

**FDASIA Workgroup  
Regulations Subgroup  
Transcript  
July 1, 2013**

**Presentation**

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

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

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

I'm here, thank you.

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

Thanks Julian. Brad Thompson?

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

Good morning.

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

Thanks Brad. David Bates? Todd Cooper?

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

Ola.

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

Great, thanks Todd. Anura Fernando?

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

Here.

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

Thanks Anura. Lauren Fifield? Robert Jarrin?

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

Here.

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

Thanks Robert. Mo Kaushal? Joe Smith?

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

Here thanks. Good morning.

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

Thanks Joe. Good morning. Jodi Daniel or Steve Posnack?

**Kate Black – Office of the National Coordinator**

I believe Steve will be on in a couple of minutes

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

Okay. Thanks Kate. Bakul Patel or Simon Choi?

**Simon Choi, PhD – Senior Science Health Advisor – Food and Drug Administration**

Simon's here, good morning.

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

Great, thanks Simon. Matt Quinn? And Kate Black from ONC?

**Kate Black – Office of the National Coordinator**

Here.

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

Good morning Kate. For – workgroup members I heard Richard Eaton.

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

Here.

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

Good morning, Rich. Are there any other workgroup members on the line?

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

Yes, Elisabeth George.

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

Thanks Elisabeth.

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

Mary Anne Leach from Children's Colorado.

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

Thanks Mary Anne. Okay, with that, I will turn it back over to you Brad and Julian.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Thank you very much.

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

Yeah, great. Julian, I don't know – I know you're just getting back into town, about a week ago, I sent around a pretty detailed agenda to everyone, I mean, it was more than an agenda, it was kind of my attempt to elaborate on the task that we might tackle this morning. So, I don't know if people have that in front of them, if you don't that's fine. Basically, I'd like to propose that we start by summarizing the agenda and then as I've indicated, most of the talking will be done by someone other than Julian and me this morning. So, this is really the first chance in a while for the group to debate, analyze and really peel back these issues.

Personally I submit that now that we're into July, this really is the time to start focusing, it really is the time to start narrowing down the range of topics that we've been talking about in order to ultimately be able to provide, in about three weeks' time, the full working group a fairly focused set of recommendations. And so I think part of the task that we all have is to start separating the important from the unimportant and really trying to bring some prioritization to these topics. So, in the email that I sent around, first off, I offered a high level proposal for how we might organize the next basically eight days. And that is to spend this morning talking about the three regulatory sub-systems – regulatory systems rather, that we've been talking about for the last two weeks, namely ONC, FCC and FDA, and figuring out if they're deficient in any specific way, when it comes to regulating HIT. So that, I think, really as I'm proposing it anyway, would be the primary focus of this morning. And so I'll elaborate more on that later on.

We would also talk about, on Wednesday, Julian is going to spend an hour leading a discussion of the group on reporting issues, because they cut across three agencies, we really haven't spent a lot of time talking about the shortcomings when it comes to collecting data. And so I propose that for the agenda this Wednesday. Also, Wednesday we'll talk about ambiguities. So today I said deficiencies, Wednesday I'm suggesting ambiguities, I'll try and distinguish those two. I'll do it now and then I'll do it in more detail later. In my vocabulary, I'm suggesting that a deficiency is an aspect of a regulatory system that needs to be – a written aspect that needs to be changed. All regulation in some manner is open to interpretation and has ambiguities in it and not to diminish the importance of ambiguities, but that's a separate issue from when you have a written regulatory system that is ill-fitted, ill-tailored, inappropriate for regulating a given subject matter.

So I'm proposing that we spend today talking about that, talking about where the systems, as written, are deficient and then spend a portion of the time, not much, but a portion of the time on Wednesday talking about where the system simply need to be clarified, because it was written in an ambiguous fashion. The third area then and this is – the ambiguities in this next area are specifically called out by the statute the next area is duplication. So where do the three systems overlap one another, maybe they're not fundamentally broken, but they overlap each other in a way that's potentially at least redundant if not conflicting. And then finally, the topic for basically – I think it's a week from today, it's the 8<sup>th</sup>, isn't that a week from today – the big picture issue that – discussion that Joe will lead on okay, we've kicked the tires on the three existing ones, we've talked about the deficiencies. Is there some better way to do this, taking sort of a more of a blank sheet of paper approach and saying, can we come up with better way? So that's kind of the choreography for today through a week from today. And so let me now just summarize a little bit of the data input that you've already received for today.

So number 1, you have received information from particularly the Safety & Innovation Workgroup. The middle of last week, I think it was Wednesday; I distributed a document that we've been watching develop for now a month and a half, but it's this framework for assessing risk of patient harm. And the primary content is all contained in a one-page Microsoft Word document that's basically a chart that shows a set of dimensions associated with software and then examples of lower risk, medium risk and higher risk activity in each of those areas. So as I say, I think people are probably familiar with it; hopefully you've had a chance to look at the most recent draft. But these are the safety issues, number 1, that we on the regulations team are supposed to be focused on and making sure that they're somehow addressed by appropriate regulation – number 1 that they're addressed and number 2, that they're addressed in a risk-based way. That is that the requirements are tailored in some manner to the identified risk.

The secondary work of that group is innovation, obviously, and this morning, only about 45 minutes ago, we distributed to you the current version, as of last Friday, of the innovation side of the equation. And it's a, I don't know, 35 slide PowerPoint, it's been under development, the Innovation and Safety Workgroup examined it on Friday, I gather they're making changes to it. And I would draw your attention to the fact it's basically broken down into three parts. The first part – interestingly enough, they took the approach that they wanted to critique the current regulations, which I think they candidly admit kind of overlaps with what we've been doing in this working group. Then the second part is the part that I find really interesting, it's the part that I think we will find most useful in our work, and that's innovation requirements, and it's basically slides 20 through 28. And I looked through the stuff, I got the stuff over the weekend while I was traveling, I looked through the stuff this morning. And the slides are kind of dense and a bit cryptically written, to the point where if you just read them, it may not be completely obvious what it is they're talking about in terms of what these risks are, risk to innovation I should say.

So I would commend it to your reading, but also it's my hope, and I think this is right, that in the call tomorrow of the whole working group, it'll be the plan – it's Keith's plan I believe, to go through this and to explain the sub-working groups thinking on each of these topics. So, generally I would commend it to you, hopefully you have a chance to at least peruse it, probably not, given that you only got it 45 minutes ago. But we need to make sure that as we go along in the next couple of weeks, we weave in these issues into what we're doing, it really is important that we stay coordinated in that regard. So I really hope you're able to participate tomorrow to hear kind of first hand from Keith what these issues are.

