

**HIT Policy Committee
FDASIA Workgroup: Regulations Subgroup
Transcript
May 22, 2013**

Presentation

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

Thank you. Good afternoon everybody. This is MacKenzie Robertson in the Office of the National Coordinator for Health IT. This is a meeting of the HIT Policy Committee's FDASIA Workgroup, the Regulations Subgroup. This is a public call and there is time for public comment on the agenda. The call is also being recorded, so please make sure you identify yourself when speaking. I'll now go through the roll call. Julian Goldman?

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

Present.

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

Thanks Julian. Brad Thompson?

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

Here.

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

Thanks Brad. David Bates? Todd Cooper?

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Beautiful day in San Diego.

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

Thanks Todd. Anura Fernando?

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

Here.

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

Thanks Anura. Lauren Fifield?

Lauren Fifield – Practice Fusion – Senior Policy Advisor

Here.

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

Great. Thanks Lauren. Robert Jarrin?

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

Here. Hot as hell in Washington, DC.

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

Ditto. Thanks Robert. Mohit Kaushal? And Joe Smith?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Joe. Steve Posnack?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Steve. Bakul Patel?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Bakul. And Matthew Quinn?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Matt. And Mike Lipinski from ONC?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Mike. And for the full FDASIA workgroup members, I have Elisabeth George.

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Elisabeth. And Richard Eaton?

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

MacKenzie Robertson – Office of the National Coordinator – Federal Advisory Committee Act Program Lead
Thanks Richard. Are there any other workgroup members on the line? And any other ONC staff members on the line? Okay, with that I'll turn the agenda back to you Brad and Julian.

Julian M. Goldman, MD – Partners HealthCare System / Massachusetts General Hospital
Thank you.

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

All right. Well thanks very much MacKenzie. So Julian and I were just talking. We haven't had much opportunity, Julian and I, to sort of coordinate in preparation for this, but I put some slides together in the hopes that they could sort of lay a foundation for the discussion that we have. I think we're scheduled for 90 minutes, I know one or two people need to leave at 5. But basically we wanted to cover four main things, as you can see under discussion section of the agenda. The four tasks are, first, just getting some general agreement on the background of what it is we're supposed to do and how we're supposed to go about doing it. I only have two or three slides on that topic, and I don't think they're terribly controversial, but I'll be very interested in seeing whether we're all on the same page.

Then the next two topics are kind of procedural or organizational. The first one is staying coordinated with the other two subgroups. I just want to talk about mechanically how best we can do that. One thing is certainly we can read the minutes of the other groups. I'm prepared to give you a brief update on what I heard in the call on Monday of the Safety and Innovation group. It'll be very brief. But anyhow, I just want to frankly think about how we do what we need to do in conjunction with what they're doing, because I really do think the two other groups drive a lot of what we will do, we kind of respond to issues that they identify.

Then third, I'd like to talk about work done by other organizations. And I think personally this is an important step because we have very little time between now and August to come up with whatever we're going to come up with. It just doesn't make any sense to me to try and frankly reinvent any wheels that are already out there, at least if they are out there. And I also think in some surveys of other organizations and thought that they have given to these topics, that there are a lot of good ideas out there. So, I want to talk mechanically about how we get our hands around that, how we sort it, sift it, analyze it and ultimately make use of it.

And then finally, getting started on the substance. There are about two or three questions that I identified out of the six or seven questions in total that we're being asked to address, that seem to make sense as starting points. Because we don't need to have all of the work from the Taxonomy Committee and the safety committee in our hands in order to tackle those early questions. So that's what I'm proposing in the way of an agenda. Julian, do you have any thoughts, or anybody else as to the appropriateness of those four items for today's call?

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

Brad, I think we're spot on.

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

All right. Well, let's go ahead then and talk a little bit about the background. So what I did in coming up with this slide is simply cut and pasted out of that one page document that we all received when we were first invited to sit on this group. And these are – it was one page and it had questions that relate to taxonomy, it had questions related to safety and innovation. These are the questions that related to regulation, what our subgroup is tasked with, and I so assume you've all seen it. I'm not going to read it to you, but what I want to find out is, to the extent you've studied this as you prepare, are these the right six questions for us to be considering. And when I ask that, I'm asking both if it's under-inclusive, over-inclusive or simply if there are other issues that you want to tackle. How does this seem as a sort of charter for our individual subgroup? Any comments?

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

Brad, this is Elisabeth. One thing that has come up in a number of different calls that I've been on, and has been – we are focused obviously very much on patient safety and innovation, but one of the other areas that seems to keep falling off the discussion is privacy and security risks or aspects. And I'm not sure – it might not need to be regulated because of patient safety, but there may be a privacy or security requirement that puts it into a different realm of regulation.

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

You're thinking exactly in parallel, and one of the next slides I'm going to get into is the substantive areas of law that we might want to consider. So, by all means let talk about that, in fact, I want to lay out kind of the range of issues and get a sense as to where we ought to be focusing on, but I agree with you entirely.

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

We've obviously spent enough time together.

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

Yeah. Any other thoughts on these six questions? I'm sorry.

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

Hi, this is Mo. I've been getting up to speed with all the email traffic back and forth. I know there have been other subcommittee discussions as well, and a lot of the discussion's been around, I think, looking at regulation retrospective, as it's already been implemented in other areas, say medical devices, etcetera. And I think we have a real opportunity here to sort of start with a real blank slate in some respect, given that many of the things that we're thinking through are involving a very new space, very new technologies. And I would like a discussion before we jump into the very specifics, around how things have been done before around, how do we actually like things to be done in an ideal world, just to frame the conversation in a much more pro-innovation way, given my personal bias.

Lauren Fifield – Practice Fusion – Senior Policy Advisor

Yeah, and this is Lauren. I was actually also thinking sort of along the same lines. I don't know if this is meant to be encompassed by kind of point five on the slide there, but just sort of thinking about regulation as an innovation. So not necessarily going back to what we have, which is not to say we should create new wheels where existing ones would work, but yeah, thinking about how we can be innovative in creating regulation or suggesting regulatory structure.

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

Okay. All right. I certainly hope we have the opportunity to do that.

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

Julian. Yeah, Julian here. We've – we, in some of our preparatory work, we did speak very much to the point, especially as you framed it Mo and as you – that it was amplified, that it's important for us to keep in mind what we hope to achieve with this work. As opposed to jumping right in to what some of the – it's hard to frame a barrier for something or a gap if we don't know what it is it's a gap to achieve, or a barrier in what we're trying to achieve. So I think we are like-minded on that and Brad and I have discussed that in terms of how to get to that point, so this is just a way to lay the background to get to there.

Lauren Fifield – Practice Fusion – Senior Policy Advisor

And this is Lauren again. And it's sort of a question and it – I guess it's, I don't know if it's for you two or for the agency folks on the line, but, as I've sort of been thinking through, particularly on kind of some of the apps that could help consumers, but maybe even into different technology for providers. Are we intended to consider only kind of the FCC, FDA and ONC as powers of jurisdiction or might there be – could we also consider other agencies like the FTC where consumer protection may actually be the best way to kind of reach an end goal of protecting the consumer in their use of an app or along the lines of privacy or in other ways. Or are we supposed to sort of really just think about the three agencies involved?

