along a continuum and reflect the continuum, everything from what clearly, if there is such a thing, shouldn't be regulated and something that's either regulated now or should be regulated in the future. It's a huge challenge given the short timeframe we have, but I think we have to convey, if we're going to really be honest about a regulatory framework, that there are areas that we feel fairly sure about, others we don't and to make sure that people understand there's a great deal of ambiguity. And that these apps and the applications are going to change over time. So it's a balancing act between acknowledging the complexity and making something understandable to regulatory concepts.

Keith G. Larsen – Intermountain Healthcare – Medical Informatics Director
Keith Larsen, Intermountain Healthcare. Just a couple thoughts; I think that again, as was just expressed, I think that it's hard to define edges of the scope. I think the definitions are sufficiently broad that it encompasses all this, anything we can think about. So it really comes down to what do we practically regulate not what we can regulate, but what we practically can regulate because just like as was stated, the FDA has signaled over time the desire to regulate certain things like EHRs and it's a practical consideration of risk and doability to do that. Just like the discussion about the part and the whole, the hard thing is that the part in the whole discussion is, I don't really know the whole until I see it, in my hospitals. Because of the way that people are very innovative on their own, just like Dr. Smith was talking about, about connecting technologies to solve their problems. Everyone's trying to solve problems. They're trying to use the technology and leverage it to do it. And they will come up with a combination that may be unique.

And so the notion that you can govern that from the level of an FDA is impractical. And so as we talk about this, I think we're trying to think about how do you put feedback mechanisms in at a local level in order to look at how you not only govern that combination, but you learn from it and distribute that capability. Again we have people that are using Excel spreadsheets and treating patients, that are filled with calculations. And if what we do is regulate things so tightly that I cannot have something go through the normal process, in order to get a very regulated true, a very defined manufacturing process and late for my need, what you're doing is pushing your technology actually into a more unregulated state. So those are just the cautions I think. We have to accept some risk and we have to be able to monitor it at different levels and be accountable at different levels.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
And Meghan gets last word before I bring up a couple of other things.

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So, it's not a comment but maybe a request. Just based on the discussions of maybe the last 20 to 30 minutes, I think it would be helpful for me to hear again from Bakul and maybe other members of the group, to hear what the FDA's traditional, historical approach has been to where the boundary is in the practice of medicine versus where I think the majority of their regulation is, which is the manufacture, distribution, and that type of thing. So that would be very helpful, I think, if you could restate what the official perspective is. And I think in a similar vein, maybe it would be helpful, if you are willing to, to talk a little bit about FDA's traditional approach to enforcement discretion. I don't know that's going to open up a can of worms, but that can help a lot because I think that can help soften or temper or help us understand a little bit more about the potential flexibility in regulation.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
So one thing that came up as a recurrent point is, should currently regulated devices be in or out? Anna, I heard what think is a reasonably strong consensus that they should be in and Brad brought that up. I think our main focus though should be – we should be looking at things across the continuum as Rich suggested and I think our biggest focus should be on things that are not currently regulated. But things that are heavily regulated today, do interact with those other things, we have to think about that too. We can also consider making the recommendation that Elisabeth suggested that we should perhaps think about putting some devices in these new frameworks, that might be something that would advance the ball.

And we also really do have to think about all of our recommendations in the context of what the world is like today. Mike and Lauren made points about this, the notion that software might be changing every two weeks, that does not really fit with the usual FDA regulatory framework. And Mike's point about the way the apps are developed using – interacting with all different types of software which are developed in different spaces.

I just want to close by making a comment about whether or not there are real risks, Brad brought this up, and we haven't talked very much about that. But it's pretty clear to me that there are real risks associated with software. One example is a hospital in Pittsburgh in which the mortality rate one up several-fold when they introduced the new computer entry application. This was for kids who were being transferred in for special care. Now it turns out that when you examine things closely, the organization didn't follow a lot of the basic precepts for how you should do that. And there are two other organizations who introduced exactly the same vendor application into their children's units and actually found that their dashed their mortality rate went down. But the mortality rate went up and it wasn't by a trivial amount.

Another example we talked a lot about a lot in the IOM Committee that a number of us served on was when providers are interacting with HIT software and they encounter an issue that's clearly related to the software that resulted in a problem. Many vendors have tried to discourage providers from communicating with each other about those issues. And the number of these instances is not trivial. We don't today have an appropriate mechanism for making sure that people can share things like that. So that's the sort of use case that I hope we'll address going forward.

I want to thank this group for their hard work, it's a really very useful framework. We'll more time to talk about the margins of things tomorrow, but I think we have a broad approach for thinking about what's in and what's out again. A lot of – I would agree with a number of people who have commented that we do have a lot that's in, but I think that that's okay. And we will then just need to come up with approaches to address this from both the regulatory perspective and then the risk and innovation perspective. So thank you all, we're going to reconvene at 1:00 p.m. And the two meetings are in subgroup areas, MacKenzie, do you want to tell us about that?

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Sure. The two breakout rooms are directly across the hall as you walk out, so please for the Regulation Subgroup go to the Franklin Square breakout room and the Risk Assessment and Innovation is in the McPherson Square, again, right across the hall there. Also, we won't be able to do any live webcasting

for the breakout rooms, but there will be two listen only phone numbers that will be – that members of the public can dial into and listen to the breakout sessions. So, they'll be posted up on the webinar screen.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
So thank you all and we will reconvene at 1:00 p.m.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
And lunch is outside. I will have them bring it in.

Operator
All lines are now bridged.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Operator, are the lines open?

Operator
All lines are bridged.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thank you. I will turn the agenda back over to David Bates.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Thank you MacKenzie. Next, we'll have report outs from the groups. We'll hear first from the Regulations Subgroup.

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
Thank you Dr. Bates. This is Julian Goldman, I'm going to be the voice for at least part of the report back, and I look forward to having other members of the subgroup who participated, please feel free to – please raise your hand and get my attention if there are any omissions or misrepresentations of your ideas. So, in our subgroup we talked about a number of topics. Obviously, given the time we have here, we can't review all of it in detail, although we'll be able to share that as time goes by and in our phone calls. Here is a high-level list of some of the things we discussed.

We talked about the clarification of the notion of regulation and the fact that in a number of discussions, especially this morning and other times, the word regulation was used almost synonymously with FDA regulation of medical devices, and yet, of course, our charge is broader than that and the regulatory landscape is broader than that. And, we won't go into any of the details here, but that was part of our conversation and we thought it was important to explicitly call out that idea. Also, there's another – there's the reality versus the vision, there's the regulation that's written and then there is how – the details of how it is applied, and both of those might be – undoubtedly will be important and have been important and that we can, if there are more details and if that needs to be expanded upon, I will – I think that was a signal not to do that. Okay, so –

M
– I was just talking about that.

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
– for those of you on the phone, we just had a strange electrical problem here. Okay, anyway, if we want to go into detail, anyone just raise your hand and we'll go into detail on any of these topics. Then we talked about the notion of the scope of safety, and we have been using almost a shorthand in the presentation, and as Brad articulated this morning in the slides, the notion of safety kind of just very, very generally. Because after all, this is the Regulations Subgroup and that's the purview of other experts, to go into further detail. But we wanted also to be clear that there are many dimensions that are relevant here. There is the safety of the system and the safety of a patient or user, as well as things that can be done to improve healthcare more generally. And Todd, you had brought up a few specific points about that and if you want to elaborate, please go ahead now.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
Yeah, thank you Julian. From our standpoint, in the standards space especially when we're talking about risk assessment, risk management, we talk about harm, right. So you have hazards to situations that lead to harm and in harm, we have safety as one primary high-priority aspect, but effectiveness and security as the other two aspects of that. So the idea was in the regulatory side to talk about harm and then hopefully we can factor all three aspects into what comes out of the RA&I group.

