

**HIT Policy Committee
FDASIA Workgroup
Regulations Subgroup
Transcript
May 30, 2013**

Presentation

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

You're going to be live, so you're live now on the Internet. So they're going to be listening in to the discussion.

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

That's what I'm saying, do we need – as we speak, do we need to say our names –

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

Oh, yeah, it would be helpful for them, sorry.

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

Did you guys hear that, that they're live, they're listening to us and so same rule applies, you need to say who you are when you speak, so that folks can follow along. What we – its Lauren. Julian had to step out for a minute he'll be back. Why don't we go ahead and get started, because we've got quite a lot to do.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Todd.

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

What I want to propose is a time management approach to this roughly hour and 40 minutes. Julian and I have been talking about the various topics we need to cover and there are really four different topics that we want to talk about. The first topic, we're going to do about 15 minutes and I'm going to play back to you what you guys told me by email about the objectives you want for this group. So that's about the first 15 minutes. And as you'll see, what I've done is basically try to organize it in a way that groups common themes, but as much as possible, use language that you gave me. Where two people were making the same one, I only listed it once, but I tried to organize it in a way that you could see what all your other colleagues have on their minds in terms of goals and objectives. So, 15 minutes and I think it's useful exercise because it gives you a better sense where others are coming from.

Then we have two primary topics, and we'll spend 45 minutes on each topic. The first one is ambiguity, that's one of the specific charges we have from the statute is to identify regulatory ambiguity – causing the problem. And then the second topic is duplication. All right, we're going to spend 40-45 minutes on duplication. So we're going to save all bit of time at the end, about 10 minutes or so, to talk about how we launch into the remaining portions of our mission, which are really looking at safety and innovation and how regulation – our charge is how regulation addresses the safety and innovation issues that the guys next door are going to talk to us about. So really kind of plan the rest of the summer a little bit, as to how we're going to tackle some of these things would be the endpoint for the meeting. Does that sound like an appropriate way to go – proceed?

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

So – and, we're going to cover ambiguity and duplication –

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

Today.

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

Okay, and what are the other ones going to be?

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

So the last 15 minutes is not to really to cover safety and innovation, but to talk about sort of organizationally how are we going to approach safety and innovation. How are we going to get the information from next-door over here and what are we going to do with it when we get it? How are we going to meet in June and July, the choreography for how we’re going to talk about it, not so much the substance of the choreography.

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

And at some point it would be helpful to me to sort of go through the various types of regulations that might be considered...I can’t remember if we’ve done that before.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

I think that’s one of the things that Joe mentioned also was just – in the bag today.

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

Right.

W

That would be helpful.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

So let’s talk about that in the choreography section, as we talked about how to structure our remaining interactions, having a session like that sounds like it would be very valuable and a good way then to launch into safety and innovation issues. Start with a download on what the regulatory schemes are, then when we get to safety and innovation factors; we know better how they are impacted. Okay.

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

Right. So, first topic then is the results of this exercise. So hopefully you all received an email from me, I don’t remember exactly when it was, end of last week.

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

I don’t believe I have, but I’m with the Taxonomy Group, so I wouldn’t have been on your –

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

So, I only sent it to the folks who are listed in the Regulations Group. And so what I asked everyone is, in our last phone call, people had said, let’s see where we’re all at in our goals and objectives for what we want to try and accomplish in developing whatever work product we have on the regulatory side, right. So I asked that question of the group, I asked you to send emails to me and tell me what you wanted to try and accomplish in the Regulatory Group. And so, I generally tried to organize it – this is the slide you saw earlier, but I generally tried to organize it in terms of primary mission, which is safety. How can we do that? And then sort of secondary mission is how you minimize side effects of regulation? How do you minimize impact on innovation and some of these other things?

And what I thought I would do, and this is apropos, you all just said it would be great to know what the existing regulatory themes are, I thought I'd put up on the slide, and I'm not going to draw on this, kind of the existing intelligence as a were on what good regulations look like. So this is President. Barack Obama in 2011, issuing this Executive Order, which is an updated Executive Order that was 20 years old at that point. And so this is what the White House says good regulation looks like or accomplishes. And it's written obviously generically, FDA, USDA, I mean, this is for all of them, but at a high level. These are all some of the things that I was hearing from people, so I just wanted to do this to level set, and I'm not going to go through this, you can read it at you're leisure, you've got a hard copy of it. But they talk about these elements here; this is the directions that they to the agency itself, a thought process for how you go about selecting the right kind of regulation to meet a circumstance, right. And then finally some of the very themes that we've been identifying, which is, the White House urging innovation in approach and respect for innovation to ensure our future, the benefits of innovation and the need to take flexible approaches. All right, so I'll let you read that, it's self-evident what it says. I can't really add anything to it.

So what I did then is, as I said, I took all of your emails and I compiled those. Now you've got a written version that is earlier than this version, I've added to it because a few people were late, and I'm not looking at you Jared – were late in turning in their comments. So this is more up-to-date than what you have in written form, and I can email it to you so you have the most current version. So again, all I did is cut and paste what you guys said, edited a little bit to make it a little bit more succinct. So on the first issue, the kind of primary focus, protecting patient safety. All right, making sure that the regulation is narrow, tailored to its job. That is kind of like my chemotherapy argument, that magic bullet, that silver bullet that hit only the cancer and leaves the rest of the body fine.

Level of risk. Several people kept observing that a stratified approach that respects the fact that not all risk is the same, but again sort of narrowly tailored to the particular strata's of risk involved. And then this argument about functional areas as opposed to the version of a product. This was kind of a flexibility approach of saying don't write a regulation that will become outdated tomorrow because it's technology specific, try and write a regulation so that it will apply regardless of what the particular technology was.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Brad, can I ask a question about the first point, if the regulation narrowly tailors to its job? I mean particularly the FDA has been operating, it's not just whether the regulation's narrowly tailored, but how they're enforcing or the guidance they put out on it. It seems a little more nuanced than that. So I agree with the point, but I think there's also another level to consider, which is, are they – okay, so the enforcement discretion in a particular area, because you could have a broader regulation that's hard to re-regulate, but then narrow it in other ways.

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

So that's a really good point as to what is regulation? Is regulation the stuff written on the book or is regulation the functional end of what an agency does, which is a combination of what's written on the boat, how they interpret what's written on the book, how they act, how they stratify, how they prioritize what they do. All of that, we are an adoptive vocabulary, all of that is big "R" regulation and the thing written in the book is small "R" regulation. I know, but there is a difference between the two and it's a very important practical difference. Okay. So this is what people said about that. So, while minimizing side effects. The very first one, several people necessarily as part of charge is to figure out how to protect innovation, or at least to recognize. And I thought this particular comment, I thought was the most nuanced, recognize that sort of relative space that we're in, the relative immaturity of health IT and the urgency of ensuring we're protecting innovation at this stage. A more mature technology doesn't need to be protected in this manner quite this way, so recognizing that.

Flexible and market-driven is similar but different, right, flexible is always a good attribute for regulation, it's always good to allow creativity in the hands of the industry to figure out the best way to meet an objective. So rather than prescribe exactly what the company has to do, state the objective and let the company creatively figure out how to meet that objective. Allow for off-label use. So this is a concept that sort of is borne out of FDA's regulation of intended use. And that could be too metaphysical about it, but intended use is the way you regulate a manufacturer, because that's what a manufacturer controls is their intent. They don't control how the ultimate user uses it. So this argument is, again maybe focus on intended use and not try and regulate the practice of medicine where the consumer might choose to use it in a way that the developer of it didn't intend or it morphs or it evolved as software as a process as much as anything, it changes over time. So allow for that downstream flexibility to make the best use of software.

Expedience. If there is a regulatory process, please make it a quick one. Please make it one that folks can deal with in sync with lifecycle of software. Because software changes constantly and so forth, whatever the process is can't drag on for years or it's out of sync with the regulatory. And then lightweight from a cost compliance standpoint is very important. Patricia?

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

I have two questions for you. On your previous slide, the focus of risk was patient – sorry linked to risk and patient safety. Is there any consideration of patient safety risk of innovations that aren't being brought into market or aren't being used? Could you flip back? So, regulate on – no, I'm sorry, you were on the right one there, regulate according – it's the second risk to patient safety, assume that there's a product and is this product or software risky to patients as opposed to, does the absence of this innovation cause a risk to patient safety?

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

Right. Julian and I were talking about that over lunch, that's a very important feature, it's a very important part of the calculus of setting where the bar ought to be, because you're balancing the need to innovate with the need and progressive bring things to market with the need to not do harm, to not injure people. So, actually that is kind of embedded in an awful lot of these.

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

So, that's – it's clear to me to not do harm with a particular entity as opposed to overall safety. And then on the next slide I have another question about in protecting innovation is there a way of thinking about a risk regulatory framework that actually is promotive of innovation that ultimately leads to greater patient safety, rather than look at how we achieve patient safety. I mean, it potentially – want to be careful that the risk framework does not freeze practice as it is right now and say we want to just stay within what we know now. What we can do, what are the risks, but what we know now and what we can do but are there opportunities that might actually have – lead us more towards innovation.

