

**HIT Policy Committee
FDASIA Workgroup's
Regulation Subgroup
Transcript
July 19, 2013**

Presentation

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead - Office of the National Coordinator for Health Information Technology

Thank you. Good morning everybody, this is Michelle Consolazio with the Office of the National Coordinator. This is the Health IT Policy FDASIA Regulation subgroup. This is a public meeting and there will be time for public comment at the end of the meeting. The meeting is being transcribed, so please make sure that you identify yourself when speaking. I'll now take roll. Bradley Thompson?

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

Good morning.

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Julian Goldman?

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

Hi, good morning.

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Good morning. Anura Fernando?

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

Here.

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Lauren Fifield?

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

...good morning.

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Hi Lauren. Todd Cooper? Robert Jarrin.

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

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Mohit Kaushal, and I apologize if I butcher your name.

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

No, that's perfect. Good morning.

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Joseph Smith? David Bates? Jodi Daniel? Matthew Quinn?

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

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

And Bakul Patel.

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

Good morning.

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Good morning. Are there any ONC staff members on the line?

Kate Black – Office of the National Coordinator for Health Information Technology

Yeah, Kate Black is here.

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

Mike Lipinski.

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Thank you...

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

And MacKenzie Robertson.

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Thank you everyone. I'll now turn it over to Brad and Julian.

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

There are also other members here.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

There are other members on this call.

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

Of the Working Group generally, beyond the subgroup.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Correct.

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Um, okay. MacKenzie, do you know...do you want to just identify yourself? Sorry.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Meghan Dierks.

Jeffrey Jacques, MD – President, Neonatal Solutions – Aetna

Jeff Jacques.

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

Elisabeth George.

Michael Flis – Regulatory Affairs Director – Roche Diagnostics

Mike Flis.

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

Martin Sepulveda.

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

Drew Hickerson.

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

Meg Marshall.

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

Jackie McCarthy.

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Is that everyone. I'm sorry. Now I will pass it over to Brad and Julian.

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

Great, well thanks and...

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

Great.

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

...good morning everyone. And by the way, could you let me drive the PowerPoint if you wouldn't mind. Thank you.

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

And my...as we chatted before, my connection will improve in about 5 minutes and until then, I'm going to be in the background and Brad's going to be speaking and driving.

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

Well, and I don't want to do too much of the talking today, this is really I guess the final opportunity of this subgroup to come together in support of recommendations to be made to the full Workgroup. My apologies for the early start, I know those of you on the West Coast it's very early, but thank you all for coming. This week we've tried to use email a fair amount in order to advance the ball and get as many comments as we could by email and make as many improvements as we could to the document, in advance of the call today. I noted that I think it was maybe 15 or 20 minutes ago, Julian sent around a new version of the document that had improvements to two different slides, I think it was...I'll have to look here, I think it was slide seven and nine.

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

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

So if those of you who are by your computer, when I get to those two particular slides, I'll be referring to what was sent in email, as opposed to what's on the screen. But Julian and I caucused briefly before the call today and we decided that we would basically tackle the written comments that we got first and then go into additional comments that anyone on the phone wants to offer. But the basic process is that we have just under now two hours to come together on an agreed upon work product. And Bakul's email from this morning is really the perfect launching point for that idea.

And Bakul observed that I had been typing on it something cute like this is the views of the typist and not necessarily anybody else and we've got this footnote...this footer rather at the bottom of the page that just describes it as work product. And basically I think most of you recall that we decided to do that early on because we didn't want any intermediate draft being misattributed to the subgroup, particularly in the early drafts, when it was Julian and me, we're sort of sitting there typing provocative stuff to put on the screen. But certainly, at that time, no one else had seen anything we were writing.

Now we've been into a more incremental improvement phase over the last couple of weeks, but still, until this group is finished, I didn't want to characterize it as reflecting the group's view. So that'll be kind of the final step, indeed, right before we go to the public discussion, basically I'm going to ask if we have a consensus on whatever the version is two hours from now. So that'll be kind of the final touch point for this group, and then it'll go to the full group, and obviously the full group then will get a chance to look and see what it agrees with and weave whatever there's a broader consensus on into the report of the whole group. So that's the process and I just wanted to address Bakul's observation up front. But any discussion around that, is that a sensible way to proceed? Bakul, does that meet your concern?

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

Yeah, thank you for taking that into consideration, it's really important for us, it's best to sort of understand where things are aligned and not aligned and if there are differing opinions, we definitely welcome that, but we need to know where those points are so as we get into designing the framework, we can understand where the touch points are.

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

So in line with that, one of the comments I received from David Bates, our fearless leader, is that he wanted the title page to be more direct and before I had said something like improvements or something to the regulations and he suggested Report of the Regulations Subgroup, because that's ultimately what it is. So I have redone the title page to reflect that and at the end of this call, for whatever there's agreement on, I'll be removing both the footer and the draft statement. So let's go on and I think most of the rest of the comments I have at this juncture are from David and so he sent around nine comments and some of them are fairly substantive and so I suggested that we simply go through them as a group.

His first comment, those of you who have email, you might want to look at it, but I'll read the comments. The first one is, didn't the group consider what current regulatory frameworks are and whether or not new regulatory frameworks might be helpful? I...the short answer is yes, we spent quite a bit of time doing exactly that. As you recall, back in June, over a 2-1/2 week period of time, we had five conference calls where we examined each current regulatory framework and were basically evaluating the weaknesses, duplications and so forth. So, the process that we followed, right or wrong, is to take all of that content and then take the deeper discussions that we had the first week of July, where we went deeper into the reporting issue for example. We went deeper into specifically where the duplication is and where the ambiguous statements are and so forth, and started to synthesize all of that.

You guys remember, for example, that the analysis of the FDA regulatory framework was 60 slides long. I forget how many slides on ONC and FCC had quite a bit of content as well. So, I...David, I don't think is on today, but I can explain to him the process...

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

I...yeah, I actually am on.

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

Oh super. Okay. So...

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

So what I wanted was just some acknowledgement of that, so maybe a slide describing that, because from my perspective, just was not as clear, from the presentation, where all this was coming from. And then...

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

You want us to document it.

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

Yes. And then also just to talk about new frameworks, because really all the discussion is focused on the existing thing.

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

Yeah, so when it comes to new frameworks, we had a couple of conference calls on that, one that Joe Smith led on kind of the...where we talked about the European framework and we talked about several other...comparing it to industry approaches...industry-driven approaches and so forth. But the bottom line is that at least to this point, there hasn't gelled a consensus that we move to a different regulatory framework, that the last two slides of this presentation are kind of the closest we come to that, which is kind of the big picture strategy of where we ought to go. So we considered alternative frameworks, we just haven't coalesced around any recommendations that those alternatives be pursued.

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

And what...I'm...wasn't clear to me that that's where the group landed and the Innovation Group also suggested a potential new framework and there's some overlap between what they did and what this group did. I don't know if people have had a chance to take a look at Keith's slides, but I wondered what people thought about those.

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

That's an open-ended question to anyone. David, to your point about what the consensus of this group is, obviously this group should speak for itself. We've been working on these slides for a couple of meetings now and this is what we've discussed, so...

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

But the slides still say on them, produced by a typist, they may not represent the perspective of the group. They don't...I mean...I

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

Were you here a moment ago when we were talking about that topic? Because Bakul raised that and I was just explaining that that was a leftover caption from the first version, because I didn't want to be so presumptuous through multiple versions of saying that this was a report of the group until the group signs off on it.

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

Well, I came in at 5 minutes after, so I missed Bakul's statement.

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

Okay. So that's just a historical artifact at this point from the first version that truly was just the typist, but we've been doing iterations now for several meetings.

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

What are they saying?

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

I'm sorry could you say that again.

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

I just wonder if anybody else has thoughts about this.

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

David, this is Meg Marshall. Is your...is the outstanding question regarding how the Innovation slides also cover some of the critique of FDA and ONC?

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

Well they don't just cover the...they don't just critique those things, but they offer sort of the beginnings of what a different framework might look like. People may or may not have had a chance to digest them, I don't know.

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

Julian Goldman here. I wonder...just two comments. The first, just to clarify is that as we started off the call, we made it...we discussed, Brad presented, that the slides will be changed after this call. The footer and the slides will reflect the fact that they have been vetted and have been discussed extensively and so that language would be removed, and I think that's the part that you had missed, that initial few minutes of discussion.

The second point that you're bringing up regarding the recommendations made by the other groups, I don't know that we're prepared today to discuss that and I think it's an important question. And maybe we could discuss that towards the end of this call, or after addressing the things that we're better prepared to discuss, and then determine how should we proceed, given the timeline, the meeting schedule and any other deadlines that exist, in order to assure that there's been appropriate cross-fertilization of content across the groups. Would that be a reasonable approach?

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

I suppose so. I do think that these slides need to say something about the fact that...about what other frameworks were considered, whether this group feels that there is no need for any new framework. And I do not feel like that...

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

Has been covered yet.

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

Yeah. And I also felt like it would be useful just to not in 60 slides, as Brad described, but in maybe 1 or 2 slides to attempt to say, this is what the current FDA framework is, just level zero, level one, level two, that would be helpful.

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

Perhaps if we could just get a quick sense, because a number of topics like this, in terms of additional work, will be coming up I assume during the call and Brad if I may, I go down this line of discussion for a moment. What are our capabilities or restrictions with regards to meeting again with the subgroup, vetting any changes to our slides in the near future and so forth and how to stay within our deadline and our timeframe? Perhaps someone from the ONC could answer, I'm not sure who knows the answer.