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
Thank you. And of course, there are people who spend much of their lives teasing out these differences, understanding them and then implementing them, and they're quite important. Next, we talked about, rather extensively discussed a review of the published literature regarding regulatory duplication and ambiguity, and Brad presented a lot of information about that the work that he and others have compiled. We then discussed the notion of what the deliverables would be from the group and that will be a privatized list of ambiguities and duplication that require resolution and identification of potential new issues that will need to be avoided. So in the proposed new regulatory landscape, where might new problems surface? And then some specificity on proposed solutions if they can be identified a proposes solutions, if they can be identified and proposed as ideas, there's a plan to do that.

Now, as Brad mentioned this morning, in a sense we are waiting for input from other groups to do some of our work, yet given the interest and the timeline, we can't wait forever. We just don't all have that luxury. So we're all trying to move ahead in parallel while also sharing information. But when we receive recommendations from the other groups, we will evaluate those work products and use those to guide and refine our recommendations. Brad, did you want to comment at all on that?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
No –

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
Okay. So, to continue, we also discussed a number of specific examples and based upon recommendation and advice that we've received, especially from the chair and others that use cases are necessary to drill down and understand the specifics, we talked about some specific clinical examples. And we used that to try to understand what level of specificity and detail are needed to then guide some of the regulatory recommendations or the system recommendations. And the specific examples that we went through will follow in additional slides in a moment and they include the representation of medical data – medical device sourced data in the electronic health record, challenges of accurate time stamping of clinical data. Something that we discussed this morning regarding the complexity of technology, not necessarily being aligned with the risk of the use of that technology. And with – there's a specific example we will use. The broader issue of interoperability and the implications, and really just touched on that and how could we leverage the benefits of health IT in terms of surveillance of product performance and systems in the future.

So, to go through specific examples, I just realized that I don't have a pointer as part of this system, but that's okay, we'll just work through it, it'll work. So in this example, you have on the screen, thank you Brad for the pointer, but on the phone, I can't see it. In this example that you're looking at is a box on the right, which is a photograph of the front of a simulator that can generate pulse oximetry signals, just like a patient, but it's controllable. On the left are three photographs of a pulse oximeter at different point in time. The pulse oximeter on the left, the three of them, one of them was set to the averaging time of 16 seconds, that's a user selectable averaging time, the middle one was set to 8 seconds and the bottom one to 2 seconds.

Now what we did is, we took the simulator – I know this is – I figured the audience can't see it – thank you for trying to help me. Thank you. I didn't want to tease them with...the remote folks. So what we did is we took the simulator and we put in a desaturation profile to mimic, for example, what might happen with a patient who has sleep apnea or is desaturating from medication or other problems like that. And we started with a saturation of 98 percent, dropped it to 70 percent, then went back up to 98 percent, so that's what the simulator did. It did it three times. The pulse oximeters on the left, which is a picture of each when it showed its lowest saturation, notice that the lower saturation displayed at the top left was 84 percent, even though the actual saturation was 70. And that's because the long averaging time smoothed out the transient event. And at the middle image at 8 second averaging time, it displays the lowest sat of 77 percent and then with 2 second averaging time 70 percent. This is well understood, this has been published for years in the literature, manufacturers know this, clinicians know this, especially those who do studies with pulse oximetry. All the sleep labs know this; they have to set their instruments to the right setting.

The reason for showing this slide is the fact that the EHR does not necessarily store the averaging time of the pulse oximeter. So there's the data that's been sourced, and then starts to get propagated through the system, but without a complete data set to interpret later on. And so we have to ask, as we start to move further away from the medical device and from the patient, what happens to our understanding of the data and its completeness and are we using it correctly. Because you would look at the top box where the data at 16 seconds, and you would think that the patient's oxygen saturation never dropped below 84, when in fact it had dropped to 70. If we just take this a little further, the next slide, we'll see – yup, that one reason this may have happened –

(Indiscernible)

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
Yup, I know, I got so excited. So if we take this to the next slide, now the photograph on the top left is a photograph of a physiological monitor, a bedside monitor that monitors saturation and electrocardiography and so forth. Look at the blue arrow, it points to an alarm message. It says that the SpO2, which is the oxygen saturation, dropped down as low as 84 percent, so there was an alarm on the monitor. But if you look at the box on the right, that's a photograph of the electronic medical record and the arrow points to little blue marks that go across the top of the window. That is the oxygen saturation being represented, and the value never drops below the upper 90s. So here's an EHR that does not record the data from the medical device. We don't know – why is it that the medical device said the patient's oxygen saturation dropped to 84 and it's not represented in the EHR.

And this just happened on Tuesday, it's fresh in my mind, I took these photos, puzzled a little bit about where the data went, but not too puzzled because one can understand how some of the system interactions occurred, and some of them are based upon configuration settings and otherwise. The point of this is to show that as we look at what happens to the data, there's a lot that we just don't understand. That we don't know the configuration, we don't know what it was, if we look at the data historically and we mine that data, either on one patient or a population, it's hard to know what we will learn. The etiology for this, the reason for this is probably because of this slide, which shows that the EHR is recording data once every 60 seconds and we don't know where in the 60-second period it grabs the data from the medical device. And if you are looking at a transient event like the drop in oxygen saturation, it could have picked the data anywhere along the way and therefore we can't predict what data will actually show up on the EHR. And that's the current state of the art.

Now, moving on to a different topic related to device clock-time errors as another example of drilling down to understand this and how it would influence the regulatory recommendations. We know that clock errors, all of us know clock errors can undermine system integrity when you have multiple components of a system all interacting. And in this case, clock time is likely to originate with a medical device and then be propagated through the system with clinical data. And so this has been addressed a little bit in the public space and the economists and other places. And here's a clinical example from a medical device. On the left, that's a blood gas machine and the time of 1206 is circled, but the actual – the correct time is 1210, as evidenced by other clocks in the room, and by others that you don't see in the slide. But if you follow the dotted line, it shows you that the timestamp of 1206 is the one that shows up in the EHR. And so this – and of course, this is an example and it could be much worse or sometimes they're spot on.

But in order to dig deeper into this and pursue this, our organization – our research group has been undertaking a study on this and studied five hospitals 1700+ medical devices are represented in this slide, and it shows an average offset of time of 25 minutes, but the maximum offset is much, much greater. In fact, the next slide shows that these are the incorrect dates and the greatest error was 42 years on that medical device clock. And the reasons for this are many, and some devices are old and they are not – they were never developed or intended to have their clocks set through a network connection using NTP or a Network Time Protocol. But others are intended to be set that way and then there were complexities there. The point is, how do we handle this in terms of the accuracy of our data? Should this be part of the regulatory pathway that we address since we know it undermines data integrity? So in summary on this point, device clock time errors can undermine system integrity and create emergent hazards. In other words, we don't really know what the problems might be, but we know that if the fundamentals aren't strong, if the reference time for devices isn't there, who knows what problems could emerge and how should we prepare for that. It could lead to treatment errors, because of incorrect lab values and the wrong time, incorrect blood pressure values that are either much older than known, than anticipated. Another example that we have identified is data may be stored in an EMR and not put into a timeslot until a future time is arrived at. If the medical device clock time is set to the future, the EMR waits until that time has arrived at and then it drops the data into that timeslot, so you end up with a predictive medical device, which is pretty cool. So is this really an example of an inoperability problem that needs to be addressed in the proposed framework, is that how we should think about this.

The next example is a specific clinical example to illustrate the notion that the complexity of the system and technology does not necessarily align directly with what we think of as a hazard or risk. I'm assuming everyone here is familiar in some way with patient controlled analgesia, or a PCA system, one in which you press the button to receive a dose of opioid or narcotic, typically used after surgery. If you haven't had it, you probably visited a member or friend in the hospital that has had one of these. These pumps are quite sophisticated and they have a number of settings to prevent or reduce the likelihood of overdose. So it's like the stop – like one of those buttons on the corner for traffic, you can keep pressing the button, but there's a limit to how much medication you'll receive.