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

That's a perfect set-up and let me take a cut at that, because I have two slides that are specifically – I just want to tease up the issue and then everyone pile on and help sort it out. But let me just propose a way of thinking about it. As I read the statute, section 618, the creation of this organization, this working group, it seems to me that it's focused on iden – on analyzing the three areas that you identified, FCC, FDA, ONC as the primary areas of focus. But as I read it, it talks about duplication and so forth, which doesn't necessarily mean duplication between, for example, FDA and ONC and FCC, it could mean duplication with other laws or regulation. So I have listed on this slide, a whole slew of relevant laws, and you just rattled off, off the top of your head several that are on this list.

So, I think the answer, I'm saying this out loud for people to challenge it, I think the answer is that our input, we're giving input remember, we're not developing a regulatory system. We're giving input, but I think the input that we give could be, for example, look the three agencies don't, I'm making this up, the three agencies don't need to focus on privacy and security because HIPAA already does. Or the three agencies don't need to focus on the advertising of apps because FTC already does. Or whatever we might want to say, state boards of medicine and pharmacy do an adequate job of regulating caregivers, or whatever point we're trying to make. So my interpretation of the statute is we're to focus on the three, we're to offer input, not specific regulatory systems as recommendations, and we can take into account all the other laws and regulations that exist when we're making the recommend – offering the input on the three regulatory systems. Now, you guys want to tease that apart or tear it apart or toss it out or – how did I do?

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

This is Bakul. I think you did great. So, yes, so from a very high level I would say, if – and as this relates to all subgroups, if there are things that the group – this subgroup or others identify things that are outside the box, clearly identify those. I mean talk about it, recommended, but identify them as this is not what was in FCC, FDA or ONC's bucket, but here are some considerations. So absolutely tee up those, but flag them so that we recognize when they are in or when they're out.

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

This is Jodi Daniel. I would completely agree. I think that if there are other laws or regulations that we need to be paying attention to, that have a role to play where they're – it could be part of the regulatory framework, I think you guys should identify those, even if they're broader than three agencies. I think the way it was described – what you have here on the slides and the way you described it makes perfect sense to me.

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

I agree, too. This is Matt.

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

Any other comments or questions or concerns on this topic of scope basically, what we're to look at. Okay. So as we think about regulation, and we think about the three areas, ONC, FCC, FDA and we think about all the other laws that kind of impact this area, I just – sometimes I get maybe a little too structured, but I just had to put on a slide, at least generically how those issues will kind of unfold. And so to me, typically there will be scope questions. As we look at each regulatory system, there will be scope questions. So, what's in that scope, what's out of that scope? What gets regulated and what doesn't get regulated? And taking a fairly nuanced approach, because in some regulatory areas, a statute might be written broadly, but the agency has interpreted it or decided to apply it a bit more narrowly. Holding kind of in abeyance, under what would be referred to as enforcement discretion; some areas that might literally fall within a statute, but for whatever reason don't merit active regulation. So I predict or I put forth that scope questions will be part of what we discuss.

Then secondly, in most regulatory systems, there will be degree questions, to what degree is something regulated. At FDA, for example, I pick that because it's the area I know best, there are three classifications, right. But generally, we take a risk-based approach, which means that we stratify different technologies according to risk, and those stratifications then determine sort of the regulatory bucket in which they fall. And then finally you get lifecycle questions. So, a piece of software is born, lives and ultimately dies and there are different regulatory requirements along the course of that lifecycle, from pre-market before its ever introduced into the marketplace, manufacturing, promotion and then in the post-market remediation and reporting, for example of adverse events, is a sort of a typical broad, lifecycle set of topics.

So, as we go forward and start looking at best practices and answers to the questions and features and things that we would offer input on, we'll need some system like this or like something else, to kind of organize that thinking, so that we can keep track of it as we go along. Any reaction to this kind of organization, is there a better way to do this? Well if not, I mean –

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

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
We can revisit this. Yeah, please.

Jodi Daniel, JD, MPH – Office of the National Coordinator – Director, Office of Policy and Planning
This is Jodi, Jodi Daniel again. The one thing I would, I'm just looking at this and thinking out loud, but is making sure that – I mean, I think the structure makes sense. But when you talk about lifecycle regulation that it's not just from the developer's perspective, because there may be some other piece of the lifecycle like implementation or use of the product that may be different than just the kind of FDA construct. So it would – I like the model that you have here. But I just want to make sure that when we're talking about the lifecycle regulation of the different pieces of it, that it's also from – it may be from different perspectives – not – there may be something based on the user, how the user implements it or customizes it or that sort of thing that isn't just about the developer.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
Great point. And so, we ought to constantly challenge or revisit how we structure this, but I think that's a great point.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.
So this is Todd Cooper. Just to – I was thinking the same thing. In fact, there's been a lot of work done, especially coming out of Canada, around health software and the lifecycle around that. And it has – it's interesting because it has a significantly different type of a lifecycle, which has been kind of a cause of contention between more traditional device type development lifecycles and health software, which may or may not be regulated. And as part of that – so I can provide some of that input into this group here. But as part of that also Dr. Baker from the NHS in the UK has a concept of the safety baton, and actually as you go through different parts of this lifecycle, that safety baton gets passed to different entities. And so we should also think about that in the case of who exactly is involved along this lifecycle process, just as was mentioned.

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

Lauren Fifield – Practice Fusion – Senior Policy Advisor
Yeah, I completely agree. Particularly given that a lot of the work I have done is on the ambulatory side of practice, there's a definite cultural and user component to any sort of implementation and reporting. And so, yeah, really thinking about sort of not just the things that go into a product, but sort of thinking about how the product or functionality is being used and by whom it's being used. I think it has a really big impact on again some of the ways that we might get feedback, the ways that that – might be iterated and the way we think about the regulations and trying to enforce anything.

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

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

Brad, Julian here. I think that we have observed within the FDA regulatory paradigm, the challenge of the isolation or siloing of the requirements in the lifecycle. Today, and historically, there's been a problem of tying these different phases together and they're treated somewhat independently. The FDA's initiative in this area I think they call the Total Product Lifecycle Initiative, which I guess that's been – they've worked on that over the last several years, to find a more integrated way to address the product lifecycle.

Because there may be issues that are identified early on in the premarket phase that would perhaps require additional or different post-market surveillance and that, in my – to my knowledge, and I don't know all the details, but I think it hasn't been done in an integrated manner and hence the effort at the FDA to integrate it more. And I think an example would be, as we look at devices, we are looking at devices that are – that fall within the scope of health IT that are connected, that can transmit data.

Then one would expect to see the kind of reporting of either problems or performance issues or whatever they might be, or usage statistics, for example, which can be automated and which could be assessed in a manner that's much more sophisticated than is done today, for medical devices or health IT. It is the approach that's used routinely in non-medical settings, to track device usage and performance, it's done for engines and vehicles and many other domains. So I'm a little concerned about following the model that already exists in terms of the different phases on that siloing in that manner. And you could probably shed more light on this Brad, with your expertise in this area. So I'll stop there.