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

Right. So let me be clear what these slides are, too. I think I said this at the outset, but I want to be clear. I'm just reflecting back the written comments that I received. The intent of this is not to make this a committee work product –

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

Okay.

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

– these will never be seen again after today, as far as I'm concerned. This is for your benefit to see what your colleagues around the table identified as their hot button issues. So we don't need to nuance any of this because this is –

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

I was going to say, some of this actually would be helpful potentially as committee work product, I would think –

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

Well then, if we do that, then we've got to – the words –

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

(Indiscernible)

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

We've got to take up these comments and we've got to craft it and that becomes a task in and of itself, and we'll have to decide, as a group, where the most value is. Let's get to the end of this and talk about then how we want to use it. All right? So, I called these ancillary goals because this isn't, strictly speaking, these are policy issues, but they don't fit neatly into a bucket that I've had before. The first one relates to what agencies are involved, right. And I interpreted that first line is me, but the rest of it is comments that I got from other people. I interpreted these people's remarks as saying, look, there's a certain predictability that comes with staying the course with a give agency. If FDA has regulated in the past, there's a certain predictability to leaving FDA regulating it in the future, and so that's part of what I interpret – those are my words. And Julian and I did not participate in this exercise, we didn't contribute to this, this is just what I heard from you all.

So, the first comment that I put in this category, avoiding duplication among agencies. Again, that's part of the mission of the group, it's right there in the statute. This is an example that was included in the comment, I honestly don't remember where these comments came from, and so I can't even identify that. But the comment was expressing, as an example, meaningful use definition and the CDS issue, I assume it refers to potential FDA regulation of portions of CDS. We had – I shmushed together, it's a long paragraph, but several people wrote about the need to preserve FDA's role and I took all those comments and put them in the same paragraph, it may not flow in perfect eloquence. But, basically observing that they want to keep FDA in its current role regulating that it currently does, suggesting that this group, the FDASIA working group recommend what tools FDA has at its disposal to nimbly change the way it regulates.

So I interpret this comment just saying FDA has a statute, the statute is broadly written and within that, the FDA could be – we could suggest to FDA that they use some of the things that they already have, like exempting certain devices. And I think you've heard that from a few people, haven't we over time, come to realize that certain devices are lower risk than maybe they were originally, that are HIT and they ought to be down-classified, as an example, also the idea of exempting from GMP, clarifying some of the ambiguous terms and utilizing some other special resources that the agency has at its disposal. A lot of comments on the agency things. Another one suggesting ONC role, again I grouped the comments together related to ONC, saying that ONC should set standards and use certification criteria to impact the interoperability of medical devices. That actually was not Julian, he did not participate in this. And further talking about the positive things that ONC can do. And then likewise, FCC, identifying a role for that agency, that there are positive things that FCC does and those need to be built upon, basically making sure for example, that adequate spectrums is allocated for use of – HIT. And then finally, I put this under the agent's expertise category, because that seemed where they fit the best. A couple of people made the observation, we ought to utilize data and the HIT system itself to regulate and heal itself, as it were, that HIT has special capabilities associated with it that could be used to gather information about what works, what doesn't work and not be self-regulating, but supplement the regulatory process.

M

That's surveillance then.

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

Surveillance, yeah. And then another comment that's self-explanatory, develop a consistent level of knowledge and expertise to facilitate predictability and trust. So they're wanting the agencies in part, I'm interpreting that as making sure the agencies stay on kind of the cutting edge and understand these technologies so that they have the capabilities and knowledge to participate in the best way possible –

Then there were on variety of comments just about clarity, which makes sense, because ambiguity is one of our core aspects our mission, identifying it and correcting it. And so, we had people say things like the regulations need to be clearly writing and predictable and any categories ought to be clear as they can be. Another comment came in basically focused on the complexity of the EHRs, how they connect to medical devices and drawing lines between the regulatory. I interpret this comment as saying understanding what falls within the FDA, what falls within ONC, making sure that we can separate out this huge interconnected system of HIT.

International harmonization. I thought that was a really good comment, I forget who made it. But to not look at this in isolation, but to consider the international implications because so many of us are in this business in that manner. And there is, to that end, a committee, the International Medical Device Regulators, are going to be working over the next 18 months to focus on that very topic. So, in fact, Bakul I think is intimately involved in it, and it's going parallel, so there's a need to coordinate. Mike?

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

Hi, Mike Lipinski with ONC. There was actually even an Executive Order that when there are new regulations that you had mentioned another – regulation related to looking at other countries regulations to see where there can be consistencies in the adoption of new regulatory requirements, particularly for like multinationals that would be in that space. And clearly some of the agencies – that who are under some of the requirements of the European Union and our requirements. So, I just thought I'd mention that the OMB has already taken a stance on that type of approach and it would probably fit under the charge, if you wanted to, for regulatory duplication.

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

Well yeah, yeah, good comment.

M

That's a good point, international duplication.

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

So the last – I think it's the last comment, was a couple of people commented on the evolutionary nature of regulations and the need to ensure public participation throughout. In other words, this group is helping out during the summer, but I don't think by the end of the summer all HIT regulatory issues will be resolved. And so I think the point of the comment is making sure that there's adequate public input at each stage of the decision-making, as this thing gets sorted out. So as I say, this is basically I'm reporting to you results of a survey, they are what they are. I didn't try to heavily edit, other than to fit them together a little bit and organize them and eliminate some duplication. There are gaps I'm sure, there are some things that aren't listed here, because it was an unscientific way, I just asked people to say what was on their mind. But it does, with those major caveats, I found it interesting. I found it interesting what was on different people's minds about what they were most concerned about, heading into this process in the way of trying to accomplish. So, as I said, my plan was not to try and get – make this a committee work product in the sense that the committee would say, yeah, we agree with all of that and it's holistic and everything like that. It's just survey results.

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

The comment that I had intended to make, but never got emailed to you was, it was just at some point this would be helpful to me if we pick a few use cases and the juxtapose them against some of the regulatory framework suggestions that we're trying to make and use those to illustrate how that approach might be helpful.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Todd Cooper. I would assume, based on the presentation this morning that's coming out of the Taxonomy Group, we should actually be able to get a representative set based on their approach so we could actually look over that spectrum of types of scenarios.

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

So let's talk about that in the last 15 minutes where we plan our next steps, let's figure out all those kinds of things that would be helpful for us to do. What you would find valuable for us to do, as we're planning our summer.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Okay.

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

So, I propose to move on. I thought this was a useful exercise as kind of a launching off point. As you saw from the presentation earlier, a couple hours ago, I listed five things I discerned from the statute principally to be the areas of focus for this group. The first three all related to safety and innovation, do we regulate too much, do we regulate too little, but not general questions, specific questions. Are there specific safety issues that are unregulated that need to be regulated? Are there specific costs that we haven't factored that suggest the regulation is too burdensome? Those questions. The last 15 minutes we're going to talk about how do we do that, how do we get the input from the others and move forward on that, Julian's going to lead that discussion.

The second, the last two questions were ambiguity and duplication, those are both called out in the statute. And so I propose that we deal with those first because they aren't just dependent on what others are doing, right, so we can go ahead and immediately tackle them. So what I didn't do is prepare a general lecture on what FDA, ONC and FCC law are. What I did is a step kind of one beyond that, which is to say, let's look at the published literature and see what has already been identified as ambiguities in the law. So let's start with ambiguities and we're going to start by basically looking at these like ten different reports, and I'm not going to go over these, because I did in the conference call a week or so ago. These are the same reports that – before.

So what we did is, some of these are long reports, I have a copy of every one of them right here if anyone wants to look at any – why are you laughing? People do read these.

M

Paper, paper's unique.

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

Yeah, I printed them. So what I did is, I took the papers written by various folks that I've heard of, and we went through and we tried to answer first the ambiguities. And not every report is written in the same fashion and a lot of reports seemed to jump right to the solutions they wanted to propose and they of jumped over the step of what's wrong with the current system. And I like some of the ideas of the

Bipartisan Policy Center. There wasn't much substance in the report about the problem they were trying to fix, whether it was ambiguity, whether it was over-regulation, and it wasn't, not a lot of it was called out. But we did scour it and this is the summary of what we found in this particular report, and it's not so much ambiguity as I'm saying for example with FDAs current regulatory approach is not suitable for standalone HIT, it's a pretty broad statement. I have some understanding probably of what they intended, but they didn't spell out what they were trying to accomplish or what they were trying to identify. And they were making observations about health IT and how different it is from traditional medical devices.

So, I'm reading between the lines here, I'm not quoting Bipartisan Policy Center, I'm guessing as to what they had in mind. And I'm going to give you an example of what I'm guessing they had in mind. There is a regulation, Part 820 called the quality system at FDA and it was written a couple decades ago and what was primarily intended to be addressed was hardware, was mechanical devices of various sorts. And so this regulation goes through in fairly significant detail, still at a reasonably high level, but still in detail, that you have to worry about things like the lighting, is the lighting in the manufacturing facility adequate for the manufacturing to be done, right. Cleanliness, all sorts of things that are very relevant with traditional medical devices, not terribly relevant to standalone software.

