

**HIT Policy Committee  
FDASIA Workgroup  
Transcript  
August 13, 2013**

**Presentation**

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

Good morning. This is Mike Lipinski with the Office of the National Coordinator for Health Information Technology. This is a meeting of the Health IT Policy Committee's FDASIA Workgroup. This is a public meeting and there will be time for public comment at the end of the call. To remind everybody, the meeting is being transcribed and recorded, so please remember to announce yourself when speaking. I'll now take roll. David Bates?

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

Here.

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

Anna McCollister-Slipp?

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

Here.

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

Anura Fernando?

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

Here.

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

Elisabeth George?

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

Here.

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

Esther Dyson?

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

Here.

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

Geoff Clapp? Jackie McCarthy?

**Jackie McCarthy – Director of Wireless Internet Development – CTIA: The Wireless Association**

Here.

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

Jared Quoyeser? Jeffrey Jacques?

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

Good morning.

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

Good morning. Jonathan Potter? Joseph Smith?

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

Good morning.

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

Good morning. Julian Goldman? Keith Larsen?

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

Good morning.

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

Good morning. Lauren Fifield? Martin Sepulveda?

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

Good morning.

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

Good morning. Mary Anne Leach?

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

Here.

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

Mary Mastenbrook? Meg Marshall?

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

Here.

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

Meghan Dierks? Michael Swiernik?

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

Here.

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

Michael Flis?

**Michael Flis – Regulatory Affairs Director – Roche Diagnostics**

Here.

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

Patricia Brennan? Richard Eaton?

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

Here.

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

Robert Jarrin?

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

Here.

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

Drew Hickerson?

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

Here.

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

Todd Cooper?

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

Buenos dias.

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

Mohit Kaushal?

**Mohit Kaushal, MD, MBA – Partner – Aberdare Ventures/National Venture Capital Association**

Good morning.

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

Good morning. Paul Tang?

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

Here.

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

Bradley Thompson?

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

Here.

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

Jodi Daniel?

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

Here.

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

Matthew Quinn? Bakul Patel?

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

Hi Mike and good morning everybody.

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

Good morning. Turning to HHS staff, ONC staff?

**Steven Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator**

Steve Posnack.

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

Elise Anthony.

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

FDA staff? FCC staff?

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

Matt.

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

Any other HHS staff on the line? Okay, I'll turn it over to you David.

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

So thanks so much, Mike, and I want to thank everybody again for all their hard work. Presented to the Policy Committee last week and was a busy agenda overall, the report went very well. We received a lot of positive feedback in general and then, not surprisingly, lots of suggestions about how to make the report even better and clearer and we'll go through some of those today. In the first part of our agenda today, I'd like to go through the comments from the Policy Committee and talk a bit about how we might respond to them and talk about whether there are additional things that we need to do in the report to respond to them. And then second, I want to go through some changes that I've made already with respect to specific feedback that came in on the current slides. If you have small, specific changes, especially errors or clarifications, I would suggest just emailing me, but if there's anything that will affect our intent, I would suggest bringing it up today.

In addition, the groups are working on their two-pagers and for the subgroup leads that we have, I wonder if you could just say a word about where you are with those or what you're thinking is about those. Brad, I know you're on, do you want to –

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

Is Julian on? I didn't hear.

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

I didn't hear either.

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

Okay. I don't know, somehow there was confusion, I guess, last week. We've got a draft and I was on vacation and I thought Julian was distributing it, but I don't think he did. I asked Jarrin and he had not received a copy, so I'm assuming it's not gone out. So, I have it, I can send it out. I can send it out now, but we haven't done that yet, so we haven't gotten any feedback yet from members of the subgroup, so, my apologies to everyone.

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

No problem, it's – this is a heavy vacation time and I'm pleased that we're making forward progress. Paul, I know you're on, I don't know if Keith is on.

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

I'm on.

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

We – for the risk matrix, being distributed with the risk matrix itself is a two-pager that's primarily a definition and some elaboration on the – how do you use this. So I think –

**W**

Louder please.

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

The group's been receiving that and I think David that seemed to meet the intent of the two-pager and happy to expand on anything that you think is appropriate.

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

Okay, and Keith, any –

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

Yeah, I haven't supplied the two-pager yet. I've been off on some small vacation, but I'll get that in.

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

Okay. Okay. Great. Okay, so that –

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

This is Patty; I just want to let you know I'm here.

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

Okay. Patty, and do you want to say a word Patty?

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Just that we've been really pleased about the additions to the slides of the examples outside of the EHR. And I don't know if you've brought it up yet, but there have been some issues raised by the Janet Marchibroda and the Bipartisan Policy Center about how we're interpreting this – I'd like to make sure we address on this call today.

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

Sure.

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

David, if I could – this is Brad again. If I could ask a clarifying question, the two-pager that we're working on, when people say two pager, is that meant to be words of limitation, are we limited to two pages, because we were working on it last week and we were really having to cut it down to get it to two pages. We did, but now when I send it around for comments, I just want to know, are we limited to two pages?

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

Well the intent is to try to stick to two pages. I understand it could be much longer than that.

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

Okay, that's actually more work because refining it down to two pages requires a lot more editing so if we're concerned about the work, then actually I would say let it grow beyond two pages, but I just want to understand where the two page thing came from.

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

This is Esther. The challenge is, if you want people to read it honestly, two pages are more likely to get read. And then my suggestion would be add an appendix or something, but for something to have impact, shorter is better and it is worth the work. Just stick everything else in an appendix or something, but, give them two pages so they really get our point, and then refer to the rest.

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

Actually it seems to me the PowerPoint serves the purpose of the crystallization for people who are attention challenged, they can look at the PowerPoint. But – I mean, these are really complicated topics, very big, complicated topics and so I'm just worried that artificially cramming it down into two pages is difficult. We could even add an executive summary for those who are attention challenged.

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

Yeah. Okay, I mean, make an att – do an exec summary, but just make sure that there's something that people will actually read.

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

This is Jodi Daniel, if I can jump in. I mean I think to kind of play off of David's comment, I think the goal is to have an opportunity to explain some of the more kind of – the more challenging issues, provide a little bit of context for some of this. I don't think it has to be comprehensive and touch on every single point that's already in the PowerPoint, obviously we have that as well. So it's really an opportunity to provide context or to flesh out something a little bit more detailed than you were able to in the PowerPoint where there was kind of a more rich discussion. I don't think it has to – you're right, if you try to put the PowerPoint into a two-page document for each subgroup, it would probably two pages at least. So I would say pick the things that are most important to communicate and it's really to help us to make sure we have the understanding of some of the issues that you want to make sure are brought to our attention.

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

Okay. So one general point, we did not say much in the report about interoperability and Joe Smith had a comment here, especially around interoperability with respect to devices. Do you want to say a word about that Joe?

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

Oh sure. So earlier in the year, as part of Congressional testimony, we worked out a little bit of a background paper on the value of medical device interoperability for safety, for efficiency and for savings in healthcare dollars. And came up with a pretty careful analysis that made it look like there was about 35 billion dollars on the table that would largely accrue to hospitals if we could achieve medical device interoperability. We've had a fair bit of discussion with stakeholders, the vendors, the hospital system CEOs and each one of the regulatory agencies around the table today and the upshot of that is we've gone forward with the notion of setting up a standalone organization, the Center for Medical Interoperability. Which is dedicated to this concept of achieving true medical device interoperability so that information from the many devices that surround patients in hospitals can smoothly and functionally interoperate between those devices and then have all of that information achieved back in the medical record.

I mean we've largely missed an opportunity for interoperability in electronic medical records and I think there is an opportunity to achieve such in medical devices. And so just a bit of that level of awareness. And also I think perhaps in this – in our work together we can flag the potential value of medical device interoperability in terms of its impact on safety and efficiency and at least for our agenda, the notion of pulling some dollars out of the healthcare system. And so I'm not in any way trying to make a splash or make this about our efforts, it's just that we see this, we've heard this in the conversations here in this call and in an activity organized by the FDA the Medical Device Interoperability Coordinating Council. And we've had enough stakeholder verification that we've set aside the money, created the organization and have started to hire people into that organization. So if there's a way of reflecting that tone or sentiment in our work together, that would be wonderful.

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

And this is Anna, David, I just wanted to emphasize that that's a critical element as well from the patient perspective. For those of us who have multiple medical devices for chronic disease, it's absolutely critical to empower patients to be able to encourage interoperability amongst medical devices.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

This is Patty Brennan. An so somewhere in the introduction to interoperability it seems to me it would be important to lay out the common problems of interoperability in one sector of our field is in medical records interchange and another part of our field, it's device-device. And it would be useful just to specify that we're speaking to both of those.

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

Good point. Okay, any other thoughts or comments about that? Okay. So what I'd like to do next is go through the Policy Committee's observations, questions and requests. And I want to make sure that we move through these and then we get to the slides and we'll move through the changes in the slides, too, and let people come up with – I'll open it up more generally. So the first point that was brought up was that we were asked to provide more clarity on HIT that is out of scope, in particular what HIT would be considered a medical device and out of scope for even enforcement discretion. I guess I felt like we were – we tried to be reasonably clear about that, but would be interested in thoughts about how we could be more clear about it.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

David this is – I should bring up Janet's comments.

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

Sure.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Okay, so some of you on the workgroup have received comments from Janet Marchibroda directly, but it's specifically speaking for the Bipartisan Policy Center, and her concern is that we need to be much more clear about what aspect of electronic health records, health information systems and health information exchange has to be listed with the FDA. She's referring to slide 12 of David's slide deck, if those of you are looking at his slide deck. And actually, now it looks like it's slide 11 on this slide deck. The concern is that we have scoped HIT too large and that haven't really helped advance the thinking about when is an HIT application a medical device? When is it something that presents risk, but is not a medical device and should be regulated. And when is something – an HIT application out of – not needing to be considered under the regulatory framework.

