

**HIT Policy Committee  
FDASIA Workgroup  
Subgroup #1: Taxonomy  
Transcript  
May 15, 2013**

**Presentation**

**Michael Lipinski, JD – Office of the National Coordinator**

Good afternoon. I am Michael Lipinski with the Office of the National Coordinator for Health Information Technology. This is a meeting of the Taxonomy Subgroup of the Food and Drug Administration Safety and Innovation Act Workgroup, also known as the FDASIA 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. Before we proceed to roll call, I want to share two pieces of information with the subgroup members. First, subgroup members can send any documents they wish to share with the subgroup to me or to MacKenzie Robertson for posting on the member portal. And second, the health IT blog is available for soliciting public input on subgroup topics and questions, so, if you want to make use of that tool, you can let us know and we can post the questions or topics to the blog. At this point, I'd like to proceed to roll call. Patty Brennan?

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Here.

**Michael Lipinski, JD – Office of the National Coordinator**

Meghan Dierks?

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

Here.

**Michael Lipinski, JD – Office of the National Coordinator**

Richard Eaton?

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

Here.

**Michael Lipinski, JD – Office of the National Coordinator**

Elisabeth George?

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

Here.

**Michael Lipinski, JD – Office of the National Coordinator**

Drew Hickerson?

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

Here.

**Michael Lipinski, JD – Office of the National Coordinator**

Mary Anne Leach? Meg Marshall?

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

Here.

**Michael Lipinski, JD – Office of the National Coordinator**

Mary Mastenbrook?

**Mary Mastenbrook – Consumer**

Here.

**Michael Lipinski, JD – Office of the National Coordinator**

Jackie McCarthy?

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

Here.

**Michael Lipinski, JD – Office of the National Coordinator**

Thank you members. Are there any staff with ONC on the line?

**Jodi Daniel, JD, MPH – Office of the National Coordinator**

Jodi Daniel's here.

**Steven Posnack, MHS, MS, CISSP – Office of the National Coordinator**

And Steve Posnack.

**Michael Lipinski, JD – Office of the National Coordinator**

Staff with FDA?

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

Bakul Patel.

**Todd Mitchell, MD – Food and Drug Administration**

Todd Mitchell.

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

And Simon Choi.

**Michael Lipinski, JD – Office of the National Coordinator**

And staff with FCC?

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

Matt Quinn.

**Michael Lipinski, JD – Office of the National Coordinator**

And then lastly, before I forget, any other FDASIA Workgroup members on the line?

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

Todd Cooper.

**Michael Lipinski, JD – Office of the National Coordinator**

Thanks Todd. Thanks to everyone. And at this point, I will turn it over to the co-chairs, Patty and Meghan.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Sure. I'd like to begin and then I'll have Meghan make her opening remarks. This is Patty Brennan. I want to begin by thanking the FACA staff and support team – for their rapid response and their gentle coaching of the two co-chairs, who are a little naïve to the process and got out a little bit ahead of the game, I think. I also want to thank my co-chair, Meghan. We've met once already last week to try to find a way to prepare ourselves for the meeting in DC at the end of this month. Just to let you know what we're working towards, we hope to have a – two 1-hour conferences, one today and the second one will be Tuesday, I think it's May 29 – 28, right after Memorial Day, to prepare a report that we will deliver in Washington on May 30. Our plan is to use this meeting today to scope out the territory of taxonomy, to hear perspectives from this group and to begin to react to the straw dog. We'll be using the portal and also the – as needed, the Blog to both communicate and solicit input. Now I'd like to turn to Meghan for her opening remarks.

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

So hi, this is Meghan Dierks. Thanks very much Patty. Again, also echoing thanks to those of you who volunteered to serve on this group, and I think it's very important because we'll help frame for the other two subgroups how they go forward by giving them a sensible sense of scope. I think we had a document that was circulated that I think was helpful, it gave the outline of the potential scope options, and we'll talk about those in today's meeting. I find it helpful and would encourage everyone to refer frequently back to the background context, which is what the workgroup itself is intended to produce, and that's the proposed strate – recommendations, proposed strategy on an appropriate risk-based regulatory framework pertinent to health information technology. So that should always sort of be informing our deliberations and what this subgroup puts out.

