HIT Policy Committee
FDASIA Workgroup
Regulations Subgroup
Transcript
June 6, 2013

Presentation

Kate Black, JD – Office of the National Coordinator
Good morning everyone. This is Kate Black. I'm with the Office of the National Coordinator for Health IT. This is a meeting of Regulations Subgroup of the Food and Drug Administration Safety and Innovation Act Workgroup. The FDASIA Workgroup is a workgroup of the Health IT Policy Committee which is a Federal Advisory Committee. This is a public meeting and time has been reserved near the end of the meeting for public comment. Just a reminder that this call is being recorded and we ask all speakers to identify themselves when speaking. Before we begin, we'll take roll. Brad Thompson?

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

Kate Black, JD – Office of the National Coordinator
Julian Goldman?

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
Here.

Kate Black, JD – Office of the National Coordinator
Anura Fernando?

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Here.

Kate Black, JD – Office of the National Coordinator
Lauren Fifield?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Here.

Kate Black, JD – Office of the National Coordinator
Todd Cooper?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.
Good morning.

Kate Black, JD – Office of the National Coordinator
Robert Jarrin?

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

Kate Black, JD – Office of the National Coordinator
Mohit Kaushal?

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

Kate Black, JD – Office of the National Coordinator
Joseph Smith?

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

Kate Black – Office of the National Coordinator
David Bates? David? Okay. And our federal ex-officios, Jodi Daniel?

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

Kate Black – Office of the National Coordinator
Matthew Quinn?

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

Kate Black – Office of the National Coordinator
And Bakul Patel?

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

Kate Black – Office of the National Coordinator
Are there any other members of the FDASIA Workgroup at large or federal partners?

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

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

Kate Black – Office of the National Coordinator
Great, thank you guys so much and with that, we will turn it over for opening remarks to Brad and Julian.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
By the way, is there someone who's able to give me the rights to advance the slides? This is Brad Thompson.

Caitlin Collins – Altarum Institute
Oh sure, you're logged in as Brad Thompson, right?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yes. Yes, so that would be great.

Caitlin Collins – Altarum Institute
All right.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Well Julian, maybe I'll just say a couple of things and then turn it over to you. I guess what I'd like to do is start with a confession. We're all trying to do this thing really quickly, just because of circumstances, and that's proving a bit challenging and so when we looked at the schedule for June, we realized that frankly meeting in the second half of June, because of schedules, was going to be very difficult. So we decided we needed to meet relatively early in June, in order to make some progress. But we also needed to get some work done to basically make this meeting productive and I was off traveling, doing other things and Julian was off doing good at AAMI all week.

And so I asked some colleagues of mine, a partner of mine, Kim Tyrrell-Knott, who joined our firm last year but she had been Deputy General Counsel of GE Healthcare and responsible for their Health IT Businesses. I asked Kim if she could lend a hand and Scott Feil, who is an expert in taking these regulatory requirements, he's a scientist by training, not an attorney, an applying them to health IT. And both of them graciously agreed to step in this week and help, together with a couple of summer interns, thank God it was summer, we were able to get some people to help put this together. But this is really about the first time that Julian and I have seen this document, and that's not ideal, of course. But let me propose collectively how we can view this.

As was described to us last week in the face-to-face meeting, the ultimate objective is a PowerPoint type document of behalf of the whole working group that captures the analysis of the group. And so this PowerPoint should be viewed simply as a starting point, something for us all to dive into and if it proves to be useful, great; if it proves not to be useful, that's regrettable. But it's really up to the group to make this work product its own. And so the way I view it, we can spend some time going through this this morning, while we're all together, and then people can have time, I know you only got it shortly before the call, as I only got it at 8 o'clock last night. You can all sort of tear it apart, add notes to it, send those notes to Julian and me and we can sort of continue the editing process for as long as it takes in order to get something that really reflects the thoughts of the group in total.

So please just view this as a starting point. This is just meant to basically provide some rather – well, to overuse the word, basic information and allow us to get going. But let me also take a step back and talk about kind of the bigger picture. And Bakul and I had an opportunity during the face-to-face last week to talk a little bit about what the task is for this subcommittee and how we might accomplish it. So, as we talked about last week, there are really three different major tasks that we have in front of us. The big one is figuring out whether the regulatory systems of the three agencies are overkill, under-kill or just right or to put in a fourth category, maybe just conceptually not optimal. And so that's one major task, and we really didn't spend much time on it last week because I had wanted to defer that discussion until we heard more from the other two workgroups, and we heard more last week.

The two that we tackled when we were together were ambiguities in the law and duplication in the law. And we left the meeting last week, I've got some homework assignments basically to take a lot of the raw material that we looked at, put it together in some lists, and shoot that back to all of you. We can then massage the list and then ultimately what we discussed doing was prioritizing the list, figuring out what the most important ambiguities to tackle were and the most important areas of duplication. So that's the master plan, and as I talked to Bakul about how to tackle that first issue, is the regulatory system too much, too little or just right. We decided that the best way to do that really was to dive in and look at each of the three regulatory systems that are the primary focus of the working group and to start to parse those regulatory requirements, really look at them almost individually, although not at a truly micro-level. Not looking at the actual regulatory language, but dividing them out into the categories and then sort of number one, making sure we understand what the purpose of the requirement is, what the risks are that it's designed to address. And then asking ourselves does it fit, does it make sense in this HIT world that we've been talking about and the world that the Taxonomy Committee laid out for us last week. So that's – this is step one in that process and if we were to do this according to this plan, we would take FDA, we would take ONC and we would take FCC each separately and we would do that same thing. We would go through and look at the requirements and ask those basic questions.

So that's what you have in front of you, and so it has like four basic elements to it. The first is a bit of an exercise overview, which is just to describe the mechanics of how we put this list together and at a more mechanical level, how we'll go about assessing them, and so we'll talk about that in a few minutes. I wanted to put one use case here, and Julian asked me how I proposed this use case, and there wasn't really any specific magic to it. I had a variety of use cases that had been developed by a coalition that I work with, and I just borrowed one of theirs, rather than invent one. I took this mechanical ventilation weaning in part because I thought Julian would find it an interesting one, given his field of medical practice, but there wasn't much more art to it than that. And we'll have to ask ourselves if it's too specific, because what I don't want is a use case that's too idiosyncratic, that focuses us on issues that are unique to one particular use case and not more applicable generally to other forms of HIT. So, we've got to talk about whether this is the right example.

Then the third part of the presentation would be this parsing of, as you can tell, basically sub-chapter H of Title 21, which is the medical device regulatory system in the US that FDA administers. And then we'll get to the part that I know Joe Smith is anxious to get to, which is the big picture assessment. So, I didn't start with the big picture, I propose not to start with a big picture, because we all kind of have to get on the same page as to what the regulatory requirements are. And then having done that, we can sort of sit back and say, well okay, given what the Safety Committee has told us about both safety and innovation, given what Taxonomy Committee has told us, how does this regulatory system work that we just went through. And so I propose that as a final step in this exercise. But let me stop here and turn it over to Julian and just ask Julian, number one Julian, have I laid out what we wanted to cover in this meeting and do you have any other words of wisdom for us as we get started?