Janet also raises concerns about aspects about consideration of EHRs in particular as a medical device might make it subject to the 2.3 percent tax on medical device revenues. There's a concern that we've also expanded the interpretation of what constitutes – and how it should be presented forward. So let me just stop there and say, if I'm understanding correctly, David, we're asked for – to give guidance about essentially three classes of HIT related – HIT applications or entities, those that must be regulated but are outside of this risk-based regulatory framework that is a medical device. Those that are HIT but not – but should not be considered – excuse me, do not need to be considered regulated under this structure and then those that should be specifically regulated under this risk-based structure.

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

So let's actually look at slide 41 if we could, because slide 41 is where we get to the specific recommendations about this.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Okay.

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

And I've – to – I think that what we're trying to say, and people should correct me if that's not accurate, I mean we tried to say that HIT should not be subject to FDA pre-market requirements, except in the three situations as listed here. We've been asked for kind of even more clarity about that, although I felt like we were reasonably specific. The point about a vendors being required to list their products moved out of the HIT – sorry, out of the FDA recommendations, because I don't – I think our intent was not to be specific about who the product should be listed by. I mean what we need is some sort of registry or list of the products that – which could come from ONC, it could come from other places, but we need – to enable the post-market surveillance, there has to be some list or registry of what the products actually are. And so the changes on slide 4, which are not really content changes, just changed basically the way the bullets – the indentation of the bullets, are intended to address this issue.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

So what you're recommending David is that we're – slide 4 on mine is charge – is that the one you're intending to speak to, where we changed the bullets?

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

Slide 41.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Forty-one, okay, I'm sorry, I thought you were referring us back to a different slide.

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

No. The charge hasn't changed.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

No, I didn't think so. Slide 41 is measure of regulatory impact on innovation? That's the slide 41 in the deck that I have from the 10<sup>th</sup> of August.

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

You're looking at the wrong deck, I think, it should be the 11<sup>th</sup> of August.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

All right –

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

The heading is specific recommendations –

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Okay, I will find it, so I don't want to hold things up. But you're sense that the concerns that have been raised are – by Janet's group are actually not issues right now because we've actually addressed them?

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

No, well, I'm interested in other's opinions about this. I think it's an important point.

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

So this is Paul Tang –

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

David, this is Jared Quoyeser with Intel. Quick question regards on slide 41, we have it “to be defined clearly by FDA,” is there aspects of, in consultation with ONC or is it definition defined by FDA solely?

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

Well –

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

I would recommend it be in consultation with ONC.

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

Yeah, no, I think that – I definitely think it should be done across agencies.

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

Okay.

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

Yeah.

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

And it’s not clearly defined across the presentation.

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

This is Paul Tang. As far as Janet’s questions, I think this – it’s a question of potentially misunderstanding, and we’ve gone through it here, but the broader public hasn’t had the opportunity – had the benefit of hearing our discussions. So it sounds like we should be clearer that even if it is part of the risk-based framework, it doesn’t mean that we’re recommending that it be regulated in the traditional sense.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

That’s correct Paul.

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

I think we have three categories. One is whether it’s even defined as HIT –

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Right.

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

– and that’s, I think, the biggest thing that the taxonomy group did for us is say, claims-based process – claims systems are not “HIT.” So that’s one group. And then yes, that does mean it’s excluded from the risk-based framework that we are talking about. The second distinction is – in our risk-based framework, we would recommend not be – we would recommend having enforcement discretion as an example, and hence not be regulated at the current time, and others, which we said, probably should be at least examined, if not regulated. But I think people are substituting be part of risk-based regulatory framework as us prescribing it being regulated, and maybe should be the point of greatest clarification. Because I think that, as you said, we have addressed this, but maybe we haven’t made clear in our words, or at least – the biggest thing is, being part of the framework does not mean being recommended for regulation.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Right, I agree –

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

Yeah, thanks Patty. So the point about device – the FDA has defined a device, that’s – we’re not changing their definition, it either is or isn’t a device in their definition. They’ve always had, we’ve already agreed up front, they’ve always had the authority to regulate, so, we’re not changing that, we’re just – and I think that’s what Congress asked us to do, is provide input about a framework. So how would they decide between the various kinds of regulations, the requirements and where enforcement discretion might lie? So I think we’ve said all those things, we probably haven’t been as clear as we could, for a public who hasn’t been listening to all these conversations. If I got that right, even –

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

No I think that is right.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

It sounded right to me, but others might want to weigh in.

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

This is Mary Anne Leach. I just – I’m looking at slide 13 where it’s a little more graphically represented and I think maybe we carve up this slide a little bit with what was just discussed. I think Paul, you brought this up, HIT – what it’s not and where it’s excluded, like claims, HIT but not regulated and then examined but not regulated. I mean I think there were some sub-categories that we could put into the in scope, out of scope columns, maybe that a picture might be easier to communicate than text.

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

This is Jodi Daniel, if I can jump in. Let me tell you what I think I’m hearing, which is there are certain things that are out of scope for Health I – that are not Health IT, so they’re just out of scope, totally. There are things that, once we look at what’s in scope, there are some things that are currently – that are devices and some things that are not. Obviously if it’s not a device, it wouldn’t be subject to FDA authority, but it could be subject to other kinds of oversight, whether ONC, private sector or something else. If it is a device, then there are some things that are already being enforced by FDA, and there was some conversation about those things. And then there are some things that may qualify as a device and Health IT, but they’re in a gray zone.

And in that gray zone, I think there were – what I saw in this slide was lots of discussion about the kinds of things that you can do, depending on the risk, for addressing that gray zone. And the who was not clear to me, and I think that it's fine to leave that open, which is, maybe as David was saying, listing is appropriate, but it doesn't mean that it has to be listing by FDA, it could be listing on our CHPL, our Certified EHR Products or it could be a private sector listing. So I wasn't interpreting the recommendations to be its in scope, therefore its FDA but more it's in scope, it is not – stuff that's not currently being overseen by FDA or ONC and then how do we handle those? Well there's a risk matrix that you all came up with, there are some ideas of how you can manage that risk and then there's a third question which is, who would do it?

And it think they've all gotten conflated a little bit. So Steve and I were talking about this, we kind of thought as almost like the football field with the two end zones, there's like FDA over enforcement on one side and ONC oversight on the other side. And there's kind of the big football field where there's the gray area of things that are Health IT, but that haven't really been subjected to oversight directly – enforcement directly by either agency. And the questions that I've been hearing you all debating are about how to manage that gray area, how to understand what the risk is, how to understand what things can help to manage the risk. And then the third question, which the agencies will struggle with is, who? And in some cases I've heard who is the private sector, in some cases I've heard who is ONC or FDA, but I think that we're – the confusion was that some folks were thinking risk-based regulatory framework that gray zone then means it's FDA. And I don't think that's what I've heard you all say, but I would be interested in hearing folks talk about that a little more so we can have clarity.

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

So this is Brad. I think the source of – I agree with everything Jodi just said and I think we're all, in fact, saying the same thing. Paul said the same thing. I think the source of the confusion is the top of slide 11, because the top of slide 11 makes it sound as though what the Taxonomy Committee did was very simplistically bucket "A" or bucket "B," one of two categories. And as Jodi just said, that's actually not what we're trying to do, we're not trying to sort it on that basis. It's much more nuanced than that. So personally I would get rid of the top of slide 11 and instead say something like taxonomy, the group evaluated technologies for possible regulation along the following guiding principles or something, but not make it sound as though we've put it all into one of two buckets. Because Jodi just explained, we didn't do that.

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

So can I make one suggestion perhaps along those lines, and maybe this will clari – so what I heard Patty agree with is, what the Taxonomy Group did was separate those which are – fall under HIT and those which do not.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Yup.

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

Is that right Patty?

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

That's definitely – that gave 8 or 9 characteristics.

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

Correct. So I think that alone would actually solve half of the definitional confusion. Because people interpreted slide 13 as being in and out scope, they interpret those words as saying regulate on the left and don't regulate on the right, which is – which went beyond – which wasn't what we meant. So if we make it as simple as they just helped us scope what is called HIT that would probably help with some misunderstanding about that first step.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Paul, I hate to disagree with you – once again. Slide 12 is the characteristics of what characterizes something as HIT or not. Now I may have gotten this confused, and David, you'll have to set me right, that what's on slide 13 is something that is an example of actually the word would be – I think that it's a set of products. And we are saying that these – this column on the left, these are examples of HIT and may be subject to risk-based regulation.

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

Yeah.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

And on the right are – they are HIT, but they're out of – they're not to be subject to risk-based regulation. So we're not saying there's no HIT in claims processing software, we're saying that for the purposes of this risk-based regulatory framework these are information technology services that we're not going to be putting in scope. And this is where it does get a little bit – it gets a little bit confusing because if you go down the characteristics on slide 12, clearly the right hand column of slide 13 shares enough features with each other that indicates and of course these are not HIT entities to be regulated or to be considered for regulation. The ones on the left have to be considered, but may be regulated in some other way, not just by the risk-based regulatory framework. I'm getting it confused again.

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

Patty, this is Bakul, can I ask a clarifying question?

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Yup.

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

When you, and I'm on slide 12 by the way, when you – on this slide it says defining characteristics of Health IT –

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Yup.

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

– the word Health IT, are you referring to technology or associated characteristics with technology? I think that may be one of the confusion points, as I'm listening to the discussion here. Because when you look at manufacturer, distribution model, intended use – intended use may be a particular type of technology, but the distribution model and product lifecycle may not necessarily indicate it's a technology thing that you're calling Health IT or not.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

I guess when you use the word technology Bakul, I'm hearing it used quite broadly, so a decision algorithm, for example, which is just a software formulation of logic –

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

Right.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

– would be considered Health I – health informa – I mean if the word technology – then we'll just take that off, but what we were saying is that any entity first to decide whether or not it's HIT should be looked at from these eight perspectives. And that if its – there should be some description of who the user's going to be, where in the lifecycle, that was to account for even mature products may still need to be considered HIT under this framework. We talked about distribution model issues about whether or not someone was providing it free of charge to people in their own practice or their friends versus putting a soft – shareware on the internet versus –

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

Yes.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

So these to me are, if you will, attributes that anything that one wants to consider as HIT should be useful for describing it.