For your background also, as you know, in this working group, we've spent the last five –

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**  
Brad –

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

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**  
Julian here. Just while you're on that slide deck, the one that you just mentioned, I think slide 12 raises an interesting question that we'll have to spend – somehow sort out with the groups. Which is, it invokes the notion of medical device versus HIT and treats medical device – and as you said, it's hard to tell just from the slide deck what was actually discussed. But in looking at the slide itself, it does differentiate between medical device versus HIT, and under – but that's the title, but the physical layout of the slide is physical device versus software. And so we may be inadvertently mixing the ideas of medical devices as hardware versus HIT as software. And –

**Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC**  
I agree completely, yeah.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**  
So, I just wanted to flag that for further elucidation as we move forward.

**Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC**  
Yeah and I think that's a great question Julian, if you wouldn't mind asking tomorrow in the call when this is presented –

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**  
Yeah.

**Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC**  
– you might raise that for discussion in the group.

**Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated**  
I'm not sure if I was on the call on the Friday, I was on the call and we were going through these slides and at one point, I did pipe up. Because I was trying to make sure that people understood that as a lawyer that deals with medical devices, I don't specifically see a difference between a hard tangible product and some other product that is not tangible in form and function. And I tried to make that point, but it obviously did not make it in there, but it is something that raises that kind of an alarm bell in my head at least.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**  
Well, and that most modern medical devices are – have both software and hardware of some kind, as opposed to say pneumatic devices and other purely physical devices.

**Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC**  
And FDA has obviously been regulating standalone software for decades, so – and just as a point of process, these slides, I think, were written Friday morning, before the call, Jarrin, and so I think they're being revised as we speak, before the call tomorrow.

**Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated**  
Okay, that's helpful. Thanks Brad.

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

So we may very well find that this issue's been addressed in the next deck.

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

Right, got it.

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

All right. So other inputs for today's call then include the last five calls of this working group. And just to recap, we had two calls on FDA. The middle of last week, I think it was Wednesday; I distributed an up-to-date deck from that FDA portion. I've been fielding comments from various people and weaving them into the deck to try and address comments as we go. So I gave you the most up-to-date draft on Wednesday of last week, obviously it's very detailed, it's like 65, more than we'll want to go through again, anyway. But, you have that for your background. You have the two presentations, one on ONC and one on FCC, where we tried to peel the onion a little bit and understand the issues – the regulatory issues in each of those frameworks. And then last week we had the discussion of other regulatory frameworks, both purely regulatory, there may be other federal programs or may not even relate to HIT, but also private initiatives that are ongoing, in an attempt really to broaden our thinking about kind of what regulatory best practices are in general. And what we can explore in the area of best practices to recommend for HIT. So quite a bit of content sort of led up to this call today.

So here's what I want to frame to all of you or for all of you as the question I propose that we discuss. In this call, as I said at the outset, I'd like to focus on deficiencies of the current regulatory system. So by deficiency, I'm referring to something that is written, some specific element of one of the three regulatory systems that is not well tailored or is not appropriate for HIT. And so I included five different kind of ways in which that might be true and I'll just read those, in case you don't have that in front of you. Number 1, a regulatory requirement that is broader or more onerous than needed to assure the safety of HIT. So, when you look at the Safety slides that we got from the Safety Committee, are there areas where the regulatory system is simply unjustifiably burdensome, based on the risks that were identified, or simply too broad, not nearly focused enough on those safety risks. That's one possibility.

Second, a failure of the regulatory system to be risk-based; that's one of the specific criteria in the statute, and are there areas where the regulation doesn't utilize available mitigation? There are ways to manage the risks that the regulations fail to adopt or it simply doesn't focus appropriately on the risk aggravating circumstances. We simply miss an opportunity of the regulatory system to manage high risk. So that's a second way that they might be deficient. Third, is there some way that they simply aren't focused on a safety issue. As you look at the range of safety issues, are there gaps in any of the three systems that allow a safety issue to go unregulated.

Fourth, do the regulatory requirements unnecessarily interfere with some specific needed feature of innovation? I'm sure that lots of them interfere with innovation, that's kind of what regulation does, the question is, do they inappropriately do that, do they unnecessarily interfere with some aspect of innovation. And then finally, do they miss a sensible opportunity to promote innovation? One of the things that the Innovation Committee, or working group rather, has been talking about is, are there ways to affirmatively encourage innovation through regulation. So, are there missed opportunities to do that? I'm not sure who's driving the slides, but could you pull up the one-page that I sent out this morning? There we go.

So I said that Julian and I wouldn't talk very much, and I couldn't help myself, I have one slide on the FDA topic, because that's the topic I'm more familiar with. But as I was sitting over the weekend trying to figure out how I would answer these questions, even just for FDA at a high level, I developed this one slide, and I have a code here. The "A" stands for ambiguous; the "B" stands for broken. Broken is a different word that I'm using for basically figuring out if the regulatory system is deficient. And again in light with my suggestion that we focus, I tried to stay a little bit higher level than the 60 slide FDA presentation, and I tried to prioritize, again taking my own advice, what are the biggest picture, most important issues, as I see them, through the review process that we went through.

And these 8 areas all have important ambiguities, and I'm not going to go through those today, because that's really the point of Wednesday. But three of them also have areas where I think they're broken, where I think the regulatory system is deficient in some way related to the criteria that I just went through with all of you. So specifically, the first one is the wellness and disease borderline issue. And you guys remember this from probably our face-to-face meeting, but let me just remind you of what the issue is here. The FDA statute basically gives FDA the responsibility for regulating medical devices that have disease-related claims that is, related to the use or treatment or mitigation or diagnosis of disease. And they do not have jurisdiction over articles used to encourage general wellness. So if I put together an app that helps you exercise for general fitness or helps you manage your diet for general health or makes you do other things that are just generally part of healthy living, those are not FDA regulated.

Well the problem is that particularly in mHealth, which is admittedly a subsection of HIT, there are an awful lot of apps coming into the market that reference a disease, but do so in the context of a really low risk piece of software. So for example, you'll have a diet software, and the diet software might reference diabetes, it might reference obesity, which as of two weeks ago, is now recognized by the AMA as a disease. But fundamentally, it's a way to count calories or otherwise help you manage your diet. And under the existing FDA rules, it would be regulated as a medical device because it references a disease. I submit that's inappropriate, that is, to use my own criteria, that's a failure to be risk-based, to say that a simple mobile app that does nothing more than count calories or whatever, should become a regulated medical device, simply because it includes a broad, well understood disease related claim. I'll go through the three of these and then I'd like to open it up for discussion.