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
Thank you Brad. I think you did, of course, as usual an excellent job. But Brad and I, we have been communicating a bit offline in preparation for the call today and in fact, we circulated some comments, not publically yet, on the slide deck which some thoughts to address after the meeting. And as far as the use case, I think it's not a bad use case, of course. We've used it in some other venues because it's a fairly rich example. I think there might be – we do have a small library of use cases that we developed as part of the FDA initiated medical device interoperability coordinating council, with a fairly large group over the last 14 months or so. So, this is good. I think there are some others that might open us up to some other applications and ideas that this one doesn't, but I don't think we need to spend any time on that on this call. So, I'm going to hand it back to you Brad, thank you.

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

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
Can I jump in to ask a question?

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

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
This is Jodi Daniel. I'm just – you mentioned talking through all of the different authorities, are you just – I see that the only one listed in the roadmap for today is FDA.

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

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
Was the intent that you start with FDA because they're kind of – it's a logical place to start and then would be looking at the other regulatory frameworks that might fit in, ONC, FCC, maybe others at a later call or –

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Exactly. That's exactly the plan.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
Okay, I just wanted to make sure I understood. Thank you.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yeah, I mean, to some extent, I don't know why, I guess I picked FDA first because we only had a week and it's what I know best, so I went with what I know best, but we do have to get to the other two fairly quickly and at the end. I want to see if we can get some volunteers, I'm kind of hoping I can cajole Jarrin for example, to help with the FCC one, because he knows that system so well. So we need to figure out how we're going to do something similar, if that's what the group wants to do, for the other two. All right –

Lauren Fifield – Senior Policy Advisor – Practice Fusion
This is Lauren; just in the interest of making sure that we have action – I'm happy to put together something on ONC process, if that's helpful.

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

Lauren Fifield – Senior Policy Advisor – Practice Fusion
I also wonder, before – I don't know if these materials are made available to the public, but I do – I am a little concerned that the materials that we're not able to see until right before the meeting would be perceived as work products of the whole group. Is there any way to indicate on these materials that not yet reviewed by the workgroup?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
That's an excellent point, and yes, there ought to be, I mean I ought to be able to put – I have to chuckle, someone in my office must have grabbed a template, at the bottom it says attorney client communication privileged and confidential, this is anything but. I mean, it's a public meeting. But I ought to be able to come up with a good heading or footer or whatever that says basically exactly that, that this is raw work product of Brad Thompson or something and not something that the committee has reviewed.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
If you want to change the footers on that and just send it back to us, we'll make sure to post the – we'll change what –

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

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yeah, that would be awesome, I just know that even – I think Jodi maybe has mentioned that someone has – folks will listen to the HIT Policy Committee meetings and then all of a sudden people start assuming things and – okay, like I said, I signed up for ONC and yeah, great. Thank you.

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
Julian here. There may be a few other edits as well that Brad and I have communicated about in the background, so maybe that's the same time to take a look at that.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yeah, I mean, in all honesty, there are edits I want to make too –

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
Yeah, so there you go.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
– I literally saw it the same time Julian did last night at 8 o'clock and so, yeah, we ought to do that. All right, so let's go through it. And basically this initial stuff, I don't – we don't need to spend a whole lot of time on, initially, it'll make more sense as we go through it and then we can come back and if we like it, we can make revisions to it or so forth. But, as the group was putting it together, basically what we wanted to do is, I'm going to – just one slide, what the mechanical ventilation weaning is, and I feel silly, I really ought to have Julian present it, because I don't understand it at a medical level like Julian does. But I also don't want to get too deeply into it, unless that becomes relevant, in which case that might be helpful.

And then, as I said, review the FDAs current regulatory framework and then kind of what the team did, that put this together is, is develop this system of putting green dots, yellow dots and red dots to indicate kind of that there's an FDA requirement that seems to fit without any significant modification. Maybe interpretation, but not modification of the regulatory requirement, then yellow to sort of connote those that are close but require some modification to make it fit. And then those that just flat outright seem silly, in the case of HIT, in which case they put a red dot on it. So that was the system the team came up with, I thought it was a decent system, but I'm not going to sit here and tell you that all of the green, yellow and red dots are correct and I know none of you have even had a chance really to look at it. So, I'm not proposing that we spend a lot of time on that.

So the mechanical ventilation weaning, this is something – can I just – Julian, can I just turn it over to you to – you would do a far better job of explaining what this is.

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
Sure. Yeah, and in fact, I think the way I would couch this is, just consider it as a system that is looking at data from different monitors and other information about the patient from the electronic medical record. And this would be a patient who is on a mechanical ventilator to support their breathing, perhaps after surgery or lung injury, pneumonia or something like that. And we're looking at a clinical decision support system that would at the simplest level provide real-time information about the patient's status, maybe alert staff to advance their, what's called – what used to be called the weaning from the ventilator, to allow patient to take over on their own. Now this term has been changed and typically, it's called liberation from mechanical ventilation, so you might see either one of those terms.

And as the use case gets more sophisticated, it potentially could include the reduction of the oxygen concentration in the breathing system from a high concentration to a lower concentration that would be more typical of the patient who was not using a ventilator to breath and also assessment of the patient and so forth. It also might include smart alarms, because there are many devices on a patient at that time and many of the alarms are false alarms. That's the general idea. It's a very complex use case, which is one of the reasons I think we may want to look at another one. And I don't know that it needs this complexity to achieve what we need in this task – in this activity. But anyway, that's the general idea and I can answer any questions but I don't think it's worth drilling down much deeper than that, unless there was a specific point Brad that you thought we needed to make to identify a specific concept.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Well from, just at a high level, from a design standpoint, these are – this is a software that's kind of fully networked, right, I mean it's –

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
Yeah, well it would have to be, today it isn't. Today, looking at this list of information, some of these things would be acquired by a bedside physiological monitor, the thing that people see that has the EKG and the blood pressure on it, for example. Other information would have to be obtained from other devices, such as the ventilator itself and there may be information that would require manual input or obtaining from the electronic health record, such as co-existing disease. And these – all of the data today is not typically available in one place. It would be very rare for that to be the case, because of the lack of complete interoperability in these devices and systems today.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Um hmm. Okay, okay.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Julian and Brad, this is Anura Fernando. Could I ask a question here? Would it be beneficial to not only have the description of sort of the device, or the clinical scenario here, but also to explicitly describe an interoperability scenario? So that when we talk about software, you just mentioned the fact that it's networked, that describing how the different components of this clinical scenario may be communicating with one another, so that we can hone in a little bit and identify areas where there currently aren't regulatory requirements for specific interactions. Would that be at all helpful?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
I would think that would be helpful and, the best way to do this, and Julian raises a great point of whether this is even the right use case to pick, and so we'll have to come back and assess that. But for whatever use case we do ultimately pick, it seems to me that after we go through the exercise, we'll kind of be identifying issues and then we might come back and try and make the description of the use case richer, to better set up the analysis that we do. So, it may be that we actually want to come back and tackle the use case toward the end, after we've done more of our analysis, to identify, as you just say, just what the issues are and therefore, make sure that the use case frames it well, because I think that's important.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Thanks. Could I formally propose then that we update this to include specifically an interoperability scenario derived from this?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
I just made a note to do that very thing. So, if we stick with this one, absolutely. If we change to a different one where that's maybe not an issue, then we'll have to revisit that. But, I just made a note of that.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Thank you.