Unfortunately, there may be programming errors, there may be differences in sensitivity to medication, and family members may press the button, that's called PC by proxy, happens quite a bit. Patient may lean on the button and receive a dose inadvertently. Patients have pressed the button thinking they were calling for the nurse when in fact they kept dosing themselves with opioids. So, all of the things you could imagine have happened, every single one of them. And patients are either injured or die as a result of these complications. Probably somewhere in the range of 1 to 3 patients per day in the US, but because of the challenge of reporting, we don't know the numbers and we'll get to that in a moment, because it directly relates to how we look at a framework of safety of health IT.

So if we – as the text on this slide explains that over-medication could be deadly and so how could we improve this and how severe a problem is it? Well, it's pretty severe and this slide – the next slide shows just examples from any Internet search that can show you the death here of an 11-year-old girl from narcotic-induced respiratory depression. Or the next URL talks about the importance of the need to address is from a system level. A coalition was formed to try to address this in 2010. Or if we look at the financial impact on a $9.9 million lawsuit as a result of this. So from any perspective that you take, from patient safety, financial or just frustration, it's a big issue.

In 2005 the Anesthesia Patient Safety Foundation made these recommendations. The recommendations were, why can't we use monitors like pulse oximeters and respiratory monitor, things like that, tie the information together and then use that to stop the medication infusion when the patient gets into trouble, and call a nurse or other competent professional, to intervene before the patient is injured. Reasonable, wonderful recommendations that was 2005. That Safety Foundation held another meeting, five years later on the same topic because progress had not been made and part of the reason progress hasn't been made is that – actually, there is one manufacturer that does produce a system like that. But the concern about the regulatory requirements, the confusion really and concern, the perceived barriers to developing and deploying systems like this have been enough to interfere with their development. Whether or not that reality exists, that's the perception. So we have to think about that in the work we do together that we can – if we introduce too much fear, it won't be very helpful.

Now this is an example in which the risk to the patient is very low, because if you add a safety system to PCA, all that will happen is that you may stop the infusion pump unnecessarily and so the patient will have to call the nurse because they're in pain. A system like this may be considered technologically complicated with sophisticated algorithms and data fusion, and stopping an infusion pump, but in fact the increased risk to the patient is very low, as low as one could consider with a system. So that's the purpose of this example.

Now, what actually happens, and I mentioned we don't really know what the injury – severity of injury is with PCA systems, why not? Well let's think through this example. If there's an injury to a patient due to a failure of an intravenous infusion pump, if smoke comes out of the pump or breaks or overdoses the patient because it fails, it's very clear. Hospitals know that they will call the manufacturer and they will report that to the FDA, the manufacturers will do the same. So that's not ambiguous and the discussion we had in our group was, that probably it is not something that we should be addressing within the scope of this work. But then you start to go a little bit further. What if the injury is in some way related to health IT related contribution, like the bodyweight error calculation conversion of kilogram to pounds that results in an incorrect dosage setting on the pump. Or allergy data is lost in the system or is incorrect and therefore the patient is injured because of the system. Who is that reported to today, in terms of at a national level? How is that data aggregated or does it just stay within the hospital or is it never reported?

Then you take it one further step, how about the injuries that are occurring with PCA systems due to the inability to integrate devices in health IT systems? Does anyone report their inability to develop new technology and their inability to save lives? Well that doesn't happen at all. But if we think about this as we are doing, from our perspective, at a national agenda, that's probably the way we need to be thinking about the introduction of new technologies like this to improve safety.

Interoperability of course came up, it came up this morning, Joe Smith made a few comments about interoperability and I think we've kind of, in the discussions recognized that interoperability is a key enabler of HIT-based healthcare transformation. I doubt there are many arguments about that point. And part of what we're seeing today is not really interoperability, we're seeing systems that are being glued, kluged or otherwise brought together and in an undisciplined system integration, and we know that's introducing new hazards, and that was discussed already. So what should we do about that and what can we do within the scope of the work we are doing. And then what about reporting?

So let's think again about things we just discussed, the reporting of the PCA system and other events. In other domains, we all know that IT systems help with surveillance. They help improve surveillance and automate surveillance, automate data collection and analysis that is the strength of IT. Certainly, it should be in health IT. So one of the things we discussed is, could we possibly reduce some of the pre-market regulatory burden of some of these – of health IT related systems by in turn improving the quality of the post-market surveillance of these systems. And also we discussed the fact that it's so difficult today for manufacturers to know how and to whom to report certain problems. Have they met the level of severity that requires reporting? And if it's a medical device, a certain category it goes in one direction, if it's another device, such as a radiological device, it may go elsewhere. What gets reported to a hospital, what gets reported to another association? So we could increase that complexity inadvertently when in fact, nationally we probably need to bring all that together under one umbrella and then have a means to address these reports, collect and address them, whether they fall within the regulated or "non-regulated" space. So we spent a bit of time on that as well.

In this – the purpose of this slide is kind of to embellish and introduce the idea that in all the other domains that we feel are safety critical and important, we have data logging in some manner, whether it's planes, trains or automobiles. And so collecting data at an appropriate resolution, whatever that might be, from the devices and systems, whatever that might be is necessary for us to understand, look at hazards, and understand how to mitigate problems in the future. And our research group is doing some work on this, which is, there's a bit more detail on this slide, but really not broadly and not across the health IT space. We don't – I would say that we don't know how to do that. And I think we discussed a bit about that gap and that maybe this needs to be one of the priorities because without the data, we don't know what to do and we don't know what to fix and we don't know how to address the problems.

So proposed next steps with regard to safety and the regulatory framework, I'm using the word safety broadly there, as we discussed in our group that developing use cases to tease out the regulatory framework requirements are important. What is it that the regulatory framework should address from the requirement standpoint? We need to include high and low acuity examples, certainly different venues, whether it's in-hospital, whether its mHealth settings, just to use that broadly notionally. And then perhaps from those use cases, identify some of the needs that are common across the landscape. I think that's the last slide and I want to ensure that members of our subgroup contribute, add, correct and whatnot at this point.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Answer or questions?

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
Yeah, this is Todd Cooper. One of the points that we discussed in this breakout was number one, the scope of systems that was coming out of the taxonomy group and the need to get some exemplars to help inform the use cases, for example, what Julian was just talking about. So one of the issues before our group is sequencing, right, because they're linked, what systems are in and what are out, the framework between innovation and risk and then the regulatory touch on that. So they're kind of linked sequentially, but we can't wait and so we had to get going. So one of the issues is how we manage that and how we get the output of one to inform the other, and hopefully sooner than later. And this is a good example of that is, we can come up with some exemplars, like Julian has done here, but it would also be nice if we could get, fairly early, some of those coming out of the Taxonomy Group, in your mind are representative of the different kinds of systems across the scope that would then help inform the work of this group.

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
Thank you for adding that and that was the intent, of course, with some of the content here, to use these as examples of the kind of information that would benefit our group that the other groups can provide. I think there's a, I can't say a hand up, but something's up down there – there's a name up.

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
It's me Julian, Meghan Dierks. So Julian it was interesting. I don't think I've thought about it, but I wanted to ask if the group explicitly addressed this. So the examples you gave prompted me to realize that we're thinking forward on new technologies that become marketed in the future. But did you explicitly talk about whether any regulatory approach would want to deal with retrofitting to existing systems were out there, or is that totally off the table. Because what we are in, large healthcare facilities are an accumulation of lots of technology that's in a wide range of maturity. And you don't just sweep it all away and start anew. It ultimately is all sort of added on to.

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
Well, one of the things we did discuss was that there was an assumption that the regulatory framework that will be proposed would somehow end at the point of product development or prior to deployment, to use. That was – there was – some people had that mental model and I didn't realize that, I think some of us had a completely different mental model that perhaps it was relevant to both pre- as well as post or the period of use. So that's one of the things that surfaced just by creating use cases and discussing them. The idea of retrofitting, well I think what we did discuss is the idea of reporting, so the assumption is that one would report current systems, not only future systems. But that would, if we – that may indicate gaps in our current systems, for sample, data logging is an example of a current gap. So once we start to go down that pathway, it identifies that we don't have the data we need, perhaps, to draw conclusions that are needed. So I think that's as close as we got to the point you are asking. Geoff?