And I maybe just want to also emphasize that I think one of the challenges that we will face in this subgroup will be as we define what's in scope or out of scope, trying to characterize it using as generalizable a terminology as we can versus giving specific examples. And then also harking back to a comment that Bakul Patel made last week, that being sure that however, we describe the entities or things that are in scope versus out of scope that we also think a little expansively. Meaning – and maybe through our generalizable terminology so that it actually doesn't paint us into a corner for future technologies that we haven't yet realized. So, I think that's it for my opening comments.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

So this is Patty and I note that the staff support has provided us with an agenda for today, you may want to refer to that, but basically, from about this time until about 5 of the hour, we're going to be having an open discussion. In addition, they've provided us with some materials and a straw dog. I'd like to begin by asking those present to offer general comments and then we'll spend about 10 or 15 minutes doing some perspective providing and boundary settings of these boundaries pointing to – and then we'll get into more depth looking at specific proposals. So let me open this to anyone who would like to begin with formal comments – with informal comments, sorry.

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

This is Meg Marshall. I have a question, a general question around how the overlap of the workgroups will occur. So, if we're looking to define the boundaries, if you will, of and I'll just say health information technology and its framework, how will that interaction occur with the risk assessment group, for example, if we're looking to propose a risk-based framework. And perhaps this is something that the answer is that we'll work it out in the in-person meeting, and I know we were talking about this little bit in the previous meeting, but I'm curious as to whether you have any additional information, based on your discussions as chair and vice-chair, over the past week.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Meghan, do you want to start or shall I?

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

Well, so you may want to start. I think my sense is really just from the meeting that we had last week, which was that I think our work, we actually will frame the boundaries, as you described, of how the subsequent discussion in those other two workgroups goes. So I think that's what's important about what we get done. My sense is that after today's discussion, we may not have enough in writing to distribute, but as soon as we get to a point where we feel as though we have some sort of initial draft, that may be an opportunity to distribute it to the other co-chairs. But I'm speculating so Patty, did you have thoughts on this?

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

So there will be iteration, I received a message today that we're going to actually begin to do the report up at the meeting next week with our group going first. The idea is that is intended to – we will propose our view of the taxonomy and what is included and excluded in the process, but we will have to be open for discussion and refinements, so that what we're bringing forward next week will not be a finalized taxonomy, but rather our best guesses of starting taxonomy. I'm sorry, what we bring forward on May 30 will be our best guess at the taxonomy. Does that help?

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

It does. Do you think that there will be opportunities for maybe a coordinated workgroup or workgroup calls between the two, prior to that in-person meeting or is that essentially what we should look at as our goal for the first time receiving feedback from the risk assessment group, for example?

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

To be very honest I think that it's unlikely that we'll have much of a written document today. We may have minutes from this meeting that we can circulate and certainly post for comment. Meghan and I had hoped to have the time before the main FDASIA meeting in the end of May to actually have a few dates to post something and get reaction, but I think that is really unlikely. We can solicit ideas or things that the other workgroups are hoping we include in our description, through the portal, and that may be the best way to handle...

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

This is Jodi Daniel I can jump in. One thing to note, we are trying to plan the agenda for that in-person meeting and our current thinking, in talking with David Bates, is that we would start with the taxonomy group and have some time in the morning to work through some of what you've come up with, with the larger – the full workgroup. So even if we can't do much beforehand, and it would be great if we could, we will have an opportunity to have that conversation before they go too much farther in the in-person discussion.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

I think that's quite helpful and I just want to echo – this is Patty, and I want to echo the comment that Steve sent to me. Steve Posnack sent to me in an email today, which is that it's our expectation that this group will actually only have the Taxonomy subgroup will only have these 2 meetings. And that we will be, after our report up in the May 30-31 meeting, we will not need to have additional meetings, unless something is deemed really critical for us to get back together again. Are there other comments? Well, I'm certain we're going to get some other comments as we go through, so please feel free to burst in going forward.

If I can call your attention to the – what's referred to on the document as – I just got it pulled up with Taxonomy Subgroup, I'm sorry, the Straw Man – Straw Dog. I'd like to have a chance to begin to walk through that together as a group. Those of you who are at the...today should see a document called FDASIA Taxonomy Straw Man, those of you who received it in the mail the title of the document is the same. As a point of context, Meghan reminded us earlier, that the section 618 of FDASIA, I'm sorry, we're working towards this report on a proposed strategy and recommendations on an appropriate risk-based regulatory framework pertaining the health information technology including mobile applications. And our special focus is overall for this workgroup is the risk-based framework, but our focus of the Taxonomy Workgroup is to talk about what's in and what's out of that phrase of health information technology including medical application.

