

**FDASIA Workgroup  
Regulations Subgroup  
Transcript  
July 8, 2013**

**Presentation**

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

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 Subgroup on Regulations. This is a public call and I will just remind everybody to identify themselves when speaking for the transcript. I'll go through the roll call. Julian Goldman? Brad Thompson?

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

Here.

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

Thanks, Brad. David Bates? Todd Cooper?

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

Hola.

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

Thanks, Todd. Anura Fernando?

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

Here.

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

Thanks, Anura. Lauren Fifield? Rob Jarrin?

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

Here.

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

Mo Kaushal? Great, thanks, Rob. Mo Kaushal?

**Mohit Kaushal, MD, MBA – Partner – Abdare Ventures/National Venture Capital Association**

Here.

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

All right. Joe Smith?

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

Here.

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

Thanks, Joe. Steve Posnack?

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

Here.

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

Thanks, Steve. Jodi are you on? Okay, Bakul Patel?

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

Here.

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

Thanks, Bakul. Matt Quinn? ONC staff members, Mike Lipinski?

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

Here.

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

Thanks Mike. And Kate Black?

**Kate Black, JD – Office of the National Coordinator for Health Information Technology**

I'm here.

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

Thanks, Kate. And for the full FDASIA Workgroup members Anna McCollister-Slipp?

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

I'm here.

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

Thanks, Anna. And Jeff Jacques?

**Jeffrey Jacques, MD – President, Neonatal Solutions – Aetna**

Here.

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

Thanks, Jeff. Mike Flis?

**Michael Flis - Director, Diabetes Management Systems, Regulatory Affairs - Roche Diagnostics**

Here.

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

Thanks Mike. Are there any other Workgroup members on the line?

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

Keith Larsen.

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

Great, thanks, Keith.

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

And Elisabeth George.

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

Thanks, Elisabeth. I'll turn the agenda over to you Joe.

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

Well, terrific, hey, so thanks to Brad and Julian for asking me to kind of start this off as a kind of a bigger picture discussion. I think I'm going to rip through some slides pretty quick to try to drive some stimulus, please understand none of this is meant to either foreclose or conclude this is really just meant to kind of stimulate some additional thinking. I think where we've been is I think readily understandable from our call in the Federal Register. I think you've all seen this announcement but I thought it was good to point to a couple of things.

Early on in that call in the Federal Register it talks about seeking broad input from stakeholders and then as we got down to our particular Workgroups under the Regulatory Subgroup the questions posed are the things we've largely been trying to answer with Brad and Julian's leadership and it focused really on current areas of regulatory overlap among the FDA, ONC and the FCC, and what are they, encouraging us to be as specific as possible, and if there are what actions we could take and I think that has what – it's that phrasing which has driven us to focus so much really on inside the box if you view, you know, FDA, ONC and FCC as kind of the three vectors of a box, you know, how is this being handled in the moment. And, so this I think is an opportunity for us to be a little perhaps more blue ocean or freewheeling and say, what, you know, if we think broader what else could we think about and I don't intend to be the gatekeeper for how broad our thinking can be but rather with input really from Donna, Lee, Lauren and Anna, David Bates, and Martin Sepulveda the folks who kind of offered some thinking and I've tried to capture that as much as I can in the following slides to kind of drive some additional discussion.

And so we've been through the three regulatory systems and I'll briefly summarize that and today we're really here to see how much broader our thinking can be. I think this is stolen wholeheartedly from Brad's last summary and I think it speaks to where a view would be that the FDA has some opportunities where, you know, perhaps there are some remaining ambiguity and I think we talked about this at the last call that ambiguity isn't necessarily a bad thing it can provide leadership or at least latitude for innovation and that perhaps there are some opportunities that simply need to be fixed as Brad would point out they're broken as written in the law and I think here we're looking at, you know, that particular list, I think that's been very helpful, but again, it's from inside the box, it's from, you know, what's really happening at the FDA at the minute.

And I think we've seen that there are some important things perhaps most notably unclear guidance at the moment around mobile medical Apps, but we're all told that's coming quickly. Around ONC, you know, we've done the same exercise and I think Brad's appropriately drawn attention to the fact that we – in ONC's regulation there really isn't yet an opportunity for legal enforcement as brought out by that first issue, and then this vexing issue of assuring safe configuration at the individual location winds up being an important consideration as well.

And then FCC issues I think not so many, but really a notion of post installation surveillance, how can the FCC manage that and I think so this has left us with each of the individual agencies what are the potential limitations so the approach as it stands. And then appropriately drawing attention to some cross agency issues and here reporting of safety issues, I think we had a great discussion from Julian about alternative reporting structures what they might look like and in talking about this over the holiday weekend, a comment I'd make for Lauren and I'll speak for her until she joins the call here under the reporting safety issue.

**Lauren Fifield – Senior Policy Advisor – Practice Fusion**

Hey, Joe, I'm here, just wanted to say.

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

Perfect.

**Lauren Fifield – Senior Policy Advisor – Practice Fusion**

But keep speaking for me but I'm here for the record.

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

No, no, no so please, I mean, you had an important comment to add on this, kind of the first row here reporting safety issues and the potential role for AHRQ.

**Lauren Fifield – Senior Policy Advisor – Practice Fusion**

Oh, go for it.

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

Did you want to say something about that?

**Lauren Fifield – Senior Policy Advisor – Practice Fusion**

Well, I was just going to – keep going and I'll talk about it later.

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

Okay.

**Lauren Fifield – Senior Policy Advisor – Practice Fusion**

But I just wanted to say for the record that I was here, you're doing awesome.

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

Okay, terrific and so, you know, the next was this notion of interoperability issues and I think we've all come to appreciate and understand just how central that is as we try to go forward and I won't belabor this because I think we've covered much of this, it's really been our charge to look at the three vectors that exist, the FDA, ONC and FCC and what the issues or limitations reside within those organizations and as we think about an amalgam of those regulatory postures what issues are left to be resolved. But, perhaps and I'm going to now take off from I think Brad's last slide from the last meeting, is can we think about a bigger picture?

What else might need to be done or if in the rather unrealistic and naïve viewpoint of if we could start all over with a blank piece of paper what would we really want and maybe that approach can drive us to look perhaps differently at the pieces that remain to be fixed in each of the organizations and reveal some other opportunities for regulating in a way that perhaps gives greater safety but also greater latitude for innovation.

And so, here's my attempt at some graphical humor it's the best I could do over the holiday weekend, maybe we should try to think a little bit outside the box. And so here's I think an open question, what elements of regulation are required to drive, encourage and allow health information technology and mobile medical Apps to achieve their full value in reducing medical errors and then making crucial patient specific health information available when and where needed, and report, track and aggregate patient data within and across organizations.

And those aren't all my words, you know, the ONC issued its health information technology patient safety action and surveillance plan and I've largely borrowed some of the phrasing out of that July 2<sup>nd</sup> issuance to try to put us at least in line with some current thinking around this particular question and then what elements need to be avoided because they impede, frustrate or discourage innovation and don't add materially to safety. I think that's the kind of conversation we ought to have at this point and perhaps gives us an opportunity to look at what other opportunities there are as we look back at the three different organizations and their strengths and weaknesses.