It also contemplates a monolithic building where you built the widgets. And software, as you guys know better than I do, if it's a multinational company, you can have five guys in India, four guys in Texas and Brazil and they're all contributing parts and so forth. And then so you ask where the manufacturing facility is and everyone just looks around like you're an idiot, why are you asking where the manufacturing facility is. So I'm interpreting, and maybe I'm getting it wrong, but one of the things I would guess they had in mind is that standalone software – traditional model and the wording of a number of FDA regulations just doesn't relate to the reality of how software is developed. So that's my kind of interpretation of it.

And Health Regulatory Coalition has identified a couple of ambiguities. The first one is the dichotomy between wellness and disease, all right. FDA regulates products, and you saw the definition about one hour ago, regulates products that are used in the cure, mediation, treatment of disease or other conditions in humans. Disease is the lynchpin. If I make something for use to treat diabetes and that's the intended use, that's how I intend it to be used, it's regulated. If I make something that is intended to help people live a healthier life, they get an app that they use to track their diet and their exercise and the amount of sleep they get and the amount of stress they're under. And I just say, hey, here live a healthier life, keep track of what's going on in life, live a healthier life, it's not regulated. So that part's easy right, diabetes regulated and wellness not.

The fact of the matter is though, those areas are converging, as we know more and more about how a healthy lifestyle impacts disease, chronic disease, the diabetes, asthma, all sorts of conditions, it's natural to intend it to be used really for both, for both general health and wellness but also with an eye towards how it impacts disease. So by merging those together, it creates an ambiguity as to which software ends up being regulated by FDA, right. And it's an issue that has existed for decades. As we learn more about how food impacts healthy lifestyle, Cheerios in 2009 General Mills, the Chairman of the Board of General Mills got a letter from FDA saying, Cheerios are a drug because you are suggesting Cheerios are used in the management of cholesterol, so, it's a drug. That's the same issue, it's connecting stuff we use, whether it's food or a mobile app or whatever, used in general life management that's indicated for disease.

The second ambiguity is what's referred to as the accessory rule. The accessory rule is decades old and it's very simple. It says that anything that's connected to a medical device is regulated in the same manner as the medical device to which it's connected. All right, it made perfect sense 20 years ago. You had an ultrasound machine you plugged a transducer into the machine, the transducer obviously regulated the same way the machine is. Now, everything's connected to everything else and you've got all this tangled mess of interconnectedness, part of it is a medical device, part of it is an electronic health record, there's MDDS somewhere in there, because it's taking data out of the device and sending it over to the electronic record, but then all these other systems as well interconnected. So which ones get regulated and which ones don't? It's an ambiguity.

CDS Coalition Papers are trying to figure out the dividing line between the CDS the FDA ought to regulate and the CDS that FDA should not regulate, CDS clinical division support, right. So the essence of this software is software that does something analytical to data and makes a patient specific actionable recommendation, all right. Some of that stuff is really high risk, some of that stuff, for example, would tell you what chemotherapy dosage ought to be and if you get it wrong, if there's a flaw in the algorithm and the software gets it wrong, then people get hurt. So there's a level of CDS which is serious, there's a level of CDS which is nothing more than add the four or five numbers of an APGAR score so you can have it basically dumped into a medical record at the end, but the doctor could just as easily add five numbers between zero and one, zero and two, whatever. So, you have incredibly simple, and I know simplicity doesn't mean risk, I got that and I'm going to rely on Julian to help us understand that. But my point is, there's some CDS that deserves regulation, some which doesn't and that's not defined right now and that's an ambiguity that the CDS industry wants resolved.

A number of us, Jarrin and Julian and a few others, participated back in January 2010 in a big meeting that FDA hosted. CIMIT is a group that Julian's affiliated with in Boston, Continua is a trade association, and it was a three-day gathering designed to do what we're doing here, identify the ambiguities that are preventing the achievement of greater interoperability of systems. And unfortunately, my record keeping isn't complete, because there's a bunch of work product with the higher risk, higher acuity setting that I don't have in my records. So the stuff I have here reflects some of the lower acuity stuff, and we need to capture – I don't know if you've got it or maybe Jarrin's got it, we need to capture that. But the whole point of this three-day conference that the FDA hosted was to identify ambiguities. So what were those ambiguities that were identified. The scope of FDA regulation, which is in the mobile space, exactly where does the line get drawn, and that's FDA again – this is July – January 2010, in July of 2011, then the FDA published a draft guidance, trying to address these very issues and that will be soon final, as I understand it. So this one is on its way to being resolved, or at least –

So then, we get to the level of FDA regulation, right. So, one of the things that we're charged with is really coming up with a risk-based program. FDA has a risk-based program, but the question is, which product ends up in which risk category? And that was an ambiguity that this conference identified as an area of concern, because it wasn't clear, for example the interconnectedness between a Class 1 device and a Class 2 device, does that raise the risk level of the whole system? So that was an issue that was identified. Intended use questions. This is really to the heart of what I think in software is frustrating a number of people, is software, probably more than any other product, morphs over time. We learn about how to use software, we tinker software, we approve software, the end user tinkers with software and infuses the software. And so in FDA's world, something gets approved and the intended use is frozen at that point, based on what is approved, the approved intended use. So what happens downstream is that intended use continues to evolve, it creates a real ambiguity.

Evidence required for clearance. So folks were saying, okay, if FDA – if we're subject to FDA and we have to get clearance, what kind of evidence do we need in order to get that clearance? That's not something that the current FDA guides document tells and I'm not going to dwell on this. There's a difference between evidence required and then the standards for required, so people were raising a whole bunch of issues about what characteristics the software had to have in order to meet FDA standards. And these are some that would come up – that conference sort of came up with, and I'm not going to –

Design controls. Again, software's developed in a way that's pretty different from hardware and keeping track of what the design elements are when it's an open-ended system, when it plugs into potentially undefined system, how do you deal with that for FDA? That's not a traditional issue that FDA has had to deal with, and it creates a major ambiguity.

Root cause analysis. So one of the things FDA does is, when there's a problem, it asks you to recall the product, it asks you to file an adverse event report, right. So if you've got a medical device here, it's connected via MDDS over here, and it stores – the data are stored here and analyzed in CDS over here and then populated in the EHR over here. And you notice that something's wrong in the EHR and you have no clue where in that whole system something went wrong...(Indiscernible), it's a big deal. I mean, it's a liability, it's a crime not to report, right. And there might be six different companies that made a piece of this system and one of them has a reporting obligation, but who is it, right? And correspondingly if you have to withdraw it from the market, who has to withdraw it from the market. So those are major ambiguities that the conference identified back in 2010. And then, I forget who it was, but somebody said, is there a benefit, can we share this information and collectively learn from it? Someone was being very proactive, I –

So, Institute of Medicine. All right, the major report, I don't know, 50, 60 pages or something and we went through this in order to try and understand what the – again, first phase we're looking at ambiguity, so we were looking at the IOM report trying to pull out the ambiguities that are identified. One of the main focuses of that report is sharing adverse event information and I gather one of the things that really rubbed the authors the wrong way is, there are contractual provisions out there that kind of frustrate the sharing of one of the information. So a number, I think, of folks involved in writing the report were sharing that frustration. I put this in the ambiguity category because it's kind of not clear what the legal requirements are for either restricting the flow of information or how to deal with a situation where there are these contractual complications. But that seemed like I could put it in the ambiguity category. That was about the only main ambiguity that I got out of that report. Again, that report was mostly focused on solutions and safety issues, but not so much the analysis of the regulatory scheme itself.

So one of the articles on this list that I gave you was a whole – a couple of large articles, this is one of the large articles and potentially they're just talking about weakness of EHRs and the lack or the ambiguity of whether there was a regulatory problem with an EHR that wasn't functioning correctly. Because FDA said, we're not actively regulating EHRs, so I think this author's basically saying, look, EHRs need to be regulated, but I don't see any really applicable regulation. So it was kind of a general comment. And then a lot of HIPAA stuff which may very well fall outside of our scope, if we limit ourselves to the three agencies. And so this was the case that this academic was putting forth for a more significant regulatory scheme, and I'll let you read that. We don't need to –

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

Brad, can I ask a quick question?

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

Yeah.

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

This is Elisabeth George. The question I have is, you just made the comment about if we're limiting it to those three agencies, is there an opportunity for us – for considering the regulation as to way it wouldn't need to be regulated if it's potentially already covered by something outside of one of these three agencies?

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

Right. That's a great point and in our first phone call, and I don't remember if you were able to participate in the first phone call, I laid out two different groups of regulations. The first one was the three regulations and I asserted that that was the primary focus, because it was a focus of the stature. But on the next slide, I had like 15 different regulatory and legal schemes that we could take into account. For

Example, if we're saying that there's duplication, it doesn't mean that we can only look at duplication between FDA and FCC, if there's product liability or whatever, that's adequately regulating it, absolutely I think we can take that into account.