The second is kind of a similar issue and that is, FDA has an old, old rule called the Accessory Rule, which says that if you plug something into a medical device, it becomes regulated basically in the same manner as that medical device, if that's the intent is to plug it into the medical device. So if you take a generic cable that has, for example maybe a USB port or micro-USB port at one end and maybe Apple's proprietary connector at the other end, to connect a blood glucose meter into an iPhone, and you market it for that purpose, it becomes a Class II medical device. That is the case because number 1, you have this arcane rule that says that anything plugged into a medical device is regulated in the same degree. And then secondly, it's because structurally, FDA does not have classifications for very low risk accessories, and as a result, in my opinion, things like a simple cable, which has connectors at each end, could be regulated as a Class II or even a Class III medical device. So that's the second FDA issue that I submit is broken.

The third one, I put it all together, post-market requirements. This includes things like adverse event reporting and corrective action recalls, all the things you might have to do post-market. And here, basically I submit that the FDA system is inappropriately broken, and to go back to my five criteria. I would say it's insufficient in a specific way to assure the safety of HIT because as we've talked about, and I think the Innovation Committee – Working Group rather, has talked about, when you have a network of software and hardware, it's often not clear who's responsibility a given hiccup might be. It might be that two different systems are not working with each other, an interoperability issue that Julian, Joe, and others have talked about. Or it might simply be that it's unclear and we can't get the data even to determine where the system went awry. In those instances, the current FDA system that assumes basically that a single company will know that its device is responsible for the screw-up and then will take responsibility for fixing it that that model that's embedded in the FDA regulations, doesn't work in the network environment of HIT.

So I would submit that those are three examples of where FDA regulation, anyway, is broken and I would be very interested in people's reactions or thoughts to those three areas.

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

Hi Brad, this is Anura Fernando. Just relative to the risk discussion that you had with the USB cable example –

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

Um hmm.

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

– when you identify part of a system like that as low-risk, does that mean that the risk has been deferred to let's say one or both of the endpoints with the cable no longer carrying the burden of risk? Or that the data communicated across that cable, irrespective of the risk to the endpoints, is inherently low because of the inherent reliability of that type of technology?

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

I would submit it's the latter, at least that's what I have in my mind, that I thought you articulated it well. It's the inherent low risk of the function of the cable in comparison to the simplicity of the cable itself.

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

Okay. So from that perspective, I guess what I'd like to propose for further discussion is that we look at the possibility of deferring risk associated with that function. Because if you have a Class II device or two Class II devices that are being interconnected, and the data that's being transferred is of equivalent risk, then the ability to transfer that data across the cable, despite the simplicity of the technology, is still potentially at that same level of risk. And so, if we were to have a mechanism to make either endpoint less dependent on that data that's being moved through the cable, then I would tend to agree with that. But if we're saying that, the technology is so inherently simple that it can be sort of de facto classified as low risk, I wouldn't agree with that because the reliability of that data moving across it still has the same level of risk.

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

I guess I'm submitting that this situation is not altogether different from the MDDS classification itself that puts in Class I regardless of the source – regardless of the medical devices involved, basically software and related hardware that does nothing more than store or transfer medical device data. In that instance, even if the data come from a Class III device like an implantable defibrillator or something, the software that performs that basic, simple, well-understood functionality is Class I. So what I'm suggesting is something like a cable, which might be used to transfer data for more than just transfer purposes, it might be used – associated with analyzing the data or whatever, that such an accessory becomes over-regulated simply because FDA hasn't taken the time to develop a classification regulation like MDDS.

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

Brad, this is Elisabeth, and I guess I would agree with you on that, is because I think that one of the things that has been done elsewhere is that I know we've had products where using the whole modular concept is, we've had a modular aspect that had a PMA and another part of that system actually was 510 (k). So there is, in my mind, there should be no reason why that whole concept of modularity can't be defined. And I do agree with your structure of saying that there is ambiguity as well as aspects of overregulation.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

So you're giving – Julian here, you're giving an example in which you were successful in doing what you thought was the appropriate – if I understand correctly and please correct me if I don't. You're giving an example where you were successful in doing it the way you thought was appropriate, but you felt that it was a bit of uncharted territory and you had to figure that out on your own as opposed to having a clearly identified pathway ahead of time.

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

Yes, and basically what we ended up having to do was, it was multiple meetings with the FDA and exactly doing what you said, and so it was we did it for our product on a case-by-case basis. And I think that that's where we don't want to have to do that, because obviously if you – sometimes what could happen is, is that if you don't go to the FDA and work with them, you may be under-regulating something, but if you do go to the FDA, you may inversely be overregulating it. So there would be the inconsistencies.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

And Brad, what I heard Anura commenting on, and you responding to, I think, is the notion that you're not proposing here that something necessarily be not regulated. But that it may be more appropriately regulated in a category such as MDDS, which is a regulatory category, but one that might be more suitable for widely adopted and implemented, standardized technology used for communication.

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

That's exactly right, yes.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Okay. And –

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

So it's structural in the sense that it takes FDA to engage in rulemaking as they did for MDDS.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Um hmm.

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

Brad, this is Anura again. Just to close the loop on that a little bit. With MDDS, we have the two options of Class I exempt and Class I non-exempt. Would you agree that if the risk is deferred to the endpoints, or the risk is sufficiently low, then the exempt classification would come into play and then if there were risk mitigation dependency in that cable, let's say, that address special risks, then the non-exempt classification would come into play in that scenario?

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

I think that makes sense, yeah.

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

Okay. So I think I understand your previous comment and we're aligned now. Thanks.

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

Okay. Yeah. Thank you. Any further comments on the proposed three areas of brokenness, the what I would say is overregulation of certain disease-related claims, overregulation of certain accessories for lack of a better – or more appropriate classification, as Julian points out, not exempting them, but a lower classification. And the structural I almost want to say impediment, but it's much more than that, the structural inappropriateness of the FDA post-market requirements applied to an area where networked products will not fit the model.

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

So Brad, are you only looking for problems with the current approach or – gaps at this point, too.

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

So, well I just wanted to see if there was general consensus on the three that I identified. Now I want to just open it up, so I'm interested in number 1, David, honestly the way I was going to do it is number 1 problems and then number 2, gaps. So I was just going to separate those discussions for no good reason actually. So, other examples – and so I just picked FDA because it's the area that I'm, of the three, most comfortable with, I mean of ONC, FCC and FDA. Let's take it – let's go one by one then. Anything else on FDA where someone wants to identify brokenness, some existing requirement that does not fit HIT?