And so, I wanted to offer a little commentary around safety and HIT and maybe this will spur enough energy on the call that other people will start talking, but I think it's important to make a critical distinction between causing and allowing or incompletely preventing harm, you know, I think much of the safety organizations that we've built are all about attenuating circumstances where harm can be caused and so we look a lot at the medical device, regulation around the FDA and we're really talking about minimizing the harm of those products.

Health information technology offers I think more of an opportunity to resolve safety issues than primarily be a cause of their own and so maybe that puts this, having us look at it in a slightly different posture and I think this point and I'll apologize to Jodi if she's on the call, because no one likes to be quoted, but I think what you said here is something many of us would agree to that so far the evidence we have doesn't suggest that health information technology is a significant factor in safety events and that said of course, ONC is very interested in understanding where there may be a correlation and how to mitigate those risks, but I think we have to perhaps have the opportunity to look at this more as how do we enhance through regulation the availability of a potential solution and less about how do we mitigate the intrinsic harms of it.

And so, with that doubtless opportunity to reduce harms we might even get to a point where if we induce regulatory delay here we may be paradoxically viewed as causing some of the harms that we could otherwise mitigate by the availability of this technology. So, maybe that's pushing it too far, but I'd like us to consider that, you know, while in medicine we say first do no harm in other circumstances it's the notion that first one must act and maybe we're biased a little bit more towards positive action here because of the enormous opportunity to impact adverse events that are occurring in the healthcare system not necessarily caused by health information technology. I want to stop for a minute...

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

Joe, this is Anna...

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

Yes?

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

I just wanted to say I don't think that's overstating the issue. I mean, I can think of several personal instances in which I don't know if harm would be the right word but certainly making it difficult to do certain things that would make it easier to provide better self-care is the way that I would describe a lot of the Health IT stuff that I interface with as a patient with Type 1 diabetes.

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

I wonder if – thank you, thank you Anna for that comment, I wonder if anyone else has any commentary that maybe this is just a qualitatively different beast that we're trying to regulate and maybe our safety concerns are perhaps directed at the healthcare system which has many, but health information technology as a vehicle for reporting and preventing but not necessarily causing or it could be I'm alone on this call.

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

This is Anura Fernando here, I just wanted to mention, you know, while it's true that this particular technology can certainly help improve the safety situation across the system, another view to consider is that whenever you look at an overall system and you introduce new elements whether they're beneficial elements like risk controls themselves or just functional elements those elements themselves may have unintended consequences in other parts of the system.

And so it may not be just the HIT itself but the effects of the implementation of HIT on other parts of the system like the medical devices themselves or other infrastructures that may need to be considered. So, you know, looking at it not only from a functional perspective what the Health IT is there for, but also considering the impact that having that beneficial functionality might inadvertently cause on existing regulated portions of the overall system.

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

I think that's a...

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

This is Keith Larsen.

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

Go ahead.

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

I'd like to pick up on that idea a little bit, it makes me shudder a little bit because the idea that – well, here's why, because it seems to invite regulation into the implementation process which I think that it would actually do more damage than help and when we're looking at this thing – I mean, it goes back to our idea of status quo, what is the problem we're trying to solve and what is our solution and what are the possible unintended consequences of our solution.

And what we have is, with Jodi's quote and from the IOM report, is that there is not a lot of evidence that what we're doing is causing direct patient harm with these systems, we clearly have to test for these things and everything else, if the only justification was that we have patient safety issues that it probably is – I don't know if you adjust the whole regulatory system. I think you're adjusting the regulatory system because the fundamental character of this, like you were saying Joe, is different and should be looked at it in that light and create a regulatory framework that meets that type of characterization or that type of product.

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

Well, it's not surprising to me that we're going to have some difference of opinion and I'm trying to – by virtue of being perhaps a little – taking a polar view here try to stimulate some of this, but I, you know, on this point I'll probably own this point of believing that, you know, if in fact the presence of health information technology has unintended consequences with the behavior of some regulated medical devices that perhaps the onus falls on those regulated medical devices and their interaction with the health information technology system and not dominantly on the health information technology system itself, but I think, you know, this will obviously be an area for additional commentary.

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

So, Joe, let me just add one piece here and I know in a lot of the discussion, this is Todd, in a lot of the discussions that we've had over the last few years as we've looked at this space of how do you manage network health technology. A key component of this interface between just generic Health IT technology and specifically regulated medical systems is, just understanding what is that reliance upon and utilization of those services and once you – and documenting that.

And then once you do that it provides you the information that you need when an event does occur to be able to go back and drill down saying, well what exactly happened or to be able to envision up front what are the kinds of sources or hazards that exist out there that might be results from the failure of some IT component somewhere in that system and a large part of the issue today is the fact that we don't understand those linkages and we don't understand what kind of critical capabilities are kind of reliant upon their operating in a specific way. And so at a minimum just understanding what those requirements are will help us a whole lot. That doesn't mean you have to regulate every piece of it, but at least understanding those linkages.

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

That's a good point. Well, at peril of moving us along, but at the same time trying to be perhaps a little more provocative I'll take us to the next slide and this is meant to provide kind of a relevant context for other things that are happening and the relative regulatory intensity around them and so cigarettes are responsible for 1 in 5 deaths they are sold in grocery stores and our regulatory posture, as recently approved by the Supreme Court, is that we can now have graphic warnings about their use, right?

So, these are products that are not designed – at least I'm unaware of the design elements that are meant to make people better or to reduce harms and yet our regulatory posture I would argue is remarkably liked and we're talking about, you know, flammable drug delivery systems that deliver carcinogens to the lungs and, you know, our regulatory posture is one of only providing graphic warnings. In another system, which experiences real crashes, but perhaps, you know, a much more material and tangible crash, automobiles we look at ten million crashes a year, we have 30,000 fatalities it's the number one cause of death in individuals under the age of 34 in the United States and our regulatory posture is that we provide relatively light, and I would argue, minimal operator licensure, we have some safety rankings by NHTSA and then some post market surveillance. But again, our regulatory posture I think given the magnitude of the adverse events has to be considered as remarkably liked.

When we look at hospitals we appreciate that somewhere between one and three and one and seven patients are harmed giving rise to what some estimate to be 200,000 preventable deaths, we have a very complex regulatory posture over hospitals, over practitioners of healthcare and over the technologies used within them, but in this setting I think HIT could be viewed more as an objective reporter or a potential solution than a proximate cause and so the question would be what is the level of appropriate intensity of regulatory oversight over this actor in this system given the context of the regulatory intensity over other things we live with where the, you know, the proximate cause is much more clear and the magnitude of the challenge is perhaps even greater.

And so, I'm just trying to – if we're going to step back at a big picture I tried to go to the largest I could grasp in terms of giving some rationale for a level of intensity of regulation in this space. I'm hoping that that stimulated some thought.

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

Well, this is Brad, so you're trying to be provocative so you provoked me I'm going to say something and that is that, you know, as we all know law and policy are a bit of sausage making and the fact that in other instances we've, I'll argue, under regulated cigarettes to me is hardly an argument for suggesting that we therefore ought to under regulate everything else.