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

I see. So, those may be sort of taking distribution model or lifecycle or something that may be characteristic of Health IT that could be considered – or technology, that could be considered Health IT.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Right.

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

I – no, I get that and I've listened to some of this discussion and I think when somebody looks at this slide and then follows up with slide 13, people are thinking about is it – what the previous slide, how does it represent in the in scope box versus the out of scope box. And that may be one of the confusion factors that we may want to think about clarifying.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

So to me there's – we're going to get into this moving parts discussion again, but there's an issue of what constitutes HIT –

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

Yah.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

And then there's the issue of whether what constitutes HIT is something that should be subject to risk-based regulatory framework or not subject to the risk-based regulatory framework. And it might be not subject to that because it's a device and it's already regulated elsewhere, or it might be not subject to it because it's not used in the process of clinical care, and that's where the decision tree comes into place.

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

I see.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Now where I see...my original understanding of slide 13 was that this was – I would actually change it – completely to take the decision tree idea off of it and just have this as an elaboration – if we made slide 13 just an elaboration of only item number 7 on slide 12. That is, only product categories, then it is likely that product categories in the left side would be subject to risk-based regulation under this framework and it is likely that product categories on the right side would not be subject to it.

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

That would make – .this is Bakul. That would make it clearer for people who have not been part of this discussion at least.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

The one – I'm going to – I will modify this slide David and I'll send it to you and if I've grossly misinterpreted the line of thinking that you have, we can revisit that.

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

Okay. Great.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

All right, thanks.

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

We should move along, but this has been an important discussion. And I think it was really the – this is by far the biggest issue that people felt that we were not as clear about as we might have been. Let's – we talked a bit about the gray areas, so I'm going to actually skip that one. There was a comment that objective certification has benefits, particularly versus subjective and the commenter felt that the federal government should always use an objective approach.

The next issue that was brought up was how the free flow of safety information can be assured. And in particular for – if the databases are going to be publically available, how should that information get there? And there was a suggestion that we consider outlining suggestions about how to organize this. There was a bit of that, but we didn't get into it very deeply, and there were questions like should it just be spontaneous reporting from vendors or should it be from frontline users. And the FDA presented one really fairly impressive model set of mechanisms which has been used for devices, and then there were questions about whether that approach could be taken and used as a model and modify it or whether we need something else. So let me just stop there and get people's thoughts. It seems to me like this is one place where we might want to supply some more detail.

**W**

Which slide are you on David?

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

This is not really related to a slide, here we're on the comments from the Policy Committee. It's addressed in, let's see – it's addressed on one of the slides – let's see, I'll tell you in a second – but we don't get into very much detail on it, it's addressed on slide 40. And we were just asked to supply – consider supplying some more specifics about how this would actually work. So we really just describe it – the challenges, but not what we think a solution should be.

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

One possibility – this is Paul Tang – is do we agree with the IOM recommendation and can we – and if so, could we endorse that and then that provides more of the details? If not, then I think we might be asking ourselves what more of those details are.

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

I mean I think we – I personally do agree with the IOM's recommendations. And Paul, do you remember some of the specifics around that?

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

Yeah. So the idea was that in order to feed this system, and this goes along with the learning health system, there has to be reporting that can be aggregated and is protected from a liability point of view. So one of the characteristics was the reporting from vendors would be mandatory and the reporting from users – end-users, would be voluntary. But there is a place for this information to go where it could be aggregated and analyzed, in a non-punitive way. And sort of the model was aviation, because it's non-punitive – in fact, there – protection, and that the investigation, the analysis is also non-punitive, it is not connected with an enforcement agency, that's the NTSB model, so that the information, the learning can be assimilated and redistributed to people who can benefit without a judgment. So that's sort of some of the principles that were in those recommendations.

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

So comments about those.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Hard – David, this is Patty. It's hard to be against it, I guess the question is, if the Policy Committee is asking us to provide some operational guidance about this, it seems a little bit out of scope to me. I mean I think we can make some –

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

What do you mean by saying that it's out of scope? I mean, it's a set of principles around how to potentially set up something that would ensure free flow.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Well, maybe what I mean – when I say out of scope, it just seems a little more detailed than I think – than I'm understanding where we are. So it may be that if – the principles are fine, I guess the logistics is what I don't want to get into. So I can – the principles, but I don't want to say it should be anonymous website, public reporting or it should follow the FAA structure.

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

I think we'd be putting it forward as a model, but –

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

Yeah. How it gets implemented would be something that the tri-agencies can work out, and I think ONC, even in its Safety Plan, has put forth some ideas. I think Patty the reason that we might want to provide at least those principles, or endorse somebody else's principles, is because a big chunk – my understanding of where we ended up is this big football field we actually recommended. And I think this is the combination of the Safety Workgroup and the Regulations Workgroup ended up with this strong, robust surveillance as a main part of our recommendations for the framework. Therefore people would say, well how would you – what would constitute robust surveillance? And this is pointing at something that some other group spent a lot of time on, if we agree with those principles. That's why I think the –

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Yeah, okay, I see what you're saying, I see what you're saying. So you're really saying, it's really the principles and the framework, it's not going into saying and this is vendor we should use or whatever.

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

Right. Oh yeah.

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

So Paul, this is Bakul. Is it possible for the group to articulate? I mean, I keep hearing and I've seen in the IOM report the reason for being non-punitive, etcetera. But given the principles about – I mean articulated in the principles that we have from the statute about risk-based, patient safety, enhancing innovation and avoiding regulatory duplication, if those principles were lined up to justify one of those big causes or big asks, I think that would be very helpful.

**Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.**

This is Lauren Fifield. Can you guys hear me?

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

We can.

**Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.**

Okay. Great. I think that the general concept of reporting as outlined in the IOM report works, but I think that – I think it would be important to add a few more implementation features. One of the things I think is a little problematic about saying that it's vendor-only reporting is that while that might work in a medical device setting where a medical device might have a more set constrained intended use, in the context of an EHR or Health IT software, it would be very difficult for a vendor to submit data that would be at all relevant. Tracing information back to what was happening in the clinical setting without that user generating a report would make the data sort of useless. And so I wonder if the intent was not to say that it should be vendor submitted or transmitted, but user reports generated. And I also think that if we really believe that Health IT software, while it might not be regulated in the same way that an FDA medical device is, it's part of a broader health technology ecosystem, I think that there are going to be big issues with aggregation.

So not just analysis, but aggregation between the current kind of MAUDE database that medical device manufacturers submit to and their recommended PSO framework that the ONC recommended in their Health IT Safety Plan, I think there's also by way of saying that vendors should submit, a huge cultural element that would be lacking. There's real problem or real opportunity for problems with users, so providers, clinicians thinking that vendors are, regardless of whether it's punitive or not, reporting things on their behalf that they don't and – in the transportation industry, the culture actually really relies on the end-user, that being pilots and flight attendants to actively report when they see something. And then finally, I think that the sort of entity who has jurisdiction over creating common format so that the data submitted is standard and can be aggregated and analyzed, isn't clarified and is a bit confused by the PSO Safety Act of 2005. And so I think it would be worth letting the agencies sort of specify agency, the government, the private sector, whomever, a way to get common format. So, I think that in general the concept of the IOM report might work, but there are a lot of gaps that I see.

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

Yeah, it's just a chance to respond –

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

Go ahead.

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

– to Lauren. So just to add some more detail from the IOM recommendations, one is the user – the end user is encouraged to report, so it's just voluntary for the end users and mandatory for vendors. And what vendors report could be – originate from – the other piece, as Lauren correctly points out is, there's so much detail and the context for a report. And so the other arm of that is – that's part of the analysis arm, is that they go back, just like NTSB does or the aviation, go back to the reporter and get some of those context, because that's important analysis, as Lauren points out. And the other piece is AHRQ is sort of the owner of the common format, so yes, there would be some way that would have to evolve, but a way to capture information that's important for the aggregate analysis.

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

Hi, this is Anna McCollister-Slipp and part of what I think would be helpful is if we gave a little bit more specifics. And one of the things that I'm a little puzzled by, frustrated with is that we're looking at – perhaps just confused, is that we're looking at NHTSA and – and NTSB and those guys, which I think is completely appropriate and helpful. But we have a whole collection of information technology models, specifically ones that consumers are familiar with like the rating system, where users can provide as little comment or as much comment as possible, has created this whole ecosystem of constant iterations, constant improvement and constant development so that basically we're asking everybody to provide comments when they find errors in the system.

It's not an attempt to attack a particular manufacturer or, in this case, an EHR vendor, it's to say, hey, when I was inputting patient record "X," I noticed that this didn't work. And it gives the ability for more and more people to easily report, and to provide input, so that the vendor, without any kind of punitive environment, whether coming from FDA or ONC or AHRQ or whomever, can then correct those fixes. And it becomes a much more dynamic, iterative process and that is what enables the consumer information technology world to grow and to foster and become the ecosystem that it is where you've got this constant development, iteration and growth and creativity. And it's a participatory process, it's not the vendor releases something, everybody waits for the vendor – report on it, FDA to rule on it and then three days later, maybe some errors get fixed along the way. It's where everybody is involved in the process and I think something like that would be incredibly helpful for healthcare.

And again, I've never done this from an electronic health record perspective in a hospital, but from a consumer perspective, as somebody who uses three medical devices that generate electronic data, this would be immensely helpful. Because all of us find things that don't work quite so well, but once the device is – the app is released, it's basically cemented there for another couple of years until the next iteration makes it through the regulatory process. So, I think if we could make some specific recommendations, and I know I keep coming back to this, but I think it would – there are lessons that we could learn from information technology systems and industry that we're not incorporating specifically.

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

Okay. So I think we've a couple of points there. So one, we could point to the IOM recommendations around this, saying that we have certain concerns about the specifics of doing that, and I think we can also leverage what Anna just said, and point out that another adjunct to this would be using an approach like what she just suggested, to help improve these tools. Let's move on.