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

Brad, Anura here again.

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

Um hmm.

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

On the issue of – let’s see, labeling for example. When we were going through the regulations one by one previously, one of the things we talked about was the fact that when you have we’ll call them emergent properties in the system where you have manufacturer “A” and manufacturer “B” having their devices integrated into the system, you may get a third property “C” that is neither a function solely of “A” or “B.” And so, in that kind of a situation, wouldn’t labeling be broken and not just ambiguous, but wouldn’t we potentially need entirely new regulations there?

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

Um, so help me understand a little bit of the regulatory problem that that creates. What – can you make it real world for me? What difficulty, either for a vendor or for a user, does that create?

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

So in that situation, you have a device from manufacturer “A” that has a particular intended use as a standalone and then maybe indications for use, although that doesn’t seem to have been real well developed yet, in terms of how you would do that for systems integration. You would have manufacturer “B” with another intended use as standalone, and maybe indications for use in an integrated system. But, the ultimate clinical benefit of integrating those two together would be under the sort of design of the system integrator and so in that situation, it would be the system integrator who would determine really the intended use and constraints and so forth, associated with the emergent property, property “C” that’s neither a function of “A” nor “B.” And so there seems to be some challenge in labeling and so forth when you have that type of multivendor system integrated.

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

Anura, let me just restate that a little bit differently. So in some measure we have the problem of off-label use being unregulated, and it’s a standard problem at FDA in the sense that when a drug company develops a new drug for a specific type of cancer. When it’s put into the marketplace, physicians might make cocktails putting that drug together with other drugs, in order to either better treat the intended form of cancer or to treat some entirely different form of cancer. It’s once it’s put out there in the marketplace, the marketplace makes whatever use of it it wants to make of it. And so that is a problem, the question is, is it a problem that we feel we need to solve, is it a risk that needs to be regulated, and that’s what I’d like to put out for the group’s discussion.

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

I think – this is Todd. Anura brings up a point close to what I was also thinking about, in the sense that when you look at a lot of health software, the lifecycle in terms of when does it actually get literally implemented is very much further down the road than what we typically see in a medical device product with the current process. So I’m not sure how we want to address that, but we need to be able to have a system that can look at a level of concern assessment and associated regulatory framework that recognizes the lateness of when all these pieces come together and can potentially do exactly what Anura said. Not only at that point you can assess what the level of concern is or the actual risk, but you might have these emergent properties.

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

What do others think? This is a pretty crucial issue, whether regulation beyond the initial intended use, initial labeling is a gap in the system that we need to figure out a way to address.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Brad, Julian here. I just want to go back for a moment to your example of the use of drugs and pharmaceuticals. It’s an interesting thing that sometimes happens which is, there are interactions that occur at the physical level, and so drug – a new drug comes to market and when used as directed, there are no problems. And then we discover physical incompatibilities between that drug and another drug, and for example, those incompatibilities can cause the drug to precipitate and maybe block an IV, which – and make it – actually block it like a plug, make the IV useless. Or the incompatibilities could affect the absorption of one drug by another drug in the stomach, and many people have discovered that that happens, for example with certain antibiotics and milk or calcium.

And so there lies – the more complex and sophisticated types of interactions on kidney function and on other things like that, but then there are these certain, very basic physical interactions. And to some extent, that is analogous to what we're talking about where we somehow have to take into account that we don't cause a product to crash when someone connects it to a network that varies in some slight and subtle way from the way it was tested. Which then means that if we're talking about medical devices and health IT connectivity, there has to be a level of robustness in the system to allow for the variations that will be merged over time, in the sense that Todd Cooper just presented in that things are not clear right up front. And therefore, what might be the risk to the product and to the system, as Anura presented. So one way to state this is that, and this certainly is a rough form that has to be finessed, but is that the intended use of a medical device, when planned for use in a broader, connected environment such as a health IT system, has to take into account certain basic connectivity functionality. When connected to a network, certain things will happen that work and that won't be operational at all times, and if it's important for the safety of the device or the patient, then it may be important for the device to monitor the network, health and connectivity, which is done routinely for alarm systems, for example. But which may not be important when transmitting a diabetes related blood sugar value from a glucometer to a laboratory reporting-type system or office system or home monitoring system. It just may mean that you have to wait a bit longer or connect again, with no – no likely potential for harm to the patient. I think we have to build in some of these attributes of the system, as we think about these problems. Reactions?

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

Yeah, what I hear Julian proposing is kind of a middle ground it's an intriguing one. In the past, most of the health industry has wanted to draw the line and say to FDA, stay out of off-label use; you can prevent off-label promotion by vendors, but stay out of off-label use because that's the provenance of the healthcare system. And weaving in the innovation theme, if you, FDA try to get involved in that actual use of these tools, you will stifle innovation and you really have no business doing it, the risks don't justify it, it's more important that we give physicians and other end-users the latitude to use the products as they see fit.

What Julian is articulating is kind of a middle ground saying okay, well we still don't think FDA should actually regulate the end use, but they need to work with the vendor to make sure that they've taken into account kind of all the reasonably expectable combinations, permutations and possibilities of producing a network device. And what we know likely are the risks, really a risk management model. I think it's a very good suggestion and I'm interested in people's thoughts.

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

This is Mary Anne. I would concur with that and support that. We have, in pediatrics, a lot of off-label use occurring, but that is where a lot of the innovation definitely comes from, and ways we can apply new tools to pediatrics. And I know it happens on the adult side as well, so I would think a middle ground would be a way to foster innovation while protecting patient safety. And a way to track off-label use might also help developers know what's really needed in the market.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

And also, as you just pointed out, it does bring us back to something we'll talk about in the near future, which is just how do we track and collect information about events that occur, when they're part of the broader system.

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

Right.

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

This is Elisabeth –

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

Any further discussion?