Geoffrey Clapp – Better – Co-Founder
Go ahead. Yours is a follow up to this and mine isn't exactly.

W
Actually, it was a slightly different direction.

Geoffrey Clapp – Co-Founder at Better
Ah, go anyway.

W
There you go. I wanted to thank Dr. Smith for his comments in the session, surprise, huh, about – because he helped us think – he helped me think more broadly about the idea of a regulatory framework might put different emphases on different parts of the process. So that post-market operation or surveillance might actually give us a set of information, maybe about present or even emerging technologies that might be helpful in a way different than what one might do at the point of shipping or one might do at the point of certification. So he broadened the idea that the framework might not only address a range of technologies, but address them in very unique ways.

M
If I may add, I think we know that these systems – many of these systems don't exist, right, until they're installed at the point of use, wherever that might be. And so it's expected with systems that have interacting components or – well, that's what makes it a system, that there are emergent properties, things that are hard to predict or impossible to predict or impossible to predict. So if we don't monitor after its installation or usage, we will probably inevitably miss important things.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison
This is going to make for a very challenging set of accountabilities. Because once you've shipped a system and then added a locally branded addition onto it and then morphed it over several times, the original developer may have no accountabilities and the institution operating it may have more accountabilities.

M
Think of it – Geoff if I may, just I apologize.

Geoffrey Clapp – Co-Founder at Better
Please.

M
I think of it as an example say of something that may fall in the lap of the National Highway Traffic Safety Administration, some problem on the road, let's say cars are starting to not stay on the road, increase in accidents. If we don't have everyone sit down and discuss any changes they made to tire performance or composition, road surface, signage, lights, speed limits, vehicle weight, I don't know, everything, acceleration, without looking at all of those elements in the system and bringing all the parties together. And I don't know enough about the NHTSA approach to know about accountability, but clearly having all of the parties at the table to at least figure out what the problem is and how it should be solved, I would think is an important part of our agenda. Regardless of account – not that accountability is trivial, it's very important, but we do need all the parties in this complex system to work together. That's just my opinion. Geoff has his card up.

Geoffrey Clapp – Better – Co-Founder
That's actually really interesting, I mean about accountability. I think that coming out of the innovation group, the Risk and Innovation Group, and some of the things we were talking about shifting the way we think about regulatory and things like that. It was particularly interesting for me, and I'll admit some places where I've screwed up in the past. The VA was our – this is a previous life about eight years ago, but the VA was our biggest customer, we were bringing in data from all kinds of medical devices. That exact time issue you talked about there. Everybody pointed fingers at everybody else and on the re-solicitation, they said, fix this or you're out and all of sudden, everybody fixed it. It's amazing when you're the biggest payer how you get to pull that kind of stuff off.

But I think that also brings up the idea that some of the examples and problems, if I was listening on the phone or I think we but through this this morning as a group, I would think, oh God, they want to regulate date formats. And it think that as a group, if as we come out of this we start talking about best practice ideas, opportunity for private industry to step up and do thing, that we're not suggesting per se as a group or as individuals, this should be the law, but these are the problems that need to be fixed. And they may be done through regulation, they may be done through economic levers like the VA telling us you're going to lose your national contract, they may be done through all kinds of different vehicles. And I think that as we start to think about the outputs of this group, there is probably some collection of proposed best practices or problems that we think should be solved that if we can create a conversation around those, as industry leaders here in the room, we have the opportunity to potentially address the problem. I'm pretty sure no regulation is going to say, that's the date format you've got to use.

But if we can start talking about those things, thinking about them in the RFP process, we might be able to create more change than a particular piece of legislation. So, I think the examples you gave are great, I am hoping that there's a way for us to pull them out into whatever documentation we have saying here are some problems and some potential best practices. And if your research group or other people can contribute to that, I think we'd be doing well by the industry not to lose the nuggets as we abstract into general guidelines. So, thank you.

Elisabeth M. George, MS – Philips Healthcare – Vice President, Global Government Affairs, Standards & Regulations
This is Elizabeth George. I think just to continue on on that, I think we did have a little bit of that discussion about the whole aspect of shared responsibility. And that yes, we're targeted at the FDA, ONC, FCC, but there are a lot of other regulation areas, certification areas and responsibilities, as was just mentioned over there, that are going to be shared. And I think if we have the opportunity to identify potentially why we don't need to regulate something through one of those three, because there are sufficient controls or mechanisms elsewhere that will cover that, that's also an opportunity for us and I know we discussed that earlier in our other calls, as well as today's meeting.

M
One last comment? And, I forget whether it was Patricia or Geoff, in terms of responsibility. In national across state boundaries, transnational interactions where you have for example, we were talking earlier about reading of images that are farmed out to different countries so you can get the cost savings. And so when things happen in that international ecosystem, how do you tease out the responsibilities there?

M
I may just return for a moment to the discussion on, I think time was useful. There is – sure the format for time is essentially standardized and NIST and other – the world depends on it. But there really, as far as I know, there is no requirement for a medical device to have a means to have the correct time. Now in Meaningful Use Stage 2, the EHR now has a requirement, in some way, to have an NTP reference timestamp for incoming data. That doesn't help if the data was stored by a blood pressure monitor, for example, for an hour, you can only stamp when it arrived, you don't know what time the measurement was taken.

So if we keep going back – I believe it's essential that we keep going back and look at the system in this case, we can't fix it by just looking at that piece of EHR regulation, without also looking at the source of the data. And I don't know how we will capture that in terms of the regulatory framework or how it will be captured in the future by the regulatory framework, but without returning to that system perspective,

I don't know how we could resolve these issues.

Geoffrey Clapp – Better – Co-Founder
That'd be great. And I also think that earlier, and I'm going to say it was Joe, I think it was Joe who brought up patient reported data, family reported data. As they come in, the sources of data and their use in the clinical process as a theme that we've now heard in two or three or four contexts. And again, that may be the type of thing that we highlight as something that's important, that at least we'd want regulatory clarity. For example, like if I – whatever the answer is, again, we're not here to make policy, but this seemed like an area, I'm going to steal Bakul's language that he used with us, but it's important to have clarity over some of these data sources and how they might be used. Now what the answer is, what the regulations going to be, that's not for us to decide per se, or at all, forget per se, at all. But this is clearly a theme that's coming up that we need to document as a theme and something we want to have in our report of data sources, its integrity and its use.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Okay, thank you. Let's go to the next subgroup, which is the Risk Assessment and Innovation Group.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
We used the feedback we got from the discussion, not necessary specific to our group but a lot of the discussion that came out of Meghan and Patty's workgroup. To update our slides, we had three questions we posed to us in the limited time. One is, do we have any blind spots in the dimensions and the framework? Two, have we sort of talked about, in an adequate way, the spectrum of things that can happen for each dimension. And three, what about waiting? Are there things that stand out as most important or things that are not important at all.

So in the first one, I'll just point out some of the things that we updated. One, let's say in the purpose and intended user, we added – so it's not just having a license to practice such and such, but possibly you need to be credentialed, trained or in some way prove that you're skilled at using this software. And that would lower the overall withdrawal risk for that. So, you can see how that's almost like a labeling requirement. In the blue cluster, which has deals with the risk and its quantification. We separated transparency and the ability to mitigate harmful conditions, so those were lumped together before, but they're very different things. Transparency is the difference between something that spits out really well understood data, such as your weight versus something that on the right-hand side is a black box and even a knowledgeable, credentialed user can't necessarily know what's going on inside. On the other hand, ability to mitigate does influence the risk profile of a software system. And so if there's a human knowledgeable intermediary that can intervene, that has the capability, not just a bystander, that would be a lower risk and when it is operating in closed-loop function, that's a higher risk.