The next comment that was made related to the coordination of agencies and we were asked to comment about on how the agencies could better coordinate and for what areas and topics this – we think this would be of particular priority. So, do people have thoughts about that? Hearing none – we do have some remarks about that and we can expand on those a little bit. And I know Brad, for example, has thought about this a little bit and I may just follow up with him on this one. Let's also just talk next about liability concerns. We were asked about – what about liability concerns and are there ways to address them, and specifically this related to issues around somebody reporting a safety issue with a piece of health information technology that they were using. And there was a question about, do there need to be safe harbors for vendors who take certain actions?

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

This is Brad. We talked about this just a little bit in the Regulatory Working Group back toward the end of June. We didn't come up with any specific recommendations, among other things we were trying to evaluate whether existing liability laws in effect provided some greater assurance of safety and effectiveness such that regulation was less necessary. So we looked at it from the opposite side, under the duplication charge of the section 618 statute. And we didn't reach any definitive conclusion, as I recall, on that.

There is a longstanding principle in medical device law that in medical device reporting, there needs to be some allowance for the fact that people need to be able to report relatively freely, without having to go talk to their product liability lawyer and wordsmith everything that they report. So it's been a very useful principle to allow reporting, in that sense, in a non-punitive environment where you don't have to worry about plaintiff's lawyers being able to take it and try and make something out of it. So from that standpoint, it would seem to me sort of equally applicable to any HIT that gets folded into the same kind of reporting obligation. I'm expressing that as a personal view, we didn't discuss that as a sub-working group, so that would be my only thought on it.

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

Okay.

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

One of the concerns I've heard from vendors, in terms of PSOs, the PSOs protect the provider, but does not protect the vendors, maybe that's something that needs to be addressed. The interesting thing about the aviation model is, you actually get – they actually encourage report – the only way this works is if we have enough data to do the analysis and learn the lessons. And one of the ways they chose to promote reporting was to actually give credit for reporting on things, even if they – if you're caught speeding, but if you report it, you actually wouldn't be prosecuted for speeding, if you report it within a certain amount of time. So interestingly that gave more incentive to report, even if it incriminates you on some mild things. You don't escape crimes, but you escape, I don't know, these are my terms, civil infractions if you report in a timely way, and that really boosted the reporting and hence the ability – the amount of data that was available to mine for the lessons and knowledge. So I don't know how much of that we can take advantage with the current thing, the only thing that seems missing a bit is the protection of vendor liability for what they submit to the PSO. But it can have this sort of as Brad was saying, it can have this salutary effect if we have the right protections and incentives in place.

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

This is Keith Larsen. There was another concern that was raised which was that by having a freely reporting system, does it become a basis of liability, not necessarily a report – a vendor report, a series of user reports that then raise the liability of the vendor. I mean that was expressed in the meeting also. And especially when such reports again were incorrect, they were citations or that and how does that work in the same liability model?

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

I mean it seemed to me that the way that that would work is that it would go through the typical legal process. If something happened, like it was found that there was a systematic problem with a vendor, then they probably should be liable. So I wasn't sure that we needed any specific exemptions around that.

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

So I guess we ought to just be clear as to what the potential for non-punitive – what that means. So if I'm operating a medical device or HIT and it hurts somebody, okay, I can't help myself by reporting it and therefore somehow insulate myself from liability. I mean the injury that I caused somebody is going to create liability and the reporting doesn't somehow save me from that liability. Further, if I report it, the fact of the incident is then out there, so any plaintiff lawyer can go and read those things and see what happened and then investigate, and they would maybe bring an action against the company and then through the court's discovery, they would find out all the details about it.

Really all we're talking about is not using the statement in the report as evidence in a proceeding against a company. So that's some benefit, because it means how you word it isn't quite as important, if you have that protection. But that's all it means, you're still liable, you're still putting the information out there, people can still use that information to investigate you. It just means that the actual document that you submit can't be used against you in a court of law. It's a fairly narrow benefit.

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

Okay. Let's move on. Next thing that came up was related to labeling and someone noted that there are obviously FDA requirements for drug labeling around intended use and we were asked could such a process work for HIT and/or devices? There is intended use for devices, as I understand it, it didn't make sense to me to expand that really to HIT, but –

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Doesn't make sense to me. Did they give any thinking about it?

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

I cannot remember more than what I've just said, really.

**Lauren Fifield – Senior Policy Advisor – Practice Fusion, Inc.**

David I also think that there was a question about the device labeling intended use and potential liability implications so that if the health IT wasn't used per its intended use specifications, that as is the case in the world of medicine prescription, that there are additional liability implications.

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

Um hmm.

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

This is Elisabeth. I think the other thing that was here was is with medical devices, if there is off-label use that medical device manufacturers do have obligations as to what we're supposed to do with regards to that, both in the aspect of communicating to the user of their off-label. But if we then determine that it is going to be consistently utilized off-label, then it's our obligation to then resubmit our devices for – with a new 510K for that new intended use. And so I think that – so we already have that and those of us that have medical devices that are Health IT, we do that already so I'm not sure I understood either. I was at the meeting and I'm not sure I understood where they were going with that either, David.

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

Okay. Thank you.

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

Anura Fernando. Just one thought here, I'm not sure how the Policy Committee was thinking exactly, but one possible way to view this could be looking at labeling as a mechanism for coordination across a system or a means to facilitate systems integration. If we look at the factory automation industry, for instance, and we look at safety systems that are put in place in factories, you have things like punch presses and then you have what are called light curtains that if somebody gets too close to the machine, it'll shut the machine down. When you have two different vendors providing something like the punch press and the light curtain, the labeling on the products, in terms of capturing key safety attributes and communicating those to the system integrator, become very important, and so if we look at the analogs in the healthcare world, when you have to deal with products from disparate vendors as a systems integrator, having that minimum safety information available on labeling related to intended use and indications for use could be useful.

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

This is Paul. I have a couple of comments about labeling. One, I think labeling was meant to be used in a good way, i.e. reinforcing our transparency recommendations because – and we even defined a little bit, at least in the two pager for the Risk Group, what do you need to be transparent about or what it's helpful to be transparent about. Another interesting thing that did not come up in the Policy Committee, but could be a bug turned into a feature example, one of the concerns or potentially criticisms of HIT are in increasing cost, and we've all recognized that there are fraudulent ways of doing that and there are ways of it being just a reflection of better documentation. There are products, I think, that are marketed to increase charges, it would be useful to have those labeled as such or, if it's not labeled as such and the vendor's promoting that in "off-label use," that also might be an interesting or useful concept. And I'm not sure I'm being very clear, but in a sense you want to promote what you're intending to do, we should have recognition of your promotion of something that your product does not intend it to do. So if it's intended to help you take care of patients, it's not intended and you should not be promoting it for increasing healthcare charge costs or something.

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

I'm struggling with generalizing the concept to HIT, because it's used in so many different ways.

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

Yeah, as – this is Anna McCollister-Slipp. As an innovator for a small startup company, we have an analytics platform that one of our clients is using for – for a prototype clinical decision support, we'd never even – it had never occurred to us that people would use it for clinical decision support. If we had to go through a regulatory process and include a label to document, I mean the things that I've seen pharmaceutical company or device companies go through in terms of labeling and negotiating with FDA on that whole process, I mean we would just give up and not allow our product to be used there. So, I think it's potentially very burdensome. I would think it would be similar for like the small app producer, who may have a really good idea for an innovative application that could be used for outpatient care in one form or another. If you have to go through a labeling process that looks anything like the current device labeling or drug labeling, then I just think that would be incredibly onerous and I'm not completely sure what it would provide as a benefit.

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

This is Matt Quinn from FCC. I would just throw in that the labeling requirements and needs of consumers might be different than the labeling needs of professionals. And in the case of some Health IT that is not implemented as sold, there might be a mitigating strategy is the documentation that comes with it. So maybe thinking about what smart and not so smart implementation or configuration options are as part of labeling as well – just some thoughts.

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

David, this is Bakul. I'm just listening to the conversation and thinking perhaps folks are saying, one of the requirements of the framework should be is products should be labeled so they're not misleading. I may be oversimplifying it, but that may be one of the themes that's running across everybody's conversation.

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

Yeah. I mean I think we didn't recommend labeling at all for this. It's obviously one approach for – but the issues that HIT is so composite and it has so many uses that I'm just not sure how effective as an approach it would be.

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

This is Mary Anne. Yeah, I think labeling would be difficult. Where are you going – where would we label and where would people see it? Would it have to be on a login screen? I think there are so many entries, so I don't know if you can label it.

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

Yeah.

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

I don't know if labeling is practical.

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

Right. So I would suggest let's move on. This has been a useful discussion. The next issue that was brought up was self-developed and open source IT, and we were asked how to address that, in particular with respect to listing. That is to say, if we are going to ask people to subscribe to some sort of list, how will it be handled for these types of IT, any thoughts or comments about that?

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

David, this is Patty. That was part of our intended interpretation on – I'm going to – I want to go to the exact page before I give the wrong page number, but on our, I think it's our slide 12, now – maybe this is where they're asking for clarification of. But number 4 of the characterization of the distribution model, that there may need to be a different set – a different type of listing for open source distributed through a licensing procedure, like LGPL versus pop to my website and download my app for free versus I'm going to charge you for this versus you're in my practice. So I think that rather than being prescriptive, I think we might want to give some type of direction that says it should be both minimize burden but ensure compliance with a wide variety of distribution models.

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

This is Meg Marshall. So one comment that I would add to that is that open source isn't necessarily always a distribution model, but it could lend itself to additional configuration within the site itself. And I would just direct back to the slides around the local accountability and the local configuration, but I don't have the exact slide number in front of me, but I think that that would also address some of the concerns around the open source as well.

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

That's helpful.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

That's very –

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

And then the next two things were really comments, so I'm going to skip those, and then we were asked, the last point from the Policy Committee is we're asked about what options within a potential framework could enhance both interoperability and trial-ability. And by trial-ability what was meant was small-scale trials of HIT products and/or applications in a protected environment.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Oh I see like in order to demonstrate safety and efficacy, we might actually have to try something out in a real environment and this is to put the protection –

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

Yes. And we might have exemptions from other requirements if someone is doing a small-scale trial.