If I can call your attention to the statutory definitions, the definition of health information technology from the HITECH Act is hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information. And then the Social Security Act does further define what is health information, any information, whether oral or recorded in any form or medium that is created or received by a healthcare provider, plan or public health authority, employer, life insurer, school or university, or health care clearinghouse; whether it relates to the past, present, or future physical or mental health state of an individual, the provision of health care to that person, or past, present, or future payment of the provision of health care.

Now the FDA provides us with a definition of what is a device and this is the end of our statutory definitions. A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component which is nec – or accessory, recognized in the recognized in the National Formulary or the United States Pharmacopoeia, or a supplement to them, intended for the diagnosis of disease or condition, or the cure, mitigation, treatment, or prevention of disease, in man or other animals and is intended to affect the structure or is intended – to affect structure of the – and function of the body of man or other animals, which does not achieve primary intended purposes through chemical action within or on the body of man or other animals and which is dependent upon being metabolized – not dependent upon being metabolized for the achievement of any of its primary intended purposes. So this basically means “don’t eat your cell phone.”

But it’s time for us now to think about what needs to be – we need to augment these statutory definitions to address the concept of mobile medical applications. I’m going to pause again to see if there is a starting point of comments that anyone would like to present.

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

So Patty, this is Meghan Dierks. I just wanted to get one point of clarification around the very last comment that you made. I think it may have been unintended, but you’re not focusing just on mobile medical applications, but any health information technology.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Well actually, that’s a good starting point Meghan because the FDASIA section 618 explicitly says mobile medical applications. And in the context of –

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

– including but not –

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Oh yes, yes, I see.

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

– not unique, yeah, I think I may have misheard your comment. I just wanted to make sure that it was including mobile applications, not focusing exclusively on the mobile.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Right. And so that’s part of what we’re here today to begin speculating about is what constitutes health information technology including mobile medical applications, recognizing that certain things we may define immediately as being out of scope, such as electronic health records implemented by the Cerner system. So we’re going to be talking about what’s in and out of scope and perhaps it would be helpful for folks to begin to just offer their comments about what they think must be in or definitely should be not included in our scope here.

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

This is Elisabeth George, I have a quick question on that is that, I heard the comment made that electronic medical records, for example, might be excluded, and I guess I’m wondering why we would go to that because I’m not sure we all have even the same definition of what is encompassed in an electronic health record. Because there are some people that are participating in this and there are medical device manufacturers that actually have Class II EHR systems that fall into the definition of the FDA’s medical device definition. So, I guess I wanted to make sure I understand when we say we exclude something or when we are going to exclude, that we all have the same understanding of what the definitions are, because we’re all coming at it from a different playing point. And as I mentioned on our very first call, I’m okay with identifying something as excluded, but we all need to make sure that we all understand what the scope of an exclude or an include is, so that when we do have that discussion on May 30 and 31, we understand how we’re discussing the associated risks, etcetera.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Meghan –

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

So Elisabeth, this is Meghan Dierks. That I think maybe touches on the suggestion that I made early on, which is, to the extent that we can avoid using a term or an acronym or anything that's commonly used. Instead – maybe attempt instead to describe it as a functionality, something that does the following, we believe is in scope, something that does the following we believe is out of scope. And this may not be the ultimate solution, but I think that may help us a little bit, because I agree with you that some people when they hear a term like EHR, they think about a complex system of systems, hospital information system and others may think of it as just a single stand-alone application loaded on to a hand-held.

But I think if we strive to do more describing something that functions in the following way, we believe is in or out of scope that can help us. And I think maybe the other thing that would be helpful is that ultimately as we construct this list, that we also put – that if we feel it's helpful, we put what this subgroup defines – how we define certain terms that are within that item. And then lastly that we also always strive to put a rationale to why we felt that it was in scope versus out of scope; I think the rationale is going to be very important as well.