In the third group, the complexity group indicated in green, added a couple of things that came up in the

Taxonomy Workgroup, so it's not only the complexity of the initial software, but there's a maintenance phase to that, and how does that affect the risk profile; similarly the complexity, not only of the initial of the implantation, in the next row, but the upgrades that are required. And in the fourth group, which is indicated in blue, that's the how it interacts with other parts of the system, hardware or software. And interestingly, this was one of the things that someone raised a suggestion, should we even eliminate this as a dimension in and of itself. And I would say, after listening to Julian that may be the biggest part of his example. So, that might give credence to keeping this front and center, just because it's so important. And this has nothing to do with, I should use this as a preamble, this is not saying regulate or not. So the right column doesn't say regulate and the left column says – this is just a way of thinking of the risk when you deal with software. So, that's the caveat for all of this. And the final one had to do with network conductivity, and we actually didn't get to that.

The second piece is specification, sort of the words and they're approximately right, and we've edited that based on today's conversation. The third question we asked ourselves is the waiting. Is there something that stands out? One was, gosh if the first green two rows that should be all you need to worry about. And there's other perspectives of saying, you know, actually each of these five things have come back to haunt us in some way, so those are things that we need to keep in mind. One way to use the proposal of the first one being a standout is perhaps in the decision tree that the Taxonomy Workgroup looked at, mainly as a rule out, as an exclude. So if this thing is just information only and the layperson can use it in that capacity and understand that, then it's free game, it's very low risk. Otherwise you go to the next step and so on and so forth. That might be – we may use that, borrow that technique in terms of how to think about risk.

Some things didn't make it onto the list, we couldn't figure out how, at this point, we obviously are going to have follow-up calls, one is the notion of post-marketing surveillance. We understand it may not be a way you think of risk prospectively, but clearly, just like in the FDA drug world, learning as these systems get into use is an important part of assuring its safe use. So that's a thing we want to incorporate in our framework. Content was another topic that came up, it doesn't specifically appear here, but this – an example is clinical decision support. Some people, some vendors totally stay away from it for fear of having any liability and fear of regulation. But how do we deal with that in terms of the risk framework? Third point was security that came up in Taxonomy Workgroup. Clearly, malicious attempts to disrupt anything that was originally designed to be safe to become unsafe, so how do we capture that risk? And the fourth one I already mentioned, use of a decision tree may be one of the ways you navigate this and you build in some implicit must haves in the way you construct this framework.

So that's an update, I'm happy to entertain any comments or questions on that or other comments from the subgroup before we move onto the innovation risk.

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

Perhaps I'll just ask the first one. Do you intend to populate the medium risk? I think it would be valuable to, I can...I mean, this is going to be a core part of what you'll do.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
Sure. And I'll also mention our next step is to use exemplars to test for further blind spots. And so it sounds like all three groups could use exemplars, we might find some common ways. I think we want to avoid doing just the corner cases, because then we're just going to design this just overbearing things. So, we've got to get the common themes first. But we could use a common set to sort of test all the subgroups activities, I would think. Joe?

Joseph M. Smith, MD, PhD, FACC – West Health – Chief Medical and Science Officer
There was a point drawn earlier, and I think Meghan, you brought it up, around the notion of singular or pivotal or unique information for which there is no other context available and how, that's a piece of data that single point of failure can result in erroneous decision-making. Whereas if there's context available, kind of collateral, parallel information that there's inherently less risk and I didn't see that contextual variable caught.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
We need to add that, that's a good point. It's in the ability to mitigate. So I think what you're doing is, you're saying does the human have a chance? But let's corporate that into the mitigation.

M
Interestingly, it kind of goes anti-parallel to your last line around connectivity because the more connectivity you have, the greater the opportunity for that context, whereas with less conductivity you have less. So a standalone operation may in fact be the highest risk implementation as opposed to a connected one. And so it's kind of an anti-parallel concept.

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

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
I'm just – I'm trying to think a few steps down the road and I'm trying to think of how the agencies would act on the information that we give them. And it seems as though the exercise so far is a relative risk exercise that is, identifying low, medium, and higher relative to each other in those dimensions. And when it comes time for the agency to decide are we over-regulating, under-regulating or is the regulation just right, in addition to the relative degree of risk, absolute degrees of risk are going to be important because it might be in one of those lines, even the higher risk is not very high, and doesn't deserve to be regulated. In some cases, the lower risk might still be fairly high and need to be regulated. So, the relativeness is helpful, but it seems like an absolute piece needs to be fitted somewhere in there in order to be able to make regulatory decisions off of it.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
We – it would be very challenging to come up with an absolute of almost any of these things. But also we felt it was out of scop – what we're trying to do is provide a framework for the tri-agencies to think about their roles – their roles and the roles of others in assessing and mitigating a risk to the public, basically. And we see these as multiple dimensions to consider, we're not doing the judgment piece for them or recommending that. And also I just don't think there is such a thing as an absolute.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yeah. No, to be clear, I'm not suggesting that you make the judgments for the agency, by all means. I just don't know how, if I were at the agency, I would know what to do on the basis of this information. I agree that absolute is a terrible word, because it suggests a high confidence. But FDA for example, in 2010 went to – made a presentation to ONC with some data that it had collected and I thought that data was very useful. The problem is, the data's dated, it's three years old at this point and I don't know if anyone's given any thought to updating the data. But, I think there are data out there, both in the hands of the agency as well as studies and other material. So when I say absolute I'm not suggesting what's scientifically and feasible, I'm just suggesting trying to capture an order of magnitude, because it seems to me in our – in the Regulations Subgroup, basically we're going to look at your framework and suggest regulatory features to the agencies. And I don't know how we would do it when maybe – as I say, maybe the highest risk really isn't very significant, in which case we don't – even though there's a relative distinction, there's no reason to relegate at all because even the high risk is low risk.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
One friendly suggestion about this is, you could consider adding some text about what some levels are risks are, some of which we know from patient safety related things, to sort of help anchor the discussion a bit. I mean, in many instances what we'll be looking at is, the risk is this, one way might be a little less this other way, but – Matt?

Matthew Quinn – Federal Communications Commission – Director of Health Care Initiatives
I think that Brad's comment is really right on and it's one of the things that we discussed was looking at this framework, which describes categories of risk and ways to describe risk and arraying it across the different – the taxonomy of the different types of technology and users, etcetera. And then hanging off of it current and potential data sets to inform what's going on. So everything from Maud to hazard manager to ECRI's doing in various places, and then think about where the gaps are and the data that would be needed to inform this going forward to have some better certainty around that and then putting that there. That could lead to an understanding of what some of the big chunks, the 80:20 of risk that are associated with, for example EHR use or HIE or consumer health IT, whatever. Mitigating approaches for those and then thinking about – mitigating approaches that are grounded in experience and evidence of use, either in a regulatory context or not, and then handing it over to say okay, agencies figure out which of these require regulations and which of them don't, and making that judgment. So, I think that we're talking about, that Brad and I are talking about the same thing in that discussion.

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

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
I was just going to ask if Paul had ideas about, and maybe it's something you guys should think about in the subgroup is, when you say higher risk, medium risk and lower risk maybe exemplars would be useful. When you think about end-stage death would be the highest risk, if you think about it that way. But obviously where you'd cut off those demarcations actually mean a lot, and so maybe that's something they should think about.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
There are two areas I can think of where there can be more quantitative risk assigned, severity is one of those, because it can go from very innocuous to life-threatening. The other is the likelihood of a risk situation popping up. It tur – in the discussion actually, for each possibility there is a cascade of associated risk likelihood of even happening and who – what human might be in the middle. The trouble is the combinatorial enumeration of that makes it really hard. And then – so we started out – in fact, the columns were labeled, low risk and high risk, and so we backed off because even on the call, you could – everyone – it's just like one person's cost is another person's revenue, same thing. One person's high risk is another – and Anna brought this up too, well what is my risk tolerance as an individual that should be considered. And how do we factor that in there, so, that's how we ended up with, okay, well we're never going to come up with even a subject low and high, so that's why it was lower and higher. So that's how we ended up with –

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
Yeah, and I totally understand your point and it's – this is Bakul. I was just saying that maybe just to get everybody on the same pages, to sort of put some examples and then maybe dimensions, as Joe mentioned, about single point failure, multiple – I mean, I think it's all good, it just needs translation from the page to people's head.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
Correct. So that's what we expect to get out of the exemplar test. So as we go to exemplars, we're going to find each of these half-gradations, and that's sort of working its way towards more quantified.