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

It's almost like investigational drug use or in the standards world it's a trial standard for something – wait, standard – anyway –

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

It's like – I mean, this is Keith Larsen. It's again like the example that was given during the meeting is that you go through all the approvals and everything else and then you get it out there and find out that it missed the mark completely. It's the idea that you have a safe way to try out things with knowledgeable and cynical users that are looking for problems, as an investigation, and able to do that early on, without going through a lot of regulation to get to that point.

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

Right. So Keith, could we maybe add something in the innovation area that specifically addresses that?

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

Yes. There's some reference to it, but I can expand that.

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

That would be great.

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

Can – this is Brad. Can I just – I just need to understand better the issue here, whether there's a problem or not. For example, if we're talking about FDA regulated software, there is a clear, regulatory pathway for doing this, it's the investigational device exemption. And for products that are deemed low risk and you're allowed to self-determine that, initially anyway, if you determine that your product is low risk, which the vast majority of regulated HIT would be, you don't need to apply to FDA in order to do these small-scale trials. You need to work under the oversight of an IRB, which is just to get some third party knowledgeable validation that what you're doing makes sense and won't hurt people, but it is pretty light. So what's the issue, what are we trying to solve here?

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

Well I think – I agree with you Brad, but I think we could note that that is already the case and just make the point that any framework needs to really facilitate trial-ability.

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

This is Anna McCollister-Slipp. I was speaking with some of the diabetes device manufacturers about these issues and one of them did mention to me that they have, and these are the people who – this particular device as a Class III device, so it was more like MDDS and some of the data input systems that do event marking around this particular device. They said that they had tried to – or they were hoping to be able to get consumers to use the device beforehand, but they were told that they couldn't do that because the agency – the FDA would consider that to be open label – or, I'm sorry, pre-market promotion of the device.

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

So we need to –

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

So something like this would give them the ability to go out to consumers and say, tell us everything you like, tell us everything you don't like and we'll be able to incorporate it into this, because now you have to wait until the next iteration of the device comes out, which is usually a 2-3 year cycle.

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

So we need to know a lot more about that. We've got Mike Flis in the group who is an expert in diabetes related products working for Roche Diagnostics. What you just described had a little bit of a conflict, you described it as Class III, Class III is the highest risk products, and then you mentioned MDDS, that's Class I, that's the lowest risk products. So, in the diabetes space it could be any of those, Class III would be, for example, an insulin pump that is going to take information from the body and manage the pump, that would be Class III. If it's a blood glucose meter, it's Class II. And then there might be some MDDS, which would be Class I. And to me, I'd hate to take that one anecdote and put it into a presentation because we haven't tested it and I don't understand it and from my experience, there are pathways to do this. So, I just don't want to have a whole committee put a recommendation together without a little bit more information about the problem we're trying to solve.

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

I think that's completely fair. I don't even think that that example was cited previously in terms of being why we have that in this deck, but, I just threw that out there since you were wondering if there was a problem that starts with a need. And you're a regulatory expert, I'm not, in terms of what is what, although an insulin pump is actually Class II.

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

The pump itself is, but if you make it into a closed loop with HIT, it becomes Class III.

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

This is Mike Lipinski with ONC and I just wanted clarification regarding Brad's comment about the FDA process. So the underlying assumption there is though then that product would already fall under the FDA regulatory regime, so it wouldn't really – I mean, it would have to essentially fall under, you're saying, under the medical device definition before that would kick in?

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

Yeah.

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

Okay. So that wouldn't address any – some of the HIT that may be in the gray area and we're not quite sure if it's under FDA's medical device definition.

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

This is Bakul. Let me sort of interpret what I heard. I think the discussion should be not about whether that product would fall under FDA's thing, I think the discussion is more about those tools are available and then gets applied in medical device world today. And how it gets applied to either the gray area or whatever we call Health IT as defined, can be a consideration that the workgroup can present. And I just want to make sure that we're not talking specifically about FDA and I think that's where some of the comments came from. One other thought, and I want to pose a question to you either for Keith or others who when talking about this trial-ability, is there a difference or a distinction that you guys make regarding trial-ability for as in beta testing or technical feasibility of a product and usability of a product? Or is it more about trying it on patients; that's really two different sort of regimes, patient protection becomes a bigger issue as opposed to usability becomes a different issue. So I want you guys to think through that process before we make some assumptions.

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

This is Keith just to answer that a little bit. The example that I'm familiar with, and we all have our own life experiences, have really been not on very low risk things, it's really on decision-making systems involving real patients and involving then development leaders that include physicians. That essentially we talk about a closed loop system but then we also talk about effective closed loop systems where people accept the recommendations, even though there's an experienced clinician in the loop. In this case the experienced clinician is a developer and looking specifically for problems in the algorithm before it becomes generally distributed. So it is really working with – it's not a low risk thing, it's really a trial of the algorithm as well as the technology that's hosting the algorithm.

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

Right. No, I understand. I think – I just wanted to point out that there may be two different issues, people are talking about trial-ability in terms of very low risk products that don't have big patient impact or experimenting on patients would fall into the, I am terming it as beta testing as – like the industry thinks about. And then you have this other issue on the table where drugs and medical devices today, and go through to make sure the patients are protected while trial and – trials are run or investigation happen.

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

And again, the same concern is that you are putting in controls to make the patient as protected – the whole – I mean this whole discussion that number 12 refers to was, what are the attributes that should be recognized that would actually enhance both patient safety and innovation? And the two things that were listed under here, the two bullet points was interoperability or standards that allow people to communicate or do small changes and communicate those. And then the trial-ability discussion was really this idea of how do you fail fast on things so that you understand what they are and are able to make better products faster. That was really the context of this discussion.

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

Great, that helps, thanks.

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

So this is Jodi Daniel, question for the group. So I'm following up on Brad's comments and then the comments about the fact that there may be products that are not devices, that are not subject to FDA authority. Are there particular things that – activities or criteria or things that could be done to make sure to protect patients or individuals during trials or product testing, like Brad mentioned, IRBs. Are there things we can learn from the FDA rules on trials for devices that would be good to apply in concept more broadly? Or – I'm just wondering when we get out of – so FDA already has some rules on this, since we're talking about Health IT more broadly than FDA device authority, are there some lessons to be learned from that that the group would want folks to consider for Health IT more broadly, when products are being tested?

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

So maybe I can offer just a bit more background, because it feeds into that – this is Brad again. Generically speaking there are two main things for low risk technologies that FDA expects when you're in this trial phase. The first is that you get kind of an independent third party oversight, in that particular case, it's the IRB, which is kind of uniquely suited, in some ways, by composition and training to look at the study, look at the risks and make sure that you've done an appropriate job of planning your trial. Then the second aspect is informed consent, that is, if you're testing something on a person, going all the way back to the rules on informed consent, the basic rules on informed consent, you have to make sure that the person understands it and understands the risk. So, those are the two basic principles that have been applied, and so if we wanted to apply them more broadly than just those things that qualify as a medical device, I guess I would submit those as two principles that have served that purpose.

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

And that's typically what we do already in doing trials of this. Sometimes when risk is very, very low, informed consent is waived.

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

It should be – we should just emphasize that informed consent isn't only about risk, it's also about privacy and so when people's information is being used under HIPAA and other requirements, they have a right to know that their information is being used in a certain manner.

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

Okay. I want to – so this has been a great discussion. A few follow ups around this. Let's move on and just talk through the changes in the slides since last time. There's a new slide 10, which is a hidden slide. I don't know if that can – can that – is that coming up on the webinar? I'm going back and forth between my –

**Caitlin Collins – Project Coordinator, Altarum Institute**

No it's not currently being shown, do you want it to be?

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

Yes, if you could.

**Caitlin Collins – Project Coordinator, Altarum Institute**

Okay.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

David is it called patient controlled analgesia?

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

It's called patient controlled analgesia, yeah.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

(indiscernible)

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

And this is just a slide from Julian, which kind of expands on the example of regulation causing harm. And I think it will be non-controversial, but I just wanted to point out that we'd added that.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

It's very helpful.

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

Okay. And then next, slides 11 through 14 include multiple small changes. Patty, do you want to highlight anything there?

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

No, I'm on the right deck, by the way everyone, so you don't have to worry about that.

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

Okay.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

I – no, I appreciated the decisions and I know the deliberations and that we had to come to some compromises about language and terminology. I did change – made some changes to slide 13, even as we spoke, to try to clarify the issue of first we decided whether or not an entity is an HIT, then we determined – make a determination whether the entity is subject to risk-based regulatory framework or not using the decision tree. And what's really important to remember is that slide 13 is only one of the characteristics and that slide 14 demonstrates only one aspect of what would be considered the decision tree. So neither of these slides are meant to be comprehensive. Thank you.

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

That's good.

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

David, this is Brad. I may have missed it, but is there agreement, consensus that we need to change the top of slide 11, that – I had expressed the point of view that I thought that was the source of some of the confusion –

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Right, and I did change it – I'm sorry, slide 11? Oh, what did you want to do on slide 11?

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

So presently it says taxonomy assigns HIT to one of two categories and then includes these two quotations. I proposed to do away with that, at a minimum just do away with it and speak to it, because I think those words caused people to get confused. But if you wanted to replace it with new words, it needs to be something more specific, I'm afraid.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

I – Brad, if it's okay, let me give that a try. I think – I do agree with you that it's got – it raises questions right where it is, and because right before this slide there's a description of the charge. That perhaps what would make sense here, and I'm going to try this with our text description first, is that the taxon – what the purpose of the taxonomy is to provide guidance about what constitutes HIT and then provide a framework for understanding assignment to a risk-based regulatory framework and I think we can go ahead with that. So, that'll go back to David and I'm sure it will come back to the Committee one more time.

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

Yeah, that's helpful. It wasn't clear to me actually how we were best going to manage it because it seems to me like there are a few different ways to do it. Other comments on these slides?