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

I think that would be MacKenzie or the new person, sorry I didn't get your name.

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

Michelle?

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

Michelle.

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

Is that Michelle?

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Hi, this is MacKenzie, I'm just looking up now to see when the next Regulations Subgroup meeting is...

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

We don't have any more.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

...so if you need to schedule a couple more, we can always do that and plan those meetings in. So if you need additional meetings, we can add them to the calendar.

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

And when would...what's our drop-dead date for any additional meetings, what's the time for the closing...closing time?

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

Well...

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Are you talking about like the timing for like reporting back up to the Committee? I'm not sure exactly what you mean by closing time?

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

I have to have some sort of draft by 7/26, so...

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

Yup, okay.

MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Thanks David.

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

So David, this is Meg Marshall. Is the intent for the 7/26 meeting for you to dry run...have a dry run through of the presentation for the Policy Committee or are we still looking at potentially having changes next Friday.

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

The former, but it could...but we could make some substantial changes after the 26th, I mean, this group's...this Subgroup's work doesn't have to be done by then, but it would be nice to have at least a pretty direction, which I think you already have.

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

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

So I'm going to ask...

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

Okay, so we have time...sorry, didn't mean to cut you off.

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

This is kind of a silly...this may be a silly question, but what is the possibility of potentially delaying the Policy Committee presentation? Is that a hard date that we can't move or if we get into substantial changes, the week before, I'm just a little nervous if three days before if we're making substantial changes, for you to be able to represent that back to the Policy Committee.

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

Sure. It's not moveable. We do have to hit it.

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

Okay. Thank you.

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

So I'm a little confused here because we're talking about kind of Plan B when I'm not sure we've thoroughly examined Plan A. Plan A is to spend this morning going through these issues and to arrive at conclusions. It's not clear to me why we don't...why all of a sudden we don't think that's possible.

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

I think...

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

Well Brad, I just opened up the question so that if we during the course of this call, if we want to know whether there's time to circulate another deck with two or three slides or any other points or if we wanted to have another call to close anything, whether that was even feasible. So that we would have guidance for today's call, that's why I opened that...it was the only reason. So, I'm not proposing that we start delaying anything if we don't need to.

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

From my perspective we're still fine with Plan A, too.

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

Okay. Can we charge ahead then and we'll examine at the end of the call if we've been able to achieve Plan A.

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

That's the next step.

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

Okay. So David, you've already covered your second topic of putting in a brief slide or two about FDA and that's certainly easy to do. We can add something that has the classification process and the implications of that classification process, if that would be useful. So, let's go on. The third question is, are there any things the Regulation Group believes should be regulated with respect to HIT, which are currently not regulated? And I'll take a partial stab at answering that, which is basically to go to the end of the draft presentation, to the big picture.

And so what we've talked about in the last couple of calls is starting with the Taxonomy Workgroup report of what is basically HIT, declaring that to be unregulated with FDA, except, and so it becomes a matter of exceptions. And the exceptions include some current things that are already regulated by FDA, MDDS certainly, followed by two categories that are regulated by FDA, but not clearly delineated. And so the objective there would be to get FDA to more clearly draw the line as to what an accessory is and what the high-risk categories of CDS are that need to be regulated.

And then we've got the really smushy one, which we haven't been able to improve on in the last couple of calls, I'd love it if there is a way to do this. But to basically say look, the Safety Working Group or Sub-Working Group went through and identified a bunch of factors that increase the risk associated with HIT and if there's some way to formulate regulatory specifications out of that high risk, then that also would merit FDA regulation. And I married that with a concept that Julian brought up in the call a week ago, saying including those where the intended use makes the software risky, which is a very lame, very non-specific statement on my part, I just couldn't think of a way to craft it in a more meaningful way, because it's pretty wide open.

So, David, to address your comment, those are the areas that we've said should be regulated by FDA, but we aren't able to be very precise about it. I have talked with Paul Tang by email at least a couple of times, I've talked with other people on that committee to see if there's some way to convert the output of that committee into regulatory specifications, and so far, no one has felt comfortable trying or identified a way that they comfortably can do that. So that's as close as we've been able to come to saying what should be regulated. Now, since I added that phrase, I'm interested in whether other people...anyone's had an epiphany or some way to better frame that.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

So Brad...

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

Yes.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

...this is Meghan Dierks.

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

You're very faint, I don't know if you can get closer to your phone.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Is that better?

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

Much better, thank you.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay. So, a couple of comments that I think may produce challenges for David, who has to synthesize all this. The first is, and I'm just working off of your big picture improvements that when you talk about unregulated enforcement discretion, the concept of enforcement discretion is only applicable to something that is technically and legally regulated by the entity. Meaning the entity can choose whether it wants to enforce it, but there's no discussion that it belongs under that agency or entity's regulatory purview. I'll just list them quickly and then we can talk about them.

The second concern is that, and this is the one reason why the taxonomy group sort of took an approach of looking at functionality rather than talking about a specific labeled type of HIT. The challenge is that FDA already class...regulates more than just what falls under the MDDS, it technically regulates very specific types of decision support, and it's got actual pro codes for those...product codes for those. It also regulates other types of health IT and I think many of the things that you would...that this group is proposing to sort of declare unregulated. I think that just therefore brings into play a conflict, which was I think one of the goals of this group, to try at all costs to try to avoid conflicting, redundant or increase in ambiguity around the regulations.

And then the third comment is that it appears as though the proposed approach that you...that this group is putting forth wants to sort of say we can at the outset declare something as being high risk or low risk, and if it's a high risk, it should be regulated, versus a low risk not regulated. And not just with FDA, but with most regulatory authorities, they don't determine whether something should be regulated based on its initial risk profile. Instead they declare that by virtue of its potential functionality or intended use, it's regulated and then they use the risk profile to determine the levels of control that they propose, everywhere from minimal control, left up to the manufacturer to heavily specified or prescribe control. So I think that that's...those are the three areas of concern that I have if you were to pursue this set of recommendations is that they have the potential to create more confusion than reduction in confusion and that's just...and I think that ties to what we had been trying to sort of present through the Taxonomy Group.

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

Let me offer some thoughts on those three. The first one I think is relatively easily addressed, it's a good comment and I think if we, inside the parenthetical where it says enforcement discretion, we could say enforcement discretion if necessary. You're absolutely right, quite a bit of it would not require enforcement discretion, some of it would, EHRs being a classic example of where FDA has said, those are medical devices, but we're going to leave it alone through enforcement discretion.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

So then it would be technically under the regulatory purview of the FDA.

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

It would fall within the statute, but FDA would be affirmatively declaring its intent not to regulate.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Okay. So if you could really clarify that, because I think that doesn't come across...that's very different than say...I perceive that or interpret that very differently than a statement like FDA issues a statement they will not regulate.

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

Help me understand the difference.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Because if something falls under a statutory purview...or the ability by statute to be regulated, then technically its regulated and the FDA is just choosing not to enforce. That's very different than a public statement that says FDA will not regulate at all, meaning, it's not...it's never...they're never goin...it's not by statute within their right to regulate, so to speak. And there were...and I'm just responding to just some comments that were in emails that went around the group that I think could have generated some confusion. I think you have to be very clear and say, we acknowledge that all...there's a difference between saying we acknowledge that all forms of healthcare IT could fall under the statutory regulatory control of FDA and that they choose to not enforce. That's different than saying we recognize that healthcare IT as being outside the scope of FDAs statutory rights to regulate or statutory rule of regulating.

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

Okay, so I could change the first bullet point to take the Taxonomy Workgroup report and classify all of it as not actively regulated, enforcement discretion if necessary by FDA (Class 0), except as follows. Does that more clearly...

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Well, I'll leave it to the rest of the group to decide if that...the way of stating that is confusing...to me it's confusing when I think about the larger public response or reaction to that. And in the end, I think it's David, you're the one who has to interpret it, so if it's clear to you, then I think that's fine.

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

It's not clear to me, I think it's important to be clear about this point. I would forget about the Taxonomy Workgroup report here and just state it pretty much as Meghan suggested.

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

Okay, so give me the words. What words would you use here, how would you write it?

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

Actually Brad, can I jump in here for a minute. This is Jarrin.

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

Yeah.

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

David and Meghan, on one of the preceding slides, I believe it's slide 5, we talk about current FDA program mechanisms that could enable innovation and one of the bullets actually specifically, the first one, talks about FDA should actively establish a policy of enforcement discretion for lowest risk health IT where enforcement of regulations is inappropriate. And if you actually went down and saw the comments under it, you will note that it says enforcement discretion is deregulatory and immediate, enforcement discretion would quickly provide transparency and eliminate regulatory ambiguity and industry fear. And then the concept of lowest risk is something FDA has begun to define in health IT through enforcement discretion of EHR and EMR related software. Example given, a specific product that I found, product code NSX, which is considered software transmission and storage of patient data, which are not classified and not subject to regulation, including no registration of manufacturer, developer or listing of product with FDA.