Mohit Kaushal, MD, MBA – Partner – Aberdare Ventures/National Venture Capital Association
Hi team, this is Mo. So I like the use case, but it's a pretty sort of extreme one in terms of ICU patients do need a lot of monitoring and it's a lot of risk there. I think – I was just wondering if we would be open to also comparing and contrasting this use case with another use case. Maybe one where the acuity is less intensive, where the side effects of potential mismanagement are less severe clinically and also really highlighting what I see as the enabling power of these technologies, which is pushing care outside the hospital. And then I could argue that's never going to happen to an ICU patient and nor should it.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
I think that's a great idea.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.
This is Todd. I noted at the end – I can almost remember, it's been a long time ago, at the end of our Friday morning meeting last week, we kind of did a round table right, and we put a number of use cases of interest to the overall group on the table. I think we should go back, look at those and pick a few of those that seem representative of the space that we're looking at.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Brad, Anura Fernando here again. One of the things that – considering that the time constraints that we have with this overall project and so forth, the PCA use case has been introduced in a lot of the new standards development activities, for example, during AAMI standards week last week. There as a lot of discussion around using PCA and so we may be able to tap into a large body of knowledge. I know Julian is heading up the PCA use case work there, and so I'd like to propose further that we consider again, relative to the very short timeline that we have, that we leverage that existing work that's being done for the PCA use case in that context and use Julian, if he's amenable, to help make that connection.

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
We could repurpose a fair amount of that work, and I think what I'm hearing, and I agree with is several things. Number one, we just – we want to ensure that the selection of a use case is done hand in hand with identification of the key principles that we're trying to elucidate. And it may be related, therefore, to the care environment or it may be related to the acuity of the patient and sometimes, of course, those are not well aligned, we have high acuity patients at home and low acuity patients in long-term facilities that have higher staffing. But probably related to that and the type of devices and perhaps it will take more than one, maybe several use cases and we should, I agree, at least review those that were proposed in our meeting. As far as the patient controlled analgesia use case, that is an entire new AAMI standard focused on that because of its clinical and safety impact nationally and I assume, well, I know for certain there is quite a bit of material we could repurpose to accelerate the process, given our short timeline. I'm happy to help with that, helping to coordinate some of that use case acquisition, information and so forth and for other activities, public activities. So – back into that.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
Julian and Brad, guys, this is Jarrin, a question for you.

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
Hi Jarrin.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
Is this currently regulated and does it have a product classification code as a Class II device, a Class III device or is it not regulated at all?

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
The –

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Can we ask Bakul that question, Bakul do you know how this would be regulated?

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
Don't know that answer off the top of my head.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
Because it's helpful to understand the context of where this product is coming from, because this could be a great example of, do we necessarily want to regulate something like this at a higher classification level. Or is it low risk enough that it merits other kinds of classifications, which would really answer the question of whether or not this fits within FDA, may not fit within FDA, etcetera, etcetera.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
So, can I say a couple of things here? I think Brad, you started off the call with the intentions of sort of I would use the word cataloging, and that's just my way of thinking, of what tools, regulatory tools exist today, and then you started with FDA. Getting into this particular use case, I don't know if that was your plan to get into that right now.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Not really.

Bakul Patel, MS, MBA – Policy Advisor, Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
So maybe folks can, I mean Julian and Brad, you guys can decide how you want to, because at some point I think we're getting too far off the track and maybe come back to where you guys were generally intended to be, and then sort of come back to the point about whether it's regulated or not. I think we discussed this a lot in the in-person meeting about let's be focused on regulated or not regulated or this particular use case that gets so far deep into a standards world, may not necessarily be beneficial at this time.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yeah, thank you Bakul. I think that's exactly right I think we need to go and look at the regulations and then – and Julian said this a moment ago, basically pick the use case or use cases plural, on the basis of what we need to illustrate or help us with the analysis that we want to perform. But I think we're sort of getting the cart before the horse a little bit, we'll look at the regs and then we'll come back and figure out what use cases are needed in order to illustrate whatever points we want to make with the regs, if that's okay. Is it okay if I proceed?

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
Please do Brad, I agree completely. We can – there are many we can choose from and we just want to make it fit.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
All right. So, this slide you don't need to worry about the results, and in particular, I'm going to obviously make sure the footer is clear that this is work product, I haven't even really figured out whether I agree with this. But it was designed by the team that I mentioned helped me with the PowerPoint, as a way of summarizing the analysis. And I think it's not a bad way really to summarize it, it's a kind of high-level way, which is a useful thing for us to do. But these are the requirements that I propose to go through. So some of this is a little bit, in my opinion, too detailed or more detailed than we need for this purpose, in which case I'll say that and in a next iteration, shorten it up in various places. But we basically went in numerical order to look at the regulations and what they require.

And so numerically, when you start with 801, labeling and it's broken down into these various subparts and we actually go through each of these subparts. I'm going to go fairly quickly through some of these things, because I don't think they raise terribly interesting questions for us. But first, at a high level, the way we do this is identify the purpose, so trying to state in plain English what the objective of the regulation is. Then we try and provide what the regulation says, in a very summary form. And then we sort of asked ourselves at the end does it fit with HIT. And in this particular case, what the team that was working on this came up with is to say, look, when it comes to labeling, what's unique about labeling with HIT is it's not so much a printed document that is – that physically accompanies a physical product or maybe even is affixed to the product, a label on the product. But most labeling for software is actually a part of the software itself. And that raises some unique considerations that when you change that labeling, you're actually structurally changing the coding, perhaps, of the software itself and that impacts the quality system requirement for design controls that when you change one thing, it has a ripple effect on other aspects of the software. So at a high level, that's what the team came up with.

Now what I'm going to do is, I'm going to stop and ask questions – or ask if anyone has additional topics, but I recognize full well that you probably want to reflect on this, you probably want to take it and study it in a quiet moment and identify things later that may be an issue. But there may also be things that pop into your head as I go along, and I want to make sure we capture those. So, at a high level, anything else that you all would identify as kind of unique or special or different about HIT, that would make it somehow a different fit, maybe a more awkward fit than a traditional physical medical device?

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Hey Brad, this is Matt Quinn from FCC.