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

This is Meg Marshall. I would just be really interested to see and perhaps provide feedback on that Patty in a timely manner. I think that we – I think the fact that we have spent so much time discussing this is an indication that it probably deserves some rework. I think Mary Anne has actually mentioned several times that there's a way to perhaps show this graphically and understanding that the HIT definition that we were provided, the one that was in the HITECH, that might be a good place to start. It just says, here is the statutory definition of what HIT is and then level set the discussion a bit there.

But then – I don't think we have those two categories here, I think that based on today's discussion, we inherently have three. And one is – I do like the football field discussion, so if we look at the entire boundary set forth by the HITECH definition of HIT as the football field, then within that you have – we've already made some exclusions based on the functionality. So is this a clinical HIT application or not, and that seems to be the in scope out of scope, but then once you determine that it is clinical, then that subjects you to the risk-based matrix that's been provided further on down the line in the logic. So, I think – I absolutely encourage some rework of how this is depicted. I think a lot of value has been discussed and is available based on those discussions that we had. And again, I think it might be semantics, but any feedback that we can provide on the rework that you give to David, more than happy to do, just it's kind of difficult when we received these right directly before a meeting to get that back to you. So, just kind of a general offer out there, the earlier that we can see that, I think the better.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

I'd like to propose that we coordinate this – the slide distribution and feedback through David and we, Meghan and I, are in the process of developing the two-page summary from Taxonomy that will go to the Taxonomy Workgroup first, and then to the whole group, and that's only for some efficiencies. I think some of our Taxonomy Workgroup members have really good ideas about what we – and we want to make sure they're well expressed in there before we bring it to the whole group, and so that will happen over the next, I guess, week or ten days. So –

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

We'll try to get something out as soon as possible. We actually tried to put together a graphic slide for today, but couldn't come to consensus about exactly how to draw it.

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

Excuse me, David, this is Mary Anne, when is our final due?

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

Our final is due in September, and I can't remember the exact date, does anyone else have that immediately at hand?

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

September 4.

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

So, that's pretty soon.

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

So, two weeks-ish.

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

Yeah.

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

Well I think we have great content and I think our teams and our group leaders have done a really great job. I think it's just a matter of synthesizing into an executive summary and then adding some graphical kind of clarifications where it's complicated. And it is complicated, but I think we have some great ideas on how to do that.

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

Yup. Okay. And, let's see, next is slides 15-25. Paul, do you want to summarize the changes that are there?

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

Okay, let me get to my computer –

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

Or I can. So, I'll start and then you can jump in, how does that sound? So the group refined some of its definitions and I basically just have included all the ones that the workgroup put forward. There were a number of wording changes in slide 19, which is the framework slide and then, we just used exactly the same framework slide on all the subsequent slides. And I think that the framework – the matrix slide is significantly better. So that's basically the short summary.

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

And I'd agree with that.

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

Okay. Other thoughts or comments about this? Okay. Let's see, in the next group of slides, did not have a lot of comments. One was on slide 36 in bullet three, we – which is about the FDA expediting guidance specifically around mobile devices, we got the feedback that there's quite a bit of controversy about doing this now because we're in the middle of a public comment period around mobile devices. And our recommendations are going to address this in part, the Secretary may also comment, so I think everyone agrees that the FDA in general – we would all be better off if the FDA is expediting guidance a bit more in this area, that often it takes a while to do this. I've just made this point more general. Jodi, do you want to say anything else about this?

**M**

No, I think we've largely covered it.

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

Okay.

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

So, this is Brad. Obviously we're the section 618 working group and we're the ones who are supposed to offer our view and I appreciate that there's controversy out there, but we are certainly free to make our recommendations, even in controversial areas, we're free to make our recommendations. And so this is a topic that we've talked about a fair amount internally, among the section 618 working group and so I'm not sure why we would change our recommendation because of outside controversy.

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

Well Brad, the reason is that we got feedback from other members of the larger FDASIA group that there wasn't controversy about this particular point and that we should be focusing more on the long view.

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

Can we talk about what the controversy is and have a discussion around that, because –

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

Sure.

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

– this is a – important issue.

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

So – right. As I think you know, there's currently a public comment period around this topic –

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

David, can I pause you for a second there?

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

Sure.

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

The public comment period ended a long time ago, there is no open public comment period going on right now.

**Patricia Flatley Brennan, RN, PhD, FAAN – Project Health Design National Program Director – University of Wisconsin at Madison**

Could I ask people to mute their phones, I'm getting feedback when people are speaking now.

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

So this is Jodi, this is Jodi Daniel, just to build on what Bakul is saying. So we had a comment period where folks did make comments about – guidance and we've gotten lots of – the Secretary's gotten letters as well. We – I think this framework, we were supposed to be coming with recommendations for a risk-based regulatory framework as opposed to feedback on any particular activity before either of the agencies – or any of the agencies. So I – while we've heard the conversation folks had, it would be helpful to focus – I mean if the goal is, we need better guidance quicker when new things come up, I think that's a totally legitimate and valid point to make, so I support what David said in making it more broad. But I don't know that – it is – obviously there is debate back and forth about this, there's internal discussion, but this workgroup, the charge is for recommendations for a risk-based regulatory framework, not for particular actions before either of the agencies.

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

So I think in the past we've made clear that it's really the agencies who are going to develop the risk-based framework, it's not us on this group who are going to develop it. So, we're offering our insights into what we'd like to see in the way of action by the agencies and the statute calls out mobile health. And there's really a dearth – if you look at the fifty some slides, there's really very little here on mobile health, so we're really light in an area where Congress has specifically asked us to offer a view. And so what we're proposing is that the report offer the view that getting clarity from FDA on the scope of FDA regulation with regard to mobile health should be a very high priority, something that it should do quickly. To me that seems on all four corners to meet what the statute is asking us to do.

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

I'm actually concerned about the feedback that David, I think you've gotten and maybe it's some misinformation about just saying there's comment period open about this guidance and I'm also kind of curious about the issues that are really at the heart of this. So, I'm trying to understand – can you sort of elaborate or sort of help, and you don't have to do it here, I can definitely take a call with you later to understand what the issues are, I want to get to the bottom of the issue rather than talk about a specific recommendation here in the FDASIA Workgroup.

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

And Bakul, that's obviously perfectly appropriate for you and David to do that, but I'm on the working group and I'd like to get this resolved among the working group. I mean we have to talk about it, vet it and figure it out as a group, because we have to make a group recommendation. And what I'm saying is, I said everyone – told everyone at the very first call that I represent a group called the mHealth Regulatory Coalition which is a lot of companies that are very passionate about developing mobile health products. And the most acute need they have right now is getting that final guidance so they know what's in and what's out. And so if the purpose of this working group is to identify things that will facilitate innovation, for example, that's a huge issue and there's nothing, there's nothing in the statute that says that we're supposed to only focus on the long run. Quite the opposite, we're to focus on all needs, short term and long term. In the short term, this is the number one issue, in my opinion, that the mobile health industry faces, is the need for clarity from FDA, and please don't take offense at this Bakul, but we've been waiting over two years. It was July of 2011 when that document was put out in draft, the comment period went through the Fall of 2011, the comment period is long gone and we desperately need that guidance out. So, I'm a little bit confused as to why we as a group wouldn't say, one of the greatest needs to advance innovation in mHealth is to get clear guidance from FDA as soon as possible, why we wouldn't say that.

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

So let me – this is Bakul – let me just ask the question to the whole group. Is this what the group believes, that removing the specific recommendations should be a part of the discussion here? Or what is the – and I think that's – to your point Brad, and maybe and I was just pointing out for not delaying the discussion, but I would be happy to hear what the real concerns are, so the agencies can actually think about what those concerns are and then maybe articulate what the – how can we address those concerns. So I guess the open question to the group is, is the feedback that you received – or concerns that you noted should be put on the table and I just want to hear what those are.

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

Sure. Let's hear from others what their thoughts are about this.

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

This is Anna. I thought – I mean, I would love to know what the feedback is as well, just because this seems to be completely front and center of what this workgroup is charged with looking at. I mean, I don't think it's the only thing, but I certainly think it's a critical part of this.

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

Right, no, there's a letter that was written and was signed by 150 organizations that basically took the other side of this and just said that the FDA should wait until the FDASIA Workgroup's recommendations come out, and that the Secretary's had time to consider this, before coming out with final recommendations.

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

But David, I don't think this goes contrary to that letter. In fact, that would be the recommendation that the FDA move forward with specific guidance on mobile medical apps, CDS and other related HIT issues. That's the point.

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

Let's be clear about, let's be clear about the dates. There's an open comment period for the FDASIA process through August 31, two weeks from now. I can live with that. There's a final report by this group September 4, I can live with that, too. So, FDA stood before Congress before one of the House Subcommittees and said that the guidance would be out by the end of the fiscal year, September 30. So I'm not arguing that it ought to be out in August, I'm arguing that it ought to be out in September, and what on earth would be the reason for delaying it past September.

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

If the purpose of the letter was to come out to delay the guidance document pending FDASIA's outcome and FDASIA comes out with an outcome that doesn't even mention the mobile medical apps, then we've lost the ball, I mean we really have completely not done our job. I respectfully hear what Jodi said about our charter, but, there are many ways of interpreting what the charter is, the section in the statute says contains a proposed strategy and recommendations on an appropriate risk-based regulatory framework. There's nothing in there about forward made statements only.

In fact, I think that we should be looking at recommendations on existing mechanisms that promote innovation, protect patient safety and avoid regulatory duplication, and we should also make recommendations on what a framework could be that could be developed, keeping in mind that it will take time, potential legislative action, taxpayer dollars, rulemaking and subsequent implementation. All those things take time. If our charter is to spur innovation, we're only recommending things that are going to be done in the future, which can take more years, that's an innovation killer. That's contrary to what we're trying to do.

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

So, so any others have comments?

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

So what did this say exactly before it was changed.

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

I don't have the old version open here, but it's –

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

I believe it said FDA should expedite guidance on HIT software, mobile medical apps and related matters.

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

Yeah. So, I'm not hearing any disagreement with that. I think what we should do is just go back to that.

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

I think so, too.