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

And this is Meg Marshall. I completely support everything that you just mentioned and I would add to that that the form – that the funct – and is available, should be something that's irrelevant to the definition as well. So whether any given function runs on mobile device versus whether it's accessible through cloud, I think that that should be irrelevant for at least this first pass of our discussion.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

This is Patty. Can I ask – remind people to mute their phones when they're not speaking. What I'm hearing so far is an interest in having, as people make a distinction about what they view as in and out that we try to avoid using common terms that might have actually broad and multiple meanings. And secondly, that people begin to articulate their reasoning and third that we focus not exclusively on the form factor, but on the function also. And may I just clarify with the staff on the call, is there someone taking notes or are you expecting that Meghan and I are taking notes?

**Michael Lipinski, JD – Office of the National Coordinator**

This is Mike. So we'll take notes, but there's also a transcript, I believe, that will be available from the meeting.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Perfect. Okay. Are there some other thoughts about the inclusion, exclusion or where you might see some things clearly out of the boundary or definitely be in the boundary?

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

Hi, this is Todd. Let me – there's been a lot of discussion in standards, international standards groups around this, which is where I spend most of my time. And let me just throw out one thing that's been – has popped up, as an interesting facet to here, and that is, what is the focus in terms of the lifecycle of applications? So it's one thing whenever you have kind of the development of a product that is created ready for purchase and deployment in a given institution, as opposed to component applications, which is often the case with health software, where the implementation is actually kind of at the very end, when you're actually deploying it and you're configuring it. And so where in that software lifecycle might we look to say something may or may not be regulated at this point or that point. I don't know if that's something – in terms of a characteristic that we should look at or a dimension that we should look at on this.

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

So Todd, this is Meghan Dierks. I think that's a really good point and I would maybe just elaborate a little bit on your description and ask, do we – does this group also want in the in scope versus out of scope to address specifically whether there should be regulation around maintenance, for example and/or end of life issues. And I ask that kind of thinking that that actually falls, once you've decided that you may want to develop a regulatory framework, that's just a part of how – what the dimensions of regulation might address. But, it is a little bit different, it's, for example, do we want to make a recommendation that the larger group consider whether there needs to be risk assessment and regulation around how long a product can be out there or how many upgrades or modifications or how long it can go without software upgrades, things like that.

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

This is Jackie McCarthy from CTIA and we would definitely second that and would be very much in favor of a discussion in this group about updates and software modifications and ones that relate to the medical use module as opposed to ones that are more maintenance and access related.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Could I ask for a clarification of that last comment? It was tied to the lifecycle issue, but I'm not sure I understood if there – are you suggesting that the variable lifecycle regulation's based on the intention of the object or function?

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

So, I'm saying that when you include upgrades in your definition of Health IT, I think that we would want some discussion about what that – what upgrades means and, there are upgrades of software that relate to sort of the function of the software. But there are also upgrades that relate closely to the medical use of – or sort of directly related to the substantive health information, as opposed to sort of the function of the software as software and we'd like to see additional discussion of that in the context of this definition.

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

So, this is Meghan Dierks. Maybe, if I can take the liberty to give a specific example that might help illustrate what I think you're talking about, and I'm violating my first rule, which is, be general versus giving specific examples. But is this what you mean, that let's say, for example that our taxonomy group decides that something that functions like A is within scope. Might we also want to discuss whether or not the larger group should talk about the need to regulate, for example, whether there should be mandatory exception – mandatory acceptance of software patches, for example. And I hate using that specific example, but as it is now, if one acquires a software device that's used for healthcare, you really – the purchaser is at liberty to reject any kind of software corrections or software patches that come along. And there's no responsibility or formal requirements around that, it's in essence optional. But that would be one example of whether or not we wanted to recommend that the larger group talk about risk and regulation around sort of the maybe long-term maintenance of your software. Is that – did I understand your comment?

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

Yes, that's exactly it.

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

Yeah, okay.

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

And I also had – the term of patches, but that's exactly the kind of thing that we have in mind. Yup.

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

And Meghan, I think I – this is Elisabeth, I think I also communicated to you that we need to, when we start making those cuts, thinking about is the patch for security, for privacy or for patient safety –

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

Yes.

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

– fixes. And I think that may put it little more simplistically or just for ease of use.

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

Yeah, it's funny, because I – I'll just make one sort of off-handed comment about that. I wish that patches easily fell into those bins, these sort of up –

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

Right.