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

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Before we hop into that, I – just looking at the slides and I don't have the FDA regs in front of me, but as you do the breakdowns on these, I see subpart A, C, D, E and H. Just a process question, did the folks who did this look at subpart B for example of part 801 and say, there's nothing there that's pertinent and also look at F, G, and say the same thing, but they saw that H was?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Right. They tried to parse it where a rule was clearly idiosyncratic to some special product like a birth control reg. There's no point in us talking about a birth control reg in this. So what they did try and do is weed out those that were clearly inapplicable, but they're inapplicable, I mean, they're – they don't create confusion, they don't create awkwardness, they're just dealing with perhaps a more specific subject matter that isn't implicated.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
All right, I just wanted to understand, thanks.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Well I need to verify that, because I just – as I said, I got it at 8 o'clock last night, but that's my – from my quick read, that's what they did.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
Can – this is Jodi Daniel; can I ask a quick question?

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

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
Is there, and I'm not expert in the labeling requirements that FDA has, but is there an issue with upgrades with software and labeling requirements and how to handle kind of iterations of a product, when you're talking about software and labeling?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So labeling would potentially evolve, just as the software evolves. So, if an update or something added new functionality, that new functionality would trigger additional labeling or changes to labeling, so keeping it current, both labeling – keeping the labeling current as the design evolves would be an important issue, as with any medical device that changes. But to your point, it happens more frequently with software and so it would more frequently implicate the need for labeling change.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
Brad, I think it would be helpful if you can explain a little bit, what is label versus labeling and maybe a little bit about the appellate court decision that really thrust words and deeds as part of the labeling of a product as well.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So Jarrin raises a great point, we didn't really cover definitions. Label is the thing, which is typically affixed or embedded into the medical device and identifies the device and provides some other basic information. Labeling is a much broader concept. It is anything that is designed to communicate about the function of the device, and it may have no physical proximity to the device at all. So, when a manufacturer sends out a brochure, just a sales brochure or in the case of traditional therapeutic devices, they might send out a medical journal reprint that talks about the use of their product, or any number of things. The Supreme Court has said, that's all labeling, and labeling is regulated by FDA because it all bears – potentially bears on the intended use of the medical device. And what that's designed to address is companies that may seek a narrow approval from FDA for a specific intended use. But then when it comes time to put it on the market, they're out there giving speeches or sending journal reprints or any number of things that suggest or just discuss use of the product in other settings, other uses.

So the Supreme Court has said, that's all labeling, FDA has jurisdiction responsibility over all of it and that's really different from the label, which is the more traditional information embedded in or on the device itself. So a lot of what we're going to go through really focuses on the label or directions for use, which can appear any number of places. The regs themselves, other than the intended use reg, which we're going to get to, really doesn't get into that other stuff that's mailed or otherwise disseminated by the manufacturer.

M
Or I would guess advertising?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Advertising is regulated by the Federal Trade Commission, not FDA, with the exception of what are called restricted devices, and restricted devices are the highest risk devices, typically the Class III devices or some special categories like hearing aids and other things that FDA has put in the restricted category. So very small subset of advertising gets regulated by FDA, the bulk of it gets regulated by the Federal Trade Commission.

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
I think the only thing I would add Brad is that, and this is the appellate court decision that I was referring to, there was an appellate court decision that claimed that most, if not all advertising is considered labeling when specifically done about a specific medical device that's on the market.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yeah, FDA's been advancing that theory and I don't know that we need to – okay. So, are folks comfortable, because most of these regs don't deal with that? The regs that I'm about to cover don't address those particular features.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Brad, Anura Fernando here again. A question that's related to both labeling and responsibility, when we start to move from the traditional type of medical devices to interoperable devices, we run into a situation where you may have emergent system properties that are not a function of any one device, but rather a function of the system of devices. If you have multiple vendor's devices integrated together, a) who is responsible for the emergent property that's a function of all of those devices? And b), how would that be labeled and who would be responsible for labeling that emergent property?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So that's a great question and I had noted that one actually on the next slide. So let me go to the next slide, because I think that fairly – that's directly implicated here, and it doesn't show that on the label, this is a comment I hand-wrote on my slides. So, among the labeling requirements §801.1 is that the identity of the responsible party needs to be conspicuously put on the product. So, typically, according to the language of the reg, it's the manufacturer, packer or distributor of the device. And – to determine that responsibility so that if something goes wrong with a product, FDA knows who to call and who to work with then about fixing it, about recalling any bad product that's out there and otherwise working to make sure that the public health is protected.

So the question you raised is exactly what I wrote down on my slide, which is, HIT does, because of the way it's developed and used, implicate shared responsibility, parties collaborate more when it comes to software than when you're manufacturing a widget, just by nature of the thing. So I think that's a real issue, a real ambiguity that is not addressed very well by the regs. And so I've handwritten a note on my slide that that needs to be added in here as a fit issue.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Thanks.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yup, you bet. Well thank you. Any other issues raised by the requirement that the responsible party be named in the labeling?

Mary Anne Leach – Senior Vice President and Chief Information Officer – Children's Hospital Colorado
This is Mary Anne Leach, not so much a comment about the responsible party, but is labeling a place where we consider suitability for interoperability? In other words, some of the issues we're hearing about is the issue of data integrity moving from a device into an EMR. So it would seem that labeling might be a place where we have to say, this device is not qualified for interoperability, you need to look at the device based upon the way the data's presented, or whatever.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
You guys are just perfectly setting up the segues, so thank you. So the very next reg, §801.4, is intended use and here's where I made a note, great minds think alike, about the challenges. My note was, what about an intended use that morphs over time, but your comment is an extremely important one and that is, how do you know what the intended use of software is when it's a very open-ended intended use, where maybe the products with which it will interoperate have not been specifically identified. And this is the work that groups like Continua Health Alliance are tackling, trying to figure out basically how you label product in a somewhat non-specific way to say, this product is suitable for interoperability within this family of maybe like-labeled products or something. But it's a real ambiguity, it wasn't contemplated when they wrote these regulations 20 or 30 years ago, and so it is largely unaddressed and I think ambiguous, so I think that's an important topic to note here.

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
And Brad, Julian here. I think perhaps capturing the idea that the application or the app or other software that leverages these devices in a setting where the devices or those manufacturers could never have known the specifics of what that app is doing in the future.

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

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
Maybe – I mean, this is obvious to those of us who have been dealing with this for a number of years, but it may be worthwhile to capture that explicitly.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yes, I agree. And by the way, as I said at the outset, I'd love to get comments or suggested wordings. So if you have a way that you want to articulate the issue, PowerPoint is not great for redlining. It's actually pretty difficult. But if folks could just adopt a convention of editing slides and then putting in red font what your edits are, and sending them to me. Then I'll take responsibility for collating it all together and then playing it back to everyone. So I'm writing notes, but I also welcome language. To me this is a very pivotal slide, and it gets to some of the issues I think that Jarrin was wanting to talk about and those interested in interoperability and those interested in how software morphs and is developed collectively by multiple parties.