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

Yeah, this is Elisabeth. I guess one of the things that was interesting, what I just heard was is that I wrestle a little bit with the whole off-label just because of thinking about other aspects of device. But I agree that we need to have – maybe come up with some methodology that is a good balance between the challenges of obviously not impacting practice of medicine, but also assuring the overall safety and the risk aspects. Because one of the concerns that would come into my mind is so, once we do determine how to capture these reports, how do I know if the issue is an issue with my software or is the issue with its use or with its off-label use, if we don't have a good way of capturing the desires to use a particular system in a new, innovative way that maybe we didn't think of when we developed the solution in the first place. So, it's just things we need to think about, because I do like the idea of trying to come up with – I agree with you Brad that it is ambiguous, it is a challenge to try to figure out. You want to give clinicians everything that they need to be the most effective in their jobs, but balancing all of the elements of the pentagon probably, it's not even a triangle, it's how to balance all those things is going to be interesting for us going forward.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Julian here again. I think that it may be the best term – it may be best for us not to consider this, in fact, off-label. To some extent, we're refining the definition of the intended use of the device, and if a medical device is intended to be used as part of a broader HIT system, but we don't yet know exactly how the data will be used or what the system will look like, which were some of the points that were made. I think that's, in essence, what is happening today and what we need to allow to happen more easily and more safely in the future. Maybe we shouldn't be calling that off-label, we should be saying that that is the new intended use of an aspect of the system; it's got broader connectivity and exchange of information.

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

I like that a lot and I think that again, we – what we always have to think about is that the whole – everybody, all the stakeholders in this process, how we can make sure to balance all of that. And I do like what you just described is that we do have to maybe be a little more creative with how our intended uses are so that we can think a little bit more broadly in that respect. Great idea.

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

Yeah, this is Mary Anne. I love that idea, too. I mean maybe it isn't even about labeled use, it's alternative use. I mean maybe we need to think about a concept around here that supports all these principles.

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

Any other thoughts on that topic? Okay. Why don't we keep moving then, still within the FDA topic, any other weaknesses or areas where the FDA regulatory system as it's currently devised is deficient when it comes to HIT?

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

This is Mary Anne Leach, again. I was wondering if there's a way to – and we've talked about this before, I think, but just a transparency of problem reporting. Or is there a way for me, as a provider, to set up or register with the FDA because I want to get notified of issues, not just recalls, but issues with certain devices or certain uses of devices and technology. It just seems like there's a gap in sort of public and provider access to issues in sort of a publically transparent way. This is something we're doing in the industry now with quality and safety, right? Most of us have public-facing websites that report our quality metrics. I'm wondering if the same kind of principle could be applied to HIT and medical devices where we could either explore reported issues or sign up to be notified of issues.

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

So there are presently systems for doing those things, but I'm absolutely confident they could be improved quite a bit. They come in two different flavors, one is, an FDA database of problems that have been reported, the Adverse Event Database. It isn't set up so that you can be automatically notified, you'd have to go and search it periodically in order to see if there's anything interesting in that database, interesting to you in that database. And then there's a separate database of Corrective Actions that are being taken, typically recalls or other things being done to fix or otherwise improve the information around already marketed products. Again, it's not set up so that it would sort of automatically notify you with regard to a given product; I'm sure that could be done, it's probably mostly a matter of budget and time and effort to do all of the programming that would be required to do that. But we have those aspects in those systems now, other than the notification, and they're not terribly user friendly, but they do exist.

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

Yeah, thank you, I had a feeling they did, but poking around the FDA website it's not easy to find. So –

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

Right. Yeah, agreed.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Brad, Julian here. I think – I would agree very much that we should flag this, the list – as you called the slide, issues where attention is needed. This aspect of reporting needs attention, and the attention might be that the current systems have to be updated and refined. It may be that the instructions for use are part of the problem, after all, many problems are simply not reported, even though they could be reported, through those databases. Retrieving information is extraordinarily difficult, as most of us know, so there's a usability problem. And then the problem of HIT related issues falling between the gaps in terms of what fits or doesn't fit into the FDA – current FDA system is part of the challenge. So, somehow I would think that needs to be on this list, although I'm not sure what to call it.

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

Can we weave it into your program for Wednesday, the whole reporting system? It seems to fit squarely within that and I assume you're going to come up with both a series of gaps and potential series of corrections or whatever, but –

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Yes, i – exactly, I've been mindful of that and trying not to touch on things that really are for another day, but merely to say that it would seem that we'd want it on the list here with a pointer to more information elsewhere.

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

I would agree, thanks Julian. It could be on the list as a separate issue or could be woven into post-market requirements or something like that.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Um hmm.

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

Yup. Okay, good. Good.

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

I'm battling with this comment, only because I'm not sure if it fits here or if it fits more on the third day, when we're going to be discussing a better way to assure that innovation is permitted. But one of the things that comes to my mind as far as deficiencies are concerned, if you want to call it a deficiency or, in fact a better way of doing it, is that there isn't really a lot of internal coordination and you couple that with external efforts to educate the public and work with the public in the area of health IT broadly, from the FDA. So I think that that's an issue that's worth considering here or on the third day.

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

Can you get a little bit more tangible for me Jarrin, coordination of what kind of decision –

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

Yeah, sure. So my world is more the mHealth world and something that we've been battling with for a long time is getting clarity from the agency on mobile medical apps. As everyone knows on this call, the issue to draft guidance a few years ago about mobile medical apps and we were hoping that that draft guidance would come out in a timely manner, which unfortunately, up until now it still hasn't come out and this has now been over 2 years I believe, or nearly 2 years. It was July of 2011. And not just with mobile medical apps, there's a whole dearth of issues related to health IT, including things like electronic health records and CDS, etcetera, which it would be really wonderful for the agency to be able to get that stuff out there.

Now that's one, separate and apart from whether they're utilizing their internal efforts to coordinate within and outside of the FDA. So, take that one level one-step higher, there are numerous mobile medical app developers out there that are looking for information. So they contact, within the agency, external efforts or resources like DSMICA, for example, device – what is it called, Division of Small Manufacturers, they get one answer there, then they'll speak with another agency official, within the CDRH and they get another answer on whether or not their specific device or their system is regulated in one way or another. So, it's almost like a continuation of the same issue where one part of the agency is saying one thing, whereas another part is saying something completely different.

And this is actually even happening with established, registered manufacturers, who have actually listed devices where they've put something through as a 510 (k), it may be mobile health related. And they'll modify it and when they modify it, they seek a special 510 (k) and the agency will come back and say; well you know you can't do that with this device. And that's exactly what the original intended use was for their predicate device. That kind inconsistency is very, very harmful to innovation, so if there's some way of coordinating internal efforts, where everyone is at least on the same page, or discussing the same things. For example, when MDDS came out, I myself even contacted DSMICA to try to get clarity and two different days, I got two different responses from two different officials as to whether or not an MDDS could remain a Class I device and connect itself to a Class I, II or III device, which is the conversation that we were just having. So this is kind of internal and external coordination, I think, really are hand in hand. One, they have to be aligned internally and secondly, what kind of resources are they using to get out the word to innovators? One of the things I thought would have – was really wonderful was Dr. Shuren a year ago spoke at an event on the Hill where he specifically said yes, we're going to be coming out with a medical device guidance document, mobile medical guidance document. In addition to that, we're contemplating things like issuing a new website where we would put in examples of what kinds of software or apps do fall under mobile medical designation, even having a question and answer or FAQ portal, that kind of thing, I think, would be very powerful. So I'm not sure where that fits, if it fits in today's conversation or is there a better way to assure innovation on day 3, or rather July 8. But I figured I'd mention it.

