

**HIT Policy Committee
FDASIA Workgroup
Regulation Subgroup
Transcript
July 12, 2013**

Presentation

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

Thank you. Good afternoon everybody, this is MacKenzie Robertson in the Office of the National Coordinator for Health IT. This is the HIT Policy Committee FDASIA Workgroup, subgroup on Regulations. This is a public call and there is time for public comment on the agenda. And as always, the call is also being recorded, so please make sure you identify yourself when speaking. I'll now take the roll call. Julian Goldman?

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

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

Thanks Julian. Brad Thompson?

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

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

Thanks Brad. David Bates? Todd Cooper? Anura Fernando?

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

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

Thanks Anura. Lauren Fifield? I believe Lauren is on. Robert Jarrin?

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

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

Mo Kaushal? Joe Smith? Jodi Daniel?

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

Here.

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

Thanks Jodi. Bakul Patel?

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

Here.

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

Thanks Bakul. Matt Quinn? And for the full FDASIA Workgroup members I have Anna McCollister-Slipp,

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I'm here.

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

Thanks Anna. Rich Eaton?

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

Here.

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

Thanks Rich. Drew Hickeson?

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

Here.

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

Thanks Drew. Are there any other full FDASIA workgroup members on the line? Okay, with that I will turn the agenda over to you Brad.

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

Well thank you very much. And I'm not planning to talk very much on this call, but if the person operating the PowerPoint could put up the – there you go. Basically, let me just recap where we've been and where we are. So during the month of June, we spent quite a bit of time going agency by agency looking at a fairly deep level at their regulations to figure out what was working well, what wasn't working, what needed to be clarified and where there might be overlap. And we spent half a dozen meetings doing that. The first week of July, we kind of took a step back, started looking at crosscutting issues, and started to look for duplication. We started to look, did a deep dive specifically on the reporting area, because that was a theme that had cut across all agencies. And then earlier this week, I think it was on Monday, we had a session on the big picture, that is, after having done all that, we took a step back and said, is there a better way to do this?

Well now, we're at the phase in our subcommittee's life where we need to start making decisions. As you know, the time frame calls for the whole committee, the whole working group rather, to be done with its work by August 7, 2013. We're going to need, as a subcommittee or as a sub-working group; I keep saying that wrong, to get our input to the full committee in about a week. So, at this juncture what I'm proposing that we do is really work on what the final set of recommendations would be, coming out of this subgroup. And so that's the point of today and that's the point of the call that we have scheduled for next week. We only have these two meetings left. So today, we're going to go through this PowerPoint. This PowerPoint is really only, I'd say nine slides long, because there's a title slide and then there's a table of content slide; there's really only nine substantive slides. And the length of the PowerPoint is very deliberate and I'll explain why.

On August 7, 2013 the whole workgroup will be – not all 29 people, but on behalf of the whole workgroup, David Bates will be presenting to the HIT Policy Committee. His presentation will be in the vicinity of 20 to 30 minutes long. It will be a PowerPoint. So what would be the best is if we as a subgroup could coalesce around roughly nine slides. I had to talk to David to find out kind of what exactly our allocation would be in that final presentation, but nine seems like a reasonable starting point. So what I'd love to do is for us to really coalesce around nine slides, finish it in our next call, in a week from now, and then David can take that and I'm sure he'll have to do something to fit it together with the output of the other two working groups, but it will give him a really good start, in terms of fashioning the presentation for the ultimate work product.

Now we had a good bit of discussion about kind of the form of the committee output. When I say we, we had a call last week of the co-chairs of each of the working groups, and basically it's going to be a PowerPoint. We're pretty much locked in to it being a PowerPoint, but Keith Larsen very astutely I think, suggested that we make use of the notes section to amplify the issues that are addressed in the actual PowerPoint and that will do a couple of things. Number one, all of the HIT Policy Committee will get a copy of the presentation; the presentation presumably will include the notes section, so they would receive all of it, both the main slide and the notes. And then the notes would form I think a very valuable basis for David as he prepares to give the oral presentation, it can kind of script out what we would propose him to say orally about the written slides. So as we're going through this, all you're going to see through the webcast is the actual slide itself. And in fact we were just chatting a moment ago, somehow the few notes that were on there already got stripped out, it's probably my fault, somewhere along the line, but I need to get those back in. But next week certainly, when you look at this again and you look at it outside of this webcast format, please do look at the notes in addition to looking at the slides themselves.

So what I've done, we've got basically two hours in this phone call. What I've done is tried to take the summary materials from each of the sections, kind of what we've gone over in the last six weeks. So the title slide isn't particularly important. The questions considered these are the questions you've seen numerous times. And then, as you remember, we saw this last time, there are a total of three issues – three slides rather, on the FDA issue subtopic. We've got this nomenclature of "A" equals ambiguous and "B" equals broken, and we've had a couple of people who suggest that I include on this first slide, in the notes, an explanation for David so that he understands what those two terms mean, and I can do that. There's a little bit of debate around the work ambiguous, some people saying ambiguity doesn't necessarily equate to bad, and that's true. But we're using the word ambiguous as it's used in the statute, and as it's used in the statute, the task of this group is to identify ambiguities that need to be removed, so, we're only looking at bad ambiguity, not good ambiguity. So let's make sure we're all square on that. Whenever we say something's ambiguous, it has to be in the context of bad ambiguity that you want to see resolved by the agencies. So, I'll put that in the notes, but I just want to make sure we're all communicating.

So I'm not going to go through these slides because you've seen them now two or three times, but we've got the three on FDA, the third one is beefed up. I got Jarrin's help because a lot of these were issues that he had I thought effectively articulated during the prior calls and so Jarrin helped me iron out this slide. Then we've got one on ONC, a little bit of change here, Keith Larsen helped me with the third bullet point on the configuration program. He, I think, improved the wording on that slide. We've got FCC, which I don't think has changed at all, so you've seen this before. Then we've got the cross-agency issues and I think I had asked Jarrin to help me on the second and third because the involved FCC FDA overlap and he is an expert on that and he helped me improve the wording of these two slides.

Then remember we had the better part of a session focused on adverse event reporting, and Julian took as an assignment after that, summarizing it or capturing it – the essence of it in a single slide using again the same kind of format that we've been going through. So this slide you have not seen before and we can talk about it, because it's a summary of the prior one, and then the last two slides are truly new, new in the sense that this sort of struck me, as I was listening on Monday to Joe present the big picture improvements. So, because you haven't – we haven't talked about this before, let me lay this out for you, and then basically the remaining hour and 45 minutes is for you guys to offer comments and for us to wordsmith and improve the slides.

So, I was struck by the discussion that Joe led. I thought it was an excellent discussion and that combined with Lauren's presentation two weeks earlier on all of the private regulatory or certification opportunities that were available struck me that – and reading the IOM report again, it struck me that this is perhaps one way to crystalize or summarize where I'm hearing, I think, quite a few people on the working group – both in our subgroup and in the larger group, where they seem to be coming out. And I want to touch this. So, what I'm proposing is that kind of one of the big things to come out of it is FDA say – our recommendation is that FDA says in clear terms what HIT software qualifies as a medical device. So bringing clarity to that big picture issue, how might they do that? It seems to me this is a great way to weave in the work of the other two workgroups and to start with the work that the Taxonomy Workgroup did and says that basically everything that the Taxonomy Workgroup defined is unregulated by FDA. It might be – it might technically be a device, that doesn't matter, they have enforcement discretion, but basically in practice, unregulated by FDA, except certain carve outs.

So it seemed to me it was easier to describe the tent as unregulated, then go chair by chair, and say what inside that tent is, in fact, regulated, than trying to say it the other way around. So I'm proposing take the Taxonomy Workgroup's definition, or scoping document, say all of that stuff is unregulated by the FDA except, and then I put in four exceptions. The four are – the first one is already defined by regulation, MDDS. The second one is an area where if you go back a couple of slides, we're recommending that FDA clarify that anything that is deemed an accessory to a medical device. A third category, which again is embedding in one of the FDA slides earlier, that certain forms of high risk CDS be exempted from that, and again, calling upon FDA to define that.

And then fourth, and this is where I really struggle and I emailed back and forth with Paul Tang trying to figure out what I could say here, and we didn't come up with anything, but basically trying to figure out some way to say all of the high-risk stuff identified by the Safety portion of the report of the Safety and Innovation Workgroup, that that stuff would be regulated. I would love to say it better than I said it here, I would love to say it more substantively, this just kind of in sweeping terms refers to a whole report. If there were some way to take that matrix that they developed and say, all this stuff on the right-hand side is what should be regulated by FDA or whatever – whatever the recommendation might be. I'm just having trouble translating that work product into something that looks like regulatory specs. But anyone who's got ideas, I would love to hear them. So, I'm proposing that coming out of this – that would be a recommendation of this subgroup, that we take that taxonomy group, we say it's unregulated by the FDA except carve-outs, A, B, C, D.