What we do in this nation with regard to cigarettes, I think personally, is deplorable, it's not supportable by any logical or economics-based argument, it's somehow rooted in a freedom that people ascribe to the right to smoke and I don't get it and I don't find it in the constitution. So, to have that as an argument that we ought to deregulate other areas I just have trouble with that, because it seems to argue too much.

And also it seems as though you're kind of focused on this causation argument and, you know, causation – in the law causation is very different from in engineering and you and I have had fun conversations comparing how a lawyer and an engineer approaches things. There is a concept in the law, causation called the “but for test” which is but for the action that occurred, for example someone messing up and incorrectly coding software would the injury have resulted, and that's one test.

And then proximate cause is a different test and proximate cause is are you as a developer of software for example close enough, do you owe it a duty to the ultimate user to take sort of heightened precautions to ensure that errors don't occur, it's a different question and so I'm struggling a little bit with this discussion in terms of helping to discern what the right answer is, so I'm going to shut up there.

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

No, I think that's – so Brad, I think that's great. I think there are different perspectives, I think lawyers would bring one and engineers would bring a second, and physicians would bring a third, and I think speaking as a physician for a moment I think the notion of if we wind up with heavy-handed regulation that slows the availability of a cure we feel like harm has occurred to patients and I think at one extreme one can view health information technology as an opportunity to cure or prevent some of the harms that are occurring in a complex web of our healthcare delivery system and just how – where to place that slider in terms of regulatory oversight.

You know, I don't know that we're talking about under regulating it and my giving you the opportunity to comment on cigarettes and the way we fail to regulate them is merely to say on one hand we should not look at a potential for health information technology to provide beneficial impact in healthcare with more regulatory oversight than we look at things which are really I think perhaps less well intended or that we do so at some peril because slowing a potential solution down facilitates the persistence of harm.

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

So, I completely agree with the first half of what you said, I have to disagree with the second half, the analogy to cigarettes just in my mind doesn't add anything to the analysis it is absolutely true that if HIT can improve the quality of care then time to market is an extremely relevant factor for any regulator to consider, absolutely agree with that.

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

This is Keith I'd just like to comment too. I think that what I get out of this, and I'm going to leave cigarettes alone, is – and what was put in our charter is to have a risk-based system, in other words we're responding to real risks and so it is a little bit reactive. I know that we try to be proactive in health and try to imagine everything that could possibly go wrong, but at a certain point it is a relative risk system.

You're looking at what you're trying to solve and what your cure is and the unintended consequences, but I don't – you know, we have to be to a certain extent looking at real problems and what are the risks of those real problems and the regulation should address real problems.

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

I think that's great.

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

This is Anna. I mean, I think these are really helpful examples personally. I mean, anything we do we're going to miss some sort of unintended consequences not that we're doing anything we're just providing a perspective that other people will do something, will actually, you know, write the rules.

But, every action has an unintended consequence as well as an intended one and, you know, if we – using the car example or the highway example that Joe provided, if we decided to have much tighter regulation on driving or, you know, other elements related to highway safety we may have a lower incidence of death but what would be the other consequences a slowdown and lack of mobility amongst, you know, large sectors of the population so that they couldn't get the vital services or needs, or whatever.

Lack of, you know, slowing of the commercial infrastructure, I mean, there are all – I mean we don't need to get into like the specifics of every analogy, but I think the same thing is true here as well and again in this instance speaking from the perspective of a patient the lack of – or the fear of innovating, at least what I'm told by the device manufacturers or the requirement to go through, you know, a Class III approval for even minor modifications to data entry points, is preventing them from doing things that will better facilitate patient care.

So, these are real patients that are taking drugs that could be very fatal and managing diseases over a lifetime. So, it's slowing that process. So, there are real consequences but those aren't necessarily measured currently. It's the opportunity cost as well as the potential risk and I would argue that, you know, we need to understand the potential risk in certain cases, but that the benefit – that we should give significant thought to what isn't happening that would make it better for patients to care for themselves or physicians to care for patients, or for the market to emerge in creative stimulating ways.

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

Great – great point.

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

So, Joe, this is Steve Posnack from ONC.

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

Yes?

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

I think the one thing that is perhaps in the contrast that maybe resonating for folks, and the one thing that kind of jumped out at me was the direct to consumer aspect of these automobiles and cigarettes versus other areas in healthcare where there is some ability of someone in the middle to exercise professional judgment or intervene and I don't know the right direction to go in with that, but those are kind of thoughts that were occurring to me as – that might be helpful for you guys to tease out and see if there are differences that you think would be available for innovation purposes.

The direct to consumer space obviously is something that we see potentially exploding, right, and whether or not there would be a different oversight expectation in that case with all the types of regulatory provisions.

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

I think that's a great point and I think it's one that's been made by the – you know, a risk and innovation group around, you know, in the risk matrix the notion that if you are providing information to, you know, the uninitiated naïve and perhaps undereducated consumer that you may run one level of risk, if you're providing that same information to an educated or expert consumer, or a healthcare professional with their own professional obligations and licensure, and the like that that risk is substantially and materially aggregated.

I think that has been captured and I think it's one where we're all best to remember that, you know, that in between often times, most times, perhaps almost all times health information technology has a learned intermediary on the other side and how learned that person is, is perhaps a debatable question, but for at least the overwhelming number of use cases there is a person in between that technology and an ultimate therapeutic decision, not always, as we talk about some of these close loops systems, but for the ones we're talking about here that aren't yet regulated medical devices I think that learned intermediary concept is terribly important.

At any rate, sensing a lull in the conversation trying to move through the innovation part of our responsibility and I've pulled out a couple of the drivers for innovation not that this is an exhaustive list but it's ones that I've kind of worked through here as they relate to the discussions we've had and so clearly for market-based innovation to occur there has to be identification of unmet needs, there is typically some novel capability that address the need, iteration of potential solutions with real world feedback and continuous improvement and then an actual market.

And so I'd like to develop those three themes briefly as to how they impact our work together, the first is the identification of unmet needs. Since innovators require access to the pain points of current processes it then I think flows naturally that the limitations of existing systems need to be transparently available if we're going to engender innovative solutions and so this notion of adverse event reporting and health information technology or even using health information technology as a vehicle for adverse event reporting of other systems.

I think the notion that that has to be publicly, timely, transparently available makes perfect sense for the innovator and it also aligns with the discussions we've had about safety concerns that there has to be this notion of transparency of limitations and errors and failures, it's a prerequisite for innovation that aligns with safety concerns. So, this strikes me as a situation where we're not balancing innovation so much and safety but we're looking at a vector which is perhaps parallel to each, but I'll be interested in comments to the contrary. Hearing none we'll move on.

Novel capabilities, feedback and continuous improvement. So, rapid cycle feedback is essential to turn a good idea into a good solution and so this I think also argues for timely, perhaps more timely than anything else, but transparent reporting. It also, I think, argues in this space for process capabilities of the vendors, specific process capabilities, design controls, timely responsiveness in corrective action and preventive action systems, verification and validation capabilities, and so this part, as we think about driving innovation it tilts more toward some familiar regulatory mechanisms or capabilities, quality system capabilities within vendors that are perhaps more familiar to a regulated medical device community than perhaps an HIT innovator, but I'm arguing that for the purpose of innovation those are quite helpful even if not requirements and interested in any feedback or commentary.