And I guess the idea is that enforcement discretion is where FDA has deemed that a certain product is not classified and is not subject to regulation as a result of where it falls in the risk category. So I think, because we cover this in a preceding slide, I want to make sure that you guys understand that this isn't something that's just in the last slide and is not clearly identified as what it means.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Sure. So Bakul...Bakul's on the phone, let's ask him...when you...when the term enforcement discretion is used, is...does FDA kind of make an assumption that that product or class of products for which you are choosing an enforcement discretion approach to not enforce any specific rules, do you still perceive that to be a regulated device?

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

So...

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

...that's just a form of how you go about regulating it?

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

Yeah, it's just about how we go about regulating it, it's still a regulated product, but it's how we go about regulating it, so it's another level of regulatory oversight, which is at the very bottom.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

So to me that's an important distinction to make clear, that...because that would suggest to me that...if you're going to use that term, enforcement discretion as one of the components of this framework, I think you need to be clear and say that that implies that these are then falling into...under FDA regulated products, they're just choosing enforcement discretion.

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

As a practical matter, why, I mean if I'm a maker of one of these things, why do I care?

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

It's you're either regulated or you're not regulated and the point is, that if you misbehave, the FDA can take you to task, I mean that really is the point.

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

Is that what you would say Bakul? When you operate under enforcement discretion, you can list that retroactively and regulate something?

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

So, you guys are getting into technical details. A product which is deemed regulated may necessarily...may not...may necessarily meet a definition of a device, the levels of regulation and the term enforcement discretion is, we have the authority to choose what parts of regulations that we have put forth that we can apply to certain products, just like the classification, Class I, II and III does. It does not necessarily mean that you are now suddenly not meeting the definition of a device. I think that's a distinction you need to sort of think about and rather than focusing on FDA regulated or not regulated, and this is why in the initial calls when we kicked off this workgroup, we basically said think about what levels of regulation. And sort of what matters rather than focusing on whether it meets the regulatory definition of a device or a health IT definition under the HITECH Act or some other definition. The key point here is what risks should be managed and if it fits under FDA regulation, if it's low risk as folks are pointing out, can...where...what controls and what needs to be thought about to make sure that patient safety and innovation is protected.

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

So let me maybe strip it down to its essence and avoid some of the technical discussion. I'm saying this out loud to see if I've accurately captured the sense of the Regulations Subgroup. But it was the proposal put forth by Joe Smith and others that the stuff that falls within HIT as defined by the Taxonomy Group, should not be actively overseen by FDA. Notice I avoided the word regulation altogether. All right, so the stuff that the Taxonomy Working Group defined as HIT should by and large not be actively overseen by FDA except the things that we could enumerate as falling within FDA, which are the four check marks. Now I'm open to anyone who thinks they can say that better, I've got pen in hand, just give me the words and I'll write it down.

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

This is Meg Marshall and I certainly don't think I can say that any better. I just want to ask the question, I think there may be a disconnect between the intended output of the Taxonomy Workgroup and whether it was done in such a way that it could be leveraged as the boundary of an HIT definition. And I'd like to hear Meghan's thoughts on that and how...and perhaps even David's, as far as synthesizing the output of that Workgroup's scope which was to guide subgroup discussions, not necessarily to create an artifact for external consumption or for a regulatory definition.

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

Right. Well this is David. What I would try to do is just take the Taxonomy Workgroup out of it at this point. I mean, we care about that, but nobody else does, it's sort of inside baseball. And I would say something like what Brad said, which is this Workgroup believes that most HIT is relatively low risk and does not require active oversight by FDA. I mean, I think it would be important...I would prefer to say that it is regulated, but that FDA should choose to use its enforcement discretion Class 0. I would prefer to say it that way, because that really describes what I think we mean.

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

So how about this, HIT should not be actively overseen by FDA except MDDS, medical device accessories and so forth.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Well I think that...this is Meghan Dierks. I think that statement creates a couple of problems and maybe creates more problems than it solves. One is that you must acknowledge that FDA already regulates large...actively regulates large amounts of HIT so you just can't...

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

That's why the exception, okay. So give me those categories, I'll write them down, got pen in hand, MDDS, medical device accessories, certain CDS and then we're leaving open the possibility of expanding that based on the Safety Workgroup.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

So it regulates disease severity algorithms, it...

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

That's CDS.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

...regulates...pardon me?

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

That's CDS.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Well again, that lacks a definition. I don't want to get into a sort of a tit for tat. I want to just...I'm just expressing...I think the use of broad terms like HIT and sort of declaring everything is out except for these things. When we...the Taxonomy Group acknowledged early on through all our deliberations, it was very hard to specifically come up with a definition of HIT, that's why we went and...we felt it was most important to do it from a functionality standpoint. And so we struggled with the same thing and I'm just...it'll be the last time I comment on this, that I think that these create...that this is perpetuating an ambiguity. And you have to be very cautious with declaring...when there's ambiguity around the term or the acronym or whatever to declare it's all out, when half of it is already in.

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

So that's a stylistic thing about defining what's in versus what's out and I actually think this clarifies a ton, because there are all sorts of people talking around Washington and around the country about whether FDA should regulate HIT or not. It's a very, very popular topic. And to be definitive and clear, to say, no, except those things that we enumerate, and we can enumerate them, I mean there are 1700 FDA classification regulations, if you want I can write down each one of them that's relevant, but we can write down with fair precision what FDA ought to regulate.

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

So...but I disagree. I think the answer should be yes, but they should choose not to do so except in the following circumstances....

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Guys, this is Anna McCollister-Slipp and I was very active in working with Joe and some of the others on coming up with some suggestions on specifics. And I think maybe, and I could be wrong here and I was only sort of half listening in, trying to get some other stuff done this morning, but I think rather than saying...I mean, my...what I was suggesting is that...not that FDA should regulate HIT, it's just that it shouldn't be pre-approved. I think the idea was that FDA had the regulatory discretion for HIT, but it was not to be pre-approved...FDA. The goal was to be able to create a system by which the data and all of the elements for doing retroactive risk determination will be collected and it will all be completely transparent. To be able to get that sort of regulatory discretion you had to...the manufacturers needed to commit to full and complete transparency, but that it wouldn't have to go before FDA before it could be admitted to the market. Now I don't want to speak on behalf of Joe and some of the other people in the Risk and Innovation Subgroup, but that's the intention that we were discussing and that's my...I got the sense that other people were in agreement with my perspective there.

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

That's a good suggestion that we go around and ask other people who've been silent to chime in on this. What is the view of the group?

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

Do we know who's on the call?

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

Well, from the attendance, so we've got probably 15, 20 working group members on.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah, I wasn't on the beginning so I wouldn't have been reflected in the attendance, but...but I think it's an important distinction because as a patient, I'm not particularly comfortable saying FDA doesn't have the ability to regulate anything. I...stopped on his way to the marketplace if it's low risk, I just want...I think it's completely fair for somebody if they get that sort of leeway in regulatory discretion to be able to get to the market clearly. But they need to have whatever elements are determined to be important to be transparent, whether it's access to complete data or the algorithms on the part of the...or whatever the case may be, that needs to be available in exchange for the leniency en route to market.

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

Have either Joe or Lauren joined the call? That's a real pity, it's going to be hard because they were the by far most vocal advocates for this deregulatory stance and so, I mean we have to go on and I'm trying to remember as best I can what they were articulating.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Well if you remember Brad, the last...at the end of Joe's presentation I presented like two to three slides on my recommendations, that's sort of what I was proposing on those slides.

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

Right, I understand.

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

Add to that, Julian here, as I read the slide, that first bullet says, take the Taxonomy Workgroup report and classify all of it as unregulated, but then in parentheses enforcement discretion by FDA. I think perhaps this is capturing that conflict, that unregulated is not the same as enforcement discretion, at least I don't think it is, I'm not the expert here on that point. But I think we're actually saying two different things in this slide and maybe what we're really saying is it falls within the potential scope of regulation but the default position is regulatory discretion for things that don't fall within categories that place them at known or potential higher risk.

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

So I'd like to propose that we take the determination of what's regulated or unregulated off the table, because no one here, including me, is qualified to say that. It's a federal court, it's ultimately the Supreme Court will say what the scope of the Federal Food, Drug and Cosmetic Act is, none of us have the power to decide that, unless we're recommending that Congress change something. So we need to be careful and be clear as to what we can legitimately offer a view on. So I would say that we should focus on oversight as opposed to regulation and the question therefore is, should HIT be actively overseen by FDA?

That's the question for the group and the way we've written it now is to say the answer to that is no with exceptions and those exceptions might be very big exceptions. I mean MDDS is actually a fairly small category, device accessories is bigger than that, CDS, I don't know how big the high-risk category is, but compared to all EHRs and all the other stuff that falls within HIT, it's pretty small, relatively speaking. So the question is, should FDA actively oversee HIT? I mean, that...my goodness, that's the ultimate question we've been working on all summer and so we need to get this right. Anyone else who hasn't spoken want to offer a view on that?

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

Brad let me ask you, Julian here, for a point of clarification. It would help the discussion, I think, if you could help explain the concept of actively oversee. Would that mean that if they didn't...if they were not actively overseeing something that there would still be registration and listing requirements?

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

So active oversight, good question, active oversight would mean that FDA chooses to apply any of its regulatory programs or requirements on the product. So if something is not actively overseen, it means that it would be not subject to any of the FDA requirements whether it's registration, whether it's quality system, whether it's premarket clearance, whether it's post-market reporting, adverse event reporting, market corrective action. Not overseen means not overseen, it means FDA is not in any way imposing any requirements on that category of product.