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

You raise great questions, Julian, and there ones that we've been wrestling with for a while. And so I ought to clarify. It's not my proposal, not by any means, that we propose a lifecycle regulatory approach. This is simply a framework for asking questions about how a regulatory system regulates at different phases in a lifecycle. So – but even still, I think a number of the commenters have pointed out the shortcoming of staying too close to that approach in the case of software, which isn't like hardware in the same sense that it's born, it lives for a while and then it dies.

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

Um hmm.

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

But rather software kind or morphs and moves on and oozes and flows and lives, in some cases, forever. So, I do think that's an appropriate warning that we not stay too close to this lifecycle model as we even ask questions about what the best regulatory approach is.

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

Um hmm.

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

Okay. This isn't a very profound slide, so, why don't we go on. What I want to do, I'm only going to take perhaps 5 minutes at most to do this, is report on the Monday meeting, from 2 days ago, of the Patient Safety and Innovation subcommittee. And I'm reporting not for the substance of it, but really to tease up process questions for us, that is, how we're going to work with these two other groups, because I think it's going to be essential that we work closely with them. So this first one is a strawman that they presented, I think Dr. Tang presented this one, and this is already outdated, because he put it out there, they had a rich discussion for a half hour around it, he took I'm sure copious notes and plans to do a lot of revision.

So, I put this forward not for what it is, but really for the topics that it raises. So he went through the strawman and said look, the first thing we do is identify the various sources of risk, sources related to the user, sources related or factors related to characterizing the patient and the harm. The complexity and how that impacts risk, post-market changes to the point that we've just been talking about, the customization and so forth, and then wireless connectivity issues. And it led up to this chart, and you may not be able to see it really well, I don't know how big – hit full screen if you would on your screen and you can hopefully read it. But basically what he wanted to do is kind of lay out this framework for thinking about these factors that are on the vertical axis, and then give examples of how those factors play out, kind of in a low risk, medium risk and high risk situation.

And it was meant to be illustrative, I guess, rather than specifically quantitative. But what it got me thinking is, okay, so that committee's going to be working on stuff like that, all right, they're going to be identifying those risks. And under the FDASIA section, really our job is to follow along that discussion or use or understand whatever risks that group identifies and then line up our regulatory best practices or regulatory features, to be very specifically addressed and focused on those risks. And so in my opinion, that means we need to let them make some progress in identifying those risks before we can do a whole lot. Now, I do have things to propose that we do in the meantime, things where we can collect information, synthesize it and sort of be prepared while they're doing their thing, be prepared to then really start to contribute, once they've identified those risks. But I just – I guess I'm worried, or I just want to caution us, not to sort of be in our own silo, but to be paying close attention to them.

Now, they did the same thing for the innovation side for the innovation side, I think it was Keith who put this one together, and so he put forth a very similar chart, in a sense, trying to identify what the threats are to regulation. What types of government activity, what types of regulatory activity in particular threaten innovation the most. And again, they had a half hour discussion, this chart's already outdated because they had quite a robust discussion and they're going to change it. But this too will be kind of direct guidance, I perceive, for what we have to do. And as I understand it, the Taxonomy Committee has not met, I think they'll meet next week. But as I was thinking about what's ahead of them, and how it connects to what we do, there's all sorts of different flavors, as everyone knows better than I do, of health IT. And which of these ultimately get wrapped into the work of this working group, directly impacts what style or what manner or what nature of regulatory best practices we would identify.

For example I've seen some chatter among several friends on the committee that they're interested in having UDIs be part of it, that hadn't occurred to me beforehand. But if UDI sort of does become an integral part of what HIT is, and therefore our recommendations need to include a regulatory best practice for UDI, well that's kind of a whole different kettle of fish, from a regulatory standpoint, the scope changes considerably. If you have things like MDDS, it's kind of the bridge between what I would call traditional HIT and medical devices, it's the connectivity in between the two. If that's in or if that's out, again it greatly impacts, I think, the work of this group.

Mobile technology is specifically identified in the statute. If you go to the draft FDA guidance on mobile apps, you have a couple of different flavors of mobile apps. You have those where they are accessories to medical devices. In that case, those are treated more like traditional medical devices than they are HIT, so, is that in or out; we kind of need to decide. Then another flavor of mobile app, according to the FDA guidance is those that transform the cell phone itself into a device, for example, making it an electronic stethoscope. So to me, the work of that committee, the Taxonomy Committee, has a huge impact on what we do – from a scope standpoint, what we do because the regulatory approaches for this very disparate range of different types of software are very considerable.

So, I just want to brainstorm as a group what we can do in order to sort of stay best connected to the work of those other committees. I plan to try and attend as many of the other meetings as I can, so I can hear where they're going, but beyond the obvious of listening to what they do, is there anything else? Should we offer them questions that it would be very helpful to us if they would answer? Is that a good way to interact with them, or is there something else that we ought to be doing with regard to these other groups?

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

Hi, it's Mo here. I think that's a great idea, I think, also a prerequisite provide maybe just a summary of our meetings, so not too in-depth, but maybe a couple of paragraphs of our discussion, and then ending that with some key questions that we're thinking through that we'd like to sort of tee up to them as well to get their perspective. It's more of an organizational thing.

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

Terrific. Other thoughts or ideas?

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

Brad, this is Bakul. I just wanted to point out that, I would encourage, and I'm sure others – other feds would do the same is, encourage the group, if this group finds out areas that are beneficial or input to the other – to taxonomy group in this case, feel free to reach out to the chairs and have that part of their conversation. And so, I'm just saying, I know everybody won't be able to attend other meetings, but if you have thoughts already and if this group has already thought about this, it should go ahead and reach out to those chairs.

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

I think –

Lauren Fifield – Practice Fusion – Senior Policy Advisor

Hi, this is Lauren – oops.

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

Go ahead Lauren.

Lauren Fifield – Practice Fusion – Senior Policy Advisor

So, I know that obviously everyone is quite busy and I don't want to promise other folks time, but it might be good, once we've had our in-person meeting to have the chairs of the other workgroups maybe to kind of join one of our calls and do sort of a deep dive with them. Them representing the perspective of their workgroup and kind of go through a series of questions that we might have. And obviously, I think we can email back and forth too, but it might be good to do that maybe in June.

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

And hi, this is Joe. I had a thought which is really I think complimentary to that which has been, I think Mo brought up and Julian spoke to, and it's this notion that this space really may be quite different for more than one reason. One, it's dominantly software I think we're talking about and two, it's almost all connected. And I wonder, if we couldn't start to think about the lens through which we would view regulating any part of it or interpreting any part of the risk matrix being developed or the scope that we're going to look at from the other teams through a lens by which connectedness makes a regulatory framework substantially different. And take the opportunity to innovate the regulatory framework given that we're talking about connected technologies where this notion of monitoring can be potentially instantaneous and largely without effort. And the notion of modifiability is so much stronger than it is for other things that have fallen under regulation. So I just wonder if we can't work on those parts, which are innately novel and think about the regulatory schemes, which are now possible, which wouldn't otherwise be possible.