Then what I'm proposing is that we formally embed, and this is very in keeping with the IOM report, that this issue is to be examined in three to five years in light of two things that I'm hopeful would then happen in that three to five years. The first is that the prior slide, Julian's slide, gives recommendations basically for how to improve reporting. So if those can be accomplished in some reasonable amount of time and that's why I was fuzzy and said three to five, because I didn't know how long it would take to put the reporting in place. But once that reporting is enhanced, and then we'll start to have data that we can actually use to make well-founded, evidence-driven policy decisions. So that's one reason for saying, don't regulate it, give three to five years, and wait for the data to develop based on the enhanced reporting. Then the other enhancement would be the development of active private sector initiatives. And this is where the last slide comes in because what I tried to capture here is some of the private sector initiatives that we've talked about along the way that are either in place or that folks have identified as potential ways to enhance the regulatory – private regulatory oversight.

So the four that I went back through all my notes and tried to capture, and at a high-level are, standards. You heard Mike Flis give a really good report on what AAMI and a bunch of other groups are doing to develop standards that will allow better interoperability and an enhanced HIT generally. Number two, private certification of interoperable products. We also heard Mike share about Continua Health Alliance and there are other private organizations that are seeking to take the standards that are out there and conduct certifications against those standards. Then third you've got this idea that Lauren advanced which are customer ratings. We do it in so much commerce, e-Commerce these days where we allow the marketplace to basically create information on the quality and value of products out there. What if somebody could really organize that and get that in place in the next three to five years, and we could see if that has a positive and sufficient impact.

And then finally, we've had, as I went back through my notes, a number of discussions about off-label use. And the debate has always been, if you describe FDA's jurisdiction narrowly, to focus only on kind of a narrow set of intended uses by the manufacturer. And you don't concern yourself, at least as far as FDA regulation is concerned, with what the local folks do to then take that software and maybe customize it for themselves, or adapt it in some way, that you're kind of relying on local oversight to make sure that that's done appropriately. And that local oversight is in some stage of development, it's pretty uneven, some institutions robustly police themselves, others probably not so much but waiting three to five years could allow us to see if people, the user community, would step up and really make sure on a more comprehensive basis that HIT is being used appropriately. So those were four themes that as I went back through my notes I saw that people had advanced what I thought were very cogent arguments that we ought to rely on others outside of FDA, ONC and FCC.

So just to summarize again, the gist of this big picture proposal is again, kind of like IOM, they had a very similar element to what they proposed. Define FDA jurisdiction conservatively, wait three to five years to see if enhanced reporting and the development of private sector initiatives adequately protect the safety and effectiveness of the ultimate patient. So that's new, really not discussed before. Everything else in this PowerPoint is, for the most part, discussed before. So what I'd like to do is I'd like to turn it over to Julian to get his thoughts on any or all of this. And in particular, Julian if you wouldn't mind – oops, went too far – if you wouldn't mind talking about your slide where you summarized basically the meeting that we had, and then any other remarks, Julian that you want to add on the whole thing. And then I thought we could go back slide by slide and see how close we are to a consensus.

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

Sure. Thank you, Brad. I think that – I'll ask you a question Brad in order to help just set the stage, which is, in the idea of carving out scope that you described, in a sense there – the FDA regulations address scope in the sense that things have to meet requirements to be considered a medical device. Right, something, things that you and many others are well versed with in terms of triggering the medical device criterion; so I think it may be helpful to clarify, from the discussion – from the presentation that you just made, are we talking about something that would trigger today's criterion for being considered a medical device and yet would still be out of scope of these regulations or things that are currently outside the bounds of medical device?

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

Great question and a little bit of column A and a little bit of column B. So, let me just amplify on that. The statutory definition is very broad, anything – basically anything used in the cure, mitigation and treatment of disease and John Murray at FDA chuckles and says, you know, literally an ambulance would fit the definition of a medical device. It's clearly used in the cure, mitigation and treatment of disease, but we at FDA don't really have an interest in regulating ambulances, I don't even know who makes ambulances. So we're struggling because the statute is written in a way that's deliberately comprehensive to give FDA the opportunity to regulate what it needs to, from a risk standpoint, but not regulate where it doesn't seem that regulation would add value.

So, in the area of HIT for 20 or 30 years, it's been left pretty open-ended. Back in the late 1980's, FDA had guidance out on it, it was interesting, it had some defects to it, but it actually provided some clarity. And then I forget, six or eight years ago, the FDA withdrew it and there's really not been anything since then to define the agency's sort of big picture view of what software – standalone software is regulated and what standalone software is not regulated. So there's been this void, and we've all been sort of just feeling our way along. So what I guess I'm suggesting, it's just me at this point, in this slide, is that FDA comes out with a similar document, an HIT document. And I'm proposing that that document say, that we do not plan to regulate HIT broadly, except A, B, C and D. So, in the biggest tent they say – I'm proposing they say we don't plan to regulate except where we carve out certain categories that we do plan to regulate. And I put four up here that I thought were items that the agency would want to carve out and say these things we're going to regulate.

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

Brad, if I could interject just so you could help clarify further. I'm assuming that that then requires a better, clearer definition of HIT software.

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

Well, exactly, but that's what we have, that's what the Taxonomy Working Group just spent two months developing.

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

Yeah.

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

So I'm proposing that we make use of the Taxonomy Workgroup's real hard work to say, this is HIT and this FDA will not regulate other than, MDDS, accessory, CDS and whatever else falls into that fourth bucket.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Is this what – this is Anna. Is that basically where the Taxonomy Group has netted out?

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

So my answer is I have no idea. I have – on those

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Oh, okay.

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

But here's my own sort of laymen's understanding. They were tasked with identifying the big tent, in other words, what all we should be looking at from a risk perspective and analyzing. But over and over again we said that the Taxonomy Workgroup was not defining what should be regulated; they were defining what HIT is and therefore what the focus of the Workgroup should be. So if I'm right in that regard, then that's what they did and it makes a logical definition of what we should be concerned about. And so what I'm saying is, if you pictured it on a drawing board, that would be the big circle and then I'm saying it's easier to define sort of say all of that's unregulated by FDA except, and then draw smaller circles inside of it for the areas of high risk that need to be regulated.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Okay.

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

This is Mary Anne, I'm sorry I joined late. I think, and I was on the Taxonomy Group, I think there's probably a little more work to do Brad from the Taxonomy Group, but you could certainly leverage the work they've done to date and just polish it up a bit.

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

Well, and if we communicate to them that this is how we'd love to make use of their work product and they can kind of view it through that prism and see if they're satisfied with the design of it.

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

Yeah, and I'm happy to take that message to our chairs.

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

Fantastic, thank you very much.

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

I guess I would just be interested in knowing what the logic is for including MDDS in that, because I think there are certain elements of MDDS that are pretty low risk. And then secondly, I don’t really know what you mean by medical device accessory, but we don’t need to get off on that right now. But...

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

Just to make sure we’re using terminology the same. So MDDS is an FDA regulation, it’s an FDA classification regulation of Class – and it happens to be Class I regulation, which means exempt from any pre-market clearance by FDA. So MDDS, if software meets that definition, and it’s a very well defined regulation, then it’s regulated by FDA but not subject to any pre-market clearance requirement.

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

Okay.

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

Brad, this is Anura. Just as a point of clarification, is there not an option in there that also allows for Class I non-exempt status for those devices that have special risk considerations?

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

Legally that’s an option, yup.

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

Okay. Thanks.

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

Yes.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Brad, this is Lauren. When you say clinical decision support, I think one of the things that, even as early as – I mean earlier but definitely as articulated in the hearing in 2011 that the FDA held, they define clinical decision support pretty broadly. And so, would – to say that we think all CDS should be included in Health IT in that category of being regulated seems incongruent with the sort of risk dimension, that not all clinical decision support would necessarily create enough risk to substantiate regulation. So, I don’t know if that whole bucket necessarily makes sense. We think for consideration or should be regulated?

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

So I don’t know if you’ve got the slide in front of you, it says certain forms of high risk CDS...

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay. Okay, sorry. I don’t, I don’t, and I just heard CDS. Okay, okay.

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

No, no, no, you and I are in perfect alignment there. And it’s incumbent then on FDA to define as precisely as they can, what that high-risk portion of CDS is, in furtherance of that September 2011 hearing.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay.

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

Unless we think we can define it here, but I don’t think we have time.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

No, probably not.