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

I was even thinking of other organizations like OSHA is monitoring that, or if JCAHO is monitoring that or NIST is already certifying, something to that effect.

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

Exactly.

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

We were talking about this over lunch a bit, and there are other federal agencies that have an oar in the water for various things.

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

Um hmm.

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

And Brad, all right, could you provide like copies or links to these articles you were talking about, you mentioned them at the last meeting as well, and I thought you were going to put –

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

So there’s a bibliography in your – I skipped over the slides here because we had covered it a couple of times, but 10 articles or sources are listed in two slides that preceded this.

The last one I’m only going to touch on it lightly because it’s a little bit dated. This article, even though it’s published in 2012 it was clear the author stopped writing it before the FDA Guidance came out. But, they were going through a number of what I would characterize as more technical ambiguities, in the way FDA regulation applies to medical device –

So, the whole point of that is to say, look, there’s that body of knowledge that others have already developed about the ambiguities that are out there. So at this point what I’d like to do is talk about two things. Number one, whether you agree or disagree with any of the ambiguities that were identified in those various reports. That was number one, and number two, what other ambiguities exist or if you don’t know them off the top of your head, how can we find other ambiguities that exist? We’re just going to talk –

Lauren Fifield – Senior Policy Advisor – Practice Fusion

So, this is Lauren Fifield. I don’t know that it necessarily correlates to one of the aforementioned pieces, but I know that one of the areas of ambiguity for EHR developers in particular is the broadness of the definition of a medical device that includes an EHR. And even though the FDA cites in the preamble that they do not intend to regulate EHRs, I think the sort of lasting promise that they could always regulate EHRs if they so choose, creates a lot of sort of concerns in the industry and potential duplication. Because I think one thing that’s sort of missing is that under the HITECH Act and the EHR Incentive Program give the ONC authority to create regulations that regulate electronic health records and create requirements and specifications for EHRs. So, I think there’s sort of the ambiguity and potential duplication in the EHR realm. And then, I think even though the MDDS guidance is fairly clear, I know many EHR, PHR and other kind of software developers are often conflicted as to kind of that line between their application being considered an MDDS. Whether or not it controls or presents information or just integrates with a software data kit or the device in such a way that it shouldn’t be classified. So, some gray area there.

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

Can you give me an example of where that ambiguity would fit?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

So I think – let's see, so, an EHR that integrates with an EKG machine, if it turns on and controls it, then the EHR developer would likely go ahead and classify as a low class, but still device. But if it integrates with the software data kit, that is provided by the EKG manufacturer, they might now, but sometimes the EKG manufacturer will say that they don't feel comfortable establishing a relationship with the EHR vendor if the EHR vendor hasn't chosen to also go through or classify themselves in that way. And so it's in that way you get varying interpretations, which creates ambiguity. And then I think interestingly, there are – and it's not now, but in kind of future references to meaningful use requirements, there are clinical decision – well even in current, there are clinical decision support requirements and some other integration requirements with imaging systems and things like that, that on the one hand you're being regulated to do that but that is either duplicative or at odds with or just not well harmonize with other regulations.

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

Good.

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

Are you talking about specifically within the MU requirements, like Stage 2 or Stage 3?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah so in Stage 2, EHR developers are required to have five clinical decision –

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

No, I mean –

Lauren Fifield – Senior Policy Advisor – Practice Fusion

– interventions, oh, okay. Yeah, yeah, sure, sure. Yeah. So and then there's sort of the thought or the kind of – this space, the FDA thing that they might look into with the development of guidance around clinical decision support.

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

I guess I can appreciate those ambiguities because Robert Jarrin, Qualcomm Incorporated, we have a medical device subsidiary called Qualcomm Life, which strictly creates medical device data systems through on is a – on market. And the other is the platform that we chose to also put through quality systems and list with the FDA as a Class 1 medical device. From the perspective, just strictly speaking of what you're mentioning, and I think – you mentioned the preamble, I'm assume you're speaking about the medical device – I'm sorry, the mobile medical apps guide document preamble, which mentioned that EHRs were not going to be spoken about for the context of that guidance document, but I don't think that it clearly said that all EHRs are off the table.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

It was the MDDS –

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

Okay. Yeah.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

– regulations and in that preamble, they said even though EHRs are considered to be a medical device for the definition, we will not regulate them and do not consider them purview to this regulation.

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

To the MDDS, right?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah.

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

So I guess, for me it always come down to, and I appreciate the law where – of it very much clearly saying anything can be a medical device if it falls under these different categories, QRCs – etcetera, etcetera, and for me it's all under context. You back up into where that came from, it's a hundred years of law or 200 different laws that comes from FDA regulatory stipulations including 1938 people selling snake oil to 1976 when Congress received a report where 10,000 people are either harmed, and I think 731 or somewhere around there died as a result of medical device errors. So, with that context I think the context really intended to be very, very broad so that they can catch anything that put itself on the market in such a way.

But then the FDA has a number of tools to be able to use enforcement discretion, which Jodi mentioned and a couple of other people mentioned. I think that that's one thing that the FDA has at its disposal to be very fast in being able to take certain things off the market and clear very clear about. But they don't necessarily do that all the time. When I see what an EHR is, and I've said this before, I've said it at the Bipartisan Policy Center Meeting way back when, to me an EHR is a medical device. It looks like a duck, it quacks like a duck, it's a duck. No whether or not the agency wants to go out and enforce their own rules, that's the concentric circles that Brad was mentioning in the beginning of the day that makes sense to me. So what if you're a medical device, if you're still low risk or the benefit to the population is still high that you should not be regulated and you should be either taken off completely and said, you don't have to register, you don't have to list with the FDA, that's wonderful.

Or if they feel it's so medium-low risk that it requires you to list and register, so that they can have adverse reporting, then they should talk about how you don't have to potentially go through GMP and quality systems regulation. I mean, there are tools that the agency has at its disposal that might and aren't being used in an effective way. So I can hear you saying an EKG machine in a hospital connecting into EHR, to me if the FDA came out and said, the EHR is not a medical device then there is no problem between the EKG machine connecting into you, you're not putting yourself out there like an MDDS device or an EHR. And I realize that there are some properties of the EHR that could be construed to be an MDDS. And that to me is a stronger argument of, okay, here's ambiguity where the FDA should come out and result in policy by enforce – using enforcement discretion by using guidance documents and not taking two years to put them on the market so that we all actually have a clue as to what they're considering. By telling us when things should go through GMP or not go through GMP. By clarifying ambiguous terms, like health, wellness, sleep deprivation, etcetera, etcetera. By using their internal resources such as the – such as the Device Advice and by CRH Learn, there are lots of ways that the FDA can actually come out and really proactively clinical – regulate and not regulate.

And I think that's what really falls within the scope of our recommendations, to talk about those things. I don't think that Congress intended us to come out with new rules and new regulations and legislation. I mean, that could be an outcome, but I think we should really work within what exists currently and how quickly...FDA can come out tomorrow and solve those ways to take things off the table, such as –

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

Want to talk just a minute about work product, may be where we're headed. Maybe that'll help the discussion a little bit. One possible work product would be to take stuff we've seen, the stuff that you guys come up with and make a list of ambiguities that need to be resolved in order for the HIT industry to know what the rules of the road are going forward. So as I'm looking forward to the first week of August, when we're supposed to be done, this section of the report could be that laundry list of areas where we don't know how to read the existing law or we don't know how to interpret or apply the existing law. Is that a sensible way to deal with this section of our work? You were going to say something –

M

So I'm going to draw back to one of the first slides you put up, and that was, the purpose of regulation is to solve a problem –

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

You're going to hold me to that –

M

– not to exist of and for by itself. And so what I'm struggling as I'm watching this go by is, are we trying to solve a problem around the risk of the underlying technology or are we trying to solve a problem that the regulation of the technology being ambiguity and potential duplication. Because the latter feels more like we're violating the first principle of regulation for the sake of regulation. If those fundamental problems, one of ambiguity and duplication and persistent misconception in regulation or is the underlying problem an inherent risk of this technology. And I'm going to suggest it's not the latter.

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

And I agree with you, to a point. If we were driving toward an August 1 deadline, the way I think we would go about this take the five questions in the order that they were written. First, are we under-regulating? Second, are we over-regulating? And only once we've resolved those big picture questions do we have the right level of regulation, would we get to the question of ambiguity in whatever regulations are, in fact, relevant. Or duplication in whatever regulations are in fact useful. So you're struggling, I perceive, with the order in which we're approaching it, you'd like to tackle that 64 dollar question, do we have the right level of regulation before answering the more detailed question of, is the regulation expressed in the right way or the clearest terms.

M

Yeah, I don't know how we'll solve that latter question without understanding the answer to the former.

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

Well certainly ambiguity – I'm sorry, go ahead.

M

To continue that line of thinking, how would you tease that out? If we had an August deadline and we start in August, I would say it was August 2015, how would you tease that out?