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

Based on the – this is Matt. Just to clarify, based on the nature of the systems that we're talking about and the availability of technology today, to do that monitoring?

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

Yes. Yeah, that's what I'm trying to get to, it's the notion that they're innately connected and so unlike medical devices or pharmaceuticals –

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

Right.

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

– which have framed much of the regulatory framework around patient safety, here we have things that can auto-report and can test themselves against the connected network. It's really –

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

Yup.

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

– I think it affords an opportunity different than we've contemplated previously.

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

I agree.

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

Yes, and I would add to that that we could start to look at populations of devices and see if there's a systemic problem with connectivity, with performance, with calibration and so forth. This would – again, so I certainly agree and I think we could look at many different facets of that. Or there should be a pathway to consider how that would fit into the regulatory framework.

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

You know, I like this, and in particular it came up in the risk and innovation community when it was proffered that connectedness imposed some additional severity of risk. And so my way of thinking, it may absolutely go the other way, that –

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

I couldn't agree more. I had the same conversation in venue after venue. There are both benefits and risks. And the benefits – and we tend to focus on risks more than benefits because it's a different paradigm it's a new paradigm.

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

So this is Brad. I'm struggling with the competing desires on the one hand to go big picture, because in some ways it's easier and in some ways I prefer to start with a big picture and then populate underneath. But the moment I look at a slide like this taxonomy subcommittee slide, then the lawyer in me takes over and I go through this list of 8 different types of software or related software, every single one of these has different regulatory issues. Every single one of these is treated differently. And it comes back to the basic premise that we like to stratify based on risk, and not all of these engender the same risk. Even though they might all be – you could have all of this software working together conceivably as almost one software package, but these different features, these different elements engender different risk and traditionally have merited different regulatory overlays.

So, that's why I'm struggling. I'm struggling to – on the one hand I want to talk about it, big picture, think about some of these exciting new things, as Joe's identifying and that would have the added advantage of helping us focus in the short amount of time we have. But I'm – a part of me is still kind of stuck with this notion that all these different types of software are different and should be treated differently.

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

Brad, I think you've got to fight your inner lawyer –

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

This is Todd Cooper –

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

I will try –

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

I think we could get strapped in the – drivel or minutia of kind of very picayune regulation, or we could try to elevate the discussion and look for some commonalities that could drive a new rubric.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

And I think that's exactly what the charter of the taxonomy subgroup is, to try to tease out what are those principles that should be applied, what's relevant. I think getting back to the question at hand was, how to manage our interaction with these other groups to stay in sync. And one part of that might be as we anticipate receiving something from them, we should think about what are those touch points and how might that impact – or how might we factor that into our discussions here, and then communicate that back, so that they have an idea of what kind of targets we're looking for.

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

Yeah, there were really only two ideas that occurred to me, one was in the early going communicating by posing the questions of the areas where we need input in order to be able to do our thing. And then down the pike, in late June or July, having some joint meetings then, for sort of a hand-off where they've given deep thought to risk, for example, we've given some thought to regulation and getting together and talking about how to marry that up, or likewise with the Taxonomy Committee. But I didn't have any other – and attending their calls whenever we can.

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

This is Matt. In the spirit of thinking big picture maybe, one of the causes of the need for regulation is market failure, the failure of the participants in the market to solve problems that create risk of one kind or another. And, maybe this is overlapping a little bit with the other group, but thinking about the role where industry has or could work on standards or codes of conduct or other things that have preempted the need for regulation. Just to throw that out there.

Lauren Fifield – Practice Fusion – Senior Policy Advisor

So Matt, this is Lauren. I think that's a really good point and I guess two things, one being that a viewpoint about one of the reasons for regulation is market failure and I think we need to really think about sort of that list of different health IT, some of those markets are really immature and haven't even had time to necessarily fail. Nor have they had time to really grow into what they might end up doing to serve the medical community and patients. So I think one, we should really think about maybe not necessarily types of health IT exclusively, but maybe also think about levels of maturity of different areas of health IT. But I think that's maybe one way to slice it, so for – rather than again kind of classify it by types, but also think about maturity of market, and –

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

And my query was very glass half full, not to – we don't have to wait. Regulating something that has already failed is a lot harder than thinking ahead about risks and places where immature markets could fail, and encouraging – so, proactively working to reduce the need for regulation in the future.

Lauren Fifield – Practice Fusion – Senior Policy Advisor

Yeah. Yeah, exactly. That's exactly what I'm saying. I think just because we are the Regulations Workgroup, the absence of regulation may be just as valuable as the existence, and that one way of looking at it might not be type of health IT, but instead, maturity of market could be another way to sort of look at kind of how much regulation we might suggest. So, yes, I agree with your point.

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

So here's my –

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

This is Anura Fernando. That related comment that we should consider looking also at those things that are in place or that are emerging that can potentially inform regulatory science and be used to support the regulatory processes, like recognized consensus of standards that are specifically recognized by the agencies for specific technical pieces. And also some regulatory agencies currently rely on certification that's market driven to support the regulatory processes and so should look at the possibility of those types of processes being introduced into the current medical device regulatory environment.

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

So, the comment about, for example, the maturity of a market and how that impacts regulation. I think that's a great comment, it is the kind of thing – the kind of input I expect to get from the Safety and Innovation Committee. Because they are supposed to identify for us the factors that kind of most relate to the need – or to the sensitivity of innovation to regulation and that maturity factor I would think would be one that they would seriously consider and end up identifying for us. But that's also why this is so awkward, because naturally we have this discussion and we think of that, right. But I've just got to figure out some way to coordinate, because my understanding is, that kind of – the three committees shouldn't just all be doing the same thing and my concern is that we'll drift over into what they're doing, they'll drift over into what we're doing and I'm trying to figure out a way to manage that.

The other thing I'm concerned about, and I want to ask Bakul if he would speak to this for a minute, because Bakul and I have had some discussions about this. The challenge with talking big picture is that the statute really doesn't call upon us to design the strategy for the agency, but rather to offer input on – it's kind of an open question, input on elements of regulation that would be useful for them to incorporate into their strategy. So, that maybe nitpicking a little bit, but I just want to make sure we're not – in our heads we're not thinking we're going to design a regulatory system here, rather we're going to identify maybe some cool features or useful features that the agencies ought to consider. Bakul, did I say that right?

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

I would say yes. Jodi, do you want to reflect on that a little bit?

M

Yes, so, I'm not sure what to add. I would have us work to push to do the right thing and not get caught too much up in whether or not the verbiage of the charter allows us to either talk about the way it gets regulated or an element of the way it gets regulated, rather to tra – to make the highest and best use of all the people that are engaged in the process.