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

Or we could maybe have the Taxonomy Group take a pass at it, but...

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

Well...

Lauren Fifield – Senior Policy Advisor – Practice Fusion

It might be worth doing, it’s so broad and I know that it’s one of the areas where particularly of population management, I know that in the Taxonomy Workgroup, I had cited that population management was – but I think sometimes clinical decision support is either part of an EHR or part of the population management bundle, so it might be worth trying to define, particularly as module as opposed to – or a component of something. Because I think that’s one of the things that will be most challenging is that it’s not generally going to come as a standalone, it’ll come as a part of something and have you make sure that – regulation...

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

For those who are interested, there is the coalition that I serve called the CDF Coalition that has been working on this very question for a year and a half, meeting every other week. And they’re coming to sort of the conclusion of their work and they’ve got a public webcast next Wednesday, I’ve got to look at the time that anyone who wants to can come to. It’s at noon Eastern time, where they’re going to lay out what I think, I’m very biased, is a very thoughtful approach and the lynchpin of defining what is low risk versus high risk is a concept of transparency, that if the software is not a black box, but instead allows the user to understand what the inputs are, what data is being inputted, what the logic of the CDS is and very clearly what the output is; that if it does that, it’s nothing more than an aide and doesn’t merit FDA regulation. So, I just summarized what will take almost two hours to go through next week, but at a high level, that’s what that group has come up with.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

And Brad, I have a question. When we’re saying FDA regulation, or maybe it’s a point of clarification, does that necessarily mean the same path that devices are on? Because I don’t think that the way that necessarily medical devices are regulated would be appropriate for software, or it should at least be revisited. So when we’re saying regulated by the FDA, do you mean not the agency but how they do it is still to be determined?

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

Right. So if you go back to our...

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay.

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

We have three slides on FDA; we say that basically there are all sorts of improvements that need to be made to FDA regulation...

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay.

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

For whatever software does fall with under – within it, the whole concept of modules, the whole concept of how the quality system would apply the whole concept of pre-market requirements and the whole concept of post-market requirements.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay. Okay. Just wan – okay, great.

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

Yeah. So that’s all to be taken together.

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

So, this is Jodi Daniel. I had a question – thought or question. So the way this is structured, I see the things that are ambiguous and broken and then some suggestions for things that should basically be outside of federal government oversight and your recommendations for that. What I don't see, which I think is playing off of what Lauren is asking, but maybe I'm – I don't speak for Lauren, is for things that would be – like understanding what are the components of the jurisdictions of the various agencies or the approaches that we all have taken for other types of technologies, that may be useful. Like some of the lighter touch stuff, for instance or like – weighing on some of the different capabilities that we have and how they may be helpful or not helpful, in particular contexts.

So, a couple of things that came up, I remember Farzad had asked you Brad about things that are still kind of under – that are still being tested and having sort of a stage for working through those without kind of full FDA pre-market approval oversight kinds of things. And so where there are different capabilities or authorities that the agencies have that could be supportive without necessarily this is what happens if you're a Class II device, and you have to go through all of these steps. And – which could be a helpful thing for us as we're thinking about some of the things that may be within jurisdiction, but may – a slightly different approach may be help – more helpful. Does that make sense?

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

Well that is a more positive way, quite honestly...

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

Yeah, that's kind of what I'm saying.

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

Of saying kind of where we've identified things that are broken, instead, add "C" of something for capability, a capability that may be underutilized or should be utilized...

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

Yeah, exactly.

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

More or – I love A, B, C, I just – I had to stick with that so, I'm just kidding. But, so we ought to give that thought, where there's a capability that ought to be made use of.

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

Exactly, I think that that might actually be really helpful for us in understanding how some of the capabilities may actually support innovation or support safety, without stifling innovation, that sort of thing. So, something to throw in the hopper.

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

Okay.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah Jodi, thank you. I think that helps. And Brad, I think maybe what I'm now thinking is it might be helpful to include up front in the notes that there is a difference between – I think when you hear the term FDA regulation you think of it more as a noun, like the existing medical device process, as opposed to we think the FDA should regulate, so not in that process but this agency should regulate. And so I wonder if it's worth clarifying, because I know it's even hard for me to remove when I hear FDA regulation, thinking about how they already do.

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

Certainly we can – I'm just trying to think of where it makes the most sense contextually to put that into the presentation, but that ought to be easy to weave in somewhere.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay.

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

Really toward the end, to emphasize where we're talking about scope, to clarify – to your point, to clarify that we're not talking about taking the existing approach, but rather the approach of improved, based on our earlier comments. Got it.

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

Brad, it's interesting, Julian here. Interesting to try to take the way we think about FDA regulation today, in terms of a risk-based approach in theory and context and use and transition conceptually to this category or taxonomy approach. And I wonder if that will isolate either appropriately or artificially the categorization from the risks in the intended use of the device.

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

I think it's Friday afternoon catching up with me, but I didn't fully understand that. Would you mind elaborating just a bit?

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

Yeah. We know that a technology, a device or a function in one setting with a certain user and a certain environment might be higher or lower risk than the identical technology doing the almost identical thing with a different patient or in a different setting, so a different intended use.

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

Um hmm.

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

And I wonder how intended use would be captured under taxonomy?

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

I'm not intimately familiar with the work of the Taxonomy Subgroup but I thought that intended use played a big role in some of the factors that they had identified as they were developing their scoping. There was a person before; I forgot who it was...

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

It's Mary Anne.

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

From the Taxonomy Subcommittee...

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

It's Mary Anne Leach. I was on the Taxonomy Group. I don't think we spent a whole lot of time on intended use. I think that does show up in the Risk Framework, but I think we certainly can spend some time on that.

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

I think...

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

Well actually you make a good point; it does kind of dovetail with what Paul was working on from a safety standpoint, too.

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

Um hmm. Yeah, I just might – I like the sound of this, but I am concerned that the devil's in the details and that not including intended use – and this is a conversation we had in some of the other meetings in which it was – we had discussions that one could classify the risk of a given technology. But yet as we know, it isn't the technology that determines risk in many cases, it's the use and some uses there's a higher risk and some lower.

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

But I thought the Taxonomy Subcommittee did a nice job of being technology agnostic and you guys may not have used the term intended use, but a lot of what you were describing did, in fact – does, in fact, comprise intended use. Like what?

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

I thought they were using intended user.

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

Well, intended user is an element, yeah. And I thought also the Safety Workgroup's matrix made fairly liberal use of some of the intended use elements. But I'll have to – I mean, you raise a great point, Julian. I really need to go back and look at all of that together and see if in total intended use is adequately characterized.

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

A Brad...

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

Go ahead.

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

I'm sorry Brad this is Anura again. I just wanted to also bring up that we had some previous discussions on indications for use. So when looking at how the technology is introduced into the overall system context, particularly in situations where you have multiple vendors devices possibly coming together, then not only the intended use for an individual device, but also the indications for use and sort of that system integration context is something that could be very relevant.

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

Again, agreed, and I need to look back over the whole – what the three subgroups have done together and see where that most naturally fits in.

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

Well, I don't want to belabor the point...

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

No, all good, very good comments. So, do you want to talk about your report?

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

Sure, yeah, absolutely. Sure. Well, I attempted to capture both the original – some of the content from the original presentation as well as the feedback and discussion that we had from the notes that I took during the one-hour session and from other settings. So let's go through this slide. I would say that probably shouldn't put too much emphasis initially on the A or B designation, that really is worthy of discussion and see if we have consensus on that, but I just took a first pass at that. So the first item is – so just three items here that were extracted from much lengthier discussion and the attempt was to capture three distinct, but related attributes of the reporting challenge.

The first is the difficulty in obtaining data for system performance analysis, and the focus there was especially on the technology challenges. So the description on the right says, when medical device Health IT system related adverse events occur it is often difficult or impossible to find the root cause of the failure. I took liberty here, because there wasn't much space, I used the work root cause generically, of course there are typically causes, not just one, and one could take issue with the relative informality of the text there. So I acknowledge that and if anyone feels it doesn't represent the idea accurately, please let's discuss it. I'll continue reading. Data logs may be incomplete, non-existent, not in standardized format, see the exemplar document. So remember everyone, there's that exemplar document that David posted, so see the exemplar doc and the working group meeting slides, I think to capture the richness here, we couldn't really do it all on one slide. And then I inserted a note that there's a linkage here to interoperability. These in a sense, some of these go hand in hand and we don't have an easy way to link our slides, so I pointed that out. So that's the first line here and...

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Excuse me; this is Anna McCollister-Slipp.