All of this, to me, feeds into the intended use and intended use is an extremely pivotal concept because the official intended use, the real intended use is what governs everything else we're going to talk about. Whether it has to go to FDA for clearance depends on intended use, or maybe even approval, which is the most rigorous review. How the quality system gets applied depends, at least in some measure, on intended use. So lots of the downstream regulatory obligations flow from an accurate understanding of the intended use – the true intended use of the product. So, are there any other issues here that we should talk about under this rubric of intended use?

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
One more, Anura Fernando here again. We've heard a lot of discussion around intended use versus indications for use and other context and so I was wondering if we might also consider those two specific terms, and how an assistance context, indications for use could be supported by sort of component level intended use?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Umm, I'm not sure I fully understood your question, so let me start to unpack it a little bit, because there's a lot there. So the way I think about it, intended use is a much broader concept than indication for use. Indication for use is more focused on the disease state or a clinical application of the product. Intended use is a broader concept that includes everything from the setting in which it's intended to be used, the user – the intended user, is it for consumers or for professionals, the directions for use, how it's to be used. All of those things are factors in determining the larger concept of how a product is intended to be used. Indication for use, as I said, is – this is for a specific type of cancer and specific stage or whatever, but it's much more focused on the clinical need for which the product is being deployed. With that difference, can you help me just unpack your question a little bit?

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Sure. So when you have a specific set of medical devices that are integrated with one another, often their intention is to serve a particular need in a particular clinical workflow. So there may be scenarios where medical devices can be interconnected in a sort of general purpose way, but if the hazards are identified as a function of a clinical workflow, then it may be important to constrain the device integration in a unique way for a specific workflow. And so to that end, it seems that it would at least bear some analysis to determine if intended use of the device level, from an interoperable perspective needs to be constrained relative to indications for use.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Okay, I think that's a great point and it is a fundamental point, and we're going to get to it in a couple of slides, as I recall, when we get to directions for use. A way of mitigating risk is to have whatever directions for use are necessary in order to avoid whatever the risk is that's identified. And so it sounds to me like part of what you're talking about is making sure that the directions for use are, as you say, constrained to the point where they're basically either through a warning or through a very specific affirmative direction for use, indicating how the product can be safely used, but it's a great point.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Thanks.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
I'm just writing down, if I'm silent, I'm sorry. Okay. All right, so we can keep coming back to this issue and it will actually keep arising as we go through this because intended use is such a fundamental principle. So, the next one §801.5, adequate directions for use is one of the key mitigation elements – risk mitigation elements of this regulatory scheme and that is, making sure the directions are specific enough, clear enough, focused on the right areas, such that the product can be used safely and effectively. So, it's a requirement that adequate directions for use be included in labeling and in this setting.

We've already strayed because I've noticed a number of times, the folks who are helping me put these together wanted to talk about consumer use health IT, that's important, but obviously the mechanical ventilator weaning is not an example of consumer use. But it is important to understand who your audience is, a consumer will have a different level of understanding, so if it's intended for use by consumer, that makes in some ways the directions for use more challenging, you can't assume the same knowledge that you would with a professional user. And then they note obviously the recurring theme that you'll see in a lot of these that when the instructions are embedded in the software, it raises separate issues. And so we just heard, literally on the prior slide, an example of where the directions for use need to identify constraints that are necessary for the safe use of the product, and that would be a very important element of an adequate direction for use.

Other issues where again, the task that we're doing is trying to figure out whether health IT raises new or unique issues that wouldn't – that aren't contemplated by the regulations because the regulations were written decades ago, in many cases, and focused more on physical product than on software. Unique software issues that need to be considered in determining whether the FDA reg is clear and applicable. Okay – and as I said, we're going through this for the first time; I imagine we'll go through this a few times, so.

Misleading statements, the FDA statute itself and it carries over into the regs, say, that in promoting products, you can't say things that are false or misleading, and that's a standard legal concept, it exists in the Federal Trade Commission, it exists in the Lanham Act. It exists in a number of other pieces of legislation that it isn't just literal truth that matters, that you when you promote a product, you can't – you also cannot mislead your audience. I'm not sure it's terribly controversial and I'm not aware really of unique features associated with health IT when it comes to misleading in the promotion of your product. But can anyone identify unique HIT issues in this regard?

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Brad, this is Matt Quinn. My question was, does this overlap at all with FTCs domain?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Very much, well, it's in very much harmony with FTCs domain. The law distinguishes FDA regulates labeling and FTC regulates advertising with the caveats that we mentioned, Jarrin observing that FDA will often say that what looks like advertising they want to treat as labeling, but the rule is the same and there should be good harmony at a rule level. Now one of the things that Jodi and I and others were talking about is you have to look not just at what the reg says, but how the agencies apply it. And there is, I would argue, a difference in philosophy between FDA and FTC; FDA is led by physicians, clinicians and folks who will really focus on health implications, safety and effectiveness type issues when it comes to reviewing labeling.

The Federal Trade Commission is dominated by lawyers and economists and so when they look at labeling, they look at it with a somewhat different prism, or through a somewhat different prism, and they're concerned about things that have a bad competitive dynamic and so forth. Not that they're indifferent to the safety and effectiveness issues by any means, they're not, they just have a slightly different bent, which is not surprising. That dichotomy exists for all medical devices, it's not unique to health IT, and it has been something that FDA and FTC have been working through for decades, that's existed since the beginning of the FDA regulatory scheme.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Brad, Anura Fernando here again. Someone else earlier about pushing patches up to devices and change management of some sort, I forget the exact comments or questions, but here from the labeling perspective, it seems like we may want to consider mechanisms to associate changes or patches, things like that, that are pushed up since we now have the distributed mechanism. So let's say Internet downloader or upload, into a distributed system, to ensure that the right piece of software that's being sent out is mated or matched up with the right device that is intended to receive that. So the labeling would actually have two pieces here, the originated software versus the recipient device.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Okay. I think that's a good issue, I'm not sure where to put it in this framework. I have to think about that. It's a good issue; I'll have to think about where it might fit.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
From a labeling perspective, it seems that there could be mechanisms that allow for that matching if labeling is handled consistently between the device piece and the software that's being pushed piece.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So I think that actually maybe fits in the prior slide, adequate directions for use, making sure that it's clear how that all fits together. So, I've just made a note under that slide that I think that's a good argument and I think it probably fits there pretty well.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Brad, this is Matt again. A question, historically have configuration options and those sort of things been in that intended use piece, or is that somewhere else?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Well, so intended use is the broadest concept that as I said, serves as the basis for FDA to decide how to regulate something. It determines the classification of the medical device; it determines what level of regulatory scrutiny and oversight are applied and so forth. I think the issue that you've identified really is more specific to directions for use, making sure that the directions are adequate to make the device, in this case HIT safe and effective in its actual use. So I think that's where that fits.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Okay, thank you.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Why don't we go on? So another concept in the labeling regulations, §801.15, is the prominence of required labeling. And here I made a note, there are unique issues with regard to HIT because the labeling, so much of it, is embedded in the software itself. And you have, therefore, issues about linking and how do you make something prominent when it's in the user interface and how do you make sure that people can find if there's a warning that they really need to read. Is it adequate, for example, to have the warning explained in a link or does the whole warning need to be on the same page as other elements of the directions for use? So it seems to me there are some issues associated or unique to HIT in how the prominence requirement is applied under FDA rules. Any other thoughts about whether the prominence issue raises unique issues for HIT? Okay.