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

– these periodic releases though tend to address a whole wide range of things, some of which can be sort of safety related and some may just be desired enhancements that have been on –

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

But that may be where the – depending on where we categorize the Health IT item, where it doesn't matter what it's there for or what it's fixing versus on the other end of the spectrum, where it has significant implications, no matter what it's fixing.

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

Yeah.

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

This is Meg Marshall. So I have a question around that. I suppose that I would – some difficulty in trying to anticipate the reasons that one might receive the patch, whereas a more general approach such as anything that would materially or substantially impact the intended function. I think that is in line with what we currently see for the 510k process around modifications to medical devices. We could look at something similar which is that the HIT developer would have the option of reviewing the change and being able to determine whether or not this is a material or substantial change. That way we as a group don't have to worry about whether it – if it's for patient safety it's in, if it's for patient privacy it's out, we don't have to make those types of determinations. We can just say, at a higher level if it's substantially different than the one that you had before, you're going to have to go through this process.

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

So Meg, this is Meghan Dierks, just a statement that you made kind of brought to mind one other question that I want to put out for the group to talk about. My understanding, or my interpretation or my understanding of the traditional regulated products are that the FDA regulates the manufacture, distribution and those types of things of these products, but in – once in the end-users hands, they do – none of the regulations tend to impact that. So in other words, using a surgical tool as an example, the FDA might regulate the tool and its manufacture, distribution, repackaging, reprocessing, but wouldn't – the regulations would not extend to how the doctor uses it.

Now, in the case of the task that we're facing, I just wanted to maybe have it out there, discuss it briefly and maybe we put it away completely, but at least put it out there. Would we consider the scope to be similar, in terms of we want this – as we're thinking about what's in scope and what's out and what we would put on the list of taxonomy as far as the types of things that need to be considered, do we want to frame it in terms of just the manu – from the manufacturing or do we also want to think about it in terms of the purchaser? So, that was not so eloquent, but maybe a better way of describing it is do we also want to make recommendations about – that what should be considered from a risk assessment and regulatory standpoint should also include what a healthcare entity, like a hospital, can do about complex configurability or altering software that was purchased, sort of self-altering it.

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

Yes, this is –

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

This is Matt Quinn from – oh, go ahead. I'm sorry.

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

I was just going to say an emphatic yes. We absolutely need to understand –

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

Yeah.

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

– because as a software developer, I'm not – I don't think I mentioned, but I'm with Cerner Corporation and we do provide health information technology. And I can tell you between two client sites, there's so much customization that's possible and it's true that it might create, or might be perceived to create a patient safety event at one site, would never come close that the other site because it's been customized and changed and perhaps the users have been trained differently. So there are a whole slew of things or activities that happen, even once the software's been deployed, that can certainly impact whether an activity is – the patient safety risk associated with that. Absolutely.

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

This is Matt Quinn from FCC and I would echo that, and maybe a way to think about this is, in terms of a variety of continuums. So on one extreme of what we're talking about, we're talking about pure consumer product, so health apps that are used only by consumers and only themselves. Then there are products that are used by consumers, people and clinicians and then there are products that are only used by healthcare professionals of some certification or degree. There are – another continuum is around things that are purely off the shelf and the that the end-user has no ability or capability of customizing. And then, to the other extreme, which is I think characterized by a lot of healthcare environments, where it inherently needs to be customized in order to work in a particular environment.

Another continuum is around stand-alone stuff that sits there and doesn't interact with any other systems, whether they be Health IT systems, medical devices, networks, ya-da, ya-da all the way to stuff that has to be integrated with other things for it to work, and is completely up to the end-user or the purchasing organization to implement. Another continuum is where Health IT or systems are communication computer-to-computer. Another is where the human-computer interface is inherent in what's going on. And so I would just throw those out there as – I mean, I don't know is that what a 4-dimensional set of constraints to help narrow what we're talking about. And I would also throw out that what we're really talking about is information and communications technology and complex sociotechnical systems. And I think this is one of the real challenges of getting our arms around this, in that this isn't just products, this is implemented stuff and it's not just professional products, its consumer products.

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

So Matt, that was great. This is Meghan Dierks again. So does that – so I think what I'm hearing then is that the taxonomy should probably not be limited to just these products are in or these products are out. It should also say the work of the larger group, in looking at risk-based regulatory framework should address these products, these other aspects or dimensions of information exchange and these aspects of say the lifecycle management of the products. Is that a fair assessment of what we've talked about?