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

Joe, this is Bakul.

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

Yes?

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

On the first bullet can you expand on what you're thinking there? I can – so I'll tell you what I read and then you can correct or sort of expand on it. The way I read it is if a vendor is out there and he has rapid cycle feedback he can actually improve his product or change his product offerings. Is that going to be sustainable in a free market?

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

And so I think what would make it so that it's not sustainable?

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

Yeah, I'm curious on that too. I mean, again what we're saying is that the first slide when we look at the market is that we have a transparent and because it's transparent we have a pressure point for people to improve their software and now this slide really says that we have to have the ability to rapidly respond to those pressure points and do it in a sustainable manner, which gets back to the process.

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

So, Joe I think why I was reading the first bullet different from the rest, from the other two was the other two were more on product issues as opposed to product needs, general needs, user needs. The first bullet read to me more like user needs, new products or new product features.

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

So, I do think that in the space of – in this space and in many spaces when a product fails to deliver that's an opportunity for an innovator to create a different or improved solution and so I'm not distinguishing between an unmet need as like a virgin unmet need or an unmet need that arrives because of the failure of a putative solution. I think they're both still residual unmet needs.

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

Okay, I get it, yeah that makes sense.

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

I would add one thing, when we've had the discussion on this we've also talked about capturing and the ability to capture proposed enhancements. I mean, every vendor does that with their user groups and feedback mechanisms themselves, its proprietary to their own discussion and they don't act on every single one of them but when they start to see a pattern of need they do respond to it and you could do the same thing for your transparent, more open discussion of seeing what, you know, which problems have people identified that may not be specific to the product but are unmet needs.

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

Yeah, thanks Keith, got it.

**Lauren Fifield – Senior Policy Advisor – Practice Fusion**

This is Lauren Fifield, I think on this particular point and probably other points that are related to, you know, general transparency and reporting I think one thing that definitely needs to be underscored is that while I agree with Joe that, you know, Health IT can play a pivotal role in creating a rapid cycle feedback loop for adverse events and other things happening in the care space, there is also a really large cultural component that needs to be addressed in some way and it's not to say that it should be addressed through regulation, but certainly there are huge discrepancies between adverse event reporting in the inpatient setting versus ambulatory setting and then within each of those vertical there is a lot of variety in terms of process and procedure.

And I really think when it comes to rapid cycle feedback consistency is important and ubiquity of reporting. So, I think that's one sort of cultural element and then the other is that providers, health systems, organizations really want to do this. I think, you know, in some ways what, you know, I think I've said this sort of for other things too, that in other industries if a user wants something it's usually only resources, bandwidth and time that will constrain the developer from creating technology to meet those needs, particularly, you know, if they're aligned incentives.

And I think in healthcare it's a little bit wacky in that while providers of course want to be good actors and deliver the highest care there is reticence around supporting even if there are liability protections under the Patient Safety and Improvement Act, right? And, so I think kind of stimulating a culture where not only is there consistency and ubiquity in reporting but also it is so much desired to conduct this reporting to get that feedback to improve care delivery, patient safety, you know, reduction of adverse events that the users and purchasers of technology then go out to find technology that is the best at reporting, that is the best at providing feedback loops to the organization.

Because ideally what you want is you want the users to be asking for that so that we have that innovation not only to mitigate harm but to also use the Health IT and leverage it to improve patient safety and the delivery of care, reduction of adverse events, etcetera, etcetera. I know that, you know, it's a bit different and we make these analogies often, but, you know, in the car setting generally folks are really – will make purchase decisions based on safety, you know, and so I think there are huge, huge cultural things that need to start happening and I really see a role for CMS, provider organizations, the private sector and other stakeholders to sort of work in tandem with the technologists. So, sorry, rant over.

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

No, Lauren, I think that's a great point and I think your caveat that, you know, not all of this has to be done with regulation that perhaps appropriate incentives and I think we're watching as, you know, Medicare star ratings are starting to look into quality reporting and as we put more incentives in place for organizations to simultaneously report and improve their quality I think there will be a market need for those technologies that allow you to best identify where the gaps in care are and I think that, you know, I think we're all aware that health information technology is going to be playing right down the middle of that discussion and so it again just provides some impedance for speed and to the extent that's a surrogate for light regulatory touch in getting this technology out there to have all of its potential desired benefits.

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

I think that – this is Keith, as I look at your slides and the discussions that we've had I think that as we look at this and try to look at the balance on here it's saying that it's de-emphasizing up front a regulation that's targeted towards up front certification and premarketing approvals and everything else, and enhancing the reporting function on the backend and letting the reporting function itself serve as a feedback in governance of the front end of this and that's what I think that, you know, I'm seeing in the discussion, all these discussions and again in your slides.

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

I think that is a theme that's come up, you know, when I asked for, solicited input for this slide presentation I think David Bates sent me a note very much along that line that, you know, we need to discuss this notion of very light, up front premarket approval regulatory input and a lot of post market surveillance given the core capabilities of the underlying technology we're talking about and so there is an attempt to reflect that and I think if that's readily apparent I think that's purposeful.

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

Okay, thank you.

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

On this next slide the notion of aligned incentives by the purchaser, this is the notion that, you know, there has to be a market for this technology and a relatively unimpeded free market for this technology and so I postulated that for innovation to succeed the solution can't be arbitrarily impeded from entering the market via monopolistic behavior, kind of artificially elevated switching costs and constructed incompatibilities, and I think that immediately gets you to this notion of standards-based interoperability being a pre-requisite for innovation.

If you're going to have innovation that works you have to actually get products to the market and if in fact they're impeded because you wind up having to replace an entire hospital's systems infrastructure in order to get some new product offering there you've effectively quashed innovation and so this is the notion I think even Farzad I think mentioned this when we were in our face-to-face meeting this notion that interoperability is not just good for safety and efficiency it's also good for the innovator and I'm trying just to echo that point.

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

And this is Keith, we put that in – I mean, that has come up in our discussions too, because again it's exactly what you said, it lowers the impedance to get into the market. We're not exactly a plug and play market but we can be a little bit better than we have with these standards-based interoperability.

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

And this is Anna, putting on my Health IT entrepreneur hat I would wholeheartedly concur with that. I mean, it's just impossible for small players to get in to most of these systems just because they're monopolized by the big guys.

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

That's great. So, that leads me to a quick summary of those three themes. So, if I was trying to give a potential kind of provocative answer, what regulatory elements are essential I'd say timely, public and detailed reporting of limitations including notably the current unmet need of a toolkit for automatic reporting and searching, analyzing and identifying trends within such a collection of public reports. You know I noted with some interest that in the health information technology patient safety action and surveillance plan of July 2<sup>nd</sup> there is such a call for a challenge for the development, I think it's called the patient safety reporting challenge award, the notion that there ought to be these tools and we haven't yet fully developed them or even fully contemplated how well they'll work but they will enable much of this to take place.