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

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

The only thing I would add there or I don't know if you need to add it in the little box that's longer than the PowerPoint, but a lot of the data – there are a lot of the manufacturers have the data, but it's just not available to FDA. They're not required and they're not particularly inclined to release a lot of the data they collect about these things. So there's a lot of data there, it's just not being released for anybody to do any kind of analysis.

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

Okay. Good, so, let's see. I attempted to capture that notion and clearly I didn't do it adequately when I said data logs may be incomplete, non-existent or not in a standardized format. So you're saying – okay, you would add here unavailable, so they exist but they're not available, that's the notion you're adding, right?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Exactly, yes.

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

Okay, great, wonderful. Okay, yup. Okay, that's very helpful. Thank you. Are there any other comments on this first line? And then in terms of whether this is ambiguous or broken, frankly I was stuck. I think perhaps this should be listed as broken because we have a sense of patchwork of requirements. There are reporting requirements that exist in various places, and of course FDA and FCC, and we discussed that – but I'm not certain what the best designation is and I'll look for guidance from the members on the call right now.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

This is Anna again. I would vote for broken, for it's just sort of lacking, since stuff hasn't really been written into either the legislation or the regulation. And I could be wrong, there are certainly a lot of people who would know this better than me, but I don't think FDA has the authority to collect the – data or to require it to be reported.

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

That does seem to be the case. Much of the data that's needed is not collected and not recorded and so the investigations are hampered by that. All right, let's...

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Actually, one quick thing, I don't know – I know that this is a commentary about the actual regulation, so I don't know that this is appropriate for what's on the slide, but might be worth a point of commentary...

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

Lauren Fifield – Senior Policy Advisor – Practice Fusion

And that's, I'll add a "C" to Brad's A, B rubric, cultural. I think the difficulty isn't just related to systems or common formats, but also to sort of at the level of providers and now even patients just sort of having someone create some sort of report or submission, I think is also something to be considered.

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

Idea, this goes back to the ASRS, the Aviation Safety Recording System, which seems to have very strong cultural support in that community, that reporting is considered a good thing and sharing it with others to avoid an accident or something like that is –

Lauren Fifield – Senior Policy Advisor – Practice Fusion

In the physician community?

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

No, no, in the aviation community, ASRS...

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Oh, yes, yes, yes, exactly. Yes, exactly. Actually they're – they love it, right? But I think there's...so cultural you know – yeah, skepticism in the medical community, that's right.

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

Yeah, I think you're point is great, I was just giving an example of a strong cultural support and that was the ASRS. So that's helpful, thank you.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Sure.

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

Are there any other comments on this first line?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Actually, there is one more.

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

Sure.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

I also wonder – and I know that when it comes to reporting either to whatever regulatory agency it is, it'll be mostly devices that are health IT that is regulated, but I wonder if there are products that are at the cross-section where they're both regulated and used by consumers, what – how to handle reporting to the FCC versus to another agency and kind of how you'd reconcile those or...

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

So I think that that's actually a good segue into the next line...

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Oh, sorry, yes.

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

That's good, and then we'll take it up again if we aren't covering it adequately. So the next one is that the root cause of events may span regulated and non-regulated space; and you're embellishing that further by pointing out how broad the space may be. And so here it says, what is the best model for recording and analyzing issues with systems of devices and equipment that span multiple or single regulated and non-regulated space or agencies? And within our meeting, we surveyed existing approaches from the National Highway Traffic Safety Administration, the Consumer Product Safety Commission, Aviation Safety Reporting System, and FDA MedSun; actually I left one of them out for FDA, and ASTERD, the FDA pilot on medical device reporting that's similar to pharmaceuticals, National Transportation Safety Board and Patient Safety Organizations. Further analysis is needed, we only skimmed on the surface in order to inspire us and to help guide the work we were doing, but time and resources didn't allow deeper dive.

The notion of a new construct of a Health IT Safety Administration or HITSA was discussed and that discussion was captured I think well in that one hour including that it – this is certainly is a complex. And it may or may not require an actual new entity like an administration, it could be a public/private partnership or something else that falls under HHS, and that broad stakeholder involvement was emphasized and this was a point made many times. Sometimes it was made that stakeholders, for example, have to be the users or consumers or hospitals and others that this shouldn't just fall on the shoulders of medical device manufacturers or whomever. So that attempts to capture that part of the conversation and I assigned a "B" here for probably obvious reasons. So let me open the floor to discussion, what should be changed or fixed, incomplete, unclear and does this capture what we discussed?

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

Julian, this is Mary Anne Leach. I think this looks really good and I think there are a lot of opportunities for improvement and I think this is a great framework to put forth. So thank you.

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

Thank you, other comments and feedback? In the discussion just prior to this line, the note that we will have to – we must consider that space in the regulated/non-regulated or things at the intersection, does this adequately capture that?

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

I think so.

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

Okay. Well then let's move on to the third. And the third captures an idea that emerged in our call on this topic, and hopefully it's captured appropriately here, that adverse events should be accessible early and broadly. Really this text has to be changed. It's information about adverse events, not the adverse events, but anyway, the idea here is that early access to safety and performance data to enable rapid improvements was emphasized, example of efficiency of modern social media for aggregation and dissemination. And the point was made in our call that reporting today to the FDA serves a specific regulatory function, but it doesn't always support a pathway to share information early with the community, with other manufacturers, with the users, and it doesn't necessarily help to trouble shoot and solve problems. And reporting in the future should address both gaps. I think we see that happening in other areas with large worldwide community activities for software development and innovation and so forth. And I assigned a "B" to that for that reason. So let me open the floor to discussion on this third item.

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

Julian, this is Matt.

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

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
This is Matt Quinn from FCC.

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

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
One of the paradigms, and I was just struck listening to the Asiana airplane disaster, and as part of the standard black box that's on airplanes, they collect 1400 different feeds of data.

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

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
And as they went about the analysis, they were looking not just at the machine itself, but people, machine and environment and it seems like really getting the context of sources and causes of errors in these complex sociotechnical systems really requires an approach that captures all three of those pieces. So, as we think about these improvements, think about the parallels with what's going on there and how we do that in practical terms.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
Um hmm, um hmm. That's really – yes, indeed. I wonder how – so the notion of a black box recorder, maybe that should be added and one – both context – the elements as you described them, people, machine and environment, that context is critical and that we need some way to think about that black box recorder for health care.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
The black box is one piece of it, but there's also the flight – the cockpit recorder and there's also data streams about what's going on in the weather system.

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

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Other – and other airplanes and other stuff, so the reason that people make mistakes is because they get distracted, well why did they get distracted? Well, it was a shift change or it was – there was a tornado going on outside, or whatever.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
That's – this is very helpful. I attempted to simplify the slide maybe that was too much – this needs to be included. So Matt, what I'll do is I'll take a crack at that and run that by you, as well as the others in the group and see if this can be captured and I'll get that out right away.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
I mean those sort of things changes – I don't want to say that – there are a lot of approaches to collecting data, but one of the beauty – beautiful things about computers, that they have system logs and it doesn't require somebody to manually kick a box or something every time something happens.

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

Matt, what are you suggesting though, because you're talking about data coming from like completely different sources, so how is – I'm not sure what you're suggesting for purposes of this discussion and how that would play out. You're talking about like weather data and human input and all that, so I'm not clear on what you're suggesting.

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

What I'm suggesting is that in order for us – the reason that the aviation industry is able to get to the root causes and truly understand the reason that accidents occur and the sources of risk is because they take this three-dimensional approach of people, machines and environment and apply it to their analysis of crashes.

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

Yeah, I understand that, but what I don't understand is what you're suggesting – so, this – I mean we're talking about the technology and we don't necessarily have access to all that data. What are you suggesting? I mean, that came out of the IOM report and there was discussion about like a separate agency that can collect all that data. But, this is – I don't see how that fits into the discussion that we're having here about the adverse event reporting and trying to kind of get – capture the information we can from the – and make sure it's getting to the right place.

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

I bring it up not as a specific suggestion on how to collect the data, but as food for thought on if we're going to develop a robust, learning system around – to inform and figure out where risk truly lies and how to mitigate it, that we can't just look at the machines themselves or just people, that it's these three things that work together to cause risk in these systems; so, maybe to think more broadly about data sources and how to incorporate them into what's necessary for establishing this learning system.

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

Well, if I may add, that type of – those considerations are part of every clinical accident investigation and analysis. What was the cognitive load on the individuals? Were they distracted? Were there other considerations? And as these analyses have become more sophisticated, with the recognition of the limits of human performance, so if technology allows us to tie those data elements and record them, especially if they're available to a system that could potentially be very helpful. The idea of context – we already know context switching in an EHR is one source of error, having more than one patient record open at one time is frowned upon, to put it lightly. And so we – being aware of the source of those errors could become quite important. But I don't know, I don't think we're talking about mandating it, if I understand you Matt, and I would concur.