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

This is Bakul, I'm sorry, just to ask a clarification question. Is the workgroup thinking that if such products are not actively overseen by FDA, does that mean nobody is actively overseeing this? Is that the proposal on the table? I'm just trying to help solve the problem.

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

Good question, that's not the proposal. The proposal is that FDA not. There are different requirements from ONC and FCC, this wouldn't address those and the hope would be, among other things that the private sector would develop private sector driven standards and certifications and other programs designed to help regulate. So this is very narrow or specific, I should say, to FDA.

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

I..

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

This is Keith...go ahead David, I'm sorry.

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

Yup. So, I would not favor this, I don't think there has to be active oversight but I do think it would be helpful to require the developers to register. And I also think it would be...I think we need more active surveillance, that was discussed at some length at...more ability to...more reporting systems and more transparency around safety issues that are reported.

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

This is Keith. I think that that goes along with what the proposal was and what Anna was trying to say is that it is isn't saying that there isn't a feedback mechanism in this. But it's that it's rather than have the oversight that we're talking about...I mean, the clear thing that was stated in the group was Class 0 and Class I, but then have an active program, and this is what Anna talked about too. It was predicated on having an active program of transparency where you could see how different vendors or different developers had solved the problem and what their success was and what their failures were. And replace it with...replace some of the regulatory oversight with the transparency of the system and learning system.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah, and if you remember what I proposed on the slides that Joe put up is rather than having FDA pre-approve everything, we require transparency. So there still is...it still is under the purview...the regulatory purview of FDA, we're not getting rid of FDA's role here, we're just sort of changing the way it does business, so to speak. So rather than FDA constantly having to dig through the various bugs and etcetera, we have an online system by which patients or users or whoever the intended audience is for the particular software, can rate the software so that you can easily identify bugs and you can have a much faster rated iteration.

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

But that's on the next slide and all of that's the second slide, which is the next one, which talks about in lieu of FDA regulation, some of the things that could be done.

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

And the reason for framing it that way is that what you just described would take a statutory change to give FDA that role. FDA doesn't have that role now, they could do it, but it would take an act of Congress. So, in my discussions with the group, the group actually favored doing that privately...the FDA.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

I'm sorry, Brad, it's Meghan. Can you...I missed that, can you repeat what you just said about it would require a change in the statute. What was that about?

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

So Congress has given FDA certain specific authorities. They can require adverse event reporting, they can...

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

No, I'm...I think I'm personally clear on what the statutes do allow them to do, but what was your referral of what would require new statute?

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

So setting up a, whatever you want to call it, a marketplace where people rate software...

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Oh, okay.

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

...not within FDAs power right now.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Agreed, but I don't know...

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Well I don't think any...

Michael Flis – Regulatory Affairs Director – Roche Diagnostics

This is Mike.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

...but I don't know if that's what Anna's...

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

Can you guys go to the next slide because I thought that we covered this under the next slide and I'm beginning to really lose grasp of where this conversation's going. The next slide spoke very specifically about FDA...in lieu of FDA regulation for HIT as delineated in the slide before, we recommend that FDA, ONC, FCC use their collective powers of persuasion to encourage and organize private sector oversight including creation of standards, private certification, a public process for customer rating HIT, isn't that what we were talking about?

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

Well part of the issue's...

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

It is, but Brad's correct, that goes beyond what the...

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

Correct, but this says, in lieu of FDA regulation, am I missing something?

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

I'm sorry, what slide are you on?

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

I'm on the next slide, whichever the next slide is.

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

It's the one being shown on the screen.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Oh, because I'm following Julian's versions, I'm sorry, because I thought we were directed to use Julian's, which were...

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

It should be the same.

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

It should...just to clarify, the version I sent out was the same as the one that had been distributed earlier this morning, but a few fields were completed on two slides and a footer was added to one slide, so numbering should be identical.

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

So slide 11.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

So...yeah...so I think the challenge here is if you include FDA in this, it is a fact that FDA does not actually have a legislatively or an administrative law power to do any of these.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah, and that's my understanding. I mean, part of the issue that we're considering when it comes to like just general medical device surveillance, HIT being one component of some medical devices, is that there isn't this requirement for transparency and I think this gives us the ability if we're going to have Congress change the law. I mean, right now, you just have to submit adverse events and adverse events is a pretty...it's a pretty limited collection of things that can go wrong with medical devices. But I would see this as an opportunity to encourage/ask Congress to expand reporting requirements across all medical devices so that there's greater transparency, including HIT. Because if you're collecting all of this data and most of the devices that include HIT components, whether they be MDDS or whatever, collect data at a much more granular level than they're currently reporting through the...system, then I think that should be reported and transparent. And I think that that would be a way of increasing the rate of innovation but making it much more transparent so that you can have a more active, iterative process and people understanding what their devices strengths and weaknesses are.

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

Guys, this is Matt Quinn from FCC. One thing I'd ask you guys to think about is right now we don't have really good grasp on where the risk lies in Health IT...some areas we have a pretty good idea, others we have less. And so as you're thinking about this, think about how where we identify places where we might not have anticipated that there is risk and it emerges through reporting systems, or places where we thought that there would be risk, but because of whatever's going on in the field that it's really been mitigated, how that would impact this framework. Does that make sense?

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

I think...this is Keith. I think that the purpose of the framework really was to address that question, is that you don't know all the risks up front...

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

Right.

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

...and some of the risks are very provincial to how the developer put together things and the main thing here that we were talking about is that the vendors and the developers have a very rich database of issues and feedback and enhancements. And that by sharing that information and making it more of a sharing environment that we talked about, that even though FDA has like these adverse events, are we really leveraging it to learn from in the general marketplace? Does everyone have access to it and can see it and to see what other enhancements other people want? And so the idea here was really to shift the focus from upfront work, before the product goes out, to increase the surveillance or increase the transparency of what happened with the product when it went out.

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

I think that's all encompassed on slide 9.

M

Yeah, slide 9.

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

We talk about how it's broken at the written law level, one of the suggestions being that a notion of a new construct, a Health IT Safety Administration, termed I guess HITSA, was discussed, which would involve broad stakeholder involvement be emphasized. So I think that's encapsulated. A lot of the things everyone's mentioning are actually encapsulated in what we've done so far.

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

Maybe I missed it in describing it. My point was how do we use the...as we learn more about risk, I'm just asking that we think through the practical implications of, as we learn more about risk, as it...empirical ways versus anticipated ways, how do we adjust the sticks and carrots of regulation? And what is the mechanism by which we apply the sticks and carrots of regulation or ease them off, as we learn more about this? So how do we incorporate that learning cycle...the quality improvement activities but also regulatory ones?

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

I think that the idea was that rather than try to respond to each one of those in a regulatory way, is that you're really increasing the transparency so the market rewards and punishes, essentially unsafe products, or poorly designed products.

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

But I guess...I don't...

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

All right, guys, can...I have to be the taskmaster here. We have less than an hour to conclude what we need to get done and we need to be a little bit focused on where we can achieve consensus. And if there are areas that we can't achieve consensus, then so be it, we have to let those go...

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

And Brad, to support that, we...many of these things are already covered in the slide deck so we're kind of covering territory again that we've already discussed.

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

Absolutely.

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

That's true.

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

So, and this is great, it's great that we have so many people today, it's been a smaller group in the past and I know that's in part because we've had a lot of meetings and now that we've got a larger group, there are issues that we're talking about that honestly we've talked about before. And so I need to figure out the process side of this. But let me try and get everyone focused on slide 10, okay, which seems to be the root of the problem in terms of whether there's a consensus or not.

And so the original concept at the start of the hour an hour ago was...I'm going to use different words, but I'm still I think staying faithful to what Joe and Lauren and some of the others have been advocating, is that HIT should not be actively overseen by FDA. What I'm hearing is that particularly among folks not on the Regulations Subgroup, which is important, because that's the next step for this, we go out to the broader group, is that that's a bit too I almost said...that's not the right word, but it's not tight enough. So let me just propose that, and I wish, I really wish Joe and Lauren were here, I'm worried that we'll end up just kicking the can down the road and when they're on next, we'll have to go through some of this again. But how about HIT should not be subjected to FDA premarket requirements except, and then list those areas where we think it potentially would justify FDA premarket requirements. If we focus it "except" and then list those areas where we think it potentially would justify FDA premarket requirements. If we focus it on premarket requirements, will that address the concerns that I'm hearing?

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

Hi, this is Martin Sepulveda and I worked with Joe and Lauren. I think that substantially captures the intent of what's in the slide. Fundamentally the goal was to create an environment in which those things for which there's an evidence-base that warrants some level of regulation that that appropriate level of regulation be applied. And for those things which include the vast majority of things for which there is no evidence basis that there is risk warranting regulation, that those things shouldn't be regulated. So I think the concept that, and I'll use non-regulatory terms, everything is in scope, but only those things for which there is an evidence-base that warrants regulation be regulated, I think, satisfies the intent of what Lauren and Joe put on the slide.

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

So I'm going to sharpen my pen here and I'm writing this down and I'm going to say it out loud, I wish I could type it on the screen for you guys to see, but I'll just...I'll have to verbalize it. HIT should not be subjected to FDA premarket clearance, except potentially and I say potentially because some of these categories aren't necessarily Class II or Class III, MDDS for example, is actually Class I. So, I'm going to drop MDDS off, because it's not subject to premarket clearance, so I'm just going to leave it at the last three...