The notion of standards-based vendor qualification as opposed to product certification, this I'm imaging will get some people talking or I'm hoping so, because this is a bit at odds with where we've been with Meaningful Use product certification and it's really talking not so much about each product but instead much like – and I'll argue a little bit that this is lot like CE marking standards-based vendor qualification up front and then let the market judge the product but let the regulator judge the vendor approach.

Then lastly, requirement for meaningful function, open standards-based interoperability, I might call to my colleague Brad on that second bullet and what you're – you know, how that sits with you because I know you're, you know, very much – I believe you to be very much in tune to this notion of product-based qualification and I'm wondering how it sits?

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

I'm still trying to wrap my head around this approach. So, in all honesty the way I approach thinking about HIT and what standards ought to apply is first with a risk stratification right? And so, that's kind of the missing piece for me.

If you're defining sort of all HIT as in one risk category and then suggesting that standards-based vendor qualification is sufficient for all HIT I'm struggling with that.

If you're saying we ought to start by parsing HIT into different levels of risk and for the lower risk categories, standards-based vendor qualification is sufficient I would say "heck yes" that makes sense to me.

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

So, that's good. I think I'm trying to argue that much not all, but much of health information technology does fall into that lower risk category where this would be, you know, an appropriate rubric, but again, I'm trying to be a fair bit provocative which would then lead I think an opportunity for the risk and innovation group to speak to those pieces of health information technology, which are then high enough risk to merit a different form of regulatory approach.

But this I'm suggesting for those where there is learned intermediaries where the information provided is not so unique as to be the sole point of failure, you know, I think there is only so much we can talk about in this call. But for the – you know, the bulk which is of relatively low risk where there is relatively great opportunity for having a positive impact this would be a rationale trajectory.

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

Yeah, that's the piece that's missing for me is the risk stratification of the HIT but within that construct this makes quite a bit of sense in coming, as you come from an FDA medical device background, very consistent with that approach of Class I, II or III and this is how Class I software would be treated. So, by all means it makes sense to me intuitively and every other way.

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

But I guess, can say something it's Jarrin, I guess I'm having trouble really following this only because it's so similar to the current regulatory framework which, you know, by the way is a risk-based system, you know, I keep hearing about how existing regulations are either tighter or stricter on Health IT and I don't necessarily see it that way.

You know, the existing regulations really the way that we should be looking at them is how they should be applied to new technologies and, you know, avoid, you know, ambiguity, you know, this is why we keep going back to this notion of clarity that we need clarity because we are dealing with a risk-based system. You know some of the things in the slide that you're mentioning Joe, you know, timely, public, detailed reporting companies do that now. Standards-based, vendor qualification I would argue that consensus standards are at the core of the FDA requirement.

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

Yeah.

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

You know, the part that I think is absolutely missing is interoperability and that's something that everyone has kind of punted on accept for the ONC specific to electronic health records, but unfortunately not on the medical device, you know, on the medical device side which is something that I think we all can agree on is really sorely needed. You know, and I mean...

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

So, Robert, this is Anna, I would argue that we do not currently have timely, public and detailed reporting of limitations, errors and failures. I mean, I can give you specific example from the diabetes world if you like. I mean, that just isn't there.

And as I've mentioned before I'm on the Steering Committee for MDEpiNet which is the device version of sentinel or that's what we're working toward is creating a device version of sentinel and getting access to data is incredibly difficult. I mean, it's just not possible, it's expensive you have to – you know, FDA doesn't have the resources to pay for access to all of the data and a lot of it they don't have the regulatory authority to demand it. So, and MedWatch just is not an appropriate method for collecting all of this data. So...

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

So, are you suggesting that it should be more detailed than the current regulatory framework asks for?

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

Absolutely.

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

No, I think it's not just the detail it's the accessibility.

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

Yeah.

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

To the thing.

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

I think...

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

I mean – I'm reporting problems so that the FDA can look at it rather than I'm reporting problems so everyone can look at it and learn from it. There's a difference there and also...

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

But, I think the – this is Elisabeth I think the FDA has actually acknowledged that the mode database that they're revamping and they're re-looking at it and they're redoing it because when it was created it may have served the purpose but they're realizing that it's being utilized much more broadly and it needs to be much more user friendly but technology when they created it wasn't there to be able to do the search mechanisms and all that that we all seem to love to today.

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

You're absolutely...

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

And Elisabeth, I agree with that – I actually – I agree with all of you, but my point being is that post market surveillance is something that actually does exist if it's perfect or not that's a whole other dimension of what we're discussing here. But, you know, what I'm getting at is that this framework that is already in existence is very similar to what other people are, you know, pointing to as what should be going on. So, my argument is really why are we looking at potentially recreating something that already exists, you know, I think the focus of the group should be to come up with a concrete recommendation, you know, framework if you want to call it that for speeding innovation while ensuring that these new and novel technologies are safe and that's something that we already have.

You know, I think the agencies would benefit greatly by understanding a recommendation from this group on how to deal with the current regulatory framework and how to improve it given what it does currently, you know, I just don't see, you know, I don't understand this idea that we need to create something that's new.

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

Hey, so Jarrin, let me try, you know, so, you know, 20 years medical device business we don't have timely, public and detailed reporting, we simply don't, we call for it, we have structures that seem to embody it but it's not at all working and so I'm agnostic to whether we make, you know, something that works from something that's supposed to work and doesn't or something that works and its brand new, but I'm not agnostic to the notion that in order to speed innovation you absolutely need it and we don't have it and, you know, we may argue that, well we call for it and then, you know, the execution is just orthogonal to the expectation and that's good enough, but I'm telling you I don't think so.

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

Yeah and this is Anna and I would agree with Joe and God knows I'm not a regulatory expert and I certainly don't want to speak on behalf of FDA, but my understanding as a patient representative on the steering committee is that the agency does not – and Bakul please jump in, because you actually might know what you're talking about in this regard, but my understanding is that the agency does not have the regulatory authority or legislative authority to require the kind of detailed access to data that would be necessary to do post market surveillance. So, without that...

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

But I guess I'm going – right, but I'm going back to what I'm trying to say here, it's not so much about the post market surveillance. What I'm saying is that there are methods of post market surveillance; I'm not saying whether or not they're good enough. I think that they do need to be improved and I agree with all of you on that.

My issue is that, you know, we're talking about a risk-based framework as if one doesn't exist, we're talking about a framework, a regulatory framework currently that's looking at Health IT and trying to be stricter in controlling Health IT. I don't see it that way.

So, what I'm trying to figure out is, you know, what is the recommendation, what are we trying to get at? Recreating a regulatory pathway, you know, because if it is I think that we have one in place that's doing exactly what is being described, it's not doing it to a tee and I think it could be tweaked quite a bit and there are already regulatory ways to do that.

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

Yeah, so, Jarrin, I'll try to help where I can, I mean, this is not meant to be either a recreation or a recapitulation, it's meant instead to start from a needs base what would you absolutely need and then we can have an independent commentary on whether these elements exist to the point where they're functional and I'd argue that in many cases they don't, right?

So, we've talked about do we have a functional form of interoperability, I think the answer there is clearly "no." Do we have a functional form of detailed public reporting? I think, you know, we've even talked about how some vendor contracts still have in effect gag orders around describing publically the sort of failures.