M

So what I'm hearing is this notion that well, we're imposing a regulatory framework meant for a risk profile really quite different from the technology that we're talking about and if fits poorly, so we have to address that. I think you can start that – the risk profile with technology that we're talking about, does it merit this regulation or is there a problem, is there determined safety risk that needs to be addressed. Because otherwise I think we're solving a problem that isn't the root cause and we'll just – and could lead to a regulatory morass.

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

Let me be a little less philosophical. One of the examples was wellness versus disease, all right. I submit and I'll see if you concur that certain software used in what I would characterize as high-risk disease situations, calculating the proper dosage for chemotherapy. It's appropriately regulated, it should be regulated. Okay. So the ambiguity that I'm identifying is that over at the other end, there's wellness that should not be regulated and we need to decide where from this clearly deserves a regulation to this clearly does not deserve regulation, where that line should be drawn. I'm not going to ask you today where to draw that line, all I'm asking you, as a committee work product, is to say that's an issue that needs to be resolved. And I think it does need to be resolved.

M

I can work with that, I'm just – it'll be a challenge because if we're patching a bit that's broken, you'd like it to be able to step up a level and say, that – and maybe this wasn't the opportunity, but it felt like it was, the opportunity to put in scope the notion of appropriate regulation as opposed to a work product which solves some of the problems –

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

So I think we will get to that. I sense you're frustrated with the order because we're looking to the folks next door who are doing safety to get further along so they can pass it off to us and we can say ah, okay, those are the patient risks, wow, we're hitting them with a slight sledgehammer, that's really inappropriate. Or the opposite, wow people are dying in the streets and we need to do something more vigorous.

M

So we've been talking about that very issue, the fact that the assumption a long timeline and the ability to sequence these things is part of the problem because we don't have that time. But we do need to, by the way, jumpstart that. I'm sorry –

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

No, I just was going to, in terms of a work product, I think – for me it might help if the risks were prioritized and then maybe link to a couple of specific examples. My sense is some of these are much bigger issues than some others.

M

– impacting –

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

– ambiguity.

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

So, Todd?

M

Go ahead.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President⁵⁶³⁹

Patricia – if you were in here when we talked at the beginning, I think that one of the things you had mentioned here was just coming up with a representative set of examples. As you do the taxonomy there are different pieces and then utilizing that to help us say, okay, if we have in this case, a list of causal factors and we've listed some, we'll probably get some more and then just apply that to those, and see how does that fall out? Because I think at the end of the day, when you think about the problems of ambiguity, you take that – that's from the perspective of those who are trying – who need to resolve that ambiguity and they're trying to say, is my system even in the ballpark, and if so okay, what do I need to do? So I can just go do it and get it done quickly and so that'll tease out whenever we run this matrix.

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

And that would be helpful to take a couple of use cases or exemplars to this –

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Exactly.

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

– in a sense of how the judgments are being made also. Because I think, I hear this conversation is focusing quite a bit more on software than on anything else, and I just want to be sure if that's intended? Is their intention to look at devices or centers or networks or some of the things that – that we have in taxonomy – staff has an HIE blog in here. Or is it strictly software used in a clinical judgment mode?

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

I think it's really all of the above –

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

All of the above, yeah, I think –

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

So I think – yeah I think based on the conversations this morning and – the thinking that we've had is broader.

M

Definitely broader, because like the wellness aspect is such a huge deal, especially in –

W

Right.

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

I mean that's a question I have, which I'm not sure, but there's been a lot of question on, but whether that's – whether we're putting that in the script and discussion as well, because that's a whole other...

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

It might be a good question for tomorrow.

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

Yeah, so we can just hold on to that for tomorrow, but I think it is important to go back to Todd's comment about trying to map things that we actually take maybe some typical cases and maybe one or two – cases, to show what do you do when you see something odd?

M

That gets to what Joe's talking about is, focus on real-world problems. So let's get – so that we can run it through there to say, does this really fit?

M

Because you can resolve ambiguity in the ways that are just clear, but unhelpful.

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

So Julian and I were just caucusing and sort of want to call an audible.

W

– terminology right there –

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

Our original plan had been to try and cover in the last 15 minutes, what the course would look like over the summer. I think we're going to need more time to do that planning. So, I'm inclined maybe to spend only say 10 minutes on the duplication issue, just to stimulate thinking. And then move immediately into that final discussion about how we're going to get the work product from the other committees and how we're going to tackle some of these bigger picture risk level issues from a process standpoint. We're not going to be able to resolve it, but how we're even going to frame the issue or frame the analysis.

So just in terms of work product then, for the ambiguity thing, for the moment what we'll plan to do is just summarize the ambiguities that we've identified. And at an appropriate juncture, I think the conversation that David mentioned of the hard part of prioritizing to say which are the ones that really need to be tackled because they're really impeding progress is the next important conversation on that topic. So we can go from this to a laundry list for this group to then either, maybe we can do it at first by almost voting through email. Everyone rank them, we'll see what it produces, if it produces clear modes of popularity –

David Bates, MD, MSc – Brigham & Women's Hospital & Partners – Senior Vice President, Quality and Safety 1:00:38

Yeah, I would rank them first and then have the discussion. I mean, we've done a bunch of things like this and often there's more consensus than you might think.

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

Yeah.

M

One can always hope.

W

And Jarrin's plan about – not just wanting to nitpick at what exists, we can hopefully also use that list to advise what we propose, right. So if the ambiguity was created because of just process or because of definitions being created out of step, we can do that too, right.

W

So it's not just to say, that wasn't good, that's ends up not great, it's more okay, well let's learn for the love of God. Yeah, okay, good.

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

I am going to go rather quickly through the duplication and this – probably treat it the same way of basically create a list of areas where there's potential duplication. Then circle back later in the summer, when we've got that bigger picture more clearly in mind and be able to say what's a real problem versus what's an annoyance versus what doesn't exist. So, I said at first I was going to use the written materials as a launching off point. On this particular one, the written material weren't terribly informative. I got a few things out of it. But I thought I'd put – so this first slide is Brad more than the written materials.

As I looked, for example, at software that both ONC and FDA might have something to say about, the categories at the bottom are CDS, MDDS, certain mobile apps, imaging, interoperability, hospital networks. These are all types of software that potentially, depending on the intended use, depending on how the thing's marketed and also depending on how you interpret the laws, have a couple of different regulatory possibilities. And as I was studying the ONC Safety Plan from December of last year, so five months ago, six months ago, a couple of major themes are adverse event reporting and the use of standards and appropriate design. So that's an area of what I'll call potential conflicts, I don't see actual conflict, but I see potential conflicts because you have two different agencies both with an interest in the same categories of software and the same regulatory mechanisms that potentially could apply.

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

And Brad, I can tell you that in the FDA we actually have two groups within one organization of the FDA with radiation reporting and adverse event reporting, and industry still is never sure which one to report to. So, we're – so even within one organization, there's something like that. So if you have multiple organizations, the probability is you're probably going to report to the wrong one, and it will probably get lost in the quagmire of other information so that it won't be effectively utilized for that potential issue's monitoring. So, that's another reason to think of that.

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

Okay.

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

Um hmm.

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

So again, we went back through the materials looking for examples of duplication, it seemed like the Bipartisan Policy Center had some concerns anyway about the use of Patient Safety Organizations and voluntary consensus. Again, they didn't put a very sharp focus on these issues, but they were recommending anyway, various approaches to safety reporting that potentially duplicate or identifying areas of potential duplication.

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

Can you explain this one about the duplication? I mean, I see these as having threatened the Safety Plan, which should be coming out – final. I see these as different. The safety reporting through PSOs and NPSD as sort of a different animal than kind of oversight of – that's really creating that culture of safety and trying to make sure that – knowledge built into the practice as opposed to the safety of the technology itself, although there's some – that subject. I'm not sure what the duplication concern is on this, if you can help me understand that.

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

Right. So duplication is kind of a pejorative word, and maybe it's the wrong word as a result, overlap or intersections might be a more appropriate way to characterize the interaction.

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

Is there concern that there be requirements to report like if it was something that was being overseen by FDA, that there be requirements to report adverse events to the FDA as well as to PSO or –

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

That's a potential concern.

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

Because they've also been working carefully at trying to connect their reporting...kind of reports to one and the other can be done in the same format.

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

So there can easily be coordination where there's potential overlap.

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

I don't think the reporting could get any worse.

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

Thanks Julian.

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

Brad, this is Patty. I just wanted you to know that it seems like it would be useful to separate out where the duplication comes from, a regulation or a law where there content is overlapping and where duplication in the implementation comes from. And that they're really two separate issues. And one of them being that there's – and what I had thought from our early conversations, that the regulation duplication was looking at where are the specific in the existing regulations that may already be overlapping. And then what seems to have come up in here today is that and then in the implementation of those, there is confusion and ambiguity which leads to another set of duplications, not in the regulation but in the way it's used.