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

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
Thank you. Todd Cooper. As I look at this table, as I did for the first time, I still have challenges on many different dimensions. One is the fact, and I think this follows a bit from what Bakul was saying, one is the fact that in this area, risk is very formally defined. And I know that in developing standards around this, we have tried to shy away from filling these kinds of things out because it really leads often to tunnel vision and not thinking about what is the actual risk. And when you talk about low, medium or high risk, you really need to factor in specific usages. So you can't even determine is it low, medium or high until you've factored in either the clinical or the instance of use to say, well, what is the probability that harm is going to result from the usage of this technology. And so I guess – as soon as I look at this I'm challenged in that sense and as a result, what we tend to do is provide the framework and the principles and the different classes for these with maybe some exemplars, but we don't try to assign them to specific risk levels, because you could always argue, depending as you shift around that use case. So my – I do have a question – go ahead.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
Can ask you a question, it's basically you and Bakul. It soun – for the very reason you just described, it sounds like this is a framework to take a case and then figure it out versus can you really make a framework that declaratively says, how to put some "A" piece of software in one cell. That's a question I would ask you, based on the comment you just made.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
And I would say, given a piece of software, though at one level you may be able to identify what are the potential hazards if things – if unintended consequences result, but to really assess the risk you have to say, well how is it actually going to be used? And one piece of software depending – may be used in many different contexts and as a result, has varying levels of actual or what was it, absolute risk, I think that was the term used. So my question was this, and I don't know Bakul if you had a response to that.

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

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
My question is this, what is the long-term intended usage of this table here? If it's to help us tease out those classes of hazards and how those might relate to the software, that's great. If we're actually looking at formalizing this and passing this along as a recommended method for analyzing it, then I think we really have to work through the right way of doing this to where on the receiving side, especially by the regulatory agencies that have a well-established risk management framework, they look at this and it makes sense and I think that gets back to what was said earlier.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
Let me try to propose a use for this. So for every class of software, let's say it is a simple device measuring weight, more complex like EHR or CDS, each of those has a class of risk and you might even say there's an expected risk.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
I would differ with that, but go ahead.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
There's an expected risk and where in this spectrum of risk from lower to higher does this software fall into. So a CDS, which is by definition going to provide advice, in some ways programmed to provide advice is going to be more risky, but it's expected to be more risky with potentially more benefit than a scale that gives you a weight. So I'm almost thinking there is some leveling – there's some context to risk assessment for every class of software, just for lack of a better term.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Julian? Are you responding to that one Julian or –

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

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Thank you.

Julian M. Goldman, MD – Massachusetts General Hospital/Partners HealthCare
I mean, it would be – it seems really very hard to generalize. So a weight scale – the risk of a weight scale being inaccurate depends upon its use environment or its intended use, what is that for? Is it for neonate and tracking their whatever or in-home use or use in a department store. But we can't just categorize it is a weight scale and similarly with even broadening a label to something as broad as an EHR or an EMR would depend upon again some systems that we know exist, we have to review images and waveform data in those systems and that becomes part of their intended use. So I don't know how we would paint it with such broad strokes. At least, my understanding in looking at medical devices and their regulatory claims today or their – there's a pretty clear intended use for the device, where, by whom, for what. And I'm not going to try and speak for other people who are experts in this area except, we wouldn't paint with a broad stroke and say every one of those devices is the same, we'd look and see if whether it's applicable for use in that setting. So I'm wondering how to match that kind of with Todd's comments and then with the concepts that you're presenting.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
So – and to be very specific in your case of the weighing scale, if I'm just tracking my weight over time because I'm trying to maintain a healthy weight, that's one thing. But if I've just been discharged after surgery from the hospital, I'm looking for an abnormal fluctuation in the weight that has a completely different potential harm associated – .risk associated with it. And in the one case, though the hazard is the same, if the information is either inaccurate, if the information's not available, so you can easily identify what are the potential hazards that could result in these harms, but you really have to understand again the use context to evaluate what the actual risk is.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
That's a dimen – the first dimension. It's the intend – the purpose and intended user. So for each of those examples you gave, one is a household scale and the other is to calculate administration of IV's to a neonate, there's a different intended purpose and user. And that would have to provide part of the setting for assessing whether the risk of this software. So that's part of why we're – well, at least the initial thought of why this can't be an absolute across all systems, I guess.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Okay. Anna?

Anna McCollister-Slipp – Galileo Analytics – Co-Founder
I mentioned this in our breakout group, but I'll mention it again. This is Anna McCollister-Slipp for those who are on the telephone. Somewhere inherent in this, and I don't know where, but somewhere inherent in this I think we need to include some sort of provision for the risk of the status quo. Because there is a risk inherent within the status quo, there's a risk inherent within the lack of innovation and the lack of incorporation of new technologies and new innovations. And you can get into specific examples where you're looking at dosing out insulin using a syringe versus an insulin pump. The pump is far more precise, you're much less likely to make errors in that sense. Or the risk of human errors contributing to mis-dosing insulin pumps versus the potential of a closed loop artificial pancreas. I mean there are so many different components within each of those risk equations, but inherent within each of them is a relative risk to what the current standard is and what's the comparator. Because without that comparator or context, as Todd mentioned, you don't have the ability to assess whether it's a lower or a higher risk and I think that needs to be incorporated. Because so often I feel like it's the risk of an innovation is considered without the context of what will happen if this doesn't go forward or what will happen if the regulatory situation is so murky or ill-defined or complex that people choose to take their innovative ideas and go elsewhere.

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
Would you put that in the patient safety risk or the innovation risk – which – how would – which framework would you address that?

Anna McCollister-Slipp – Galileo Analytics – Co-Founder
I would say it's both, I mean, there are risks that happen on a day-to-day basis, whether you're using a paper system or an electronic health record, whether you're using a syringe to dose your insulin or insulin pump. I mean, it's – those are risks to patients and they're risks to innovation and innovation exists to solve problems. So starting from the premise of there is a problem that needs to be solved and how do we create a system by which lots of people can come up with lots of different ideas for solving that problem. But there is a recognition somewhere within the context of innovation, that there's something that's not working as it should be or rather could be.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Mike S?

Michael Swiernik, MD – MobileHealthRx, Inc. – Chief Executive Officer and Founder
Hi, this is Mike Swiernik. Just a reaction I think what Todd was suggesting and if this isn't what you're suggesting, then it's a general reaction. But I think part of what this risk framework, at least in my mind, was a way to come up with some – eventually to come up with some buckets that you could put your software into that would make it easy for people to get into this. And I think what I was reacting to and what you were saying is that if the outcome of what we're doing here is a regulatory framework where someone says, hey I have an idea for something, is it going to be regulated? And then the regulatory body says, I don't know tell us everything about it and then I'll let you know, then I think we're kind of back to where we are right now, which the perception at least is that there's this big barrier that regulation is causing and I think that creates the innovation risk.

So at least in my mind, this was an attempt to I guess make that little bit easier for people who aren't in the industry and don't know everything about it, that they can come in and say, well let me see, I have this idea that I want to do X, Y and Z, where does it fall? And then they can look and say, okay well maybe this one part of my thing makes it more regulated and I don't want to do that, so let me work on that or something. So, and anyway, I just wanted to react to that and say there's maybe some innovation risk if we – maybe it's impractical to get to that and maybe I'm thinking wishfully, but it would be nice to see it more concrete.

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

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison
I think Meghan was actually ahead of me.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Her card came down and then came back up.

Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin – Madison
I think that we're drifting really into the use of and have we trained clinicians well enough to make judgments based on data. No. I mean there's a lot of things we need to go back to change in clinical education, so I think we really have to be – stay a little bit closer to what we're trying to regulate as opposed to how it will be used. I know we've got a fuzzy boundary there, but I think downstream users could always make mistakes, even with great data.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
I agree it's complicated. Mike Flis?

Michael Flis – Roche Diagnostics – Regulatory Manager
Hi, this is Mike. Trying to come up with new ways of evaluating risk is very challenging and this was an excellent effort. The team thought about this a bit with Bakul's guidance and Keith came up with a very interesting perspective that maybe should look at the issue from the other perspective. And he posed the question, how do we accomplish safe innovation? So rather than focusing in on the risk brick wall, turn around and start asking ourselves what needs to be in the regulatory environment in order to accomplish safe innovation? And it feels more promising if we go about it from that perspective.

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

Meghan Dierks, MD, MS – Harvard Medical School/Beth Israel Deaconess Medical Center
So this may be a little bit of an extension of Mike's last comment. But what also came up in the discussion that I thought was helpful was that we wanted to sort of temporarily table this concept of what we're trying to do is decide whether something requires regulation or not, and that the regulation is an all or none. Instead it's this framework can help you understand a little bit more about the tools you'd need to control the risk. It's not saying that because something has these attributes that it shouldn't go forward, it should never make it to market, it should never be evaluated on patients. Instead it gives you a sense for how many – essentially how many effective controls you'd need to put in place to control the risk so it could proceed and be used and make its way to patient care with at least some hope.

And it ties in to a comment that was made a few minutes ago about I think it's important to acknowledge we don't necessarily nor will we have data ahead of a time to know and we shouldn't say that we should look at the data and that should tell us what specific controls we need. Instead, you make your best guess based on the underlying design and based on the intended use and based on the range of scenarios, and you're always going to have these products used it very simple scenarios all the way up to very complex scenarios. The same exact piece of software, very different outcomes if it's calculating a dose of a water-soluble vitamin versus calculating the dose of an anticoagulant. But that as long as you use your risk framework to understand, again what safety controls to put in place, then you can also – you also want to use in your tool bag close post-market data collection. And that's the data that helps you then say okay well I made some assumptions about the controls that were going to be adequate, maybe I need to revisit them and will add additional controls. But it's that notion of data can be collected afterwards, but you have to have the ability to do it very closely and you also have to be willing to say okay, it's not – it's got to have some fluidity to it. In other words, the rules around that product to control the safety, we might have to add some, with the knowledge we gain in this early period of use.

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

Joseph M. Smith, MD, PhD, FACC – West Health – Chief Medical and Science Officer
I'd like to bring up – it's Joe Smith. I'd like to bring up a point that Anna made that I don't think we could say too often and in a rapidly innovating space, it's the issue of risk compared to what. It's been fascinating to watch wireless weight scales get classified as a Class 2 medical device when the comparison was someone used to tell me their weight over the phone. And they may not even be able to read the numbers or may not have a weight scale. And so the dominant risk from a wireless weight scale is tripping on it. And so we shouldn't get too excited about what would happen if the number's wrong if the comparison really is I don't have any number at all. And we did the same thing when we look at AEDs and we said, it's terrible if they don't work but gosh, it's so much more terrible when they're not there. And so what is the relevant comparison. And I watched with some dismay when we decided to recall devices that used to allow me to read CT scans on a non-acceptable device, which was so much better than having someone else describe to me a CT scan over the phone. And so, at some point the practice of medicine encompasses the ability to deal with inherently noisy information and I'm not sure that there's one answer for how much noise that's going to be or that that should be offloaded to central planning. I do believe that there's an opportunity for us to always think about in a rapidly innovating space, what is the relevant comparison, and it may not be the worst-case failure, it may be the absence of any information at all.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
And I think we're actually probably pretty close to consensus on this. I –

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
I was going to ask Bakul, what – is that a fair comparison? I mean, that is something we could use advice on?

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

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
When you're regulating, is it compared to the status quo? Is that how you'd think about?

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
So we don't exactly use status quo as the vocabulary, we use benefits versus risk. And you'd think about benefits that technology provides and it sort of encompasses all of that into that bucket and then you put patient risk on the other end, and you want to balance that where there are certain technologies that's exactly where there's nothing there, sort of raises the bar from negative something to even zero. It's better than having negative something. So I think we go with that balance of benefit/risk. For folks who want to learn more about that thinking, we do have a guidance out there which talks about our thinking on benefits versus risk.

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

Meg Marshall, JD – Cerner Corporation – Director, Government Health Policy
My comment is in reaction to the risk framework itself. And first of all, as a manufacturer, Cerner Corporation, I appreciate the flexibility that I think is built into this. And recognizing and understanding that a lot of these are subjective and you'd have to make a judgment call and then ultimately whether you came up with the boundary or a threshold that once we crossed we understood what we needed to do with it, I certainly recognize and appreciate that. My question is more around who is the best entity, and perhaps there are multiples, to make this assessment and make these decisions. And my question, I go back to the IOM report that defined the HIT ecosystem, if you will. So it's more than the software developer, it's the people, it's how it's implemented, it's the process. Are there any thoughts around how these decisions can be made outside of the manufacture itself?

Paul Tang, MD, MS – Palo Alto Medical Foundation – Vice President, Chief Innovation and Technology Officer
It's another Bakul – that's another agency question. We were assessing the risk and that's thinking broadly. I don't know whether we should be thinking more narrowly on what can an agency even – what's the scope of responsibility for an agency?

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
I don't know Meg if I get this right or not, but I heard part of your question. I think at this point for health IT – we, and I said this, you were either in the room or not, I said that we should just peel back to the level – the tools we have in our toolbox, rather than the classification system one, two, and three systems that we have. So looking at those tools, we could mix and match how we apply to certain technologies and we have the opportunity to do that and we've done it. Meghan pointed out the enforcement discretion as one of the tools we have, is sort of pick and choose certain things that we don't want to enforce versus want to enforce. And having a scalable framework, and somebody threw out an idea about learning from how the product sort of behaves in the field and sort of tweaking the controls that may exist. I think those are all options that we could explore.

Meg Marshall, JD – Cerner Corporation – Director, Government Health Policy
I suppose, if I may follow up. So more poignantly, the accountability for understanding that the risk assessment has been made appropriately, and I'll throw out an example. If we have a licensed product that is implemented by a provider who then chooses to customize on top of that or open source or however you'd like to – how are we going to account for the last touch, if you will? So in this risk assessment, whether something that we have deemed as low risk is now tweaked to where in its actual use and implementation would now cross a threshold and be high risk. And maybe there isn't an answer for this right now, maybe it just really is a consideration that ultimately it may be a retrospective look as far as how this classification should have been done or who should have been involved. Is that –

Bakul Patel, MS, MBA – Food and Drug Administration – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health
Yeah, I don't have an answer for that, but I could see the realm of health IT that the last touch, if you may, will happen and always will happen to some extent. So consideration as part of how that plays into either both aspects of patient safety as well as innovation and then don't forget care, because at the process of providing care you need some of that stuff. So how does that balance out, I think that's really important and I don't know if it squarely fits into one of the three columns or not, but I think that's definitely a consideration we should think about.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
So let me just note, it's 4:30 p.m. and we're at the point where we're supposed to be summing up and there's still seven tents up, so, we're going to go, if you have a comment that you could hold until tomorrow, great. But we'll go through the rest of them very quickly. And Brad, I'm going to come to you, I'm sorry I didn't come earlier, but I thought you'd forgotten to take your tent down.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So again I'm trying to think through a work product that will be of maximum value to the agencies as they deliberate. And one of the themes that I expressed this morning was the need to make the problem identification as evidenced-based as possible. So I'm wondering if there's a way to take the work product that the Safety Group is working on and frame it or express it in connection with evidence. And what I have in mind is, I have in my hand here an April 2012 report that I know several of you are familiar with from AHRQ, in fact I think Paul and David, both of you were on the committees that worked on it, but it's on enabling healthcare decision-making through clinical decision support and knowledge management. It really covers a broad range of HIT. And the report, the abstract explains that a basically they looked at over 15,000 articles and they came up with 311 unique studies. So, and I've been reading this for quite some time, I all asleep, I'm afraid sometimes when I'm reading it, but my point is, there's a ton of data out there and connecting that body of data to the work you're doing would be incredibly valuable. Because that's how the policymakers sitting in that corner of the room could then decide whether a risk is theoretical or demonstrated, and that has a big impact on whether regulation is merited or not. So, is there a way to connect your work to the evidence?