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

I was just going to ask if Jodi Daniel had any thoughts. But, yes, we want to – think about this as what would go into the framework, what's import – what does the community think, this workgroup think as important factors or key things that we absolutely must have. Or when the framework comes out or we propose a framework, what it should absolutely take into consideration, and things that are nice to have. Obviously there will be gradations in between and out of the box thinking is encouraged, so, think about that way, think about it that way.

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

Bakul, can you just be – can you give just an example, maybe, to make it more concrete, an example of something you're looking for, I won't hold you to the logic behind it, but just to illustrate the point.

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

Umm, let's just – I'm going to make it really absurd, so yes, bear with me. If we were making a box and in the box was something like the – is the framework we are creating as the feds are supposed to, and if the workgroup decided that it needs to be square or a cube, or some other shape, that shape is critical for patient safety. That input of the shape needs to be "X" is something that we should hear about. If the color of that box needs to be a certain color, we should hear about that. And obviously I'm sure you guys will think about why it needs to be this color or why it needs to be this shape, or what are the factors that would – that's absolutely needed that you as a group think it's important for patient safety, and obviously supports innovation and avoids regulatory duplication. I hope that made sense.

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

Yeah, that's very helpful, thank you Bakul. And so Joe, that's kind of what's coloring my perspective a little bit in terms of how we go about this. Because that – it can be out of the box, but not a hundred thousand foot level, I think.

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

So, this is Jodi, Jodi Daniel. Let me just jump in as far as out of the box thinking. I think to the extent, if there is something that is really interesting that can – that the group comes up with that is really out of the box thinking, I think it's fine and encouraged to bring that forward. It would be good to make it clear that it is out of the box thinking, understanding that it's something we may or may not be able to implement. It also might be good to have kind of some alternatives if, in fact, something is more out of the box and may be challenging, because it's a different way of thinking. So the reason I say that is, our Policy Committee that this workgroup reports up to is – we have been leaning very heavily on the recommendations that come out of this advisory committee, I would say probably more so than maybe some other HHS advisory committees. And people tend to look at what comes out of the advisory committee as predictive of where the agency might head, because we have relied so much on the expertise and the recommendations we've gotten. I would say we've taken at least 75% of the recommendations we get through this Policy Committee.

So to the extent that something may be kind of out there, and may not actually be predictive of where we could conceivably go, but is an interesting idea that we should really think about, or might have some elements that we could include and that sort of thing. I would just sort of make it clear that that's what it is, and maybe have some way, either say – well at least this piece of this out of the box idea is really kind of the most critical thing that we'd want the agencies to focus on. Or, we think this is a great out of the box idea, but in the alternative, there may be some more modest approach that could get close to the same place and here's what that is. And I think that might be a way of helping to be able to bring up kind of that really innovative, interesting idea that you all may come up with, that personally I would love to hear, without kind of tying our hands and where we may or may – the agencies may or may not be able to actually follow through on it. So bring those up, bring them to the forefront, but also realize that we may have some limitations and help us think about what we could do if we can't get exactly where you all are suggesting. Does that help?

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

That's very helpful, thank you.

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

Brad –

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

And I would like to propose that we move on, we're going to run out of time if we don't. Is that okay?

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

Brad, it's Julian. I just want to jump in just for a second because the – Bakul talking about a box and then everyone else talking about out of the box thinking can't help but get me thinking about this box a little bit more. I think an example that I would perhaps toss out here that's specific is that we have a specific issue of that individuals, consumers or organizations could be confused about how to submit a safety concern when the regulatory pathway is unclear. That we have – and we live – part of what we're talking about lives within the regulated space of the FDA, part of health IT currently is in an unregulated space. And regardless of anything else, a tangible, specific challenge is, how to we make it clear what the entry point is for questions or concerns about potential let's say adverse events, whatever the concerns are, how will someone know what the entry point is and how to address a problem? That is not – so that would not put us in a position where we're making a specific regulatory recommendation, but we could be in a position to identify gaps or issues that do need to be addressed and then pass that along to the various agencies to be – with a very specific question and issue to address.

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

So that's actually a good segue to what I want to cover next which is basically talking about how we might gather up ideas that fall into these various buckets and boxes that we're talking about. And then figure out which ones frankly work well and which ones are responsive to the safety and innovation issues identified by our colleagues in the other committee and so forth. So what I did is on two slides I put together a list of some of the primary documents that I've seen that basically lay out ideas for regulatory approaches in this general area of HIT, including specifically mobile health.

So, on the first of two slides, the first one is the most recent one, I think, out of all this list. It's the work of the Bipartisan Policy Center. There's a group that spent a fair amount of time this spring, or at least it was published this spring, coming up with their proposed oversight framework for assuring patient safety in health IT, so that would seem to be a natural document to look at. The second one is a document called A Call for Clarity, Full Disclosure, I was the author if it, but it was put out now a couple of years ago by the mHealth Regulatory Coalition. So, it's a little bit dated, but not much, but there's been more recent work by that Coalition and we talked about it in the call on Monday with the safety group, because one of the things that that Coalition has done is put together use cases. And the whole point of creating the use cases was so that a group like this could get really specific, not with an idea to the point we were just discussing, not to the idea of coming up with minutia of regulation but really understanding the variability of the use cases and the issues and the environment in which this regulatory system has to operate. So, I would submit that those use cases, in particular, might be helpful to this group.

The third one is some work done recently by the CDS Coalition, again disclosure, I was the author of it. But, it comes up with basically a principle to answer one question, which is, when does the user become substantially dependent on software – on standalone software? And the reason that question is so important is that that group is positing that substantial dependence is kind of the tipping point for regulation, that regulation should not occur unless the human user become substantially dependent on the software. So what that group has been working a year and a half to put together, it's about 30 companies or institutions, is a way to define that tipping point of substantial dependence.

The fourth one is an IOM report, a very good, detailed, thorough report from, I don't know, a year and a half ago, that a lot of – several members anyway of the working group were members of, participated in that IOM process and came up – did a thoughtful literature review and came up with some recommendations in a number of areas regarding regulatory approach. And then lest we forget, there are academics who have been studying this. These are different academics, and you're probably accustomed with, these are law professors who have been studying government regulation and electronic health records and HIT more generally. And so this Professor Hoffman came up with a rather substantial paper, now a few years old, but a very sort of carefully considered paper on regulatory approach. And then more recently, last year in the Indiana Health Law Review, another fairly thoughtful assessment.

The next is, and Julian can speak quite a bit about this, a group that he's involved in, CIMIT, and then the Continua Health Alliance that I'm involved in and FDA all three got together and in January, 2010, conducted a 3-day symposium on a lot of the issues that Julian's been studying now for the last 3 years. So this forum basically this proceeding sort of spun off a lot of activity looking at regulatory best practices for this whole area of networked IT that involves interoperable medical devices. So, there's rich content there.