So, I'd say manifestly we don't have that whether we say we do and it doesn't work or whether we have to admit that there are so many things written out of that public reporting that even if the process worked we've given too many exemptions. We don't have it and for an innovator and for someone interested in safety and long-term surveillance we need it. Does that in any way answer your concerns?

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

Yeah, it answers where you're coming from to a degree, but again, I'm not sure that I'm following, you know, what I heard earlier in the call is that, you know, we need a risk-based system and what I'm saying is we have a risk-based system. So, you know its two separate things that are being said, so I just want to make sure that we're all on the same page as we continue this regulatory conversation.

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

Well, thanks, I think what we tried to talk about is in fact much of what's done in HIT is so low risk as to have a risk-based threshold would put so much of it to what, you know, some would view as Class I or, you know, the minimalist risk that in fact the risk of regulating it may exceed the risk of its underlying capability and that's kind of the polar position I've taken to spur conversation, but I'm going to shut up for a while.

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

Yeah and I completely agree with that and I agree with you in every step with what you just said except that I look at it from the lens of Class I, if that's the case then it should be whatever HIT we're talking about should be deemed Class I or via enforcement discretion should be taken off the table completely and not be regulated whatsoever, it doesn't need to register, it doesn't need to list, it doesn't have to do the litany of all the other things including GMP.

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

So, let me chime in here, when I looked at this list of the three bullets that you have here Joe there was once piece, I think I mentioned it the other day that is missing which is another toolkit and that was one that for that light touch, up front process that makes it extremely simple for organizations to quickly do an assessment, you know, do I care or not, you know, where am I at in this process and capture that information and document it as opposed to, you know, some of the problems we've identified in previous discussions around the lack of clarity in this area that makes it very challenging for companies that are especially new to this space to even figure out do we need to do anything and if so what is it. A toolkit that takes what we come up with out of this discussion and bakes it in such a way that it very greatly simplifies that up front process.

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

I think that's a great point, that's a great point. All right and so this was something that I promised Brad I would do briefly and I won't go into much detail, many of the regulatory gurus on the phone will be well familiar with the CE marking process, one of the reasons it comes up is because as we look upon how innovators view the FDA versus European regulatory timelines and this is Josh Makower's study, I'm not – I don't present it here as a way of supporting it it's just that this seems to be an aggregate view of the innovator that in fact they view the timelines so much more beneficial in a European CE mark process that they often find themselves driven there as opposed to here and so to Brad's point of course this is a risk-based regulatory framework and I'm going to focus just for a moment on Class I for a second.

If we look at Class I here it is defined a low risk part of Class I is the non-sterile, non-measurement devices. Now, I'm doing this again, please don't hold me to all this, I'm trying to be as provocative as possible, but I would say that health information technology of course is non-sterile and for the bulk of it is a non-measurement device processing other bits of information. And so if we looked at just that we would get to something akin to our MDDS rules.

There are some perhaps important differences. Here if you are a low risk Class I device there are often self-declaration of capability. We get to a very simple, to Todd's point, a very simple wiring diagram for how one decides where you are, this is unambiguous and it gets you to market a device depending on whether you're very low risk or the higher part of Class I, you have to answer some assurance questions from regulatory authorities and some assurance that is not just self-declared but also some sort of – with a competent authority there is some registration.

And all this just gets us back to the point that at the end of the day the notion of qualifying the vendor as opposed to qualifying the product is a strategy which perhaps plays well when we look at a rapidly innovating space such as health information technology where if we can regulate the vendor to have certain qualifications in place we can stop the process of checking to make sure that every product aligns with a particular need.

I mean, I think we have an artifact of product qualification derived from ONC's Meaningful Use criteria, which I think we need to get away from because that's an endless regulatory burden and can necessarily slow the pace of innovation and perhaps we can adopt a strategy here which looks like a low risk CE mark process where one validates only the vendor and not each individual product.

And so, one view there is that if we define a predictable, reasonable process for low risk medical products similar to EU we can have some advantages for this low risk part of innovation and health information technology. I'm completely prepared then to take Brad's wrath.

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

That's not fair, it's not wrath let me just think it through with you and I'll share some initial thoughts that I have. So, number one the timing for considering the CE mark is a little bit off in the sense that this is precisely the time when Europe is reconsidering its CE mark approach and in fact I think you all know this Wednesday, two days from now, there was supposed to be a vote in a European Parliament Committee to reconsider the entire CE approach for medical devices. They put it off until September, but the primary criticism, one of the criticisms that's been levied against the European model is that it has this organizational structure of notified bodies that have this odd kind of regulatory customer relationship with vendors that is on the one hand they're working for government, they're supposed to be playing a quasi-regulatory role on the other hand they're doing a service for the vendors who are paying them and they're supposed to be pleasing those vendors.

And I think a number of people in Europe view that as a conflict which is kind of doomed to fail, that is that these entities are having a hard time balancing those two competing objectives, but more fundamentally I guess why I'm scratching my head a little bit is the treatment for Class I devices is not all that different between FDA and the CE mark.

For Class II, which was the focus of the slide you had on 510(k) clearance there is a big difference, getting to market in Europe is faster than getting to market in the US if getting to market in the US involves a 510(k) so I get that, that seems absolutely true.

But if we're talking about the lowest risk products we're talking about probably Class I in both places, both US and EU and there they both have this vendor-based standards process that you're talking about in the US it's the quality system, it's GMPs, it's making sure that the facilities register and list, it is very much focused on the vendor's qualifications rather than the product itself other than the testing obviously that the vendor should do in compliance with the GMPs if they apply.

So, at the low end the two systems are very similar. At the high end for higher risk people are now thinking that the FDA system does a much better job on safety, they had the issues of breast implants and artificial hips and so forth where a lot of Europeans were exposed to unsafe products, FDA did a comparison just over a year ago and identified safety issues that had popped up in the EU that had been caught in the US, I know it was a little bit of self-serving propaganda but it was still very interesting to look at.

And so, there is an argument at the higher end that the FDA system is better, at the lower end they're not all dissimilar it's in the middle where you get the argument that the EU system does a better job of getting product to market faster but I'm just not sure that that's terribly relevant for HIT. I would argue that most of what we're talking about deserves to be in Class I.

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

So, appreciate that and I'm actually finding that we're agreeing. None of this is meant to say, and to perhaps address Jarrin's point, it's not meant to say this – whatever we're proposing here or talking about kind of a needs-based, kind of bottom up approach to what's important in regulation is meant to say we need to build something entirely new to the extent it's available, you know, within an existing regulatory framework as it is here in the low end of Class I for the FDA and as it is here in the low end of Class I for CE marking. I think that is a happy coincidence that what we need is also what's available.

It does require, if we're going to get this right, that we are going to put the overwhelming bulk of HIT in this framework and we're going to work to make sure that the regulatory timelines are really quite brisk as they need to be for technology that offers an opportunity to aggregate harm as opposed to have its own independent risks. So, I don't think you and I are far apart on that, but I...

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

This is...

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

Go ahead, others?