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

So this kind of goes back to the point I think maybe Jodi made it at the outset, having this sophisticated view of what regulation is, large cap "R" versus small-cap, right. So the statutes are horribly duplicative, right because they're so broadly written that the spheres of responsibility completely overlap. And then you get the regulations, which are a little bit more specific and maybe they overlap some, but then you get down to the actual practice of what the agencies are doing and convincing people to do. And hopefully, by that point there's even less, if not complete elimination of the duplication. So I'm not sighting these as areas where I want to say there's definitive duplication, I'm flagging these as, we looked at the literature and these were the areas that were potentially identified to maybe have duplication.

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

That's a very nice structure, I mean, that's a very helpful way of even thinking about it.

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

So these all require further analysis and investigation to really understand at this level, the very granular level if there's duplication.

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

Could you go back one? Yeah. So, in reading this report carefully, the single thing that leaped out, from my perspective is that the way things are set up now, the PSO’s all collect individually, but there’s not a good mechanism for sharing it. And that’s something that we need to comment about because many of these things come in one at a time, you might have a report and Julian might have one, and other places have been able to do this successfully. There’s some discussion of setting up an entity like that, but it’s not very far along, as I understand it.

M

And it dovetails with the other thing about international harmonization, because it won’t serve at all to have PSOs that are just – not when the technology’s –

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

Right. Yeah Australia has had – success with an approach like this. They get 47 reports about one thing and then I can go to Elisabeth and say, well look, we have 47 reports about your device, this is not coincidence at this point.

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

And having worked with a lot of those organizations, some of the reasons that those countries can do it is that they usually have one medical system and they have one law and they – you put the data in this one tool or else you don’t get paid. So it’s real easy.

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

And that’s what I meant by saying it couldn’t get any worse, it’s that fragmentation undermines appropriate capture, appropriate data mining, metadata analysis and we can’t create complete pictures. That’s a good example, Australia’s done a great job.

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

That model which you just described, this is Patty, by the way, is a way that would actually provide a feedback loop for the regulation.

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

Yes, utility, effectiveness –

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

It also gets into the point that you were making about how you implement – how we implement the regulations and how FDA for instance, if we’re talking about FDA or ONC or whomever exercising – of discretion. So, FDA has a lot of different tools in its toolkit, as far as how they – if something’s within their jurisdiction, what they do is if they just require QMC or do they require to full 510(k). I mean there’s a lot – or do they just keep hands off completely. And there’s a lot of variability, do they just require listing? Whatever it is, but there’s a lot of variability of understanding what’s out there requiring some kind of process with respect to how a product is developed to full review – premarket approval. So, I think, I like the construct you have Brad about talking about regulation as not just the statute or the regulations, but how the agency – (Indiscernible) I think that’s a really good framework.

M

That’s really, really, really good. Another work product.

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

So as we studied IOM, we saw the same two things. How you approach adverse event reporting and all the different players that are involved in adverse event reporting. And then the encouragement of the use of standards, there are at least two, ONC and FDA organizations that make standards a big part of their regulatory scheme, and the encouragement of the use of standards. So, those potential areas again for overlap, but I have no idea. Certainly the report wasn't detailed enough, didn't get to that actual practice level to see whether there was duplication in practice. I'm going to – it's quarter after, so, let me just maybe draw this section to a close. Which is to say, for the work product for this section, which again we might want to delay until later in the summer, we could prepare a more careful assessment at the practice level of those two things, reporting and standards as to how the agencies actually approach those to see if there's any conflict, actual duplication in practice. That could be a work product and it's going to take someone smarter than me to do that, and we'll have to work closely with the agencies really, because they know best how they in practice apply those two different programs. So maybe we can ask the agency people to really help us put that piece together for this section. Is there anything else we ought to be doing before we transition to the next topic? And by the way Julian, why don't we go ahead and connect you. Is there anything else we ought to do under duplication?

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

This is Patty. I just was wondering if you – I like the way you summarized those last two points at the end of standards and the implementation, but will you also talk – move one level up and talk about scope or whatever the proper term about what is – so there's an appraisal overlapping concept –

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

So the first slide under duplication was, there has to be duplication of subject matter as well as regulatory program. So, is there software in common that is regulated by both ONC and FDA? If so, then are there regulatory requirements for duplicate, for those particular kinds of software.

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

Yup.

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

So again, all we've done is report on the literature, I don't want to stifle the creative thought process of the group. Is there anything else we ought to be doing to investigate potential duplications? Mike?

Michael Flis – Regulatory Manager – Roche Diagnostics

Are you going to offer I mean alternatives to duplication or where you find duplication, are you – do you –

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

I don't know if we're going to find it yet, but –

Michael Flis – Regulatory Manager – Roche Diagnostics

I mean, like for instance, if you felt that there was duplication would be an option there that you completed one process, that would then be like a deeming, which we see in a lot of places. I'm just throwing that out there.

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

I mean I've suggested it's a two-step process, find the problem first, based on evidence, then then let that problem dictate the solution. So if we found duplication then we'd come back to the group and say, how do you want to resolve it? Do you want to give it to one, the other or it take away from both.

M

(Indiscernible) – so now it's going to have purview – patient or is it now purview to flag these and –

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

It's our purview to offer features of the regulatory scheme. So we could say, a feature would be – this duplication by shifting this to this agency or –

M

Or a proposed resolution.

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

Yeah, but –

M

Okay.

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

– as narrowly written as we can.

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

So I just want to make sure I understand that. So if for example, a present medical device registered company has a mobile apps that are by Kincaid, and we know that there are hundreds of equivalent apps out there that have nothing, is that where we identify the different handling. Because that's part of the reason sometimes that's the case, because we are a medical device company that – and the FDA comes in and inspects us we're doing design process, we have to use their design controls and all that, we don't get the opportunity, and even when we try to move it to other buildings, sometimes that's –

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

So that's the opposite problem of duplication, that's a gap.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Well I think that that's an ambiguity, it's a level playing field and it's a result of an ambiguity because –

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

So that's very much in scope.

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

Yeah, okay.

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

We'll put it in more – so what else should we do, and I don't want to take too long because I want...this is important for us to figure out the third topic. But what else should we do for duplication? Todd did you have –

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

No, I don't have duplication, but I have something else before we go to transition. So go ahead and finish duplication.

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

One other question on duplication is, you mentioned it ancillary, but the things like the IMERF or the rest of the world, things are being handled very differently across the rest of the world, but we just cannot – that is a bullet item. Because I know that obviously that is and the expectation is to drive towards harmonization, because again, as manufacturers, it's a pain in the butt to have to go – and I know it's an objective, but it's not something that we can solve, I know that

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

Right. I don't know if that fits under ambiguity and duplication, it probably fits in the first three questions about the level of regulation and harmonizing it across jurisdictions.

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

Okay, a bullet item...

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

We'll fit it in there.

W

Can I add one last bullet item, just in terms of – and it's just that as we're talking sort of – we're seemingly broadening the spectrum of things that might fall under some purview, whether it's regulatory or not regulatory, but reporting and we'll now have patients, consumers as potential reporters. And then I know that there are cultural processes in place, mainly in the inpatient setting for device reporting or other adverse event reporting, but in the ambulatory segment, there's a very diverse range of understanding knowledge and practices. And so I think enforceability is also an important thing for us to think about.

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

Absolutely. I think that's an important consideration. We'll give Todd the last remark and then we're going to go to Julian.

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

You sure?

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Is this on the duplication? Or – just one point, I was going to try to make this just a get go, but you're very focused on within risk, a single harm which is patient safety. And I know I brought this up in the Risk Assessment Group, but the idea of risk as being number one priority patient safety, but also effectiveness as well as security. And so I don't know, I don't want that to be lost in the activity that we have –

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

I tried to tee up in the big room the safety issue in a way that made effectiveness an element of safety, in hopes that our friends next-door would pick up on it and analyze it. I don't know they took the bait or not but I agree with you, we need to figure it out.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

So there's a difference between talking about harm – risk of harm as opposed to making it very finely, narrowly defined as patient safety, although you want to keep that as the primary focus.

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

I would agree that we've jumbled a lot of these things together and it probably would be useful for us to tease out a few and maybe I'd like to get that in a slide then, to make sure we share with the other working groups. Your points are – you're right on.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

In other words, my hope is that when we get that assessment framework from the other group, that'll be factored in. But I think from our perspective, if we can talk about harm, as opposed to just always saying patient safety, do no harm that would be useful for our purposes.

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

Julian, it's yours.

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

All right, so I prepared a few slides to try and capture some of the conversations that we had and ideas in a way to try to also to roll out the specifics and part of what Dave was mentioning. You know, we need use cases and specifics, I think that's surfaced in a few things and I've held my tongue during the conversation to see, because sometimes it's better to have the pictures and we can use them. And these may or may not be useful, I don't know. So the slides that follow will cover these examples and this is a lot of just-in-time slide making, so it may or may not be all that good, but hopefully it will work. For those of you in radio-land, if there is anyone, this is Julian Goldman.