And then finally, and I think probably everyone is aware of this, the International Medical Device Regulators Forum is concurrently with the work of this workgroup looking at regulatory sort of harmonized best practices globally for standalone software. In their March meeting in Nice, the group decided to take this issue on, they've come up with a schedule that is about, as I understand it, about 18 months long. Bakul could tell us chapter and verse, he's intimately involved in it. But I've had some discussions with those folks because literally they're going to be doing in that International Forum, quite a bit of the same stuff that we here in this section 618 working group are going to be doing. And I've been trying to think of ways that the two activities can support each other or feed off each other, however you want to describe that. But those are some obvious sources to turn for ideas, but I know it's incomplete so I wanted to basically open it up for the group to say, okay, let's be systematic about this, let's gather up all those good ideas that are already there. Let's sift them, sort them, organize them and then be prepared to identify what we like in them. So where else should we be looking for this content?

Lauren Fifield – Practice Fusion – Senior Policy Advisor

So, this is Lauren. And first of all, I think our next in-person meeting should be in Nice also. But, second of all, I think one I guess it's sort of a bigger point and then to answer your question directly. I think one thing that might serve us really well is to sort of, even though we want to be closely integrated with the other subgroups and other resources, I think for our purposes, one thing that might help us well is first to just determine in the context of health IT, what we think the role of regulation should be. So, just pure regulatory science, I know patient safety is of course one, and maybe promoting innovation, maybe ensuring quality systems, but I know that each of the three agencies in the interim being kind of articulated what their goals were for the regulation that they oversee. So I think just sort of first defining the goals that we see for regulation of health IT would be helpful.

And this goes on to answer your question, I think in so doing, it might be really good for us to draw on non-health IT, non-health related areas of regulation to just see what else is out there in the way of just pure regulation. So, kind of agnostic of what's being regulated and more to understand different mechanisms of regulation that may or may not apply. I think in that way to, we would be able to delineate between what it is we're doing and the other subgroups are doing. And really use the subgroups and other resources, use their vocabulary, use their research, their thoughts to then kind of add input to what we see as our regulation engine – to feed the goals of what we see regulation in health IT to be.

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

So, I love the way you're thinking and the only challenge in it is time, right, the only challenge is completing our task by August. And so, opening up the doors real broadly just takes more time, and I'm perfectly willing to do it, we just have to figure out a practical way to accomplish it and still meet our objectives. In part, when I list these seven or eight sources of ideas, in part I'm kind of cheating because that's what all of these groups have done, is, to varying degrees, looked broadly for ideas and tried to propose ideas that would be useful in this context. So can we do it ourselves, yeah, absolutely, there's no reason we can't, other than we need to be done on time. So, figuring out that is the key.

Is there – can someone help me with a methodical way to do that, to look at other regulatory systems, non-IT regulatory systems? I'll give you an example of where one group here, the one I'm involved in, the mHealth Regulatory Coalition. They did exactly that and the idea was software modules, right, that software modules are different from other things FDA regulates, it makes software – standalone software different from other things FDA regulates. And we wanted to figure out a way to deal with modules that was outside the box, and we had a member who said, well, you know, the FAA, the aviation folks have been dealing with modules for a long time. Because in cockpit software, they do a lot of combining, mixing and matching various modules and they have to assign different regulatory classifications to each module. So, we literally have gone out and been studying, in some measure, the FAA approach to see whether we can basically recommend it to FDA. Likewise, the Europeans apparently have a pretty sophisticated approach to how they look at modules, and so we've been studying the European module – European approach, I should say.

So, I completely agree with what you're describing, I'm just trying to figure out a way to manage that process of how we can collectively as a working group here, do that. If no one has any ideas on that particular question, I'll be happy to go back to the first question I asked which was, you looked at these 8 or 9 sources that I identified, are there other ones that I've missed? Are there other sources of information that we could put into the mix?

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

So, yeah, just to answer that. I think I mentioned before that there's been a lot of discussion, especially around the area of health software, and I know we've worked a lot in ISO/TC 215 and in conjunction with IECs SE 62-A on trying to kind of tease out, especially common sets of definitions of terms and touch points. So what I'm going to try to do is extract some of that information and provide it to the group because as a result of the discussion of things, we've found about the really fundamental conceptual differences between these spaces and trying to find a spot of how they can meet. And there are things like, just like the word – the phrase standalone software, which means something completely different, depending on whether you're coming from a medical device background, a regulated system background or whether you're coming from an IT background. So, I'll try to provide those references to you.

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

Well in point of fact, as I understand it and Bakul can comment if I get this wrong, but the International Medical Device Regulators, that's the natural starting point for that group. That's exactly how they're starting it, by putting together a list of key terms and then trying to make sure that they're speaking the same language. Did I get that right Bakul?

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

Yes.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Right. And so what I'm talking about is information that will be fed into that group.

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

Yup.

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Sooner than later.

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

Yeah. Anything else? If not, I mean, we can go on, but I just wanted to make sure, and this isn't the last call, if anyone thinks of anything else, let us know. My thought was, I'd work with, I don't know, MacKenzie or whoever would be the right person, and try and put some central repository for these various papers that have been written. Okay, so why don't we go on. Sort of finally, I guess, to the discussion questions and I have about 5 after 5, we need to allow some time at the end for public comment, so we have probably about 15 minutes to talk about these questions. One topic I want to sneak in before the public discussion is just the choreography for the face-to-face meeting at the end of next week. So I'm going to try and preserve five minutes for that discussion. But let's turn to the discussion questions.

So what I did here is, one of the very first slides I had was the six questions that had been put forth to this committee by the three agencies as topics where they'd like input. I tried to pick three where we could comment on them early, without having to wait to see what the safety group comes with, Safety and Innovation group come up with, or the others. So that's why I selected these three, just because I thought these were all ones that were manageable early in the process, before those other inputs are received. So, the very first one, for example, identifying non-regulatory activities, existing or potential, that we need to consider – excuse me, that the agencies should consider, not just that the working group should consider.

So, I'll give you one that occurs to me off the top of my head, and again, it's a group I'm affiliated with, but the Continua Health Alliance has a certification program. And Julian, I'm sure, can much more articulately describe how the process works, I've never gone through it myself. But basically it's a program that makes very heavy use of standards, not developed by Continua, but recognized by Continua, selected by Continua, to basically form the backbone of the certification program that allows for more reliable interoperability among networked medical devices. So a robust system administered by Continua to certify could be, I would think in lieu of, for example, federal regulation. So, I simply toss that out as one to be considered. So, either – if you would, either react to that suggestion or maybe identify additional ones that we also ought to take into account.

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

Brad, Julian here. I could speak very briefly to the way that works. It's a consortium model. The members of the consortium come together, pool their resources and then do two things. Well, they do more than two things, but they decide what they want to accomplish, that's number 1. Number 2, once they make that decision, they resource the appropriate standards committees to produce standards, for example, within IEEE or HL7, or wherever they go. And number 3, they develop test tools and certification criterion so that something can be certified. And this is similar to what's done for something like Blue Tooth or WiFi, but in the Continua space, this is being done for personal and personal health and telemedicine and so forth. So that's the short version. Does it work? I think it works to help build out an ecosystem of products that can be interoperable or that can meet other purposes and from that perspective it's quite useful.