So there are over-the-counter devices, and so obviously from a use case standpoint, we probably should have put inapplicable here, because the weaning – ventilation weaning software is probably not an over the counter device. They did include this here, I assume, just because they wanted to be complete, in case we add other use cases that implicate something that might be available in mobile health, for example, for use by a patient at home. So, basically over the counter regulation means number one, you have to have certain labeling that is visible to the consumer, and the way it's written, principle display panel had in mind a retail outlet. So you go to Wal-Mart and you buy an over the counter and the principle display panel is what you see when you go to Wal-Mart.

So, when you consider the iTunes store or other ways in which over the counter software might be deployed, it seems to me there may be issues of translation, how you communicate what information needs to be in what you might refer to as a principle display panel. The reg requires a fair amount of interpretation, so it's kind of, go back to our red, yellow, green, I might put this in yellow because the way it was written requires a lot of interpretation or finagling to figure out how over the counter software would be labeled. Does that seem like a fair observation?

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Brad, Anura Fernando here again. It seems like there are some indications that lead towards usability in human factors engineering.

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

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
I don't know if that type of language currently exists in any of the regs, but if not the interoperability aspects may provide a reason for us to consider formalizing the discussion of usability and human factors in these types of regs.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
You know, and this goes back to a conversation that I know Jodi was involved in, I don't remember who else was involved in it, but, so you've got a statute that was written at a very high-level of generality, then you have regulations which are one level down in specificity. Then in the case of FDA, you have what are called guidance documents, which are not regulations, they're long documents. They're supposed to be organic, but they don't change probably as much as they ought to or evolve as quickly as they ought to. And the mobile medical app topic is one, for example, that will be addressed in a guidance document. And then below that, you have actual practice, what the agency does in reality to administer the particular statute.

The topic of human factors has not made it into the level of regulations, it has made it into the level of guidance documents, and there are several guidance documents being developed right now that implicate – or not implicate, that cover human factors. But having said that, they cover human factors from different perspectives, contemplating really physical devices, contemplating syringes and other things where a lot of human factor issues have come up. So human factors in HIT, I don't recall any real detail. Bakul, do you, is there any kind of robust discussion of human factors in the context of HIT at FDA, do you recall any?

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
So, there's – I mean Matt –

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

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
– knows very well about this, but I'll just say that the guidance that we have attempts to cover everything that we regulate and it's not specifically calls out specific human factor issues for health IT.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Yeah. So Brad –

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

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
– there's an AAMI/ANSI HE75, which is human factors engineering design in medical devices, that's really the foundation of this, along with ISO IEC 62:366 application of usability engineering to medical devices. When I was at NIST, prior to this, we took that and guidance from industry and developed a

series of guidance documents working with FDA and other folks, so this is NIST IR 77-41, NIST IR 77-42 are the application of user-centered design principles to development of health IT. And then a common industry format for reporting the results of summative usability testing of health IT. The third document that we developed, guidance document that is, is NIST IR 78-04, which is taking the examples from FDA, FAA and others in summative usability testing, and it's a three step usability evaluation protocol, for evaluation of critical use error of health IT. And then the last piece is we did an actual drill down on the issue of pediatric use of health IT similar to the way that IOM and others have done safe medical devices for children. This called out some of the specific issues related to human factors in care of children and health IT. I can – all of that stuff is available at NIST.gov\healthcare and then there's a usability tab. It's all just guidance, it's not standards, but it's based on applying the science in FDA and other federal sources.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So, to circle back, I mean, like so many things, like any other medical device, you really do have to turn to that guidance to get the concrete answers that you want. The regs do not provide that guidance. And they don't provide them for any kind of product, they don't – syringe or health IT. So, all regulated industries that are subject to FDA medical device requirements, really do have to turn to those technical documents to get a good understanding of it. So the question is whether FDAs regulatory approach needs to change in order to accommodate health IT and I'm not hearing any sort of unique issue that suggests that FDA regulation needs to change, more guidance is always good, more detailed guidance is always good. But I'm just testing this, I'm saying it out loud, I'm not hearing that this is an area where the FDA reg, for example, would have to change to accommodate health IT. Other than what I observed when we're talking about over the counter devices and I think the definition of principle display panel is written with a physical product in mind at a physical store and might need to be nuanced to reflect how health IT might be actually sold to the consumer market.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
So Brad, one of the things that we did at NIST was to take that FDA guidance and try to make it more specific to, in this case it was EHRs, so we didn't really consider too much consumer health IT and other sources, so these are guidance documents. The other piece to consider in this is that in ONC certification processes, this was addressed in the safety enhanced design certification criteria, which looked at – which requires vendors to report their user-centered design process, so it could be NIST IR 77-42 or it could be others, as well as to report the results of their summative usability testing. And so this is actually a portion of that guidance and the process used by FDA in evaluation.

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

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

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

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
Brad, I guess the direction that I come at this from is that I agree with you that the reg doesn't need to be changed because the guidance really, for me, focuses on the linkages between usability testing and being able to do risk management of the product that you're trying to put on the market.

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

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
So I'm not as concerned with the aspect of changing the regs, but maybe pushing for guidance specific to this, which I think is what Matt's going at.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
Exactly, exactly. And –

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

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
– one of the things that is, I think, really pertinent in the difference between health IT usability and medical device usability is that shared implementation responsibility. And so, system as sold isn't necessarily system as implemented and I'd like to say that the guidance that we provided really tackled that, but it's something that needs additional work. I didn't want to point you folks in any particular direction, other than I agree with what Jarrin just said. Just to make you aware of the resources that are out there and actually there's a really good presentation from Molly Story at FDA that I can send to the group as well.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
That would be great; she certainly is an expert, so that would be terrific.

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

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
All right, so let's go on. So the next category, so we just covered over the counter devices, this is prescription devices, and basically the definition of a prescription device is one for which consumer labeling cannot be safely written. And here, as I mentioned, I had help putting the slides together, I would actually state this a little differently. Something is a prescription device because labeling cannot – for consumers cannot be adequately written; there's typically one of two things that drive that. One is that the risk is really, really high for the use of the product, and so the directions for use can't be – can't adequately mitigate that risk. The other is, where the usage is so complicated, maybe not necessarily risk, but complicated, such that you need the oversight of a physician to make sure that it's done appropriately.