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Unless it's...

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

...medical device accessories, certain high risk CDS potentially and higher risk software, if we can extract regulatory specs out of what the Safety Workgroup did, based on the Safety Workgroups work. How is that?

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

Works for me.

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

Brad, this is Meg Marshall. So I just have a couple of thoughts here. We have talked before and I think very early on Bakul had endorsed this, that there could be a thought FDA that FDA...touch. And I think the term premarket approval, premarket clearance while I think your intent is because it implies a certain number of activities related to that level of regulation, perhaps it would be beneficial or valuable to talk about the activities that we think should be part of an FDA light touch. So your statement of HIT in general, because we feel that there is an evidence that it's at a high enough risk, should not be overseen, except for those that qualify, and then those should have this FDA light touch for example, and then list out those activities. And I think some of those are covered to the point that in the next slide.

But I would like to raise a point around the risk identification. So the fourth bullet here, the higher risk software use cases per the Safety Workgroup report, has there been discussion around synthesizing the output of that assessment matrix and how that could actually be distilled into something that would make sense. So as a developer, or...how do I know whether or not the piece or the intended use of my functionality would fall within that higher level risk case. I think that that's an unknown that maybe makes this a little bit more difficult to tackle as well.

And then my final point is just a request, and you may have covered it earlier in the slides and if so, I apologize. But I think that you would probably get a much higher comfort level if you would provide a distinction between, and Bakul referenced this a few minutes ago, that there are some very specific details and nuances around are you under the definition of a medical device versus FDA regulation. And I think for many of us who walk that line in what we develop every day, being considered or defined as medical device also subjects you to an excise tax, also subjects you to provider Sunshine Reporting and things like that. So you may hit a higher level of comfort in making that broad statement if you could also distinguish the definition of a medical device per the HIG.

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

So, a couple of thoughts; one is that your question about the work of the Safety Workgroup. I don't know if you were on earlier, but I had a fair number back and forth with a few members of the Safety Workgroup basically seeing if anyone could extract regulatory specs from the output of that group. Something that I could use in this presentation to define more specifically, even if it's at a high level, but define in some manner the categories that would meet this and we came up with nothing. And I don't know if anyone's...I mean, it's just an intellectual challenge getting from the output of that group to something in the form of regulatory specs, no one's been able to do it yet. So if someone can do it, great, I'd love to take it and drop it in here.

So I think the second...another point that you made is, shouldn't we say, okay, now the first bullet point is going to be limited to sort of excluding these things from the premarket requirements. The second bullet point then, that's on the existing slide, it says for the regulated software, it will be important for FDA to improve the regulatory system as outlined on slides 3-5. I guess I would propose expanding that reference to also add if there's something specific we think ought to be done. I've heard David say a couple of times here, shouldn't some of these people register their facilities. Okay, if that's the view of the group that you want this excluded category to be subject to registration that would be an ideal place to say that. So let me put that on the table first, do people favor asking vendors...I'll call...the word of the statute is manufacturers, manufacturers of HIT to register their facilities, is that something the group wants to see done?

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

Brad, I guess...this is Jarrin. Just I'm a little confused, I guess, with Meg's prior comment because she mentioned that part of what I guess is in some of the interest is that you avoid doing things like paying the medical device excise tax. If you're subject to enforcement discretion, and you're taken off the table, and I'm saying that informally, then you're not required to register or list anything, therefore you are not subject to the excise tax. So if we were to go back to forcing HIT vendors to then register, then we're sticking them right back into the place that we're trying to have...we're trying to get them...we're trying to avoid.

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

Exactly. So people have to make that choice. Understand that if you require them to register, then they also have to list what they make, and that's the trigger point for the tax. Now...

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

Which is why...and I want to go back to the whole argument of enforcement discretion, pro or against. The fact of enforcement discretion is look, you're a device, but we're not going to regulate you because of enforcement discretion where we're using discretion to say that we're not going to actively regulate you. I actually think that's a pretty cool vehicle, which can actually foster innovation and avoid stifling some of these wonderful technologies that many of us are actually working on. The fact that it's...the fact that you're a duck doesn't negate later that well, I'm not going to call you a duck, you're a duck, you're always going to be a duck. You may have to go in a pen or you may be free-range, but you're a duck, you're always going to be a duck.

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

A free range duck?

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

Yeah, can we put free-range duck in the slides, please.

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

So let me...so we have a clear choice, we have, I think a clear choice. One is, do you do what Jarrin suggests and you say this HIT ought to be subject to enforcement discretion and that means not registering and not listing or, you're saying no, they need to register and list. So can I get, I don't know how to do a vote on the phone, but can people express...I'll state it one way and see if anyone pushes back, it sounds like Jarrin would. Is it the consensus of the group that we ought to recommend that HIT manufacturers register their facilities and list their software products? Who would oppose that? Jarrin, can I put you down as one, sounds like you would oppose that.

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

Sorry I was on mute. Yes, of course I would oppose that.

W

So, this is...

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

Okay. So who else would be in opposition to that?

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

Put me down. This is Keith.

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

Brad, can I interrupt for just a second.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Brad, can Meghan...yeah, oh, go ahead.

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

Brad I was going to interrupt for one second. I was going to ask, maybe a point of clarification when people say oppose or for, to that previous statement you just made, it would be good to understand what's driving those votes or those opinions. Because it's important to sort of understand wh...are there economic issues, are their patient safety issues, are there innovation issues.

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

That's a great point.

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

If simple registration listing, the cost of that or just the act of doing that is causing the issue, when that input comes to the feds, we can understand what's driving that, as opposed to simple yes or no.

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

Good, so it's a good suggestion.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

And Brad...

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

So let me go back to Jarrin...

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Brad, before you do the poll, this is Meghan Dierks. I just want to clar...I wanted to put a point of clarification out there that again, registration and listing is one of the specific tools that the FDA uses in its current regulatory framework. And I think you should be cautious to say that that would be an a...that would be applicable to everything that came under regulatory...under FDA regulation. And this gets at the crux of what your group could do, which is to propose other tools, other regulatory tools to add to the standard set, so it is not necessarily true that even with the most minor degree of regulatory oversight that one would have to do registration and listing. That is the current framework but that's what your group can do.

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

I got that. I got that. All right...

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

So don't force people to say that it would...you absolutely have to vote yes or no, just say, do you have another suggestion.

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

No, no, no. Look, I'm going to exercise the chair's prerogative. I'm asking a question, we can then ask a subsequent question if that is not what the group wants to do, we can ask a subsequent question, should we recommend a different regulatory oversight? I got that. I understand that. I want clarity or closure on this question first and then I'll move to the next question. All right, so to Bakul's point, it is important that you say why you think this; is it your concern about the tax, because again not all medical devices are subject to the tax, those, for example, that are sold at retail would not be subject to the tax and so forth. So it doesn't automatically mean that the tax applies, but it does mean that you're in that zone, all right. So let me understand, Jarrin, let's go back to you, you voted first. Your opposition, is it because it's unnecessary for safety and effectiveness, is it economics, what is your reason for opposing?

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

My reason for opposing is that if you make a...the lowest level risk health IT, which includes many mobile medical apps, which are clearly in my industry, if they pose little to absolute no risk to a human being, then I think that making...forcing a company, which is usually a garage entrepreneur or someone in a college dorm, to register and list their device with the FDA is unduly burdensome. Therefore, if we exercise enforcement discretion for those lowest risk apps, which there are many that were enumerated by FDA even a year ago, during a briefing on the Hill, then they're clearly just not going to be regulated. Sure, you may be a medical device, you are a medical device because of what you're saying, but you're so low risk that we're really not going to look at you, therefore go forward and innovate.

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

Great. Keith, I think I also heard you vote against it, what's your thought process opposing registration as it exists today?

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

Well I think I'm going down the same road as if it...but I would like to ask another question, what does it achieve just to register if...what would that accomplish, outside of the act of registering itself, what more does it give us? Does it provide any benefit?

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

So that's a great...yeah, that's a great question. Typically the rationale for registration and listing is it forms the database that FDA uses for its inspectional purposes driven by the imposition of a quality system. So normally what would happen is a firm would register, they'd go into a database and then periodically, depending on what kind of product it is that they listed, FDA would show up at their doorstep and inspect for the quality system. If we're not imposing quality system on these folks, then registration and listing is a more sort of, I guess, academic exercise of knowing where the firms are so that they can be communicated with. But you're right, it's a...I shouldn't say...I shouldn't speak for the group, but that's my understanding of the issue.

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

Brad, if I'm not mistaken, I think it also would help in reporting any issues or problems and say the standardized way to refer to the product and some means, kind of a handle or a label to track things. So I think that's...for some of what we're talking about, we put a heavy emphasis on the need for thinking about innovative reporting approaches. And if the kid making the product in the garage and releasing it, if we don't know anything about a product in any database anywhere, and no way to report problems with it, then we may be throwing the baby out with the bath water. But there are many parts of the registration and listing as Brad just described, and again, I'm not an expert at this but we have to be thoughtful of fact that if it's not at the FDA. And of course the question was very specific that you posed Brad, that we by not having that pathway, we have to have some other pathway based upon, I think, the consensus of the group on the many calls that we've had, some way of extracting...