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

No, no. I'm just thinking about as we make recommendations, to think broadly about data sets that do occur – or data sets that do exist, data sets that could exist and don't and other sources that we may or may not be leveraging to get this full context. Because frankly, one of the things that I fear is just the data that we capture in – reports or in reports from PSOs or whatever does not provide adequate context for learning.

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

Matt, this may be a conversation you and I may want to have offline, but in our Safety Plan we talk a lot more about kind of collecting data and kind of the sociotechnical environment and other things that we're going to be doing separately, although in companion to these discussions. So, it may be a good offline conversation. And I completely agree with you, I'm just not sure that – I think it might complicate this discussion a little bit.

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

All right.

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

Well, this has been a useful discussion, I think. And I would add that we have a DOD sponsored research project in our lab on developing an open-source data-logger for clinical environment. Work is in the relatively early stages overall, but we've been struggling to understand how best to obtain and record the level of context that would help with adverse event analysis and system improvement. So a topic near and dear to my heart, and I agree it is complicated and unclear as to how we should ultimately reach that point. Is there any other feedback on the third point, any other discussion or comments, any changes that are recommended? All right, I will take a look at this slide with an eye towards making a few minor changes based on the discussion and perhaps adding something to the note section of the slide to capture the additional richness, so that we don't overly complicate the core content.

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

That would be perfect.

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

All right, well Brad, why don't I turn this back to you.

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

Okay. So, we kind of – what I wanted to do, and what we've done in the first hour, is focus on the new stuff first. But now I want to sort of go back through and cover the stuff that you've all seen before, but to try and make sure that we're in good alignment as we head down the final stretch here. So, the question slide isn't terribly substantive, or isn't for that matter, terribly important other than sort of context. I mean, these are the questions, as I perceive them, anyway, that we've been wrestling with for the last two months, and that we've tried to address in the subsequent slides. Are there any comments on the questions?

So then we've got the three slides on FDA. And again, we've gone through these a couple of times and I don't know if there are issues, but I just want to run through them and see if there's anything that we have missed so far. So I'm not going to repeat all this stuff, well I guess just at a high level. I mean four basic items. These, the first three, are all kind of jurisdictional questions. By that I mean they relate to the scope of FDA regulation where either in the case of the first two, current FDA regulation is too expansive, but in all three areas, there are ambiguities that need to be resolved. The software modularization, as you remember, is really the fact that FDA regulations, to Lauren's point, really wasn't designed with software development in mind and software being developed from many pre-existing modules creates ambiguities around which modules are regulated and which ones are not. So, there's sort of a theme running through all four of these issues that are identified on this first slide. Any comments or changes or edits to this first slide?

What I'll do, if I get some time, I'll take on the FDA slides. I'll try and type some stuff in the notes section to guide David as to the context or the background for these points.

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

Brad, is this a place where you might want to put in intended use as Julian had described?

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

Umm, we had intended use on this slide earlier, and characterized it as an ambiguity because the concern was that FDA wouldn't know how to tackle software with an evolving intended use, where the actual intended use of the developer may be very constrained, but in the hands of the ultimate user, it might be used much more. We removed it, I think maybe two or three meetings ago because a couple of folks, I think Keith in particular and I think Joe and maybe some others, said that particular ambiguity we like, because it allows us to be more creative and it allows ultimate use to frankly escape FDA regulation at the local level. And that's what then led me to insert in that very final slide, the 11th slide, that if we wait a couple of years and watch what the industry does, maybe with a little cajoling, we can get more sort of local control and accountability over the actual use of software. So, I think I'm going to deal with it in the last couple of slides, in that context, rather than here in this context, because it really goes to the holistic solution and so I think I'm going to have to figure out a way to address it in connection with that holistic solution.

So the other slide, this is the more operational slide. So the first slide was FDA scope, this slide is more the operational one and basically where we've been in the past is to say the three major requirements of FDA all struggle or don't really fit the standalone software paradigm. That in the first instance, quality system, those regulations in part 820 were written with physical product in mind and there's a lot of simply interpretive questions or ambiguities when trying to figure out how to apply those principles to standalone software. In the case of pre-market, when you have a piece of software that's got a fairly truncated intended use, that is it's simply a component maybe and fits within a larger system and is interoperable with an unspecified network, it creates challenges for figuring out how to get it through the pre-market clearance process. And so, clarity from FDA on what is expected there would be very helpful.

And then finally the post-market requirement, this dovetails a little bit with the adverse event reporting but it's much broader than that. A corrective action, who has to take the corrective action when a network breaks down and something needs to be done to fix it? The ambiguity is around responsibility and the fact that there's some level of shared responsibility make it difficult to figure out how the FDA requirements apply. So these are the three main operational FDA requirements and the ambiguities and misfits, as it were, when they're applied to HIT. Any changes to this? And again, if I get some time, I'll try and add some notes that basically give the background to this.

This slide, Jarrin – I'm sorry, was there a comment?

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

Yeah, on the previous slide – Julian here – just looking, I don't know if it's helpful Brad, there's that pre-IDE work that we've been doing with that – in follow up from the Continua-CIMIT FDA Interoperability Workshop in January 2010, resulted in a pre-IDE for interoperable medical device system. That work continues and there's a – sorry, I was waiting for the noise to pass. There are fairly complete or extensive documentation and analysis of some of these issues and a conceptual framework for the interoperable devices for a system to be safe and to avoid overly burdensome regulation. And I wonder if there's any way to help contribute that documentation to this work or to reference it or to make a note. I don't – no, I don't want to complicate this, but you're well aware of that work.

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

Right, so, I think it's great for me to add that to the note section; so that David can identify that as a work in progress that hopefully will be very helpful in resolving those ambiguities. So, I'll definitely put a description of that project in the notes.

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

I think I added a link to a webpage in one of the earlier slides as well that touched on this topic, but we can talk about that offline.

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

Okay, I'll look around and if you remember where that was, maybe if you could shoot it to me, and I'll put it in here.

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

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

So the next slide, Jarrin, you were really the principle architect of this, although this is all things that we've talked about, this is – I thought you did a nice summary. Do you want to take the group through this slide?

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

Sure. So I think the original intent of this slide was to talk about some of the things that the FDA from a programmatic standpoint was facing, some of the challenges that it faces and some of the things that it can improve on, and also some of the mechanisms that it has to actually foster innovation and promote it. And I was thinking about a comment that Lauren made about the treatment of CDS and I'm going to try to paraphrase Lauren, if I say it incorrectly, please jump in. But basically you don't like the idea of placing CDS and certain types of software as blanket it's under the existing paradigm of FDA. And I also was struck by something that Jodi said which was, is there a way that we can go into the existing outline that Brad you have on the preceding pages, where we have an issue and then an ambiguity or whether it's broken and then a description.

So, I think that this kind of falls under the idea of that column "C," if in fact you're going to create a column "C," where we can actually put some of these things in as potential solutions under the existing framework that the FDA is under. I realize that there may be an opportunity for the group to come up with recommendations of things that all the agencies and very specifically some of the agencies can do going forward, and I think that's fine. However, I think that there are things that the agencies, specifically the FDA, have at its disposal currently and they could do immediately, and I think that was the intent of this slide.

So if you go through the slide, and you go through the bullets, the first one is FDA lacks internal coordination of policy on Health IT software and mobile medical apps, and then we kind of go – we flesh them out. The second bullet is the FDA should utilize external facing resources to proactively educate the public about how policies and regulation impact Health IT. Third, FDA lacks policy and guidance on Health IT software and mobile medical apps. Fourth, FDA should actively establish a policy of enforcement discretion for lowest risk HIT where enforcement of regulations is inappropriate. And then very lastly, FDA should assess exemptions from GMP for lower risk HIT.

If you want to actually reformulate the slide, and you want to put it in order of importance, I think that probably starting off with FDA should actively establish enforcement discretion for lowest risk HIT and then go next to FDA should assess exemption from GMP for lower risk HIT. In other words, if we were to put that as the first bullet, the lowest risk HIT, it may be inappropriate to enforce regulations on them, even though they are, by default, medical devices, they shouldn't be regulated, and that's the idea behind enforcement discretion and that's something that the agency can use as a tool. And if in fact they do that, then basically those items, those products would be off the table. They're not enforced, they're not regulated and they are not required to register or list with the FDA, which then goes to other peripheral issues that I'm not sure many people have raised here, but there's this whole notion of the device tax, etcetera. So, that's a real specific, very hardcore solution.