So either of those things tend to be the risk that the prescription status is meant to address. And the conclusion of the folks who were helping put this together is, that there wasn't any tailoring that needed to be done for health IT that the same principles that govern physical devices could be applied to HIT when it comes to deciding what HIT ought to be prescription or available by prescription. Is that, I haven't thought about this very much, is that right? Are there issues unique to health IT that would need to be addressed here to decide whether something should be available only by prescription? Okay, I wasn't able to think of anything, but we'll continue to think about that.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
This is Jodi Daniel, could I just ask a question. I assume this doesn't preclude – there are probably certain things where a doctor may prescribe some kind of device, even if it is potentially available over the counter. That wouldn't implicate – this is just about the labeling and whether it can only be offered through a prescription? I don't know if that was clear.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
I'm not sure I understood your question, I'm sorry.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
So this is only about labeling, so it's only – this is only about whether it must be only offered through a prescription as opposed to whether it may be offered through a prescription. So if there – there may be a device, for instance, that a patient may choose to get on their own or a provider may choose to prescribe for them, because they want to make sure their patient uses that device. That would be covered by the labeling requirements, it's only where it must be issued only by a prescription, is that correct?

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So the topic of prescription status is actually addressed a few different places in the regs. In this particular place, 109, all this reg is saying is that for a prescription device, you do not – you are exempted from the requirement for adequate directions for use, because in fact by definition, a prescription device cannot be adequately labeled or directions for use cannot be adequate for a prescription device.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
And so the expectation is that the clinician would provide the directions for use to the patient.

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

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
Okay, I understand. So if in fact in the health IT space there was some kind of mobile device that the prescriber wanted the patient to take, there may be an exemption from labeling, but then the provider would have some kind of duty to train the patient on how best to use it.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yes, but that's found elsewhere in the regs.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
And that's found elsewhere, understood. Thank you.

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

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
So Brad, Anura Fernando again, there are two areas that we may want to consider a little bit further in this regard. If we considered health IT to incorporate both sort of the traditionally considered pieces like EHRs and so forth, as well as integrated medical devices, then there may be specific software pieces like algorithms that provide certain delivery of care, as well as clinical decision support software pieces that may convolve data in a particular way to provide back to the clinicians that may need to be considered under a prescription.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Um, I love that comment and it dovetails with an area I've been giving a lot of thought, which is the interplay between the level of transparency associated with software. That is, how it reveals the underlying algorithms and so forth, and it's regulatory status and the level of regulatory oversight needed that the greater the transparency, true effective transparency, the less need for regulatory oversight because the user's able to understand what the software is doing and put it in context and use it appropriately. So, I think that's a great comment that even for prescription HIT, it may make sense to specify a level of transparency. It's not truly a direction for use, but it's related – it's very close to directions for use, but transparency as to what the software is doing and the basis upon which the software is arriving at any conclusions. I think that's a great comment.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Thanks.

Mary Anne Leach – Senior Vice President and Chief Information Officer – Children's Hospital Colorado
Or the basis upon which it's calculating anything –

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

Mary Anne Leach – Senior Vice President and Chief Information Officer – Children's Hospital Colorado
– and transmitting anything, I think that potentially is a source of error if it's sampling and averaging and sending intermittent data, I think that could be challenging.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Right. I see by the clock we have 15 minutes left and we do need to certainly preserve some time for public comment and there is a topic I want to get to before public comment, which is, just planning how we're going to do what we need to do over the course of June and July. So, I'd like to stop the presentation part of this and start to talk about process of how we're going to do what we need to do. So here's what I perceive as the next steps. I want to see if you guys perceive them the same way and then we need to figure out how we're going to do it. So, I forget, this slide deck is something like 50 slides long, we're on slide 13, okay, and it was an hour and half session that we had.

So, I would submit, but I'm very interested in your reaction, that we have additional work to do going through this deck. Then we want to do the same thing for FCC and we've got a couple of experts, I – Mo and Jarrin in particular, would be wonderful experts to take us through the FCC stuff. And we've got the ONC topic to address, and we've had a volunteer, Lauren offered to help us with the ONC piece of this. Just from a gauging the amount of time that it takes to do this, I'd say we have probably maybe three more hours of discussion on the FDA piece. And I don't know if the other ones will take quite as long, but we'd certainly want to try and have a couple of hours at least for each of the next two. So if you just do that math, you're at 7, 8, 9 hours of committee discussion just at this level of getting through these regulatory requirements. And then you have the piece that I know several folks are anxious to do, which is the big picture. So we've gotten through each of these – should we propose tweaks to these or should we propose overhauls to these will be a major discussion that occurs at the end of that.

So, I'm trying to figure out how to get all of this done in the time that we have available. As I said, when we looked at calendars, the second half of June was very difficult to schedule some time, but we need to get this done. So I'm open to any ideas, suggestions, Julian, what are your thoughts, maybe we can start with you as to just from a process standpoint, how we would tackle all of this. Because then we really need to spend most of July coming together on a work product after the discussion. So Julian, do you have ideas as to how we might go about tackling this?

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
It looks like we're going to need two to three small working groups to really dig deep into these work products and then make recommendations back – informal recommendations back to the larger group perhaps in 2-3 weeks' time. I'm not sure how to separate those, but I think some of the natural lines are showing up in this conversation, so maybe that's one direction we could take.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
So can I ask our federal colleagues would we be permitted to take our subgroup and sub-sub it, have a group focus on FDA, have a group focus on ONC and have a group focus on FCC and then bring it back altogether? I don't know how many people would want to skip more than one of those, if everyone wants to do all three, then there's really no point in breaking down into subgroups. If some folks are willing to say, I don't care so much about the other ones, I want to focus on one of the three, and then subgroups would be efficient.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
You know Brad, one of my concerns though is that I don't necessarily know that our role is to simply take a look at what exists and provide feedback on it. I think part of it too is to provide guidance as to kind of future regulatory pathways that may take from kind of some of the greatest hits from all three of these. And so I fear that if we split up, we're just going to end up providing feedback about what already exists and not take that critical step of saying, okay considering kind of greatest hits of what exists, what would we propose.

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

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
If I can just add the greatest hits idea, I think the flip side of that is that we were also charged with identifying the gaps and the needs.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yes, that as well. Yeah. And I – I mean, I feel like there are whole trade organizations or whatever it is, probably legal groups, meet up groups that talk about the FDA regs or ONC regs and kind of that study of them. But I want to make sure we don't kind of get so lost in kind of saying yeah, that works, that doesn't, that we don't kind of, as was pointed out, identify gaps and kind of provide guidance as to what tools should be used to address health IT.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yeah, so I agree wholeheartedly that – and as I indicated from a process standpoint, I was preserving that big picture discussion for the end, in part because – so, let me ask. If what we just did has value. I was trying to accomplish two, what I hoped, create value in two different dimensions. One is just educational, because I wasn't sure everyone had the same background in the FDA requirements and I thought this would give us a basis then for then having that bigger picture discussion. And the other is, from an end-product standpoint, I know, I think, I don't mean to speak for FDA or others, but I think the federal agencies would be really interested in this level of comment as well, in addition to what we as a group want to get to, which is the larger picture discussion. So, in an ideal world where we aren't time constrained, my perception was this added value and was a natural starting point, but what does the committee think about that? Has this been valuable?