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah and this is...I'm sorry, I didn't mean to interrupt. This is Anna. I'm just wondering if there's a way that we could use registration but turn the process on its head. I mean, say if you register...because I think it might be helpful for FDA and patients and everybody else involved in this ecosystem to know what's happening and what's out there. So maybe those who register would be entered in the system, would be able to participate in this sort of ongoing marketplace of ratings, rapid iteration, etcetera. So if you choose not to register would be FDA would have the discretion if they're found and have quality issues or some other issues that could affect patient safety, then they would be under the potential for greater regulatory enforcement than those who had registered. So that registration, first of all it needs to be easy and not something that's burdensome, because we don't want to create a system by which the people in their garages and their dorm room or whatever are not motivated or interested in innovating in health, that would be very bad. So we need to have registration as a very easy process.

So secondly, it needs to create either a safer environment that...so that people...we know what's out there and we can understand what's happening and it can be within this process of transparency. If you choose not to do that, that's okay, but it's under the potential duress of greater regulatory burden.

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

Okay so if I can continue to go around the table, we've heard a couple of folks and their opposition to registration and listing, is there anyone else who would oppose that recommendation?

Michael Flis – Regulatory Affairs Director – Roche Diagnostics

Brad, this is Mike Flis. I'm actually going to vote the other way. If...

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

Vote...what does that mean?

Michael Flis – Regulatory Affairs Director – Roche Diagnostics

I vote in favor of requiring registration and listing if this is the mechanism we're going to use to bring quality data from post-market experience to make it transparent and create this learning environment that everybody is pursuing...should be using...

(Indiscernible)

Michael Flis – Regulatory Affairs Director – Roche Diagnostics

...it's no longer for quality system inspection at the facility, it's for providing these companies a means to upload their quality experience.

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

So I'm presuming that everyone...I asked the question in a very definitive way, or specific way because I wanted to be able to assume that anyone who was quiet would support, by the way I framed it, would support registration and listing. So, I'm hearing...

W

Okay, now this...

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

With that added context, now we get into the reeds because now we're talking about very different...a very different approach as to why we would cause companies to register and list, including the lowest of the low HIT products, which are the ones that I'm arguing shouldn't have to register and list. And I'm talking about drug dose calculators, for example, why? Because you can do those calculations on a regular calculator so what difference does it make, I mean, those kinds of things. If we're going to inject that kind of context, then we're going to have to really go through a real examination of all of these scenarios to come up with an answer of should or should they not have to register and list.

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

I have to agree with that, that that's...this is Meg Marshall. My silence is not that I'm endorsing one or the other, I'm actually abstaining because I don't think it's a fair question. I think there are other activities that we could be looking at, other than the simple registration. And the way that it's been posed is it looks like high risk HIT automatically should fall within the preapproval process, and I'm not sure that that's the case either. We haven't really seen a good way to define risk, as far as low versus high and actually it's my opinion that even the high risk HIT at this point should not fall within the pre-submission process, but that it would actually have more of the...some of the activities that are part of the pre-registration, but not all of it. So, I would actually, I'm abstaining from the question because I'm not quite too sure how to answer it and get all of the concerns out there.

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

Julian Goldman here, I'd like to jump in Brad with a personal opinion and experience here in answer to your question. I am of the opinion that we absolutely need some way to track devices...to track manufacturers and to track devices. I think calling it registration and listing implies that we continue using the system as it exists today and I believe that that's problematic and not necessarily appropriate or suitable for the full range of health IT related devices that we have under discussion currently. And I can speak for my hospital, when we fell under MDDS, and I've been involved in registering and listing our facility for a homegrown incredibly simple software to transfer data from a device into an EHR. Very low risk, essentially a harmless application that has triggered the internal need for development of a quality system in our hospital with significant expense and manpower over the last year or two, many, many meetings and it's been very burdensome, out of proportion to the application for the software that was developed. But that is the current regulation and we've done our very best to follow it.

I think that's an example of the problem with just using these terms in a simple way. And of course, many people on the phone know this, and I'm stating the obvious, but I think it's a bit simplistic. And I'd like to echo what I think Meghan said, which is that this is...and Dave and others, that this is our opportunity to raise the issue that we need a different...may need a different regulatory framework. I believe we do need a different regulatory framework, so that we can be aware and monitor and track and have the means for reporting, but do it in a way that's appropriate for the risk, complexity and so forth of the devices. With that I'll stop.

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

Hi this is Mo and I've been quiet and listened, but I completely agree with the last two statements. That has been my dilemma all the way through and I think Julian you stated my opinion perfectly.

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

Yeah, this is Dave Bates...

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

So...

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

Could I just come in. I'm not wedded at all to any particular thing, I just want something that would enable tracking so I agree, too.

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

Say that again, tracking what?

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

I would just like some approach that would enable tracking. It doesn't have to...as Julian said, it does not have to be the current approach, I don't want something that would be duly burdensome.

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

Okay. So I'm getting kind of excited because I hear a consensus emerging and I want to see if we've captured it. I'm pressing using the words registration and listing because, not to be simplistic, but to be precise, those are existing frameworks and I wanted to know whether people supported using those existing frameworks. What I'm hearing is the answer is no, we don't want to impose those existing frameworks on HIT, what we want is a more tailored approach to tracking the identities of those engaged in developing and selling HIT. And it would have a different purpose than the traditional registration and listing where that purpose is focused on allowing for FDA inspection, by and large. This would serve a different, much less formal purpose of facilitating kind of the creation of a community that would allow for learning and certain other proactive things that could be done to enhance the ultimate quality and safety of HIT.

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

Brad, when I mentioned tracking, I also meant...maybe I wasn't explicit, but I meant a means to report, so for the users, consumers and others to report and share any adverse events or problems. So not only the data...

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

So, only to the reporting slide...

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

Yes, exactly. Exactly.

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

Brad, this is Bakul. I just want to make one correction to your statement you made...

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

Um hmm.

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

...and I think Julian tried to correct it, the registration listing as it stands currently is not only meant for enforcing enforcement activities, it is just...enforcement activities are just one of the things that is used as a result of knowing who the manufacturers are and where they are.

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

But it brings certain baggage with it...

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

So the group can discuss whether those baggages are worse for health IT and for other reasons they may or may not be. But I'm hearing other folks, including David, talking about the need really is to knowing who it is and what products are out there so a foundation for a learning system can be built.

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

I agree with you that it's remarkably similar in that way to the way the registration and listing functions now, but that system seems to include some baggage that people oppose and that's why I said it the way I said it, that we're not in favor of using the existing registration and listing process because of all the baggage that comes with it, but rather something more tailored. Now, when I say more tailored, I mean registration, to be clear, takes about 20 minutes. You get on the computer, you go to the FDA website, you answer a bunch of questions and you're done. Listing is an annual thing that you let them know what product, by categories, you're making. So let's be specific. What...when you say less burdensome, what do you mean? What would this tracking and...what would this tracking system look like that's different from the existing registration and listing process?

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

I don't think it's the act of...like you said, the act of registration is not the burdensome, it's the...it's exactly what we were talking about, what Bakul was talking about is that given that I'm registered, what are all the activities that I'm subject to. And just like as we were talking, I really buy into the argument that David and Anna and the first person, I didn't catch the name, was talking about is that if we're going to have a transparent reporting system, you've got to at a minimum identify what you're talking about so that you can bring all the data together and be able to see it. And so I guess it's really...it's not the act of establishing a record in a database, it's really the act of what do you inherit when you do that.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Right. And I'm saying, my argument was if...and I hate the term registration, but maybe it's entering the marketplace or joining the mark...whatever nomenclature we want to adopt. But that there would be...that that would be more of a free environment, if you choose to be out there and transparent and participating in this ecosphere marketplace that is or is not moderated by FDA, however we want to construct it. Then you're less subject to more draconian potential regulatory oversight, that...this because you're being open and free and adhering to sort of the rules of this marketplace, you're given more leeway because you're participating in a system that gives you rapid feedback and rapid iteration.

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

See, that's where I get confused and maybe it's my lawyers hat, but when you talk that way, then I go to slide 11, existing slide 11 and say, shouldn't that just be a private thing? If it's going to be voluntary and you're rewarded for just voluntarily submitting yourself or subjecting yourself to it, that's not a government program.

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

This is David Bates. One place that I disagree is whether this should all be private, I don't think it should. I think there has to be some federal involvement or it will not happen.

(Several people speaking over one another)

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

Let me...can I put a proposal out there. So, let me modify what I said before, I'm...you can tell I'm trying to reach a resolution that everyone can support, so...

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

Right.

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

...something about a federally created tracking system that allows for the participating members to be rated by...who's going to rate them, customers? I mean, is it like eBay or Amazon, you go and you rate...give feedback to someone you've bought something from?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Yeah. Yeah, and if it's an EHR, then it would probably be physicians or hospitals or CIOs. If it's a mobile app, it would probably be...

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

So let me be clear, is it mandatory to participate, but then obviously it's voluntary for the customers to actually take the time to go and give feedback.

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

I'm not actually so interested in the rating part of things, I'm much more interested in the...as Julian mentioned, in the adverse event reporting. So I want to have a listing of people who are creating things and then have people be able to report adverse events or safety issues, which can then be aggregated.

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

So, I got that, and I'm going to preserve that. But David, unless you'd object, there's a big group, I perceive, that is really interested in this rating system. Several people have been pretty strong advocates of that, so unless you object to that being included, we can do both. We can have both the rating system and the connection to the reporting system.

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

So...

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

I think the rating system...go ahead, I'm sorry.