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

Yeah. Very helpful. Comments on that suggestion?

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

I 100% agree with him – with Jarrin, this is Elisabeth. Ironically enough, I guess I'd say unfortunately that's not just an issue in the mHealth area –

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

Right.

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

– much of that inconsistency or variation occurs across all of the medical device arena, which does force many of us to have to escalate if we get varying answers, and I think some of that becomes part of what I know at the congressional hearing that you were at where one of the gentleman was quite upset when you guys answered the question of, well it depends –

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

Right that was –

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

(Indiscernible)

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

It was –

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

– and that's the life of being in regulations, I guess is that, it depends. And I can probably make anything from a not a medical device to a Class III if you give me enough words that you want me to – you tell me what you want the answer to be, I can make it that. So, I guess –

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

Yeah, we could have. Okay –

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

This is Todd again.

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

Go ahead.

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

Just one quick comment and hopefully maybe Julian you can take this up on Wednesday, but, attendant to this discussion right now, tooling is extremely important, both in the front end as well as in the back end. And if what we're trying to do is strive for an appropriate, hopefully light touch regulatory process in the front end where you can quickly determine, does my device fall or my system, my software, whatever, fall within this regulatory area. And if so, how can I quickly do an assessment as to the level of concern about the functionality about that device. And I think if we can bake this into tooling in the front end, to really help those who are not familiar with the regulatory processes, and don't have a lot of resources, but would be able to access that and get a very consistent, clear, quick determination, that would be very helpful. Balanced, again, with a strong back end surveillance and highly usable system, so we can watch and make sure that that assessment is appropriate in reality, when these systems are deployed.

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

So there are several ways, it sounds like, to address this deficiency, as it were. One is to make sure that there's – that there are those at the agency who are willing to help explain what the regulatory requirements are. A second is, uniformity, that is, to get to the issue that both Elisabeth and Jarrin identified of conflicting advice, making sure that there's one clear person who can speak on behalf of the agency as a whole, in a way that is, if not binding, at least reliable. A third is to have clear rules in order to minimize the need to ask questions, to have simple, clear, well-explained regulatory framework that diminishes the ambiguities. I mean, it seems like those are all three ways of getting at some of these issues that you're identifying. Right, good. Other FDA related – I see where we've gone about an hour, so I want to wrap up FDA fairly soon, so we can get to ONC and FCC, but on FDA, other deficiencies that you would identify as needing to be fixed?

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Brad, Julian here, I'm just going to jump in and just say that Todd, I did capture some of what you said that I think is applicable to the meeting we're going to have in a couple of days. So, I heard you and I noted that.

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

Thank you.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Sorry Brad, back to you.

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

Okay. No, that's fine. Thank you. So my plan was to go through each of the three agencies and then step back and have as a fourth questions, gaps. And this gets to David's question earlier about when do we identify gaps. And I thought it made sense to go through the three agencies and then step back and say, okay, where are the gaps. So, let's move on, let's just take them in the order that we considered them as a group, ONC. Does anyone have areas where the ONC regulatory system is what you would call deficient or in need of fixing with regard to HIT regulation?

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

Brad, this is Anura Fernando again. Just not so much a specifically targeted area, but sort of generally speaking, when we're talking about sort of voluntary versus mandatory regulations, does that create any level of incompatibility in terms of the overall regulatory path for the system? And then when we talk about health IT versus a medical device, and Julian referenced a slide earlier, right at the beginning of the call, that sort of gets at this, do we have a clear understanding of how to define boundaries so that we can merge the regulatory path between these three agencies. I just wanted to put those out there to sort of maybe drive some discussion.

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

Can you expand on your first concern about mandatory versus voluntary; can you expand on where you think that becomes an issue?

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

Okay. So, if we have health IT systems that are optionally subject to a set of regulations and part of the purpose of regulations is to deal with ultimately patient safety, we're going to at that point clearly end up with some systems that are not under regulatory purview whatsoever yet have a level of risk associated with them. And thereby become unregulated and potentially unsafe or systems with very little oversight that can be deployed. And so if there are safety concerns that exist with the fundamental technology, then it seems there needs to be some baseline of regulation that isn't entirely voluntary and not necessarily financially incentivized only.

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

That's very helpful. And just to tease that apart a little bit more, I'm not going backwards, but to use the FDA by an example, clearly FDA's mission over the last hundred years has included protecting us from evil people. Originally, evil people came in the form of snake oil salesman and others who would hawk basically drug-type remedies that were shams, that didn't do what they said they would and in fact, could even be harmful. And fast forward to today, I mean there's a cadre of about a hundred folks at FDA who go for significant FBI training because their job is to go after bad people, people who make knock-off products, people who make things that are woefully lacking in quality, just because they're trying to make a quick buck and so forth. So FDA has always been a law-enforcement agency because there have always been, even in healthcare, people who will break the law for a buck. And so when we talk about voluntary standards versus mandatory, it's important to understand fully the risk of human nature, that is, what a bad actor, an intentionally bad actor could do in a given situation. So, we just – I just toss that out there for discussion.

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

This is David Bates I have another example. I agree with – about the role, that Brad just mentioned is an important role. Could I introduce another one or do you want to –

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

Please, yeah, go ahead. Please.

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

So, one area which ONC I think could do better with is in post-implementation testing of whether certain safeguards are included in systems. And what I'm referring to in particular is some work that was led by Jane Metzger, et al; they developed a – what's been called a CPOE Flight Simulator, which basically lets hospitals check to see what safeguards are in place. And studied 62 hospitals from around the country, published the initial results from this in 2010. In the first round, simulation detected only 53% of the fatal – potentially fatal drug orders and it detected only between 10 and 82% of the orders, which would have caused serious harm. Furthermore, there was almost no relationship with vendor.

So what this argues for is some checking not pre-market checking, but some post-market checking and the postscript to this is that organizations really didn't have a sense of whether or not they had the right decision support in place or not. Sometimes they had it in their system, but it wasn't turned on, and most systems found this to be very, very useful, and their scores have improved a great deal over time. But right now, no such checking in is required on a routine basis. I think this is the kind of thing that is really sort of different from any regulatory approach that we've been using, but it's one that could result in a great deal of benefit and it would be in line with what everyone wants to achieve, which is that these systems will deliver on the desired benefit.