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

This is Matt. I agree, but I'd love to hear other folk's perspectives.

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

So this is Todd again –

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

This is Drew Hickerson.

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

I think, I agree 100% and I think it's very important for us to identify these different dimensions because whenever you're putting together, for example, a risk-assessment framework, you need to have these perspectives in mind to think through the different aspects of how it might be applied. So, more important than anything I think, is to give a good set of these on down the road to the other groups.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

This is Patty. I found Matt's comments helpful also and also whoever was speaking earlier about software. What I was hearing was two really important things, one was the products as shipped versus the products as used and the second thing that I was hearing was the recognition that some of our risk assessment needs to be tied to both context as well as the nature of the user. Other comments?

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

This is Drew Hickerson. And I just have one thing to add on – the fact that it's not just the intended user or the expectation of the user, but I think it's also the manner in which that user receives the product. So I think there's a different expectation on the fact that the consumer, if they receive that product on a public market, such as say an iTunes store or an app store versus they receive it from a provider themselves. I think that the level of expectation varies.

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

This is Meg. I'm not sure I would agree with that statement, simply because if we looked at trying to remove the form from the function itself, regardless of whether this is used on an iPad or it's used again on a desktop PC. I'm not sure that it matters a whole lot where it comes from, if it's from – store or if I have an in-person health rep – I think that it falls within that same form does not equal function suggestion.

**Steven Posnack, MHS, MS, CISSP – Office of the National Coordinator**

This is Steve from ONC. I think, and Drew correct – I'm sorry if I'm putting words in your mouth, but I think what I heard from your concept was that there's a level of trust maybe as a dimension here. That if I go to my healthcare provider and they say to me, here's a particular thin – software application that you should use, they may be in a position to have vetted that beforehand, as opposed to like me just going on and downloading Angry Birds for Healthcare.

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

That's correct. And I think another example is, for instance, if you go to the iTunes store and you download say a fitness tracker. You don't assume that your healthcare provider necessarily has access to that information or if they become alarmed at some inaccuracy, they're going to contact you. Whereas if your healthcare provider directly provides you that application, yet that application is not connected back to a system that that provider has access to, well, your level of expectation is much different.

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

I'm not sure – I don't know if we have any providers on the phone, but, that seems like an awful lot of responsibility for the provider to take on in vetting and understanding the solutions that may or may not be tied to what he can offer or what he's vetting.

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

So, this is Meghan Dierks –

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

And I guess the quest –

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

– and I happen to be a provider –

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

But I guess, this is Elisabeth and I guess the other question though that comes up is that so just because I got it from iTunes, I – if you think about the number of people that now have iTunes things and they're downloading, their intelligence level may not be at a level to make those – that kind of a decision and they may assume that if it tells me something that I am getting clinical direction, and then the potential risk. So, that's – I think that's part of what we have to make sure we understand, what is it intended use and how is – and then we have to at least think about the potential use. I mean that's what we in the medical device area, even with all the smart doctors, we have to make sure that we think about those off-label or those unintended uses in part of our risk assessment. And I'm sure Bakul is probably would agree with me on that side.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

This is Patty. I think that last point is particularly important about who vets and what people expect has been vetted. It's about 20 to the hour and we have about 15 more minutes for this level of the conversation. I want to take a minute to take – ask you to call your attention to the second page of the taxonomy handout. There were a potential 12 options identified here, most of which seem to have been addressed implicitly or explicitly in our conversation that include aspects of scope based on functionality, types of users and the desire to explicitly limit or make any specific statement. Can I ask if there are any comments about the possible scope options, things we should take off the discussion completely and say we absolutely don't even want to go there, or do these all remain relevant to all of you?

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

This is Meghan Dierks. I feel like the scope options are good, I don't know if we're going to include all of them or if we're going to emphasize one versus the other.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Okay. Any other comments on this?

**M**

This is – one thing that, to go back to the comments and discussion before about specific names of applications having specific definitions and/or some being terms of art, I think that the more that we talk about function and use and description of what they do, rather than, for example, a specific technical term, will be better. Because, we've been talking about electronic medical records for a long time and exactly what constitutes one is still a term of art.

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

This is Rich Eaton. I'm thinking that not necessarily excluding any of these scope options, but I do believe that the one that states about health IT's functionality/purpose for use or why it's used fits in well with potentially how one would assess the risk for a particular application. So, it's certainly, I know we've talked about it today, but I think those two go together well and I think the regulations group would be helped by this kind of making this foundation. So, certainly should keep that.