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

If it's both I'm fine, the rating system should pretty clearly be done in the private sector, the public sector does not want to get into that.

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

Except I just heard that that was what the value of this was, in addition to allowing reporting would be it would create an opportunity for that rating system.

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

If you have a public database, you can get a listing for anyone and the...and ratings tend to be quite controversial and they're...in other sectors, they are better operated by the private sector.

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

Yeah, you don't want to imply a government endorsement of the ratings.

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

All right, then I'm back to the way I had it where the rating system is a private thing and we leave it and hope somebody takes the initiative and creates it, but this tracking system basically is to connect to Julian's slide number 9, to facilitate adverse event reporting.

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

Yeah.

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

Brad, let me also speak with a specific example if I can to I think hit this point home. Over the last 15 years or so, we've had the opportunity to use and cycle through a number of different bedside EMR type products for the real-time care of patients. And some of those products, some of those vendor's products have been...have gone through the FDA pathway. I'm speaking as generally as possible, FDA pathway, so certainly registration and listing. The other products we've had have displayed patient's vital signs and other clinical information, and when we speak to the vendor, we've been told, well no, we did not go through a regulatory pathway, this is not...it isn't necessary. But of course they then say, you should not use the data on the screen for patient care in real time, you should only use that for reviewing something. The something, I can't imagine what that is, because I am an anesthesiologist and I stand at the head of the bed looking at that screen and using it for all real time purposes, all vital sign information is reviewed on that, all medication, the strength and laboratory values and so forth.

But vendors over the years, including today, have said, well, this is not a requirement, there's regulatory discretion, we have not filed with...we have nothing to do with the FDA at the moment, that could change in the future, and we're cautioning you, as a physician, that you can't rely on it in that way. And that's really outrageous, and we also have an...it's just outrageous. I mean if we do anything in this activity that we're doing, we just can't have that happen anymore. It's...and it isn't the technology, it's not the kind of screen, it's not the kind of software, but it has to do with the risk of the application of that technology and I think we all agree that that's a really...I hope we agree, that that's untenable now. And there hasn't been a way, for example, to then report a problem with a product like that. There's...you can report it to the company if you wish, but in truth, most of the times, companies are...unfortunately are good at saying, we never heard that before, you're the first customer to ever tell that to us, and you...

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

So let me put some language out there as a quasi-motion or whatever, but I'm trying to keep us focused and figure out what we can say in this spot...

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

Hey Brad, can I jump in just for two seconds, I'm really sorry, because I'm seeing two different things that I think people are kind of glossing over and I just want to make sure that we understand the distinctions. One is this idea of creating this non-registration registration type vehicle that's not FDA necessarily, it would be for all class devices to be able to reach adverse event reporting in whatever new schemata we come up with, which is what is on slide 9.

The other is this idea of registration and listing, which brings all the baggage in, which is exactly what I would like to avoid, for the lowest risk devices, which are Class 0, for example. One thing to keep in mind is that FDA, since Bakul said something, which is very important, sure, there is adverse event reporting, we've all talked about how bad it is and it needs to improve, etcetera. But that is one aspect of what the existing registration and listing could provide, in addition to the baggage, which includes things like audits and etcetera, etcetera. So if we were to approach this from the perspective of, the FDA having established the Class 0 through enforcement discretion, but still making it a part of being in the health IT community that you have to register with them. But making sure that they made the distinction that once you register, you are not subject to audits, etcetera, but you would be subject to adverse event reporting in whatever new mechanism they come up with. I think that would be a way of not recreating the wheel and something that's completely distinct outside of something that already exists, which could actually accomplish a lot of what we're talking about. Does that make sense?

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

So...it does, but let me go back to kind of our charter, and our charter as I understand it is not to design the regulatory system, but to identify the objectives that we want the agencies to consider as they design the system in the fall. So let me...so I'm not directly Jarrin answering your question, I'm stating it more generically, with the idea if this captures the spirit, then it's up to the agencies to figure out what...how best to do it. So let me...I just want to get this out there and see if this captures the view of the group. I'm reading what I wrote.

HIT...I can't even read what I wrote...should be subjected to a tracking system to facilitate the adverse event reporting on slide 9. HIT should be subjected to a tracking system to facilitate the reporting on slide 9.

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

Yeah, I mean I would just have a statement here. I mean I think we're...what I think we're trying to say is don't think that premarket is necessary, but that there should be some post-market, and it's important to make that clear. I thought 10 and 11 were the summary slides.

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

No, 10 and 11 are not summary slides, it's additive, it's all additive to everything in the presentation. So I'm not changing the first recommendation, the first recommendation that we went over just a moment ago was, HIT should be subject to FDA pre-market requirements except potentially...excuse me, I left out a critical "not." HIT should not be subject to FDA pre-market requirements except potentially accessories, certain CDS, I'm paraphrasing here, and the stuff coming out of the Safety Workgroup. Then bullet point below it, it says, for the regulated software it would be important for FDA to improve the regulatory system as outlined on slides 3 and 5. Then after that I'm proposing the sentence, HIT should be subjected to a tracking system to facilitate reporting on slide 9. And then the last one remains there, this classification...I might need to change the word classification, this would be provisional to be re-examined. We haven't gotten to that. But David, to your point, this is not a summary of everything we've said before. Everything we've said before is in addition to this.

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

This is Meg Marshall. I'd just like to make a couple of things clearer. It seems like you're creating a statement without having foundational definitions of health information technology or a definition of risk and I'm just curious as to whether that means that the group is endorsing the HITECH definition of HIT, and if so that's fine, I just think it needs to be stated. And perhaps we're endorsing through lack of synthesis with the Risk Workgroup or maybe lack of conflict with the Risk Workgroup, we're actually endorsing the ISO definition of how to identify risk. And if so, that's fine, I just think that it...that they needs to be clarified out there somewhere before your broad statement. So kind of creating that foundation before that happens.

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

Hi, this is Mo, I completely agree with that as well. So I haven't joined in on the Risk Framework debate for a couple of calls so it would be interesting for me to get up to speed and maybe the group can tell me where are they on that classification. Because if there's sort of somewhat of a consensus around subdividing HIT into risk, I think we could tag-team onto their classification for this statement.

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

Right. And the point is, if I'm creating what...I think what I hear Robert saying is, this garage guy that's an extremely low risk, something that would otherwise be defined as Class 0 or Class negative. That I'm just tracking...I don't want to simplify the use case, but I'm not a clinician, I'm tracking weight or I'm tracking my own blood sugars as compared to my diet or my weight. I'm not sure that that's something that we're proposing be included in this registration of manufacturers. I think that...what I'm hearing is that there's something that says it's low enough risk that it would not be subjected to this. So then now you have to look for the definition again, number one of HIT, but then also, how are you segmenting HIT into that risk space, and I think those are two major keys that we're missing.

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

Well, if I can, so this is where the awkwardness of it comes in in these subgroups, because what I'm presupposing is that this will be blended with the output of those two other subgroups. And that those questions will be addressed dead on or square on in their presentation so that by the time you combine these, you've had, I would hope significant discussion on both of those two points before you ever get to the regulatory recommendations.

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

So David, could we just discuss that and if that's the process and the expectation.

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

I'm trying to capture exactly what the issue was, could you go through that one more time Brad.

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

All I'm saying is that we wrote these slides in a fairly truncated manner because we envisioned that this would be packaged somehow with the output of the Taxonomy Subgroup and the Risk and Innovation Subgroup. And that concepts like HIT and what's included in that and the concepts of risk would be addressed previously in the presentation that goes to the HIT Policy Committee.

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

Yes, exactly. That's correct.

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

So I was hesitant to try and say anything here, because I basically just want this to flow as seamlessly as possible from those other discussions.

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

And I would agree with that, that's Keith...this is Keith Larsen. I don't think the intent was to make this a summary of all the groups, but to be additive to the other groups.

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

Yeah, well said. We are...

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

Umm, maybe...

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

We are rapidly running out of time...we're rapidly running out of time. We do, I think, need to allow a decent amount of time for public discussion today, because we've covered so much. I want to make sure we leave at least ten minutes, so that means we only have about five minutes left that we have to figure out what we're going to do. So I'm just going to put something out there, to see how close we are to closure. So I've given you kind of the new first bullet point on this slide 10. There would be a revised second bullet point that would add to what's already written with a statement about the need for tracking. And those are the changes that I'm proposing to make to this, the report of the Regulations Subgroup. And that at this juncture, it would make sense to me to have whatever remaining discussions need to be had among the whole group.

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

Brad.

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

Yeah.

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

This is Mike Lipinski with ONC. I just want to make a few quick points before we proceed further. One is, I heard at some point when you were deciding whether or not, I think it was on the compare...the rating process for products and were best to house that. I think you guys should always make your best recommendation and then like an alternative. So in that example, if you really think it would be best to have it in the government's hands, and then secondly in the private, that would be the way I would go.

I wouldn't make a decision on not holding it and saying...recommending the federal government because you think that there would be endorsement issues, because that was one concern I heard. And the government has ways that we deal with these tough endorsement issues all the time with objective criteria, with disclaimers, we have websites all over the place that have products from the private sector listed on them. So, I'd rather you guys not make determination on what operationally the government can do or within its own legal confines. I mean some things are obvious where it's clear that we don't have statutory authority and we would have to go to Congress or something. But I think you should make your best recommendation based on what rationale other...rationale outside of what you think the governments operational or legal restraints are and then...