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

Is it possible, I'm just trying to think of what existing structures are out there, is it possible that this could be framed as an issue for the Federal Trade Commission that basically is responsible – it's charge or charter or statutory authority is to ensure that vendors deliver any promised benefits. If a vendor says something's going to do something, it needs to it and they need to have evidence to show that it will do it, before they can make that claim. Does that legal authority help David in any way do you think?

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

I don't think it does, because it's actually not really the vendor's responsibility. The vendor has sold users a perfectly good product, it's really more the responsibility of people once – of providers once they're actually using these systems.

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

I see, okay. Any discussion, reaction, thoughts? I'm sorry –

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Yeah, Julian here. I mean this does, of course, open a very rich area, but I wonder if it's really possible to look at the operation of or the set up or configuration of an EHR in isolation? One could see that there might be the training issues, practice issues and I'm just thinking about it from a regulatory perspective of where are those things managed. The FDA does manage things like that, which require training, where appropriate, and other risk mitigation strategies for medical devices, where appropriate. The need to – it's routine after set up or delivery of medical devices to an institution to have certain safety checks, and there also are instructions that are accompanying medical devices that will describe the inspection that's required after installation in a medical facility, which might be fairly simple.

But it could address things like the basic configuration and ensuring that those – that settings are reviewed, for example. And then there are issues that relate to the transfer of information, say the display of information in the electronic health record that comes from a laboratory system, and assuring that that's transferred and displayed correctly and that there aren't conversion errors or errors due to the ADT feed or the patient specific information. So, from – just thinking through the comments that Dr. Bates just made, there may be a number of places where – a number of touch points that I think probably underscores the complexity of the work that we're all facing. I guess that doesn't help any, except to say it's complicated. Sorry, go ahead.

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

No, I agree with all that. Yeah, and the one use case that this has been built out for is the one that I mentioned, but it could potentially be used for many other things.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Um hmm. And Brad, you were mentioning the, I'm looking at non-medical products and commerce and I was, in preparation for some of this work I recently spent time looking through the Consumer Product Safety Commission and some of the ways that that system operates and I feel like I've only scratched the surface. I've also been looking for parallels there between what is done in that space and how that may or may not be relevant to what we're addressing in these meetings. It could be quite helpful if we do have any experts in some of those other spaces, if they could lend a hand or be available to answer questions.

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

I don't remember Julian if you were on the call, but we did go through part of that last Wednesday, when we considered the other regulatory systems outside of the three that are the primary focus.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Ah, that may have been the only call that I missed, so there you go, figures.

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

Yeah.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

All right, I'll catch up on that. Thanks Brad.

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

Yeah, you might just listen to that.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Yup. Okay. Thanks.

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

So any other deficiencies, for want of a better term, with regard to the ONC regulatory system that we need to identify? Okay –

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

Brad –

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

Go ahead.

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

Brad, yeah, it's Jarrin. So, there's something that's out there and – is Jodi on the line? Jodi or anyone from ONC?

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

I am on the line.

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

Great. Hey Jodi. This is something that always pops up, I know that you and I have spoken about it and that it's part of what's being considered for Meaningful Use Stage 3, and that's the inclusion of patient-generated health data. And I don't want to get into a policy discussion about that aspect, but at the deeper, foundational part of what that means is really interoperability between medical devices and health IT or rather, electronic health records. And I know that the FDA I believe last year, embarked on trying to organize a private sector effort to try to get to the core of interoperability, the medical device interoperability, coordinating – I believe it was called, and this is something that's always been there, kind of sitting out there in the wind. I don't know if there's a way that we can put in a placeholder for this type of discussion. Because I think that this is an important aspect of what's going to be coming down the line, or at least be able to infuse some kind of notion for the idea of the learning healthcare system, as we keep talking about, for these types of future issues. Because this is obviously an issue that's going to have to be tightly coordinated between ONC and FDA, which is not necessarily being done now.

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

There's two different things which are – although very related, which are device interoperability and then so generally as well as interoperability between devices and certified EHR technology, which may be a subset of the bigger picture. And obviously, we have something to say about the latter, but not about the former. So, I think that's where it might get a little bit of an issue with coordination, which is – because we'll come up with standards and we can identify standards for connecting to an EHR, but don't necessarily have authority over the devices that are connecting to the EHR. And we don't have authority over the devices talking to one another, which could be more in FDA space than ONC. So, I think there's a couple of issues there, and it might be worth teasing it out.

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

Okay. Good. Not good that it exists, but good that we identified it. Any other issues on ONC before we switch gears and talk about FCC?

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

So, just one more Brad, this is Anura again. The issue that Jarrin just raised goes exactly to the point that I was trying to raise in the beginning, is that we don't yet have a clear boundary between what's called the device and what's called the IT, and the relationship between devices and IT infrastructure really blur. And then when you introduce wireless access to this, then you have emissions and immunity considerations and things like that. And it seems that we really fundamentally need a technical basis for coordinating the activities of the three agencies. And looking at the differences and how those regulatory paths are currently structured may help us to identify how to better coordinate them. So, going back to the voluntary versus mandatory, etcetera.

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

Okay. All right.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Julian here. Anura's bringing in the notion of the technical basis for coordinating the activities and I'd like to add, there's a technical aspect and then there's the risk aspect, which isn't always aligned with the technical complexity. But I agree with what was said and I think we're really introducing a fundamental and very important problem, and as Jodi, you stated that it seems that it's clearer that what falls within the ONC purview is the device to certify EHR interoperability and device-to-device interoperability would seem to fall into the FDA purview. I think that the subsequent comments show that when one teases this apart technically, there may not be a basis for that distinction, that from a medical devices perspective, whether its communicating with something else that's labeled as a medical device, or communicating with something else that's labeled as health IT or a certified EHR, may make no difference whatsoever from a technical perspective, and that is probably part of what is introducing extensive complexity into the discussion, and then lack of clarity in the regulatory ownership of the systems. So I would propose that I'm really pleased that this came up in the way that it did and I would propose that we identify a way to tease this out in greater depth, because if we don't, I think it will remain an intractable problem that is a problem both from a regulatory perspective and also from an innovation perspective.

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

Any other comments on this particular issue or ONC more generally? Okay. Why don't we move on to FCC, so we're doing the same thing as for the other two and we're interested in any areas where there's some aspect of FCC regulation that you would say is deficient or not working appropriately for HIT?