**W**

I would agree.

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

Yup.

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

I mean because again, the tenor of the letter was really for us to weigh in on it and so, it was pushing back on this so if we avoid that, seems like we're not even addressing that.

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

Right. Okay.

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

I just can't see the possible benefit of saying we have to wait until everything gets figured out and rehashed through Congress when we come up with a new regulatory structure, to give guidance to people who are interested in developing innovative applications. I don't see how that benefits anybody.

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

Right.

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

Maybe I'm missing something, but I don't see how that benefits anyone.

**M**

Yeah.

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

Okay. So, and let me – let's move on.

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

David, I'm sorry, but just to go back to slide 28. I don't know that we talked about slide 28. It's a technical slide, but there's an error in it, I believe. It says current FDA medical device regulation, it's a table. Under Class II, on the right hand side, it says two levels, Class 1, no premarket clearance, Class II, premarket clearance. I think it's just very confusing to put that Class I no premarket clearance. That's actually above it, we repeat it two places and I don't understand why we do that.

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

So the reason we added that was because we got the feedback from the FDA that the slide before was inaccurate. Yeah, but see, that doesn't make it accurate. I think what Bakul was saying before was, there are certain Class II devices that are exempt from premarket clearance. So Bakul, can you speak to that, that's – I think that's the point you were trying to make.

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

Yes. That's right Brad – this is Bakul. And I have some edits for you David, I can give you just to technically correct it. It's really, I mean if you just remove the Class I sort of label before that, certain types require no premarket clearance and certain types require premarket clearance in Class II. And in Class I there are certain types require quality systems and certain types don't. I think that's the level. So if you were to sort of graduate this – even further graduate Class I, Class II, Class III, Class I has 2 types of oversight and Class II has 2 levels of oversight.

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

Okay.

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

It's important to sort of – and the reason I was bringing it up is not all Class II and not all Class – all products that are deemed Class II need to go through premarket clearance review. I was trying to get that point across.

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

Bakul, if you're willing to propose some specific wording edits, that would be great.

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

Yeah, I can do that or I can work with you Brad, to sort of do that.

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

Whatever's easiest.

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

Okay.

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

Thank you David.

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

And so – yup, thank you. And the one other thing I wanted to note is on slide 41, I added a bullet that – towards the bottom that says which agency should perform the post-market surveillance will need to be determined, but that cross-agency collaboration will be essential, because several people asked us to be more specific about that. Does that seem like a reasonable way to address this?

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

Sounds great.

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

That works for me.

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

Okay. Good.

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

Can I have – this is Paul, can I have one question on the first bullet, the checkmark –

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

Yeah.

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

– it calls out clinical decision support separate from the third checkmark, higher risk software use cases. Is there a reason why clinical decision support has its own bullet?

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

Just because it's been a historical existing classification at FDA where the others are more generic. And so, I mean to be technically correct, I would put something like the word other in front of higher risk software. But the other two are called out because they're existing, historical FDA classifications where the third is sort of a catchall for the software that you guys in the Safety Group had identified.

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

Okay, that's helpful.

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

Great. Okay, so next steps. If you have any additional suggestions, please send them to me; a couple of people have suggested specific things. It will be easiest to make changes if you refer to a specific slide. We'll be working on the two-pagers over the next bit and you should be seeing those soon. And as soon as we have a next version, I'll go ahead and distribute it. Let me just ask – open it up and ask if there are other questions before we go to the public comment period.

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

David, when did you want to start distributing the two-pagers?

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

Whenever you're ready. You can do it now if you're ready, within your group.

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

All right.

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

Okay. Other questions? Okay, once again –

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

Just a – David, I mean, if you're ready to go to public, I just wanted to cover one path forward issue, not substantive issue. There's an opportunity for diplomacy when you go back on September 4 to the HIT Policy Committee, this is something that you and I have talked about before. But it just seems maybe prudent to, in a very nice way, remind the HIT Policy Committee that this is a little different from what they normally encounter where they create a subcommittee and they go off and do work and then the HIT Policy Committee makes the ultimate decisions about what the report will say and then transmits it to the Agency. Here there's actually a statutory directive that it be this group, based on the composition of this group, that makes that final report and final set of recommendations, and that they're certainly free to offer their own comments. If they want to comment on the report, that would be great, but they really can't change the report from what we give them.

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

Yeah, I mean I'm not sure if that's – the last part is strictly accurate and Jodi, do you want to comment about that? You're on?

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

I'm sorry. I missed that comment.

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

The comment was – Brad's comment was, that this is different than a usual committee, which it certainly is, and it was formed as a result of statute. He was suggesting that the Policy Committee cannot change the recommendations of this committee, and I just didn't know whether that was the case or not.

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

Yeah the way the Federal Advisory Committee Act works it's the committee itself is the one that is chartered and that has the legal requirements and the ability to make recommendations to the Agency. So it's the full committee, and that committee is set forth in statute with very specific details about who can be on the committee; most of the appointees are appointed by GAO with some appointees from Congress and the smallest number appointed by us. So there's a lot of specificity on how that Advisory Committee was formed and the membership of it and that is the committee that is actually empaneled and chartered to provide recommendations directly to the agencies. So there – it is required that we have a discussion at that committee and that that committee be the ones that decide whether or not to forward on the recommendations or anything that – decide what they want to share with us as advice to the agencies.

So, we can't tell them they cannot change anything. Obviously they – I think they rely on this group as having the expertise and that's how we've always set up these workgroups where we push the specific expertise on the workgroup that the full committee may not have. I think David, the reason we had David as the chair was because he's on the full committee and can go back to the full committee both as a member of the workgroup as well as a member of the committee. And kind of be able to assure folks about the richness of the conversation and the fact that folks have been heard and the value of the recommendations that are coming forward, including all of the insights that were discussed through all these committee meetings. But we can't tell them that they can't change them, it's – they're the ones who make the recommendations to the agencies, so they can do as they please.

Now, that said, I just want to note that while we can't as agencies rely legally on the recommendations of a workgroup, we do have all three agencies represented on this workgroup as members, which is not typically how it's done. Again, this being a slightly unusual group, and we've heard all of the richness of the conversation and discussions, we are not obligated to follow the recommendations of our Advisory Committee and we do have the benefit of all of the discussion that's happened at this workgroup level. So, be rest assured that we've been listening and we've heard all the conversation and that is obviously part of our thinking as we will go forward and put forward the framework.

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

So it sounds like there's a bit of a conflict because Congress specifically asked this group, not the existing HIT Policy group to opine on these topics and the statute is very specific about the composition of this group. And you guys, as I understand it, labored long and hard to figure out how to get each of the different constituencies identified in the statute, onto this group in a reasonably small, if thirty can be called small, number. So I understand that the HIT Policy group has its own legal standing, but it's not the body that was asked by Congress to issue a work product, it's this group that was asked to issue the work product.

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

I think that it's clear that the Policy Committee was very pleased with all the work that we did and with the recommendations overall and I think that they'll take the recommendations very seriously. So I think that there's a way to frame it that will make the point that you wanted to get at Brad, without pushing any particular buttons or without crossing the line about the FACA rules, which as Jodi has just outlined, are quite clear. And I apologize for cutting things off, but we do need to take public commentary.

**M**

I think – aren't we – we are scheduled through one David if you need additional time.

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

Oh, we are?

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

Yeah, we're scheduled to go to one o'clock, so I was confused about that as well, so thanks. I'd just – I'd like to go and just – I just want to say a couple of things. I get the FACA rules and the FACA legislation for FACA. But this was a specific piece of legislation that specifically called out to create this group. And from the beginning, and we actually had a debate about this with Jodi and on one of the earlier calls in the Regulation Workgroup and never really came out to any kind of a decision from any of us of where it stands. There are many ways of interpreting many things, you get a bunch of lawyers together and we're not going to agree. But the idea behind this, and the legislative history behind the creation of section 616, which was the original legislation which then became section 618, which ended up going into law, was for this body to be created to come out with recommendations pursuant to this specific subsection. It was not intended to be rolled up under the other FACA.

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

Can I jump in here for a second? The language – this is Jodi again. The language in FDASIA said, the Secretary may convene a workgroup. So we were not required to do this. The Secretary had discretion to determine how to administer her programs and the best way to get that feedback. Congress did not, in fact, create an advisory committee under the Federal Advisory Committee Act, and we can't just create Advisory Committees outside of that Act. And in fact, there are limits on how many Advisory Committees the Department can put forward.

So we in fact used our – both our – the legal limitation as well as authorities we had and used our discretion in how we set this up – at the Secretary's discretion. And so the agencies have a lot of deference on how they set up their programs. In this case we were not required to do anything, we did it, we did it consistent with the statute, we did it consistent with the Federal Advisory Committee Act. And we can debate this all day, but this was the approach that the Secretary chose to take, this was a decision by the Secretary's office, because it involves multiple agencies, and this is where we are. And I understand that there are folks that are not necessarily happy with that, but I think to – this is where we are, and to David's point, the Policy Committee does value the input of this group and was very favorable toward David's presentation of the views of this group. So I'm not sure what the concern is and there isn't really a different – I mean at this point we are where we are.

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

Jodi, I guess I agree with you that we can argue this the entire day, and we probably are better off not doing that. However, let's say that we take everything at face value, what is being said to us is that all of the meetings, which I believe there are 30 plus meetings that have been held, each an hour and a half to three hours long, with massive input from all the people on this working group, who are the experts of these issues, are going to be sent to the HIT Policy Committee and at the whim of any one person at the Policy Committee, something can either be chopped off or modified. What expertise will those people have to be able to do that, especially given that some of the things that were being discussed at the HIT Policy Committee weren't being articulated in the correct way because there's a lot of context that was missing. That doesn't give me any kind of affirmation that in fact, the work that we did as a group is going to be upheld. If anything, the Policy Committee should act like the MDDS of Policy, they can transfer it, store it, convert it from Word into a PowerPoint or a PDF and then move it on to the three agencies.