And I guess not to comment directly on that, but I think it's relevant, is that we have to keep remembering that we are talking about patient safety and safety in healthcare sometimes we – although we may not log burdensome regulation. We have to recognize perhaps that something in that space might be needed to support safety, because safety is sometimes the stepchild of other initiatives. But the Continua work, I think, has been very – has been performed quite thoughtfully and implemented with great skill. But, some of it is orthogonal to what we're trying to accomplish, it seems to me. And I may be missing what the possible connection is to address the regulatory side.

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

Yeah, this is Joe. I'd largely support that. I think the notion, if you put up a strawman argument you know that there's a non-regulatory activity, but it is the recognition of interoperability standards, it doesn't impose a requirement, but it says, these are easily recognized and there's Continua or others, as the recognition standards, I think that's largely done already, where those standards exist. But I think that's perhaps an example that you're speaking to. And to Julian's point about the interaction with safety, I think Julian I would agree that interoperability does have an important impact on safety, so I can see that as being one of those things that might fall into this question 1 that you're driving to.

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

And so the goal of the Continua program is for a market-driven solution in the following sense. The goal is for healthcare providers to say, look, when we source vendors, we want people who are certified – whose products are certified to meet the Continua standards. So that's the hammer, as it were, in lieu of governmental regulation, having really the purchasers insist on that certification. So that's a model and I don't know if you guys want to – we can either debate its effectiveness or we can go on to identify other such activities. I'd almost rather collect as many as we can and then maybe when we're face-to-face, debate the relative merits or demerits of different approaches, but just to get it started, are there other ones that folks are familiar with that they want to make sure get considered as a part of this discussion. I mean, one other I thought of was Haptique, I know that in the last week or so the media reports suggest they're taking a change of direction. I don't know anything more than I read in the media, but the Haptique approach would be another possibility.

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

Brad, I think there is a common thread that's worth capturing here, which is that in some of the alliances that exist there is a very good pathway to identify problems and feed them into the alliance to solve the issue across all of the devices in that space. And in other alliances, there is not a good mechanism for that. So an example would be if your thumb drive has a problem related to the connectivity of the standards or you have a WiFi issue, I mean, not as a consumer, but as a manufacturer trying to implement it. If you feed that back to the WiFi Alliance, what you want is that – well you want that to get fed back to the Alliance, you want the solution to be propagated across the entire ecosystem and some alliances are good at that and some are poor. And I mention that because I think that that general concept, that we don't want problems to continue to be siloed at the level of a given manufacturer, but we need it to be sil – driven across the ecosystem for health care is a key attribute of a good exemplar.

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

Very helpful.

Todd Cooper – Breakthrough Solutions Foundry, Inc. – President

Another one that I know has been discussed a lot and used to varying degrees is the creation and leveraging of assurance or safety cases, and that can be referenced as part of materials that are submitted in regulatory submissions. But in the general sense, they really help, especially if you have a template tailored for your specific area, they really can help you quickly think through what are the safety implications here, and what are the mechanisms that I might employ to address those and verify that they're actually working. And I know the efforts that again the NHS did to help increase their maturity in the safety of their health information systems was to employ the use of safety cases, so we should look at that.

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

Okay, great suggestion.

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

And this is Joe again. I wouldn't lose sight of the fact that both of those last suggestions provide some comfort for a regulatory approach which perhaps has a lighter touch up front with this kind of – the surveillance and rapid identification of issues and correction that would be pro-innovation in this space. So I think as we look through concepts like this, I think the notion of looking prospectively at how they're going to impact not just the regulatory structure, but also its impact on the speed of innovation, I think is helpful.

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

Okay. Other non-regulatory activities that you want to identify, put in the bucket for either now or later discussion? Okay. We'll keep thinking about all these questions, this won't be the last time we talk about it, I'm sure. Let's go on to the second question, just to keep the discussion going a little bit. Identifying current areas of regulatory success and best practice, that's the question and then there's a little editorial from me, these are things we want to preserve or even expand, just to put a finer point on them. So I'm kind of starting with a positive, instead of talking about what's not worked, let's talk about what has worked. Where have you seen regulation, and to the point made earlier, I don't think you need to limit it to HIT regulation, where have you seen regulatory approaches that maybe could be used in HIT that have done well, that have succeeded in some manner.

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

This is Anura Fernando again. Looking at the approach that OSHA has taken for regulation of electrical systems and interoperability as well as the different parts and pieces that are involved in electrical power distribution and so forth might be a good place to look for some useful information.

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

Are you by chance knowledgeable about that enough that you could send me a key paper or description or something that would be – that I could circulate to the rest of the group for them to read up and learn about it?

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

Sure, definitely.

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

Because I'm clueless. That would be very helpful.

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

Yes.

M

At risk of torturing my friends in the FDA, the notion of the CEMAR process that approves a process of manufacturing not necessarily a product, might be applicable to software, perhaps quite quickly. You know, the notion of using best controls – if you use best controls, you're good to go with, you know the post-market surveillance that we were talking about earlier.

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

Okay. Good idea. Other systems we ought to think about that have apparently worked well somewhere else? Or, for that matter, existing HIT regulation, if there's something that's really working already in this space right now and ought to be preserved, I think that's fair game to identify that as well.

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

This is Joe again. I heard rumblings that maybe when we get to regulating CDS, we'll start talking about how if it's completely transparent in the way it makes decisions, transparent and referenced, that that falls outside of a regulatory purview. That as a concept seems attractive.

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

Now Bakul, I'll have you know I didn't tell him to say that. So –

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

Hmm.

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

Brad, Julian here. I – you and I have chatted offline about this and I – this is kind of a bomb notion, but we've – it seems like other regulatory approaches that should be considered are those that are used in other non-healthcare environments that are designed to cover both the regulated and non-regulated product space. The things we've talked about like the National Highway Traffic Safety Administration, NHTSA model or whatever's used in aviation, for example, where there's a means to bring to the table all of the parties, whether they have regulated or non-regulated products, to discuss potential safety issues and their resolution. How could we bring that conversation in here without making it too onerous or complicated? It seems though, that we can't ignore that.

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

Julian, I apologize. I'm following you at a high level, but can you get a little bit more specific with me, what you want to accomplish or what you want to do?

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

Sure. Well one of the things we're discussing here are what are the other regulatory models that are used in other domains.

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

Um hmm.

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

And an example would be that which is used in transportation, for example, in the National Highway Traffic Safety Administration or NHTSA.

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

So how do we identify those, for example, the example you just gave. How do we find and learn about those?

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

Well I think that that – I would imagine that it isn't – would be terribly difficult, given the kind of committee this is with the contacts that we would have, that we could look for – we could speak with someone with an expertise in that area and look for the parallels. And we could describe some of those parallels in which something like an organization like NHTSA, and I'm making some assumptions, because I don't know all the details, but an organization like NHTSA is empowered to bring to the table the folks involved with the whole range of products and services related to, for example, automotive safety. And if there are safety concerns that are identified, there is a venue to discuss and address those, and not always in a "punitive regulatory manner."

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

Right.