Okay, so here's a list, EHR to medical device data representation gaps. So is the data represented completely, are there issues with transmission of data? And I think specifically what's really the challenge that we are facing is that we're talking about covering a system that has FDA regulated and other spaces – I was going to say non-regulated, but it's really everything, right? It's – and there's also been some jumbling of terminology because it's useful in many settings to say, use the word regulated synonymously with FDA regulated medical devices. But really here we're talking about all different kinds of regulation and we should be careful.

Another related is data time stamping and the implications that has, again as a specific example. Exploring the idea that technology complexity is not necessarily aligned with severity of risk, and I just picked an example, it could be any one. The issue of interoperability, which is a gigantic topic, but maybe there's a little bit – we can leverage something on that. And what should we do about surveillance of health IT systems, a conversation we were just having and invoking the idea that in other areas that we have deemed important nationally, we actually make sure that we log data somehow in order to address and improve the quality of systems. So the first example is this very simple clinical examples and with specific intent.

M

It's a great one.

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

On the right this is a simulator that acts like a patient whose oxygen saturation is falling and rising, by using a simulator, you can repeat the experiment. We take the oxygen saturation and start at 99, drop it to 70 and then have it rise back up again. Connect the stimulator to a pulse oximeter and change its averaging time setting. Here it's set at 16 seconds, here it's set at 9 seconds, here it's at 2 seconds. And then we just took a picture of the screen when the pulse oximeter displayed the lowest oxygen saturation and notice that the longer the averaging the time, the more the signal is smoothed, so the lowest saturation ever displayed on the top oximeter is 84, the middle one is 77, the bottom one correctly drops down to 70% because it's set to 2 second averaging mode.

Okay, so this has been understood and published for decades, just repeated the experiment to have some useful data to look at. So what's the point? The point is, what is the real oxygen saturation of a patient when then undergo this desaturation? What is the data that you see on the screen and what is the data that you see in the electronic health record? And in order to know that answer, you have to know the setting of the device, what is the averaging time setting? Well the averaging time setting is a setting that is not typically sent into any electronic health records. So when reviewing data, you can't interpret that, and diagnoses are made based upon this, made for sleep apnea, made for neonatal apnea, made for a host of things. Now here's an example related to that that just – it goes one step further.

On the top left is a picture of a bedside physiological monitor that was being used on a patient, this is not simulated, it is real data. In fact this is data from Tuesday of this week when I was in the OR, and I was looking at the screen and I saw there was a low saturation error message of 84%...not error, I'm sorry, but an alarm of 84%. I thought, that's kind of interesting because I turned my head a few degrees to the left and I looked at the electronic medical record being used on the patient, and here it's in the OR with pretty frequent data capture update, and this top line, the blue marks, that's the oxygen saturation. And you will notice that there is no drop in oxygen saturation that was captured by the EMR. But the monitor says that the saturation dropped, and actually there was an alarm.

So what happened? Where's the data? The questions we would ask here is, well, we think the monitors right, we're not really talking – the monitor's correctness is not within the scope of our conversation as far as regulation and safety. Let's assume it's a medical device, it did its job, everything's fine. But why was the low saturation data not recorded by the electronic health record and why is the alarm not captured? Is this a configuration issue? Is it a design issue? Is there an intermittent problem? And I put in a brand name because it is handy like Kleenex, so I said, is it an IT issue? Is there an intermittent problem with the Cisco router so we had – drop out? How in the world would you possibly know what's going on? And this is what we're really facing today, we don't know for sure. Now in this case, I'm reasonably sure about what happened, but I can't prove it, there's no data and without data, we can't troubleshoot and we can't really understand.

What I think happened is pretty straightforward is that when you have a change in the value, when it drops and rises, we don't know where in the data stream the sampling is performed that sends data into an EHR this is not – does not appear to be configurable today in any system. We don't actually know and it's the interaction of these different components in the system that we can't characterize, we don't document and therefore we introduce risks in the system. And that has treatment implications that are quite profound in some settings. So now shifting gears, and I don't have to shift, I can stop for discussion or I can –

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

I do have a question. First of all, this is a wow, interesting. Very, very clear, but to me it focuses downstream on the regulation problem. It focuses after it's in operation and from the Taxonomy Group's conversation, we were looking at regulation before delivery to market, and so, I just want to clarify. Are you suggesting that we should actually broaden the taxonomy beyond the what's delivered to market and what has to be shown, perhaps maybe this needs to be shown or two, considering utilization of are you just suggesting we should know more at market.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

What's the concept of deliver to market in health software?

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

Ah, I would – that's a great question. I'm going to propose that we don't discuss it.

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

All right, there you go. But, the Taxonomy Group has sort of made a comment.

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

I propose we discuss it in a few slides.

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

All right.

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

I thought you included things that were already on the market. Meghan suggested for you –

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

I actually thought we were encompassing the whole lifecycle of the –

(Indiscernible - multiple speakers)

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

We were talking about the lifecycle –

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

I thought – and all those other activities –

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

We can come back – I thought actually the conversation I had with her was that the issue of regulation focuses at the point of market.

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

But these examples will make it –

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

No, no, I got it. I got it.

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

– and we have to cover both.

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

Depending on where you're being regulated will determine what post-market you have type thing.

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

So here's an example of clock times, so medical device clock times. So clock time errors in a system, right, are a bit of a problem because they undermine system integrity and they create emergent hazards. We don't know where the problems will surface later. And again, I think in our sphere of thinking here, this can go either way, but we're talked especially about clock times that are originating with medical device data, on patient readings if they get propagated. So here's an example, again some pictures because they are worth many thousands of words.

On the left is a medical device, a blood gas analyzer, there's its clock time of 1206. The clock on the wall, the clock on other things and clocks I'm not showing, all show the correct time, which is 1210. The reading from the medical device, the timestamp of the blood gas analysis of the lab test goes into the EMR with a timestamp from the medical device, which is incorrect. Now one example doesn't make a case, but a magazine article usually helps make the case, as we all know. And the data from a study that we are almost finished, this is data of 1700 medical devices in the slide, but we're up now to around 2000 from five hospitals show that the errors are all over the place because of a number of factors. Some medical devices you can't set the time to the network, actually, most cannot be set unless they're designed as my network physiological monitor is, it's – equipment. Also the devices can be time set, and we can't – and the way it's done today is we have staff running around hospitals twice a year changing clocks which then – so, there's a whole host of issues.

But the point is, it is a real problem and it has real repercussions. And by the way, this slide just shows errors in minutes, average of 25 minutes across these four hospitals. But the next slide shows the errors in days and years. And here's one that's 42 years off. So, this is the data that we may have propagated – these are system issues, specific examples. And the question is, is this a – do we treat this as a – how should we think about treating this in a regulatory framework? Is it an interoperability problem? It's fair to frame it that way. Should it be solved in the proposed framework, perhaps. But it certainly can introduce treatment errors and I feel perhaps most importantly, or equally important barriers to the analysis of adverse events. It's very hard to reconstruct –

So going to the next example, this is an example to talk a little bit about a complexity of a solution or the technological complexity versus the risk of harm to the patient and improving patient safety. So, everyone here has either had PCA system where you push a button and get some morphine, or you visited a patient in the hospital who's had one. So the basic system is, patient has always been thought to be inherently safe, because the systems were designed and we all thought this was brilliant, you can't overdose because you only push the button when you're having pain and you can't push it if you're already so sleepy that you'd be overdosing. But in fact, we think between one and three people die in the US every day by friends and family who push the button or a patient that leans on the button, or a programming error or a whole host of other things.

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

You mean there are not lock-outs, some minimum or –

M

There are lock outs –

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

But a single dose could be enough to someone so sensitive if they receive another medication, right, if there's a concentration error, so –

(Indiscernible - multiple speakers)

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

– any number of – so, there's a whole host of things. And the point is, it's relatively safe but it's not perfectly safe and we don't even know how unsafe it is because the numbers aren't known because of the reporting problem. So, it's been proposed that we can make safer systems and just to emphasize how concerning these systems are, here are just – this is a simple Internet search of 11-year-olds who died, of a multi-hospital coalition that's trying to fix this system, of a 9.9 million dollar settlement. So, no shortage of how significant it is and yet we really can't even manage without these things. The Anesthesia Patient Safety Foundation tried to bring together experts to solve this problem in 2005, and has essentially made no progress on this in all these years. So, what do they recommend? They recommend that if the monitors that are on the patient show that the patient's getting into trouble, the oxygen level's dropping, respiratory rate is dropping, stop the medication and call the nurse or examine the patient. It doesn't sound like rocket science.

There is one manufacturer who built a system that does that, but it is not widely adopted in the marketplace. So, building a system like this, so how could it fail? Sounds – so, it's complicated, the algorithms have to be built, the devices have to be integrated and if the system fails and it doesn't stop the infusion and call the nurse, the system is no less safe than the one we have today. So the harm of building an integrated system like this to do exactly what's being proposed on that slide is that if the risk of failure of that system makes the system no less safe than it is today. So that's an example of high potential benefit, improvement in patient safety with very low risk of increasing any harm to the patient, unless we just come to rely on this...so, yes, go ahead.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Fine, you go first.