For lower risk HIT though that do still merit being in Class I for example, the FDA can assess whether exemption from GMP applies. One of the things that we were talking about was the Quality System Regulation because it's a very cumbersome, burdensome thing to go through a full-blown Quality System Regulation. Well maybe the FDA can appreciate that some lower risk HIT may not necessarily need to go through a full blown GMP, so that's the idea behind that bullet. And of course the remainders are things that they can do to really kind of help foster innovation. One thing is really coordinating internally their position – their policy positions on health IT software and mobile medical apps. Again, I'd mentioned I think this before, but there's been a lot of information spread between and among the industry, especially with manufacturers of medical devices that they get different types of understandings, opinions, etcetera from different parts of the agency, and that's just – that's bad, that could be really harmful, especially to a new manufacturer.

Then the next one that the FDA should utilize external facing resources to really educate the public on what the policies are and the regulations and how they impact health IT. Again, that could be used as a very forceful, very quick way of disseminating information. Lastly, the guidance – guidance actually could probably be moved up, that's a very forceful way for the agency to give an idea, a snapshot of their current thinking, the day they issue the guidance. And currently it takes a long time to get these guidance documents produced. It should be much quicker and continuous. Guidance shouldn't take two years; it should take probably two months, and then keep getting them out there, as much as they can. So that was, I think, the idea behind this slide.

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

Are there any comments for Jarrin? And by the way Jarrin, I heard you kind of suggest that if you had this to do over again, you might reformulate or structure it at least in a different way, feel free, after today, to do that if you want.

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

Sure.

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

And also Jarrin, if you want to put some notes at the bottom to guide David as he delivers, if he uses these slides, the notes would be very helpful.

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

Sure.

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

Anything for Jarrin? Okay.

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

I'm sorry, one quick comment or question here. When we talk about – I'm sorry, this is Anura Fernando. When we talk about classifying risk, the Risk and Innovation Group has had a lot of discussion around that, do you see that being a function of technology or severity of the impact of failure?

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

Now is that question for me or for Brad?

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

For you Jarrin, based on how you framed things here.

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

Yeah I think it's – I mean, it's kind of both in a way, but it really at the end of the day is, what is the harm to the human being or the animal that we're discussing, because that's really – that goes back to the statute.

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

Okay, good. So from comments I'd made previously, I had a level of discomfort around classifying risk based on perceived complexity of technology, because even very simple things, like a piece of copper wire, they have sometimes unusual failure modes under various conditions. And so perceived complexity, that's not the basis of classifying risk and understanding the failure modes and the implications from the perspective of intended use and indications for use and introduction of hazardous situation in that context, I'd be much more comfortable with that. Thanks.

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

Okay, good, any other comments on this slide for Jarrin?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Lauren Fifield.

Unidentified Speaker

Go ahead Lauren.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Just one thing that I don't – maybe it's part of something else – so I know I keep saying things that don't actually apply to the slides, but more gaining inspiration from the slides. I do think that there are others – when it comes to assessing risk, I also wonder if we shouldn't encourage the FDA to look at risk that already exists in the clinical setting? Or to start compiling more analysis on sort of the baseline because I worry that sometimes because we're so focused on a framework for health IT, we're addressing first the technology but really the end goal is the actual clinical care and outcome rather than the technology in and of itself. And so I wonder if really encouraging a baseline wouldn't be helpful there.

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

Can you amplify on that, what does that mean encouraging a baseline?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

So okay a great example would be for prescribing, if there are errors in prescription rates because of handwriting or because a nurse or NA or someone writes down the wrong prescription or just using technology there's a – and something gets double-dosed; but errors can come from a variety of sources, in the context of actual clinical care, right. So, I think one, just sort of understanding errors that happen just within the clinical setting whether it's because of technology or not, would be helpful. And then also trying to figure out how many of those errors actually follow through to patient safety impacts or if there is an impact on patient safety. Because – in some ways I think by starting with the technology, if we start collecting every error, that that doesn't really result in an impact to clinical care, then the scope could be much broader than it needs to be.

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

This is going to sound a little...

Lauren Fifield – Senior Policy Advisor – Practice Fusion

I guess it's maybe just – no, no, no, I'm sorry, go ahead.

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

I was just going to say, I feel myself sounding a little bit bureaucratic, but I really would love to see the Safety Workgroup weigh in on that, because that's fundamental to their exercise. I mean, they're to identify where the safety risks are and those safety risks ought to be relative to the baseline that you just identified. That seems to be very material, to me; in their commentary on is this stuff. Is there safety risks associated with this stuff?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah, actually I think that's not too bureaucratic, I think that's actually probably exactly where it should fall and it should probably fall in advance of this part of the presentation anyway. So, maybe I can just send a note – I haven't been listening to all of their calls, maybe they've even talked about this, but, I'll send a note. I think that's right. Again, this is more inspiration from the slides.

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

That's a great idea and it seems to me, very relevant to the exercise.

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

Lauren, and again, I just want to remind everybody that this slide, the idea behind this slide is that these are mechanisms that the FDA has literally currently as part of their regulations and part of their policies. Whereas some of the things that we're coming up with in the recommendations I see as things that the agency could do or that the agency should do, and obviously that will take time and effort and whatever rulemaking extends from our exercise, from the FDASIA, whether or not it goes even back to Congress and Congress decides to do something with it that's Congressional. I think all of that will take time, potentially years, and millions of dollars and these, at least for the purposes of this slide, these are the kinds of things that they can do tomorrow.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

This is Anna. I think this is really helpful just from the perspective that Jarrin just stated. I mean, what I would hate to see happen, and what I think is happening is that a lot of the people, the 22-year-old coders who have great ideas, who could really be doing cool stuff, that is sitting in the garage or their dorm rooms, could be coming up with something very inventive and innovative and helpful. And I would hate to see the regulatory structure or concern about GMP or having to figure out those processes get in the way of that. If they're going to be using their mobile apps to control multiple medical infusion pumps or something like that, that's one thing, the agency should be involved in that. But if it's just some sort of a calculator or some other type of low-risk app, I think requiring them to even meet the Class I definition of standards might be a little onerous.

And then secondly, this may be completely off topic or unrelated, but since I've been like looking through all of this, and I certainly don't pretend to be an expert on the FDA, but in some of the advocacy work that I've done, I've certainly worked with a lot of really smart, very committed, very overworked – people at FDA. I'm thinking if this is the report to Congress, maybe somewhere along the way we should make a recommendation to the policy – to the HIT Policy Group, that Congress needs to allocate money to the type of people who are needed at the agency that have the skill set to push this stuff through. Again, I don't know anything about the specifics or the dynamics and I don't know Bakul's workload or whatever, but I would just think that there's – based on my limited engagement with people there that that might be something that's getting in the way. Hiring people is not particularly easy these days, hiring people with the skills to be able to assess this kind of stuff and understand it both from a policy as well as a technical perspective can't be cheap. And I would think that given some of the political climate, there needs to be some degree of suggestion if we want this, you need to fund it.

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

Jarrin, what do you think about shrinking the font on your slide or something, but somehow putting in a bullet about making sure that the relevant agency functions are adequately resourced?

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

No problem, I would love to.

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

And you might, if you want, you can move some of the sub-bullet points to the notes section that would be for David to speak to, if you run out of space on the slide or something.

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

Right.

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

Is there anything else for Jarrin on this slide?

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

I thought I heard Jodi pipe up earlier.

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

I don't have any comments. I'm good. Thanks.

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

All right, so, let's go on to ONC and Julian, I think you were the principle architect of this slide. Do you mind leading us through this again? You've taken us through it before so we don't need to go through it in detail, but basically just giving everyone another opportunity to express any thoughts they have.

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

Yes. Well, this is really an attempt to capture some of the discussion that we had in the meeting, as we talked about. The first item on the list is mandatory elements. I did not create this text; it was carried forward from one of the previous presentations. So, I don't know that it needs any more comment. The next one is assurances – I'm sorry, was someone commenting?

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

This is Brad. So I was just going to remind everyone of the context around the first row. That was the issue of vendors and others who were – did not have the public's best interest in mind, but rather were looking out for their own interests and the need for regulatory tools that have the force of law behind them, as opposed to a voluntary standard. So, not that – we had a lot of back and forth, no one was suggesting that the certification program ought to somehow be reconfigured into a mandatory program, it's just an observation that the ONC structure doesn't presently have that mandatory element in it.