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

So, I'm not proposing to change slide 11 because I haven't heard any consensus on a different approach and it seems to me, based on comments, that they've actually several have been supporting this approach. So what I have it on the screen, says in lieu of FDA regulation, as delineated before, we recommend that the agencies use their collective powers of persuasion to encourage and organize private sector oversight including third bullet point down, a public process of customer rating. So, the government...the federal government would be the encourager of it, the persuader of it, but it would be housed as a private sector, that's what I'm hearing in the group and let's see if that's in fact what the group is saying.

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

Yeah, I'm not saying that, I'm just saying that overall, when you make any recommendations, to keep that in mind as to try not...I don't want to say try not to, but like make determination what the government can do like on endorsement grounds or operationally.

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

Can you be specific where you think we haven't done that, because we're down to the final three minutes of this discussion.

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

I don't...I mean other than the comment I heard about there would be endorsement issues...

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

I think that was just a general comment to not shy away from things and they'll sort it out.

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

Yeah, basically he doesn't want us to say, this is not something the government can do.

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

We shouldn't self-filter.

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

He's just saying this is something should happen.

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

Okay. All I...

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

And then Brad, two other quick comments. If we have, if we think there are needs for clarification of the slides, for instance the ONC slide, I do see somebody updated on what they meant by where mandates were necessary, that had been revised which I think that is good. But if we think we need more clarifications, should we just send any type of comments to you on that?

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

Well...

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

I know we're running out of time...

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

So let's talk about the segue. We're basically out of time, what I would propose is that we pass...we make this, as amended today, we make this the report of the this subgroup, we pass it over to the Workgroup and then the Workgroup is going to develop whatever the whole Workgroup wants to put together for presentation to the Policy group.

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

Brad, Julian here...hold on just a second. Just because we're segueing away from the slides we were talking about and we were wrapping something up, I just would like to propose and just see if there's a quick reaction, we delete everything before the first comma on that big picture improvements. I think it confuses the issue and if I'm mistaken or if I don't understand, then please rapidly correct me. But, I don't see why it should be con...the conditional statement should be there in the first part of the sentence.

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

Be specific, what language are you talking about?

(indiscernible)

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

In lieu of FDA regulation for health...yeah, in lieu of FDA regulation for health IT as delineated in the slides before comma, we recommend etcetera, etcetera.

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

All right, so...

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

If we can start the slide with "we recommend."

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

So I'm proposing to strike that. Any objection to that?

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

I'm good with that.

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

This is Dave Bates, I disagree with the general approach of saying that the federal government shouldn't play a role in any of these areas.

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

I'm sorry, where do we say that?

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

(Indiscernible)

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

I think all he was saying is by taking out the predicate there, we're just saying that regardless of what happened with FDA regulation, we're asking for the collective powers of persuasion to encourage and organize private sector oversight.

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

Right. I'm...

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

You're turn Dave, I think it's...

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

No, no, I'm in favor of taking out the predicate...

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

Okay.

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

Okay.

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

...but I think that they might want to...those entities might want to use more than their powers of persuasion. I don't think all of the...personally should be in the...necessarily be in the private sector.

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

Anyone else feel that way?

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

I can see where David's going to, because again, what you're saying is the role of government is to do something the private is not doing and maybe setting up this reporting system would be a good role.

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

I didn't see this as the exclusion of other pathways, I thought this was in addition to anything else.

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

Okay, so I mean I could...and I could reword it to make it I think in a way that everybody would agree with it.

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

So tell me what that rewording is, because this will be the official one, we have to agree on it now, this is the last time we're getting together. What do you want it to say?

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

The private sector...we believe the private sector also has many important roles including...

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

So you're taking out really the whole reference to the federal encouragement.

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

Correct.

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

What do others think?

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

We could say something like together with the federal government or something like that.

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

What do others think?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Well I think what, and forgive me, was it Michael with ONC, I think what he was saying is we shouldn't really focus on whether it's FDA or anybody else, that we should just say this is what needs to happen, this would make it work better and then they can figure out the specifics of whether or not that's private or public sector action. So...maybe I misunderstood...

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

Well if we have a view, if we have a view that one is better than the other, it's incumbent on us to express that view. So the question is, do we care how we get there or do we just want the private sector to do these things?

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

I mean for some of them I personally think the private sector's better, for some of them I think that it's better done in the public sector and so I just would not state it this way.

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

Which do you think should be in the public sector.

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

So the ONC has already played a very important role in terms of creation and adoption of needed standards. It's also likely to play an important role in certification. And the other two are definitely private sector.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

And as a sub-bullet I would also include increase transparency and access to data. But, again I think that this could be done through the federal government, one of the agencies or private sector or a combination of both. I don't know that we need to come up with that recommendation in the remaining three minutes of this discussion.

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

Right, I'm agreed. There does not seem to be a consensus around the who, so we ought to just stick to the what. And the what is that these things need to be created. So I propose to say something like, we recommend the following areas be developed...further developed.

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

That works for me. I would recommend adding transparency, but maybe that's in a previous slide or something.

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

A public process for customer rating HIT that increases transparency?

Anna McCollister-Slipp – Co-Founder – Galileo Analytics

Well and my data transparency in terms of all data collected.

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

To increase transparency, okay.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

Brad, before we go to public comment, could we ask David to talk a little bit about the expectations and the activities over the next week and what next Friday's meeting looks like? I'm very curious as to how the workgroup reports are going to synthesize.

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

Sure. So I am sure that I will not have...we will not have a perfect draft by next Friday, but I already have a kind of a shell in which...which includes a little bit of a preamble and a conclusion. And then the intent is to fit the three group's reports together into some sort of coherent whole. Right now it's going to be way too long and there has to be a little bit of reconciliation too. And I'm going to do absolutely the best that I can and I'll have some federal help between now and then, and...but what we have next Friday is likely not to be...is likely to be highly imperfect and probably way too long, that's what I would expect currently. So that's the...that's going to be the general process.

Meghan Dierks, MD, MS – Division of Clinical Informatics – Harvard Medical School/Beth Israel Deaconess Medical Center

So in next Friday's meeting would you be doing somewhat of a dry run then, talking through the synthesized slides, imperfect as they are, to kind of...so that the Workgroup can hear your thoughts and your interpretation and be able to provide feedback.

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

Yes exactly, I'm going to...my approach will be to try and circulate things ahead of time, not to run through all the slides, because everybody will have seen them. I'll highlight a few things, which I think are important points that we need to discuss, but then let people bring up whatever other issues they have. And there'll be some things that we have consensus about and some things that we don't and that will be important.

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

All right, so we need to wrap this up because I wanted there to be some time for public comment, it's only fair. My assessment is, I'm saying this out loud to see if anyone disagrees, I've been taking down...I've been trying to say the exact words in taking down these edits, I think I've got them. So my proposal is that I'm going to take the draft word off of the document. I'm going to make these changes that we've just discussed and I'm going to send them to David as the report of the subgroup and let him handle next week leading up to the call of the whole group in terms of combining the work of all three subgroups. Is that acceptable to everyone?

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

Yup.

Michael Lipinski, JD – Policy Analyst – Office of the National Coordinator for Health Information Technology

Brad, I just wanted...this is the last one I wanted to make, this is Mike Lipinski with ONC. We put out a request for comment to the general public...and we asked for comments by the 30th of June that we would pass on to the FDASIA Workgroup and we have been able to put those comments together and everything, and they should be distributed to the Workgroup...the full Workgroup later today, just wanted to make you aware of that.

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

Okay.

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

Okay.

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

All right, with that, Michelle, can you open the phones for the public?

Public Comment

Michelle Consolazio – Interim Federal Advisory Committee Act Program Lead – Office of the National Coordinator for Health Information Technology

Sure. Operator, can you please open the lines.

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 public comment.

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

You said we do or do not.

Caitlin Collins – Project Coordinator, Altarum Institute

We do.

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

Okay.

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

Okay.

Caitlin Collins – Project Coordinator, Altarum Institute

Marilyn Waxberg, your line is live.

Marilyn Waxberg – Director – Siemens Healthcare

Very good. Thank you very much. This is Marilyn Waxberg, I'm with Siemens. I first want to make a statement on our thanks to the FDASIA group, I know there are multiple people on the call that are across the other working groups and really appreciate all the hard work that has been done by these groups. The discussion today about the pros and the cons and the current issues I think is extraordinarily important and again, very pleased to hear this lively discussion. It was mentioned very early in the call, and I certainly hope it's not lost, would like to see, as David suggested, the show of alternative frameworks that were considered and some additional information associated with them as to why there couldn't be alignment on some alternative. Thank you for allowing me to make this comment today.

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

Thank you Marilyn.

Caitlin Collins – Project Coordinator - Altarum Institute

We have no more comment at this time.

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

Okay. So the plan going forward will be, I will take these comments that we discussed, I will put them into the PowerPoint, I will send it to David, but copy everyone. And David will take over the pen next week and be working on the full group report and I gather we'll all get to participate in that on Friday. So with that, I want to thank everyone. This was a very, I thought very spirited discussion and I love that, because people are passionate, this is important stuff. People are earnestly expressing their points of view and really only out of that can we come up with truly a group consensus. So thank you for the very constructive discussion from everyone. I appreciate it and I look forward to the next step.

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

I concur Brad. Thanks everyone.

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

Take care.

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

Thank you Brad and Julian.