W

(Indiscernible) – I'm thinking that the HITECH definition of HIT is really broad, like any but device that is driven by software.

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

So this is a good point, and I think it's an opportunity and important for us to emphasize that we're not – let me go to the next slide to address what you just said.

W

I always appreciate –

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

I'll go back if needed. So –

M

– agree with you and I always thought that health IT is everything which includes the sensors, the applications, the devices, etcetera, but you guys chose to only talk about EHRs.

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

Well in this example, I did try to segregate that –

M

– certification and the rest of this –

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

But we said we have more authority than what we – we said that with certified EHR technology because that's what's tied to Meaningful Use, but that we have broader authority than that to cover other health IT. So, we –

M

But we still haven't seen interoperability of medical devices or uploading patient generated health data, which seems to be stricken now from Stage 3 –

M

No.

M

Ask the Policy Committee.

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

So, in the interest of time –

M

Bring us back –

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

(Indiscernible)

M

Well I, that's on the record now.

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

I want to clarify what was brought up. So, I think that – let's just be clear. If there's an injury due to a pump failure, if the medical device fails, everyone knows they call the FDA and the medical device manufacturer and their lawyers, that's very clear.

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

It's the other way around –

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

But this is not something that is really an issue today. Now, the system may not be very good, it may be very hard to get the data out, we don't have data logging so we don't know what happened, but, that's, I think, really not – doesn't have to be within our scope necessarily, but that can be discussed. Now if the injury is due to health IT related contribution, in the example I gave you, so the setting of the pump was wrong because the bodyweight conversion from kilograms to pounds or the other way was incorrect, if allergy data is lost and so forth, who does that get reported to today?

W

Is that induced error or was that a software coding error?

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

And whatever it is, because we don't capture the data, it's not reported to any single central authority, anyone who collects the data for a national purpose. We don't even know how prevalent it is and we have no way to address this. So go to the third example, where the injury is due to the inability to build a system like this, because we don't have interoperability or there are concerns about the regulations that are...and therefore the concern of the regulation is impeding be innovation. Not necessarily the regulation but the concern, no one reports that they can't fill the product, right, we don't have people lining up saying, this is a product I meant to build but I'm not building it, so we still have thousands of people that are injured or die every year. So that's how I tried to tease that out in anticipation of your questions. But I didn't know what Todd was going to ask.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

No, I think I was going to underscore that you said one company actually has one of those systems out there, but it is specifically the topic of this group, which is regulatory ambiguity, that scares them off. So even though from a technical standpoint, it's very highly doable, because of the regulatory issues primarily, it scares companies away from that specific kind of innovation.

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

That and the fact that we don't collect our data well and so we don't know how big the problem is and the next slide gets to that.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

If I can also, so, I think another thing to consider is that regulation can definitely be powerful when a market has failed. But I also think that agencies and industry can do well to help the market do better. And what I mean to say here is that if we had more data, then maybe purchasers of technology might be more inclined to factor patient safety or low adverse events into their buying decisions. And I don't know that that's something that is necessarily done consistently. And so I think, yes of course you can stick it out with regulation, especially of things, but I think you can also have the market sort of more hungry and desirable of sort of, oh, this I'm willing to pay more or it's great that this device has less errors, but again it comes back to – that data.

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

A great point. There are some initiatives on that that are probably outside of the scope of the conversation right now, but I agree –

Lauren Fifield – Senior Policy Advisor – Practice Fusion

It's just something for us to think about that part of our suggestion can be ways to help the market help itself.

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

Yes. Yes.

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

I mean I just want to comment that I do think we have a market failure here. In our IOM committee report, we had a lot of consultation with some of the major HIT vendors, we had everyone come in, we talked to them extensively about this. And there are just a number of ways in which I think the market is falling short today. I also – I think it would be a mistake to go too far on the regulatory front, so we have to find some sort of happy medium.

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

And I guess I would also caution using that only because again, sitting in the space I do, having hosted more than 100 FDA inspections, there is huge ambiguity as to when to report, and we’ve had products where we’ve had to change our reporting because of the FDA’s interpretation and the investigator or the center’s interpretation that shift. That suddenly now we have a lot of MDR reports, but we’re not killing anybody, we’re not hurting anybody, but we have a lot of reports. So, it’s a balance you have because you have to take into consideration.

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

One of the next slides I’m going to propose a lot more reporting, but anyway.

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

I’m not just saying it’s reporting, but I want again consistency.

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

All right, just a couple of comments on interoperability. I think we know it’s a key enabler of health IT based healthcare transformation, and we probably need a way to make sure that we address that somehow. But – and what we’re seeing today is a lot of undisciplined system integration, which can introduce hazards. And there’s a word hanging there, I don’t know why it’s there – like I said –

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

User error.

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

Yeah, exactly. This is an example – these are statements that have been endorsed. This is a resolution from the American Medical Association along with those 17 medical societies that have endorsed this statement. And I think it may be useful to us in this context to show that there is an end-user need, user here, not the patient, but in the healthcare related societies – medical societies and you can see that there’s a demand. So I don’t know if that’s helpful from a –

M

It gets you onto the point though around regulation that can propel the market, I mean, if there is an opportunity to purchase something that you know will be interoperable, then you as a purchaser can do that, that fuels the market. In the absence of standards based interoperability recognized by the agencies to label this, that never happens.

M

Mackenzie wanted me to pass along a note that its 2:44 p.m. now, it’s scheduled to end at 2:45 for a 15 minute break and gather again in the main conference, so...

M

What if we locked the doors?

M

– 5 minutes or so to –

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

Well, just about done with this part. So, that was the reporting. Now we're going – I guess we've covered a lot of this, but here, let's just talk about reporting. I think that one of the important things for us to discuss and be aware of is, we should be IT strength is surveillance, just ask the NSA - delete that from the record. IT strength is surveillance..

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

It will be deleted.

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

So, this is where we have to consider how to really leverage and I think should we go even further and say that everyone is concerned about "increased regulation." Again, we tend to make that synonymous with FDA regulation, but maybe we could reduce the premarket regulatory burden by making the post-market side, especially in the health IT space, part of the way we take a fresh look from the regulatory framework. And that way we can – because it's not an industry, it's in all major industries all the time, that's how problems are detected.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

And that's a theme that flows coming from the high-risk medical devices, so the FDA in particular has this as an interest, but is looking for areas where this can be demonstrated safely. I think this is one of them.

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

Okay. So then, that's that. And then data logging or however this is – this is a notion, not a device that in planes, trains and automobiles, this is how we do things. If it's important, we log the data. And you can get on the Internet and you can buy trained data logging devices for a few hundred dollars. I don't know, play with them at home on your model train set. These are available. This is a mature technology. Now how we do it in healthcare is not clear, not mature, and I believe it needs to be one of our national funded research focuses, to figure out how do we record enough data to playback events from clinical environments to understand that we are managing things correctly, identifying device failures and so forth. And when this is done in these other domains, these are examined across multiple agencies, manufacturers, everyone sits at the table, like the National Highway Traffic Safety Administration. And some work that we've done in the past is to call it HITSA, the Health IT Safety Administration and going back a few years.

So this is the last slide and maybe some of the next steps are that we fine use these or other examples. I certainly am not – it doesn't matter. Whatever we can come up with that will help with use cases that Dave proposed that we use to drill down, and what Bakul Patel kind of mentioned in a few conversations already is, we should be thinking about that what we're providing are requirement for the new – and there are specifics that drill down. Brad mentioned very specific recommendations that we can make. And then kind of the more general pieces or what are the requirements that we need and including the various high, low acuity spaces, mHealth of course, as well as everything else. And then maybe we could look at common needs across these use cases to help us.

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

So just to draw this to the close, we have to plan for meetings in June or July. And the basic plan would be to use what comes out of next-door as early as possible, as an overall guide to the risks both to patients and innovation. Take a few use cases, take those risks, go through the list of risks and ask ourselves a question for each risk. Are we overdoing it, underdoing it or just right? And figure out whether looking at all of those risks, we're doing it too much, too little or just right. And then on the innovation side, asking are we unduly frustrating it in any way that is avoidable, any way that without losing the patient, we can still maintain innovation?

That's a tough thing to do and it's going to be real tough to do it over the phone. But that's the task ahead of us. So we're going to look for probably a couple of dates in June for some conference calls. We're going to try to get what we can this afternoon out of the committee next-door to use as our guide. They're not going to be done until July, just like us, but we can't wait for the handoff until July, we're going to take whatever they have at this moment, develop those use cases and then talk them through to figure out if we're over-regulating, under-regulating or the porridge is just right.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

And I'd like to emphasize what we stated earlier about getting some exemplars from the Taxonomy Group looking at the different hazards or aspects that cause ambiguity and then running them through. This is a bit of a separate activity.

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

So, we'll just do that all by email. You'll be getting the thing where you vote on what times you're available and we'll pick a couple of dates and try and get it set up as soon as we can. Okay. Any last items before we adjourn?

M

Thank our co-chairs.