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

Thank you Brad, indeed. The next is based upon one of the use cases that was discussed, and was a very interesting conversation that – and I think this again goes down to the – drills down to context that there can be variability in the application, installation and use of health IT. And safety depends on upon that appropriate post-installation configuration. So there does not currently appear to be a means to require a minimum education level for use or to follow specific guidance on installation and configuration, and yet we know that that can be a source of hazard. Is there any discussion on this, any comments, questions?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

This is Lauren, on the first point, on the mandatory elements. I think one thing, and maybe it's for – discussion, is that I think you, as Brad phrased it, maybe we need to actually put better clarifying language in about kind of those areas where there might be bad actors in the system or the market might not be addressing certain areas appropriately. I do think that it might be worth saying – having the ONC or whoever considers an assessment process by which they can determine if the market and industry have addressed certain concerns of those types or areas of interest and sort of have a program that's flexible enough to – out those elements once they're corrected for. Again, that's just sort of is this is, I think, a new point but just sort of struck me as you were, Brad and you were talking about that first one.

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

Help me understand in a little bit more tangible way. Can you give me an example of what you have in mind?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah, so I think that there are certain things that particularly since so much change has happened and occurred in health IT around meaningful use and just as healthcare has – the healthcare industry enlarges and embraced technology. And so I think that there were some legacy trends or things in place that the ONC or even other regulators may have found to be a problem and I think they've actually done a really good job, so if they keep doing it, of expressing when they find issue with something that's going on in the market, because they've heard feedback from providers, users, whomever, and I think they've done a really nice job of addressing those things outside of a regulatory framework. But then there are requirements like price transparency as an example, that's gone into meaningful use certification. And I think that that's addressing something that's kind of a current issue.

But let's say, and again, I don't necessarily feel this way about this particular one, but if they do an assessment and the market is addressing well enough price transparency – not necessarily that you don't have to regulate it anymore. So just kind of taking away regulatory items when they're no longer necessary and when they're addressed by the market. I think having that kind of flexibility could be good, and I guess I further support just the way that they have addressed some things outside of the regulatory framework.

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

Well maybe what this is an opportunity to do what Jodi asked us to do at the outset, maybe we can add in a row about a capability that they have to assess programmatic elements and flexibly add and subtract over time to make sure that only the most useful are being carried forward. Add that as a row of a capability that we'd like to see them exercise in the future.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah. Yeah, I think that would be great.

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

Okay. Julian, I don't know if you...

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

Yeah. Sure. Yeah the next item – go ahead and let's just stay on this, we captured it, it came from – but let me go through it certification program. ONC should avoid its certification approach because the certification approach is most damaging to innovation, and by defining specific solutions, potentially damaging to patient safety by endorsing the less optimal solutions. I don't recall the source of this line Brad; I think it came from the early...

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

This is Keith. Is Keith on by chance? He was going to be late on the call? Nah, doesn't sound like he's on. Keith was very passionate about this and in fact, supplied the language for this one.

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

Uh huh.

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

It really is coming out of the Safety and Innovation Subgroup, the innovation side particularly of the Safety and Innovation Subgroup, was passionate about certification's kind of locking in design elements and frustrating creative and innovative thinking. And so Keith wrote this one and asked us to insert it. I don't know if anyone else is on that subcommittee who can maybe add some more color to this one?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

This is Anna I'm on that subcommittee. And yeah, that's right, I mean there's a sense that, and again this was not meant as any criticism toward Jodi or Steve or any of the guys at ONC, because no way – there's no way to get around this. But the way that certification has been perceived in some respects is that a lot of the EHR vendors have become sort of the lowest common denominator and people are shooting for what the certification standards are and then sort of not really going beyond that. And they're getting lots of money for achieving these standards, but they could be doing so much more, but they're not bothering because they've achieved the standard. I don't know exactly how to get around that, within the context of the Meaningful Use, the Incentive Program, but that was what part of the discussion was, that there's so much more that could be done, but nobody is really going there at this point because they're too focused on the standard.

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

Keith was really good about giving me language – is that Keith?

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

Yeah, this is.

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

Oh, okay, sorry – because you gave us some good language for the notes and it – we were remarking earlier that somehow I lost the notes section. I've got to get that back, but, do you have anything you want to amplify on this one?

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

Yeah. I think that one is, and it goes back to the idea that I have to precisely measure something and what damage it does. The hard things with the certification program, in this particular case, this certification program is essentially it's writing requirements for software. And the problem with that is that if you take a look at the impact on the industry, there were CPOE systems before ONC did it's certification. There was decision support before ONC put certification. There was med reconciliation before ONC did certification. And in fact, we were treating patients using these systems and yet look at the amount of work that organizations have had to do, not to create CPOE systems, but to meet the test – the particular test case that's put in front of them to get certified. And that's what I'm saying is that that's what kills innovation is that it's giving a – it's the opposite of the flexibility that we talk about in that Appendix D where it says, what things kill innovation, one of them is that you only have one pass to get something done. And by putting the very precise language and putting into regulation essentially a requirement for a functional requirement for software, you only have one pass and you have a test case that has to be met and there's no flexibility in the test case, because you can't have flexibility or then you get accused of not applying the regulation consistently. So even if you realize that your test case is bad, you pursue it in order to be consistent. So I just think that these systems really do damage and homogenize the different options that you have. Anyway, that's – you can tell I feel – this is a big deal because – I mean, I really have to deal with this regulation every week and almost every day.

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

So Keith, this is Steve from ONC. I think, because I make you deal with this every single day and every week, I mean I think you're raising two distinct points in my mind...

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

Uh huh.

Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator for Health Information Technology

One is, the certification criterion that we have for CPOE is pretty general, but the other point that I think is distinct from that is that in order for someone to prove the outcome expressed by the certification criterion, there is an expressed way to test it. And in cases where the testing is being perceived as being inflexible, people are just doing that test, which may not necessarily be the way in which they would have approached it in a more innovative light. And that the testing – like the – what you're more focused on is that the testing be more flexible.

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

I'm saying that if what you have is you're trying – let's take one I dealt with this week. Intermountain Healthcare is known for its decision logic. I mean, we've been in the medical decision business since I've been here, in 1976 and 1975, even before I was here. And yet what we were doing is that we're reading the use cases and we're going to have to do development to meet specific requirements in there that, quite frankly, we will never use again outside of the testing mode. For instance, the idea that, and I'm getting very specific on examples, but that's really the world that this creates. The idea that I have decision support logic that uses demographics, uses problems, uses medications, and uses allergies and lab data. Okay, so the requirement, the test case says I have to have an alert that only uses demographics, okay, and we're saying, well what is that a work, I mean, what is that intervention that I only use demographics? Do I register the patient and come back and say, well did you know you're old? Again, it doesn't – it – where if what I was saying, if you take the policy level of that regulation and say that what you should be able to do is have automatic monitors on these sources of data and be able to mix the data to come up with an intervention. And then I can sit down with a tester and say, this is how we did it, we've met the effect of it.

Then you have a more flexible enforcement, but you still have the issue that – okay, so there’s the first issue is the testing. The second issue is essentially these are functional requirements. I write functional requirements every day and work with a group of developers. I can tell you that as clear and clean as I think that I write those requirements, it is a constant dialog, daily dialog to clarify, to think through the problem, to polish the requirements. If we write requirements like that into regulation and you have a public comment cycle with it, and then that’s it, you’re really stuck with some things that are not very clear. And in the case of having to consistently applying in the market, won’t become clear, even if they’re wrong, even if there’s admission that the Stage 1 requirement that I be able to alter an allergy alert or intervention, no one knew what that was. I mean, what do I do with that? Do I turn off some allergies; is that something I would put in my product? It was such an odd use case, and when Stage 2 came through, essentially there was a statement that this really didn’t work. But that could have been cleared up in Stage 1, so there’s no flexibility once you get into the point that it’s regulation. And yet it’s very precise on behaviors. And so you have a lot of work that’s being done in companies that is reworking – I mean EPIC for instance, need to redo their CPOE system. They had one, but in order to meet the specific use cases or the specific designs that are in the regulation, you end up doing work that is non-valued, it’s non-contributory, under the auspices of raising – But you can create a market, again with something like the meaningful use regulations, that creates a market says that you have to have an end result where physicians are using CPOE systems. You can do that without describing the particular functions of the CPOE system. I just – again, I think that trying to do this is just too hard to do, I mean, to get a small group of people to put together functional requirements for software in the entire nation.

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

I need to keep us moving along, we’ve got to...

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

Yeah, sorry.

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

No, that’s fine. We’ve got a couple more things we need to tackle. Is there anything else though on ONC before we move on to FCC?

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

I think...

Lauren Fifield – Senior Policy Advisor – Practice Fusion

I – Brad...

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

Go ahead.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

No, no, Brad...

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

Is that Keith, were you going to say something Keith? Go ahead.