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

Brad, Anura here again. So we've talked about the MOU between FCC and FDA, for instance. It seems there needs to be a more tangible mechanism for coordination. So a way to exchange data on both incidents as well as corrective actions from a regulatory perspective when we find safety and effectiveness of devices or systems being impacted by things like electromagnetic compatibility issues or the emissions and immunity kinds of issues we just talked about a few minutes ago.

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

Okay, specifically what do you want to see the two agencies do better? Can you get more tangible for me?

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

Sure. Maybe something like a reporting structure for post-market surveillance that's coupled together, so that the issues from each agency can be fed across agencies.

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

Good. Okay. Very helpful.

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

Yeah Brad, I second that and I also – is Matt on the line, Matt Quinn? So I think what came up in the presentation that we all coordinated with Matt, with Julian as well, is that the FCC does have a very robust and stable Equipment Authorization Program and it's interesting because you have to go through that to be able to show the commission where you fall, are you an intentional radiator, an unintentional radiator, an incidental radiator, etcetera. And some of the questions that are being asked of a device manufacturer that has to go through that on the FDA part, I really am having trouble discerning between the difference. I guess it all comes down to one is trying to ensure the safety and efficacy of the product and the other is trying to parse out what type of harmful interference your device may cause. And there's got to be a better linkage between the two, especially if you are able to get your equipment authorized through one that has to count for something with the other. And I'm not necessarily sure it completely does, I feel as if so it goes to the FDA, it becomes part of that record, but they still want more. And that might be troublesome, because that might be a very duplicative thing.

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

Um hmm. Okay.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Well it sounds – Julian here, just to follow on with the conversation that we had with the FCC about this. It sounds like the process is that there is a relatively robust reporting system within or into the FCC and then matters are handled directly between FCC and the FDA where it is deemed necessary to do so. And how that's done might be wonderful, I think perhaps it just isn't clear to the public and I don't know that anyone – I don't know if there – truly if there are any concerns about that at all, but it would seem that we would need to understand that better for the purpose of the FDASIA activities. And maybe that should be done in a more comprehensive way, a more systematized way across all the agencies or in more transparent way. I just think that is a topic worthy of examination.

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

Okay. Good. Other issues related to FCC where we have concerns about the existing regulatory system? Okay. So the last topic is taking the ultimate step back, now that we've gone agency by agency, FDA, ONC and FCC and asking ourselves are there any gaps. And this is an area I think where David may have a comment, but I'm also interested in anybody, as we've looked at the safety issues identified by the Safety and Innovation sub-workgroup and the innovation needs. As you look at the constellation of the three agencies together, are there gaps? Are there places where the totality fails to address some particular risk? In totality, are the three regulatory systems too much, too burdensome in relation to the risks that were identified? Is it too inhibiting to innovation with regard to some of the specific areas of innovation identified by the other workgroup? So, this is kind of a bigger picture discussion that will kind of feed into or lead into the discussion on the 8<sup>th</sup>; so, big picture, how do the three systems together – regulatory systems, look. David, can I start with you? Did you have a further gap you wanted to identify?

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

Sure. I do. I mean I think that there are obviously places where there's too much, there's some redundancy, but from my perspective, the biggest gap is that there is not a place for people to report safety issues that they're having, that then results – related to HIT, that then results in their being aggregated in a very substantial way. And so I personally think we would be better off if there were some better post-marketing check in place and with those checks, there has to be a way of aggregating information across a large number of organizations. We've talked about using the PSOs to be a place where people might report issues that they have, and that's a reasonable option because PSOs do have legal protection. But right now there's no mechanism to aggregate information across the PSOs and without that, I think that represents a substantial safety gap.

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

I know Julian plans to spend a good bit of time on Wednesday talking about that issue. Julian is there anything you want to say this morning, in advance of that or do you want to defer it to your discussion on Wednesday?

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

I think it's worth deferring and I'm getting the sense from the conversation today that as things have evolved, the discussion Wednesday will be even richer than it would have been otherwise.

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

And I'm fine with having a longer discussion on it on Wednesday; I just wanted to throw that on the table.

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

No, it's very fundamental. Yeah, Julian and I share your concern. Other gaps, looking now sort of at the bigger picture of the three agencies fit together and the work of the other working group, what would you identify as either gaps or the opposite side of the coin, overregulation? Any others? Okay. Well, we actually got through what I wanted to get through in only the 90 minutes, and we do want to open it up for public comment. But before I do that, just to kind of go over the action of the next several days.

So, tomorrow, as I mentioned, we've got the full working group is going to meet and I, for one, am going to be very interested in hearing the report out of the Safety and Innovation Workgroup and the specific issues that they've identified. And now that we're farther along, I suggest that we really listen carefully to see if there's anything else emerging in that discussion that we haven't factored in in what we're doing, so that we can identify it for the better of the group. Then on Wednesday, we're going to have the two topics, we're going to have the first hour, and if it goes beyond that, I think that's okay, but it's an important topic, the topic of reporting. And Julian's going to lead that discussion.

Then I'm going to go through a discussion of ambiguities, and I'm going to start with a slide you've already seen now on the FDA. I'm going to talk about some of the ambiguities at FDA and I would really appreciate it if other people would come having identified ambiguities in ONC and FCC. That's different in my mind, as I said at the outset, from a deficiency. That's just an area where the marketplace and patients would be helped by greater clarity in the form of a guidance or something that explains the regulatory system in more detail and with more specificity. And we'll also be talking about duplication, areas where the regulatory systems duplicate one another.

And then on the 8<sup>th</sup> is when we're going to have the discussion led by Joe Smith as to whether if you set the current system aside and just think on a white piece of paper, is there a better way to do this than the existing way, even an improved existing way. So those are the next several meetings and then right after that, we're going to start rolling up our sleeves in developing a sub-workgroup work product that summarizes our recommendations in these areas in a way that we can transmit it to the whole working group for their review and consideration. So, that's the process as we envision it for the next couple of weeks. So, any comments, questions, anything else we ought to talk about before we go to public comment? If not, MacKenzie or, I don't know who can open up the lines for public comment, but we'd be quite interested in hearing any other comments that anyone would like to offer.

## **Public Comment**

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

Operator, can you please open the line for public comment?

### **Caitlin Collins – 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. We do not have any comment at this time.

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

Okay. Well thank you very much. So the call tomorrow of the whole working group is at 12:30 Eastern time. I look forward to that discussion and I very much appreciate the robust discussion this morning, it was most helpful. Take care everyone.

### **Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Indeed, have a good day. Thank you.

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

Thanks everybody.