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

Yeah, this is Elisabeth I guess I want to fully agree with all of what you said, to one addition I would like to comment on because I know it came up earlier with regards to post market, one of the interesting things with regards to post market in the CE mark environment there are two aspects that are different. Number one, presently the whole aspect of malfunctions do not get reported to the competent authorities and so there is a significant number of MDR reports that we submit to the FDA that do not go to the competent authorities.

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

Right.

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

But inversely in the countries many of the countries are imposing device registries and they're able to do that for a couple of reasons and some of that is that incentive aspect. There is a little bit of de-incentive. You won't get paid as a doctor if you don't put this information into the registry.

So, basically they have, in some cases, and one in particular the metal on metal hip example where in the UK they had much earlier information than the FDA did because they had a single payer system in the UK with a mandated registry requirement. So, they were able to see a significant trend sooner.

So, you know, again there are many similarities but the bottom line is, is I think as Jarrin has been saying is, is that they are all risk-based methodologies and so if the proper risk is determined then there are already systems available and I will admit having been in this industry for as long I have they are definitely not all effective, you know, the devil is in the detail I guess.

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

And Elisabeth I totally agree with that and that detail is what we should flush out, those should be some of the recommendations.

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

Yes.

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

To make sure that we keep FDA and the other agencies understanding how they have to move, you know, things like guidance documents like the one that you brought up Joe the mobile medical guidance document that should have been issued 2 years ago when they originally issued it, they had, you know, a workshop, you know, did all these things behind it, received, you know, 700 pages of comments, etcetera, etcetera, and we're still waiting for the final document, that should not happen, that does – that's what impedes innovation not delaying it.

Delaying it is what is impeding innovation. Innovation would have happened, you know, a year ago, a year and a half ago if they would have gotten the thing out to the public to, you know, help guide the public about their current thinking. Current thinking means exactly that, everything that's happened up until that point. What goes forward is the innovation and we need that.

So, I totally agree with those comments Elisabeth and I want to make sure people understand where I'm coming from, because if the tweaks need to happen that's where we can really jump in and give solid recommendations and make that happen.

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

Yeah and I think the point that Elisabeth made which is also very clear is having a requirement for adverse event reporting is not the same as having adverse event reporting and for innovation and for safety you actually need not the requirement but you need the reporting and so whether it takes other inducements or incentives in addition to regulation that's the need. The need is not for the requirement. The need is for the behavior and so I'd leave it at that.

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

I'd like to just add, you know, I see kind of a convergence here and it's kind of exciting, but I'm also trying to figure out how we can really make the most use of it. I hear a lot of people, whether they're in this group, whether they're in the Safety and Innovation Workgroup, whether they're in Taxonomy really saying in essence, not using these words, but this is my interpretation of it, that classification in a risk-based regulatory process is incredibly important and that making sure that HIT doesn't get over classed, meaning assigned to a higher risk category, higher than it deserves, is pivotal to innovation.

And so, if we look at classes as kind of four classes the three FDA plus Class 0 which would mean unregulated enforcement, discussion whatever you might want to call it, I would love to see us as a group, small group, regulatory group, largest group whatever it might be, but basically giving some regulatory specs to FDA saying here's how you parse the risk of HIT, here's the stuff which I think we're all kind of saying would be the vast majority of HIT that belong either in Class 0, unregulated or Class I vendor-based regulation, it doesn't deserve Class II regulatory status, but we have to be able to say that in a meaningful way, by that I mean use the Taxonomy Working Group's distinctions and the safety distinctions from the Safety Working Group to say, you know, here's what belongs in these classes.

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

Right, right Brad I think that's a great point and it's – I've been I think in an attempt to be provocative not articulating that point, but I think that's right. I mean, as we talked about, you know, sliders of risk I don't think we ever talked about where we're going to draw the line in that slider, where along that gradient of risk we're actually going to say, and, you know, beneath this and maybe it's all of it, but it's certainly the bulk of it, beneath this it's Class I or Class 0 and in Class I these are the kind of behaviors that we're going to need.

But, I do draw a distinction between this is the regulation we need versus this is the performance we need and we've not yet gotten the performance that the existing regulations in the way they've be executed on gives us confidence that we're getting kind of the behavior that we need to drive the system as fast and as well as it can be driven.

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

Very true, agreed.

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

On this last point we've had a lot of talk about what happens with local modification, we've pegged it as a gap for the FCC and how they do things. It's risen to a level of concern that, you know, there are going to be unintended consequences when, you know, Billy in a hospital puts two different vendor software elements together and "oh by God whose responsibility is that." And I've offered this up before, but I'm going to stick to it and say that, you know, given that there are endless permutations and combinations of the tinkering that occurs at, you know, each site of care the notion that we're going to centrally manage that I think we just have to walk away from that, that's not practical. I don't think it's desirable, but it's certainly not practical.

And that HIT like other tools in medicine may often have its greatest value when knowledgeable, experienced and inspired practitioners are free to alter and adjust, and enhance, and that that process of regulation here can be as local as the tinkering is done.

I mean, you know, so again the analogy to the scalpel for the tool, you know, the requirement is that it's sharp and sterile and beyond that it's use kinetics are determined by the operator and the performance of that use is determined by the structure in which that operator works and so that's the hospital, there is a medical board, there's a statewide board, all of this can be done locally and I think it frees us up for having to think about this as a central planning issue and merely, and I don't think we're tossing it down, I just think we're recognizing that the best review of this is closest to where this activity occurs and that's going to be in the healthcare system that put these things together.

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

So, Joe, and I don't know if you've been in all the prior calls where we talked about this, but we talked about it a little bit last week and it seemed to me here is where the issue came down to. The reason that FDA doesn't regulate the practice of medicine is because there are local regulators that regulate the practice of medicine. It doesn't need centralized review and regulation by FDA. There are regulators of doctors at each state, if not local, level.

The challenge is making sure that that same level of local control in fact exists over how HIT is used and deployed. And I'm not the expert in it that you are, but a doctor is simply one user of information and not necessarily the one doing the local modification of the HIT.

So, the question for you, the question for all of us I think is how do we make sure that there is good enough local oversight as there is over doctors and how doctors use other therapeutic products, how do we make sure that HIT has that local responsibility such that federal responsibility is unnecessary.

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

So, I'm going to back up a little bit. The reason the FDA doesn't regulate the practice of medicine is not because others do it's because they were never given the authority to.

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

Please, congress made its determination, if you go in the legislative history, just to speak precisely; congress never gave FDA authority because it was regulated at the local level.

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

So, I think we can both agree to parts of the argument. I don't think we have to assure at a federal level that the folks who put it together do a good enough job if we can imagine that the Joint Commission can do such a thing or even that the, you know, a patient safety organization or the quality system of a given hospital appropriately addresses this issue and I don't think we even have to prescribe how it's done at that local level we can merely acknowledge that it needs to be done at that local level. No? Do we have to solve all of it from a central level?

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

Well...

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

This is Keith, I agree with you Joe. I mean, again we have local control of it. We have committees just like we do on any introduction of any type of technology or any type of change in the process in our hospital and we have form's committees that you can't even change a form without having some kind of review of it.

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

Absolutely.