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

Just one final thing, addressing – it also...there was the fact that the ONC certification, because of – and this is a small effect, I mean it hasn’t been – but it’s had a deep impact, is that its enabled and empowered other certification processes, in particular Surescripts. So, I can’t meet the needs of ePrescribing without going through Surescripts, so now Surescripts is empowered without accountability to give me another certification process that I have to meet. And so – anyway, that was the only other one. Sorry.

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

Thanks. Nope, I appreciate it. Lauren, were you – did you want to say something?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

So, let's see. So I think that part of the – I definitely feel some of – points, and I think particularly when it came to some of the HIT Policy Committee's recommendations for Stage 3, and even in Stage 2, there was some prescriptiveness to kind of to the actual development of functionality and – when it came to some of the meaningful use certification requirements for 2014 edition and Stage 1 requirements. So I think that that should be avoided. But what I will say is, I think that one, because Meaningful Use and the Certification Program statutorily isn't going away, I don't know that to say that the Certification Program shouldn't exist is really a suggestion worth making. You said it seems to me that some more productive thing is to ensure that the ONC and other regulatory bodies have – actually, hold on a second, let me – one second. Hi, sorry about that. So I understand your motivation, but I think having that ability for a regulatory agency to assess whether or not its regulations are of use to the market anymore is important. Part of the reason Meaningful Use even exists is because the market had failed so terribly and that's not for everyone, but by and large the market has. And so what I would agree with is that if it seems like there shouldn't be any certification necessary by the government because there are enough accreditation, certification or non-those types of structured programs, but assurances of the market, but different health IT is meeting the right standards and facilitating the correct capabilities for providers, then yeah, then there shouldn't be these regulatory pathways that are necessary. But because meaningful use statutorily exists for at least another couple of years, through 2021, I don't know that saying that the Certification Program shouldn't exist will work, but rather that they should really focus on goals that HHS is looking to accomplish and making sure standards exist, but letting technologists and vendors figure out the solution would be my...

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

Yeah, in – thing that Meaningful Use is independent from certification, giving the justification that I have to have certification in order to do meaningful use, and what was the failure in the market that meaningful use was addressing?

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

This is Jodi Daniel, and Steve, feel free to jump in, but there is – ONC is required to create a Certification Program and meaningful use is tied to certified EHR technology. So, there's actually a statutory basis for what we've set up. So, I just wanted to put that out there.

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

(Indiscernible)

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

When we decided initially that we were going to even contemplate things that would require statutory changes, so I don't think that would preclude this, but I think Keith what you're hearing is a number of people wondering how practical this suggestion is in its current design. And I wonder if you would be willing to sort of go back, cogitate on it a little bit and think if there's maybe a way to frame this that can get at the objectives you want to get at, yet maybe without doing quite so radical surgery as you've proposed here. Are you willing to take this back and think about it some more with this input?

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

Yeah, I can. Again, I think that what we were asked to do though was to – if anything, I understood that what we were doing is that the regulatory framework may not be working and I just want to note that in this case, I – yeah, I can go back. I'm just worried that in time you have somebody that – a small group defining functional requirements which is inherent in a certification process, you get these types of effects. And that's why I'm saying that that approach, I don't think is helpful.

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

I understand that, but as a...

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

I'll rework it.

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

But yeah, we're a consensus group...

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah, and to clarify Keith, I would strongly support saying what you just said about not requiring functionality requirements or prescribing features, definitely. And I would also support proposing a framework within which the certification program – itself or just figuring out how that would work, given the fact that there is a Meaningful Use Program that requires a Certification Program and that if CMS continues to create meaningful use requirements, how we might address the sort of complimentary need for certification. That maybe that could be something that's changed over to a private – or whatever, but I just wanted to make sure that our language wasn't just sort of impossible, or at least it was – that...

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

Okay.

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

And I – thank you.

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

We do need to...

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

I'll go ahead and do that.

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

So, I'm going to summarize the changes to this slide. I'm going to add a row at the bottom, a new row on the – suggesting that ONC make greater use of its capability to review and periodically adjust, through these program reviews, the regulatory requirements, say that that's a core strength that we would like to see used more. And then Keith is going to cogitate on the Certification Program line and try and figure out some approach that might produce a consensus with the group. So let's go on, we only have about five minutes before we need to turn it over to the public. The FCC slide is obviously much shorter. I think Julian you wrote this language, am I right in that, and would you mind just asking – summarizing it and asking questions on it?

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

Sure. What was discussed was the challenge that we're facing currently in healthcare facilities, but undoubtedly we will see this more in other – and health environment of the managing potentially interfering or actually interfering sources of wireless communication and electromagnetic compatibility challenges. It's well documented it is a significant problem. So you see that when deploying – as we increase the number of wireless transmitters and receivers, certainly in the hospital, things like infusion pumps that are increasingly wireless and they use the wireless capability to communicate – that as information for programming pumps, for uploading drug libraries, for sending information to the electronic health record. And there are challenges for manufacturers who assess the performance of a device, how the device will perform once installed in a busy location with many other devices that are wireless, and there are problems for health delivery organization to identify the source of a problem, document, analyze and report. And clearly this has been a vexing challenge already for health IT. And it's labeled here, as post-installation surveillance to help emphasize that aspect of the challenge as distinct from other pre-installation testing that would be required as well. I wonder if this slide really should include an additional line so there's pre-installation wireless test as post-installation. Let me open that up for comment.

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

Yeah. And by the way Julian, please feel free to propose those other topics that you just rattled off.

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

Okay.

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

We only have about a minute or so, but anyone have any comments for Julian?

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

This is Anura again. Would it be helpful at all to introduce language using the term safety and effectiveness into this, to help correlate what FCC is doing to what FDA is doing to facilitate interaction through the MOU?

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

That topic might fit better under the cross-agency issues. We talk about it in connection with the two coordinated reviews. I don't know, maybe it would fit better here, I don't have a strong opinion, I'm just reminding everyone that we've got this other slide.

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

Yeah, it's a little tricky in that these things can affect safety and effectiveness, but one could assess performance – I don't know, take that back. Anura, you ask a good question, tough to answer, worth thinking more about, maybe we could discuss this a bit more offline and see how we could formulate an update.

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

Sounds good, thanks.

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

Okay, we're going to need to make sure we allow some time for public comment. Let me just kind of summarize where we're at and what the next steps could be. So, I think that through the course of these two hours, various people have taken assignments to make revisions to this. I think Keith is going to work on that final line on ONC. I think Jarrin is going to work on the slide regarding FDA program. I think Julian is going to work both on ONC slide; also the reporting slide and the FCC slide.

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

Um hmm.

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

I'm going to work on the first couple of FDA slides, trying to put some context there and put some context under the big picture stuff, because that was – we actually started with the big picture issues and I think people made several good, helpful observations. So let's just talk about mechanics. If everyone who's taken on a task could get their revisions to me by say Tuesday, close of business, on Wednesday I could turn around another draft. And that would give everyone a bit of a chance to respond by email, if they have kind of word-smithing that they want to do, and I'd really like to give everyone that chance before we're on the call, because the call is Friday morning, and it's our final call, we only have one more call left. And we kind of – we need to make decisions and finalize the work product on that call. So I'd like to have as many of the issues nailed down before then as we can.

So if everyone can get me their stuff by the end of the day Tuesday, Wednesday morning I'll distribute to the whole subgroup the next iteration. And then over that next day, if anyone's got word-smithing or specific changes that they want to see, if they can send those to me by email, then right before maybe the Friday call, I'll get out yet another draft with any changes, and we can then consider it as a group and hopefully reach some conclusions. And what we may do is, I don't know, try and figure out if we can do the webcast in a way that allows for real-time editing, so we can actually come to closure. We'll have to look into that, but that's the plan. How does that sound to everyone? Is that going to work with everyone's schedules?

Julian M. Goldman, MD – Medical Director, Biomedical Engineering - Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
Sounds good to me Brad.

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

Great, so why don't we do that and unfortunately, we only have a couple of minutes. I apologize to anyone who wants to make a comment, but I'll certainly hang around as long as necessary. So, can we turn this over to the public for dial-in?

Public Comment

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

Sure. Operator, can you please open the lines for public comment?

Rebecca Armendariz – Project Coordinator, Altarum Institute

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue. We have no comment at this time.

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

Okay. And again, I'll say to anyone in the public, I welcome written emailed comments as well, especially now that we're in the final stretch, trying to get all the good input that we can. So we'll proceed as I summarized a moment ago and we will all talk again on Friday. Sorry for the West Coast people but it looks like it's fairly early in the morning on Friday, so Lauren, my apologies and Joe Smith and whoever else is on the West Coast. But, hopefully we'll wrap it up then and then we'll come together as a full working group and tie it all together. Thanks everyone, hope you have a wonderful weekend.