M
Yes.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
Yes.

Matthew Quinn – Director of Health Care Initiatives – Federal Communications Commission
This is Matt from FCC, absolutely and thank you so much for pulling this together.

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

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
I'd love to take the credit, but I didn't do it.

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

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
Yeah, this is Jodi. Understanding and actually hearing people talk through what the – how the rules apply in a health IT context, I think is very helpful for me; it's not my area of expertise, so I am learning a lot from it.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
This is Bakul. My suggestion would be twofold. One is I think I will echo that this is useful for everybody to understand sort of the intent behind the it – behind the regs that each agency has. I would propose just in essence – for in essence of time, probably keep – lets split up the educational part from actually getting into gaps and I think understanding what's in front of us and then knowing what the gaps are may be useful. So just an option you may want to think about that Brad and the group put their heads together and come up with the educational part first, and so we can get through that first and then tease out the rest of the gaps and nuances as we walk through them again.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
If I hear what you're saying Bakul, you're suggesting that I take something like the current PowerPoint and we maybe not have as much discussion about gaps as we go along, but get through that presentation, maybe more quickly, and then go back and discuss gaps. Is that kind of what you're proposing?

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
Something like that because right now with, I don't know, 50 slides or so, it may – and the rate we went through today, maybe not a feasible goal to accomplish in three hours.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yeah, no, I mean, we only got a quarter of the way through and there's a lot of interesting stuff coming up.

Bakul Patel, MS, MBA – Policy Advisor Office of Center Director, Center for Devices and Radiological Health – Food and Drug Administration
And we didn't, and maybe people should take notes on their own, as you're going through, as questions come up and that's something that can be done over email. I'm just thinking out loud how we could efficiently move forward, while not – I'm just thinking the last regulation on your slide may get the least amount of attention and maybe that's the most important one.

Mary Anne Leach – Senior Vice President and Chief Information Officer – Children's Hospital Colorado
Yeah, or maybe we don't try to go through 50 slide presentation on the call, but we all do the pre-read, send it to us ahead of time, we'll read it, study it and then talk about it by exception and I agree Bakul, we sort of need to focus on the last piece there.

M
Yeah, agree 100%.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
The only hesitation I have is I found the discussion I hope beneficial in two senses. One is that I got a lot out of it in terms of ways in which the requirements may not fit as they're written. But I also, as hard as we tried in the time available to explain the regulatory requirements and the purpose, giving people a chance to ask questions seems pretty important, because I know these slides cover really dense topics very briefly. And I was hopeful people found the dialog helpful, just in understanding the slides.

Anura S. Fernando. MS, MD – Principal Engineer, eHealth – Underwriters Laboratories
This is Anura Fernando again. I absolutely agree. I think having some level of discussion and opportunity for question and answer is critical to getting us all sort of level set and speaking from the same page.

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

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.
So, we're running out of time.

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

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.
In terms of subsequent calls, because obviously you outlined, we need to spend time as a group.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yeah, so we're going to just have to sit down, Julian and I and the other organizers will sit down and try and come up with some calendar suggestions for maybe two hour blocks that we can do over the course of the month of June, to try and work our way through this. If we can – if I can ask – so, let's do some assignments. Lauren, it sounded like you might be comfortable doing the same kind of presentation for ONC, is that right?

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yeah, and just to clarify my understanding of what that entails; it's the EHR Incentive Program, the kind of certification process for EHRs, is that kind of what you want me to –

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Yeah, so we ought to talk about that, but my perception is that it ought to be – ONC has a broad mission, only a portion of which is regulatory. And it seems to me that we're focused on the regulatory portion of the ONC mission. Did I get that right Jodi and the others?

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
Yeah, I think it could be a little bit broader than that, because we do have statutory authority that goes a little bit broader than our – what we have regulated so far, which may be relevant as you guys are thinking about recommendations to us. So I would say anything that we have regulatory authority for, whether or not we regulate it. And Lauren, if you'd like to touch base with me, I'm happy to talk with you offline as you're thinking this through.

Lauren Fifield – Senior Policy Advisor – Practice Fusion
Yeah, I was just going to say, why don't I just connect with you to this end. Because I think that's helpful and I think understanding a little bit of overview of the organization itself would be helpful, since I think the FDAs been around a little longer and might be a little bit better understood, so yeah. But Brad, to answer your question, yeah, and I do think that what has been provided today is really valuable and I would hate for any one of those – members to not get this for FCC or ONC.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Okay. So can I ask Jarrin and Mo, would you guys be willing to collaborate on an FCC version of this?

Robert Jarrin, JD – Senior Director, Government Affairs – Qualcomm Incorporated
Yeah, I think we should collaborate with Matt as well, but I'm willing to do that. Mo? I'll volunteer Mo for him – Joe –

Joseph M. Smith, MD, PhD, FACC – Chief Medical and Science Officer – West Health
He's volunteering in his mute button.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
All right, so we'll get the choreography worked out in terms of when to schedule those, we'll do that offline, but in the couple of minutes remaining, can we kick it over to public comment? I don't want to –

Kate Black – Office of the National Coordinator
Sure.

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
Brad, one second, Julian here. I just want to mention quickly that we are also looking forward to getting feedback from other working groups that may play into this very soon, so we just want to, in our process, want to keep that on the radar.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
And that's a great suggestion and also, I would just urge people, we can do as much of this via email as you want to, so, you've got the slide deck. I'm going to try and update it, but please, by all means, just start sending comments on the deck in advance.

Kate Black – Office of the National Coordinator
So this is Kate Black from ONC, thank you all for your interesting and helpful discussion today. I'm going to ask the operator at this time to open the lines for public comment. This is just a reminder that comments should be limited to three minutes per person and that working group members are not required to respond to those comments.

Public Comment

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

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Well one of the things I would just more, maybe I'll regret saying this, but the document is public, I mean I'm going to change a couple of things and I'm going to put a proper footer on it, but it will be made public. And so if anyone who's a member of the public wants to comment on the document as well, I would welcome comments from anyone, not just folks on the working group. Anything to make the analysis better would be terrific. Julian, is there anything else we ought to address?

Julian M. Goldman, MD – Partners HealthCare/Massachusetts General Hospital
I think we did a good job today covering what we could in the time we had, we certainly have more work to do and appreciate all the hard work.

Jodi Daniel, JD, MPH – Director, Office of Policy and Planning – Office of the National Coordinator
And this is Jodi Daniel; I'll just suggest Brad and Julian that you reach out to MacKenzie with your schedule to try to put some more dates on the calendar. And I think given the amount of time you all are talking about meeting, we might just have to kind of work with your schedules and get as many people as possible. I know with summer vacations and things, it may be tough, but we'll just put the times on the calendar and hope as many folks as possible can make it.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
I think that's wise. I just want to thank everyone, terrific discussion. I got a lot out of the discussion, it was wonderful and we'll keep plugging along. Thanks everyone.