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

I just think if you make this a central – centrally – I think that you state that you're accountable at the local level for the assurance of reviewing these and doing the safety and leave it at that. If you try to make this a central control the products themselves are going more not less towards customization and change at

the site of care and the local site of care needs to be accountable for that, but I think that we can leave it at that.

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

So, I know we're running short on time. I'm going to go – I briefly summarized the points from the prior discussions. Anna McCollister-Slipp had I think some important specifics to add to the conversation and I wanted to make sure that she had an opportunity. Here I think there are two slides which are derived from an e-mail she sent me late last night and I just wanted to give her a chance to kind of go through this. Anna are you still with us?

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

Yeah, I'm still here and again these are just some sort of – some ideas that I would have if I were blue skying a way to sort make this work and to create a system that would enable both maximum innovation and rapid cycle iteration as well as accountable and transparency.

So, I don't necessarily want to read through each of the elements of the slides, each word of the slide, but, you know, transparency I think is absolutely important, you know, we have to find ways to protect IT but all documentation on the processes, data, etcetera needs to be provided so that you can do post market surveillance.

I think we need some sort of, you know, in exchange for – it's certainly more effective than either, I would say, local or federal oversight system for Health IT, some sort of on-line rating platform would be much more efficient and effective. You know, if you look at whether it's Amazon or iTunes or any of the on-line sites where, you know, WordPress.com for plug-ins whatever the case may be people rate them and you live and die based on your ratings and people can provide feedback.

So, it's a much more efficient method for allowing for further innovation, rapid cycle iteration, bug fixing, etcetera, because you're called – the bugs are called out in a public forum either the developer responds to it or they don't. And if they don't then people, you know, trash that App in their ratings and they move onto something else that somebody else does that's much better. I think it's incredibly effective, you know, it works very well with the mobile Apps that I have or that I've downloaded that are related to health issues and the better ones are the ones that float to the top.

Data sharing and transparency, we've already talked about this. There is so much data that is collected about devices and only those that meet like the minimum requirement basically like lowest common denominator somebody died or was severely hurt by this device malfunction are the ones that get reported to FDA and FDA has acknowledged the issues, they're looking at ways to fix it, but I think we have the opportunity to use this process to require much better data sharing and transparency which is going to be absolutely critical for safety as well as innovation.

Standard data formats; there is no excuse whatsoever for having custom data formats that limit people access to their own data or to their patient's data. Open APIs, if you've got a device and it collects and generates data you need to have an API so that other people can access that data and be able to use it and once the data is obtained through your API then that device manufacturer should no longer be accountable to what happens to it.

Operating system and usability, you know, there are two major platforms that are out there Windows and MAC, if you're going to have something that's downloadable versus cloud-based it needs to be able to operate on both of them if you're serious about having a medical device.

And then in exchange for that I would say that, you know, we could give greater freedom, you know, the products can be released without prior approval to get the – you know, device manufacturers or the software manufacturers get the ability to do rapid iterations and modification as long – and including medical device supportive software as long as those modifications don't affect the platform that operates the device and I'll give you a specific example.

I have a continuous glucose monitor that's awesome, it works really great, it's, you know, recently approved, but it has event marking that is completely limited and I've talked to the device manufacturer a couple of weeks ago at the American Diabetes Association meeting and I said we would love to be able to get input into the development of the software as we're going but FDA considers that to be premarket approval or premarket promotion.

So, the process as it currently works doesn't make any sense. So even marking does absolutely nothing to the operation of the continuous glucose monitor. It's a software component that is there to enable the data to be more helpful as a tool for managing your health. So, I don't know why that would need to be regulated as a Class III medical device. Essentially what's happening now, these kinds of new rapid iterations aren't happening and I think that could be much more efficiently handled.

And then in exchange for all of that, you know, device manufacturers will be able to compete based on their consumer ratings through these on-line rating platforms which is something that you can't currently use in your marketing materials. So, those are my blue sky, pie in the sky thoughts. Again, you guys are the regulatory experts I'm not, but this seems to me to be very common sense approach. I'm sure there are a million things that I'm missing or don't understand, but those are my thoughts.

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

So, this is Brad, a lot of that I think lines up with what could be accomplished under existing regulatory schemes. A lot of what you describe would supplement the existing regulatory schemes that are, you know, having the ratings and so forth, the consumer ratings kind of in addition to what the existing regulatory requirements would impose. But a lot of these other things could be done if the appropriate, you know, classifications were established and appropriate guidance was given from the agencies.

So, it's kind of very consistent with what I'm hearing – it's more specific in some ways, but very consistent with what I'm hearing from others and sort of as I sit here reflecting, I mean, we've gotten to the end of our hour and a half so we're going to need to do public comment and then wrap it up, but one of the take-aways I'm kind of focused on from today is there really seems to be good alignment that a risk-based model of the kind that's embedded either in the European system or the US system of classification makes sense so long as most of the HIT is either in Class 0 or Class I.

And so I'm wondering if David Bates can somehow lead us through or maybe on the regulatory team we could do it, but somehow make some recommendations to the agencies as to where to consider drawing the lines between the classes, maybe take the work of the Taxonomy Group and look at it and see if it can be framed in such a way as to define Class 0 or Class I. But, unfortunately we're out of time for today, because we're just about to hit 4:30 and we do need to allow the public time to participate. So, unless there is further comment can we kick it over to the public comment portion?

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

Let's go.

**Public Comment**

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

Operator can you please open the lines for, oh, sorry was there any comment? No? Okay, operator can you please open the lines for public comment?

**Caitlin Collins – Project Coordinator – Altarum Institute**

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

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

Okay. So, our next call of the Regulation Sub-Workgroup is Friday, this Friday from 3:00 to 5:00 Eastern Time. So, we've got that call this Friday and then we have a call next week. We basically only have those two calls left as a Sub-Working Group.

So, what Julian and I, and probably others if we can lasso them in are going to need to do is come up with a first draft of kind of what this Working Group, Sub-Working Group would propose to the rest of the Working Group and so taking all the work that we've done but really distilling it down as succinctly as we can, because the ultimate objective then is that it be woven into the report for the whole Working Group, which just for point of reference is only going to be about 20-30 minutes worth of presentation the first week of August to the HIT Policy Committee.

So, it's going to be only 15-20 slides I think in total for the whole Working Group. So, we really need to crunch ours down to be as concise as possible in order to be used for that purpose. So, that will be the task. We're going to take two cuts at it and we'll get a draft to you just as soon as we can for your consideration before the Friday call but that's the plan. Are there any questions by anyone?

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

No, I'd just like to thank Lauren and Anna, and Martin, and David for commentary to help drive this to where we ended up.

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

And thank you Joe for all of your leadership in pulling all that together and presenting it. It was very thought provocative and I know that's what you were going for. It produced some very interesting discussion and I think led us in a path that, to me anyway, is very encouraging and very exciting. So, thank you very much.

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

All good.

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

All right, everyone, take care and look forward to talking on Friday.

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**

Thanks so much.

**Keith G. Larsen, RPh – Medical Informatics Director – Intermountain Healthcare**

Thank you.

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

Thanks, everybody.

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

Bye now.