**W**

This is –

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

Yeah, this is Todd. I'd just say, I agree with Rich and the items one through C are kind of scary, like black holes, you could descend in there and never find your way out.

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

This is Meg Marshall. My comment around this scope, actually I could tie back to my earlier comment. I could see a valid approach as far as the taxonomy proposing a large definition or a large boundary, if you will, and then having the risk assessment folks come back and maybe categorize within that. So taxonomy says, this is the broad level of things that we are considering, but then the natural inclusion or exclusion happens based on that risk assessment that occurs within the next steps. I guess that was more of a question than a statement.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

It sounds like you're making a recom – I mean; you're making a consideration around both the taxonomy and the processes by which the taxonomy gets applied. Is that accurate that we want to – we're making this...

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

I think an obs – this may be a general observation that there might be some interplay between the two and that our definition may end up getting – the scope may end up with that consideration, occurring naturally, based on the risk assessment discussion.

**Steven Posnack, MHS, MS, CISSP – Office of the National Coordinator for Health Information Technology - Policy Analyst**

Patty and Meghan, this is Steve, from ONC. May I make a potential suggestion?

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Sure.

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

Sure.

**Steven Posnack, MHS, MS, CISSP – Office of the National Coordinator**

Okay. So, I've been listening and it seems like in terms of maybe a framework for the taxonomy for folks to think about, and this is just a proposal to toss on the table, it sounds like we could kind of walk through, and I think in kind of tables here. So the column titles that I have, a column would be who, the next column would be the setting that the health information technology is used in, the next one would focus on the lifecycle and the kind of roads within that would be the different points in the lifecycle. The fourth column would be kind of why it's used, what's its meant to do, and it seems like underneath each of those, the group might be able to frame it's thoughts about what your best feelings are for what you'd like the other groups to talk about. I don't know if that would be –

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

I think that's a really helpful starting point. What I also heard was the customizability, which might fall under lifecycle or might be a separate column and also the source, for consideration. Whether we want to consider that getting something from iTunes or Shareware program from a public open-source website is a different kind of a risk factor than getting something that is shrink-wrapped from our clinician.

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

Well Patty, this is Meghan Dierks. So that's actually not a – that's actually a very good point in that the current, for medical devices, the current framework is that if I'm in my garage and I make something, I happen to be a surgeon. If I'm in my garage and I make something, as long as I don't sell it or package it or advertise it or anything, I in theory can use it on someone –

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**  
Right.

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

– whether it's safe or not, and that's the traditional framework. And I think one of the things we do want to put on the table then is whether or not we would – one of the things we want to have as under maybe a column header is, maybe it's under that who column header, which is not who uses it. But maybe who creates it and whether it's created for a single time use or created for the purposes of marketing and distribution and profit, or even non-profit.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

I think this is going to be a point of discussion that we're going to have to be open to hearing a number of perspectives on. We are coming up to the last 5 minutes of our conversation time, and then we will go to a public comment period. So, let me turn back to the group to consider the last aspect of our straw dog, which is, potential differentiating criteria, and what's composed again sounds quite similar to what I was hearing here; function, intended users, whether we have hardware, software or a service and whether or not something is mobile. Are there –

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

So this is Todd. Just one thing, I've heard munged a bit together is the use, in terms of what does it do from a technology standpoint, but also obviously, we're thinking from a care provision standpoint. So we want to make sure, I think they're two different aspects. I want to make sure they keep those separate.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

I'm sorry, could you differentiate those two aspects again, I don't think I got it clear enough.

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

One is functionally what does it do, like the list that you have here as the first bullet.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Um hmm.

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

The other is: What is its intended use in terms of providing some healthcare purpose? So what is the clinical intent or what is the healthcare intent of it.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Oh, I see. I see. Thank you, that's helpful. Other comments?

**W**

I guess I have a question regarding the fourth bullet, whether mobile or not. That would seem to fall within the form, not necessarily the function, and probably worthy of a discussion, but are we looking at including trying to understand the different types of mechanisms that make – that the function could be available on, such as mobile or cloud versus desktop, things like that?