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

Geoffrey Clapp – Better – Co-Founder
First, the only reason I didn't hold my comment until tomorrow is I'm unable to be here tomorrow, so I wanted to start by saying thank you to everybody. Because I'm not going to get to say thank you tomorrow, for everyone's openness and discussions and it was actually really good, this is so much better than being on the phone. So thank you, first of all.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President
I figured I'd just put mine in an email tonight.

Geoffrey Clapp – Better – Co-Founder
Well, yeah, you could do that to, if you like. Thank you everybody but Todd. So, but the thing I did want to bring up, and it's a little bit to Joe's comment was, we also have a – we talked about innovation, that's our group. When we talk about the status quo, I think logically that makes a lot of sense to us, right, well if it's better than the status quo. The problem is, I have no idea how to define status quo and I'm 100 percent sure that status quo what happens at PAMF is 100 percent different than somewhere else. And so, when we think about the clarity, we think about what's important about the legislation guidelines or things we want to do, one of the things that's important it, can people read this and make decisions. Can they understand what they want to do? And I think the status quo thing is great, but let's keep digging down to, is there a way to take something as logically appealing as status quo. And drive it into here is a way for you to know whether this is regulated or not, just not regulated by the person that you talked, that's status quo for them. I think defining status quo as part of defining the process leads to all kinds of more ambiguity. And I think if I was on – again if I was listening on this phone call thinking, I've got a new idea I want to be able to build something. And it started with, is this better than status quo, I'd go, oh God, how do I define status – where do I start to figure out what status quo is or get consensus on that, they need 50 more people a little smarter than us to figure that out.

So, I like it, it logically appeals to me, but it think we've got to drive that down a little bit to a way that is actually actionable. And so – with that I'm just going to run out of the room before Joe gets me, to catch my plane, but no. Thank you, Joe, because I really appreciated your comments today.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Do you have a last point? Is that a tent that's up, I can't tell.

M
Yes. So to build on Meg's comment around accountability that risk assessment has been made appropriately. This really builds on the idea that as we use data to move from a theoretical to an empirical understanding of risk and what really is important and what is leading to the high severity, that will lead us to another area where we can understand mitigation approaches to those. So, what has worked? So for example, if there are errors resulting from patient mismatches, what are ways that organizations or manufacturers, etcetera, throughout the lifecycle have used to address this? And that's a whole different conversation than the actual levers, including but not limited to regulation. And so, mitigation strategies and the levers to ensure that they're used in the monitoring that needs to go on to see if, for example, ones that aren't regulation, that are voluntarily are being used, is a way to do that. And to see where – that's where you can attach the accountability piece.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Okay. So I want to thank everyone. I'm just going to sum up here quickly and then we'll go to public comment. So we started off the day by hearing from the Regulation Subgroup, Brad summarized a lot of material. A couple of the points that came out included that we really need to utilize prior work and I think the most recent comment also underscores that. Another thing that stood out for me was we did talk this morning in that report about the status quo not being the safest state. There are many regulatory frameworks that do consider what the risk is at baseline and I think there's interest in doing that. I will note that sometimes you start at a relatively low level of safety, you improve the level of safety, but there's still some obvious problems when you get to this better level and there's an opportunity perhaps to even get to a higher level if you deal with some of the issues.

Then we heard from the Risk Assessment and Innovation Group and Paul introduced some of the dimensions of safety risk which included purpose/user, characterizing patient harm risk, complexity of the software, integration with other systems, components and network connectivity and brought forward the strawman and talked about the attributes that one might consider in applying regulations. We spent a

large chunk of the morning on the taxonomy report and Meghan and Patty brought us through a long list of scope options and introduced a few organizing principles including that approaches should be platform agnostic, they should apply a variety of product categories, and the part's in scope, the whole's in scope. At the end of the day, they ended up relying most heavily on the decision-tree approach. And as we went through the individual examples, I think many things were clear, some were clearly on the borderline, some things that ended up out, we could make arguments about.

We then did face-to-face breakouts. You've just heard about what the reports were there. In the Regulation Group we did talk a lot about ambiguity and duplication and what we might identify there in terms of lists of things that are currently ambiguous and things that are duplicative. And then it was very useful to go through some of the examples which Julian put forward which could be used as use cases. In the Risk Group they largely went through the framework which we just discussed. And I think that overall there is relatively little change from this morning.

Now tomorrow we'll cover a number of issues, there are some things we'll talk about in terms of taxonomy and what's in and what's out, notably for example information exchange, that's one I think that is a bit gray. We'll probably – and then we'll go into some broader issues. But if there are specific issues that people would like discussed, please just share them.

M
Innovation risk.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
Yup, so innovation risk. So that would be a good one to talk about, and/or just send me an e-mail tonight and we'll add them to the list. We do have a fair amount of flexibility tomorrow, so there's a good bit that we should be able to get through. And it's very nice, as has been noted, to be able to do it face-to-face so that we can really go back and forth. So, questions or comments about that summary? And, from our federal colleagues, anything that you would like to – okay. Hearing no further comments, MacKenzie, could we go to public comment?

Public Comment

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Sure. Operator can you please open the lines for public comment on the phone and while we're waiting, if there's anyone in the room who would like to provide a public comment, if you could please come up to the table. A few notes on the public comments. I will be limiting them to three minutes and the workgroup members are not required to provide a response. Go ahead.

Alan Merritt – Web Specialist, Digital Communications Services – Altarum Institute
If you'd like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
And we do have one public comment in the room. If you could please identify yourself.

Michael Marchlik, MS – Vice President Quality and Regulatory Affairs – McKesson Provider Technologies
Sure, Mike Marchlik from McKesson. I think that it is evident that the selection process was really great, it had – there was a lot of good discussion, a lot of great debate, which I thought was really good. A couple of points. I was very pleased that the Taxonomy Group was talking about the platform and whether it should be platform agnostic or not, I know there's debate on that. But as a manufacturer, I think as we port more of our applications into mobile, what we wouldn't like to do is be in dual regulatory framework, just based on platform. We think that pretty much the aspects of it are platform agnostic, so we would agree with that.

The concept on the relative risk, I come from my background working in nuclear and process industries, I think the debate over relative versus absolute risk, I think a lot of what you'll see is, it's all relative at the end of the day, even in nuclear power plants. We never get to the absolute. So I think that focus on relative is important. I think it would be good to look at things like risk scoring models, for example. You have all these different factors, I know most of you in healthcare you use risk scoring models, we do it in the credit areas, there's opportunities there I think that might be beneficial to take a look at.

The other thing is also from what Todd's talked about there is a lot of work in the standards area, like 80,002 standards, looking at how we apply risk management to software, has some very interesting ideas that I think would be helpful for the committee to take a look at. Thank you.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thank you, very much. Are there any more public comments in the room? Any public comment on the phone?

Alan Merritt – Web Specialist, Digital Communications Services – Altarum Institute
We have no comments at this time.

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thank you very much. David, I don't know if you have any closing remarks? I would just say that tomorrow's agenda starts at 8:30 a.m. in the morning, as opposed to 9:30 today, so even earlier tomorrow.

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety
So we will just start a bit earlier and please do feel free to e-mail me any suggestions tonight. Thank you all.