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

So all I will say on this is, we did what we – go and talk to some government lawyers, we did what we were legally able to do and what we thought was best for the agency to get this input, consistent with Congress' intent. All of the 30 some odd meetings that you talk about, they're all on the record, we have transcripts of them all, they are publically available and the three agency representatives have participated in each and every call, so we have had the value of that input. So, rest assured the Policy Committee is only making advice to us, and we have the entire record as well. And that said, they get to make the recommendations to us, as the final arbiter, that's the way the FACA rules work and we are going to comply with our – obligations. Our General Counsel will not let us rely on the advice of – an Advisory Committee, we are – the final version that comes from the Policy Committee is what is the official advice to the agency after coming out of the whole process.

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

So, this is Bakul. Can I – let me try to help here a little bit. The point – I think the point folks are making here may be whether the details of the discussion will be heard by the agencies or not, as they're putting the framework together and I think the answer is yes, we are. We will have the discussion, as Jodi pointed out, we have those details captured in the meeting minutes, the transcripts and the recordings. So we will take those as part of the full process. The Policy Committee will get a summary as you guys have seen already, and will at the very high level, will be the highlight of the recommendations that come through, but the details and – at least between ONC, FDA and FCC, we know where information lies and we'll be using them in developing the framework.

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

So Bakul, we just have to speak honestly, right? And I have complete faith that you guys know all of the details, because you have sat here with us throughout these 30-some meetings and you've heard the details. I'm not concerned about you being unaware of the details. I'm concerned about politics, not details. I'm concerned about politics not substance and I can only imagine the discussion that will go on and I just want to make sure that if the Policy Committee changes the recommendations of this committee, that everyone understands that what comes out of that will not be the section 618 working group report. It will not be – I mean Jodi has made a big point about this being voluntary and that's true. So if the report is changed, and if it comes from that Policy Committee, then it is no longer, it is no longer the working group required – or not required, authorized under section 618, it is a different group, it is the HIT Policy Committee. So the agencies will not have done what Congress allowed them to do, didn't mandate, but allowed them to do.

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

Umm –

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

I think we have to agree to just disagree on this point.

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

Yeah –

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

Well see, it may be academic, if there are no changes, then it's all academic.

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

That's really where my head is –

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

But if there are changes, it's not academic.

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

I think it's very unlikely that there will be, based on prior experiences. Okay. So let me just open it up again and ask if there are comments on other topics.

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

David, this is Jodi Daniel. You had raised, a little while back about you put two issues together and we talked about one in great detail and not the other as much, and I would love some more interested what the workgroup were thinking. You mentioned interoperability and trial-ability and we started talking a lot about the kind of testing of new devices, but not as much on the interoperability side of things. And I'm just wondering if there were any other thoughts to address those questions that came up.

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

Sure, so one concrete thing that we can do is add something that refers to what Joe described earlier, but I'd be interested in other thoughts about what we could do around interoperability.

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

This is Anura Fernando again. One of the issues I raised when we were discussing labeling was establishing a mechanism to communicate key attributes that need to be established between components that are integrated together in a broader system. And so whether it's labeling or some other mechanism to effectively communicate those key pieces of information, I think having such a communication mechanism will potentially facilitate improved interoperability. A simple example of this is also, if you look at appliances that you plug into the wall. Well here in the US we have 60 Hz and 110 and 120 volts and so when you look at the marking or the labeling on the product, or you have that information on the product that it can be plugged into the branched circuit in the electrical system in your house, then you know you can safely do so. So having somewhat of a fairly simple and straightforward means of communicating indications for use, in that broader system context, as well as potential contraindications I think will be important.

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

Thank you. Other thoughts?

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

I'm sorry, Anura Fernando here again. One other related topic that also ties to a few other things is the notion of risk and hazardous situations. So to achieve interoperability, it seems one of the elements that should be considered is this common basis for risk at the level of devices that are being integrated across the system. The table that was put together by the Risk and Innovation – I'm sorry, Safety and Innovation Subgroup, started to look into that and establish some norms around – to address that. We discovered as we were going through the process that there was some inconsistency in how risk related verbiage was being used and how risk related terms were being applied.

And so I think having that consistency between the output of this working group, as well as the general body of knowledge around risk management is very important. And I haven't gone through and looked at this latest set of slides from that perspective, but I think we have a number of people who are heavily involved in risk management standards, like ISO-14971 and so forth. And to go through and make sure that the language that we're using is consistent with that I think will also help with interoperability.

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

Good point.

**Todd Cooper – President – Breakthrough Solutions Foundry, Inc.**

David, this is Todd. Maybe you could also just include a reference to the FDA recognized standards for interoperability that were put out there, was it last week, I think Bakul, or two weeks ago, as exemplars. And I think in there it includes the kinds of standards that Anura was just mentioning.

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

Yeah, that's a good suggestion.

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

Yeah, I'd second that. I think to the extent that the agencies can point to standards based interoperability structures, it gets to this point of manufacturers then being able to label their offerings as meeting those standards. And while not specifically perhaps labeling, it does give an ultimate purchaser of such technology the opportunity to understand why they can expect some form of functional interoperability once purchased and installed. And so I think it does start with there being recognition of standards based approaches and then I think you can kind of cultivate a virtuous cycle of activity around interoperability.

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

Great. So, other thoughts or comments, either about this or about some other area? Okay. Well I apologize for not realizing we were going until one, I just mentally it's on my calendar for 10 to 1, but I was obviously aiming at 12. So I want to just thank everybody. So next steps, again, get me any changes that you have, I'm expecting specific ones from a number of people who have been identified. We'll add a few things to address the Policy Committee's issues in several specific areas around interoperability, around liability, the point around self-developed and open sourced IT. And with that, let me just thank everybody and Mike, if you could open it up for public comment.

**Public Comment**

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

Operator, can you open the lines for public comment?

**Caitlin Collins – Project Coordinator – Altarum Institute**

If you are on the phone and would like to make a public comment please press \*1 at this time. If you are listening via your computer speakers you may dial 1-877-705-2976 and press \*1 to be placed in the comment queue. And we do have a comment.

**Marilyn Waxberg – Director – Siemens Healthcare**

Hello, can you hear me?

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

Yes.

**Marilyn Waxberg – Director – Siemens Healthcare**

This is Marilyn Waxberg, I'm with Siemens. I'd like to make a comment on the issue that there seemed to be some silence on. There was a question that came out from the Policy Committee asking that coordination of agencies to be addressed and I would like to encourage this group to look at some recommendations for coordination between the agencies. And possibly more specifically to establish an ongoing advisory committee which not only consists of cross-agency, but also includes stakeholders as well.

In addition I'd like to make some supporting comments of, there was, last – in the last few minutes there was a discussion on risk management. I very much support and would like to encourage some further information being placed in the report including the – recognizing that there is probably a need for a method of stratification for HIT that should be developed as everything that we place that is in scope in HIT will not come to the same level of risk and oversight. An additional comment, there was mention of the FDA's list of recognized standards, again during the last portion of this call and I would like to encourage the group to continue to look at recognized standards, those that are not just national, for interoperability, but to get international standards in general. And that international standards be considered as these standards not only are important as mentioned by the group, but also that – a best policy in general does support using standards which already exist. And of course cross-agency coordination on interoperability is just very, very important.

Lastly, I think there needs to be some further clarification on a recommendation that was made on a public process for customer rating of HIT to enhance transparency. There already is available public information that comes from trusted sources and I'd like to encourage that this be teased out a little bit more or the concern is that we could end up with something that's more like a Yelp commentary than something really that is of trusted source and of value. Again, I would like to personally thank all the folks that have been involved on the FDASIA Workgroup, they've done a phenomenal job in such a very, very short period of time, and really want to thank their dedication in volunteering for this. And I hope that the work actually does continue. Thank you.

M

Thank you.

**Caitlin Collins – Project Coordinator – Altarum Institute**

And we do have another comment from Janet.

**Janet Marchibroda, MBA – Director, Health Innovation Initiative – Bipartisan Policy Center**

Hi, it's Janet Marchibroda with the Bipartisan Policy Center. This is more of a process question, perhaps you could answer either during this meeting or a subsequent meeting. As we've been watching this process, one of the great benefits of you all being part of a Federal Advisory Committee – is that it creates transparency, it enables public input, so people on the ground can provide input. And we're also pleased that HHS, through the Federal Register, issued a request for public comment and you actually said in that request that anything received through June 30 would inform the workgroup. And as you all well know, the public can still comment up until the end of August. So this is my process question, I was wondering if you all, either during this meeting or otherwise, could describe and clarify whether the workgroup is expected to take into consideration public comments, and it wasn't clear, given review of some of the transcripts, and if so, what's your process for doing so. Because we think that that's one of the biggest benefits of having an open, transparent process.

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

This is David Bates. Let me just comment that we did review all the public comments up through 6/30 and we will not have an opportunity to go through them – the subsequent ones as a group, but will take them all into account.

**Janet Marchibroda, MBA – Director, Health Innovation Initiative – Bipartisan Policy Center**

Thank you.

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

And I'll just add – this is Jodi Daniel, that the agencies will be able to look at, and we will look at all the comments we've received through the end of – from the beginning to the end of the comment process, in developing our recommendations for the framework.

**Caitlin Collins – Project Coordinator, Altarum Institute**

We have no more comments at this time.

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

Okay. So this is the last scheduled call for this group before the final report. There will be more – significantly more electronic communication between – a considerable amount of electronic communication between now and then, but I also just want to thank everybody for doing this work. It's been a lot of hard work over the summer. I feel that we have produced a set of output that will be useful to the agencies and it's been just a pleasure working with such a talented and knowledgeable group of people.

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

Thank you David for all the work that you've done.

**W**

Here, here. Thank you David and everybody.

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

Agreed, it was a lot of work guys, a lot of meetings. Now go enjoy your summer.

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

And David, this is Joe, you have an interesting definition of pleasure if you found all pleasure in this.

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

Thanks David for the leadership of this diverse group.

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

Thanks everyone.

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

Thank you all. So enjoy the rest of your summer. Take care.

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

Bye.

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

Bye, bye.

**M**

Bye everybody.