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

So this is Meghan Dierks. I tend to want to be, just my personal preference is wanted to be agnostic about what you're describing as the form, and instead look at the functionality. I think this is where there are – there is a slightly different risk profile when something relies on a wireless – the wireless technology versus a stand-alone. So the only thing that I see is that if a particular product sort of was being evaluated for its risk and the regulatory framework that it might just have a slightly different set of additional constraints or requirements if it was also – if it also had this interdependency with a wireless network, for example.

(Multiple speakers)

**W**

Just a point – so, around the wireless part, are you thinking that would be more what we would traditionally have seen from the FCC and like band, megahertz and things like that and communication mechanism or, I guess I'm trying to understand a mobile that may be more risky than another one.

**M**

Well in terms of, for example, visualizing an image, it's one thing to visualize an image on a monitor that transmits the data where a physician looks at it, it's quite another to visualize this on a mobile device. So, we should keep that in mind.

**W**

Okay.

**M**

The mobile device doesn't have the clarity of the image; it doesn't have the detail, so we need to keep that in mind. Information is different, in effect –

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

Yeah, I was actually, this is Meghan Dierks. I was thinking more of the former versus the latter. I think there – these are two separate, equally important issues. One is, is there a dependency on the function or safety of the product if it also relies on some other technology like the wireless – like the bandwidth of the wireless network. The second is just the hardware on which the software might be functioning might have some depend – the safety might have some dependency on the size of the display. That's kind of an aspect of the end use of it.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

I think it sounds like –

**M**

The display, ambient light, there are a whole host of things.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

This is actually sounding to be like a very important point that we're going to have to spend some time on because it has to do, I think, with the – how tightly coupled the function and the form are and there may be different risk appraisals if the form and – the form factor and the function are very loosely coupled versus ones that are very tightly coupled. And it sounds a little bit like echoing a conversation we had about 30 minutes ago about whether a system – an entity was embedded in the larger system or free-standing and you could envision both and I think the radiology example is a very good one. We have time for one or two more comments before we go to public comment, are there any other comments that that people need to bring forward?

**W**

One thing that I would be curious about looking into, again around the differentiating criteria, we talked about the integration with other systems. So, if something runs off of, I'm just going to throw this out there, like a Microsoft for example, what would the impact be or the reach, the unintended reach if Microsoft was one of the products that was used to create what essentially ends up being underneath the framework. So, it may not be differentiating criteria, but maybe just something that we have as a discussion point.

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

So, this is Meghan. So you're thinking about it's important for us to figure out a boundary point, right, so do we go all the way back and start talking about or including the platform on which the separate product was – am I understanding that correctly?

**W**

I think so, yes.

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

This is all about putting a – yeah –

**W**

– the integration and –

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

– the floor – yeah, putting a – coming up with a floor on what we're discussing.

**W**

Yeah.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

I think that's really helpful. Let me turn back to the – I don't know who was leading the program at the beginning, but to open for public comment. So how do we proceed with that?

**Michael Lipinski, JD – Office of the National Coordinator**

Patty and Meghan, so you're – the workgroup members are not required to provide responses to the commenters and we try to limit every comment to 2 minutes each. So, if you guys are ready for public comments, I think, is it Caitlin or the operator who would open the lines to the public comment.

**Public Comment**

**Caitlin Collins – Altarum Institute**

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

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

Thank you very much. I will give my thanks – this is Patty. I give my thanks to first of all, our workgroup members, very good conversation, thank you for being so invested, thank you for your flexibility and whatever it took to get you to be here on this call today, I appreciate that. We will speak to you again on the Tuesday after Memorial Day and I want to thank the staff for your assistance. Meghan and I will certainly meet at least once before then and we'll have some synthesis of our notes together to share with you. And Meghan, I'll give you the last word.

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

Oh great, the last word. Well, one other thing that I'd just invite anyone who participated today in the discussion or really just took more of a listening role, if you have things that you want to put in – any notes that you want to put down and either distribute to the subgroup all together or channel them through our coordinator or through Patty and myself, I think that would be great as well. Just want to encourage you and open you to do that, keep you open to doing that.

**Patricia Flatley Brennan, RN, PhD, FAAN – University of Wisconsin at Madison**

And thank you very much, I want to wish everybody a happy and very safe Memorial Day weekend, which won't be this one, it will be the next one. Thank you so much, thank you to the staff and thanks Meghan. Bye now.