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

But it could be through information sharing and such. So I think we could learn – there should be a number of ways in which we could learn more about what the implications are, in terms of how – is it appropriate to standup anything like that or what are the lessons that could be learned, both successes and failures, in that domain, that we could apply to healthcare.

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

Okay. Very good. Thank you. So, we've got about 10 minutes left. I want to save at least 5 minutes for public discussion, and I can stay on as long as we need to, but, I want to sneak in a little bit of discussion before the public comment to plan for the in-person meeting next week. So, I received an email that kind of lays, in 10 minute segments, the agenda for that 2-days. And just to give everyone a general sense of it, in the morning, after a bunch of preliminary discussions, the Regulations and Risk Assessment Subgroups will each have about 10 minutes to update the group about what we've done so far or where we are so far. So Julian and I will get together and talk about how to summarize in 10 minutes what we've just covered. And then there's going to be, I guess it's a plenary session, meeting of the whole sub – the whole working group rather, would be involved in a report-out of the Taxonomy Subgroup and then discussion about that report out. So that would go on for not quite 2 hours. So the majority of the morning really would be spent on the Taxonomy topics.

Then in the afternoon, if I'm reading this right, right after lunch, the Workgroup splits into two different groups, Regulation and Risk Assessment, and I assume the Taxonomy people go kind of wherever they want to go. So we split out and we have for 2 hours basically a committee meeting, where everyone on this phone call plus whoever else drifts in would, in a separate room, talk about whatever we want to talk about. And then the second half of the afternoon is report out and discussion. So, we would come out and report and then there would be 45 minutes of discussion among the whole plenary session, and then the Risk Assessment people would do the same thing. So – and then the second day is kind of more synthesizing, identifying cross-cutting issues, less work in the individual working groups and more as a whole – as an entire working group.

So, I guess what I would love in the couple of minutes we have remaining is, any suggestions or ideas as to how to prepare what we ought to try and accomplish during the 2 hours when we'll be working on our own in that early afternoon. What would you find most productive as a group?

Lauren Fifield – Practice Fusion – Senior Policy Advisor

This is Lauren. As I mentioned, I think, it would be great as we're working kind of on our own, to think about goals of regulation in health IT, sort of the broader goals that if we were to suggest – if we were to provide recommendations to the agencies, for them to be successful, what would they be successful in. Is it just patient safety – assuring patient safety, is it assuring quality of products and is it assuring innovation, improvement to healthcare. So I think that could be helpful. And I also think sort of planning out some of our next meetings and whether it's bringing in folks from transportation, cosmetics, SEC, to get sort of out of industry regulatory feedback or a working session with other subgroups in workgroup to sort of add goals and then also kind of outline of next steps and owners.

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

Okay. All right. Are you – can I ask, are you expecting some controversy with regard to goals? I mean, everything you just said, quality, safety, innovation, I said, wow, boy I'd love all those things. Is there controversy that you're expecting?

Lauren Fifield – Practice Fusion – Senior Policy Advisor

I don't expect controversy, but I think if we have a clear sense of what we're trying to achieve, or what we would suggest should be achieved through regulation, will one have a better idea as to where regulation may not be appropriate or necessary? And that maybe some other treatment could get to that goal. And I also think that it'll help us maintain our subgroup's purpose and not get kind of bogged down in just considering taxonomy and risk and innovation, but rather really produce kind of the regulatory tool. Whether it's sort of taking from other industries, it's work that already exists or sort of out of the box, we want a beta program where risk isn't even a consideration and limited access folks are allowed to use apps and the whole lifecycle process happens all at once. And that's that sandbox they have, or whatever it is. But again, I think having those goals will kind of give us buckets to say, okay, in order to achieve this – patient safety, surveillance or reporting is a good tool. And we'll use Taxonomy Subgroup and Innovation and Risk Subgroup product – work product to inform kind of how we're thinking about those regulator tools or mechanisms. But I just think that having goals for ourselves will help – structure.

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

For what it's worth, I'll just share my own experience with setting goals. I don't find much controversy in setting them, I think it's kind of easy in a sense to set the goals.

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

Yes.

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

The challenge is the trade-offs between the goals. So where one particular regulatory approach would really increase patient safety, but at the cost of innovation, which do you do? Do you protect innovation or do you go for patient safety? Or, where you have speed to market issues on the one hand, speed to market is terribly important because you save patients by getting to market quickly. But if it's at sacrifice of quality, it's no good. So it's the trade-offs between the goals when you start to get to specific regulatory approaches that start to create the choices to be made, that's what I'm struggling with, is how to get to a meaningful place in the discussion.

Lauren Fifield – Practice Fusion – Senior Policy Advisor

Yeah, I agree. I think that that's – I would say that that's part of it, too. So is the ultimate goal patient safety at any cost or is it that some areas of health IT or just in general we may be willing to take on risk to advance medicine, to improve delivery of healthcare or to promote or maintain innovation. So I think that's going to be part of it, too. It's not just what are the goals outright, but sort of given the role of health IT in the healthcare universe, how can regulation help, how can it hinder, and again how do we prioritize those goals, because they're not always in perfect harmony.

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

Well, we are just about at the end of our time, and I know we're obliged and I want to get to the public comment. I feel bad that we're close to the end of the hour and I certainly can hold on if others can as well. But can we start the public comment process?

Public Comment

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

Sure. Operator, can you please open the lines for public comment?

Caitlin Collins – Altarum Institute

Yes. If you are on the phone and would like to make a public comment please press *1 at this time. If you are listening via your computer speakers you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. We do not have any questions at this time.

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

Okay. Well, I don't know how you want to wrap it up. This has been a really good discussion, I think Julian and I are going to have to sit down and give some thought as to how to propose to all of you that we structure the discussion when we do get the time face-to-face. It's a precious time – precious opportunity, so we want to figure out how to make the most of it. So, Julian and I will talk more about that and come back to you with some ideas. But, anything else that we ought to talk about before we adjourn, from anyone? Julian, are we okay?

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

Brad, it's Jarrin. Are you guys going to be providing anything to us before the meeting next week?

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

We're really just at the beginning point of even thinking about how to do next week, so I don't know if we will or not.

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

So this is MacKenzie. I'll just give two options, if you want to distribute materials. We can either upload them to the workgroup resources page in the portal, I sent an email out to all the workgroup members reminding them of how to log in. So we can either upload documents there directly or we can just use a reply all to the email appointment. So, it's up to you.

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

I mean Jarrin what I would like to get to you at a minimum would be these documents that I listed on those two slides of prior documents. And I suspect you've seen virtually all of them, if not all of them, but those would be the keys from my perspective, for the discussion. But if Julian and I, after we reflect come up with some worksheets or PowerPoints or something tailored to the event, we'd want to get that to you as well.

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

Yeah, that's what I'm more interested in, I've got the other stuff.

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

Yeah. Well, Julian and I are going to need to talk and try and figure that out. Any other, we're at the end of our time. Any other comments or questions or concerns? If not, I don't know who I turn this over to, but I think we're through.

M

You turn it over to the cloud.

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

All right. Well thanks everyone. Take care. We'll look forward to seeing everybody in person.